“India actually is the ideal genetic milieu”:

Race, ethnicity and transnational biomedical research in the post-genomic era

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Declaration of Authorship

I affirm that this thesis and the work presented in it is entirely my own.

Sibille Merz

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Abstract

This thesis explores the discourses and practices that promote the ethnoracial qualities of the Indian population as a valuable resource for pharmaceutical research and development. As India has become a key location for global clinical trials, population genetics and pharmaceutical consumption, I examine two central research questions. First, how does ethnoracial diversity, comprising both biocultural markers and socio-political concerns, shape the design and conduct of global clinical trials? And second, how are specific populations constituted and mobilised along these criteria by various stakeholders for numerous and often contradictory objectives? Grounding my analysis on a range of primary sources, including 42 qualitative interviews with scientists and policy makers, archival material and ethnographic data, I argue that biomedical scientists must negotiate multiple understandings of and interests in race and ethnicity, often rendering their meaning fundamentally obscure; in the post-genomic era, arguments about population heterogeneity or homogeneity have become a welcome avenue for myriad scientific, commercial and political projects. I also illustrate that researchers carefully calibrate notions of difference and sameness in construing the Indian population as a multivalent resource for such projects, rendering Indians ideal experimental subjects *and* biological citizens alike. This thesis thus extends the sociology of race and racism as well as debates in science and technology studies probing the revived concern with race and ethnicity as objects of scientific analysis through generating primary data *and* critical reflection. Underlying my argument is the notion that social constructionist reasoning has not helped dismantle categories of biological difference such that sociological enquiry must develop a broader understanding of how, when and why these are regaining traction. Ultimately, this thesis illuminates the discrepancies between the value of human diversity within and outside the laboratory or the clinic and emphasises the dearth of engagement with the structural inequalities conditioning global health research.

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Chapter 1: Introduction

> India actually is the ideal genetic milieu, is ideal for clinical trials, ideal for drug response measurement, because it has an enormous genetic diversity that almost covers the world diversity (Professor Samir K. Brahmachari, biophysicist and medical geneticist, public sector, India, February 2017).

> India is a potpourri of people and that's why Bombay is a good place to do clinical research because we get the mix of patients. . . . We don't have only *Marathis*, you know, people from this region, we get people from everywhere, it's a melting pot really (Professor Tista Nayak, pharmacologist, ethics committee member at a public hospital, India, March 2015).

Queried about the manifold advantages of conducting clinical trials in India, scientists regularly proclaim the qualities of the Indian population as a rare opportunity for transnational biomedical[1] research. Indian patients and research participants are 'treatment naïve' and impoverished, allowing for shortened enrolment timelines and reduced costs to maximise pharmaceutical profits. They also have, in addition to an entire range of infectious diseases, disease profiles similar to patients in 'the West'. Trials for non-communicative diseases such as cancer, diabetes and cardiovascular ailments are the most common studies conducted for multinational pharmaceutical corporations. But most importantly, clinical and genetic researchers such as, here, Professors Tista Nayak[2] and Samir K.

[1] I will use the terms biomedical and biomedicine in the sense suggested by Adele Clarke and colleagues (2003: 162) who argue that the prefix 'bio' signals "the transformations of both the human and nonhuman made possible by such technoscientific innovations as molecular biology, biotechnologies, genomization, transplant medicine, and new medical technologies". Since World War II, biology and medicine have become tightly hinged such that, as Peter Keating and Alberto Cambrosio (2002: 299) also find, "practitioners of the activity known as biomedicine can no longer say beforehand whether a particular research project, clinical investigation, or even clinical intervention will result in biological or in medical facts."

[2] Unless noted otherwise, all respondents and companies have been given a pseudonym and anonymised as much as possible; see Appendix 1 for details on respondents.

Brahmachari[3] agree that Indian patients are profoundly interesting with regards to their genetic constitutions. Described as an "ideal genetic milieu", a "potpourri of people" and a "melting pot", Indian genetic diversity, they suggest, offers pharmaceutical and biotechnological companies exceptional prospects for pharmacogenomic, clinical, and genetic linkage studies into population differences, disease progression and variations in drug response. Indeed, political economic analyses note that multinational companies find India attractive due to its large, ethnically diverse population that allows for research into various ailments (Joseph, 2016). Local Contract Research Organisations (CROs) advertise their services with similar promissory claims: "One billion reasons to study here", one Indian CRO finds, since "Indian people have 6 to 7 advantageous genetic populations [and] all major races are represented in India with Caucasian being the most prevalent".[4] The "Indian clinical research industry has very strong fundamentals including a genetically diverse patient pool",[5] insists another, and by some, the Indian population is even described as providing "a goldmine" (Apte, 2012: 982) for scientific research. The subcontinent's genetic diversity, it seems, is imbued with unique potentials, brimming with opportunities for drug testing, niche standardisation and biomedical marketing.

Against this backdrop, this thesis draws on qualitative interviews, ethnographic data and archival material to empirically examine how Indian biologies are described, enacted and mobilised in and for transnational biomedical research.[6] Pervaded as they are by references to ethnoracial[7] categories as seemingly meaningful units of scientific analysis, I explore the discourses and practices of the multinational pharmaceutical industry, Indian clinicians, medical geneticists and healthcare entrepreneurs as expressions of a new interest in specific ethnoracial

[3] Professor Brahmachari explicitly waived his anonymity for this thesis.

[4] Pharm-Olam: https://pharm-olam.com/region/conducting-clinical-trials-india [last accessed 23 February 2018]

[5] Clinnex: http://www.clinnex.com/clinical-research/4-reasons-why-clinical-research-in-india-is-all-poised-for-growth-in-2017/ [last accessed 23 February 2018]

[6] Transnational biomedical research, similar to the terms global clinical trials or multi-regional clinical trials, which I will use interchangeably, refers to the practice of researchers and sponsor companies from industrialised countries in the Global North, mostly Europe and the United States, conducting clinical trials in countries of the Global South (Orth and Schicktanz, 2017). Such research can be conducted through the use of CROs or by sponsor companies themselves.

[7] While I will distinguish race from ethnicity when warranted for analytical precision, and when informants explicitly differentiate between them, overall, I will use the merger 'ethnoracial' to refer to the bioscientific constructions of human diversity that often draw on cultural and biological registers simultaneously.

constitutions. This thesis utilises the Indian clinical trial industry as its main research site to think through two central research questions. First, how does ethnoracial diversity, comprising both genetic markers and socio-political concerns, shape the design and conduct of global clinical trials? And second, how are specific populations constituted and mobilised along these criteria by various stakeholders for numerous and often contradictory objectives? In other words, this thesis explores the scientific, symbolic and material currencies of Indian biologies in transnational biomedical research, inflected by the increasing valorisation of genetic diversity, the dominant US-American[8] racial paradigm, and the powerful status genomic research has acquired in national bioeconomic projects.

In response to existing research that has focused either on the ethics and economics of globalising drug research or the reification of ethnoracial groups in (pharmaco-)genomics, this thesis explores how these domains are institutionally related through the rise of ethnoracial diversity as a source of informational, social and commercial value (Parry, 2005; Reardon, 2005). The globalisation of clinical trials, I argue, warrants critical scrutiny not only regarding their proper ethical conduct. We also need to interrogate the ways in which the genetic properties of specific populations are marshalled for different political and economic projects, amplifying yet also contradicting prevailing forms of exploitation in often unexpected and non-linear ways. In this sense, this thesis offers original empirical data and critical reflection contributing to the sociological literature on the status of race and ethnicity in the biosciences as well as on the globalisation of clinical research, teasing out their relations and tensions by illustrating how, which and why specific concepts of population are mobilised as valuable assets for drug research.

1.1 Genetic diversity and the new biopolitics of race

Biomedical researchers (e.g. Chin and Bairu, 2011; Kadam and Karandikar, 2012) and critical scholars (e.g. Joseph, 2016; Sunder Rajan, 2006) alike have long pointed to the pivotal role the genetics of the Indian population has acquired for clinical research, often described through racialised nomenclature. Anthropologist of science Kaushik Sunder Rajan (2006), for example, describes how its unique

[8] I use the merger 'US-American' to disambiguate the United States of America from the wider Americas and counter US-centrisms in academic writing.

qualities, said to represent the entire spectrum of the world's genetic diversity, have rendered the country an attractive location for pharmacogenomic research. As one of his respondents, a renowned Indian geneticist, proclaims, if multinational pharmaceutical corporations "'want Caucasians, we'll give them Caucasians; if they want Negroids, we'll give them Negroids; if they want Mongoloids, we'll give them Mongoloids'" (Sunder Rajan, 2006: 95). The geneticist's enthusiasm not only illustrates the enduring scientific occupation with racial biology and the benefits it is ascribed for the study of variability in drug response. It also demonstrates the ample scientific potentials the Indian population offers due to the presence of what are presumed to be the world's major racial groups. In addition, given the increasing interest of US-American federal policy in measuring differences between populations, as sociologist Catherine Bliss notes, the convergence of ethnoracial classifications and transnational research has "crystallized into a concerted policy wherein all globally designed research would filter through a system of categories pertinent to the U.S. sociopolitical context" (Bliss, 2005: 333). This opens up new terrain for sociological enquiry into both the resurgence of race in the biosciences and the postcolonial politics of transnational biomedical research.

Few have sought to investigate the connections between these strands further, treating offshored clinical drug trials and the politics of ethnoracial description as parallel but largely disconnected socio-scientific developments. In contrast, this research suggests that they are mutually constitutive through novel biopolitical practices wherein, as anthropologist Stefan Helmreich (2008: 464) observes, the "biological entities that inhabit this landscape are also no longer only individuals and populations—the twin poles of Foucault's biopower—but also cells, molecules, genomes, and genes" (also Cooper, 2008; Gottweis, 1998). Genetic constitutions have emerged as a central target of biopolitical practices, and specific genetic populations are increasingly considered vital assets for the advancement of scientific knowledge, public health and the creation of economic profits. Since scientific conceptions of human diversity never appear in isolation but are always influenced by other problems and concerns, the narratives advertising the unique qualities of the Indian population introduced earlier promise rich material for sociological investigation.

The perspective of biopolitics is pivotal to understanding the value specific populations are imbued with in the post-genomic era wherein conceptualisations of

the human body are, yet again, subject to critical scrutiny. As Evelyn Fox Keller (2015: 9) usefully highlights, the Human Genome Project (HGP) signalled three fundamental changes in the discourses and practices of human genetics: first, it fuelled the growing commercialisation of genetic technologies; second, it (paradoxically) recuperated the scientific concern with human difference rather than sameness that has often been framed through race; and third, it provoked a reworking of biological understandings of genes, genomes and genetics. As such, the prefix "post" in "post-genomics" does not merely indicate temporality but rather a fundamental transformation of how the relationship between the human body and its natural, socio-political and economic environments are conceived.

This thesis will primarily be concerned with the resurrection of concepts of race and the increasing scientific attention given to environmental and cultural factors in the moment the "postgenomic genome" (Fox Keller, 2015) is being reconfigured as a highly reactive and flexible system rather than a static collection of genes instituting specific traits (ibid.). As Janet K Shim and colleagues (2014) equally emphasise, in post-genomic research, the scientific focus on difference and the inclusion of racial and ethnic minorities is joined by the growing concern with the synergistic interactions of genetic and environmental determinants on human health and disease. As such, familiar conceptualisations of population may be reworked while new concepts emerge, shaped by shifting scientific rationales, economic agendas and cultural understandings.

Against this backdrop, this thesis focuses on the simultaneity of multiple and often contradictory vectors mobilising specific populations along the interests of global biocapital, public health and national governance. Feminist science scholar Catherine Waldby (2009) aptly argues in her analysis of Singaporean biobanking that populations in the global bioeconomy figure simultaneously as biological resources for experimental research, as potential therapeutic markets and as biological citizens, embodied political subjects exercising their rights and obligations in relation to the state. This thesis demonstrates that their genetic makeup not only renders Indian citizens ideal populations for biomedical experiments but, as members of an imagined Indian "genetic community" (Simpson, 2000), at least some of them are also construed as future consumers and addressed as self-conscious, proactive patients-in-waiting. In other words, what this thesis explores are the discursive mobilisations of the Indian population, or rather of

multiple Indian *populations*, for different and often seemingly opposed bioeconomic projects (Foucault, 2003; Fujimura and Rajagopalan, 2011; Hinterberger, 2012b). The plethora of terms used to describe population typologies in genetic and biomedical research—*qua* race, ethnicity, ancestry, nation, continental geography, a specific genetic marker or a combination of all these—reveal that populations, as sociologist of science Amy Hinterberger argues, "are not only multiple but they are also unruly entities which tend to shirk any kind of discipline imposed upon them" (2012b: 76).

In doing so, I will illustrate that contemporary discourses recuperate an inherent ambiguity in conceptualising Indians between the conflicting poles of proximity and distance, pivotal to anthropological and medical investigations of Indian populations since the eighteenth century (see Chapter 4). Historically, research was characterised by an innate indecisiveness over Indians' precise status and appropriate classification, allowing scientists and colonial administrators to sometimes categorise them as fellow Aryans and hence 'whites' while at other times depict them as racial Others, oscillating between admiration, acceptance and outright contempt. While today, explicit value judgments are increasingly rare, this fundamental ambiguity continues to shape representations of Indian diversity. I will show, for example, that most drug developers construe Indians as biological relatives of 'Caucasians' or, as I will argue, as *almost white, but not quite*, for the purpose of global clinical trials that rely on the fundamental uniformity of human biology (see Chapter 6). Other research agendas such as those advanced by the Indian Genome Variation Consortium (IGVC) foreground Indians' internal heterogeneity to advance the emancipatory promises of public health genomics (see Chapter 8), while Indian healthcare start-ups promote a unified conception of Indianness that asserts a degree of biosocial homogeneity and conjures an affective attachment to the nation (see Chapter 9). Contemporary research, it appears, carries forward a long trajectory of scientific deliberations over who precisely "those pesky billion" (Kittles and Weiss, 2003: 38) are. It is one of the main arguments of this thesis that it is precisely the flexibility of population categories and Indians' inchoate status in ethnoracial taxonomies that make Indian population diversity such a fertile resource for biomedical research and political mobilisation alike.

Perhaps the multiplicity of populations and the longevity of racial nomenclature to describe them would not be problematic in itself. However, as Michel Foucault

(2003) has warned, the problem of population is always a problem of power, and biopolitical techniques establish new modes of regulation, control and management. Critical theorists David Theo Goldberg and Philomena Essed astutely write about racial classifications of population that "[a]ll variations on and through race serve as codes and manifestations of power more generally, and they so often factor more or less quietly into a complex of causes for political, economic and social conditions" (2002: 4). This means that it is not enough to describe the perplexing multiplicity of Indian population conceptions and the biologisation of what are rather vague and constantly shifting amalgamations of biological, social and political markers. What needs to be asked as well is, as Hinterberger (2012b: 76) emphasises, *what is at stake* in such conceptions, how they are negotiated by the multiple actors in the field, and, ultimately, who reaps their benefits. I will demonstrate that the Indian population is mobilised for the creation of "biovalue" (Waldby, 2002) for global pharmaceutical companies while leaving millions of Indians without adequate healthcare, but also by local actors for the politically progressive objective of repurposing out-of-patent drugs to specific subpopulations. As such, there is not only an inherent ambiguity in conceptualising Indian populations, but also an intrinsic tension between the biopolitical practices governing them.

What this tension also points to is the simultaneity of life-affirming and life-denying biopolitical techniques in the realm of global drug development. Researchers investigating other transnational biomedical networks of which India is a part, for example organ transplantation (Cohen, 2001, 2003, 2011; Scheper-Hughes, 2000), stem cell research (Bharadwaj, 2008, 2013) and assisted reproductive technologies (Pande, 2010; Rudrappa, 2012; Vora, 2015), have shown that while novel biopolitical strategies augment the vitality of *some* bodies, they also sacrifice the integrity of others. As Foucault prudently wrote, "the power to expose a whole population to death is the underside of the power to guarantee an individual's continued existence" (1978: 137). Historically, it was precisely *qua* race that decisions about who was to live and who was to die were made, and existing research suggests a continuation of such demarcations between countries of the Global North and South.

In contrast, some contemporary theorists of the biosciences in Euro-American scholarship tend to view the murderous underside of biopolitics as a thing of the past, or as tragic but exceptional happenstance (e.g. Inda, 2014; Rose, 2006). They

foreground a new politics of life that takes as its object the biological vitality of racialised bodies. Anthropologist Jonathan Xavier Inda (2014), for instance, writes that contemporary scientific ways of thinking about race do not aim to stigmatise or subordinate racialised populations, but are guided by the hope for increasing their health and well-being. While I agree with the broad thrust of these arguments, the nearly 100 Indian patients who have died in clinical trials over the last few years challenge any neat distinction between murderous and vital technologies and illustrate the enduring antinomic relationship between life and death in biopolitical practices.[9] As such, this thesis aims to complicate the somewhat reductionist, binary narratives about a rupture between the old and the new biopolitics and explores through empirical data how both not only continue to proceed along the lines, but also challenge the explanatory value of race, class, caste and nationality.

This biopolitical framework shares analytical grounding, epistemological interests and political motivations with a set of loose and fragmentary positions that have been referred to as race critical theory (Goldberg and Essed, 2002), rooted strongly in a Foucauldian perspective that foregrounds the discursive deployment of population descriptors as a means to order, distribute and manage populations. These positions question the validity of race as an empirical object and focus instead on the socio-discursive practices through which racial populations are recreated in perpetuity. In contrast to the canon of critical race theory which risks reproducing naturalised differences by leaving the non-sensical character of race relatively unquestioned, this body of thought aims to unhinge the assumption that race explains entrenched social and material inequalities—or indeed, anything. While critical race theorists tend to reify race "because they seek to construct their analytical *concepts* to reproduce directly the commonsense ideologies of the everyday world" (Darder and Torres, 2004: 41), race critical theory propounds, as I aim to do in this thesis, that it is race itself that must be accounted for sociologically, investigating its precise conditions of possibility and the effects of its circulation. In other words, it is not race which explains but race itself requires explanation. As Rogers Brubaker (2002) warns, sociological research should not leave unchallenged the very categories of ethnopolitical practice it analyses, and refrain from adopting

[9] Figures on the precise death toll vary significantly, especially between accounts by civil society organisations and the government. Independent non-governmental organisations have claimed that in 2012 and 2013, there were around 4,000 cases of severe adverse events, including deaths, while the government claimed the figure stood at 506 severe adverse events and 89 cases of death (The Times of India, 2014).

them as its own units of enquiry. In this sense, I am not treating the Indian clinical research industry as merely another racialised bioeconomy, but aim to explore the precise ways in which different markers of race and ethnicity 'stick' (Ahmed, 2004) to Indian populations, why (or why not) and with what effects.

The thesis approaches these issues by devising a research strategy that blends a number of qualitative data collection approaches. In contrast to research that concentrates on one specific laboratory, project or technology, I have aimed to construct a broader survey of the discourses and practices around ethnoracial diversity in global drug research. My mixed-methods approach combines primary data from 42 interviews with scientists, regulators, policy makers and civil society organisations, archival research in India and the UK on historical modes of classifying Indians, and ethnographic data from observations at industry conferences, newspaper clippings, advertising materials, annual reports, government publications and scientific journals, most of them available online. Data were collected between August 2014 and February 2017; I began my data collection early in the process to guide the clarification of my research questions and continued gathering materials alongside drafting first chapters. Interviews were arranged through snowball sampling after initial contact to the hard-to-access setting of the pharmaceutical industry was established through a gatekeeper, and archives of interest were identified through consulting secondary literature on anthropological and medical research on race and caste in India.

I have approached these materials from a range of theoretical perspectives rooted in Foucauldian accounts of biopolitics, race critical theory, and (postcolonial) science and technology studies (STS) to navigate my multi-sited, multi-disciplinary and variegated research field. The thesis pulls together these divergent analytical perspectives to produce an empirically grounded and theoretically enriched account of how researchers mobilise ethnoracially diverse populations in transnational biomedical research, aiming to engage how these generate new, or reproduce old, geographies of justice and injustice. Before outlining the chapters in more detail, I will offer a brief overview of clinical research in India and the juridical-regulatory infrastructure of multi-regional clinical trials within which my analysis sits.

1.2 Setting the scene: clinical research in India from manufacturing to service delivery

Pharmaceutical research and development in India dates back to the British Empire but only properly took form with the introduction of the Drugs and Cosmetics Act in 1940, subsequent amendments in the Drugs and Cosmetics Rules (1945) as well as the establishment of the Central Drugs Standard Control Organization (CDSCO) and its controller, the Drugs Controller General (India) (DCG(I)) under the Ministry of Health and Family Welfare (Chaudhuri, 2005; Imran et al., 2013). At the time, the Indian pharmaceutical industry was dominated by manufacturing rather than the discovery or invention of new drugs and treatments; most importantly, it had been set up against the British export of raw materials and subsequent re-import of medicines and was intended to build medical self-sufficiency in the wake of national independence (Chaudhuri, 2005). Part of future Prime Minister Jawaharlal Nehru's political project of building a scientific infrastructure for national regeneration, it became a central sign of the rationality and progress of the nation, and an important instrument to establish the social and economic independence of its healthcare sector. Drug manufacturing processes were developed through close cooperation of the private and public sectors, especially with the Council of Scientific and Industrial Research (CSIR) that is still at the forefront of government-sponsored scientific research (see Chapter 8). The first clinical research centres were set up in Bombay, now Mumbai, in 1945 and over the next sixty years, the Indian Council of Medical Research established various research initiatives into tuberculosis, leprosy and viral diseases as well as cancer and genetic disorders (Bhatt, 2010).

With the therapeutic revolution and the shift from manufacturing to research and development in the 1950s, however, multinational corporations began to dominate the market as Indian companies continued to develop processes for the manufacturing of drugs for local needs. The liberal licensing policies set up in the Drugs and Cosmetics Act amplified this trend so that the indigenous industry gradually lost its successful status (Chaudhuri, 2005). It was only in 1970 that the government reacted to the increasing dominance of multinationals by introducing its own Patent Act, changes in the Foreign Regulation Act (1973) and the New Drug Policy (1978). These "positive discrimination policies", as Sudip Chaudhuri (2005: 29) describes them, introduced patents for manufacture rather than products

which meant that Indian pharmaceutical corporations could manufacture drugs already on the market as long as they found a new methodology to do so. It reduced the life of drug patents from sixteen to five years from the date of sealing and limited the processes that could be patented for each drug to one; earlier, *all* processes involved in the development of a molecule could be patented provided they were new.

These steps practically eliminated the monopoly that global pharmaceutical companies had in the country and led to the significant growth of the local industry, including the development of a bulk drugs sector that enabled Indian drug prices to be amongst the lowest in the world. In 1988, Schedule Y of the Drugs and Cosmetics Act came into force, establishing regulatory guidelines for the permission of foreign and local clinical trials. In its early version, the Schedule supported the growing generics market. For example, it required foreign companies to conduct Phase III studies in India prior to the drug's marketing approval and limited foreign companies exploiting India's cheaper production and labour costs by introducing a phase lag. As such, by the early 1990s India was not an attractive location for international clinical research; both its patent legislations and regulatory limitations to foreign research presented serious obstacles for the multinational pharmaceutical industry. Articulating explicit nationalist and anti-imperial sentiments, determined to free its science sectors from their colonial origins, Indian state actors aimed for self-reliance and autonomous decision-making in the country's biomedical and pharmaceutical industries.

During the 1990s, however, India experienced a transition from four decades of central planning and Fabian socialism to an increasingly liberalised, privatised and globalised economic regime. The New Economic Policy, announced by the central government in 1991 under the pressure of the World Bank and the International Monetary Fund, implemented various changes aimed at opening the economy to private and foreign investment, including a reduction in import tariffs, the deregulation of markets, the reduction of taxes and greater foreign investment. These changes led to the entry of private actors into many core sectors such as education, healthcare, transport and energy supply. Many have characterised these changes as processes of displacement and dispossession through which millions of farmers, workers and artisans were deprived of their lands and means of livelihood (e.g. Bhattacharya, 2010; Chatterjee, 2008).

The most significant consequence for the field of biomedicine was India's joining of the World Trade Organisation (WTO) and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which required the country to provide strong protection for intellectual property rights and a product patent system (Williams, 2001). As a result, the Indian pharmaceutical industry turned from the manufacturing of generics to the discovery and development of new molecules, attempting to establish a market model similar to that of the United States (Sunder Rajan, 2006). In 2005, the government also revised Schedule Y after heavy criticism by the local and international pharmaceutical industry for the restrictions it imposed on the growth of a clinical trials sector. With the aim of boosting India's status as a global biotechnological player, the updated Schedule lifted previous restrictions on early phase trials and removed the compulsory time lag, granting greater freedom to sponsor companies (Nundy and Gulhati, 2005). It stipulated Good Clinical Practice (GCP) responsibilities for ethics committees, investigators and sponsors and suggested formats for the documentation of consent forms, reporting of adverse events and ethics approval (Bhatt, 2010). As a result, trial activity in the country increased from 54 studies up to 2006 to 320 in 2009 (Ravindran and Nikarge, 2010) and up to 787 in 2012 (Ravindran and Ved, 2013). Within a decade, India's pharmaceutical sector was transformed from socialist protectionism and five-year planning into one of the fastest growing biotechnological markets in the world.

However, it was mainly the bio-services sector, including contract research and outsourced clinical trials, that constituted the main driver of Indian biotechnological growth. While some analysts predict a shift to more strategic outsourcing and a transformation of CROs from mere service provision to full service collaboration (e.g. Drabu et al., 2010), to date the Indian clinical research industry largely consists of service providers for multinational companies. One of my respondents, Dr Kaushik Bansal, an Indian clinical pharmacologist and translational medical expert now working for a major pharmaceutical company headquartered in Switzerland I will call Quintosh Pharma[10], describes Indian clinical research activity thus:

[10] Though several large multinational pharmaceutical companies are headquartered in Switzerland, I have decided not to name Quintosh's precise location as it might reveal the identity of the organisation.

> The research is very rudimentary, at a very infantile state at the moment. Basically, it is in infancy. The Indian pharma companies don't have the resources or the know-how to conduct indigenous research, so it must be dependent upon the companies like Quintosh to do the research for us. The research scenario in India isn't so great I would say (Dr Kaushik Bansal, clinical head, multinational pharmaceutical company, Switzerland and India, August 2014).

The quote illustrates that a clear discrepancy exists between the aim of biopharmaceutical innovation and the actuality of service delivery. As Sunder Rajan also observes, while "attaining a culture of innovation is the rationale offered by many Indian actors who embrace global techno-capitalism, the route to its potential realization is contract work for Western companies, work that is not innovative and for which intellectual property resides with the contracting agent" (2006: 189).

Widespread consensus in bioethical (e.g. Emanuel et al., 2004; Macklin, 2004; Orth and Schicktanz, 2017) and sociological (e.g. Cooper and Waldby, 2014; Petryna, 2009; Prasad, 2009; Sunder Rajan, 2006, 2017) debates is that for transnational biomedical research to be ethically justifiable, it needs to have clear and substantive benefits to the host community. Given the reality of service provision though, global clinical trials rarely correspond to the most immediate health needs of the majority of India's population for whom a core concern remains the absence of quality primary care and the inaccessibility or unaffordability of essential medicines. Bansal admits with astounding candour:

> I mean it's only natural that the Western world will develop drugs for diseases that are prevalent in this part of the world. Why would they worry about something that is happening in Africa, or, say, in the Indian subcontinent? They have no motivation to do that. And they will anyway never get the revenues out of that drug, even if they did develop it. . . . So, yes, there is a tendency to neglect a lot of diseases which don't impact the Western world (Dr Kaushik Bansal, clinical head, multinational pharmaceutical company, Switzerland and India, August 2014).

Bansal confirms what critics have long accused the pharmaceutical industry and the Indian government of: global clinical trials are part of the country's strategy to boost bioeconomic growth rather than part of a very much needed effort to improve general healthcare. Clearly, what clinical trials in India accumulate is value, not health (Sunder Rajan, 2006).

In sum, India has experienced what bioethicist Salla Sariola and colleagues (2015) term "Big pharmaceuticalisation": Capital is largely concentrated in the hands of multinational pharmaceutical companies, increasingly using their market power to influence political decision-making processes and regulatory practices. A new commercial research culture has emerged that is driven by the epistemic skills and capacities of private research enterprises, especially CROs. However, a public debate over the human costs of pharmaceutical research and development, including questions of access to new medicines, has also been sparked. In 2011, a public interest litigation was filed by civil society organisations such as *Sama* and *Swasthya Adhikar Manch* regarding the death of seven girls who were forcibly enrolled in an HPV vaccination study. This led to the Indian Supreme Court suspending 157 previously approved trials in an attempt to tighten the regulation of clinical testing in India, a business that had, until then, generated annual revenues close to $1,6 billion (Limaye, 2013). The Court reacted to what are said to be over 4,000 incidents of serious adverse events, including at least 89 cases of death, which have recently unsettled the global scientific community as well as the Indian public (The Times of India, 2014). Indian CROs were found to have tested new substances on survivors of the 1984 Bhopal gas disaster, and the recruitment of illiterate young girls from remote areas for an immunisation study in 2009, sponsored by the Bill and Melinda Gates Foundation, caused a nationwide outcry (Kumar and Butler, 2013; Shetty, 2011). Up to 40 trials involving the US National Institutes of Health (NIH) alone were put on hold by the Indian Supreme Court.

After clinical research activity had been brought to a near complete halt—the number of trials dropped to 150 in 2014 and to 81 by mid-December 2015 (Pharm-Olam, 2016)—the DCG(I) made a concerted effort to overhaul the approval process for clinical trials and introduced major amendments to the Drugs and Cosmetics Act. For example, it issued a draft guideline on mandatory audio-visual recording of the informed consent process and stipulated the inclusion of government hospitals in trials. It also broadened the parameters for compensation in case of trial-related

injuries and death, and introduced tighter regulations for the registration and vetting of ethics committees, CROs and special expert commissions, so-called Subject Expert Committees (SECs) (Bhatt, 2014; CDSCO, 2013; Saxena and Saxena, 2014). Respondents unanimously welcomed these revisions, or at least their overall direction. On the requirement of audio-visual recording, for example, Dr Shilpa Reddy, based in Mumbai and working for Santora Therapeutics, another large multinational headquartered in New York, finds:

> It was still felt that, in India the illiterate population being quite large, and nobody wants to feel that someone's being taken advantage of, and therefore we felt to make it more robust, and in case there are any legal issues that come up or questions that come up, there was a proper consent taken. So because of that we brought in another step of an audio-visual recording, which honestly, if you ask me, and we interacted with many investigators, and the majority of them are very happy about it, because they say 'well, we used to always do this, now it's being recorded, so we are also better off', and the ones who are not happy with it, we are also happy not working with them. Because you know, we don't want these types of people doing research (Dr Shilpa Reddy, physician and principal investigator, multinational pharmaceutical company India, March 2015).

And Dr Suresh Kamireddy, an oncologist and director of local CRO ClinSync in Hyderabad, confirms that:

> It's good, it's good for the research. It's more documentation work that we need to do, [but] it's also good for the research subjects, and the safety of the subjects is the most important things . . . , to make sure that the subject's rights have been protected (Dr Suresh Kamireddy, CEO of CRO ClinSync, India, March 2015).

However, despite this enthusiasm, some multinational pharmaceutical companies had already orientated themselves towards other lucrative locations after years of regulatory stagnation, and the new guidelines were seen as significantly limiting their operations. After lengthy negotiations with local stakeholders, some of them

were revised to accommodate for the needs of multinational capital, but at the time of writing, India still witnessed only a gradual resumption of global clinical trial activity.

1.3 Biologies without borders? Existing regulations on ethnoracial variation

As India became subject to international legislation on intellectual property under the aegis of the TRIPS Agreement, it also entered a transnational space governed by multiple guidelines and recommendations on the collection of ethnoracial data in clinical research, and the careful management and calibration of population differences. Two are of particular significance for the analysis in this thesis. The first is the guideline E5, Ethnic Factors in the Acceptability of Foreign Clinical Data (hereafter E5), by The International Council for Harmonisation (until 2015 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), or just ICH[11], issued in 1998.[12] The second is the FDA Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials (hereafter Guidance), first published in 2005. The latter is based on the recommendations set out by the Revitalization Act in 1993 that made the inclusion of ethnoracial minorities compulsory for all federally funded research and FDA marketing applications, as I will describe more fully in Chapter 2. The two guidelines are shaped by different political and economic considerations, and illustrate divergent understandings of racial, ethnic and national populations. I will briefly discuss each in turn to provide context about the regulatory and classificatory infrastructure of my analysis.

As multinational companies left the confines of the United States and Western Europe to decrease the cost of drug development and gain access to new markets, they encountered the problem of inconsistencies between national standards that produced significant delays in trial and drug registration. Consequently, the pharmaceutical industry aimed to persuade the main regulatory authorities, the

[11] India is not a member of ICH but occupies observer status.

[12] At the time of writing, the new draft of ICH E17, General Principles for Planning and Design of Multi-Regional Clinical Trials, was being finalised and opened for suggestions and feedback from the scientific community. Though most data for this thesis was collected before the draft version of E17 was launched, respondents considered E5 to be an important stepping stone to globalised drug development but expressed excitement in anticipation of E17. Nonetheless, apart from highlighting the importance of considering potential ethnoracial variations when planning multi-regional studies, the new guideline does not explicitly address this issue and refers back to ICH E5 for greater detail.

FDA, the European Medicines Agency (EMA, at the time the European Agency for the Evaluation of Medicinal Products, or EMEA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to harmonise their regulatory standards for drug testing and registration (Abraham and Reed, 2002). To realise this, the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA) organised the formation of ICH in 1990, bringing together key industry associations and these regulatory bodies. Throughout the 1990s, ICH members developed several technical guidelines on toxicological testing and other safety-related aspects of drug development.

An in-depth account of these developments is of little significance for this thesis (for such accounts see Abraham and Reed, 2002; Kuo, 2005; Laan and DeGeorge, 2013) but the making of E5 on the acceptability of foreign clinical data illustrates how drug developers have historically sought to overcome human variability in multinational research and diverging understandings thereof. This is crucial for three reasons. First, it exemplifies the non-scientific drivers of conceptions of diversity, pointing also to recurrent tensions between pharmaceutical companies seeking to tap into new therapeutic markets and regulatory authorities aiming to protect local populations from potentially harmful new medications. Second, this also means that conceptions of population, race and ethnicity sit uncomfortably between offering numerous potentials for research and constituting non-economic barriers to transnational research and trade. And third, E5 establishes the significance of non-genetic factors of drug variation on a par with genetic polymorphisms, sharply distinguishing the study of variability in drug action from research in genetics. These tensions point to the difficulties of global harmonisation.

The aim of E5 was not to provide a comprehensive analysis of the nature of ethnoracial differences but to develop a workable proposal for managing them across multiple boundaries. At its core was the transformation of culturally saturated and highly contested notions of race and ethnicity into a globally valid and scientifically legible formula for the creation of a single market of proprietary drugs between the US, Europe and Japan. As conference documentation illustrates, its impetus was primarily borne out of the Japanese reluctance to succumb to a universal interpretation of human biology (D'Arcy and Harron, 1996). Rooted firmly in a dialectics of difference, Japanese drug regulatory policy presumed an

ethnically unique population that needed to be safeguarded from intrusion by foreign and possibly harmful medicines (Kuo, 2005: 204). National myths and socio-political imaginaries thereby contributed significantly to how ethnoracial difference was defined, much to the dismay of other ICH delegates. US-American representatives especially pressed for a more scientific approach to human variation and appeared to interpret Japan's hesitancy as part of its protectionism vis-à-vis global markets (Kuo, 2005). Its insistence on ethnoracial specificities was perceived as an unnecessary obstruction to the shared goal of facilitating transnational drug research. In the end, a fragile consensus was reached by developing an operational definition of ethnoracial difference as a factor that could be 'bridged' between different jurisdictions by extrapolating clinical trial data from one country, region or population to another (ibid.).[13]

Multiple rounds of negotiations produced a list of 'objective', 'subjective' and 'pharmacologically relevant' variables, aiming to identify the specific properties of a given drug itself that would make it sensitive to ethnoracial factors (D'Arcy and Harron, 1996). For example, a narrow therapeutic dose range, a high rate of metabolism especially by enzymes known to exhibit genetic polymorphisms, and low bioavailability making a drug more susceptible to dietary absorption effects are some factors indicative of a drug's propensity to have variable outcomes (E5: 13). In addition, a list of population characteristics was also drawn up. Unlike other initiatives to streamline racial and ethnic classifications in health across Europe and internationally (e.g. Aspinall, 2007; Bhopal, 2004), E5 does not stipulate ethnoracial groups *per se*, but treats race and ethnicity as composite variables that can be broken down into their individual constituents and assessed separately. Though it descriptively refers to the "three major racial groups most relevant to the ICH regions (Asian, Black, and Caucasian)" (E5: 12), it does not use these categories analytically but distinguishes between extrinsic ethnic factors such as environmental, cultural and economic determinants, and intrinsic ethnic factors, most notably 'genetics' and 'race'. This approach has aptly been criticised for biologising race, rendering it a static, essential and objective category (Kahn, J., 2006). However, it also emphasises the significance of non-genetic, environmental and cultural factors in shaping drug response, and the complex interactions

[13] A bridging study, according to ICH, is "a study performed in the new region to provide pharmacodynamic or clinical data on efficacy, safety, dosage and dose regimen in the new region that will allow extrapolation of the foreign clinical data to the population in the new region" (E5: 6).

between intrinsic and extrinsic factors that drug developers need to consider when interpreting variable results. Not least, this technical approach promised a way out of the deadlock that the meanings of race and ethnicity are inherently difficult to pin down: by disassembling the categories into (some of) their discrete components, a practicable strategy was developed by examining each in turn. This appeared to satisfy both critics and defenders of the race concept whose primary concern was the harmonisation of their pharmaceutical markets for scientific benefits and commercial gains (D'Arcy and Harron, 1996; Kuo, 2005).

E5 thereby stands in tension with the FDA Guidance on the collection and reporting of ethnoracial data. The Guidance implemented the NIH Revitalization Act of 1993 which required that both women and members of ethnoracial minorities be included as research subjects in all federally funded research, and that this research be "designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial" (NIH, 1994: n.p.). Shortly after, the FDA removed existing restrictions on the inclusion of women in clinical trials and made the adequate representation of ethnoracial minorities mandatory, including their classification according to criteria laid out by the Office of Management and Budget (OMB) also used in the US census (Epstein, 2007). The classifications for race, according to the OMB, are African American, Caucasian, American Indian and Alaska Native, Asian, and Pacific Islander and Native Hawaiian; for ethnicity, Hispanic and non-Hispanic are the only categories. In light of the increasing number of studies conducted abroad, the Guidance concedes to the collection of "[m]ore detailed race and ethnicity data . . . when appropriate to the study or locale" but recommends that "these more detailed race and ethnicity data be related to the identified OMB categories of all clinical trial participants when submitting such data to the Agency" (FDA, 2005: 4).

Though work on the formulation of E5 was taken up at around the same time as the Revitalization Act was passed by Congress, their objectives have been perceived as conflicting, if not contrarian. The wealth of responses to the FDA draft guideline by pharmaceutical corporations, above all by the US industry body Pharmaceutical Research and Manufacturers of America (PhRMA), illustrates the industry's concern that imposing US-American ethnoracial categories on global populations will inhibit the globalisation of drug development and marketing (Kahn, J., 2006).

Comments explicitly referenced E5 and its distinction between intrinsic and extrinsic factors as preferable, criticising the OMB definitions of race and ethnicity for leaving the impression that these were static and scientifically objective categories. Industry representatives bemoaned the inconsistent definitions and questionable accuracy of race and ethnicity categories, ironically, as Jonathan Kahn (2006) observes, assuming it was *possible* to develop a more scientific and globally accepted definition. However, the point here is that FDA requirements were perceived as hampering the establishment of global markets: while the operational approach to ethnoracial variation of E5 was seen as opening up new possibilities for international trade, FDA guidelines were repudiated as introducing barriers to the globalisation of drug markets.

Nonetheless, both guidelines illustrate existing tensions around the significance and management of ethnoracial diversity in the global arena and diverging interests in harnessing its benefits. They also emphasise the pivotal status of the nation state, here Japan and the United States, in shaping population descriptors, belying talk of a truly integrated transnational space. Population diversity is not only a source of ethical and economic value for corporate and public health actors alike but can also act as an impediment to the global integration of biomedical research and capitalist production. E5, in particular, exemplifies attempts to transcend ethnoracial categories and produce standardised human subjects abstracted from their local particularities to make them globally exchangeable. In this thesis I not only explore the different meanings of human diversity and their effects, but also existing efforts to flatten these (see Chapter 7). Such processes are never neutral, but steeped in power and inequality, especially as they take place on the highly uneven playing field of transnational biomedical research.

As such, this research is not primarily an exploration of scientific practices in the laboratory but investigates the overlapping and sometimes opposing vectors of biology, clinical practice, regulatory policy, cultural narratives, industrial research and marketing strategies. Postcolonial science scholar Amit Prasad (2008) pertinently argues that laboratory practice is not the only and, undoubtedly, not the most important site for examining the production of scientific knowledge. He therefore advises that analytical attention be equally placed on other levels and domains. Critical scholarship, he writes, may use analyses of lab work merely as a backdrop for a broader discursive analysis of specific projects or policies. In this

vein, I have examined basic research only to place it in dialogue with national and transnational policy making, industry funding criteria, everyday biomedical practice and broader bioeconomic objectives. Before turning to a critical survey of key authors and texts that have shaped my analysis, I offer a brief outline of each chapter.

1.4 Chapter outline

This thesis explores how novel biopolitical techniques and discursive practices mobilise the Indian population as a locus of value for myriad biomedical projects in complex and often contradictory ways. Chapter 2 offers a systematic survey of the literature that has shaped this research and situates my work within the existing body of knowledge. Chapter 3 outlines my methodological foundations and discusses my approach to the assembled qualitative data. In Chapter 4, I trace historical representations of Indianness from philology to eugenics to illustrate the intrinsic ambiguity of scientific knowledge about Indians, thus emphasising key continuities but also distinctions from contemporary conceptualisations. I have chosen to ground my analysis of present-day scientific narratives in readings of the historical literature because I find the historical record of knowledge production not only central to an understanding of current processes, but also to the operation of biopower. Chapter 5 turns to the meaning of human diversity and the re-emergence of racial concepts in contemporary drug development by recourse to my empirical data from interviews with key scientists and policy makers. I argue that though few researchers adhere to a notion of racial essences, the familiarity and common-sense character of the concept promises at least *some* certainty where there might be none in truly scientific terms. While it may be unproductive to proclaim the return of scientific racism, such approaches nonetheless usher in a novel set of ethical and socio-political problems. Chapter 6 situates India within these discussions and analyses the concrete effects of existing ideas about race and ethnicity for multi-regional trial designs. I illustrate that Indians' historical ambiguity as almost white, but not quite, renders Indians similar enough to Euro-Americans, facilitating the relocation of clinical trials to the country. This demonstrates the reproduction of the Caucasian as the standard human and recuperates the figure of the Indian as the 'brown', 'non-white' or 'heterogeneous' Caucasian. Chapter 7 engages Indian trial participants' bodily diversity, genetic and non-genetic, which clinical researchers

seek to commensurate for transnational comparability. I show that the assumption of biological and metabolic universality that biomedical research relies on risks erasing local idiosyncrasies as well as the requirements and demands of Indian bodies to emulate those of the drugs' future consumers. Exemplifying, again, the significance of the standard human—more often than not a euphemism for Euro-American—existing efforts to flatten diversity also reveal the subtler asymmetries in global scientific collaborations. In Chapter 8, I put the perspectives of the pharmaceutical industry in transnational biomedical research in dialogue with a national genetic research initiative, the Indian Genome Variation Consortium (IGVC), to explore their contrasting objectives and conceptualisations of Indian diversity. I find that the simultaneous mobilisation of Indians' genetic resources for nationalist projects and commercial exploitation, resulting from the state's collusion with the multinational pharmaceutical industry, stratifies emerging forms of bionationalism or genomic sovereignty. This increases the risk of exploitation for certain populations. Last, Chapter 9 turns to India as a site of biomedical consumption to contest existing accounts of India as merely a location for drug testing, countering representations of Indian patients as passive 'guinea pigs' devoid of agency. Rather, it explores what concepts of population are mobilised to encourage consumptive practices. Here too, national imaginaries fuel conceptions of biological difference and Indians' genetic constitutions become the locus of myriad hopes and possibilities—at least for some. In the conclusion, I will return to consider some of the key issues raised in the thesis and reflect on their consequences for future sociological enquiry.

Chapter 2: Literature Review

Ever since the publication of Ashley Montagu's *Man's Most Dangerous Myth* (1997 [1942]), there appeared to be a broad consensus in the scientific community that race inaptly describes human biodiversity. Buttressed by the findings of the Human Genome Project (HGP) that, as human beings, we share 99.9 per cent of our genetic code with one another, many have announced the death of scientific race thinking. Paul Gilroy (2000: 37), for instance, anticipates that though genomics "may send out the signal to reify 'race' as code and information . . . there is a sense in which it also points unintentionally toward 'race's' overcoming". At the molecular level, race, it is assumed, becomes less salient as a marker of human diversity, reprimanding scientific studies disguising as biological what is, in effect, primarily a political category. At the same time though, sociological scholarship has disproved such utopian accounts by documenting the increasing encroachment of ethnoracial categories in biomedical practice and research, and warned of a perilous return to eugenics 'through the backdoor' (Duster, 1990). A crude proxy for human genetic diversity at best but used extensively nonetheless, post-genomic bioscience has revived the idea of (ethno-)racial categories as useful surrogates for biological variation. Critics therefore voice concern about their "molecular reinscription" (Duster, 2006), "molecularization" (Fullwiley, 2007b) or "genetic reinscription" (Abu El-Haj, 2007), rife with stigmatisation, unequal access to medical treatment and economic exploitation.

This chapter critically surveys the seminal thinkers, arguments and critiques of ethnoracial classifications of human diversity in scientific practice. It comprises a description of existing work while also identifying leading concepts, definitions and theories that have informed this thesis. To situate my own intervention in these debates, I will both identify important dimensions of previous work on the subject and discuss what I perceive as shortcomings, tensions or areas for further analysis to be addressed in subsequent chapters. I have organised the literature on ethnoracial classifications in bioscientific practice into five sections that each sketch specific arguments about their constitution and effects. Section 2.1 explores the turn to diversity in biomedical research as part of a larger policy framework that sociologist Steven Epstein (2007: 1) describes as "inclusion-and-difference paradigm". These accounts are key to understanding the multiple factors that have

contributed to the new attention to diverse bodies, and to the complex ways in which bureaucratic categories, scientific objectives and personal values interact in producing race and ethnicity as meaningful variables in bioscientific practice. Section 2.2 moves to discuss the resurgence of ethnoracial classifications in population genetics, genomics and pharmacogenomics, illustrating distinctions and similarities to earlier periods of scientific deliberations on race as outlined in the literature. I also argue that, despite its politically progressive intents, the commonplace sociological insistence on the nature of race and ethnicity as social constructs misses an important opportunity to investigate precisely why and how they are gaining traction in specific contexts. Elaborating on this, section 2.3 illustrates the entanglements of scientific, commercial and political motives in reviving ethnoracial categories, using the debates around the paradigmatic example of BiDil, the world's first race-specific drug. I suggest that though this literature is vital in illuminating a growing commercial interest in human difference, it tends to neglect the economic limitations of biomedical niche markets and overlooks discrepancies between the value of diversity within and outside the lab or the clinic. Attending to the complex relations between diversity, science and political economy is especially relevant as we move beyond US-American social realities: Section 2.4 emphasises the need to resist the unmediated export of the categories and technologies pertinent to the US-American context and illustrates how the politics of human biodiversity have been conceptualised in other national and cultural settings. Last, section 2.5 aims to contest the notion of a new biopolitics on the molecular level, outlining existing work that details the social lives of new biomedical technologies in postcolonial contexts like India. Drawing on such anthropological work, I close by proposing that we must attend to the myriad complexities of biomedical concepts and technologies when they 'travel'.

2.1 Turning to difference

The history of race, ethnicity and medicine is rife with narratives of suffering and abuse. In the United States, an expansive body of literature has detailed, for example, gynaecologist James Marion Sims' exploitation of enslaved African women to develop techniques to repair vaginal fistulas (Ojanuga, 1993; Reverby, 2017); the observation rather than treatment of impoverished Black men in the infamous Tuskegee syphilis study (Jones, 1981; Lombardo and Dorr, 2006;

Reverby, 2009); and unsolicited medical experiments on Black prisoners and children long after the Jim Crow era (Hilts, 1998; Washington, 2007). In colonial India, anatomical scholarship buttressed the biologisation of race and was used as scientific evidence for India's historical inferiority to justify imperial practices of conquest and rule (Bhattacharya, 2011; Pande, 2009; Robb, 1995). Elsewhere, public health discourses associated phenotypical difference with filth and pollution, literally "'brownwashed'", as Warwick Anderson (1995: 640) writes, "with a thin film of germs". Of course, the imbrications of race and medicine culminated in the unspeakable atrocities committed by Nazi doctors in Germany (for overviews see Eckart, 2012, 2006; Hohendorf and Magull-Seltenreich, 1990; Kudlien, 1985; Proctor, 1990; Spitz, 2005). Contemporary medical practice continues to be characterised by enduring inequalities *qua* race and ethnicity (for a general overview see Bhopal, 2014; for an overview of the US-American context see LaVeist, 2005; Smedley et al., 2003; Williams and Collins, 1995; for the UK see Nazroo, 1998; Nazroo and Karlsen, 2001; Parliamentary Office of Science and Technology, 2007).

However, existing descriptions of the entanglements of health, medicine and inequality have recently been complemented by accounts of progression and struggles for inclusion. American sociologist Alondra Nelson (2011), for instance, disrupts staid narratives of exploitation and describes the less well-known health activism of the Black Panther Party in California in the 1960s. Drawing on extensive historical research as well as interviews with former party members, she recounts how the party actively fought for biomedical integration, access to equitable healthcare and the establishment of alternative knowledge paradigms through recourse to anti-colonial thinkers and activists. On the other side of the Atlantic, Ros Williams (2015) empirically explores the inclusionary practices of public stem cell banking in the UK which, almost half a century later, seek to increase the representation of ethnoracial minority donors in the hope of ameliorating existing disparities in stem cell provision. Anthropologists Ciara Kierans and Jessie Cooper (2011), through analysing NHS Blood and Transplant campaign adverts, equally find increasing efforts to enrol ethnoracial minorities as organ donors: despite their higher statistical likelihood of needing a life-saving organ at some point in their lives, only approximately one per cent of registered donors identifies as Black or minority ethnic, alerting the health service to the need

for targeted recruitment practices. Such moves, Kierans and Cooper argue, must be seen as explicit responses to national concerns around the stigmatisation, discrimination and historical exclusion of specific ethnic and racial groups in healthcare services and research.

Important historical, cultural, and material differences between the UK and the US aside, and the limitations of such an Anglo-American focus notwithstanding, Epstein (2007: 1) describes this new, biopolitical policy framework aiming at the increased integration of ethnoracial minorities in biomedical projects as an "inclusion-and-difference paradigm", a new imperative for studying the medical effects of bodily difference according to race and ethnicity. Like the authors cited above, he, too, avoids an all-too-easy link between exploitation and biomedical research and details how, in the early 1980s United States, an eclectic assemblage of health advocates, politicians, civil rights activists and medical researchers pushed for the greater inclusion of women and racial or ethnic minorities in biomedical experiments. Their argument was not only that every group in society is deserving of biomedical attention and care, but also that the 'standard human' in medical research, used as a stand-in for all of humanity, was in fact largely white, male, heterosexual and middle-aged (Epstein, 2007). Biomedicine was found, as Epstein (2009: 38) writes, to be consciously or unconsciously singling out "a particular sociodemographic group as the ideal specimen of humanity—the ones most worthy of study—and then to treat knowledge derived from the study of this group as universal". In response to this, a broad movement for inclusion insisted that a whole variety of social differences were also medically meaningful and claimed that it was inappropriate to extrapolate findings from one 'kind' of patient to another. Moreover, these scholar-activists found that the exclusion of minorities has led to their disadvantage when it comes to accessing experimental therapies, rendering issues of access and social justice core demands of the movement.

Arguments about the sustained exclusion of minorities from research may be somewhat exaggerated, if not factually wrong, given the long history of exploitative experimentation on marginalised social groups within and outside the US. Jill Fisher and Carey A. Kalbaugh (2011) also usefully highlight that claims about the exclusion of minorities have largely focused on therapeutic trials whereas minorities are actually overrepresented in early phase studies in healthy volunteers that are often relatively well-paid. Indeed, Nelson emphasises the very ambivalence

of biomedicine in relation to impoverished African Americans which has both abandoned and overexposed them in what she calls a "dialectic of neglect and surveillance" (2011: 164). Critiques of exclusion are nonetheless pivotal for the development of the policy framework within which this thesis sits: the call for expanding the pool of research participants led to the launch of the 1993 Revitalization Act in the US, a piece of legislation that made the inclusion of women and ethnoracial minorities mandatory for all NIH-funded studies. The Act sought to ensure that research was designed in a way that allowed for separate analyses of whether the variables under study affected women and minorities differently than the standard white male (Epstein, 2007). It has been implemented by all federal agencies including the FDA that offers extensive guidance for clinical researchers on the collection of data about race and ethnicity (see FDA, 2005). For example, NIH grant application forms now comprise a chart on which investigators must detail their recruitment targets according to gender and race/ethnicity (Epstein, 2010: 66), and FDA policy recommends "the use of the standardized OMB [Office for Management and Budget] race and ethnicity categories for data collection in clinical trials" (2005: 2). This is to both ensure consistency in demographic subset analyses, and to make these analyses more meaningful for the evaluation of potential differences in the safety and efficacy of pharmaceutical products.

The war on the standard human, then, has meant that biomedical attention shifted from the postulation of bodily universality integral to medical practice and research to a focus on the diversity of biological constitutions and social realities, at least in the US. But linking important quests for equality and representation with scientific arguments about embodied difference, reformers also helped revive primarily *social* categories of difference as biologically real. The assumption was, Epstein (2010: 65) writes, that the categories relevant to identity politics were identical with the categories relevant to medical practice. This meant that the inclusion of minorities assumed to have previously been underrepresented in research, and the measurement of differences between them, has also reproduced them as biologically distinct. In other words, through categorical alignment work that causes "classification schemes that already are roughly similar to become superimposed or aligned with one another" (Epstein, 2007: 91), bureaucratic and scientific classifications were rendered functionally equivalent. Kierans and Cooper (2011) describe a similar trend for their case of NHS recruitment practices, arguing that

the criteria used to determine immunological compatibility for organ transplantation erroneously treat membership to sociocultural groups as proxies for genetic makeup. Though criteria have been somewhat modified, this did not precipitate a shift in the broader categorisations across which matches were made. As such, we witness, they write, a "remodelling of ideas of genetic sameness and difference that in fact translates straight back into the racial and ethnic categories that shape our understanding of who is 'like' whom" (Kierans and Cooper, 2011: 13).

It is this dual mandate of inclusion-and-difference rather than an unequivocal exclusion or exploitation of minorities that appears to increasingly characterise contemporary entanglements of science, race and ethnicity. Indeed, genomics, as I will detail in the next section, has been attributed a similar transformation from being a science decidedly disinterested in difference to one devoted to mobilising its potentials for ameliorating health disparities (Bliss, 2012). Bliss (2012: 3) highlights that this comes after three quarters of a century of science policy designed to *prevent* rather than encourage research on biological differences according to race. Here, too, it was an assortment of anti-racist activists as well as scientists themselves affected by stigmatisation that pushed for greater awareness to minorities' potentially higher disease susceptibilities and differential drug reactions. Their "anti-racist racialism" (Bliss, 2012: 15) represents a new ethos in biomedical science which, similar to the inclusion-and-difference paradigm, purports to use ethnoracial analyses to ameliorate social inequalities. This ethos emphasises the importance of health equity and of granting different members of society a genuine participatory role in the design and conduct of studies aiming at their improvement.

Research by Epstein, Bliss and others usefully highlights this novel approach to ethnoracial diversity in science that aims to rid itself of its pernicious past, often driven by ethnic minority physicians themselves and their quest for social justice. Their work is seminal in that it details key characteristics of this new science and policy and lays out fundamental distinctions between contemporary and earlier manifestations of 'racial science' (see section 2.2 for this discussion). It is vital for this thesis since it illustrates not only why and how researchers are increasingly conscious of biological differences presumably pertaining to race, but also how they do so *reflexively*, merging their subjective experiences, political aspirations and ethical commitments with their scientific practice. However, despite the growing number of trials conducted outside the United States (Allison, 2012; Glickman et

al., 2009), few sociologists have moved beyond acknowledging the increasingly transnational character of biomedical research, and the implications this may have on the politics of recruitment and classification. To some extent, this is understandable as they investigate a phenomenon rooted in and predominantly concerning the US-American context (though, as shown, similar developments have been documented for the UK). Epstein himself explains that while narrowly focusing on one national context might seem surprising when tracking the decidedly global industry of pharmaceutical development, national political struggles and institutional as well as epistemic cultures remain powerful contributors to the definitions of medical and social policies, categories and identities (2007: 7). Indeed, it is a core argument of this thesis that the significance of national imaginaries and material histories remains key to shaping categories of difference in biomedical research.

Nonetheless, the globalisation of clinical research is deeply permeated by the rules and regulations set by the FDA as the globally most powerful agency (Carpenter, 2014). Not only are over 70 per cent of the firms involved in global drug development headquartered in the United States (Epstein, 2007: 7). The US-American market also remains the most lucrative for pharmaceutical companies (for current figures see ITA, 2016). As political scientist Daniel Carpenter (2014: 1) writes, "[b]ecause admission to the U.S. market is the preeminent site of profit for the world's drug companies, the FDA's veto power over entry into the American health-care system translates into global economic and scientific reach". As such, international companies applying for NIH funding or seeking FDA approval must comply with federal regulations such that global practices of recruitment and retention are inexorably inflected by US-American objectives and policy frameworks. This means that the planning, conduct and analysis of multi-regional trials in India, which this thesis investigates, are also, at least to a certain extent, shaped by the parameters and policies of US-American regulatory policy on inclusion and *vice versa*. Furthermore, in the contemporary global arena, as Chapter 1 has laid out, multiple national paradigms and policy frameworks interact in infinitely complex ways.

This makes attention to their entanglements and concrete effects for the organisation and mobilisation of human diversity imperative for our understanding of how bodily difference is produced, sustained and translated in an increasingly

transnational world. So far, there is a real dearth of studies examining the global varieties and effects of inclusion-and-difference, and the transformation of US ethnoracial classifications when they travel. A notable exception is anthropologist Ian Whitmarsh's (2008) ethnographic study of asthma research in Barbados. Though not the primary focus of his work, Whitmarsh elaborates on the politics of classifying Bajan identities as Afro-Caribbean or Black according to FDA criteria. The stabilisation of the highly relational character of race into a single classification, neglecting its internal heterogeneity according to ethnicity, nationality, and family history, not only transforms it into a biological marker akin to the reification Epstein envisaged. Independent of recent evidence on genetic ancestry, researchers also examine variations in medically relevant genes through more traditional means, for example the categories used in the US Census or physical appearance. Moreover, the frequent self-identification of inherently mixed Bajan patients as Black illustrates the global influence of North American political culture that has made the label popular, not least because of the latter's historical prejudice against racially mixed people (Whitmarsh, 2008: 112). Like Whitmarsh, I find that postcolonial states, medical researchers and local physicians deploy, contest and transform the categories available to them, in often inconsistent, if not contradictory, ways. His ethnographic account of the multiple translations between medical practitioners and lay people, distinct geographic spaces and diverging cultural understandings of human diversity therefore offers a valuable extension of Epstein's focus on the US-American policy of inclusion-and-difference.

2.2 Race and human diversity beyond nature vs. nurture

While Epstein describes the larger developments in policy making related to race and ethnicity (also to gender and age), a distinct yet associated set of debates has addressed the resurgence of ethnoracial analyses in genetics and genomics in the dawn of the HGP. As is well known, the mapping of the entire human genome revealed, in then-US President Bill Clinton's words, that "we are all 99.9 percent genetically the same regardless of race" (The White House, 2000: n.p.). The 0.1 per cent that distinguish us, of which only 3–10 per cent are associated with geographic ancestry (Feldman and Lewontin 2008), were said to occur mainly due to distinct patterns of genetic markers, especially of so-called Single Nucleotide Polymorphisms or SNPs, locations of variation in DNA that are caused by genetic

'typos' occurring during cellular division (Wilson et al., 2001). While SNPs can generate genetic variation by causing differences in the codes for proteins in our genes, they do not correlate to any of the phenotypic traits commonly assumed to be racial. The HGP, in other words, sent out the clear message that race has no basis in science. In fact, its very methodology presumed biological commonality: what it sought to generate was "*the* reference" sequence, providing the "genetic terms in which all individuals would be expressed" (M'charek, 2005: 5).

The enthusiastic celebration of the end of scientific race thinking, however, may have been premature. Shortly after the findings were presented, the NIH launched the Pharmacogenomics Research Network that assumed that the 0.1 per cent that we do *not* share were actually quite considerable for understanding variable drug response (Fullwiley, 2008). Likewise, Stanford population geneticist Neil Risch and colleagues argued for both the existence of five major populations based on continental ancestry that can broadly be mapped onto what were historically understood as races, and for the significance of race-specific treatment in clinical practice (Risch et al., 2002; also Andreasen, 2000, 2004; Rosenberg et al., 2002). According to them, it would be irresponsible and ethically erroneous *not* to take race into consideration when making clinical decisions. Even those actively rejecting racial terminology have receded to proxy notions such as genetic or continental populations or biogeographical ancestry often transmuting into racialised language. In short, there has been a surge of research into medically relevant genetic differences between human populations, often reifying race as a biological category.

The question critical scholarship (e.g. Abu El-Haj, 2007; Bliss, 2012; Roberts, 2012; Rose, 2006) has asked in this context is not only whether the post-genomic idea of race is essentially the same as the one produced by race science at the turn of the twentieth century, but also if it is generative of similar social and political logics. These questions are, of course, too comprehensive to be answered conclusively here. Suffice it to note that the literature has largely agreed on at least three fundamental differences between nineteenth century race science and its post-genomic relative. First, contemporary usages of race are based on the logics of statistical probability rather than typological conceptions of human difference. Aiming to detect relative or *clinal* variations between humans, novel genetic approaches usually calculate a population's (or an individual's) specific risk factors or percentage of genetic

admixture, making them an inherently probabilistic science refraining from absolutist statements (Abu El-Haj, 2007; Brace, 2005; Graves, 2001; Roberts, 2012; Stepan, 1982; Zack, 2002). Second, despite the enduring prominence of population genetics, genomics has precipitated a new focus on the individual rather than a specific group or population. In contrast to the statistical logics of eugenic practices, post-genomic bioscience focuses not on the collective (the population, the race, the nation) but on individual health. Its aim is to determine the potentiality of future illness rather than singling out specific groups as pathological or defining one's 'true' race (ibid.). And third, as described earlier, some theorists attribute post-genomic bioscience a decidedly antiracist nature as opposed to its earlier murderous formulations. This is part of a larger paradigm shift in which the contemporary nexus of race and genomics no longer has domination and subordination as its end but is rooted, as Inda (2014) argues, in the life-affirming pole of twenty-first century biopolitics. Of course, these seeming discontinuities should never prevent the rigorous questioning of the normative and political dimensions of this new science on race, letting oneself be deceived by its charitable logics (Benjamin, 2016b).

In the sociological literature, the return of scientific discourses about race has been scrutinised from multiple perspectives. Accounts that are social constructionist in nature insist that genetic justifications for race are utterly misplaced and risk confounding political for biological markers. In line with wide-spread agreement in sociological scholarship on race (e.g. Banton, 1998; Frankenberg, 1993; Winant and Omi, 1994), Dorothy Roberts, for instance, argues that "[r]ace is not a biological category that is politically charged. It is a political category that has been disguised as a biological one" (Roberts, 2012: 4; also Braun, 2002; Witzig, 1996). These interventions serve as an important reminder that race, as a scientific concept, was carefully manufactured also by legal, political and economic vectors, with multiple and often contradictory meanings depending on the context. Research emphasis on genetic explanations for disease disparities, as historian of science Lundy Braun also finds, is problematic since race is a social category that describes individuals whose ancestries are often highly diverse. Therefore, concludes Braun, "social explanations, not genetic ones, for disparities are most informative" (Braun, 2002: 160). Making raced-based assessments in the physician-patient clinical encounter can be misleading at best and dangerous at worst.

In line with but expanding social constructionist arguments about race, medical sociologist Troy Duster (2004) turns to the actual effects of racial constructs on health and emphasises the complex feedback loops between biological markers and social realities. For example, he illustrates that it is not skin colour or specific genetic traits *per se* that determine African Americans' higher rates of cardiovascular diseases. Rather, darker skin colour is associated with reduced access to scarce resources, healthcare and a constant exposure to racial discrimination causing inordinate amounts of stress that taxes the body. Not disagreeing with its theoretical foundations, Duster nonetheless concludes that social scientists cannot retreat to the safe haven of social constructionism but must elucidate the concrete, tangible consequences of societal divisions on health and the body. As Anne Fausto-Sterling (2008) writes, attending to such feedback mechanisms provides a framework for the study of human differences away from an ultimately futile distinction between nature and nurture, and allows for examining the contributions of geographic ancestry, individual experience, class and gender to variable patterns of health and illness.

Their interventions resonate with other critiques of social constructionist theorising in the sociology of race and racism, arguing that we must move beyond the commonplace truism that races are socially constructed (Banton, 2015; Carter, 1998; Fields, 2001). If anything, as prominent historian Barbara J Fields (2001: n.p.) puts it, the axiom so "readily available to a German Shepard dog or even a Golden Retriever" should be the starting point for, not the conclusion to a scholarly argument. The assertion of the non-biological nature of race has failed to preclude the emergence of novel discourses of ethnic or cultural difference and has reproduced the category's polarising functions between difference and sameness (Banton, 2015; St Louis, 2002). It has also been unsuccessful in accounting for corporeality and embodied difference by maintaining an unproductive antagonism between the social and the biological (St Louis, 2004). Though initial claims about social constructionism helped raise awareness and challenge traditional assumptions about what is 'natural', describing race as a social construct, ultimately, has not helped dismantle it.

As such, some sociologists and science scholars agree that maintaining an artificial dualism between race as biological and race as socially constructed, which renders race an either-or proposition, conceals more than it unveils (Berger and Luckman,

1967; Haraway, 1991; Hartigan, 2008; M'Charek, 2013; Montoya, 2011; Runciman, 1998; St Louis, 2004). Such dualisms, as anthropologist Michael Montoya asserts, "reinforce both sides of the argument while maintaining a hold on the modernist logics of divide and conquer" (Montoya, 2011: 30). Not only are the foundations of social constructionism found to be theoretically weak—their conceptual basis could easily be undermined by the discovery of just *one* association between race and biology—but such approaches also divert attention from developing a broader cultural understanding of how, when and why race comes to matter (Hartigan, 2008). Rather than summarily dismissing it as socially constructed with little to tell us about corporeality, these approaches seek to comprehend the specificities of new biomedical technologies and the cultural processes through which race is gaining traction in science. While the assertion that race is a social construct has long functioned as a kind of interdiction against research into biological differences, they aim at developing more robust and effective critiques that can genuinely account for the complex expressions of human diversity.

As such, Amade M'charek (2013), for example, tracks how race gains its multiple meanings or is enacted (Mol, 2002) through the complex and multifaceted practices of scientific technologies. She illustrates how different technologies produce different versions of race, ethnicity or population, merging pieces of clothing, skin colour and snippets of DNA with the specific anxieties, expectations and imaginaries of a given society. Not only does she thus avoid the trap of treading binary distinctions between nature and nurture, but she also attends to the multiplicity of race, unravelling how "it is done differently in different practices" (M'charek, 2013: 424). The constructionist account of race is important as it emphasises that concepts of race do not arise in a social vacuum and foregrounds their historical emergence in early modernity. Nonetheless, moving beyond dualistic notions of nature versus nurture is core to understanding the pervasiveness of ethnoracial categories, and how different scientific practices and biomedical technologies both reify old and produce new configurations of human difference. M'charek's assertion that race is neither a traceable, biological marker nor a societal chimera but is "made relevant and materializes in a variety of ways" (M'charek, 2013: 424) helps grapple with the multiple versions of race and population emerging in this thesis.

Furthermore, the turn from confronting the existence of race to analysing the practices through which it is produced and sustained is pivotal. The actual ethical question, for me, is not what race *is* but what race *does*. Though grappling with what scientists mean when they deploy ethnoracial concepts, as Chapter 5 does, is core to dismantling it, this should not detract from investigating its concrete effects. As Nikolas Rose argues, we should not primarily ask what a concept means, but rather how "it functions in connection with other things, what it makes possible, the surfaces, networks and circuits around which it flows, the affects and passions that it mobilizes and through which it mobilizes" (1999: 29). The seemingly infinite struggle over the actual existence and precise meaning of race should not displace the analysis of why it is pervasive, and the politically significant question of how to best mobilise against *racism*, both inside and outside the lab. In some sense, Ian Hacking (1999: 5) hits the nail on the head when, critiquing social constructionism, he demands: "Don't ask for the meaning, ask for the point". In the next section, I explore the political and economic incentives that race has offered in the context of contemporary biotechnologies and *vice versa* to develop this point further.

2.3 The new value of human diversity

Laboratory ethnographies and interview-based enquiries into the scientific and material practices that reproduce race as a meaningful scientific concept have been complemented by scholarly investigations into the emergence of biomedical technologies developed for specific ethnoracial groups. The most (in-)famous example is the drug combination isosorbide dinitrate/hydralazine marketed under the trade name BiDil, approved by the FDA in 2005 for treatment of congestive heart failure specifically in African Americans. Its notorious history has been widely cited (Bibbins-Domingo and Fernandez, 2007; Brody and Hunt, 2006; Inda, 2014; Kahn, 2004, 2012; Pollock, 2007; Roberts, 2012; Seguín et al., 2008a; Temple and Stockbridge, 2007) and I will refrain from reconstructing it in detail here. However, important to remember is that developers retrospectively combed the data from the earlier Vasodilator Heart Failure Study (V-HeFT) after failing to secure a patent for BiDil, revisiting data for differential effects of the study drug *qua* race. The subsequent American Heart Failure Trial (A-HeFT), enrolling exclusively self-identified African Americans after it was found *post hoc* that BiDil appeared to be

more effective in prolonging survival in Black but not in white patients, confirmed the investigators' hypothesis that there was a racial difference in response to BiDil. The design of A-HeFT, however, was deeply flawed. For example, there was no non-Black control group to which BiDil's alleged superior effects in African Americans could have been compared to. This means that the only actual finding that A-HeFT established was that BiDil was effective in Black patients, but not that it was any less effective in white patients. Also, it is still unclear *why* BiDil was more effective in the A-HeFT than it had been in the V-HeFT study. As anthropologist Anne Pollock (2007) explains, this may well be attributable to the synergistic effects of BiDil with ACE inhibitors not previously combined, the inclusion of women, or differences in the aetiology of heart failure between patients in V-HeFT and those in A-HeFT. Nonetheless, data from A-HeFT convinced regulators of the efficacy of BiDil in self-identified Black patients rather than in those with the presumed markers for responsiveness to the drug, and granted its developers, then Boston-based biotech start-up NitroMed, a new patent for marketing the drug exclusively to self-identified Black patients. NitroMed's stocks skyrocketed, tripling in value in the days following the approval of BiDil (Kahn, 2004).

Though this story has been recounted *ad nauseam*, it has instigated a set of arguments that continue to linger in the sociological literature about race and biomedicine, providing a crucial backdrop for this thesis. First, in addition to the incentives created by the policy framework of inclusion-and-difference and scientists' own, often justice-driven motivations for deploying ethnoracial categories, the story of BiDil illustrates the commercial enticements induced by the neoliberal market mechanisms of product differentiation and niche marketing, and the intellectual property-based patent system for the development of population-specific technologies. Scientists often deploy race strategically to pursue political but also commercial aims. The reason why BiDil was marketed as a drug exclusively for African Americans, as Roberts (2012) rightly argues, had at least as much to do with its commercial as with its medical appeals. For NitroMed, it was not only about saving Black lives but also about being granted a new patent that could lead to significant profits. This has led a variety of thinkers to argue that there is a new value in racialised tissue (Inda, 2014; Kahn, 2004; Koenig et al., 2008; Pollock, 2007; Roberts, 2012; Rose, 2006).

In contrast to sociologist Richard Titmuss' warning of the "world-wide phenomena of racial prejudice and its association with concepts of blood impurities, 'good' blood and 'bad' blood, untouchability and contamination" (Titmuss, 1970: 20), today an almost inverse logic appears to be at play. As Inda (2014: 74) explains, "biomedicine and the biosciences today are highly subject to the exigencies of capitalization, with shareholder demands and profit obligations heavily shaping the medical problems that these knowledges of life seek to address". In the context of BiDil, this means that specific populations are seen as potential sources of value, of 'racial vital value' as Inda calls it, "the economic value generated by fostering the vitality of racial bodies" (ibid.). In line with the assumption that biopolitics is no longer explicitly aligned with the murderous side of biopower, he argues that BiDil exemplifies the contemporary biomedical focus on nurturing the lives of previously marginalised communities. BiDil is thereby the most prominent but not the only example of biotechnologies developed for specific ethnoracial groups. Geneticists Sarah Tate and David Goldstein (2008) count at least 29 medicines claiming to differ in safety and/or efficacy according to race or ethnicity, and eight per cent of new drugs approved by the FDA between 1995 and 1998 carried specific warning labels (also Ramamoorthy et al., 2015). As such, BiDil joins an entire range of biomedical products—race-specific vitamins, genetic tests and jogging shoes are just some examples (Whitmarsh and Jones, 2010)—seeking to address ethnoracial health disparities through technological means.

The second lesson to be learnt from its development is that, though BiDil itself is not a pharmacogenetic drug with its precise metabolic pathways and causal mechanisms remaining fundamentally obscure, it has stoked fears that ethnoracial categories would not become superfluous once a truly personalised medicine has been established. What Kahn describes as the "politics of the meantime" points to scientists' claims that race is but a stepping-stone on the path to the promised land of pharmacogenomics, but also to the "choices regarding allocation of resources and framing of health-related priorities that such claims enable" (2012: 18). Kahn worries that even as genomic milestones are being reached, the use of race continues unabashed, and public health priorities are being shifted from making healthcare accessible and affordable for all to searching for technological fixes based on spurious assumptions about human diversity. The combination of institutional

mandates, personal values and commercial incentives continues to provide powerful inducements for the adoption of often crude categories.

Such accounts are important as they alert us to the variety of political and economic vectors buttressing the status of race and ethnicity in science. In fact, they have sparked my own curiosity in empirically exploring the reach of this commercial interest in difference, especially on a global scale. Does the recruitment of Indian patients, for example, not only aid pharmaceutical executives to increase the politically mandated diversity of study populations for FDA marketing applications (a hypothesis I will scrutinise itself), but are there also economic benefits derived from harnessing Indians' racialised tissue? If so, in what ways and for whom? After all, Indians' increasing purchasing power and quest for cutting-edge, personalised healthcare is increasingly being noted by various biotechnology and pharmaceutical companies (see Chapter 9). Are new ethnoracial markets evolving for Indians or Indian Americans and if so, what ideas about Indianness drive these? For which Indians will these be accessible and with what (health) effects?

My empirical data suggest, however, that the pharmaceutical industry has a very limited interest in harnessing human diversity for the creation of niche markets (see Chapters 6 and 7). What the constructionist objection to the commercial exploitation of race in biomedicine tends to ignore is, first, that a sustainable economic model for financing pharmacogenomics or the creation of biomedical product differentiation is yet to be developed. As sociologists Adam Hedgecoe and Paul Martin (2003) write, while there has been increasing discussion of the commercial potentials of clinical treatment based on the targeting of small-molecule drugs to patient subpopulations, little to no attention has been paid to the highly speculative nature of pharmacogenomics and the fact that few working technologies actually exist. Both the hype created and the anxiety caused by the prospect of pharmacogenomics ignore that its uptake in clinical practice is quite uncertain, and that drug companies remain fundamentally disinterested in stratifying markets and limiting their consumer base (Pirmohamed and Lewis, 2004; Rothstein, 2003; Smart and Martin, 2006; Tutton, 2012, 2014; Williams-Jones and Corrigan, 2003). As Pollock (2007: 253) aptly states, the discussion of BiDil and racialised medicines has tended to mobilise an undifferentiated notion of 'pharmaceutical companies', but there is significant stratification within the industry. If anything, BiDil exemplifies the challenges and promises of 'small Pharma', smaller biotechnology and

pharmaceutical companies with strong incentives to innovate (Pollock, 2007; Rothstein, 2003).

The commercial failure of BiDil should also have alerted sociologists of race and biomedicine to the limited potential and flawed economic rationale of marketing products to economically marginalised populations. Pollock is attuned to this, arguing that "African Americans are betwixt and between with regard to pharmaceutical grammars of consumer capitalism on the one hand and neglected population on the other" (2012b: 55). Though BiDil created significant boost by its promise to address the long-ignored health issues of marginalised groups, it ultimately failed to reach its market as these same groups simply lacked the funds to purchase it (also Inda, 2014). According to a report by the *Wall Street Journal*, only about one per cent of the 750,000 eligible Black Americans suffering from heart failure were taking BiDil one year into its sale (Westphal, 2006). While BiDil's poor economic performance has been regularly explained away by stressing specific market aspects such as the availability of generic versions as well as tactical errors including its pricing and lack of marketing to hospitals, such arguments miss important insights from both the sociology of pharmaceuticals and the history and sociology of race and racism (Pollock, 2007: 247).

For example, given the long history of medical abuse that they had had to endure, African Americans displayed an entirely rational suspicion of an experimental drug developed exclusively for them. Roberts (2015: n.p.) recounts an incident at a community engagement meeting for BiDil during which an elderly Black woman stood up in protest and shouted: "'Give me what the white people are taking!'". What Ruha Benjamin (2016a) calls "informed refusal" reveals that it is by no means ethnoracial minorities' 'anti-science' sentiments or a lack of information, as some scientists and policy makers frame it, that prevents them from participating in projects of biomedical consumption. Rather, such refusals must be seen as very much informed, resilient decisions to speak back to scientific authority, shaped by centuries of exploitation and neglect. As Benjamin argues, in contexts characterised by structural violence more by than by consumer choice, individual refusal or even collective forms of conscientious objection are quite sensible responses. As such, it is entirely comprehensible that many African Americans turned against a pill that was advertised solely to them.

Not least, the new 'racial vital value' must be scrutinised in juxtaposition with the lack of value ascribed to racialised and other marginalised lives outside the lab. The rise of the Black Lives Matter movement (Camp and Heatherton, 2016; Taylor, 2016), for example, responding to the enduring, lethal state violence inflicted upon Black bodies, makes blatantly obvious the deep asymmetry between scientific and political arenas. Benjamin is attuned to this, aptly noting that "our investment of both time and money in reengineering biological life far exceeds our collective will to transform social life" (Benjamin, 2013: 176). The focus on *race* (in the lab) tends to prevent the analysis of *racism* (in society) as if the first could exist independent of the latter. Analyses of the value of human diversity must account for this political reality: racialised bodies may matter in the lab or the clinic, but beyond this domain, their value remains firmly in question.

Though BiDil and the cultural politics of race it is embedded in are quite specific to the US-American context, important lessons can be learnt for other contexts as well. As shown, commercial incentives exist for targeting medicines to specific populations, though they may be somewhat limited and not applicable to all sectors in the biotech and pharmaceutical industries. Moreover, I will argue that concepts of race and ethnicity are indeed underwriting the search for global sites for clinical trials, though it is often ethnoracial sameness or similarity rather than difference driving these efforts. Most importantly, however, what BiDil shows is that the incentives for race-specific medicines are deeply permeated by the specific national, cultural and economic configurations in which they emerge. The very recognition of African Americans' higher rates of heart failure as a central scientific concern is centrally predicated on the particular history of transatlantic enslavement (Lee, 2009; Merz and Inda, 2016). The focus of federal policy and research into African rather than, for example, East Asian ancestries cannot be explained away by scientific rationales alone but stems from a core interest in remedying the specific legacies of slavery and segregation. As Inda (Merz and Inda, 2016) argues, BiDil can be understood as a form of racial redress, a hitherto unprecedented effort to remedy the historical sufferings of African Americans. Scientific interests and concepts of difference are intimately tied to national imaginaries and historical narratives, and the symbolic capital core to the production and consumption of pharmaceuticals is steeped in a society's specific hopes and promises. Therefore, Chapter 9 focuses on biomedical technologies that have been developed specifically

for the Indian population, investigating the kinds of claims and promises they mobilise and the specific versions of the Indian population they conjure.

2.4 Genomic sovereignty as postcolonial science policy

Despite the global reach of NIH policy on inclusion and the transnational proliferation of neoliberal market mechanisms capitalising on human diversity, one must be attentive to any unmediated export of US-American categories, politics and technologies (Skinner, 2006). Hinterberger (2010) warns that when considering the development of human genomic variation studies, for example, research tends to pose US-American categories and experiences as universal. Rose (2006: 11) even claims that the preoccupation with the North American context distorts global discussions of race and genomics. We must be wary of the very assumption that race is the primary or even a significant category of concern in biomedical research outside the US (Hinterberger, 2010; Ventura Santos et al., 2015; Wade et al., 2014a). Ideas about human diversity "travel across time, between locations, between institutional settings, between spheres of expertise, and between experts and the lay public. In transit, these ideas do not remain the same, but are rather interpreted and remade" (Schramm et al., 2012: 6). As such, attention needs to be paid not only to how US-American categories and ideas about race change when they travel, but also to how different national governments, scientific networks, epistemic cultures and local publics mobilise selected aspects of their histories and cultural narratives to form novel approaches to human diversity in and through biomedicine.

In contrast to the research undertaken by Hinterberger on Canadian genome research, most negotiations of human diversity I explore in this thesis are firmly tied to US-American regulatory policy given the attractiveness of its drug market and the global influence of US-American science. In fact, though I share the astonishment over the somewhat self-referential North American debate that has perplexed many (M'Charek et al., 2013; Schramm et al., 2012), part of my very research interest lies with probing *just how* influential these debates have been, and what effects they have had on other understandings of human diversity. My research explores the very relationships, entanglements and contradictions of ethnoracial concepts in complex, multi-sited scientific networks as they travel from and back to the United States. As part of this, however, I also explore Indian

genomic research initiatives and local entrepreneurs capitalising on Indian genomic variation, the kinds of populations they construe and the economic and health benefits they promise. In this context, I have found the emerging literature on the function of genomics in revising or substantiating national narratives about populations outside the US, especially in the Global South, particularly helpful. It illustrates not only that race is by no means the only meaningful category of difference in bioscientific research, but also how postcolonial governments lay claim to their populations' DNA to devise new forms of "genomic sovereignty" (Benjamin, 2009; Hinterberger and Porter, 2012; Schwartz-Marín, 2011; Schwartz-Marín and Restrepo, 2013). This resonates with anthropologist Aihwa Ong's assertion that, especially in Asia, "biotechnologies are allied to nationalist efforts to overcome past humiliations and to restore national identity and political ambition" (Ong, 2010: 3). To state the obvious, sovereignty, here, is not narrowly understood as the concentration of state power in the hands of the political elite and the military but in a broader sense as encompassing a series of governmental practices aiming at population control, surveillance and regulations vis-à-vis global markets.

In response to the increasing awareness of the implications of genomic variation for health as well as the economic value of diverse tissue in pharmaceutical development, several governments in the Global South, including India, have begun to exercise a kind of protective ownership over the DNA of their populations (Benjamin, 2009; Egorova, 2009; Schwartz-Marín and Restrepo, 2013; Wade et al., 2014a). Through the processes of strategic calibration that Epstein (2007) describes, they thereby conjure new biopolitical entities such as 'Mexican DNA' (Benjamin, 2009; Schwartz-Marín, 2010), 'South African DNA' (de Vries and Pepper, 2012), 'Thai DNA' (Seguín et al., 2008b) or 'Indian DNA' (Benjamin, 2009; Egorova, 2010) based on specific degrees of genetic heterogeneity and homogeneity. As Benjamin (2009: 341) explains, these policies assert deeply nationalist sentiments of self-determination in the face of increasing globalisation of biomedical research and forms of bioprospecting (Hayden, 2007; Parry, 2005). The investment in, and adoption of, innovative genomic science and technology is seen as key to breaking the cycle of dependence on industrialised countries and to furnishing developing countries against emerging biocolonial threats (Hardy et al., 2008; Seguín et al., 2008b).

Such efforts have been celebrated as laudable interventions with regards to the myriad health problems these countries face. Global health ethicists Abdallah S. Daar and Peter Singer (2005), for example, recommend harnessing genetic variation for the development of new or the 'recycling' of existing pharmaceuticals. Through an approach running counter to what they refer to as 'Western' or 'boutique' personalised medicine, they advertise deploying carefully defined genetic populations and differences between them for the creation of targeted therapies and drugs. This form of postcolonial pharmacogenomics, considering not only genetic differences between individuals but also between different human groups, can have significant implications for public health in the Global South, they hope (for a discussion of this point see Chapter 8).

From a sociological and race critical perspective, however, Benjamin (2009) warns that these efforts implicitly brand national populations or specific subpopulations as genetically distinct from others in a move that naturalises regional or nation-state boundaries. Furthermore, Ernesto Schwartz-Marín and Eduardo Restrepo (2013) in their comparative analysis of state-sponsored genome initiatives in Colombia and Mexico find that the very idea that genetic patrimonies belong to nation-states or specific ethnoracial groups is the outcome of a genetically reified understanding of human diversity which they refer to as biocoloniality. Biocoloniality, unlike biocolonialism which, according to them, supposes an epistemic rupture with older forms of colonialism, acknowledges Foucault's supposition that biopolitics has always been about the management and exploitation of the life of populations. As such, they link claims to genomic sovereignty not merely to the novel, molecular capacities of post-genomic bioscience, but firmly embed them in the overlapping rationales of modernity, nationhood and colonial awareness (ibid).

Celebrations of empowerment and national self-sufficiency overlook that the efforts of genomic sovereignty inherit the perils of the geneticisation of life through which national and group identities are increasingly understood as genetic affiliations diagnosable by blood tests (Benjamin, 2009; Egorova, 2013). Though they do so in the service of improving public health and realising social justice, they tend to ignore that the "geneticization of national populations impacts groups differently, enriching some and dispossessing others, solidifying and weakening group ties to the nation-state in unexpected, and potentially detrimental, ways" (Benjamin, 2009: 342). In the case of the Mexican Genome Diversity Project, for example, it was

found that the discourse of national genomic sovereignty actually masked a highly non-altruistic enterprise in which Mexican geneticists, in cooperation with transnational pharmaceutical companies, were plundering the indigenous heritage of the country (Schwartz-Marín and Restrepo, 2013). Accusations of biopiracy equally haunted the Colombian Human Expedition's objective to protect the genetic materials of indigenous communities and ethnic minorities (ibid).

Borrowing from bioethicists Barbara Prainsack and Victor Toom (2010), anthropologist Yulia Egorova (2013) therefore describes this Janus-faced nature of postcolonial genomics as "situated dis/empowerment", attending to the "simultaneity of both empowering and oppressive effects" (Prainsack and Toom, 2010: 102, cited in Egorova, 2013: 293) of DNA technologies. As such, she draws attention to the ways in which these technologies inhabit both oppressive and enabling elements. Juxtaposing the use of genetic ancestry tests by Jewish communities in southern India in an attempt to prove their Jewish identity and the branding of India's genetic diversity as a valuable resource for multinational companies, Egorova argues that biomedical technologies can both contest and reinforce global relations of inequality.

Independent of how one assesses the concrete projects of genomic sovereignty on the continuum between empowerment and exploitation, what these debates illustrate is the kinds of symbolic capital DNA technologies possess, especially in the Global South. They also foreground the nation-state as a key actor in devising new forms of governance (Fortun, 2008; Pálsson, 2007; Pálsson and Rabinow, 1999) and the nation as an imagined community in shaping geneticised categories of belonging. This contrasts with most studies focusing on the US-American context, find Peter Wade and colleagues (2014) who argue that in Latin American genomics, racialised meanings are intrinsically wrapped up in ideas about the nation. As these meanings evolve around the figure of *mestizaje* (mixture or hybridity), the particular configuration of race they observe is one of an 'absent presence' (Wade et al., 2014b, 2014a). The trope of *mestizaje* functions to deny the significance of race while it nonetheless lingers prominently in the very conceptualisation of mixture and informs the creation of national identities. In other words, they find that the particular genomic expression of race is through concepts of nation which, here, function as convenient vehicles to circumnavigate the "deep-rooted ambiguity"

(Wade et al., 2014a: 497) of race in Latin America (Silva, 2007; Ventura Santos et al., 2015; Wade et al., 2014b).

In India, categories of race equally criss-cross with those of language, caste, region and ethnic or tribal groupings, shaping a peculiar genetic mosaic characterised by both heterogeneity and homogeneity. The longstanding national paradigm of 'unity in diversity' is reinvigorated by the findings of the IGVC, mobilised for the explicit aim of national cohesion and widely distributed through popular media and artistic representations. Contrasting Mexican nationalism rooted in hybridity, Indian geneticists are keen to emphasise the separate-but-equal nature of Indian populations. Though each mobilises different conceptions of heterogeneity, both national genomic initiatives marshal pre-existing narratives about biological and cultural proximity in their efforts to map genetic variations and to understand their implications for disease risk (Benjamin, 2009). Juxtaposing the currencies of Indian diversity for commercial exploitation and national aspirations, I thus contribute to developing a more complex account of how genomic sovereignty operates both with and against the tenets of global biocapitalism.

2.5 A politics of life itself?

The literature on genomic sovereignty foregrounds the multiple categories of difference emerging through contemporary biotechnologies, and the hopes and promises associated with them. It contributes to but also challenges the growing debate on what Rose terms the 'politics of life itself', a new molecular biopolitics concerned with "our growing capacities to control, manage, engineer, reshape, and modulate the very vital capacities of human beings as living creatures" (2006: 3). In contrast to the biopolitics of the eighteenth and nineteenth centuries aimed at improving the health of the population (Foucault, 1978, 2004; Rose, 1994), contemporary vital politics, he claims, aim at governing human individuals at the level of DNA. These new forms of governance go hand in hand with calls for self-management especially in the field of health, aiming for patients to assume responsibility for their potential future illnesses and become active consumers of medical services (Rabinow and Rose, 2006; Rose, 2006). As such, they produce new forms of 'biological citizenship' in which shared genetic traits, diagnoses of illness or treatment regimens provide the basis for new kinds of somatic identification and

affiliation (also Petryna, 2004; Rose and Novas, 2005). Paul Rabinow similarly describes such modes of collective identification as forms of 'biosociality' within which "it is not hard to imagine groups formed around the chromosome 17, locus 16, 256, site 654, 376 allele variant with a guanine substitution" (Rabinow, 1996: 102). Such groups, he argues, have access to a variety of experts beyond the medical profession as well as narratives, traditions and a plethora of pastoral keepers to aid the understanding of 'their' conditions and devise ways of intervening into them. Both authors, as well as others who critically assess the myriad social implications of the new biosciences, chart important transformations in the vital politics of somatic bodies and selves. However, their work has not remained without critique, and two main arguments are particularly relevant for this thesis.

First, rather than being substituted by the politics of the genome or the cell, the politics of population at the aggregate level is still an important terrain of the politics of life (Braun, 2007; Hinterberger, 2012a; Raman and Tutton, 2010). This is especially so in the Global South where postcolonial governments increasingly seek to align their populations with the needs and demands of the global bioeconomy (Greenhalgh, 2009; Wahlberg, 2009; Waldby, 2009). Molar bodies and populations remain at least as crucial as objects of life optimisation as cells, genes and genomes. The demand by Daar and Singer (2005) to mobilise key differences between populations for the aims of public health described in the last section exemplifies this well. While personalised medicine is usually understood as developing drug therapies targeted at the individual, here, it is human groups and the distinctions between them that are becoming the targets of biomedical technologies and biopolitical techniques. In India, the biopolitics of the IGVC are very much aimed at charting specific populations for the delineation of health interventions and the creation of new markets based on these populations, frequently in cooperation with transnational pharmaceutical companies.

Second, ethnographic research has shown that far from producing powerful opportunities to harness or gain anything remotely profitable from being biosocially active, individuals and/or collectives in emerging neoliberal formations in the Global South face myriad constraints. These range from the unavailability of resources to the incapacity to organise around a medical condition or syndrome to social isolation and stigma. Anthropologist Aditya Bharadwaj (2008), for example, illustrates in his research on infertility clinics and stem cell laboratories in India

that longstanding cultural expectations and social pressures for women to conceive are central features in the ways in which women's bodies are not rendered biosocial but bioavailable. Given the need to conform to social expectations of fertility, the only sociality women are able to exercise is to cooperate with clinical medicine and their wider familiar networks that often have a vested interested in their reproductive biology. Bharadwaj is thereby informed by Lawrence Cohen's (2001, 2003, 2005) exploration of kidney donation in South India, demonstrating that the often impoverished and indebted donors who trade their bare life are characterised by their common operability or bioavailability, the availability for the selective disaggregation of their cells or tissues for reincorporation into another body. Especially agricultural debt in rural areas, exacerbated by the liberalisation of the Indian economy in the 1990s and growing international competition as well as cyclic male unemployment, migration and sometimes alcoholism have forced thousands to turn to the increasingly visible clinics and private hospitals to sacrifice a kidney.

Rather than forging new ways of identification, new biomedical practices and technologies have, in the context of postcolonial India, produced operability and bioavailability as central features of its rising bioeconomy. While this is not to claim that biosociality does not exist, as Chapter 9 will discuss, it seldom produces powerful individual or group identities (for exceptions see Ecks, 2005; Heitmeyer, 2017). Rather, the biotechnologies of organ donation and clinical trial participation have created a market predominantly for marginalised and socio-economically dispossessed Indians who have nothing left to monetarise but their own bodies, or pieces thereof. Though I will aim to problematise dualistic representations throughout this thesis, what Nancy Scheper-Hughes (2000) demonstrates for the case of organ donation also applies, to a certain extent, to global clinical trial participation: the biosociality of a few (here: drug consumers) is made possible by the bioavailability of the many (here: research participants). Importantly though, this division does not run along a neat West/non-West binary: Indians themselves are figured simultaneously as bioavailable patients for biomedical experiments, as future drug consumers and even as biological citizens contingent on their gender, class and caste positions.

In sum, theorists of the politics of life itself have been charged with implicitly basing their analysis on the neoliberal politics of advanced democracies in the so-

called West. They tend to ignore that articulations of medical practices, formations of belonging and informal regimes of labour in the Global South may stem from different genealogies of biopower than the ones located in Western modernity. Not least, the formulation of biocoloniality explored earlier proposes that the molecular capabilities of the post-genomic era go hand in hand with longstanding dynamics of modernity, nationhood and global inequality against which new forms of genomic sovereignty have been devised. Critiques also illustrate the key role of the postcolonial state in devising such biopolitical practices and the simultaneity of molar and molecular techniques of governance. Indeed, as Sujatha Raman and Richard Tutton (2010) point out, biopolitics may also involve the periodic exercise of sovereign power; though it largely works through self-governing participants, "it also permits the illiberal management of unruly individuals or groups by appealing to the notion of a 'society' that is internally complex and that may periodically require intervention by the state for its maintenance and security" (Raman and Tutton, 2010: 715).

This perspective may also explain how the Indian government can concurrently cultivate collective strategies of intervention aiming at the well-being of the population *and* expose them to potential exploitation through biomedical practices in the name of bioeconomic development. As postcolonial theorist Dipesh Chakrabarty (2000) explains, the dominant narratives of (bio)capitalist development identify what is perceived as a lack or lag in the development of a specific subject, population or nation, and define the progress of such a subject, population or nation towards a pre-determined end. Since the bioavailability and making productive of populations as trial participants is central to India's becoming a global bioeconomic player, the poor's integration into the biomedical industries as research subjects not only renders their bodies a site of exploitation; it also appears legitimate in the name of development and biomedical innovation. Considering such multiple politics of life (and death) is crucial to understanding the convergence of the postcolonial state and the market, the molar and the molecular, and a plethora of struggles around citizenship, inclusion and social justice. The additional perspectives discussed here allow for a finer-grained analysis of the collusion between novel biomedical technologies, biopolitical techniques and new forms of political participation. In this vein, I hope this thesis will contribute to a more complex account of the politics of life when applied globally.

2.6 Conclusion

This chapter has described and critically assessed the core literature on the biopolitics of ethnoracial classification of human diversity in post-genomic bioscience within and outside the West that have informed this thesis. Subsequent chapters will each detail specific aspects of these debates through recourse to my empirical material from archival research, interviews with scientists, regulators and policy makers, and ethnographic data gathered at professional conferences, on industry premises and through available resources online. Before doing so, I will detail how I have approached these materials and the ethical challenges I encountered on the way.

Chapter 3: Methodology

This chapter discusses how I utilised a variety of qualitative methods for this research and the methodological limitations and ethical challenges I encountered doing so. Given the complex, multi-sited nature of my research field, I did not draw on a single methodological framework but devised a methodology inspired by the principles of multi-sited ethnography, constructivist grounded theory and a genealogical approach to archival materials. I have combined semi-structured interviews and archival sources with ethnographic elements, focus group discussions and documentary research to analytically trace the uses of scientific classifications of human populations across a range of disciplinary, institutional, spatial and temporal contexts. The discussion below will outline how I crafted my field of research using these methodological tools, and the ethical predicaments and intellectual anxieties I confronted. The chapter also considers some of the practical decisions made about the selection of research participants, sites and organisations along with the processes of collecting and analysing my data. Throughout the chapter I will use examples from my fieldnotes, attesting to some of the challenges, but also the more productive moments of the research process.

3.1 Crafting the field

When I embarked on this project, I was only vaguely acquainted with the debates outlined in the previous chapter. My knowledge of them deepened as I went along, revisiting the literature and refining my research questions. However, in seeking to bring into dialogue two seemingly distinct phenomena (ethnoracial classifications in clinical research and the globalisation of drugs trials), and to connect multiple, geographically distant spaces (India, Europe and the US), the limitations to my understanding were also recast, in part, as the result of the dearth of empirical data and theoretical literature on the subject. In fact, 'the subject' itself did not exist; there was no discrete subdiscipline or field of enquiry independent of my research as if simply awaiting discovery (Amit, 2000). Rather, such a field needed to be laboriously constructed or, in anthropologist Vered Amit's words, it had to be "prised apart from all the other possibilities for contextualization to which its constituent relationships and connections could also be referred" (Amit, 2000: 6). As

Amit argues, the very notion that a bounded field exists autonomous of the research through which it is discovered is fictitious. As such, the construction of my field was already an analytical exercise. There could be no tidy distinction between devising a methodological approach and accessing the field. Both were intrinsically entangled and shaped by each other. Also, I often had to make do with what was accessible rather than what I considered appropriate or necessary. Any attempt to neatly map out research strategies from my office in New Cross was almost immediately disrupted by the nearly impenetrable, secretive nature of the pharmaceutical industry and the inaccessibility of policy makers and regulatory authorities, let alone the messy nature of social research itself (see section 3.3). In short, I was not approaching a well-defined social world. Rather, I was crafting my own field out of the discursive, material, human and non-human elements of the situation I was interested in, guided by the theoretical principle that the precise constitution and mobilisation of different concepts of population in globalised drug research must be empirically investigated.

The questions I asked, the sites I visited and the people I spoke with were also inflected by my own intellectual and personal journeys. What Caroline Knowles (2000: 60) calls "fieldwork mechanism" describes the opportunities transnational fieldwork offers the mobile researcher, opportunities to reconnect with a former life or escape the current one, always sustaining the possibility of alternate senses of self. Having relocated to Britain from Germany initially to study postcolonial theory at Master's level and then again to research race critical theory for this thesis, my questions reflect the very issues that had animated my own, politically driven and affectively charged, decision to leave 'home'. My choice of India as a field site, in addition to the empirical richness it promised, can barely be viewed as objective either. Since my first trip across the country, from Kashmir to Kerala equipped only with a backpack and the naiveté of a recent high school graduate, I have sought myriad opportunities to return to the subcontinent, driven by both spiritual thirst and intellectual curiosity as well as the professional networks and personal friendships I began to develop. This included an extended period during which I worked for a human rights organisation in New Delhi and Lucknow before completing my undergraduate degree in political science in Berlin. As my familiarity with India, and with New Delhi in particular, increased over the years, revisiting the country as a doctoral researcher filled me with anticipation and

excitement. Returning to stay with the Mehtas, my 'Indian family', in the southern suburbs of the capital also provided the warmth and support so central to this adventure. As such, the link between my field sites is also profoundly autobiographical as I anchored myself in a moving landscape between places I have considered, at various stages of my life, 'home' (Knowles, 2000).

The absence of empirical data or a theoretical corpus which I could simply apply meant that the methodology I was developing was inevitably informed by multi-sited ethnographic approaches, discourse analysis and tenets of constructivist grounded theory, all the while shaped by the relational, professional and financial resources and opportunities available to me. The transnational nature of my research interest may make my inspiration by ethnographic methods appear somewhat peculiar since the aim of ethnographic practice has long been viewed as producing thick descriptions of singular, temporally and spatially contingent events and groups (Clifford, 1986; Geertz, 1973). Defined by its attention to mundane, everyday processes and face-to-face interactions, expanding ethnography's commitment to localism seems contradictory at best. However, as George Marcus and Michael Fischer (1986) argue, the reconfiguration of the spatial relationships between the 'local' and the 'global' over the last few decades also necessitates the reconfiguration of ethnographic research practices. Traditional, single-sited ethnography, they note, is not sufficiently equipped to understand the complexities and multiple causalities that characterise contemporary social worlds. Les Back, in this context, also argues for the need to develop a *global* sociological imagination since the nation state can no longer be regarded as the prime container of sociological analysis and imagination (Back, 2009; also Bhambra, 2014, 2013).

Marcus and Fischer therefore suggest multi-sited ethnography as a (partial) solution to this predicament. Multi-sited ethnography, in Marcus's (1995: 99) words, proposes that

> any ethnography of a cultural formation in the world system is also an ethnography of the system, and therefore cannot be understood only in terms of the conventional single-site mise-en-scene of ethnographic research, assuming indeed it is the cultural formation, produced in several different locales, rather than the particular conditions of a set of subjects that is the object of study.

Multi-sited ethnography defines as its objective the study of social systems and phenomena which cannot be accounted for by only focusing on one site (Falzon, 2012). It does not imply the mere multiplication of sites the researcher travels to, even though, as Mark-Anthony Falzon (2012: 2) notes, multi-sited ethnography has "greatly enlarged the discipline's [anthropology's] carbon footprint". Rather, it constitutes a conceptual topology that requires us to think differently about field sites in relation to fundamental analytical and theoretical assumptions about the social world (Sunder Rajan, 2005: 31). As I have proposed, delineating a specific field or object of study is therefore not a form of methodological groundwork, but always already part of the analytical labour of doing empirical research.

Marcus's device of following people, things, stories, metaphors, signs and symbols across different spatial contexts inspired my own strategy of tracing the categories of race and ethnicity in contemporary clinical research practices across scientific disciplines, governmental institutions and geographical spaces. Though mine is not an ethnography *per se* given the temporal, financial and institutional constraints of this research (and, not least, the growing consciousness of my own carbon footprint), I draw on anthropological methods and include, for example, elements of observation alongside the use of qualitative interviews and archival data. In addition, I have consulted a variety of published and unpublished printed materials such as industry reports, proceedings of scholarly conferences and interviews with key actors in popular magazines and scientific journals. My approach to these materials is decidedly ethnographic in that I seek to understand the different elements and voices of those authorised to make truth claims about human variation (Rabinow, 1989). Early in the process, it became clear that the research field I was constructing required the analytical engagement with a range of objects and perspectives to construct a fuller account of the dynamics of post-genomic bioscience and clinical trial offshoring. As I will discuss below, my interviews with scientists, and particularly policy makers, sometimes drifted towards general issues and formal company lines. To produce more than "thin descriptions" (Duke, 2002: 49) reflecting official government or industry discourses already in the public domain, I needed to creatively deploy a variety of research strategies within and beyond the space of the interview (also 3.6).

To construct fields of research from multiple sites and sources, Adele E. Clarke has developed the approach of situational analysis, building on and expanding the

classical tools of grounded theory through an engagement with the premises of the postmodern turn (Clarke, 2003, 2005; Clarke et al., 2015). Similar to other constructivist interpretations of grounded theory, she aims at disentangling Strauss and Glaser's original formulations from their positivist roots and takes into consideration more recent theoretical and methodological developments. As Kathy Charmaz and Antony Bryant (2011: 293) write, constructivist grounded theory "acknowledges the influence of the researcher on the research process, accepts the notion of multiple realities, emphasizes reflexivity, and rejects assumptions that researchers should and could set aside their prior knowledge to develop new theories". Clarke particularly seeks to supplement its focus on social processes and actions with a multiplicity of alternatives through cartographic mapping, suggesting a methodological perspective able to grasp the complexities, differences and ambiguities of the social world without forcing them into a single, coherent narrative. Such an approach explicitly includes non-human actors, contemporary and historical discourses as well as silences into the analysis. Relational mappings, in her and her colleagues' words, works "against the usual simplifications in particularly postmodern and potentially feminist and critical ways . . . [and] capture and provoke discussion of the many and heterogeneous elements, their relations to one another, and the messy complexities of the situation" (Clarke et al., 2015: 14).

The mapping of the different actors and discourses, including those who are absent, involved in this research helped me gain a more comprehensive idea of the complexities and contradictions that define my field. I sought to map out geographical, institutional, personal, discursive and technological relations and connections and used them as analytical tools to guide my analysis. Though I initially sensed that grounded theory as a "set of general principles and heuristic devices rather than formulaic rules" (Charmaz, 2006: 2) was inevitably going to be part of my theory/method package, I was somewhat uncomfortable with some of its original premises. For example, grounded theory has been regarded as "abstract of time, place and people" (Glaser with Holton, 2004: n.p.) whereas critical interventions, especially by feminist scholarship, have convincingly argued that there can be no innocent, transcendent "gaze from nowhere" (Haraway, 1988: 581). All knowledge is necessarily embodied, embedded, and situated within a specific context, and, as I will detail later in the chapter, one must recognise the partial

nature of knowledge production and one's own position within it (Haraway, 1988; Harding, 2004; Skeggs, 2007). To assume that knowledge stems from a location of transcendence and universality equals abdicating responsibility for one's productions and representations.

Furthermore, the analytical and conceptual capacities of grounded theory are hampered by its orientation towards coherence and commonalities rather than allowing for the contradictions, incoherence or, in other words, the messiness of social research (Charmaz and Bryant, 2011; Clarke, 2005; Law, 2003). The impossibility of formulating an objective account of the social world, and the unruliness of the social world itself, imply that one's research methods must not amount to a form of "intellectual hygiene" (Law, 2003: 3) which cuts off incongruous findings or multiple interpretations to make the research look neat. As I will discuss, my research subject often felt like a moving or shape-shifting target, but there was nothing to be gained by attempting to discipline my data into a definite, unambiguous narrative. On the contrary, the messiness of my findings disrupts commonplace understandings of the nature of race and ethnicity in contemporary bioscience and allows for a more nuanced and complex account. As Clarke (2005) concludes, we need to resist grounded theory's search for purity, coherence and a singular basic social process, and allow for the possibility of a multiplicity of such processes. This also means taking more serious surprising, contradictory or paradoxical data.

In short, the analytical devices of travelling, following, tracing and mapping have shaped my methodological strategies and the delineation of my research field. Indeed, Danish psychologist Steinar Kvale (1996) has framed postmodern knowledge production with a travelling metaphor as opposed to the 'mining' process of modern approaches to research (in Clarke, 2005). While mining implies the unearthing of objective knowledge waiting to be uncovered, cleansed and verified through correlations and comparisons, travelling proposes that the researcher wanders about, asks questions and gathers collectibles of all sorts. In its postmodern understanding, knowledge consists of heterogeneous discourses and practices that are patched together, reconstructed and brought into conversation by the researcher herself whose embodied experience of travelling necessarily inflects which fragments, sites and images are included or excluded. In my travelling from site to site and back and forth between them, I have collected a wealth of data that

refuses to be forced into a singular, unidimensional or unidirectional narrative. Laying out connections and discordances in multiple situational, topographical and relational maps helped me see the range of positionalities that make up my research field without having to exclude or dismiss some as invalid or insignificant.

3.2 Historicising the field

Perhaps the most important contribution by postmodern grounded theorists such as Clarke and Charmaz to my own research is their insistence on the centrality of discursive formations and historical trajectories. While grounded theory in its initial configuration proposed that theory not only be transcendent and universal but also ahistorical, Clarke aptly argues that "historical, visual, narrative, and other discourse materials and nonhuman material cultural objects of all kinds must be included as elements of our research and subjected to analysis" (2005: 145). Including such discourses and taking seriously the theoretical framing especially Foucault has offered to the study of social worlds is part of her project of 'pulling grounded theory around the postmodern turn' (Clarke, 2005). Historical research on the ways in which Indian populations were conceptualised from comparative philology through eugenics has allowed me to provide another dimension to my interview-based and ethnographic data, adding explanatory depth and contextualising contemporary ideas (Gidley, 2012). I conducted this research in the India Office Records at the British Library, the London School of Hygiene and Tropical Medicine and the Wellcome Trust in London; the Bodleian Libraries at Oxford; and the National Archives of India (NAI) and Nehru Memorial Museum and Library (NMML) in New Delhi (see section 3.7).

As much research in genetics and biomedicine has proposed a fundamental epistemological break between pre-War race science and post-War human genetics, it is imperative to attend to the historical origins and continuities of present day scientific discourses. German biologist and historian of science Veronika Lipphardt (2015) argues that critical enquiry must engage geneticists' classifications and sampling strategies, but particularly interrogate the historical narratives they mobilise to justify them. In my research, I was interested in mapping both the continuities and ruptures in how Indian biological diversity has been represented from early Orientalism through colonial anthropometry, eugenics and ultimately

human genetics. Sparking this interest was my hypothesis that though India's myriad population groups have been described through the lens of caste for the objectives of colonial governance, the biological markers of race classifications promised certainty where theories of caste did not. As I will discuss in Chapter 4, scientific knowledge production about Indians was influenced significantly by the dominant parameters of European race science. Moreover, contemporary descriptions of Indians as almost white, but not quite, illustrate its enduring legacies. Therefore, I have consulted a variety of archival holdings in the UK and in India to empirically investigate the conditions of possibility of contemporaneous representations of Indianness.

Migration scholar David Fitzgerald (2006: 10) refers to such combinations of fieldwork and archival research as a way of historicising the field that allows connecting past and contemporary dimensions without necessarily constructing a linear conception of history. Though he is aware of the limitations of multi-sited research which may often amount to nothing more than uncritically 'chasing things around', he illustrates how the integration of interview materials and archival data provides ethnographic or interview-based studies with much needed historical depth. Attending to the history of specific ideas or social phenomena can safeguard the researcher against the often claimed but overly simplistic assertion of novelty and aid her understanding of the complex entanglements of histories and present realities. In this sense, Chapter 4 will provide historical depth to the recent genetic confusion over 'who those pesky billions are' and trace contemporary ideas about ethnoracial diversity back to early anthropological scholarship.

By way of example, prominent globalisation scholars such as Arjun Appadurai (1996) or Manuel Castells (1996) argue that people, commodities and information are increasingly deterritorialised, in constant movement and unconstrained by time and space. However, such claims provide a false foil of sedentary societies and restricted movement of ideas and goods, and the assumption of novelty is, in many cases, grounded in contemporary research alone (Fitzgerald, 2006). As Anderson (2014, 2009, 2002) reminds us, framing transnational phenomena such as scientific research through the lens of globalisation as a temporally distinct set of phenomena specific to the last sixty years ignores a plethora of postcolonial genealogies that have long illustrated the entangled realities of research, migration and trade. "In imaging the 'global'", Anderson further asks, "as the product of unprecedented

flows and circulations, do we tend to ignore its uneven terrain, heterogeneity, and contestation?" (Anderson, 2012: 1). Historically grounded research informed by postcolonial perspectives enabled me to grasp such connections and contestations, and to firmly anchor my project within sociology's original historical consciousness (Gidley, 2012; Mills, 1959).

I have therefore decided to begin my analysis with an exploration of the historical traces in contemporary narratives about Indianness, contextualising and historicising the main tropes and themes recurrent in my interviews. This does not suggest a direct, linear or unidirectional trajectory between past and present ideas, a 'total' rather than a 'general' view of history (Foucault, 1989) that seeks to reconstitute the overall structure of a specific period. Rather, I have taken a genealogical approach to my archival data, using history as a way of diagnosing present realities. Writing such a Foucauldian 'history of the present' does not entail an exhaustive exploration of the historical record but aims to trace specific contemporary ideas and concepts through an investigation of the social conditions under which they were formed (Foucault, 1989). As such, I have interrogated historical debates on comparative philology, Aryanism and race-caste relations as histories that continue to inform and naturalise processes of ethnoracial classification in India.

Such a non-linear understanding of how and under what conditions scientific concepts are formed, replaced and recombined informed my understanding of the contingency of concepts of human variation, and my search for dissonances, ruptures and zones of ambiguity between the past and the present. As I will detail later in the chapter, I was often surprised and unsettled by the empirical data I collected through interviews as they challenged or even contradicted the ways in which the 'resurgence of race science' has been portrayed in the literature. This was not only an issue of maintaining an open and critical stance towards data (Tonkiss, 2012). It was also a question of the epistemological rationale and political appeal of representing present discourses as mere repetitions or returns of past regimes, as if there could be an unchanging, almost metaphysical essence of a science of race that keeps cropping up in different guises under different circumstances. Foucault himself reminds his readers that "one should totally and absolutely suspect anything that claims to be a return. One reason is a logical one: there is, in fact, no such thing as a return. History, and the meticulous interest applied to history, is

certainly one of the best defences against this theme of the return" (Foucault, 2002: 359). Rather than reconstituting an overall essence of a science of race or human diversity simply returning in perpetuity, my methodology draws on archival materials to make historical data intelligible in light of particular questions in the present.

3.3 Staying with the trouble

Despite my best efforts to delineate a precise field through multi-site and multi-method research strategies, it often proved difficult, if not impossible, to identify commonalities and typical strategies of negotiating human diversity in my data. I continuously revised and improved my questionnaire (see Appendix 2) and used information about my respondents to adapt my questions to their professional expertise. For example, FDA regulators were asked about their concerns with globalised clinical research whereas primary investigators in India were queried about the concrete implications of FDA inclusion policies for their daily work. Where necessary, I cited interviewees' publications or relevant policy to match their interests and demonstrate my familiarity with industry conventions and discourses. I also intertwined data collection and analysis in an iterative process, and follow-up questions via email sometimes helped clarify specific aspects of a conversation. Nonetheless, I was never certain I had asked the 'right' questions, spoken to the 'right' experts or had drawn the 'right' conclusions from my empirical data. As I interviewed professionals in a variety of positions and capacities that were dispersed over continents, my research sometimes felt like chasing a moving target, as if it escaped or dissolved as soon as I had put my finger on it. I was, in John Law's (2003: 5) words,

> dealing with a slippery phenomenon, one that changed its shape, and was fuzzy around the edges . . . something that wasn't definite. That didn't have a single form. A fluid object. Or even one that was ephemeral in any given form, flipping from one configuration to another, dancing like a flame.

My reaction was usually either, as Law puts it, to "ask reality to adjust itself" (2003: 4), or to question my own capability to conduct sociologically interesting and methodologically sound empirical research. Discomfort, uncertainty and anxiety

were constant companions during this project (for a critical discussion of feelings of inadequacy see Michael, 2012).

Negotiating these uncertainties, two things dawned on me. First, the social world I was studying was too messy, unruly and recalcitrant to be disciplined into a neat explanatory framework. There could be no singular or straightforward answer to the kinds of questions I was asking. And second, Clarke's approach to mapping explicitly demands we represent not only the differences, contradictions and other possible interpretations of our data but also address the doubts, omissions and anxieties that come with them (Clarke, 2005). Perhaps inconsistence and uncertainty are not merely by-products of empirical research, but rather intrinsic to it. As sociologist Yasmin Gunaratnam argues, "[t]he fundamental problematic of interpretation . . . is that it is always a risky, emotion-laden and ethical business" (Gunaratnam, 2009: 59). The task, according to her, is to practice "our crafts in ways that aspire to the honing of technique and skill and that give recognition to our being touched . . . while all the time remaining faithful and vulnerable to the unknown" (ibid.). Seeking to find ways of discussing insecurities and vulnerabilities while remaining faithful to the aim of conducting coherent analyses was crucial to my development as an engaged and reflective researcher.

This also meant that I needed to continuously reflect upon my own social position as a scholar, and the social effects and epistemological limitations it entailed. As noted earlier, one must abstain from assuming a decontextualised, disembodied vantage point, and recognise the partial and situated nature of all knowledge production (Haraway, 1988; Skeggs, 2007). However, the multifaceted and transnational nature of my research field defied an unambiguous description of my situatedness. Rather, it is proof of the relational and radically contingent quality of social identities. Like my respondents, I spoke not from a stable, coherent perspective (as a white, female, middle-class researcher, for example), but from a variety of positions shaped by the social roles and hierarchies of different societies. As I shuttled between countries, disciplines and institutional domains, I also moved between different social positions contingent on whom and where I was interviewing, with interactions structured by varying expressions of race, class, gender, nationality, age, location and professional expertise. This sometimes facilitated, sometimes stymied my aptitude to understand and relate to my respondents' experiences and knowledge claims.

The messiness of the empirical world and the partiality of perspectives should not, however, dissuade the researcher from partaking in social research altogether. Partiality does not devalue empirical research, and much is to be gained from buttressing progressive political projects with evidence from empirical data. Indeed, Donna Haraway has encouraged her readers to 'stay with the trouble' (Haraway, 2010, 2016) rather than ignoring or giving in to it if they are to formulate more critical and more responsive accounts of the social world. Though at times, it felt ambitious, if not utopian, to envision a research project that spans multiple continents, disciplines and discursive arenas, my interest was fuelled by the commitment to a greater understanding of, and a more "response-able" (Barad, 2007; Haraway, 2008; Reardon et al., 2015) engagement with, the effects of scientific knowledge productions and policy on human genomic diversity. The ethico-political obligations of this project lie with hoping for and envisioning a world that is radically inclusive and affirms a diversity of lives––within and outside the lab. And with hope, or promise, as Jenny Reardon and colleagues (2015: 28) argue, "there is always trouble". In the following sections, I will detail how I negotiated such trouble but also discuss the more fruitful moments in my research process.

3.4 'Whose side are you on?' Ethics, trust and motives for participation

Howard Becker's provocative question, "whose side are we on?" (Becker, 1967), addresses several of the methodological and ethical dilemmas I was confronted with during this research. My interview participants often enquired, implicitly or explicitly, whose 'side' I was on, whether they could trust me, and how I, in turn, could be of use to their own motivations for participating in the research (also 3.6). The question also points to my own discomfort with and the ethical quandaries involved in developing sympathy for my respondents and their personal stories. Not least, it reflects the possible implications of encountering research materials or data that contradict prior, perhaps dearly-held theoretical or political assumptions. In such instances, as Becker notes, the researcher might well be tempted to "suppress those findings, publishing with scientific candor the other results which confirm his [sic] belief" (1967: 240). Having previously addressed the openness to surprising or contradictory data, in this section I reflect on how I navigated issues of partiality and trust in my research encounters.

In ethnographic or interview-based social research, not only does the researcher study her subject, but the subject also studies the researcher. Consider the following fieldnotes from my interview with Dr Prashant Nath, CEO and medical director of one of India's oldest CROs located in the 'cyber city' of Gurgaon, just outside New Delhi:

> Having found my way through the dusty outskirts of the metropole on a hot Saturday afternoon (India defies any notion of the 'normal' work day or week in the rhythms of capitalism) and cleared the usual security proceedings, I finally sat across from Dr Nath in a lofty, air-conditioned office fitted with large windows and marble floors. Over the mahogany double wing doors, Dr Nath's name and title were engraved in ostentatious, golden letters. After the usual introductions, still somewhat distant, Dr Nath insisted I first answer some of his own questions about myself and my research before beginning the interview. Clearly, he had extensive experience with investigative journalism that made him suspicious of such interview situations. As I later found out, he was also practicing his own interviewing skills and tested my ability to confidently present the rationale of my research. It turned out that he had himself recently embarked on a PhD project in sociology in his free time, studying the ethical dilemmas of conducting clinical trials in resource poor countries such as India! Much to the dismay of his supervisory team since, as he smirked, 'the joke is they pollute me, and I pollute them'.

Dr Nath's story is exceptional in that he was my only respondent who had formally enrolled in a social research programme and was familiar with the methodologies of qualitative research. Nonetheless, participants regularly queried, directly or indirectly, whose side I was on. Indeed, the practice of 'checking out' the researcher is a common feature of 'researching up' (Duke, 2002). As Susan A. Ostrander emphasises in a similar context, "gaining access is not the same as establishing the trust required for getting useful data" (1993: 9). Though I was usually introduced to them by a colleague or professional acquaintance, a sociologist from the University of London interested in a topic that has recently received much negative media

coverage could cause blowback for pharmaceutical industry executives and brand management.

Some respondents were reluctant to share anything with me beyond publicly available information and demonstrated their mistrust in myself and/or my research in numerous ways. The following excerpt from my research diary illustrates this:

> Upon their request, I had sent my two interview partners, both working for a multinational pharmaceutical company in Mumbai as Medical Director and Head of Regulatory Affairs respectively, my carefully formulated and nuanced schedule of question a few days ahead of the interview. I knew this was going to be an important interview and I wanted to make sure everything went well. It did not. Successfully crossing half of Mumbai (around 19 miles) by public transport in the midday heat, I reached their office just in time. As none of them responded to the janitor's phone calls, I was, after the usual security and identity checks, ushered up to the meeting room they had reserved for our conversation. After what felt like an hour but was probably no more than twenty minutes, the two of them walked in, accompanied by another colleague responsible for regulatory training. The atmosphere was tense, and while they formally offered me tea and coffee, I could tell by the inexpressiveness of their faces that they were not willing to go one line off the script they had prepared for the interview. I had made clear from the very beginning that I was not a journalist or an activist by providing my supervisor's credentials, emailing from my official university account and citing the British Sociological Associations' ethical codes. However, their distrust was unconcealable. The standard ethical practice of asking whether they would allow me to record the interview as well as assuring them that the transcript would only be for my own use and that any information given would be treated with absolute confidentiality only exacerbated our already fragile relationship. Needless to say, they did not authorise me to use my recorder. Throughout the interview they circumnavigated questions

> about their own work and referred to official legal and policy documents. My question about the potential challenges emerging through the globalisation of drug development was dismissed as unproductive. Better I focus, they suggested, on the benefits of globalisation such as the faster availability of drugs for Indian patients. Asking about the significance of ethnic and/or genetic diversity in their respective fields of expertise, they assured me that this was indeed significant but that I needed to talk to academics rather than the industry. After a painful hour or so, we ended the interview, not without me promising them that I was going to type up and send them the notes I had taken during the interview for their validation.

The suspicion with which I was treated at this company was rather exceptional yet most of my interviewees were, to say the least, cautious. The public outcry over unethical clinical trials in India, for example the studies enrolling the victims of the Bhopal gas disaster, invariably haunted my interviews, and asking questions that contained the term 'race' was often met with concern, received as an accusation of wrongdoing or as evidence of my own questionable politics. As I progressed through the research and became more experienced, I modified and paraphrased questions pertaining to race to avoid such confusion. Some of the interviewees were also reassured after I described my research design more fully and reiterated my commitment to confidentiality and anonymity. Some, however, remained disinterested and apprehensive.

The encounters described here illustrate that research participants are not passively determined but employ different tactics to withdraw from or transform the interview situation. My participants often had their own sets of expectations and motivations for taking part in the research. Many respondents shared their time and experiences out of genuine generosity, interest and, at least some, the belief in the importance of the research. Some also made explicit, especially in India, that an additional rationale was my potential, as a researcher and a 'Westerner', to represent their work to an international audience in a more beneficial light than recent media coverage had done. Public accusations over clinical exploitation, the hypothesis that, as Dr Nath puts it, "the sponsors are MNCs [multinational corporations], out to rob India, [whereas] the patients are . . . guinea-pigs, they

had that guinea-pig gene fixed into them the day that they were born", was a recurrent topic in my interviews. As an academic, my interviewees suggested, I had a responsibility to develop more nuanced representations of the clinical research industry, foregrounding practitioners' human values and real concerns about patients' lives.

In some sense, human values and actual concerns—as well as often fierce critiques of the multinational pharmaceutical industry—was indeed what I encountered during the research. True, many respondents, especially at more senior management levels, refrained from going beyond what Karen Duke describes as "the official line" (Duke, 2002), company policy rubber-stamped by public relations and communication offices. Though I had made clear in my description of the objectives of the interview that I was interested in their personal perceptions and everyday experiences, it often proved difficult to remain in control of the interview dynamics and encourage interviewees to express their own perspectives. But recognising when informants were evasive or used institutional language, and finding ways of moving beyond such pre-prepared statements not only helped me develop as an engaged researcher but also became a crucial part of my analysis itself (Figenschou, 2010). Many others, however, eagerly shared their personal reflections, worries and hopes that often deeply resonated with my own. There could be no doubt about their care for their patients and their sincere commitment to the elimination of health disparities. Having embarked upon this project with the explicit purpose of building a critique of pharmaceutical capitalism and corporate profiteering, determining whose side I was on thus became a more onerous exercise than I had imagined. Indeed, the more likely meaning of the charge is, as Becker argues, that "we fall into deep sympathy with the people we are studying" (1967: 240).

The relationship I developed with some of my participants significantly impacted the research with regards to trust, mutual expectations and my increasing wish to do justice to my respondents' perspectives. Some of the ethical dilemmas which evolved from this were also deeply personal as I had been given access to the first institution, Quintosh Pharma, by an acquaintance working for the company at the time. Opening a closed network to me in a profession that treats all data as proprietary exhibited an enormous amount of trust on their part. As accessing the pharmaceutical industry without any prior point of contact is nearly impossible

(Mwale, 2014), their labour and our collaboration was indispensable for the success of my project. However, it also meant that I continuously wondered whether the trust participants extended to me was the result of specific expectations about the outcome of my research, endorsements by more senior scientists, or the execution of a command. Not seldom were my requests for interviews forwarded with the one-liner "she's an acquaintance of [a colleague]", serving as a subtle but effective reminder of physicians' oath to collegiality and cooperation. My objective to develop a critical account of scientists' practices was therefore paired with the constant concern over betraying my gatekeeper's and other supportive interviewees' trust, and my unease over tarnishing their professional reputation.

These concerns are also reflected in how I negotiated issues of anonymity and confidentiality. Existing ethical guidelines such as by the British Sociological Association (BSA, 2002) clearly state the requirement to receive informed, if possible written, consent from research participants, and to respect their privacy by distorting any information that would make them identifiable to others. However, my gatekeeper advised me against bringing a consent form to interviews as this would only raise suspicion about my intent and make the encounter appear unnecessarily formal. As such, I only asked those respondents to sign a consent form whom I had approached independently or via snowballing. Nonetheless, all participants were informed through initial email contact and at the beginning of the interview about their rights to confidentiality, anonymity and withdrawal from participation. Only a few disagreed with the conversation being recorded, in which case I took notes and typed them up immediately after.

Anonymisation itself was no straightforward process. Though I did my best to disguise the voices appearing in this thesis, those familiar with the close-knit networks I tapped into, especially in India where clinical research is a relatively recent phenomenon, will have no difficulty identifying my participants *qua* their location, professional affiliation or specific expertise. Moreover, some participants were not concerned with being anonymised "as long as I did not say anything bad about [for example] the Chinese government" (in which case I have anonymised them nonetheless for their own protection). Others acknowledged that anonymity was impossible given their status as well-known figures in the public domain. Some also explicitly asked for their real names to be used given their substantial interest in being interviewed, as explained above. As such, decisions with regards to

anonymity and disclosure were not only the result of ethical deliberation but were also taken in light of practicalities and some of my participants' implicit expectations of reciprocity. Being named was undoubtedly an opportunity for them to promote their perspective on the subject and enhance publicity for the ethicality of their work, a cause towards which I felt a strong sense of obligation. Those who waved anonymity were sent full transcripts of the interview to ensure I had captured their words correctly and to give them an opportunity to change or delete specific passages or details about themselves.

3.5 Meeting respondents

In total, I interviewed 42 scientists, regulators, policy makers and activists across Switzerland, the UK, India, Australia, Singapore, Hong Kong and the US with different professional backgrounds and connections to the pharmaceutical and life science industries. 22 worked for multinational or national pharmaceutical companies and one led his own CRO in London. I interviewed four managers of Indian CROs, four individuals working as consultants for the pharmaceutical industry, one who headed the clinical pharmacology unit at a major public hospital in Mumbai, the UK NHS Chair of Pharmacogenomics, two academics (one with a background in the humanities and an expert in biotechnology), two FDA employees in leading roles, one NIH representative responsible for the implementation of the Institutes' diversity and inclusion policies, a medical statistician at the European Medicines Agency (EMA), a renowned Indian geneticist and an Indian healthcare entrepreneur. I also conducted an interview with a key individual at an Indian women's rights NGO who had worked extensively in the field of reproductive rights, access to medicines and clinical trials in India. Not surprising given the gender gap in science occupations (Beede et al., 2011), most of my interlocutors were men but fifteen of them were female, including the scholar-activist working for the Indian NGO. From this relatively small sample, however, it is impossible to say if their gender had any impact on how respondents approached the questions I raised. 28 interviews were conducted in the UK, during multiple field visits to Switzerland and a three-month stay in India, while 14 were conducted telephonically or via Skype.

My gatekeeper introduced me to the first respondents in Switzerland and further contacts were established through snowball sampling, a technique with several benefits for researching difficult-to-reach subjects such as closed social and professional networks (Atkinson and Flint, 2001). Few were identified independently and contacted directly via email. Upon early attempts to gain access to the field through 'cold calling', most organisations and individuals I had reached out to did not respond to my emails or return my calls (also Mwale, 2014). This was equally true for my efforts to gain access to Indian drug regulators. Some potential respondents also dropped the conversation after having initially agreed to be interviewed. For example, four geneticists of the IGVC I will discuss in Chapter 8 consented to participate, but only one, Professor Brahmachari, eventually offered me a concrete appointment and answered my questions. After sending multiple follow-up emails seeking to confirm appointments, I eventually gave up. My inability to return to India just for these interviews undoubtedly amplified such difficulties as dialoguing via email is not customary in India and phone numbers were rarely available.

Most respondents I had met in person, in contrast, were happy to refer me to a colleague they knew to be experienced in the field, but the reliance on gatekeepers also meant I was introduced to whom they knew best or deemed most collegial rather than who might have been most suited. Due to this gatekeeper-bias (Groger et al., 1999), many respondents were hand-picked by managers and some appeared to respond to what they must have felt was a duty to their supervisors. Collegiality, professional hierarchies and real or imagined obligations rather than expertise or interest in my research often shaped whom I did and did not speak to. This certainly presents a significant limitation to my study.

Interviews were qualitative in nature and lasted between 30 minutes and two hours. They were conceptualised as semi-structured. This can be effective when interviewing experts as they tend to grant the researcher some degree of control over the interview while simultaneously allowing enough space for respondents to bring up issues they deem important (Thomas, 1993). They can also save time where it is already short (ibid.), which was indeed a recurrent issue. Most of my respondents work long hours and have extremely tight schedules, and while some were extremely generous with their time, others granted me at most 30 minutes, especially when the interview was conducted over the phone. Often, these

interviews were also repeatedly interrupted by incoming calls or requests by colleagues, and I was frequently kept waiting or placed on hold. While all but one respondent focused on what they could do to help me, some were also abrasive and expressed their disinterest in my research by limiting the time spent with me. As such, it proved challenging in some interviews to build rapport with participants and develop a necessary level of understanding, trust and engagement.

I recorded all but three interviews, and transcribed interview files and typed up notes immediately after the conversation to avoid the pitfall of a time gap between recording, analysis and writing up (Miles, 1983). Re-reading transcripts multiple times, I inductively created initial codes using the precept of constructivist grounded theory, coding line-by-line for specific interview passages and sometimes paragraphs, specific incidents and linguistic registers (Charmaz and Bryant, 2011). After defining general trends and themes in my data using the qualitative software NVivo alongside collecting further data, I revisited my transcripts to select the most significant codes to answer my research questions. I then developed and refined my theoretical categories and their properties through the method of constant comparison (Seale, 2012). For example, as I will discuss in Chapter 5, researchers across different contexts exhibited a great deal of uncertainty over the status of race as a scientific category, though few rejected its existence altogether; common-sense ideas and taxonomies were buttressed by novel biomedical technologies and demographic classifications, lending race a new quality with enduring significance. I found that race, for them, constitutes an *uncertain certainty* though responses differed according to professional expertise, cultural context and personal experience with discrimination. In the language of grounded theory, the concept of uncertain certainty, with its properties of 'professional expertise', for example, became a core category as I sought to theorise how drug developers perceive human diversity.

The process of forging connections between concepts was thereby aided through creating multiple situational and positional maps, charting relations, ruptures and non-articulated positionalities (Clarke 2005). Though digital programmes for creating mind maps and charts are available, I used multi-coloured pens, markers and old-fashioned paper to draw my maps as it gave me a much deeper and more embodied connection to my data than visualising it on a computer screen. Using Clarke's analytical tools for the creation of situational maps, I did not aim, as

explained earlier, to establish systematic correlations but to organise and visualise the relations between the myriad positionalities, actors and themes delineating my research field. In addition to revisiting full transcripts regularly, experimenting with multiple mapping techniques allowed me to develop an in-depth familiarity with my data.

3.6 Interviewing experts and the limits of listening

Unlike core-set analyses that identify and research the most influential scientists in a specific field (Bliss, 2012; Collins, 1974; Michael et al., 2007), I was interested in researchers with the practical, real-world expertise of *negotiating* rather than *studying* human variation as part of their everyday working lives. With this, I stand in a specific tradition of interviewing experts that views them not as a source of information about a specific subject area of which they are external observers (Bogner et al., 2009). Rather, experts are addressed as experienced participants in a specific organisational process or research area through which they have gained extensive practical expertise. Their knowledge is not considered superior as such but is interesting because it is practically relevant and may have direct consequences resulting from their decision-making power (Krause and Robinson, 2017). I chose respondents for their involvement in various stages of the drug development process at which I envisioned issues of ethnoracial difference to crop up, rather than pharmacogenetics experts or geneticists themselves.

Though all my respondents can be considered experts in their specific fields, interviews defied some common assumptions about the process of 'researching up'. For example, most informants, as described above, were initially suspicious of the intellectual and political aspirations of my research, but relaxed after I assured them I was interested in their subjective experiences rather than the 'correct' answer. While time restraints remained a recurrent issue, some participants even put in the effort of thinking with me, and from the perspective of sociology, through the questions I raised. Dr Bansal, the pharmacologist I have introduced in Chapter 1, interrupted my questioning to curiously enquire "so what is the perspective of *sociology* on race?" and listened attentively as I briefly introduced him to some principles of sociological scholarship on race and ethnicity. Another respondent, Professor Nayak, admitted almost apologetically that "I'm not really good about

sociology, my sociology is a lay person's sociology, so, you know". Though it is often argued that knowledge is the very source of the elite's powerful position vis-à-vis the researcher, in my experience respondents often exhibited profound insecurity about their levels of knowledge and reflection and were curious to hear my or other interviewees' responses to assert their own (also Duke, 2002).

These examples contest the conventional understanding of power relations in empirical research, especially in instances of researching up. Sarah Neal and Eugene McLaughlin (2009) rightly criticise the conceptualisation of power in interview situations as statically residing in "the explicit structural positions of either the researcher or the research participant rather than as an ambiguous, fluid, multi-directional dynamic, which can flow unevenly across and between different positions in the research relationship" (2009: 969). They therefore propose to apply a 'post-structuralist filter' to debates of power in qualitative research encounters (also Smith, 2005). Power does not reside within either one of the people involved in the research encounter but can shift and change between them.

Furthermore, their critique is also aimed at the very definition of experts and elites (see Littig, 2009 for similarities between interviewing experts and elites) wherein the power imbalance between the researched and the researcher is in favour of the former. As Katherine E. Smith writes, "the idea that 'elites' can be neatly defined and treated as consistently powerful is a view which relies on a rather simplistic idea that there is a dichotomy between 'powerful elites' and 'powerless others'" (Smith, 2005: 645). Such an outlook, she explicates, ignores the preposition that modalities of power can be negotiated and reworked within the course of a research project, or, in my case, a single interview. When my respondents left their comfort zone—the expert knowledge and scientific discourses of clinical pharmacology—to think through my questions from a sociological perspective, they opened the possibility for our power dynamics to change. For a short while, I became 'more powerful' *qua* my knowledge of a discipline that was alien to them. In other words, my respondents became what Smith terms "vulnerable elites" (Smith, 2005: 650), acknowledging the possibility for individuals, independent of their professional status, to feel insecure or exposed in interview situations. Her suggestion resonates with my experience that though my respondents are undoubtedly part of a scientific and economic elite, they are not essentially or permanently powerful.

This is not to deny that, as a young, female researcher, I sometimes felt vulnerable myself when interviewing predominantly older men in relatively powerful positions. This is especially since interviews took place in the unfamiliar and often decidedly masculine spaces of science and knowledge production, mostly respondents' own offices. Though I was not, unlike other female researchers in similar situations (for example Figenschou, 2010), exposed to openly sexist attitudes, many informants commented on my being a woman and a social scientist (often belittled for its 'softness') in a male-dominated world. Some also made references to my "looking young", "sounding young" or "looking good". In particular, the intimacy created by my status as a colleague's acquaintance, though indispensable for getting access, let some of my interviewees to downplay my competence and professionalism. In one instance, a respondent, when later asked by my gatekeeper about his impression of the interview, solely commented on my physical appearance. Creating an awkward moment for my gatekeeper, too, this reflects the subtle but persistent misogyny female researchers often encounter, especially when interviewing in male-dominated settings (Odendahl and Shaw, 2002). Though my gender may also have facilitated access and influenced the outcome of the interviews in a positive manner (Figenschou, 2010), coupled with the general dismissal of qualitative research methodologies and moments of infantilisation, such experiences sometimes led to a feeling of powerlessness and devalued the rigour of my work.

In my experience, expert-interviewing was rife with other problems as well. Even though I prepared extensively for each interview, consulting the scientific literature as well as reading up on respondents' backgrounds and fields of expertise, there were obvious limits to how well I could prepare. Especially the creation of an "ad hoc pidgin" (Laudel and Gläser, 2007: 91) for communication during the interview remained a challenge throughout the research process. As Grit Laudel and Jochen Gläser (2007) explain, interviewing experts requires the negotiation of a level of scientific depth that is both appropriate for interviewees to describe their research in necessary detail and general enough for the researcher to understand and follow up with relevant questions. Preparation was also restricted because I interviewed experts across an entire range of roles and contexts. In contrast to ethnographic accounts of a single lab, scientific field or policy framework, my study required the understanding of several "epistemic cultures" (Knorr-Cetina, 1999) simultaneously.

Sometimes it was also difficult, if not impossible, to find relevant data on my interviewees' backgrounds given the lack of publicly available information, or my gatekeepers' limited knowledge of their colleagues' specific area of expertise. Unlike Shadreck Mwale (2014), I found that those experts familiar with the questions I was interested in, well-known policy makers aside, usually worked 'behind the scenes'. My inability to be adequately informed certainly influenced the level of detail with which my interviewees described their work to me and meant that they probably explained their work in much simpler terms than would have been necessary, or interesting, for my research.

Last, there is, of course, a limit to listening as such. Though listening rarely operates alone, the findings of this project would have been greatly enhanced had I been able to make use of other sources of (ethnographic) data as well. The possibility of observing experts at their place of work, visiting their labs and taking part in additional industry conferences or company meetings were hampered by the limited financial and temporal resources available to me as a single researcher studying a multi-sited field. Though I agree with Prasad (2008) in that the lab has been an unfairly privileged location for research on scientific practices, interviews and documentary analysis alone did not allow me to develop an in-depth account of the nitty-gritty of clinical studies as an important context of the practices to which interviewees referred. If it is true, as Pierre Bourdieu (2000: 141) argues, that we learn bodily, there is only so much that reading and listening, even repeatedly, can do. Emerging oneself in "the fire of action in situ" that allows the researcher to "put his [sic] own organism, sensibility, and incarnate intelligence at the epicentre of the array of material and symbolic forces that he intends to dissect" (Wacquant, 2004: 8) remains a central objective of social research that this project can only partially meet. The financial and temporal constraints I encountered mirror how access to information, and thus knowledge, continues to be shaped by the unequal allocation of resources (Cook, 1993).

A note is also in order about my decision not to interview patients or clinical trial volunteers themselves. There are, of course, myriad reasons for sociology's traditional preference to study those who have been excluded or exploited. I do not wish to dispute that it is crucial to make visible and give credence to those voices and knowledges that have been marginalised in society and seek to empower them in doing so (Duke, 2002; Kalra, 2006). Adding Indian study participants' voices to

this thesis would have certainly made it a much thicker description of the social world I was studying. However, studying vulnerable groups is itself fraught with ethical dilemmas (for discussions of vulnerability particularly in transnational biomedical research see Have, 2016; Macklin, 2004; Orth and Schicktanz, 2017) and the kinds of analytical and conceptual issues I was interested in do not occur at the level of a single trial. Neither do they directly involve participants. As the aim of this study was to make a broad survey of the main concepts and historical narratives on ethnoracial classifications in the discourses and practices of transnational research, I knew from the outset that I was not going to write about participants' perceptions and concerns *per se*, though of course they may have enhanced my understanding of the issues at stake. As such, I considered it ethically problematic to conscript a vulnerable population for a study that could, by design, not have an element of reciprocity or an immediate impact on their situations. Enrolling them for this research, in my view, only ran the risk of perpetuating their marginalisation and exploitation. Instead, I sought to express my concern for their lives *indirectly* by exposing some of the structural constraints that render them vulnerable in the first place, and more *directly* through political activism and the support of local charities and NGOs working in the field of health education and human rights.

3.7 In the postcolonial archive

In addition to interview-based data, my research draws on documentary and archival sources to contextualise contemporary scientific discourses and add a further dimension to the real-time data provided by my interviews (Gidley, 2012). As explained earlier in the chapter, my aim was to trace their historically-situated, contingent and heterogeneous conditions of possibility. Overall, I have consulted six different archives: The India Office Records at the British Library, the holdings of the Ross Institute at the London School of Hygiene and Tropical Medicine, and the Wellcome Trust's Archives and Manuscript section in London; the Bodleian Libraries at Oxford for its Max Mueller Papers; and the National Archives of India (NAI) and Nehru Memorial Museum and Library (NMML) in New Delhi. I identified relevant archives through bibliographic snowballing, and an intensive training course in historical research methods provided by the Institute for Historical Research at the School for Advanced Studies, University of London,

equipped me with effective archival research skills. In a relatively brief period, I learned how to systematically search for relevant documents, cite historical sources and compile bibliographies. The training significantly enhanced my skills as a qualitative researcher and qualified me to work with a range of archival holdings. It did not, however, prepare me well enough for the rather tedious yet instructive exercise of navigating a postcolonial archive, as I will discuss below.

I approached my archival sources and data not as factually accurate representations of social realities but as 'social facts' that are produced and circulated in socially organised ways and construct specific kinds of representations (Atkinson and Coffey, 2011). Archival sources do not constitute mere windows into the past or provide an objective account of the reality they refer to. Rather, they produce, as Ben Gidley (2012) notes, contextually specific and historically contingent discourses that are necessarily partial representations of the social world. An archive is not just "that whole mass of texts that belong to a single discursive formation" but is conceptualised as the "law of what can be said" (Foucault, 1989: 143, 145). As such, I interrogated the texts I encountered as productive of specific social relations and asked how scientific ideas and bureaucratic categorisations of Indian populations and groups are being created and verified within them.

Placing emphasis on the productive nature of historical data rather than their facticity, two points warrant explanation. First, I have sought not to condemn statements on the nature of the Indian population as obviously racist by today's standards, but to read them as products of, and as themselves generating, specific social realities. I have considered the scientists I encountered as people of their time, and their palpably racist arguments as indicative of both wider trends in science and in politics. And second, this means that one cannot condemn earlier scientific ideas and theories as mere 'pseudo-science', even if the empirical basis for their claims has been robustly dismantled (see e.g. Gould, 1996). Few scientists broke with the dominant canons of scientific procedure of their day, and to dismiss their work as pseudo-science means we misunderstand the nature of the scientific enquiry itself. As historian of science Nancy Stepan (1982) argues, race science was never pseudo-science but often even robust, good science according to the standards and methods of the time. Despite these epistemological convictions, I found some of the statements I encountered rather difficult to process emotionally, and research at

the NAI in particular involved more breaks for *chai* from a ramshackle tea stall nearby than I envisioned.

Rather than examining historical texts as factual evidence, then, I asked how the archives were socially and spatially organised (Foucault, 1989). Chasms between what I had expected to find and what I ultimately did find also reflect the social nature of archival collections, especially in postcolonial contexts. Though a sustained source of frustration, my experiences during my research in the NAI point to the political embeddedness of archival records and the predicament of colonial artefacts in postcolonial collections. Consider the following excerpt from my fieldnotes:

> It took me almost a week to grasp the basics of the archive. In the absence of digital catalogues, effective search systems or English-speaking staff, it was only when I met Mingma, a fellow PhD student from the History Department at Jawaharlal Nehru University conducting research in the archive, that I came to understand the operational procedures necessary to obtain access to archival documents. She must have watched my slow but steady descent into despair over the number of handwritten slips I was permitted to submit three times a day, the information needed and where to obtain it, and my struggle to communicate more complex issues in Hindi than my by now rudimentary language skills allowed. After I had finally skimmed through all, mostly handwritten, illegible and dusty catalogues of the archive's holdings listing documents per year, rather than topic, I found I had consulted the wrong archive altogether. The papers I was interested in were held at the Private Archives, one floor up in the red, sandstone and somewhat extravagant building typical of New Delhi's governmental architecture (when I first encountered it, I was reminded of Achille Mbembe's (2002: 19) assertion that the 'status and power of the archive derive from this entanglement of building and documents'). After another lengthy security procedure involving various signatures and copies of my passport, I sat across from the director of the Private Archives at his heavy desk loaded with papers of various kinds. I

> explained to him that I was interested in the Risley collection and handed him my request slip scribbled with information on the date, accession number and description of the collection I had deciphered from the catalogues. To my surprise, he smirked and sent one of his clerical staff to hand me another, even dustier and even more illegible catalogue that detailed the collections of the Private Archives. When I asked him, slightly exasperated, what the relation between the two catalogue systems was and how I could quickly find the information about the Risley collection I needed to retrieve, he simply said: 'this', pointing to the one I now held in my hand 'is the *right* one'.

Though I do not wish to amplify well-rehearsed narratives of neglect and decay in postcolonial archives, often serving as evidence of inefficiency and carelessness (Buckley, 2005), the condition of the holdings at the NAI, including its catalogues, significantly limited what I was and was not able to access during my stay. With documents damaged or lost, pages loose and covers separated, the state of the collections problematises assumptions that colonial archives are key to postcolonial nation building and the creation of national identities (Basu and De Jong, 2016). This is despite the fact that as a foreign researcher, gaining access required me to produce a research statement signed by Goldsmiths, University of London, and a letter of recommendation by the German embassy, creating the appearance of protectionism and preciousness. Equally, an A4 sheet of paper, hanging at the walls inside the readers' room and listing extensive though partly unintelligible rules about what not to do in the presence of delicate archival documents suggested their historical significance, at least for archive staff (Buckley, 2005). But rather than merely illustrating the lack of resources available to such archives, and the labour involved in navigating them, the short encounter described above also exemplifies the nature of archives themselves as sites of knowledge production. An archive's architectural, spatial, and cultural organisation, its modes of classification, sorting and ordering reflect critical features of colonial politics and postcolonial state power. In other words, what I was and was not able to find in the organisational labyrinth that is the NAI is emblematic of the larger politics of archival practices in postcolonial India, and the visible and invisible imprints left by colonial administration.

As my conversation with the director of the Private Archives revealed, which documents were digitised, restored or even available on site was the outcome of years of negotiation with the exiting colonial administration. The NAI is not just a metaphor of "collective forgettings" (Stoler, 2002: 94), but also of the enduring epistemic violence of the colonial state that took with it what it desired. As the director explained, the majority of key documents on British colonialism in India was held at the British Library in London despite the Indian government's repeated efforts to repatriate them. Others changed hands illegally, bought and sold clandestinely in the chaotic first years of independence and Partition as the newly sovereign state was wrestling for authority. Efforts to restore the archive's holdings in those years, and judging by their condition ever since, focused on those moments and figures most central to India's resistance and postcolonial state-building processes with documents from earlier periods being rather scarce. An additional journey to the West Bengal State Archives in Calcutta where I might have been more successful turned out to be too time-consuming after I was advised by its head archivist to allow for at least a week to ten days just to work through their equally hand-written catalogues. Again, this reflects the spatiotemporal contingencies of this project, curbing what I was able to access and learn about.

Though it is perhaps only reasonable given national archives' powerful role in shaping collective identities to focus on heroic national figures, I was somewhat perplexed to learn that representations of British colonialism through archival records appeared to be predominantly in the hands of the British themselves. Given the intimate links between textuality and power, I found the fact that the authority to define, represent and rewrite the history of Empire still primarily lies with the metropolis deeply disturbing. If, as Nicholas Dirks (2015: 47) writes, history serves as a principal form of governmentality as much as governmentality expresses itself through the categories and concepts of historical thought, who writes this history, where it is written as well as who does and does not read it is profoundly significant. On the other hand, archives, like museums, shape public perceptions of what its valuable and important (Schwartz and Cook, 2002), and the NAI's neglect of some earlier collections might equally be a decolonial strategy of putting colonialism, including its significance for Indian culture and identity, in its place.

In more concrete terms though, this meant that in order to access the most relevant materials about the colonial practices of sorting and governing Indian populations,

I had to return to the metropole itself. While, of course, what counts as relevant or interesting is itself an epistemological and methodological question worth debating (Michael, 2012), this reflected a common pattern I encountered during my interview practice: the power to make decisions, shape knowledge and influence transnational (science) policy continues to lie predominantly in the hands of actors in Europe and the US. Though relations between companies, scientists and policy makers, as this thesis will illustrate, are much more complex and cannot be neatly mapped onto real or imagined dualisms between "the West and the Rest" (Hall, 1992), it nonetheless meant that my historical research became firmly embedded in my methodological strategies of travelling, tracing and mapping.

The materials I *did* find in both India and the UK included rare books and journal editions, unpublished manuscripts and pamphlets, personal correspondence amongst scientists as well as between scientists and the colonial administration, police reports, conference documentation and images of various kinds. In the well-organised archives that I visited in the UK, equipped with online search engines and materials indexed by keywords, I sought to interrogate specific tropes and themes found in the public domain by recourse to their conditions of possibility. Here, I was interested in the ways in which scientific arguments were developed and justified, but also the social, economic and political contexts for their emergence. In particular, I focused on moments of doubt, uncertainty, resistance and discursive change as scientists sought to make sense of the ambiguity Indian population diversity posed. Given the constraints described above, in the NAI (as well as, to a lesser extent, the NMML) in New Delhi I had to resort to alternative methodological techniques. Where private compilations such as the Risley collection were unavailable or document titles illegible or absent altogether, I routed my search around specific incidents and events and combed through as many available and (seemingly) relevant records as I could, primarily from the Home department. By way of example, the first complete census of India in 1881 provided ample opportunities to investigate the ways in which researchers and policy makers alike agonised over the correct, or the most practical, mode of classifying Indian populations. Likewise, I aimed to understand how in the wake of the Mutiny of 1857/58 scientists sought to rationalise the increasing focus on differences rather than similarities between Europeans and Indians.

Data collected through these strategies were analysed deploying the tools provided by situational analysis as described earlier in this chapter. The principles of situational mapping, as Clarke (2005) has proposed, can simultaneously be applied to different types of data such as, here, interview data and historical discourses. Indeed, including (here: historical) discourses enriches the domains of social life researched by more traditional grounded theory approaches (ibid: 21). As such, as with my interview material, I created codes according to the themes emerging from the data and regularly revisited collected materials and notes to refine my analysis. Preliminary codes and concepts were correlated with one another in multiple maps to organise my thoughts and aid my interpretation. Ultimately, I selected those concepts that appeared most significant to address my research interest. Here, too, I did not depart from a purely inductive starting point, as per 'traditional' grounded theory, but my interpretations were inflected by prior research in the field as well as my motivations, reflections and findings as I went along.

3.8 Conclusion

A number of key principles have provided the methodological foundation for this research. Social worlds do not exist independent of the choices the researcher makes, and the decisions I made and interpretations I offer in this thesis are shaped by my own situatedness, theoretical sensitivities and ethico-political aspirations. There is no neutral, objective or impartial stance in knowledge production, and other researchers with distinct positions or substantive interests might well draw different conclusions from my data. Nonetheless, I have sought to 'stay with the trouble' and pursue my research interest in unmasking those motives and lines of argumentation that continue to inflect how human diversity is conceptualised, used and acted upon within and outside the lab. The following chapters offer my reflections on and provide partial answers to this enduring question.

Chapter 4: "Who are those pesky billion?" Constructions and contestations of Indianness from philology to eugenics

Dr Bhagat Singh Thind left the state of Punjab in north-western India in 1913, graduated from the University of California, Berkeley, and joined the US Army in 1917. Thind fought for the United States in World War I and, after he had been honourably discharged, applied for US citizenship in 1920. While his application was approved by the District Court on the grounds that Asian Indians were classified as Caucasians and therefore legally white, the Bureau of Nationalization appealed his case and brought Thind before the Supreme Court (Roberts, 2012). Despite anthropological and scientific 'evidence' that Asian Indians shared with their white American counterparts a belonging to the Aryan race, the Supreme Court dismissed the authority of science and ruled in favour of "familiar observation and knowledge", arguing that "the physical group characteristics of the Hindus render them readily distinguishable from the various groups of persons in this country commonly recognised as white" (United States v. Thind, 261 U.S. 204 (1923): n.p.). More recently, Dale Sandhu, also a Punjabi working in the US, claimed that the layoff by his former employer, the Lockheed Missiles & Space Company, had been racially motivated and sought to bring a discrimination claim before the California Superior Court (Baum, 2006; Goldberg, 1997; Tehranian, 2009). The Superior Court judge, however, accepted the perspective taken by Lockheed that Sandhu was Caucasian by law and therefore ineligible for compensation under the California Fair Employment and Housing Act. The judge is quoted stating that "by definition, ⁅Sandhu⁆ is Caucasian… a person who is in fact Caucasian may not complain about race ⁅discrimination⁆" (Sandhu v. Lockheed Missiles & Space Co. (1994): n.p.).

The cases of Thind and Sandhu illustrate two distinct yet interrelated arguments I develop in this thesis, the historical origins of which I trace in this chapter. First, they show that knowledge production about Indians has been significantly influenced by the dominant parameters of European race science, originating in the colonial scholarship of the late eighteenth century. While the lens of caste was central to structuring knowledge production about the Indian population, theories of race provided a biological explanation for human variation that theories of caste

did not. As such, these became inherently interesting for colonial anthropologists as well as Brahmin scholars, benefiting significantly from their collaboration with the colonial regime. In this sense, the chapter contributes to revising the conventional view that race was something that, as Shruti Kapila (2007: 474) puts it, "happened to other peoples and places", and shows that it significantly shaped scientific theories about the Indian civilisation. The chapter therefore aims to incite a dialogue between historiographies of British colonial administration based on the analytics of caste and scholarship on race science that has largely centred, and continues to do so, on Europe and the United States on the one hand, and Africa, Australia, and Tasmania on the other.

Second, the cases demonstrate that though race science usually characterised Indians as Aryans or Caucasians and therefore as kinfolk, it has always denied them the status of 'full' or 'proper' Aryans or Caucasians. At times, Indians were even considered closer to Africans or Black Malays than to white Europeans. Indians' racial ambiguity defied easy classification and instigated frequent scientific quarrels over their accurate designation. They were never easily locatable in the white/non-white demarcations fuelling racial science and allowed for the utilisation of multiple and varying categorisations contingent on the respective scientific, political and economic contexts. As such, they also challenged science's claims to certainty, and its quest for unambiguous, consistent and mutually exclusive population categorisations (though certainty, as the next chapter will demonstrate, might not be pivotal to maintaining science's cultural authority). These logics, as I will illustrate through recourse to my interview data in subsequent chapters, still pervade the production, selection and application of contemporary scientific theories about Indians. Scientific discourses predominantly produce Indians as "almost the same, *but not quite*" (Bhabha, 1994: 123) or more precisely, as almost white, but not quite, and their precise definition still puzzles scientific narratives. As geneticists Rick Kittles and Kenneth M. Weiss (2003: 33) ironically ask: "who are those pesky billion?"

Arranged into four thematic, broadly chronological sections, I outline the key historical, often co-existing but nonetheless discernible discursive formations most relevant for the arguments developed in this thesis. I do not aim to provide an exhaustive exploration of the historical record; neither do I suggest a linear trajectory of ideas from past to present (see Chapter 3). Rather, my much more

modest aim is to trace specific contemporary ideas and concepts through an investigation of their historical conditions of possibility. I will do so by recourse to the works and reflections, published and unpublished, of those scientists most influential in shaping specific concepts of race in a given era, resonating in present-day discourses, as identified through secondary literature and primary research (see Chapter 3). Such an account must necessarily remain fragmented, but it provides much needed historical contextualisation of contemporary ideas. I also illustrate existing tensions with and responses by Indian scientists and public intellectuals as well as moments of doubt and uncertainty by these scientists themselves. Despite its considerable influence, race science was never hegemonic but remained contested from within and without. These tensions provide insight into the recurring dilemmas of classifying Indian population diversity.

The first section explores two specific tropes in the period loosely spanning from the establishment of the East India Company as a territorial power in 1765 until the early nineteenth century: the Orientalist description of Indians as linguistically and ethnologically similar to Europeans, and the narrative of the 'black Aryan'. Both the role assigned to linguistics in devising sampling methodologies and the account of 'brown', 'non-white' or 'heterogeneous' Caucasians continue to inform scientific discourses about Indianness. Next, I trace the influence of the mid-nineteenth century rise of racial biology on scholarship about India, leading to the essentialist notion of a 'Hindoo type'. The interest shown by Indian scientific and political elites in the newly established disciplines of craniology and phrenology exhibit dynamic interactions between scholarship in the metropole and the colony and tell of the enduring tensions between those citizens of the Empire figuring as (often involuntary) experimental subjects and those attributed the status of scientists. Section 4.3 engages key works on the relation between race and caste in physical anthropology by way of discussing Sir Herbert Hope Risley's ethnological writings on India. I illustrate the increasing racialisation of theories on Indianness, and their political application in the making of the first national census in 1881. I also briefly emphasise the blow that growing bacteriological evidence constituted to theories of racial essences, and the Janus-faced role medical discourses occupied in relation to them as they often undermined yet also re-inscribed arguments about race. The last section addresses eugenic scholarship by both British and Indian scholars during India's incipient national independence movement. The persistent engagement by

Indians in the international eugenics movement not only exemplifies the lively motions of scientific knowledge production across geographical spaces, but also confirms the ambiguous racial status Indians occupied in the eyes of metropolitan science. To conclude, I summarise the key findings of the chapter and relate them to subsequent arguments.

4.1. Comparative philology and the construction of the Black Aryan

In 2008, the Indian Genome Variation Consortium (IGVC), a state-funded medical genomics project (also see Chapter 8), published its first findings about Indian population substructure and its implications for the distribution of hereditary diseases. In one of the papers, the authors argue that the study reveals "a high degree of genetic differentiation among Indian ethnic groups and suggests that pooling of endogamous populations without regard to ethno-linguistic factors will result in false inferences in association studies (IGVC, 2008: 17). Ethno-linguistic criteria, here, are seen as reliable and stable characteristics from which can be drawn at least preliminary conclusions about the genetic constitution of a person or a population as a whole. This focus on linguistics, and its connections with biology, is a recurrent theme in scholarship on Indian genetic variation. In this section, I briefly trace the influence of philology on constructing sociobiological knowledge about Indianness through the works of Orientalists Sir Williams Jones and Friedrich Max Müller. I will then turn to the recurrent figure of the Black Aryan still lingering in contemporary scientific discourses of the non-white Caucasian.

The origins of British engagement in India date back to the early seventeenth century but it was only with the consolidation of the East India Company as a territorial power in 1765 that British merchants, administrators and intellectuals entered into direct social and cultural exchanges with certain parts of the Indian population (Ballantyne, 2002; Metcalf and Metcalf, 2001). The emerging opportunity to study Sanskrit, particularly embraced by Orientalist historians and philologists, allowed Britons to delve deeper into Indian history, culture and social organisation (as well as nature, environment and climatic conditions). Scholars such as Sir William Jones, founder of the discipline of comparative philology and a colonial administrator, were fascinated by the beauty of Sanskrit and its similarities with ancient European languages such as Latin and Greek (Jones, 1803). While

Indians themselves were often seen as unreliable and untrustworthy, the command of Sanskrit allowed Jones to "[no longer] be at the mercy of our pundits" who, according to Jones "deal out Hindu law as they please" (Jones, 1785: n.p.)[14]. Clearly, the study of language was never a purely intellectual exercise of knowledge production, but always stood in the service of colonial administration.

Jones was to shape the model of understanding Indian history and civilisation for almost a century. Most prominently, he influenced German Orientalist and comparative philologist Friedrich Max Müller who saw language as having "of itself an intrinsic value, which recommends its study to all those who think it a worthy occupation to investigate the nature of the human mind in its first and primitive manifestation by language" (Müller, 1848: 320). Philology thus became a central tool for the study of human variation; as Jones revealed in personal correspondence with a Lord Althorpe, he valued philology not for its insights as such, but for the "knowledge to which it leads . . . which make[s] us acquainted with the human species in all varieties" (Jones, n.d.: 189)[15]. With the advancement of the discipline and its growing influence on other sciences such as ethnology and archaeology, Müller claimed at a meeting of the British Association that "it has become possible to arrange the most prominent nations of the world into great families" (1848: 324). Language was seen as forming the spirit and essence of each family of mankind and, as such, language, and particularly grammar, became central in the demarcation of racial and ethnic groups. In the context of India, this meant not only that the Brahmins of Northern India were seen as resembling Persian, Greek and Latin speaking peoples, but also that Dravidian speaking groups could be identified as having a different origin and racial constitution. Language confirmed the existence of at least two different Indian races, the Sanskrit-speaking Brahmins of the North and the Dravidian and aboriginal linguistic groups of the South. The latter preserved, according to Müller, "together with their rude language and savage manners the uncouth type of their negro origin" (1848: 348).

The focus on Indo-European similarities implied that Müller, despite his insistence on the different origins of India's population groups, conceived of the possibility of

[14] Letter to Charles Chapman Esq. dated Sept. 28, 1785. British Library, Archives and Manuscripts, India Office Records and Private Papers, Sir William Jones Papers, Mss Eur C227.
[15] Letter to Lord Althorpe. British Library, Archives and Manuscripts, India Office Records and Private Papers, Sir William Jones Papers, Mss Eur C227.

physical regeneration; while there remained "some difference between the Brahminical inhabitants of the north and the south of India . . . both . . . [show] the noble stamp of the Caucasian race" (Müller, 1848: 348). What he observed in South India, for example, was a slow and gradual civilising process of aboriginal tribes by Brahmin colonisation so that socio-culturally but also "physically only few marks of a different blood remain" (ibid: 349). Ethno-linguistic groupings were not seen as rigid or permanent as they would be in nineteenth century physical anthropology. Philology was therefore not inherently destined to support racism: as literary theorist Will Abberley (2011) notes, one might better understand comparative philology as an ideologically amorphous set of texts that was shaped by the wider discursive context of the time. It was only with the emergence of colonial anthropology that Man became seen as primarily a biological rather than a social being. Philology, thus, came to enforce rather than invent racial essentialism. Nonetheless, it significantly shaped the construction of Indians as what Ishita Pande calls the "black Aryan" (Pande, 2009: 23), a trope that pervades scientific narratives from the late eighteenth century to the present. Though World War II has largely discredited theories on Aryanism in popular discourse (Baum, 2006; Reardon, 2005; Skinner, 2006), I will show throughout this thesis that they still resonate in contemporary scientific debates about Indians as belonging to the (fictitious) Caucasian race.

As Jones and his Sanskritocentric vision of India centrally inspired the imagination of an Indo-European linguistic family, he also laid the groundwork for the production of a new theory of Aryan kinship. In what Léon Poliakov (1974: 183) terms the "quest for the new Adam", the early anti-Semitic attempt by Western European scholars to free their culture and origins from their Judaic heritage, linguistic ties between population groups were quickly interpreted as also representing genetic links. The speakers of Indo-European languages were therefore constructed as descendants of the same ethnoracial family. As Poliakov states, it was "the science of linguistics which was to give a name to these ancestors [in India rather than the Near East] by opposing the Aryans to the Hamites, the Mongols—and the Jews" (1974: 188). Even though, as I have argued, linguistic theories were not necessarily deterministic, they nonetheless marked the birth of ideas about Aryan kinship (for a critical discussion see Ballantyne, 2004).

Europeans and Indians, then, were perceived as having descended from the same tribe of Indo-Europeans that originated from north of the Hindu Kush and dispersed after 2000 B.C. south and west to colonise and conquer foreign lands and people (Leopold, 1970). As Müller noted, philology was "generally inclined to consider the inhabitants of this vast country as one great branch of the Caucasian race, differing from the other branches of the same race merely by its darker complexion" (1848: 347). This darker complexion, however, as well as what scholars and colonial officials alike perceived as physical and cultural inferiority, had to be scientifically accounted for. Müller himself argued that this "difference of colour has been accounted for by the influence of the climate" (ibid). In a lecture delivered in February 1786, Jones also found that the difference between varieties of the Aryan race was "a difference proceeding chiefly, if not entirely, from the respective humidity or dryness of their atmospheres" (Jones, 1803: 41), and thus from climatic conditions. This, crucially, also left open the possibility for complexions to change.

In a competing account, however, Müller's contemporary James Cowles Prichard, who later came to be known as the founder of ethnology, explained variation of complexion among Indian populations by their differing states of civilisation. As Prichard wrote in his first edition of the *Researches into the Physical History of Mankind* (1813: 391):

> A) . . . In several parts of India the mountaineers resemble Negroes in their countenance, and in some degree in their hair, which is curled and has a tendency to wool. (b) The inhabitants of the hilly districts of Bengal and Bahar particularly, can hardly be distinguished by their features, as we are informed, from the modern Ethiopians. (c) It is reasonable to suppose that the barbarous tribes preserve most of the original character of the nation, for the first colonists were in all probability rude people. The better orders in India, as in other countries, have gradually improved by civilization, and have acquired a different aspect.

Though he revised this view in the second edition of the *Researches*, Prichard's perspective departed from the conventional Blumenbachian framework foregrounding the 'darkening' effects of harsh climatic conditions as followed by

Müller and Jones. For Prichard, skin colour was originally black and gradually lightened with the degree of civilisation. Though radically unpopular at the time, his view represented one of the earliest concepts of colour as a marker of civilisation and constituted a foundational moment in the increasing amalgamation of linguistic typologies and their physiological representations (Kapila, 2007: 484). Moreover, the quote above confirms that Prichard conceived of Indians, or at least *some* Indians, as much closer to Black Africans than white Europeans by virtue of their physiological characteristics and phenotypical presentations. As Kapila (2007: 484) observes, accounts of race science in India as well as Indian nationalist accounts tend to forget such instances of the 'Negro' Indian. Yet, these were crucial in cementing a fundamental ambiguity in how Indians were perceived and treated.

Heavily influenced by Jones' proclamation of Indo-European resemblance though, Prichard eventually distinguished between lighter-skinned, Sanskrit-speaking peoples and what he considered India's original "race of Negroes" (1813: 391), knitting together language, racial typology and colour to devise his racial theory of the Indian civilisation. Today still, some tribal Indians, especially the populations of the Andaman and Nicobar Islands, are considered by some to be descendants of an ancient 'Negro' race, as my respondents emphasise when designating them as Negroid populations, genetically as well as culturally distinct from mainstream India.

What these different explanations of the notion of Indians as Black Aryans share is a belief in the deviation of the Indian people from the Aryan race, and their salvation through colonial education and culture. Homi Bhabha's (1994: 86) seminal description of colonial mimicry illustrates how colonial discourse brought forth the desire for "a subject of difference that is almost the same, but not quite", fixing the colonial subject as ever only partial or incomplete. In Müller's and Jones' view, contemporary Indians had degenerated from their past glory, an idea that ultimately culminated in the eugenics movement (see section 4.4). As Jones stated, one cannot "reasonably doubt how degenerate and abased so ever the Hindus may now appear, that in some early age they were splendid in arts and arms" (1803: 32). For Prichard, Indians' darker complexion revealed their inferior cultural status as compared to their European conquerors. Jones, Prichard and others effectively argued that Indians were *failed* humans or sub-humans, but humans nonetheless

(also Arvin, 2013). Central to both was the possibility of development or regeneration, not least through the colonial civilising mission. For instance, Müller, privately admired by many Indian Brahmins as the "Pandit of the far west" (Tagore, 1884: n.p.; also Bhattacharya, S., 1882) for his service to the study of Sanskrit, advocated what he termed a second conquest of India through education. He also remained committed to missionary work throughout his life, as his personal correspondence reveals. In an unpublished letter to the Duke of Argyll, for example, Müller expressed hope that religious and literary education might fuel the development of a new national literature as well as national life and moral vigour, one that was "impregnated with Western ideas, yet retaining its native spirit and character" (Müller, 1868: 358)[16]. Thomas Babington Macaulay's infamous desire to create a "class of persons Indian in blood and colour, but English in tastes, in opinions, in morals and in intellects" (1835: 171) is perhaps the most prominent illustration of the idea of inherited but partially modifiable physical *and* cultural differences. In contrast to the re-emergence of the theme in nineteenth century physical anthropology, pre-Darwinian scholarship saw degeneration as being a primarily historical, social or moral rather than a biological fate.

4.2 The growth of racial determinism: Evoking the "Hindoo type"

Inaugurated by the ideas of craniology and phrenology and influenced by Britain's increasing quest for defining its place in the world, mid-nineteenth century scholarship about the Indian population gradually favoured biological over linguistic explanations, and increasingly searched for differences rather than similarities between Indians and Europeans. Though phrenology, at least, has long been dismantled as 'pseudo-scientific' (for a critical analysis see Gould, 1996; Stepan, 1982), both disciplines nonetheless merit a brief discussion. They opened the door for more biologically deterministic ideas about the Indian race, or Indian races, and allow for interesting insight into the intellectual and institutional entanglements between scientific and popular discourses in the centre and the periphery of the Empire. Craniological and phrenological ideas were eagerly taken up by Indian scientists and literati of all political traditions, seeking to reform the

[16] Letter to the Duke of Argyll, Oxford, dated 16 December 1868. University of Oxford, Bodleian Library, Max Müller Papers, MS Eng. d.2352-3.

moral and political qualities of Indian society. Not least, reflections about which, or rather whose, skulls to use for scientific examination and public display constitute early manifestations of contemporary negotiations over genetic variation according to caste or socio-economic difference. Additionally, they reflect contemporary discussions about the impact of socio-economics on biological constitutions.

George Murray Paterson, assistant surgeon in the East India Company and a member of Jones' Asiatic Society, established one of the first theories of Indian races with the theoretical and methodological tools of European phrenology. In 1824, Paterson published his *Phrenology of Hindostan* for which he analysed more than 3,000 skulls from all over India (Paterson, 1824). He claimed to have found evidence that the 'Hindoo' skull showed, for example, a lack in the "organ of *causality*" (Paterson, 1824: 437), the "organ of *imitation*" (ibid: 437) and the "organs of *combativeness* and *destructiveness*" (ibid: 438). Through close observation of the shape and surface of the skull, especially the frontal bone, he concluded that the organs located in this region must be more 'crowded', representing little activity of the knowing faculties in the language of phrenology. Paterson hence connected 'Hindu' cerebral developments with mental manifestations to arrive at a scientifically grounded explanation of the nature of the Hindu mind and character. For Paterson, the organ of amativeness, for example, not only shaped the behaviour of the associated individual but the character of a people as a whole, leading to the 'well-known' jealousy of the Indian population. As such, phrenology centrally contributed to the growth of racial biology, also turning from the study of individual differences to the analysis of racial groups or nations. Gathering in the Calcutta Phrenological Society founded by Paterson in 1825, numerous colonial scholars and administrators were attracted to Paterson's public lectures and the Indian skulls on display (Kapila, 2007).

Phrenology introduced a new, biologically deterministic quality into the study of colonial subjects and populations and seemingly provided a scientifically sound justification for the European colonising mission. George Combe, for example, well-known spokesman of the phrenological movement, argued that their phrenological development showed that the Hindus "are remarkable for want of force of character, so much so, that a handful of Europeans overcomes in combat, and holds in permanent subjection, thousands, nay, millions of that people" (1825: 7). Despite internal disputes over the exact size and significance of specific cerebral organs that

shaped the 'Hindoo type', most writers in and around the 1830s agreed with the necessity of English laws and educational institutions to cure native ills.

However, phrenology was not without its critics. David Drummond, for example, who described himself as a former member of the Calcutta Phrenological Society, was soon "convinced its foundation was totally insecure… [and full of] ignorance and delusion" (Drummond, 1829: v-vi), leading him to publish his own objections to the discipline. Neither did phrenology simply bestow new scientific legitimacy upon the colonial project. It also found disciples amongst the Indian intelligentsia itself who adopted its central arguments in a mission of self-improvement. Kali Kumar Das (sometimes spelled Cally Coomar Doss), for example, proposed the establishment of a new Calcutta Phrenological Society intended for and by the "natives of India" as "a correct knowledge of human nature is likewise indispensable for the philosopher, the politician, the legislator, the physician, the school master, the merchant, the rich man, the poor man and even the menial laborer" (cited in Pande, 2010: 61). In contrast to Paterson's Society, members of Das' organisation were exclusively Indians, and their vision of phrenology was one of an "active instrument of regeneration" (in Kapila, 2007: 497). Here as elsewhere, the instruments of racial biology served a range of political ideas, dislodged from global hierarchies and forming new, hybrid forms of knowledge from Western ideas and local cultural understandings (also Prakash, 1999).

Other researchers and colonial administrators such as B.A. Gupte, working at the Indian Museum in Calcutta under the official title of Assistant Director of Ethnography for India, entered into lively engagements with primarily craniological premises and methods. Inspired by French anthropologist Paul Broca and his student Paul Topinard, Gupte set out to test the applicability of craniological ideas in the Indian context. As Assistant Director, he was mandated with supporting Risley's anthropological work, which I will discuss in the next section, preparing, amongst other tasks, a catalogue of skulls for public display. In doing so, Gupte actively advocated for the use and significance of racial markers developed by craniology. According to him, criteria such as birthplace and caste alone would be misleading for the determination of an individual's true character. "A strictly territorial arrangement of these measurements", he noted, "would not be

as accurate as that registering the racial peculiarities as well" (Gupte, 1909: 1)[17]. Providing the example of a Kashmiri Brahmin, he argued that "[i]f the skull of any such individual were labelled merely Brahman–birth-place–Calcutta–it would be mistaken for that of a Bengali—even of the Mongolo-Dravidian type" (ibid: 1–2). These statements illustrate that, when tasked with categorising Indian diversity, precise anthropological measurements and racial classifications offered the necessary certainty that geographical information or data on caste did not. Though caste was perceived as important for the endogamous marriage practices it imposed on the Indian population, keeping genetic groupings relatively isolated and thus facilitating classification, for colonial anthropologists (both British and Indian), racial criteria were seen as more reliable and stable population characteristics.

Gupte also expressed regret that his craniological findings were necessarily limited as he was only in possession of the skulls of "poor" Indians (Gupte, 1909: 1). Higher-caste and socio-economically better-off Indians, he explained, would not under normal circumstances admit their relatives to public hospitals where he obtained most of his human materials, even if they had died in custody. Though he himself did not further engage with the precise implications of these limitations, his reflections demonstrate the different relations higher-caste and poor, generally lower-caste Indians had to colonial science, and the enduring tensions between who figures as (involuntary) research subject and who as a researcher. They also tell of ongoing negotiations over the effects of socio-economic difference on biological constitutions and disease expressions. As I will show throughout this thesis, despite the widespread acknowledgment of the impact of socio-economic and cultural dimensions on health and drug metabolism, the scientists I interviewed do not appear overly concerned with potential physiological discrepancies between largely impoverished Indians on whom new medicines are tested, and affluent Indian or Euro-American consumers in often hugely disparate socio-economic, environmental and cultural settings. The assumption of materially similar bodies, as Gupte's reflections illustrate, remains vital to the translocal applicability of scientific theories and concepts.

[17] Craniological data from the Indian Museum, Calcutta. British Library, Archives and Manuscripts, India Office Records and Private Papers, IOR/V/27/910/2: 1909.

Craniology and phrenology refuted earlier environmentalist arguments about gradual acclimatisation and paved the way for a more essentialist account of the Indian population. As the biology of each race was produced for and in a specific environment, and racial types were determined by heredity, variations could only be produced by mixture and not by adaptation. In the decades from 1830, then, a new generation of ethnologists broke away from the linguistic paradigm, seeking to prove the original diversity of the human races. In 1833, Scottish physician and colonial administrator, John Crawfurd, authored an unpublished manuscript that anticipated the move away from the belief in the intrinsic relation between Indian and Northern European populations, as well as in the monogenist theory of mankind altogether. While his later writings were more widely circulated, the manuscript includes numerous anthropological observations on India's different languages, nations and races, often used interchangeably and largely ill-defined, that laid the groundwork for his future publications (Crawfurd, 1832–33)[18]. Based on what he saw as a series of scientific and historical misapprehensions, such as the belief in the fundamental conformity between language and biology as well as the discovery of the agricultural rather than nomadic roots of the Arias, the Aryan invasion theory disguised what were, for him, a vast variety of fundamentally different races. These distinct races differed from each other in both physical appearance and intellectual capacity. As such, Crawfurd argued, one "must come to the conclusion that the theory which makes all the languages of Europe and Asia, from Bengal to the British Islands, however different in appearance, to have sprung from the same stock . . . is utterly groundless" (Crawfurd, 1861: 285). For Crawfurd, Indians were much closer to peoples of African than of European origin.

Crawfurd refrained from delivering a precise or scientific definition of race and utilised the concept variably as synonymous to nation, linguistic group, tribe and geographical origin. In his manuscript, he consistently put race in quotation marks; numerous times he crossed it out altogether to replace it with nation and *vice versa*. The manuscript tells of his own uncertainties, and perhaps disinterest, about what exactly constituted a race and precisely how many racial groups existed in India. He found it "idle" to pursue scientific observations much further given the impossibility to distinguish between the "original" qualities of a race and those "superadded" by

[18] Description of India. British Library, Archives and Manuscripts, India Office Records and Private Papers, John Crawfurd Papers, Mss Eur D457.

culture and civilisation (Crawfurd, 1861: 40). Race, for him, was not a concise scientific concept for the analysis of human variation but a loose term to signify what he saw as inferior populations. Not least, it served to buttress colonial strategies of governance and control. Nonetheless, Crawfurd's early writings exemplify how polygenist arguments slowly encroached the study of Indian populations from the early 1800s, and the rejection of racial similarities between Indians and Europeans. Long before the Mutiny of 1857/58 that came to influence research into differences rather than similarities, one can find instances of the 'Negro' Indian alongside Orientalist proclamations of Aryan kinship (also Kapila, 2007).

Crawfurd and his contemporary, the surgeon James Hunt, thereby assigned Indians to a single classification, the Hindu or Hindoo, not distinguishing between different populations. While early Orientalists and contemporary scientific research about Indian groups single out populations in the North East (and sometimes the South) as being of a different racial origin, the two colonial researchers assigned Indians to one homogenous category. Though they took note of internal variation due to differences in location and cultural habits (Crawfurd 1832–33: 47), to them, these did not constitute fundamental racial but merely superficial differences in physical appearance. Both Hunt and Crawfurd insisted that the intrinsic difference between the Caucasian and the Indian race was not a result of external factors, whether cultural or environmental, but was shaped by inherent differences in physical, moral and intellectual qualities. While Hunt argued that human variation was doubtlessly influenced by natural and climatic forces, he emphasised that intrinsic factors such as the "mental power of the race" and the "purity of blood" (Hunt, 1863: 53) were more significant for the moulding of racial characteristics. Climatic determinants were real, but not evolutionary, and thus did not have a profound effect on the constitution of a race *per se*. According to Hunt, "[a]s a rose will under no change of external circumstances become a blackberry, so neither will a dog become a wolf, nor a European an African Negro" (1863: 57). 'Negroes' and 'Hindus' were inferior *qua* biology and thus in perpetuity. In other words, the limits of racial difference could not be transcended.

Hunt's and Crawfurd's ideas were thereby fuelled by the increasingly anti-Indian sentiment of British colonial policy, especially around the insurrection of 1857/58. Surely, scientists centrally derived their arguments from the dominant scientific

methods and parameters of the day (Stepan, 1982, Stocking, 1968), but I find that the growth of scientific productions of difference rather than similarity did not appear in isolation. In contrast, it was very much shaped by political concerns. Most research at the time made explicit recommendations on how scientific evidence about the Indian population should be used for colonial rule. Some was even sponsored directly by the colonial Government of India. In the face of the upcoming crisis, then, the terms of the discussion about the origins of the Indian population significantly changed. The anthropological, historical and medical focus became less on defining similarities between the British and the Indians but on developing an explicitly racial theory of civilisation. The racial body thus increasingly became a site for the construction of colonial authority, legitimacy and control.

4.3 Anthropometry and the pragmatics of racial classification

Contemporary scientific research on the Indian subcontinent is yet to develop a consensus on the genetic history of the caste system (Egorova, 2010). Many population genetic studies have been conducted, seeking to answer the perplexing question of the origin of Indian castes. While some researchers stress the indigeneity of genetic diversity in South Asia, suggesting that Eurasian contributions to its gene pool were negligible (Kivisild et al., 2003; Sengupta et al., 2006), others such as renowned University of Washington geneticist Michael Bamshad and colleagues (2001) argue that caste rank was nonetheless proportionate to European affinity. As such, they carry forward a long trajectory of ideas about the interrelations between caste rank, geographical location and racial affiliation. For example, civil servant and ethnographer Risley, one of the most influential representatives of colonial anthropology in the late nineteenth century, devised his own anthropometry of India through the works of Georges Cuvier and Paul Topinard, and engaged most directly the relation between caste and race.

Finding anthropometry to have clear advantages over the elder sciences of phrenology and craniology, given anthropometry's examination of living humans rather than merely skulls (Risley, 1908: 18), Risley set out to test his hypothesis that race was the structuring principle of Indian society. "The bond" holding Indian population groups together, he argued, "is one of race, and the prohibition of intermarriage merely seeks to maintain the purity of the original stock" (Risley,

1891: 240). The caste system, in his eyes, was only the embodiment of much older racial divisions: physical differences among the Indian population represented the survival of ancient biological distinctions rather than simply variations of a single, unified Indian race. The caste system as well as the race-consciousness of the Aryans preventing intermixture had led to the preservation of these original differences and to the physical characteristics of each caste representing different degrees of racial purity (the Aryan, Dravidian and Mongoloid types). As such, India's marriage practices had created conditions highly favourable to anthropology. Risley wrote in *The People of India* that the prohibition of intermarriage and Indians' "extravagant value on pride of blood" meant that "India presents a remarkable contrast to most other parts of the world, where anthropometry has to confess itself hindered, if not baffled, by the constant intermixture of types obscuring and confusing the data ascertained by measurements" (Risley, 1908: 25). Today, thousands of years of endogamy are still being commended for creating a unique environment for population genetic studies, as Chapter 8 will discuss in more detail.

Physical characteristics, Risley suggested, can be divided into indefinite characters, which can only be described more or less appropriately, and definite characters, which can be precisely measured and reduced to numerical expressions (Risley, 1908: 10–12). Indefinite characters such as skin colour were "not considered ethnologically stable enough to deserve the position of a racial characteristic, as it varies even in the same race in proportion to heat and moisture in a locality" as his assistant Gupte (1911: n.p.)[19] stated in personal correspondence. With their permutations running indiscernibly into one another, indefinite characters proved unreliable indicators for the production of scientific truths. In order to establish a scientifically accurate and detailed catalogue of population classifications in India, Risley therefore turned to the study of definite physical characters such as the stature and proportions of the head, facial features and limbs, and to the nasal index as the most sensitive means to determine racial identity. In his major works, *The Study of Ethnology in India* (1891) and *The People of India* (1908), he laid out in great detail his scientific methodology and the usefulness of specific anthropometric

[19] Letter by B.A. Gupte by the Indian Museum Calcutta, dated 19 July 1911. British Library, Archives and Manuscripts, India Office Records and Private Papers, Risley Collection, Mss Eur E295/19.

measurements. For example, Risley claimed that particularly the nasal index "ranks higher as a distinctive character than the stature or even than the cephalic index itself" (Risley, 1891: 250). Taking his subjects' noses as the starting point for his analyses, he could be sure to follow one of the most authoritative methodologies in racial physiognomy. In relation to Indian populations, the nasal index, he summarised,

> establishes the existence in India of two widely distinct types, the one platyrhine to a degree closely approaching to the negro, and the other leptorhine in much the same measure as the population of southern Europe. Between these extremes we find a number of intermediate types, the physical characteristics of which suggest the inference that they must have arisen from the intermixture of members of the extreme types and their descendants (Risley, 1891: 252).

Here, too, Indians were seen as representing the entire genetic spectrum of humankind. Risley concluded that the correspondence between the racial types established through his anthropometric measurements and the observed social structures and divisions of Indian society "enables us to conclude that community of race, and not, as has frequently been argued, community of function, is the real determining principle, the true causa causans, of the caste system" (Risley, 1891: 259). Hence Risley saw anthropometry as having provided a scientific basis for Indian ethnology and a racial theory of the Indian civilisation.

As such, Risley's anthropology also enabled the British to classify their census results in a more scientific manner. Risley himself, in a largely neglected pamphlet titled *Manual of Ethnography in India*, expressed his "anxiety" about extending his findings beyond the limits of Bengal (1903: 1)[20]. In a personal letter to the superintendent of census operations in Bengal, he also raised concern about the validity of such an endeavour in the hilly north-eastern regions. "In order to make a successful study", he argued, "it would be necessary to devote far more time than was at the disposal of the offices above named. In the hills there are few or no persons capable of giving intelligent replies, and this makes the work far more

[20] Manual of ethnography for India. British Library, Archives and Manuscript, India Office Records and Private Papers, IOR/V/27/910/1: 1903.

difficult than similar work in the plains" (Risley, 1901: n.p.)[21]. The blatant racism against North-Easterners notwithstanding, his racial theory of India was more porous and ambiguous than its political adaptations suggest. Though he put great emphasis on the significance of racial analysis, he viewed with some suspicion its generalisation to other geographical regions and population groups. Despite his reasoned explanations though, the Government of India made his anthropometric, racial approach the dominating argument in colonial anthropology for about twenty years (Arnold, 1999).

In preparation for the first complete census in 1881, for example, vivid discussions emerged over the relations between race, caste and tribe, and colonial administrators advocated strongly for the separate and independent identification of racial belonging. In official correspondence from the Statistical Society of England to the Secretary of State for India, dated 18th February 1877, it is stated that the "Sub-Committee which reported on the original forms proposed for the census added a separate column for race, observing that it could not be included with caste" (Anon., 1877: n.p.)[22]. The undisclosed author argued that "in the seaport towns there was a large number of foreigners who would otherwise be lost sight of in the mass of people" (ibid). His fear of 'losing sight' of non-native subjects illustrates the increasing importance given to racial markers for colonial administration and control. It also emphasises the connections between scientific studies of race and political anxieties such as the indistinguishability between, or mixture of, colonial administrators and their subjects, particularly given Indians' phenotypical similarities to Europeans. Capturing racial characteristics promised at least some relief from the dangers of British citizens' being 'absorbed' by Indian crowds, of inadvertent and unwanted confusion and intermixture with the natives. Again, racial markers offered a degree of scientific and political certainty that caste did not.

Despite fierce criticism by local political figures who expressed their opposition to the classifications used, and often proposed their own, Risley's anthropometry also came to inform army and police recruitments and was used for the identification of criminals and (potential) political offenders. In a letter to the Earl of Kimberley,

[21] Letter addressed to the Superintendent of Census Operations, Bengal, 21 March 1901. National Archives of India, Private Papers, Mss Eur E295, 1-10.
[22] Letter from the Secretary to the Statistical Society of England to the Under Secretary of State for India, dated 18 February 1877. National Archives of India, Home, Public, March 1878, no. 76-78.

Principal Secretary of State for India, dated 19 June 1893, the President of the British Association for the Advancement of Science reports that

> the classification of measurements, of bodily marks, and of finger-prints, afford a ready and inexpensive method of identification and the progress made abroad in organising these methods justifies the hope that the subject may be deemed worthy of serious inquiry by the various Government Departments in this country (Anon., 1893: n.p.)[23].

Concerted efforts were made to establish anthropometry and its underlying theory of racial essences as a political tool for population control and policing. For example, police reports from Kashmir and Burma at the end of the nineteenth century document the expenditure and advances made in identifying offenders through the introduction of an anthropometric system (Anon., 1895)[24]. Anthropometric measurements and racial types offered a convenient simplification of and guide to India's highly complex social order. During the peak of racial science, race, not caste, was perceived as the central principle structuring Indian society. Caste relations were merely expressions of earlier, more fundamental divisions. Moreover, the focus on their internal heterogeneity continued to break with representations of *all* Indians as Caucasian kinfolk.

Even though physical anthropometry's assumptions have largely become obsolete for contemporary bioscientific research, especially as tools for population control, Chapter 5 will illustrate through empirical data how both, the biologisation of cultural phenomena and the pragmatic simplification of what is perceived as a decidedly complex model of gene-environment interactions, continue to shape scientific narratives about specific populations. As I will demonstrate, the 'indefinite' characters or determinants of ethnoracial variation in drug response—for example climate, diets, lifestyles and medical practice—are found inherently difficult to stabilise; 'definite' factors such as genetics or race (still often deducted from skin colour in crude simplifications), on the other hand, provide a measurable, calculable and thus more reliable path to establishing knowledge over such

[23] Letter by the British Association for the Advancement of Science to the Earl of Kimberley, Principal Secretary of State for India, dated 19 June 1893. British Library, Archives and Manuscripts, India Office Records and Private Papers, IOR/L/PJ/6/350, File 1217.
[24] Anthropometry in Kashmir and Burma 1895. National Archives of India, Home, Police, December 1985, no. 121–123.

variation. Though my attempt is not, as explained earlier, to suggest a linear trajectory of population concepts from past to present, these early negotiations of 'intrinsic' and 'extrinsic' determinants are important to keep in mind for the critical analysis of contemporary theories about ethnoracial variability. This is especially so as Indians' ambiguity continues to bewilder scientific analyses. Moreover, explicit references to physical anthropology were comparatively rare in my interviews, but its most infamous markers such as facial angles, scull sizes, phenotypes and even blood quanta regularly 'slipped back in'. Though largely implicit or unconscious, this bears witness to the abiding presence of nineteenth century racial ideas and bioscientists' wrestling with their discipline's infamous yet enduring legacies.

Risley's work gained support not only from the colonial administration but also the European scientific community. His sustained correspondence and intellectual interactions with the most well-known figures in European race science, especially Topinard, demonstrate his deep connection to the European movement as well as the continuous enrichment of the emerging science of race by scholarship in and about the colonies. Risley regularly sent Topinard his own anthropometric measurements from Bengal, the North-West Provinces and the Punjab for rigorous inspection, verification and discussion. Topinard also personally invited Risley to the Paris *Exposition Universelle* of 1889 as the representative of colonial anthropometry (Anon., 1889)[25]. Though Risley's visit to Paris eventually failed to materialise due to the lack of funding, the two scholars' close intellectual and reciprocal relationship challenges the assumption that the colonies simply served as laboratories for the application of ideas developed elsewhere. In contrast, colonial scholarship contributed significantly, materially and intellectually, to its European counterpart and was therefore highly constitutive of the surging science of race.

At the same time, upcoming medical discourses about disease, micro-biology and environmental factors began to construct a theory of the tropics as a site of decay while simultaneously affirming the principal openness and fluidity of racial categories. Though I cannot discuss these ideas in more detail in this chapter (for comprehensive accounts see Arnold, 1999; Bhattacharya, 2011; Harrison, 1992; Pati and Harrison, 2009), it is important to emphasise the enduring tensions between

[25] Invitation to Risley to attend the Paris exhibition. National Archives of India, Home, Public A, March 1889, Nos 337-339.

anthropological and medical arguments. Malaria especially, as *the* illness of the tropics, came to embody the radical otherness of tropical nature and reinforced the dividing line between Britons and Indians as well as between 'martial' and 'effeminate' populations within India. Nonetheless, it was soon agreed that the disease was not specific to one single racial or religious group but could, at least in theory, affect everyone. This does not mean that race was rejected *per se*. Even though bacteriologists refuted a theory of racial immunity, most assumed, first, that race was biologically real and, second, that it shaped the susceptibility to contract malaria as well as other diseases.

But medicine also held out the possibility of contesting the more deterministic definitions of racial classifications that colonial anthropology promoted. Despite the centrality of racial anthropology at the time, medical writers and researchers seem to have found Risley's racial typology rather impractical for their own work. Medical discourse, despite its representation of the tropics as a site of decay and degeneration, seemed sceptical of the biologically stable categorisation of human variation and their representation as fixed groups. Such caution was certainly exercised as the idea of racial traits remaining intact over generations denied a role to the influence of disease and environmental factors. As such, medical science held, and still holds, within itself the possibility of contesting more essentialist and biologically deterministic interpretations of specific population characteristics.

4.4 "Throwing away the dead and dying cells": Indian eugenics and national regeneration

The concern over biological and cultural degeneration in India, often linked to the marriage traditions entrenched in the caste system, has a long trajectory. When contemporary population geneticists warn of Indians' predisposition to specific diseases passed on through intra-caste marriages (e.g. Reich et al., 2009), they carry forward a longstanding debate that arose most prominently during the eugenics movement of the early twentieth century. Despite significant differences between eugenic discourses and contemporary genetic research (see Chapter 2), the interest in detecting cultural causes (such as marriages) for what is seen as biological degeneration (such as the growth of recessive characters) persists. In this last section, I briefly map eugenic discourses in and about India, illustrating once more

the ambiguous status Indians occupied on the global grid of ethnoracial classifications, and explore how ideas about 'better breeding' fed into the upcoming independence movement.

When Francis Galton set out to discover the laws of heredity in the mid-nineteenth century, his main interest was to find evidence for the inheritance of mental or behavioural traits. As is well known, his most central assumptions were, first, that intelligence or ability were stable quantifiable entities that could be measured by simple parameters such as professional achievement; and, second, that the differences in intellectual capacities could be mapped onto known racial groups. Though he initially identified social class rather than race as the central unit of eugenic concern, it was only too easy to translate class terms into racial terms. Eventually, eugenics provided yet another channel for the transmission of racialist ideas (Stepan, 1992, 1982). Even though neither Galton nor the eugenics movement defined and deployed the concept consistently, a discourse of race was built into eugenics from the very beginning. At times, race improvement could refer to the betterment of humankind as a whole; at other times, eugenicists were explicitly concerned with a particular segment of the population which they perceived as divided into different, hierarchically ordered racial groupings. Eugenicists who self-identified as belonging to a superior group marked off inferior and unfit ones. Their difference was seen as biologically fixed and stable, and individuals were assigned to specific racial, that is, abstract types (Stepan, 1982, 1992).

At the same time, eugenics was a decidedly international movement, with eugenics associations forming in various countries not just in Europe and the US but across Africa and Asia as well (Kühl, 2013). What Stepan terms the 'quasi-international currency' of eugenics (Stepan, 1992) refers to the myriad societies concerned with eugenic research and practice in places as different as England, Italy, Peru, the Soviet Union and Japan. While, throughout the 1920s, access to international eugenics organisations was reserved for members of the 'white race', given the American and European consensus on white superiority, eugenics organisations in Japan, China and India developed their own strands of eugenic thought. Often, they thereby incorporated elements from their own ancient scriptures and social norms. Eugenics therefore shaped racial ideas about Indianness through both British and Indian thinkers, and India's ambivalent racial status allowed Indian scientists to reclaim their membership to the Aryan race. While tropical medicine represented

India as a hot-bed of disease, eugenics allowed for the recognition of at least some Indians as racial kinfolk of Euro-Americans.

In India, eugenic ideas were taken up with remarkable enthusiasm by both scientists and politicians. By the 1930s, eugenics associations had sprung up all over the country in what Mark Singleton identifies as the "raging sentiment of national degeneration, physical, moral, and spiritual" (2007: 126). Organisations such as the Indian Eugenics Society, founded in 1921, attracted thousands of urban, middle-class men (more so than women), and most social and political debates at the time were shaped by eugenic thinking (Hodges, 2006). The movement was thereby significantly oriented towards the European, especially the British, scientific debate. As correspondence between Indian and British eugenic societies shows, India's aim was to become affiliated to the London-based association and, ultimately, join the global movement of eugenics. The organiser of the Indian Eugenics Society in Lahore, Professor Gopalji Ahluwalia, for example, stated in his address to the Society's inaugural meeting that India needed to contribute "papers and if possible some representatives or better still a Consultative Committee" (1921: n.p.)[26] to the Second International Eugenics Congress. Through such contributions, India's "glorious past" and "noblest ideals" would allow the country to take up its place amongst the scientifically and racially leading nations of the world (ibid). India, if it "can muster courage", should even "invite the Third International Eugenics to India and stimulate [its] people to Eugenic thought and action and helping other Eugenic workers and making the Eugenic movement more wide-spread" (ibid). In other words, Indian eugenics closely emulated the scientific and organisational structures of the British movement.

Indians' attempt to integrate themselves into the global networks of eugenics tells of India's ambiguous and often indeterminable racial status, also in eugenic thinking. As Stefan Kühl (2013) shows, eugenic societies outside the movement's intellectual centres, that is, Europe and the United States, were usually denied official membership in any international organisation throughout the 1920s. The racist exclusion of 'non-white' organisations was, of course, based on the movement's fear of miscegenation and racial infiltration. However, as my own and other archival research (Hodges, 2006; Singleton, 2007) confirms, Indian

[26] Eugenics, a bird's-eye view. Wellcome Library, Archives and Manuscripts, SA/EUG/E.8: Box AMS/MF/147.

eugenicists were in close contact with international institutions since the early 1920s. Ongoing correspondence between the Indian Eugenics Society and European organisations such as the Eugenics Society in London and the Birth Control International Information Centre in London and New York throughout the 1920s, 1930s and 1940s exemplify the deep intellectual and institutional entanglements between the two scientific communities. In a letter addressed to the Eugenics Society, for example, president of the Eugenic Society in Bombay, R. B. Lothvala, asked for India's admission to an international, comparative eugenics programme and an official affiliation of its Society with London (Lothvala, 1930)[27]. In return, he offered the Society his full support should the London-based organisation want to publish research findings and other literature in India. Hence while 'non-whites', due to their inferior racial status, were only gradually admitted to the international ranks of eugenic research, Indians had sustained a continuous dialogue and scientific exchange with British and American eugenics associations. Though this does not necessarily imply that Indians were seen as equal, it testifies to their racial ambiguity and often close proximity to whiteness that could be utilised differently depending on the political, social, or scientific circumstances of the time. For instance, Kühl (2013: 54) shows that it was the explicit interest of British members of the International Federation of Eugenic Organizations (IFEO) to develop eugenic research in the colonies that instigated internal discussions about admitting Asian and African eugenicists to their ranks. Here, the British subordinated racial and national origin to the advancement of the scientific status of eugenics.

In India itself, eugenic societies mainly aimed at synthesising Western eugenic ideas with Eastern philosophies to create their own, unique interpretation of eugenics. As the constitution of the Indian Eugenics Society reads, the aim of the Society was to engage in the "critical study relating to race improvements" albeit "from [an] Indian point of view and having regard for Indian traditions and present conditions" (Ahluwalia, 1921: n.p.). While Indian eugenicists did not produce sound scientific research into hereditary traits or genetics, they used eugenic ideas both scientifically and politically to advance the idea of Aryan regeneration in the wake of national independence. Indeed, the political discourse of the day deployed the

[27] Letter addressed to the President, Eugenic Society, London, dated 4 April 1930. Wellcome Library, Archives and Manuscripts, SA/EUG/E.9: Box AMS/MF/147.

language of biology to argue for the urgency to restore the glory of the Indo-Aryan era destroyed by moral and spiritual decay. The aim of social reform was to awaken (Hindu) Aryanism's vital forces; as the president of the Madras Provincial Social Conference, A. Mahadevi Sastri, for instance, argued, the Indian independence movement must "throw away the dead and dying cells which encumber the organism and hamper its growth and gather other living cells which will help its growth and expansion" (1915: n.p.)[28]. A return to Vedic and Aryan principles of socio-religious organisation and the reawakening of India's spiritual, moral *and* racial superiority was seen as key. As archived documentation of the communication by the Indian Home Rule League, a relatively short-lived organisation led by British social reformer Annie Besant and aspiring Indian self-rule, shows, the idea of racial Aryanism, i.e. that the "Aryan Root Race" was the oldest and purest in India with remains of the unadmixed "Aryan root stock" (Anon., 1919: n.p.)[29], was mobilised to substantiate the claim for independence and self-rule.[30]

What Indian reformers' enthusiasm for social engineering and the advancement of the Aryan race shows, then, is how pervasive eugenic ideas became across the globe. It also demonstrates how these ideas were adapted to different local circumstances and mobilised for often progressive political projects. In the Indian case, the racial ambiguity of their subjects allowed Indian scientists and eugenicists to place themselves amongst the genetically fit and superior races of Man through the very same theoretical lens that caused the British and international eugenics movement to remain undecided about, if not hostile to, their membership and racial belonging. Nationalist reformers combined eugenic ideas and ancient Hindu literary traditions to indigenise eugenics and utilise it for their goals of national regeneration.

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[28] Presidential address to the Madras Provincial Social Conference, 5 May 1915, Nellore. Nehru Memorial Museum and Library, The Annie Besant Papers, 2/89-113.

[29] Home Rule League: the awakening of India. Nehru Memorial Museum and Library, The Annie Besant Papers, 4/96-115.

[30] The specifically Indian version of eugenics did not, however, recommend large scale sterilisation programmes or other state sponsored measures but focused on the up-and-coming field of population control. Significantly influenced by radical politician, theosophist, women's right activist and supporter of eugenic ideas Annie Besant, the question of India's rapidly growing population became the focus of eugenic thought in the country. Besant, an outspoken Malthusian and founder of the Malthusian League in England, argued for the need to control the growth of India's population, especially those segments of society that were not seen as advancing the racial status of the nation (see, for instance, the Anne Besant Papers at Nehru Memorial Museum and Library, 1907-1934; Hodges, 2006).

Nonetheless, the mainstream nationalist movement did not use race as a purely biological concept but saw the decline of the Aryan civilisation as having social rather than genetic causes (Jaffrelot, 1995). Reminiscent of what Pierre-André Taguieff (2001) refers to as racism of domination/exploitation rather than racism of purification/extermination most drastically exemplified by the Holocaust, most popular theorists of Hindu nationalism were not obsessed with racial purity but allowed for the integration of non-Hindus into Indian society, albeit in a subordinated position (Jaffrelot, 1995). Hence while the international eugenics movement left a visible imprint on scientific theorisations of Indianness by both British and Indian thinkers, their political adaptation remained somewhat limited. Hindu nationalism, ultimately, enacted a form of domination that did not entirely exclude its Others from but integrated them at the margins of Indian society.

4.5 Conclusion

This chapter has traced some of the ethnoracial theories about Indianness, from comparative philology to eugenics. Early philology established a functional equivalence between linguistic and genetic ties, and the narrative of the Black Aryan produced Indians as a degenerated version of Europeans—or, as I have described it, as almost white, but not quite. While such descriptions conceptualised race as a loose assemblage of physical, linguistic and cultural traits, the mid-nineteenth century witnessed the increasing biologisation of scientific race thinking and a focus on measurable, calculable factors to determine racial belonging. Shaped by the political context of the time, Indians were increasingly seen as racially different or deviant. Eugenic scholarship reinforced the idea of biological essences yet sought to excavate Indians' historical connection to whiteness.

Overall, the chapter has illustrated that colonial scholarship on India was directly influenced by and, in turn, fertilised the scientific racialism prevalent in Europe at the time. Race provided a welcome explanation for what appeared to be intrinsic physical and mental differences between the British and the Indians as well as between different populations within India. At the same time, scientific research about Indian races was characterised by a degree of ambiguity and indecisiveness over their precise classification, allowing scientists and colonial administrators to sometimes categorise Indians as fellow Aryans, and hence white, while at other

times stigmatise them as racial Others. In the following chapters, I will draw on my empirical data from interviews with research scientists, policy makers and pharmaceutical industry executives to explore how present-day scientific discourses divert from, but also reproduce, some of the assumptions about race and Indianness illustrated here. To do so, the next two chapters engage both the dominance of 'definite'/genetic factors marking human difference and the legacies of racialised discourses in contemporary biomedicine that inform the offshoring of clinical trials to the subcontinent.

Chapter 5: "Race, race is more consistent": Conceptualising human diversity in contemporary drug development

> My preference is to look at ethnicity. . . . Ethnicity brings in a wider range of parameters that can define a particular group. But unfortunately, it makes it less applicable in a universal context (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

Despite the assumption that the HGP would radically refigure human difference and obliterate the very idea of race once and for all, subsequent genomic research has developed a sustained interest in probing the nature of human diversity along racial lines. Rather than a focus on our shared humanity, what has emerged is an interest in studying relevant differences between human populations. These are assumed key to delivering a central promise of the HGP: translating DNA sequence information into a better understanding of human health and developing potentially life-saving medicines and therapies.

In this chapter, I examine the renewed interest in race after the HGP within the discourses and practices of corporate global drug development. Most sociological research has focused on the reification of race in (post-)genomics and pharmacogenomics, but the meaning and value of human diversity in corporate clinical studies significantly differ from lab-based, genomic research. Drawing on my interview data, I will show that analyses of diversity in drug action and disease progression need to incorporate the myriad non-genetic influences, usually framed as ethnic as opposed to racial factors, that intersect with genes and each other in infinitely complex ways. As oncologists Peter H. O'Donnell and Eileen M. Dolan argue, "[p]harmacoethnicity, or ethnic diversity in drug response or toxicity, results from the *combined interaction of many factors*, principally differences in environment, local practice habits and regulatory control differences, drug-drug interaction differences, and genetic differences" (O'Donnell and Dolan, 2009: 4808, emphasis added). Also, transnational drug development comprises an entire range of cultural approaches to medicine, scientific disciplines and areas of expertise that

may produce multiple and conflicting conceptions of human variation. Misunderstandings, scientific disputes and discordances in such multi-disciplinary collaborations frequently arise out of honest philosophical disagreements linked to disciplinary training, institutional affiliation or professional status (Jasanoff, 1993).

Most crucially, drug development is, like biomedicine more broadly, always defined by both research and practice. This means that drug developers need not only be attuned to the statistical significance of a specific finding or genetic variation but probe its *clinical* importance, too (Hacking, 1983; Sedgwick, 2014). My respondents critically weigh statistical statements about genetic variance that convey scientific certainty with less 'objective', often experiential values and clinical judgement, often challenging research in population genetics or genomics. Finally, drug development is predominantly driven by the logics of venture capital: while national governments sponsor large scale genomic sequencing projects such as the HGP to enhance the understanding of human health, drug research itself is largely undertaken by private biotechnology and pharmaceutical companies and shaped by the parameters of pharmaceutical marketing. This significantly impacts the ways in which targets are defined, where research is performed and which populations are figured as experimental subjects and/or future consumers.

Common assumptions and scientific hypotheses about human diversity in genomic analyses may therefore be reworked, translated or even rejected in the process of identifying treatment for disease. Rather than accepting that race has been 'molecularised' (Fullwiley, 2007b), the chapter therefore asks what it means specifically for drug developers, how they cope with its intrinsic ambiguities and, ultimately, why it may be given precedence over other categories such as ethnicity. This means considering the specificities of translational, privately-funded research as well as the everyday realities and pragmatic decision-making processes my respondents' research environments demand. I will argue that although drug developers are highly reflective or even critical of the fallacy of racial categorisations, race nonetheless promises at least some certitude amongst the multitude of factors influencing variable drug response. Race, for them, constitutes what I will call an uncertain certainty that may be impossible to pin down but offers some insight into the still largely uncharted territory of human diversity in clinical research. As such, the chapter expands upon existing sociological analyses by

bringing arguments about the new significance of race in bioscientific practice to bear upon the specific field of transnational drug development.

I begin this exploration by illustrating how populations in contemporary drug development are shaped along three key axes: Genomes, cultures and nations. However, whilst drug developers are attuned to the multifactorial nature of drug action, genetic explanations offer more replicable and 'objective' results that can be framed in scientific certainty, as sections 5.4 and 5.5 will discuss. Through its conflation with genetic ancestry, race, as opposed to ethnicity, is therefore re-established as a relatively stable population descriptor. This does not imply that drug developers subscribe to a notion of racial essences, and they frequently deploy the category to assess other etiological differences. Nonetheless, such re-evaluations of the causative mechanisms of drug disposition may also inflect how human groups and their specific disease risks are perceived in biomedicine—and in society. I therefore also delineate the trend to re-biologise race even where it has been defined as an explicitly socio-political category (section 5.6). I find that the authority to solve existing ethnoracial health disparities is increasingly bestowed upon genetics and genomics, potentially delegitimising sociologically and/or historically informed analyses and curtailing reciprocal interactions between the social and the biological.

5.1 "We tend to reproduce in a geographical region": Genome geography and race

Genetic differences in how populations respond to drugs have long been subject to analysis (Jones, 2011). In theory, hereditary traits may affect drug action at various stages: a drug interacts with numerous enzymes and other proteins, and reacts with blood plasma, tissue proteins and drug receptors during its passage through multiple organs, especially the liver (Meyer, 1992). However, though their significance has recently been relativised by the increasing focus on non-coding DNA (Fox Keller, 2015), drug research has focused largely on SNPs that have become the primary units of pharmacogenomics, especially those at genetic loci coding for the cytochrome P450 (CYP450) superfamily of drug metabolising enzymes. Around a dozen CYP450s are responsible for 70–80 per cent of all drugs currently in clinical use (Zanger and Schwab, 2013), and some are particularly susceptible to genetic variation. For instance, the activity of CYP2D6, CYP2D19

and CYP2C9 may show significant variability according to a patient's genetic makeup. Such variation in metabolic activity is expressed in distinct phenotypes classified as poor, intermediate, extensive and ultra-rapid metabolisers: Patients with more active CYP450 profiles metabolise drugs faster which may decrease both their efficacy and toxicity, and patients with a less active metabolic system are more likely to respond but also to develop side effects to a drug.

Despite the consensus in the field that human genetic variation is dynamic and clinal, meaning that allele frequencies change gradually with geographic distance (Kaufman and Cooper, 2008), population concepts around shared CYP450 allelic frequencies associated with a specific geographic ancestry have become a core analytic in research on ethnoracial variation. Consider the following statement by Dr Jörg Täubel, a medical practitioner and CEO of one of the UK's leading CROs, Richmond Pharmacology. Täubel specialises in performing ethnic bridging studies and brings to his work over twenty years of experience in conducting clinical trials with patients and healthy volunteers. He argues:

> Largely I should say within a given population there's a huge variability anyway, but obviously we tend to reproduce in a geographical region . . . If you look at the map, it's quite obvious that we look different, and that's not just from the outside, but of course also the differences exist in the way we respond to medicines (Dr Jörg Täubel, CEO of CRO Richmond Pharmacology, UK, July 2015).

Despite his qualified acceptance of the great genetic variability *within* a given population, the presumption here is that geographical regions map onto ancestral origins ("we tend to reproduce in a geographical region"), phenotypic traits ("we look different") and the genetic markers or SNPs responsible for differential drug reactions ("differences exist in the way we respond to medicines"). Specific genetic traits are passed on through reproduction bounded by geographic proximity, creating loose, but nonetheless discernible, populations through shared ancestral ties. While the relation between ancestral markers and phenotypic traits itself is more complex (Zack, 2002), geographical ancestry is generally agreed to constitute a meaningful basis for differential drug responsiveness.

Various genomic technologies have become central tools for the discovery of disease predispositions and the development of pharmaceutical therapies between such genetically bounded populations. While early pharmacogenetics relied on candidate gene studies that focused on a single, preselected genetic trait, pharmacogenomics has increasingly turned towards Genome-Wide Association Studies (GWAS) to identify relevant genetic variants and their association with clinical endpoints (Gamazon et al., 2012; Srinivasan et al., 2009). A detailed account of GWAS-based analyses as well as their limitations (see Richardson and Stevens, 2015) is beyond the scope of this chapter and has been thoroughly provided by other research in the field (for example Fujimura and Rajagopalan, 2011; Fullwiley, 2008). Crucial here is that even GWAS are used to divide patients into subgroups based on responder profile or susceptibility rather than focusing on the individual as such (Fujimura and Rajagopalan, 2011); at the core of pharmacogenomics currently is the stratification of patients into distinct at-risk categories or populations. Dr John Ahmed, a clinical pharmacologist specialising in ethnoracial variability at Clintech, a pharmaceutical multinational based in London, explains:

> If . . . you're asked to look at this enzyme, and you decide to look at it in this group of Japanese people, of Taiwanese people etc., . . . you can look at this in models, you can look at the activity, the quantity in these different people, and come up with these statistical statements like 'CYP2D6 has got a statistical activity in this group and this group' (Dr John Ahmed, senior director, clinical pharmacology, multinational pharmaceutical company, UK, August 2015).

What he illustrates is that GWAS and other technologies produce quantitative knowledge through statistical determinations of which SNPs may be related to specific drug effects. Such statistical estimates are always made about *groups* of patients: rather than advancing personalised treatment, statistical patterns of correlation between enzyme activity and human groups therefore constitute populations as measurable entities to be targeted for therapeutic intervention (M'Charek et al., 2013; Williams, 2017).

The division of human diversity into genetic populations, even though their boundaries are perceived as porous and increasingly challenged by genetic admixture and gene-environment interactions, provides a fertile soil for the

conflation of ancestral groups with more familiar, racial conceptions. GWAS differ from other technologies such as ancestry informative markers (AIMs), often used in commercial genealogy tests, which are based on continental or racial categories to define populations. Software used for GWAS divides DNA samples into clusters based on SNP frequency scores and does not require prior classification into distinct categories (Fujimura and Rajagopalan, 2011). Nonetheless, associations of a specific genomic sequence with a geographic location often shape the research design and practices used to construct genomic populations. In this way, bits of a patient's or donor's genomic sequence become associated with that individual's place of origin. What Fujimura and Rajagopalan (2011: 1) term "genome geography" is illustrated by Täubel's statement above, linking inherited genomic patterns with specific geographical regions and often phenotypic presentations. As such, while population may seem a more neutral term to describe human groups, populations are regularly delineated through region, continental origin or race (Nash, 2012).

Genome geography, then, becomes one thread through which concepts of population, geographic ancestry and race are rendered metonymic. While molecular analyses can provide avenues into studying human variation without relying on molar categories, *in practice*, they are often understood to be isomorphic. In fact, when queried for a definition of race, Täubel added to his description of geographically distributed allele frequencies that

> Race is more genetic. As I said, we replicate within a region, so if you have a mutation of sorts, . . . then of course that's prevalent for a region (Dr Jörg Täubel, CEO of CRO Richmond Pharmacology, UK, July 2015).

The statement illustrates that for Täubel, similar SNP variations mean shared ancestry which can be traced back to a geographical region or continent and, at least to some extent, be equated with familiar racial taxonomies. Echoing this association of race, genetics and geographical origin, Dr Alice Friedman, a senior researcher and Head of Clinical Innovation at Quintosh, similarly argued when I asked what she meant by race being an important variable for drug disposition:

> Well, I don't even know if race *is* a variable. . . . What I mean by that, on the assumption that within race you have different genetics, if you make

> that assumption. If you say that all races are the same and it actually makes no difference where you're from, it's just that you have either some genetic differences or another, then race won't matter. But we *know* that Africa, for example, do have different genetics maybe to the rest of the world, so maybe there is another element where race can be linked to differences as well (Dr Alice Friedman, global head of clinical sciences, multinational pharmaceutical company, Switzerland and India, August 2014).

Also pointing to the uncertainties drug developers face when assessing human biodiversity, to which I will return later in the chapter, Friedman emphasises the significance of race as linked to geographical origin and continental, especially African, ancestry. In doing so, she also reiterates the traditional black/white binary conflating race and Blackness. Contesting the assumption that, as she says, 'all races are the same' and only inter-individual genetic differences mattered, she stresses the explanatory value of specific human groupings based on shared geographical origins. Not accounting for population-level variation would amount to the disavowal of what she considers established biomedical evidence. Like Täubel, Friedman foregrounds genetic variability within such geographically defined populations, but she refuses to detract from racial explanations altogether.

Though neither respondent was able to offer a precise definition, both insisted on the significance of race as a marker of genetic variation *qua* ancestry. Again, statements about race are made as statistical estimates, not biologically deterministic essences, but this does not disavow the biological reality of racial distinctions. In transnational biomedical research, conflations of shared SNP variation scores and molar categories may refer to regional, national or continental populations depending on the regulatory framework and concrete research design of a study. Yet, genetic variability is often understood as relating to the "three major racial groups most relevant to the ICH regions (Asian, Black, and Caucasian)" (E5: 12). This recuperates, in a seemingly neutral fashion, racial concepts dating back to nineteenth century taxonomies.

Though not many of my respondents perform GWAS as part of their own work, the tenets of genome geography coupled with the prevalence of racial nomenclature in scientific publications (Bhopal et al., 2000; Bhopal, 2004; Smart et al., 2008) and

authoritative guidelines such as E5 imply that, as I will detail further below, racial descriptions are often familiar, readily available or "common-sense" (St Louis, 2004) categories to describe such ancestral or geographical clusters, presumptively discharged of their lethal histories. Biomedical researchers pragmatically rely on bureaucratic schemes of classification or genetic terminology that has long redefined, rather than replaced, race by geographic ancestry (Dobzhansky, 1937; Gannett, 2013; Roberts, 2012). Most of the experts I spoke to have simply accepted the genetic postulate that ancestry can be translated as belonging to one of these three major genetic groups of humankind based on geographic origin. The translation of statistical population averages into factual categories anchored in genetic ancestry and translated into continental races lends racial descriptions of populations new scientific authority.

5.2 "You are what you eat": non-genetic contributions to variation

While variation in gene expression may result in distinct metabolic phenotypes, drug disposition is equally shaped by non-genetic and clinical determinants. Among the most relevant factors are varying cultural approaches to medicine, standards of care, environmental factors, the likelihood of inappropriate drug use (especially of analgesics and tranquilisers), and particularly diets that influence the absorption and distribution of drugs. According to the pharmacological literature, food-drug interactions occur when the consumption of a specific food modulates the activity of the responsible metabolising enzymes, causing a significant alteration of the way the drug is absorbed and processed. Fruits, vegetables, teas and spices but also dietary macro-constituents such as total protein, fat and carbohydrate ratios and energy intakes can induce or inhibit how a patient responds to a drug (see e.g. Harris et al., 2003).

These factors often complicate the classification of human diversity into distinct, genetically endogamous populations as analytical entities, respondents admit. For instance, Dr Rainer Mössinger, a senior pharmacologist and pharmaco-epidemiologist at Quintosh suggests:

> You can capture information on race, but then again sometimes it may be more important that you catch information on region [or culture]. So, like Europe, you know, you can go to Europe and someone in Finland is

> quite a bit different from someone in Portugal, and someone from Bulgaria is definitely not the same as someone from, whatever, Ireland. . . . Even if you're classified as Caucasian, then you have the Mediterranean lifestyle, you have this, this and that, so you have so many differences already in the Caucasian population that of course it doesn't give you the whole answer. . . . You have a certain lifestyle that goes along with a certain population, the Mediterranean lifestyle, the diet is different, it's a little bit more laid back, things like that, and of course this doesn't mean that this applies to every single individual in the population, but in epidemiology we look at not so much the individual but the population as a whole (Dr Rainer Mössinger, pharmaco-epidemiologist, multinational pharmaceutical company, Switzerland, December 2014) .

The statement illustrates that racial markers, understood to loosely designate genetic ancestry, are only one aspect that drug developers must take into consideration when assessing clinical data or designing trials. In contrast to genetic studies, as (or even more) important may be factors relating to the socio-cultural dimensions of a patient's response to drugs that include but also go beyond mere dietary factors. Stress levels, working hours and socio-economic standards can significantly influence health and disease. Such extrinsic and behavioural factors are neither determined by genetic ancestry nor bound by geographic or nation state borders, criss-crossing with and challenging common definitions of race in both the sociological and biomedical literature. Usually described as ethnicity, Mössinger here proposes the category of region to capture clinically relevant information that transcends such boundaries (also Tanaka et al., 2011, 2016).

Within cancer research in particular, cultural and dietary habits are discussed with great concern, both in relation to disease risk and drug response. Dr Sylvie Connors, an oncologist and expert in regulatory affairs at Quintosh, stresses:

> Gastric cancers for example, there are some that are influenced by habits of people, I would say probably more habits, gastric cancer is more in Asian countries and it's probably because of the food and the spices or whatever it is. . . . I've heard, I'm sure this is not scientifically

> completely sound, but they eat very hot and drink very hot stuff, that could be, so there are certain cancer types that, or in Africa for example, HCC, liver cancer, because of aflatoxins, because of peanuts, when they are a bit moldy, that is a known cause of liver cancer. So, there are some cancers that could be indeed more prevalent in certain regions of the world. Whether that is, I mean there is your question already, whether that is genetic or whether that is more the habits of the people there, I would say it's probably more the habits, and some genetics (Dr Sylvie Connors, regulatory expert, multinational pharmaceutical company, Switzerland, July 2015).

Against the increasing focus on the genetics of cancer aetiology, Connors particularly worries about the nutritional overexposure to aflatoxin, a liver-damaging toxin that is produced by mould and often occurs in peanuts, corn and tree nuts. She here speaks to the greater risk of many African communities in whose cuisines peanuts occupy a vital role. Such communities, she argues, have an increased risk of developing hepatocellular carcinoma, or liver cancer, and their dietary habits may influence the progression of the disease as well as patients' responsiveness to chemotherapeutic agents. Not long ago, an aflatoxicosis outbreak in Kenya which affected several hundred people brought the topic to the fore in cancer and public health research (Barrett, 2005).

Respondents' concern about dietary factors illustrates that the dominant approach to disease and treatment has shifted from a monocausal and fairly reductionist model of explanation to one considering their social and individual aspects (Aronowitz, 1998). Indeed, especially food consumption is an intrinsically social, cultural and economically located practice that cannot be viewed in an "ideological vacuum", as sociologist Harshad Keval puts it (2015: 281). The ways in which food and people are tied together is infinitely complex, mediated by interpersonal relationships, social values, subjective meanings and organisational constraints (Schubert et al., 2012). Biomedicine is increasingly receptive to these social dimensions but focusing on specific cultural practices may not always provide a more precise or nuanced explanatory frame. In scientific analyses, the myriad dimensions that shape eating, feeding and other lifestyle patterns are often reduced

to the chemical content of a specific aliment or rendered the static quality of a particular population.

However, dietary patterns change over time, and early research in pharmacogenomics found that with changing diets, smoking habits or other environmental exposures, research participants' drug metabolism also shifted within a few weeks or months (Alvares et al., 1979). Studies even found that presumed ethnoracial differences, for example across Londoners or between different West African villagers, equally disappeared when such exposures were factored in (Jones, 2011). Drug-metabolising capacity is not an essential characteristic of an individual or population but responds significantly to an individual's biochemical environment (ibid.). Nonetheless, in order to be translatable into biomedical models of causality and inference, the socio-cultural determinants of disease and treatment are often stripped of their dynamic possibilities.

The danger is, then, that cultural factors are taken to almost mechanically determine a specific population's behaviours and actions. The pathologisation of culture misses the inherently dynamic nature of the concept as "a flexible resource for living, for according meaning to what one feels, experiences and acts to change" (Ahmad, 1996: 190). Rather than the static factors reducible to numerical expression needed for biomedical analyses, cultural frameworks provide fluid and flexible guidelines for action that criss-cross with other axes of social distinction and are centrally contingent on temporal, geographical and biographical dimensions. In biomedical models, however, they are often interpreted as internal, fixed properties of specific patients or populations. Though challenging racial explanations, this may also lead to the reification of cultural or ethnic groupings with similar effects to those produced by biological essentialism (Balibar, 1991; Brubaker, 2002).

Naturalised understandings of a population's cultural characteristics are central to the formulation of inclusion and exclusion criteria in clinical trials. Täubel explains that

> In practice, you are what you eat. So essentially, Japanese coming over here and living here for 4 or 5 years, eating fish and chips every day, I don't think are very representative of the population in Japan. Those

> who stay in their community and still largely eat a similar diet, that's probably okay [to enrol them in studies] (Dr Jörg Täubel, CEO of CRO Richmond Pharmacology, UK, July 2015).

Admitting that food was an inherently complicated denominator given the increasing Westernisation of Japanese lifestyles, his organisation assesses both genetic 'purity', often through participants' passports that document their Japanese heritage as well as extended stays outside of Japan, *and* cultural proximity measured against statistical averages of the population within Japan. As his organisation provides clinical services to companies seeking drug approval in Japan, he must ensure that the diasporic trial population is representative of the specific drug's future consumers. In other words, the safety and efficacy of drugs intended for Japanese bodies must already have been established on bodies considered *similar enough* (Kelly and Nichter, 2012). To do so, both genetic and socio-cultural components are key to determining a potential trial participant's ethnoracial 'authenticity' and therefore suitability for such studies. Biological and non-biological determinants are woven together to produce a decidedly biocultural understanding of a population—without breaking with its genetic foundations. The decidedly dynamic nature of cultural processes is thereby pressed into static models and causal explanations of the interrelation between socio-cultural patterns and drug effects. Despite, or perhaps precisely because of, researchers' alertness to the inherent volatility of non-genetic factors, these are often flattened into reductionist models.

5.3 National projects, national populations?

While the influence of genetic as well as non-genetic and clinical factors on drug action is widely recognised, in the practice of global drug development, ethnoracial variation is equally inflected by the pragmatics of industry-funded research, the sites chosen for clinical trials and diverging national regulatory requirements for research and marketing approval. Which populations become subject to drug testing and how they are understood is therefore contingent on the larger bioeconomic imaginaries of the nation state that often mould genetic markers, founding myths and political projects into biologically anchored and historically naturalised populations. Frequently, national genetic databases are designed to

foster economic activity and some national gene pools have emerged as highly valuable commodities (Fortun, 2008; Pálsson and Rabinow, 1999).

Dr Täubel, for instance, explains that several governments such as the Japanese and Chinese have set up local regulations for additional ethno-bridging studies that test the applicability of a new compound in their respective populations:

> The Japanese have essentially created a number of barriers. . . . For them [non-Japanese companies] in order to be able to conduct clinical trials there, they would produce a bridging study. . . . Because with the majority of medicines where you do see a marked difference in PK, you need to address that. It isn't a showstopper, but you will have to do a little bit more work than you have to when all the things are equal (Dr Jörg Täubel, CEO of CRO Richmond Pharmacology, UK, July 2015).

As explained in Chapter 1, bridging studies are performed between the regions or countries in which clinical trials have already been conducted and the jurisdiction in which marketing approval will be sought. Several regulatory authorities insist on such studies based on the assumption of fundamental differences rather than socio-historical continuities between national populations. While Japan is the most well-known case, respondents report that the Chinese, Korean, Russian, Nigerian, Mexican and, to a certain extent, the Indian regulators have all introduced formal or informal requirements about bridging 'foreign' data. As anthropologists Kimberley Kelly and Mark Nichter (2012) rightly observe, such guidelines do not mirror the US-American trend to increase the inclusion of minorities in research but rather aim at the opposite (see Chapter 2): instead of seeking to enhance the external validity of study results through the diversification of the sample, they require results from a highly diverse sample to be verified in a narrowly defined population to determine the ways in which a drug will affect this population. This illustrates the limitations of the inclusion-and-difference paradigm as an explanatory model for the significance and management of population diversity beyond the North American context; as Epstein himself admits, some countries "seek instead to subsume difference under a broad conception of national citizenship" (2007: 7-8).

Though scientists are also concerned about varying standards of medical practice and attitudes to treatment across different sites, they often draw on explicitly

biological or biosocial justifications treating such national populations as endogamous entities, sometimes based on theories of natural selection or genetic drift (Graves, 2001). However, while these may explain *some* aspects of variation in *some* cases, they fail to justify arguments for specific studies in populations such as the Chinese or the Indian which are characterised by processes of constant migration, the regular reshuffling of national borders and the existence of significant population substructure. Even for the Japanese or the Icelandic population, often considered most genetically endogamous, isolation is in fact impossible since, as Mike Fortun argues, "there's always an *and*: ridge *and* gradient *and* currents *and* oxygen *and* nutrients *and* fish *and* 'all human life within the country'" (2008: 160). Undoubtedly, enactments of national populations are deeply entrenched in cultural narratives about the origins of the nation state.

The hypothesis of Japanese uniqueness, for instance, may reflect a form of cultural essentialism rooted in the Meiji era and its concept of Nihonjinron, assuming the historical continuity, socio-cultural homogeneity and hereditary facticity of the Japanese people (Dale, 1986; Kelly and Nichter, 2012; Kirmayer, 2002). Similarly, Professor Ben Chan, a research scientist at a public university in Singapore, underlines the largely uncontested nature of Han Chinese homogeneity in pharmacological discourses in East Asia:

> I don't know, I tell my students I don't know what a Han Chinese is, actually [laughs]. I say there is no such thing, it's a fictitious idea that there is something called Han Chinese, . . . there is no strict Han Chinese race that would embrace all people with yellow skin or something. It's kind of stupid to even think that. Unfortunately, this is perpetuated even in scientific literature (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

Despite the socio-historical evidence of the constructed nature of collective national identities (Anderson, 1983), ideas about race and nation still hold, as Chan suggests, great significance in biomedical discourse and practice. In particular, the uncontested nature of Han homogeneity and purity speaks to the enduring political weight of establishing Han as the Chinese ethnic majority in attempts to rationalise the construction of a Chinese nation state (Dikötter, 1992). National populations are reified as natural, quasi-biological entities through an entire arsenal of socio-

cultural, historical and biomedical narratives. Here, too, these coalesce to forge novel or reproduce existing understandings of specific populations.

Chan himself suspects that the advancement of biogenetic particularity was, in fact, less a scientific than a political or economic argument:

> The regulatory agencies, in terms of their strategies and the reasons why they want certain data, I mean, off the record, my understanding is that there's a little bit of protectionism where this is concerned, so to get drugs approved in particular markets, they very often want data that's generated from within that particular location. So, for China they want . . . Chinese data generated from within China, the same for Japanese as well, and for various other countries. So, it's not entirely based on scientific requirements but more political and national interests that drive some of these considerations (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

Rather than sound scientific reasoning, he speculates that it was the protection of local markets and industries which, besides the reproduction of Chinese national identity, contributed to the wilful maintenance of ethnoracial categories in biomedical research. Another respondent, Dr Irene Miller who works at Clintech's Australia office in Sydney leading a team of pharmacologists specialising in drug-related inter-ethnic differences, raises a similar concern:

> I mean, I don't know if I would have any hard evidence for this, but there is definitely a barrier to multinational companies coming in to do work in these countries, and for example in Korea, there aren't the same requirements for the local Korean companies. . . . There is a flavor of, I think of the local companies having an ability to, they are on a different level of the evidence [on local populations] that's required in every country (Dr Irene Miller, head of ethnopharmacology, multinational pharmaceutical company, Australia, August 2015).

What Miller hints at is that the Korean regulators' requirement to analyse clinical data in a Korean population was regularly waived for local pharmaceutical

companies as opposed to large multinationals. This stands in sharp relief with regulators' claims about the Korean population's biocultural specificities necessitating additional data. Both respondents claim that the declaration of national uniqueness and the necessity to conduct bridging studies works to deter or delay foreign companies' penetration of the national drug market (Kuo, 2012); the assertion of ethnic exceptionality by, here, Japanese, Chinese or Korean regulators disguises their effort to grant local businesses a strategic advantage over foreign ones.

Miller also reports of one of her applications for marketing approval in India:

> The [Indian] regulators do sometimes want to see information in their population, clinical trial participants from India so sub-analyses of multi-regional clinical trials or Indian specific bridging studies have been performed. . . . And it's our understanding, they were interested in people only from India, they weren't interested in people from the Indian subcontinent, so you know, even though we might have had more data from Pakistan or data from Sri Lanka or from Bangladesh, that wasn't of interest, even though it might be a very similar drug response, it would be a similar drug response you would expect, and could be of relevance, too (Dr Irene Miller, head of ethnopharmacology, multinational pharmaceutical company, Australia, August 2015).

Even though India usually accepts clinical data packages of studies performed in the West, the government occasionally asks for additional trials in a small section of its population. Notably, these must be performed in Indian, not in Pakistani or Bangladeshi patients; here, it is not the sophisticated technologies of genomics but much more mundane techniques such as national censuses, historical narratives, state interests or the possession of a valid passport that create specific populations as subjects of clinical research. What is registered as a legible population is therefore centrally contingent on the political and economic projects of the state advanced through biomedicine.

India's rejection of data from Pakistan or Bangladesh is indicative of the co-productionist nature of how populations are produced, enacted and mobilised though both scientific research and socio-political parameters (Jasanoff, 2004;

M'Charek, 2013; Reardon, 2005). The country's enmity with Pakistan, for example, overwrites scientific and historical evidence that the two nations may, in fact, be very similar. Rather than treating South Asia as a genetically and socio-culturally integrated space, as anthropologist Jacob Copeman (2013) proposes, Indian regulators create a specifically national biocultural identity for themselves. This sheds light on how populations in drug research are centrally enacted and accrue value through national political imaginaries, illuminating the central involvement of national governments in the mobilisation of their population in and for the global economy (Ong, 2000; Waldby, 2009).

5.4 "You can't run studies based on that": Managing human variation in global research

Researchers are very much attuned to the multiple extrinsic contributions to variable drug effects. Though occasionally using both terms interchangeably, they describe these as ethnic as opposed to racial factors when queried for more detailed definitions. From a decidedly race critical stance, Chan argues:

> From our point of view, we regard race as suggesting a much more biological kind of basis for the comparisons, or for the definitions, which I believe is not supported by scientific evidence. So, I would not use the race definition because there is no scientific basis for classifying people into races. My preference is to look at ethnicity, and ethnicity is a much more definable kind of situation to identify subjects. Because ethnicity brings in a wider range of parameters that can define a particular group. But unfortunately, it makes it less applicable in a universal context (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

In a similar register, Professor Nayak also highlights:

> Ethnicity is, according to me, very important. And often more than genetics. It's also the environmental factors that are important. Like the food they eat, the alcohol consumption, the, I don't know about smoking, alcohol yes, concomitant medications, if there's a high incident

> of using medications which they themselves change, all this! But it will be impossible to study, to get all the data! But if you ask me the question 'is ethnicity important?' my answer would be 'yes, it is' (Professor Tista Nayak, pharmacologist, ethics committee member at a public hospital, India, March 2015).

Both respondents agree that ethnicity, meaning variants such as dietary habits, pollutants or concomitant drug use, is crucial to understanding a patient's response to drugs. Sometimes, such factors may have an even greater effect than genetic mechanisms. However, interviewees also emphasise that they are difficult to assess especially under real-world conditions or less applicable, as Chan points out, in multi-regional research settings.

Other respondents confirm the problems of conducting clinical research that is sensitive to ethnic variables. Ahmed notes:

> It *should* include religion etc., and whether you have a predominantly vegetarian diet or a predominantly meat-based diet, [but] it's just going too far, too much detail, we can't go that far. You can't run studies based on that (Dr John Ahmed, senior director, clinical pharmacology, multinational pharmaceutical company, UK, August 2015).

Though he himself did not always distinguish between race and ethnicity, the NHS Chair of Pharmacogenomics, Professor Sir Munir Pirmohamed, also argues:

> We won't go into diets or dietary history or things like that, because that is very, very inaccurate to get the kind of dietary history anyway unless you use very detailed dietary questionnaires and that can take a long time. . . . So, to recruit patients and to recruit people into trials is not easy, and to some extent, one has to be pragmatic, because if you subject a person in a trial to an enormous amount of questions and very long processes including follow up, then irrespective of their ethnicity they're going to say 'no'. So, there is a balance to be struck as well (Professor Sir Munir Pirmohamed, NHS Chair of Pharmacogenomics, UK, June 2016).

These statements illustrate that within the pragmatic framework of randomised controlled trials (RCTs), especially those conducted across a variety of boundaries, ethnic or extrinsic factors are notoriously difficult to study comprehensively. They are impossible to standardise given the lack of knowledge about the precise effects of their interaction and the difficulty to disentangle them from genetic influences. Though over the course of the interview, Ahmed expressed as much concern as Chan regarding the use of *racial* categorisations, he is also acutely aware of the barriers to operationalising ethnicity in this context. The variability produced through volatile ethnic factors is antithetical to the principles of scientific research which requires analytic variables to be consistent and their categories mutually exclusive (Bowker and Star, 1999; Lee, 2009). Additionally, clinical research necessitates solutions that are "practical", as Ahmed emphasises, or "strike a balance", in Pirmohamed's words, given the contingence of the RCT on the cooperation of volunteers as well as its epistemic framework that aims to answer only narrow, mechanistic questions (Savransky and Rosengarten, 2016). It is thus only outside the controlled environment of the RCT that the "complex, noisy, empirical, socio-economic, infrastructural, legal, cultural and biological situations in which biomedical mechanisms are meant to intervene" (Savransky and Rosengarten, 2016: 168) truly come to the fore, shaping the actual effectiveness of a specific drug therapy or intervention (ibid.).

Dr Robert Temple, Deputy Center Director for Clinical Science of the Office of Drug Evaluation at the FDA and responsible for approving BiDil in 2005, echoes this sentiment when describing some of the difficulties with evaluating ethnic factors:

> Ethnicity is, I have to say, not terribly well worked out. The ethnicity we think about here most is Hispanic, but what does Hispanic mean? If you're from Brazil, it probably means you're Black. If you're from Argentina, it probably means you're Austrian. Does Hispanic include everybody from Spain? It's very hard to know and we're not very good at it. And I'm not aware of too many differences that have been found based on ethnicity, at least partly because it's a very diverse population (Dr Robert Temple, FDA, USA, September 2015).

In Temple's assessment, ethnicity lacks the robust population criteria to become a rigorous analytical concept. An assemblage of ancestral origin, cultural affiliation, phenotypic presentation and citizenship status, its categories comprise populations so heterogeneous that its explanatory function is significantly limited. Despite persistent efforts to classify clinical trial data ethnically, Temple admits that "that's not very well done systematically because we don't have a very good definition". Though his account is imbued with highly specific US-American understandings of race and ethnicity, especially the emphasis on Hispanic ethnicity that defies any unmediated exportation, he agrees with other respondents that ethnicity is not a very practical concept.

In contrast, race as aligned with biological characteristics through the theorem of geographical ancestry, in Temple's account, offers a more stringent, replicable explanation of observable differences. To stay with his interpretation for a bit:

> Race, race is more consistent: Blacks are people mostly from Africa with fairly common ancestry, or at least that was once the case, and there are a few examples of important racial differences in how drugs work, and these are very well known (Dr Robert Temple, FDA, USA, September 2015).

Despite increasing genetic admixture through intermarriage causing 'mixed-race [to be] occurring all over the place', he says, racial markers based on presumed ancestral origins are perceived as comparatively stable population characteristics whose significance has purportedly been established by more robust scientific evidence. As he goes on to explain, the most important and well-recognised difference between populations, here Europeans and African Americans, was the lack of efficacy of ACE-inhibitors and beta-blockers in African American patients given their higher frequencies of low rather than high renin hypertension. Similarly, the risk of developing an allergic reaction to ACE inhibitors called angioedema was much more common in the African American population.

Without explicit reference to race and/or Blackness, at least in this statement, Dr Mansoor Khan at Quintosh in Hyderabad, a clinical pharmacologist and expert in pharmacoethnicity, also claims:

> Genetic origin is playing a less [significant] role when compared to the extrinsic factors like food, environment, pollutants or the socioeconomic status that plays a critical role. So intrinsic factors play a less [significant] role, and the extrinsic factors play a critical role in drug response. . . . The point is, we cannot clearly distinguish the population based on extrinsic factors (Dr Mansoor Khan, clinical pharmacologist, multinational pharmaceutical company, India, March 2015).

In his perspective, too, genetic/racial factors are not only more precise and reliable indicators of differential drug response. Their presumed conclusiveness also aids the design of clinical trials that necessitate replicable, mechanistic explanations. It is not that researchers are unaware of the influence of external and disease-related factors; however, genetic formulations present a narrative that can be couched in scientific certainty and consistency whereas other dimensions of variability may not. In contrast to socio-cultural explanations, biogenetic models leave less room for ambiguity and modification, facilitating the presentation of differential response and efficacy rates within a framework of near irrefutability (Keval, 2015). Scientists also forge a correspondence of common-sense understandings of race and seemingly neutral genetic constitutions, as Fullwiley (2008) aptly stresses, by bracketing out environmental factors and privileging racialised genetic variance as the primary cause of ethnoracial disparities. This is despite the post-genomic break with the often deterministic and reductionist gene-centrism so prevalent in the genomic age (Stevens and Richardson, 2015).

Such a framework may offer what both researchers and patients aspire, namely "a claim to certainty amid evident uncertainty that may lead some people to seek out other interpretations" (Whitmarsh, 2010: 765). This is firmly in line with broader trends of geneticising disease correlations and health disparities: in drug research, the theory of genetic control, or so the assumption goes, means that the basic capacities of a patient to metabolise a drug are stable and reproducible whereas extrinsic factors such as the ones outlined above, as well as their effect, frequently change (Meyer, 1992). Though some researchers eschew racial terminology and its evocation of US-American politics altogether, most view genetic sequences as invariant markers, and the groups forged through them as reliable and clearly definable sample populations. The professed objectivity of genetics promises more

reliable data than attending to the myriad non-genetic contributions of variation which can be volatile and subjective.

However, even without explicit associations to race, genetic explanations themselves proclaim scientific certainty where there might be none. Rather than a fixed, stable entity or even a "master molecule" that holds an otherwise unknowable truth about a body, a gene is, according to Haraway, a "node of durable action where many actors, human and non-human, meet" (1997: 142). Genetic markers do not guarantee a specific clinical outcome or bodily reaction. Rather, they occupy an ambiguous and often highly uncertain status as they respond to dynamic interactions between nature, history and biography (Lock, 2013). While this is not to minimise the potential for treatment that genetic analyses facilitate, what Haraway terms "gene fetishism" (1997: 142) is mistakably reading a set of heterogeneous relationalities as objective and stable entities, denying the inseparability of nature and nurture in the production of scientific facts. Needless to say, the fallibility of this gene-centrism has come to the fore in recent biological research (Stevens and Richardson, 2015), and, as Haraway claims, "[t]he fetishist is not psychotic, he 'knows' that the surrogate is just that", but he is "uniquely invested in this power-object. The fetishist, aware that he has a substitute, still believes in-and experiences-its potency, he is captivated by the reality effect produced by the image" (1997: 144).

Privileging genetic markers to identify treatment and predict drug reaction also ignores that these can significantly change shape according their social contexts. Medicines are powerful agents whose effects unfold according to the complex constellations of cultural values and social relations in which they are consumed. Whether a drug is efficacious or harmful may appear easily measurable within a natural scientific framework, but cultural analyses reveal that efficacy itself is a highly contested and culturally constructed notion (Whyte et al., 2002). Respondents themselves have pointed to the symbolic weight of cultural beliefs about health, illness and medications that have, for instance, led to Japan's diverging interpretations of efficacy and its traditionally stronger emphasis on safety (also Nagata and Rafizadeh-Kabe, 2002). Similarly, research on the placebo effect has made abundantly clear that the attribution of meaning and belief in a medicine's efficacy may be as powerful as the chemical agent itself. For example, 30 to 80 per cent of patients with chronic stable angina have measurable and clinically

meaningful improvements when receiving placebos (Emanuel and Miller, 2001). Such evidence belies the assumption that genetic information proclaims an unmediated truth about a body's essence: biogenetic or otherwise predetermined factors driving ethnoracial variation may not be legible outside their specific socio-cultural environments and clinical contexts.

Moreover, while GWAS have published thousands of common variants whose allele frequencies statistically correlate with a specific disease or trait, the vast majority of such variants have failed to reveal clear clinical utility for predicting such traits or diseases (McClellan and King, 2010). This discrepancy reveals a tension between the calculation of a variant's *statistical* significance and its *clinical* importance: statistical models make probabilistic statements about how likely an observed difference in outcome between treatment and control groups is real rather than due to chance. Clinical significance, however, measures the effect of such differences in actual clinical practice, or whether a treatment effect has a genuine and palpable influence on daily life (Sedgwick, 2014). For a genetic trait or mutation to become relevant for drug development, it must not only be statistically significant but also clinically relevant. As drug developers are not interested in researching the nature of ethnoracial variability *per se* but seek to identify possibilities for therapeutic intervention, as I will discuss shortly, they often draw on clinical judgment as much as on statistical knowledge.

5.5 The uncertain certainty of race

The certainty proclaimed by genetic models is therefore rather a highly uncertain certainty itself. The product of multiple interactions between human and non-human actors, entrusting genetics with absolute objectivity disavows the entanglements of social, cultural and natural dynamics. Even more ambiguous, of course, is the association of race and geographical ancestry, and the experts I interviewed were themselves highly uncertain of the precise meaning of race. Not only do genetic technologies significantly blur any clear-cut boundaries between them, but a fundamental ambiguity to racial categories also remains that almost always include geographical, social and biological dimensions. Dr Mössinger, for instance, pensively states:

> There may be something like an underlying genetic issue that goes along with race, which of course may not be correct. But it's just that you may have certain aspects in your genetics that are more prevalent in that population compared to, let's say an African-American patient or Chinese or Asian patients as compared to Caucasians or Hispanics, . . . no question. It's not that it's exclusively in the one group and not in the other, but it's just a different distribution. . . . On the other hand, I guess, it goes along with social aspects as well, it goes along with certain behaviours, it goes along with certain lifestyles (Dr Rainer Mössinger, pharmaco-epidemiologist, multinational pharmaceutical company, Switzerland, December 2014).

Race, here, not only becomes a single classification scheme for genetic, social *and* behavioural traits, but even the precise associations of race and genetics remain fundamentally obscured. Mössinger stresses that race is not equivalent to a specific genetic constitution but "goes along with" or, as Friedman said earlier in the chapter, is "linked" to it. The presumptive genetic foundations of race are a rather complex and shifting amalgamation of a plethora of factors. The certainty that researchers nonetheless ascribe to it may not only stem from its professed irrefutability as genetic fact but also from its familiarity and often common-sense character.

Despite the lack of clear coordinates, the very longevity of racial classifications itself conveys steadiness and scientific certainty (Fleck, 1980). When prompted for a precise definition of race, all but few of my respondents retreated to a notion of race that conscripted phenotypic markers, historical narratives and social patterns simultaneously and used different conceptualisations interchangeably. This may seem to contradict science's need for standardisation and the disciplining of ambiguity, yet critical scholarship has found that ambiguity can have a positive function for science, too. Donald Levine (1985: 218), for instance, argues that social theorists have fundamentally underestimated that ambiguity or dissensus amongst scientists can serve as the "bonding into a vital transgenerational community of a body of diverse enquirers holding somewhat different views of what are essentially contested concepts." The ambiguity of race, in this sense, produces

transgenerational ties of understanding a scientific problem (Panofsky and Bliss, 2017)

That such an ambiguous concept continues to assert authority in drug research is, then, also because the familiarity of racial taxonomies means that racial differences are expected to occur. Bansal explains:

> As a scientist, you would go with the presumption that yes, we will probably behave differently. That's the more default assumption rather than we are all the same and respond similarly (Dr Kaushik Bansal, clinical head, multinational pharmaceutical company, Switzerland and India, August 2014).

Heterogeneity between ethnoracial populations is assumed to be the norm, or the default assumption, as he puts it, which does not require additional investigation (also Shim et al., 2014). This is often the result of much more unconscious forms of knowledge in which racial concepts lurk underneath more 'rational' explanations. In other words, race is more often a convenient 'way of thinking' (Marks, 1995) about human groups than an actual scientific concept, and such knowledge claims are often hard to refute. Speaking to this conundrum, Ahmed notes:

> The drug development machine is an enormous, ponderous battleship that's very difficult to turn around. But within that, yes, that's exactly what we're doing [revising existing classifications]. It's like the FDA, they know their categories aren't right, but it's very difficult to change in the short term (Dr John Ahmed, senior director, clinical pharmacology, multinational pharmaceutical company, UK, August 2015).

Though many researchers are fully aware of the shortcomings of their categorisations, altering the thinking that has produced them is a slow and often exceedingly bureaucratic manoeuvre that remains a much more long-term objective. Echoing Temple's defence, Ahmed stresses that scientists often understood these categorisations to be flawed but did not know "what else to do"– perhaps a central feature of post-genomic research wherein, as Hallam Stevens and Sarah S. Richardson (2015: 2) aptly note, scientists are increasingly aware that human traits and diseases depend on "a mysterious set of unknown unknowns",

Moreover, biomedical researchers do not seek to probe the nature of ethnoracial difference *per se*. In contrast to genetic studies that attempt to trace human evolution or delineate patterns of diversity, my interviewees use ethnoracial classifications merely as entry points into or tools to organise a clinical study; as such, they are used to deliver *other* clinically relevant information. Consider this quote by Khan:

> So, when I have the data from Caucasians, we would like to learn, if the plan is to go into Asian populations, if they also have the same disease progression, the same disease conditions, so you would also like to have the drug approval there (Dr Mansoor Khan, clinical pharmacologist, multinational pharmaceutical company, India, March 2015).

Racially classified data are used as a point of comparison to study disease progression or expression in another population. Khan deploys the meta-categories Caucasian and Asian descriptively and strategically to examine other kinds of etiologically significant differences.

Sociologists Janet K Shim and colleagues (2014) have come to a similar conclusion, studying geneticists conducting gene-environment interaction research. They describe how the geneticists they observed used racial classifications "to *see and think through*, *with*, *and about* various *other* kinds of homogeneity and heterogeneity, such as the prevalence of genetic variants, disease subtypes, clinical sites, health-related behaviors, and environmental condition" (Shim et al., 2014: 9). As the ultimate goal is to identify more precise and actually scientific characteristics, especially those that lend themselves to the identification of intervention in the form of pharmaceutical therapy, population classifications are no endpoints in themselves but are put in the service of biomedical discovery (Shim et al., 2014; also Abu El-Haj, 2007: Rose, 2001). Unlike population geneticists, drug developers are less interested in human evolution than in the question of intervention. Racial group membership, as Rose suggests, is often only "the first step towards identifying and treating susceptible individuals" (2001: 11).

As such, a precise understanding of race may not be necessary to the primary aim of identifying appropriate drug targets and developing treatment. In other words, that race proclaims only a relative, and often a highly ambiguous and uncertain certainty may not preclude researchers from deploying it. As Temple and his colleague

Norman L. Stockbridge (2007: 57) argue in a publication defending their approval of BiDil, any attempt to avoid the use of racial categories "would have required years of work, many thousands of patients, and wholly unreasonable delay in approval of a treatment whose effectiveness had been well-documented. . . . Understanding pathophysiology is good, of course, but it ranks well behind a documented survival effect in importance". Aware of the potentially pernicious social implications of using race-based classifications, they make clear that biomedicine's effect of prolonging life expectancy ranks significantly higher than pinning down what precisely drives variation, furnishing the defence of racial medicine with explicit claims to moral superiority.

5.6 "Like canaries in a coalmine": Coping with uncertainty

The fact that racial classifications are descriptive and uncertain categories secondary to understanding more pressing relations between human diversity and health does not make them immune to exerting social or political effects. While I agree with Montoya (2011; also Banton, 2015) that the distinction between the descriptive and attributive usage of racial categories is an important one, in practice, this distinction is often hard to maintain. Even when used descriptively, ethnoracial classifications delineate the formulation of research questions, recruitment methodologies, the selection of control groups and the interpretation of obtained results. Also, biological claims about differences between human groups are likely to influence the ways in which these groups are understood in their broader social contexts. With research on genetic correlations of disease and treatment surmounting attention to their social dimensions despite persuasive evidence that socio-economic determinants are at least as relevant to health disparities as genetics (Caulfield et al., 2009), the danger is that specific ethnoracial populations will increasingly be treated as biological groups.

Evidence of this can already be seen: even where race had been explicitly defined as a social construct, it is progressively giving way to more natural scientific analyses and biological understandings. Assessing the nature and extent of ethnoracially sensitive drugs, a recent publication by FDA scientists and regulatory experts, for instance, defines race as a "group of people who share common *biological* characteristics that distinguish them from other groups". Ethnicity, in contrast,

referred to "a *social* group with a shared history, lineage, heritage, sense of identity, cultural roots and territorial identity" (Ramamoorthy et al., 2015: 263, emphasis added). The paper was published exactly ten years after the launch of the original policy statement which asserted that "race and ethnicity categories [are] not anthropologic or scientifically based designations, but instead categories that describe the socio-cultural construct of our society" (FDA, 2005: 3). This not only charges societal groupings defined by shared experiences and cultural affiliations with inflated biological significance but may also reformulate the relationship between the social and the biological more broadly.

Indeed, accommodating for the social dimensions of race does not stand in the way of re-inscribing them with genetic meaning. Dr Jonca Bull, Director of the FDA's Office of Minority Health (OMH) and a longstanding proponent of racial equality in health, argues:

> The OMB directive specifically states that race is a sociologic construct . . . and I would say what we're really looking at is what are the clinical correlates of that identification? But I think fundamentally we don't see race, by definition, as biologic but it's having correlation with certain biologic characteristics. But certainly not 100 per cent. In terms of race and biology, I think that the government framework is pretty clear that it's not purely biological, but it does have biological correlates (Dr Bull, FDA, USA, September 2015).

For her, race may be a social category yet one that aligns well with relevant biological markers. While they are not identical, their correlation cannot be ignored. Here, the importance attributed to socio-political determinants of race serves to reinforce the claim for a biological basis of racial groups and their implications for health. The statement reflects that a nod to the social dimensions of race does not inevitably compromise the scientific validity of claims to its biological correlates. Most respondents comfortably shuttle between more social and more biological explanations of race without either losing focus on the biogenetic explanation for such groups or forfeiting the scientific credibility of their claims (also Bliss, 2012).

As Bull explicates, what she terms biological correlates are like "canaries in a coal mine: they signal to us that you have to look". This metaphor is interesting for several reasons. Not only does Bull implicitly liken the clinical correlates of racial identification to biology and nature, but she also describes them as acting quasi-independently of their social environments. Canaries' sensitivity to carbon monoxide or other toxic gases is an inherited, intrinsic quality that, applied to racial differentiations in drug sensitivity, belies talk of social constructionism and exposes the latter's irresponsible minimisation of potentially harmful differences. Bull's metaphor does not merely describe racial difference through literary means. Metaphors and analogies are powerful tools through which scientific knowledge is produced (Stepan, 1986). Drawing on philosopher Max Black's interaction view of metaphor, Stepan argues that metaphors actively join two subjects not normally joined, a process through which the meaning of both parts is changed, and each part becomes associated with the other. Metaphors and analogies are not to be taken literally but constitute rhetoric tools to assist understanding rather than representing claims which can be tested for truth or falsity (Black, 1962: 37). Bull's analogy between ornithological instincts and differential drug response therefore brings biological qualities and racial affiliation into close cognitive relation. What is central here is not conceptual congruence but the establishment of a structural resemblance between the two. Shared responsiveness to chemical stimuli links canaries and African Americans' genetic constitutions to reinforce Bull's demand for taking seriously the harmful effects of racial difference in drug metabolism.

Such analogies and claims about the correlation between social and biological categories illustrate what feminist scholars have identified as the function of natural corollaries as models for the social (Douglas, 1986; Haraway, 1997; Strathern, 1992). Mary Douglas, for instance, observes how nature functions as a rhetorical resource for social classification: for social structures and organisations to be legible and *legitimate*, there needs to be an analogy in the physical world, or "in the supernatural world, or in eternity, or anywhere, so long as it is not seen as a socially contrived arrangement" (Douglas, 1986: 48). When researchers equilibrate social organisation and natural phenomenon, as Bull does for Blackness and angioedema risk, the analogy is "endowed with a self-validating truth" (ibid). Rooting racial categories in nature therefore attributes them an enduring materiality and durability.

In other words, analogies, metaphors and historical narratives are conscripted into biomedical explanations and subsequently presented as facts. Such 'non-scientific' sources of scientific explanation often account for the lack of evidence over the actually important mechanisms of human variation (Lipphardt, 2008). The construction of what Lipphardt terms "biohistorical meta narratives" (2008: 37) about specific populations offers, in the eyes of their defenders, a rational, stable explanation where there might be none in purely biological terms. Bull's metaphor can be read as one such attempt to make sense of an otherwise obscured mechanism: while the precise relation between race and, here, angioedema remains unclear, the analogy to nature strengthens her hypothesis that there is *some* relation. Suggesting comparable natural laws and mechanisms for birds and humans compensates the lack of other, perhaps more decisive knowledge.

Rather than a remnant of nineteenth century race science, Bull's desire to take seriously African Americans' heightened risk of developing adverse reactions stems from her deep commitment to social justice and racial health equity. Akin to Temple's justification for approving BiDil, here, too, moral claims for the need to take race into consideration work to effectively disarm race critical or even eliminativist perspectives. Bull frequently referenced the responsibility of science to take inequalities seriously, drawing on her own experience as an African American woman and thus her higher propensity for specific diseases. Troubling is nonetheless how racial groups are increasingly charged with biological meaning, pointing to a larger development that proclaims the epistemological primacy of biological over social explanations of ethnoracial health disparities and differential drug effects. This may well lead to a potential destabilisation of the nature-nurture equilibrium in explaining such disparities in favour of natural criteria and scientific methods which may have significant consequences for how the social world is perceived and acted upon.

The geneticisation of ethnoracial variation is buttressed by scientists' firm belief, implicit or explicit, in the epistemic authority of natural science to arbitrate upon the existence of race. Bansal notes:

> Basically, at this point in time we don't have the basis to differentiate, but we'll continue to study that, we haven't really exhausted our inquiry towards, we don't, I mean, genetics is not so far advanced. . . . So, this

> question is still open—and I won't close it [smirks] (Dr Kaushik Bansal, clinical head, multinational pharmaceutical company, Switzerland and India, August 2014).

Respondents emphasise that whether racial groupings are biologically meaningful is exclusively upon genetics to adjudicate, positing race as an explicitly natural scientific phenomenon. As the statement illustrates, scientists are conscious of the imperfections of contemporary scientific methods but the implication remains that, as renowned geneticist Frank B. Livingstone puts it, "if we keep collecting data, we will someday discover how many races there are" (Livingstone, 1963: 200)—or, perhaps, that racial ideas are non-sensical altogether. A common assumption amongst the drug developers I spoke with was that bioscientific theories were in constant progress and may, in the near future, be better equipped at delivering satisfactory evidence about which population differences are scientifically meaningful. Also, despite respondents' uncertainty over what race is, they implicitly assumed that it was the inaptness of racial categorisations rather than their actuality that needed to be established. Often, research challenging the facticity of race is charged with *dis*proving the category; as St Louis equally finds, such "naïve deductivism reveals its insecurity by trying to place a burden of disproof on racial eliminativism" (2015: 126).

In their adherence to a natural scientific framework of analysis, my respondents were certainly self-conscious and reflective rather than unaware or even dismissive of societal concerns. Contemporary scientific practice is often bolstered by subjective values and political commitments rather than an instantiation of Weberian scientific objectivity (Lipphardt, 2008; Bliss, 2012). Many respondents deploy their own experiences and beliefs in social justice to advance arguments for (or sometimes against) racial claims in science. Bull's self-identification as African American serves to buttress her demand for alertness to ethnoracial variation; often, it is not scientific accuracy but the moral urgency to intervene into health inequalities that determines the use of racial categories. Exemplifying forms of 'scientific biosociality' in which researchers think through race with themselves and their loved ones in mind (Bliss, 2012; Rabinow, 2005), Bull brings her personal experience of racial discrimination to bear upon her science.

The socio-politically charged investment in racial analyses, however, does not mean that researchers retreat to a social constructionist notion of race or seek to address racial quandaries through other means than those established within the parameters of natural science as the *most legitimate* form of science (Bourdieu, 1975). The epistemological framework within which the majority of my interlocutors embed questions of race remains that of empirical science. Though I do not, as argued, wish to advocate for a dogmatic social constructionism that evades corporeality, such scientism may increasingly displace more sociological understandings as science is held up as the arbiter of racial truth (Bliss, 2012). While researchers are reflective about their own imperfections in applying or interpreting science in relation to race, they do not challenge the epistemic authority of science in answering such enquiries. Indeed, in my experience, social and cultural forms of enquiry are sometimes portrayed as naïve or even obstructive (also Wald, 2006), potentially marginalising sociological scholarship on the nature of ethnoracial variability as the product of dynamic interactions between social organisation, bodily constitutions, health and disease. The task therefore remains, as Duster (2004) urges us, to develop models of disease progression and variability in drug action that move beyond binary constructions of nature versus nurture without falling prey to either the mantra of social constructionism or the allure of racial biology.

5.7 Conclusion

This chapter has described the scientific objectives and practical challenges that drug developers, as opposed to geneticists or other lab scientists, encounter when dealing with ethnoracial variation, alongside the political parameters that inflect which populations are chosen for research and how these are understood. It has argued that even though researchers are astutely aware of the fallacies and uncertainties of racial categorisations, these are taken to proclaim a certainty that other markers, especially ethnic, may not. That this certainty is ambiguous and highly uncertain may not be of great concern as racial categories only serve as analytical tools to probe other clinically relevant differences.

Nonetheless, seemingly neutral descriptions of correlations between race and drug action may have significant implications for how we understand both health and

illness as well as the nature of social groups. The authority with which science is endowed to frame debates on race and health can function as an argumentative closure (St Louis, 2003). It restricts the ethical debate of racial dilemmas by keeping open, despite obvious limits to past and present practices, the possibility of a future, purely scientific concept of race without engaging the ethical responsibilities such an endeavour entails. As such, the social authority of science prevails and respondents' reflectivity about the current fallacies of a racialised genetic determinism does not eradicate the ethically dangerous prospect of, one day, arriving at a scientifically robust understanding of race.

Chapter 6: The "heterogeneous Caucasian": Locating India in global clinical trials

The previous chapter has discussed how biomedical researchers define and evaluate the significance of race and ethnicity in assessing variable drug action. It has shown that race, as opposed to ethnicity, offers a narrative that can erroneously be framed as more coherent and consistent through its conflation with genetic constitutions and common-sense understandings of human diversity. As has been argued by scholarship in the field, race is thus genetically reified or reinscribed.

This chapter departs from the existing literature by challenging the well-rehearsed argument that pharmaceutical companies aim to exploit population differences for the creation of racialised niche markets. Through empirical data, it illustrates, first, the current limitations of pharmacogenetically segmented drug markets and the reluctance by multinational companies to invest additional resources in researching potential subgroup distinctions. Their preservation of population-level thinking becomes particularly pertinent in the context of transnational research which presumes that the human body is essentially the same across the globe (Lock and Nguyen, 2010). As I aim to show, second, global clinical trials rely on the identification of adequately commensurate study populations that ensure the general applicability and external validity of research results. As such, I argue that the industry seeks to locate genetic similarities, rather than differences, in their search for clinical trial sites and potential future markets. Here, ethnoracial variability is not an opportunity for marketing but rather a barrier to the globalisation of clinical trials.

Against this backdrop, the reproduction of Indians as Caucasians not only renders them biologically equivalent to the majority of the drugs' future consumers but also recuperates the Euro-American patient as the 'standard human'. Testing drugs in India promises faster timelines, reduced costs and fewer complications due to an extended understanding of Caucasian kinship. However, the flexibility of ethnoracial categorisations and Indians' ambiguous status in existing schemes of classification is also vital as multinational companies carefully calibrate the taxonomic system of the FDA, international regulations, and the ambitions and policies of the Indian government as well as local biomedical elites.

As such, the chapter discusses the mobilisation of ethnoracial categories in global research between the rhetoric of difference and sameness. As sociologist Chetan Bhatt argues, "[i]n the analytic of race, neither difference nor sameness can be sequestered, since both manifest, convey and inhabit each other" (2004: 31). Both poles are engrained in the symbolic of ethnoracial identification in what St Louis describes as an "insoluble bond between racial sameness and difference" (2005: 360). I take St Louis' discussion of 'the difference sameness makes' as an analytical lens to argue that the enactment of similarity, that is, of Indians as somewhat darker-skinned, *not quite* Caucasians, makes (a) difference in three main ways. First, it affirms the division of the human gene pool into three main groups and recuperates differences between them. Second, it facilitates clinical trial offshoring that assumes biological equivalence. And third, it inflects, and is inflected by, Indian scientific and popular discourses that have, since the colonial era, sought to foreground the country's Aryan heritage. In all three domains, the figure of the Indian as a genomic relative of the Caucasian, the *heterogeneous* Caucasian, recuperates the familiar narrative of Indians as almost white, but not quite.

I begin by challenging the commonplace assumption in existing sociological research on the topic that race is a welcome avenue for drug companies to create niche consumer markets. Using my interview data, I show that large pharmaceutical companies are unlikely to examine potential subgroup differences and even actively avoid doing so unless pressured by regulatory agencies (section 6.1). Having established their interest in biological similarity rather than difference, bolstered by the epistemological assumptions and methodological framework of the RCT, section 6.2 turns to my respondents' arguments for classifying Indians as Caucasians according to racial criteria. I suggest that this makes India an exceptionally attractive location for clinical research by examining both global firms' and local researchers' assumptions behind claims of belonging to the fictitious Caucasian race (sections 6.3 and 6.4). Last, I move to discuss India's special status as *not quite* white or Caucasian, resurrecting the historical figure of the Black Aryan and offering contemporary biomedicine new opportunities for clinical experimentation.

6.1 "The pharmaceutical industry doesn't want to study this": Contesting racialised niche markets

In the wake of the FDA's approval of BiDil, as Chapter 2 has discussed, sociological research in the field has warned of the new commercial interest in race and ethnicity and postulated a new value located in racialised tissue. However, considering the contemporary ethical, economic and regulatory impediments to pharmacogenetically and/or ethnoracially segmented drug markets, population differences appear at odds with an industry that seeks to retain the broad applicability and profitability of its products. Queried about the industry's interest in population stratification, Dr Bansal asserts:

> Nowadays people have a population-wide view. It's not an individualistic view or an individualised medicine view at the moment, and so you don't see, you don't care about these differences because they don't affect the population (Dr Kaushik Bansal, clinical head, multinational pharmaceutical company, Switzerland and India, August 2014).

The statement illustrates that drug companies maintain an interest in manufacturing drugs that work in the entire population and are often oblivious to expected or observed differences in the drug testing process. As Bansal tentatively suggests, not only are variations not noticed, they are perhaps not 'cared about' either, seldom arousing scientific or economic interest. He continues, illustrating the motives for this disinterest and the methods to justify it:

> The pharmaceutical industry does not want to study this too closely, because it will reduce the patient population they can sell their drug to. So, what they do is they try to involve everybody, and by increasing the kind of sample size, they can take care of those kinds of variations of the population (Dr Kaushik Bansal, clinical head, multinational pharmaceutical company, Switzerland and India, August 2014).

Financial incentives for developing a drug with broad efficacy and the large sample sizes now required for clinical trials flatten out existing differences and render them statistically insignificant by establishing a quantitative average of the study population. Moreover, the process of randomisation, the random allocation of participants to either the drug under investigation or the standard or placebo

treatment, ensures that biological variation is equally distributed throughout the study so that any observed differences can be attributed to chance (Lock and Nguyen, 2010; Savransky and Rosengarten, 2016). As differences between individuals are considered confounding agents or noise by clinical research experts that may skew results, the very methods of the RCT allow researchers to 'engineer out' such variations (Petryna, 2008). In other words, not despite but precisely because of the adherence to randomisation, clinical studies may be designed in a way that adverse events or unwanted results can be camouflaged or rendered invisible.

However, sample sizes are evidently related to the very definitions of significance and evidence the RCT promotes. Without disqualifying RCT-based evidence, Professor Chan highlights:

> No, we definitely *do* see differences in Chinese subjects or in Asian subjects. It's a matter of what kind of differences you are anticipating to see. If the threshold is to say 'well all I want to do is to look at major, huge differences' then sometimes it's difficult to pick up some of these, to find huge differences between populations. . . . The kind of differences that we are anticipating or that mostly occur are differences which can be relatively small, but that does not mean that the clinical outcomes are necessarily small (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

As he reiterates, the sizes and scales of contemporary RCTs facilitate the disavowal of variations in the way patients react to drugs. However, this does not mean that smaller differences which are difficult to detect but nonetheless exist have no impact on patients' health. Rather, their 'disappearance' is due to the particular kind of evidence that contemporary biomedical research is based on. As Brendon Clarke and colleagues (2013) stress, not only are there problems with the external validity of RCTs, assumed to be established by their internal validity, but the inference from the sample population to the individual patient is also questionable. There is no guarantee, they aptly write, that the individual patient will be similar (enough) to the average study participant and will therefore respond to the treatment in the same way (Clarke et al., 2013: 747).

Especially the frequent discrepancy between statistical and clinical significance, Chan stresses, may cause confusion as to which variations are meaningful for clinical practice. As Ahmed also finds:

> So much of it is actually judgment. Judgment rather than, you know, backed. And so often, when you look at academic papers, there will be statistically significant differences in xyz group, or not, but nobody actually bothers to ask what the actual clinical significance of that statistical finding is (Dr John Ahmed, senior director, clinical pharmacology, multinational pharmaceutical company, UK, August 2015).

Statistical findings about enzymatic activity cannot offer conclusive answers as to whether detected variance, or the absence thereof, may have clinical importance, too. Decision-making in medicine is, in contrast to genetics or genomics, equally based on clinical judgment that critically weighs different treatment options, potential side effects and costs, and patients' preferences for a particular therapy (Kienle and Kiene, 2011). Clinical significance, as medical statistician Philip Sedgwick (2014: 2131) writes, cannot automatically be inferred from statistical significance and *vice versa*. As such, statistically insignificant variations in drug response are often interpreted as producing similarly insignificant and uniform clinical outcomes, but this is not necessarily the case. Nonetheless, according to the logics of the RCT, such outcomes may lead the pharmaceutical industry to argue that there is no discernible variation at all as it strives to maintain an appearance of generalised similarity between populations. In other words, the issue here is not the exploitation of population differences, as in the case of BiDil, but their strategic minimisation.

The reluctance to study population differences is not the result of ignorance or bad faith but also emerges from structural constraints within the drug development business. As argued, researchers very much care about the health of their patients, often with highly personal motives. Moreover, while prevailing differences do not conform to ethnoracial categorisations, they can nonetheless have substantial effects. However, the cost of researching such differences often supersedes its benefits, and the heavy price tag attached to conducting additional trials examining

the precise determinants of variation can be a significant deterrent. Chan tellingly notes:

> Of course, the drug companies would object to what I'm saying [laughs] but we can understand it from the point of view of the economics of this entire process. Doing a lot of these extra studies does increase the cost in terms of getting regulatory approval. And obviously, if a one-dose-fits all kind of strategy can be applied that just streamlines drug development efforts, that makes it less costly than to do all these extra considerations (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

Even though the industry has recognised that a one-size-fits-all model is no longer tenable, it is palpably disinterested in performing additional studies to investigate variations given the economic disincentives to do so (Hedgecoe and Martin, 2003; Rothstein, 2003; Smart and Martin, 2006; Tutton, 2012, 2014). Though the literature on BiDil postulates a general interest in mobilising population differences for commercial gains, the picture is more complex. For example, large multinational companies that continue to rely on the general applicability of study results, especially as drug research and marketing are being globalised, seldom concern themselves with ethnoracial variation that can be explained away through hegemonic research epistemologies. Dr Jean de Boer, a South African cardiologist now working for Quintosh in Switzerland, also notes that such companies usually "prefer to ignore it [variation] unless there is a compelling reason to look at it".

While pharmaceutical executives are unlikely to admit this disinterest, Chan suggests, regulatory agencies are often the main institutions positioned to impose the examination of variation and the diversity of sample populations. From the perspective of a regulator, Dr Bull of the FDA's OMH describes her exertion in trying to justify existing requirements on inclusion in the face of the industry's reluctance to investigate population differences:

> We definitely have a conversation with the industry, and we're trying to actually help our review staff to develop their, it's almost, it reminds me a bit of when your children are young and you're trying to help them develop a language toolkit that they can use when someone bullies

> them or something, or issues come up for their own personal advocacy (Dr Bull, FDA, USA, September 2015).

As Bull emphasises by evoking the need for specific skills to defend regulations on inclusion and diversification against the 'bullying' by the pharmaceutical industry, the aims and objectives of health authorities can significantly differ from those of the industry. Suggesting even a certain aggression on the industry's side, Bull is committed to training and supporting her staff who may have to reject marketing applications if they fail to adhere to the agency's regulations on inclusion. Indeed, some clinical researchers I met sought to minimise the significance of specific regulations by ridiculing them. When I queried Dr Nath in New Delhi, for instance, about various guidelines, he smirked that Japanese regulators "believe even their rats are different". Vitiating, at least in this regard, concerns of regulatory capture and commercial bias often voiced by critics (Abraham, 2008; Williams-Jones and Corrigan, 2003), these examples illustrate the tensions between regulators and the industry, and the genuine commitment by some regulatory staff like Bull to the integration and representation of specific populations in clinical research.

To justify their own position, industry executives often distinguish the epistemological basis of their claims from those held by regulators. Dr Connors at Quintosh, for instance, argues that

> I think we try to do science, if we're not forced to do something that is based on political regulations, or, let's say, local regulations, that we have to abide to. Because this might not always be scientific, right [laughs]? We follow our development plan that is based on science. And then we adjust based on regulation. And then we can always discuss with health authorities (Dr Sylvie Connors, regulatory expert, multinational pharmaceutical company, Switzerland, July 2015).

For Connors, rather than emanating from strictly scientific rationales, regulations on inclusion originate in the political imperatives of ensuring representation and broadening access to new medicines. Her claim that regulations are not always scientific thereby serves to delegitimise approaches to inclusion that are driven by other, purportedly non-scientific concerns. She thus performs what Thomas F Gieryn (1983) calls "boundary work" to sustain her opposition: as Gieryn observes,

the construction of a boundary between science and various forms of 'non-science' aids the protection of scientific research from political interference. Boundary work, he argues, "describes an ideological style found in scientists' attempts to create a public image for science by contrasting it favourably to non-scientific intellectual or technical activities" (Gieryn, 1983: 781). More than the elimination of bad or pseudo-scientific claims, political interests are posited as antithetical to the rationale of scientific research.

However, the industry's objection to regulations on inclusion and diversification on purely scientific grounds does not stand up to scrutiny. When the FDA first introduced ethnoracial reporting in the late 1990s, professional organisations such as the American Medical Association and the National Medical Association strongly supported the call. Motivated by the concern over health disparities, they hoped that such reporting would enable analyses of potentially harmful differences in the safety and efficacy of pharmaceuticals (Lee and Skrentny, 2010: 637). In contrast, the pharmaceutical industry vehemently opposed the regulations, allegedly due to their unscientific character. However, more likely reasons were, as Catherine Lee and John D Skrentny suspect, that regulations forced the industry to spend valuable time looking into population differences, select research subjects according to government criteria and expend effort on paperwork rather than other, more profitable endeavours (ibid: 619). This was well in line with an array of other businesses' objections to similar regulations. What distinguished the industry from other sectors though was its hybrid nature as both a scientific and a commercial enterprise that allowed for it to couch the economically-driven rejection of race regulations in scientific arguments. These disguised the apparent conflict between legal regulations on race and the business logics of efficiency and profit. To wit, its identity in science gave the industry a progressive discourse to resist regulations without disclosing its unabashed profit motives.

The disinterest in studying population differences is amplified in the increasingly global context of drug development. Respondents confirmed that later phase trials would not qualify for global testing in case variations are expected or have already been detected. The chances of obtaining marketing approval in multiple countries simultaneously would also be hampered. This unquestionably adds the cost of performing an entire study in the United States or Europe to the financial burden of

conducting additional studies. When asked whether differences were something her company preferred *not* to see, Dr Connors affirms:

> Exactly, because then we have a problem and we cannot submit it [marketing application] there, that's why we hope that we don't see anything. And in the majority of cases, we don't (Dr Sylvie Connors, regulatory expert, multinational pharmaceutical company, Switzerland, July 2015).

Similarly, Dr Friedman argues:

> If then we've done it in the India population and it seems they're remarkably different from what we would expect, that would obviously be a problem, we would have to re-conduct the study somewhere else, because it would have shown that there is some sort of impact or genetic disorder . . . but generally it was absolutely comparable. . . . If it hadn't been we would of course had to then re-do the study somewhere else (Dr Alice Friedman, global head of clinical sciences, multinational pharmaceutical company, Switzerland and India, August 2014).

Both interviewees underscore that inconsistent data bar pharmaceutical companies from performing trials globally and submitting licensing applications for potentially profitable markets. As this significantly limits their consumer pool, such inconsistencies are highly undesirable. This does not mean that population differences are denied, but rather than the location of variability it is ethnoracial similarities that typically drive the identification of trial sites and populations.

6.2 "In terms of the race-concept, you could very well include them": Resurrecting the Black Aryan

One of the questions I always asked my research participants addresses the categorisation of Indian patients as Asian in FDA classifications. The majority of them suggested that these classifications were crude misrepresentations of actually existing biogenetic variations, and too extensive to actually delineate research

questions. They also found them difficult to apply outside the United States given their rootedness in the country's socio-political realities. Dr Miller notes:

> We consider the term Asian, you know, that can go from the Mediterranean over to the Pacific, you know, with complete diversity within that, and it makes no sense from the genetic point of view or extrinsic factors which might influence drug response. . . . We can't use the term Asian, we must be using more specific terms (Dr Irene Miller, head of ethnopharmacology, multinational pharmaceutical company, Australia, August 2015).

And Nayak adds:

> It's a geographic continent, it's not a racial continent, it's not a sociological continent, so, you can't dump all Asians together. Lump all Asians together (Professor Tista Nayak, pharmacologist, ethics committee member at a public hospital, India, March 2015).

Even if defined geographically, Asia comprises such a broad region that it says little about either intrinsic or extrinsic determinants of drug action. As Nayak notes, the factors that do make a difference pharmacologically, which she terms 'racial' (intrinsic) or 'sociological' (cultural or extrinsic), are not aptly captured by delineating populations as Asian.

In particular, respondents stress that Indians are erroneously classified as Asians. Nayak goes on:

> South East Asians are quite different from South Asians. So, we would be very similar to Pakistan, to Bangladesh, to Sri Lanka, but we will not be same as the Japanese. We don't even look similar! . . . So, putting Asians together is a mistake (Professor Tista Nayak, pharmacologist, ethics committee member at a public hospital, India, March 2015).

As per their genetics as well as their phenotype, South Asian populations differed from other Asians such that labelling them identically risked confounding clinical results. In contrast, many respondents preferred classifying Indians as Caucasians

as garnered from interview data. However, they also hint at existing ambiguities and divisions within that category. Chan, for instance, remarks:

> If you look at the Indian subcontinent, theoretically the subjects are Caucasian. But they would not be recognised as white, Anglo-Saxon type Caucasians. Do you know what I mean? (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

And Dr Täubel observes:

> We would normally view Indian people as Caucasians, because, leaving aside the different colour of their skin, they look quite similar to us. So, in terms of the race-concept, you could very well include them in a Caucasian trial. The Japanese, however, would not accept Indians as being Caucasians; they want *white* Caucasians (Dr Jörg Täubel, CEO of CRO Richmond Pharmacology, UK, July 2015).

Both statements demonstrate that instead of the socio-political or geographical category Asian to describe the Indian population, respondents appear to find more value in the classification Caucasian due to its presumed genetic foundations. Their assessments, for me, exemplify two main points.

First, they illustrate the unquestioned authority and presumptive facticity of Caucasian as a scientific concept. Largely eclipsed during the peak of European racial science, the concept was revived after World War II. However, this was not due to its progressive character or historical impartiality. Rather, as political theorist Bruce Baum proclaims, its recuperation was testimony of "the subtle and not so subtle ways that social and political forces have shaped the scientific knowledge of race" (2006: 7–8). Resulting from the horrors inflicted by Nazi rule and the processes of decolonisation that made a focus on inner-European similarities as opposed to differences more important, the concept rose to new prominence as it appeared to offer a less politically tarnished and unifying frame to describe peoples of European ancestry.

As such, Caucasian also acquired an irrefutable scientific status as a biological as opposed to Aryan as a linguistic concept, offering central clues for its endurance in biomedical parlance. Its value and objectivity are presumed even by the most

prominent geneticists and self-declared anti-racists in the field. Renowned population geneticist Luigi Luca Cavalli-Sforza, for instance, argues that "North Africa is populated with Caucasoid people like Europeans, but we have made sure to eliminate these populations and are restricting ourselves to Sub-Saharan Africa" (2000: 52). Even though Cavalli-Sforza has elsewhere gone to great lengths to publicly dismantle the largely phenotypical meaning of the terms and their legitimating function for social distinctions, here, he casually re-introduces the idea of a Caucasoid people spanning from Europe to North Africa and West Asia as if an impartial and objective scientific concept. This people, most notably, is not defined geographically or along continental lines but racially, or as one of humanity's three major aboriginal groups.

While precise definitions of the term Caucasian are nowhere to be found (also Sun, 2017; Tutton, 2007) the crucial point to pick out is that the term has become an accepted genetic category as a seemingly neutral descriptor of existing divisions of humankind. Despite disagreement over its precise substance or actual utility for assessing drug metabolism, the existence of the Caucasian race itself is not being put into question (also Reardon, 2005). While most researchers vehemently argue against a genetic basis for *racism*, they do not always suggest that *race* had no grounding in genetics. Most of my interlocutors agreed that race may not be granular enough for their own work but its biogenetic reality itself remains largely uncontested. This unhinges the category from its very conditions of possibility, problematically corroborating the idea that racialism does not prefigure racism or *vice versa*. Whether its intellectual precondition or engendered by it (Appiah, 1990; Paul, 2013), racialism is deeply interconnected with racism, making it questionable if it can be purged of its ethical and historical associations. While Michael Banton (2015) stresses the horizontal dimensions of racial ideas in contemporary science, these nonetheless connote a biological (and/or cultural) distinctiveness that may well, as I have argued in the previous chapter, allow for future recuperations of the familiar vertical axes signifying supremacy and inferiority.

The designation of Indians as non-white Caucasians, and therefore the implicit or explicit adherence to an interpretation of human variation as divisible into three main populations, also means that, in population and medical genetics, biological differences between racial groups are reinforced while intra-group distinctions are flattened out. The affirmation of racial similarity between Indians and Euro-

Americans is predicated on relational differences to other putative groups; sameness literally makes difference, as St Louis argues, through "the representation of difference as an antithesis that affirms the racialized self characterized by sameness" (2005: 343). The reiteration of Indians and Euro-Americans as racial kinfolk stands in a dialectical relationship to the reinforcement of inter-racial differences, and the distinctions drawn between Indians and other geographically Asian populations reinforces the idea of an ancestrally unified, although fluid and permeable, population that stretches from Portugal in the West to (some unknown cut-off line in) India in the East. Racial sameness itself may remain, as per St Louis' argument, an irredeemable project, but Indians are considered at least *similar enough* to Caucasians for recruitment and data sharing purposes in multi-regional clinical research (St Louis, 2005: 345; also Shim et al. 2014).

But, second, the statements describing Indians as Caucasians but not 'white' or 'Anglo-Saxon type Caucasians' also resurrect the historical figure of the Back Aryan I have described in Chapter 4. While ideas of racial degeneration have become less tenable, the perception that Indians only marginally missed their full inclusion into the Caucasian family remains a central trope in scientific discourse. Racially, or as per their genetic make-up, as Täubel argues, Indians are similar to Caucasians and separated from full membership only due to minor and mostly inconsequential traits such as skin colour. This exemplifies how racial markers have shifted from phenotypical to molecular traits, and how the increasing focus on the hereditary causes of drug response foregrounds the genetic qualities of the presumably homogeneous Indian population. Moreover, and equally in line with historical representations, Indians are only *almost* Caucasian: in post-genomic research, their complete whiteness or Caucasianness is similarly deferred or denied through the lens of racial/genetic purity.

The endorsement of Indians as non-white Caucasians suggests that the plethora of population taxonomies used in bioscience are not always mere linguistic or conceptual slippages, as Bliss (2012) writes. Rather, I suggest that the qualifiers 'white' and 'non-white' serve to identify 'proper' belonging to a racial/genetic population, here Caucasians. Though often declared inconsequential for the mechanisms of drug action, the symbolic power of skin colour to demarcate inter- or intra-group distinctions may not, after all, have vanished altogether. As ancestral origins, race and colour are rendered metonymic, Indians are, once again, produced

as partial, incomplete or *not quite* Caucasians, not the same but similar enough. Positing Indians as non-white Caucasians therefore delineates a numerically small but nonetheless significant distinction between Indian and Euro-American populations. My aim in this chapter is to illustrate that Indians' resemblance to, but not congruence with, Caucasians is imperative on scientific, economic and political grounds.

6.3 The value of similarity

Ideas about genetic populations not only recuperate differences between human groups but also drive sampling considerations and foster the global distribution of clinical trials by proposing a biogenetic link between specific study populations. The following is a statement by Dr Friedman:

> Because of cost factors the idea was that they would be run, instead, in India, because, I think it was five times cheaper than, say, in the US. And on the basis that it was considered that the India population is classed as Caucasian in that sense, from an ethnic point of view, and it has been accepted by the FDA in that respect (Dr Alice Friedman, global head of clinical sciences, multinational pharmaceutical company, Switzerland and India, August 2014).

I posed the same question about the advantages of running studies in India to Dr Kiran Marthak, medical director of CRO Lambda, when I met him in Mumbai. He responded thus:

> Yes, Indians are more Caucasian compared to other Asian countries. There are publications on it also. So, genetics wise, there is no problem (Dr Kiran Marthak, CEO of CRO Lambda, India, March 2015).

The interview excerpts illustrate that the narrative of the Indian as (not quite white) Caucasian facilitate clinical trial offshoring to the country, allowing companies to run studies in India at, in Friedman's assessment, a fifth of the usual cost. While cost-saving surely remains one of the primary lenses through which pharmaceutical companies select their study sites, specific population taxonomies serve as additional qualifiers for India's attractiveness.

Of course, this does not only apply to the large, multinational pharmaceutical companies headquartered in the United States or Europe, and the same holds true without explicit racial ascriptions. Below is another extract from my interview with Marthak:

> KM: We also do some work for Chinese companies and Japanese companies, they want to do bioequivalence studies in India, in Indian subjects, they can't do it in Chinese or in Japanese populations, that would not be accepted by the USFDA.
>
> Me: Oh okay. So just for me to understand, if a Japanese sponsor wants approval in the US, he goes to India –
>
> KM: Exactly.
>
> Me: Because it's cheaper, or closer, or –
>
> KM: It's cheaper, closer and resembling the population (Dr Kiran Marthak, CEO of CRO Lambda, India, March 2015).

Dr Täubel similarly notes:

> You're quite right, a lot of pharma companies use India in order to develop medicines because, of course, it is a lot, lot cheaper, and, leaving aside all the social components of that, scientifically I think that's quite justified. And if you have suspicions that there might be a difference, you can do a relatively small study to find out (Dr Jörg Täubel, CEO of CRO Richmond Pharmacology, UK, July 2015).

The point here is that, in addition to the large, English-speaking staff and biomedical infrastructure, it is the amalgamation of (racialised) genetics and economic considerations that produce India as a prime location for clinical research. As medical ethicist Donna Dickenson (2005: 46) rightly argues, clinical trials "may well be cheaper to run on populations possessing a high degree of genetic similarity . . . since the required level of statistical significance will probably be available from smaller populations". Given pharmaceutical companies' general disinterest in population differences and the assumption of biological equivalence across human groups—though in varying degrees—Indians' genetic similarity to Caucasians

furnishes them with an exceptional kind of capital for global drug development. Social or ethical concerns aside, Täubel suggests, their genetic make-up thus constitutes an exceptionally valuable resource for both biomedical science and pharmaceutical capitalism. Rather than only their citizenship, as Sunder Rajan (2006) argues, I propose that it is also their valuable molecular qualities that render Indians experimental subjects on whom new medicines are tested for markets other than their own.

It goes without saying that it is predominantly, though by no means exclusively, patients from the lower socio-economic strata without access to affordable healthcare that enrol in clinical trials for whom the path of pharmaceutical consumption remains foreclosed. As such, ethnoracial and economic factors overlap in the construction of Indians as suitable research participants. Of course, population taxonomies have always comprised both physical and economic markers, making specific populations suited for specific kinds of work and ascribing them varying degrees of humanness (Quijano, 2000; Robinson, 1983; Roediger, 1999; Silva, 2007; Williams, 1994). Within contemporary multicultural, egalitarian frameworks, such associations appear to have been transcended, dissolved in a neoliberal fantasy proclaiming fundamental equality before the market. However, what is interesting in the case of Indian clinical trials is not the recuperation but the apparent inversion of familiar tropes about specific populations. What we find is not the ascription of racial (biogenetic and economic) difference but the simultaneity of genetic *similarity* and economic *difference*. Indians are described not as different and therefore commercially valuable or *vice versa*, as in the case of BiDil, but as ethnoracially similar (but economically different) and thus ideally suited for enrolment in studies.

While regulatory agencies usually insist on data from within their own jurisdictions (see Chapter 9), racialised ideas about genetic similarities have allowed my informants to recruit participants from geographically distant locations on other occasions, too. Referred to as 'pooling' in clinical research terminology, populations considered similar enough in terms of either intrinsic or extrinsic factors can be merged to boost sample sizes and facilitate cross-regional comparisons of treatment effects. As such, Dr de Boer, for example, recounted a study in which the company he was working for at the time recruited South African Black patients into a study that sought to investigate the differential rates and expressions of heart failure

between Caucasians and African Americans. Though he himself was critical of conflating the two, in this study, he explained, his team enrolled South Africans in lieu of African Americans. Similarly, Dr Ralf Herbst, a mathematician and medical statistician at Quintosh, remembered a trial in Senegal where the multiple identifications of West African/Senegalese/Wolof were translated straight back into 'African American'. Despite greatly disparate historical trajectories, physical environments, socio-cultural conditions and ancestral origins, the presumably stable continuity of shared genetic ties to Africa firmly placed South African, Senegalese and American Blacks in the same racial category (also Whitmarsh, 2008). Temporal proximity or distance to Africa as well as the continent's huge genetic heterogeneity itself are ranked secondary to the certainty that racial as genetic relations proclaim. In fact, their similarity is *only* legible through a lens of continental ancestry that postulates great validity of familiar racial concepts.

These cases reveal that researchers must stabilise a plethora of social, ethnic and national identities to produce Indians as Caucasians, or South Africans and Senegalese as Black Americans. Chapter 7 will explore in more detail how principal investigators translate their patients' multiple and often contradictory expressions of belonging, identity and solidarity as well as different environments and cultural practices into biomedically legible and standardised formats. In such processes, the relational character of race and ethnicity, which often comprises nationality, regional heterogeneity and personal biographies, is transformed into static, biological meanings (Whitmarsh, 2008: 12). The unspecified relation to a cryptic Aryan founder population or the African continent in varying degrees of temporal and geographical proximity provides the basis for claims to biogenetic similarity. The examples illustrate that the biological meanings of Caucasian or African eclipse other ways of identifying affinity, and the equivalent populations thus produced can be put in the service of biomedical research. As such, there is a certain value located in bodies that can be strategically aligned *qua* racial markers.

The prevalence of ideas about genetic (sub)populations suggests that while the biomedical gaze assumes the body to be readily standardisable (Lock and Nguyen, 2010: 20), there may be important distinctions as to which bodies are considered more or less readily standardisable. The assertion that Indians are, as Dr Marthak notes, "*more* Caucasian compared to the other Asians like people coming from Thailand or Malaysia or China" may also mean that comparatively less work needs

to be done in standardising, translating and comparing them. The assumption behind global biomedical research is not necessarily, as Lock and Nguyen (2010) argue, that all bodies are essentially the same, but sameness or similarity are variably located in specific kinds of bodies. Though modern biology introduced the possibility of a universal human biological constitution, my examples illustrate that concepts around genetic frequencies shared by specific populations limit such declarations of universality and inflect decisions about suitable locations for biomedical experiments. Lock and Nguyen admit that the belief in biological universality does not make all bodies the same but establishes a set of hypothetical equivalences through which bodies can be rendered commensurable (2010: 176). They may miss, however, how ideas about genetic proximity and distance, often expressed through racial terminology, continue to inflect clinical research designs and sampling methodologies in multi-regional scientific collaborations.

The production of Indians as suitable study subjects also implies the reproduction of the Caucasian as the 'standard human'. Rather than seeking to locate potential niche markets, overall my respondents manage, conduct or regulate large, randomised clinical trials testing drugs primarily intended for the Euro-American market—but also always for the general population. The assumption here is that drugs tested in Caucasians will equally work in other groups, or at least, as interviewees themselves emphasise, that less powerful regulatory agencies, for example in African countries, will not possess the scientific expertise and political authority to suggest otherwise (see Chapter 10). Either way, so-called Caucasian patients are recuperated, to borrow from Epstein (2009, 2007) once again, as *the* socio-demographic group whose bodily features are deemed so universal that the knowledge derived from the study of them can be extrapolated to all other populations. While my intent is not to justify arguments about the value of prevailing ethnoracial categories, I do argue that in this way, those variations that undeniably do exist between and within populations may not be accounted for.

6.4 "Asians? We probably all eat spicy food"

The biomedical interest in Indians as a genetically similar enough population is not just part of multinational pharmaceutical companies' reduction of their research and development spending and the larger aim of Indian elites to promote the country as

a desirable location for clinical research. It is also inescapably enmeshed with historical and contemporary negotiations of the country's national identity: Biotechnologies are never just about the extraction of economic value from bodily matter, but they are typically tied to specific nationalist projects (Fortun, 2008; Ong, 2010; Sunder Rajan, 2006). Often, they seek to redress historical degradations and re-signify national identity; as Aditya Bharadwaj and Peter Glasner put it, "India is rapidly challenging its established global image . . . by aggressively colonizing the unlikely global site of biotechnology research and innovation" (2009: 6). State-sponsored efforts to sequence 'national' genomes in particular link the population's molecular characteristics with specific political ambitions (see Chapter 8).

Indians' biogenetic identity as predominantly Caucasian for clinical studies may therefore equally be coupled with the longstanding though conflicted interest of Indian scientific and political elites in foregrounding their Aryan heritage. Racial sameness such as, here, Indians' self-description as Caucasians, also makes a political difference in that it shapes collective national identification and can be mobilised for claims to historical achievements and contemporary entitlements. As my archival research on the Indian eugenics movement has shown, throughout the emergence of Indian reformism and in the wake of the country's independence, the majority of Indian scientists and legal scholars were debating and appropriating different theories on Indians' Aryanism. In India's emerging nationalist movement, campaigners sought to reclaim their membership to the Aryan race to fight off centuries of colonial humiliation. Thus, claims to the Aryan or Caucasian origins of Indian DNA have long been at the centre of political negotiations about national identity. Europhile Indian elites traditionally associated themselves with British values and cultural heritage through a racial lens; restoring their connection to whiteness also meant affirming their political authority and status. Of course, this was often denied to Indians of non-caste and lower caste status as well as ethnic and religious minorities, as I will discuss shortly.

While notions of cultural or genetic superiority are significantly more nuanced today, Indian populations' biogenetic proximity to Europeans continues to be a source of inspiration for political projects and cultural identities. For example, a study by geneticist Michael Bamshad and colleagues (2001), suggesting genetic similarities between upper caste Indians and Europeans as well as between lower

castes and other Asian populations, has been used by *Dalit* activists to argue for the indigeneity of those populations that have been ascribed a lower or no caste status and to denounce the Brahmin domination of the Indian institutional landscape (in Egorova, 2009). In another instance, right-wing Hindu nationalist groups have utilised a genetic study that disproves any major migration from the Caucasus into India to renew their claim that India itself was, in fact, the cradle of Aryan civilisation. The finding backed, as they assert, the cultural and historical superiority of the Indian subcontinent over other, especially European civilisations (Rajagopal, 2006; Sahoo et al., 2006).

Without any such direct and clearly discernible political motivations, my Indian respondents often foregrounded their own genetic proximity to Europeans. Dr Bansal, for example, vehemently rejects the FDA classificatory system that puts Indians in the category Asian:

> You can't really categorise *us* Indians in the same category as *them*. . . . I'm sure there are differences in terms of the way drug response happens in *us versus them*. It's not a very fine categorisation, I have to say that (Dr Kaushik Bansal, clinical head, multinational pharmaceutical company, Switzerland and India, August 2014).

The only trait Indians had in common with other geographically Asian populations, he went on to suggest tongue-in-cheek, may be that "we probably all eat spicy food". His attempt to distance himself from the ascribed identity as Asian may not just be based on metabolic differences and the scientific imprecision such a broad category entails. It is also tied to questions about genealogical narratives and biosocial identification that uses biological and genetic discourses as formative of national and individual identities (Rabinow, 2008).

In contrast to political movements which draw upon or commission their own genetic research, clinical studies in India occur largely without recourse to genetic evidence. Most informants were unaware of recent genomic findings, and it was often the cultural narratives about colonisation and conquest that informed the selection of study populations and the interpretation of findings. Most experts I spoke with drew on rather conventional sources and systems of classification, such as Dr Lokesh Oberoi, an Indian pharmacologist at Quintosh in Switzerland:

> North Indians and South Indians that's more of a social definition of the races, as for the clinical trials you're right, the Indian population is more clustered under Caucasian. I think it goes back . . . this is entirely my personal view, but if you look at the Indian history, and geography, and the sort of, invasion in the Indian subcontinent from the Europeans, so you need to go into the whole historical context (Dr Lokesh Oberoi, pharmacologist, multinational pharmaceutical company, Switzerland and India, August 2014).

The statement illustrates that while Caucasian is taken to be the scientific as opposed to the social classification of the Indian population into North Indians and South Indians, the basis for his claim is socio-historical. Rather than precise genetic markers, it is social histories that are used to rationalise population classifications. Despite his insistence that this was only his personal view, Oberoi argues for the need to robustly incorporate the "whole historical context" to explain Indian population substructure. Often, it is such socio-historical knowledge that is conscripted into biomedical rationales for specific research questions rather than the identification of specific genetic markers to legitimate recruitment methodologies (Montoya, 2011).

The identification of Indians as Caucasians also eclipses other recent findings that suggest two major ancient populations as the genetic forefathers of modern Indians. Rather than being purely social classifications, genetic studies have shown that Indian populations can be divided into distinct Ancestral North Indians (ANI) and Ancestral South Indians (ASI), the former having strong ties to the Middle East and Europe whereas the latter are proposed to represent the actual indigenous inhabitants of the subcontinent (Reich et al., 2009). Most respondents were aware of anthropological divisions between North and South Indians, but genetic evidence has not significantly impacted how Indian populations are represented in clinical research. Below are two interview excerpts illustrating this:

> I'm not aware of that. We don't see it actually. Well yes, if you look at North Indians, they are more of, if you look at their features and everything, it's more like the Caucasians, because of the climate also I suppose, and because of the invasion that occurred more from the

> Western part of the world, so you see them all tall, sharp featured, well-built, which is more of a Caucasian type of bodybuild, while South was the early initial Indian population, you know, short and a little on the darker side. But now if you see [look at drug metabolism], we don't see that to that extent (Dr Shilpa Reddy, physician and principal investigator, multinational pharmaceutical company India, March 2015).

> So, that [i.e. different migrations] may have influenced how the North Indian and the South Indian ancestral populations differ in terms of their genetic makeup, I think it is well documented, the South Indians for example are called Dravidians, and the Northern ones as Aryans, and Aryans because they are more of the features, even phenotypically, rather resembling European makeup, both genetic and phenotypic. . . . [They are] more or close to the Caucasian, you know, categorisation (Dr Lokesh Oberoi, pharmacologist, multinational pharmaceutical company, Switzerland and India, August 2014).

Both respondents are astutely aware of anthropological or genetic distinctions between northern and southern Indian populations but stress that few are found at the molecular level of drug response. With little interest in studying these, Reddy proposes that the Indians can be characterised as genetically similar to each other as well as to other Caucasian populations while Oberoi emphasises that the description as Caucasian, strictly speaking, only characterised northern Indians. In both instances, the generalised assumption of genetic proximity to Europeans guides how Indian populations are represented and acted upon in biomedical research. While this is being justified, at least to some extent, by the supposition that tribal and North Eastern populations seldom partake in clinical trials, it may also suggest the ongoing domination of Brahmin culture in constructions of national identity. As most upper caste Brahmins are assumed to be the direct descendants of (white) Aryans (Figueira, 2002; Metcalf and Metcalf, 2001), the representation of India as predominantly Caucasian marginalises other populations groups, ancestral ties and socio-political realities, for example Dravidian, Dalit or tribal.

Indeed, one of the most pressing questions, for me, emerging from the production of Indians as almost Caucasians remains the relation between ethnoracial signification and caste or socio-economic status. Historically, as Chapter 4 has shown, researchers such as B.A. Gupte agonised over the applicability of data from socio-economically marginalised Indians to the overall population. However, concerns about the generalisability or external validity of data from contemporary Indian trials appear scant as garnered from interviews. Though my data confirm (also Nadimpally and Bhagianadh, 2017) that the majority of Indian trial participants stem from the lower socio-economic strata of society, researchers are rather disinterested in the biomedical implications of this. This is even though, as Lock and Nguyen (2010: 175) aptly warn, "when taken up by local therapeutic economies, biomedical technologies may be used on bodies that are literally materially different in some respects from those the techniques were developed for". In Chapter 7, I will explore in more detail how such material differences between sample and target population are, or are not, being accounted for. Here, suffice it to stress again the multiple vectors shaping how Indians are represented, and represent themselves, through biomedical technologies as ethnoracially similar to Euro-American populations.

6.5 The heterogeneous Caucasian

Throughout this chapter I have suggested that Indians are not represented as *identical with* but as *similar to* Caucasians. Scientists also emphasise biological distinctions between Indians and 'full' or 'proper', that is, 'white' or European Caucasians. Dr Reddy, for instance, explains:

> There is always a controversy whether Indians should be considered as Asians, or as Caucasians of non-European descent, that's a term that they very often use for Indians, very much is similar to Caucasians but still we are not of European descent. But I don't know what it means precisely (Dr Shilpa Reddy, physician and principal investigator, multinational pharmaceutical company India, March 2015).

The description of Indians as Caucasians of non-European descent resurrects the conundrum that Indians have historically posed to scientific theories about race

based on a black/white binary. Reddy's assertion also mirrors distinctions drawn by genetic research, suggesting that the Caucasian race can be further clustered into two broad subpopulations *qua* geographical ancestry, namely "European" and "extra-European Caucasoids" (Cavalli-Sforza et al., 1994: 242). Such narratives speak to the familiar representation that Indians are somehow, but not quite, Caucasian.

What precisely constitutes this distinction, however, remains largely obscured. The respondent herself admits that she did not know what Caucasians of non-European descent actually implied—perhaps an intrinsic feature of the Caucasian concept as notoriously vague and often "the leavings of what is not black" (Painter, 2010: x). Historically, of course, physical anthropologists and other researchers postulated phenotypic differences as the most significant criteria for Indians' divergence from whiteness, as the figure of the Black Aryan exemplified. Molecular biology, in contrast, having declared the genetic traits affecting superficial markers such as skin colour essentially meaningless, offers a different, albeit only partial, answer to this conundrum. Contemporary geneticists emphasise that it is the large, though varying, degrees of genetic admixture that set the Indian population apart from Euro-American populations (Mastana, 2014). Indians are often characterised as a unique kind of Caucasian, the "*heterogeneous* Caucasian" (Chin and Bairu, 2011: 120, emphasis added) *qua* genetic variations, also bearing upon the performance of clinical studies in the country.

Geneticist Sarabjit S. Mastana, for instance, states that "[i]t is evident from many studies that the high level of heterogeneity in Indian populations . . . has kept the Indian gene pool distinct from other continental populations" (2014: 288). India is found to be second only to Africa in its internal diversity due to gene flow. While the majority of studies suggest two main ancestral origins for most Indian population groups, the characteristic feature of *all* Indians is their huge genetic diversity that transcends any clear boundaries between the postulated three main divisions of the human gene pool. As a result, the frequency of a whole array of genetic variants is assumed to be distinctive in Indians as compared to other populations (Rosenberg et al., 2006).

The description of Indians as characterised by both high levels of diversity and a fundamental 'genomic unity' (Basu et al., 2003; Mastana, 2014) must not be a contradiction. Part of the flexibility of population descriptors, as philosophers K.

Anthony Appiah and Amy Gutman assert, is that they move almost seamlessly between different levels of analysis. "When we need similarities", they aptly note, "we can appeal to the higher level—the subsuming category of the Indo-European; when we need differences we can move lower down the taxonomic tree" (Appiah and Gutman, 1996: 57). At the level of mitochondrial DNA used for tracing material lineage due to its non-recombining nature, Indians are found to be characterised by genomic homogeneity (Basu et al., 2003; Kivisild et al., 2003). This means that members of the Indian caste system—the origin of tribal groups is thought to be distinct—are generally accepted as genetic descendants of the Aryans no matter the precise direction of Indo-Aryan migrations (Mastana, 2014; The HUGO Pan-Asian SNP Consortium, 2009). More conventional human population genetic studies though, using single gene polymorphisms, have demonstrated larger ethnic and geographic variability due to multiple important migrations after the Aryan era and specific social practices such as the stigma on inter-caste marriages that have prevented widespread admixture (Bhasin et al., 1994; Papiha, 1996).

In short, while a conclusive agreement is yet to be reached, researchers assume principal ancestral continuity (with some variation according to geography and caste status) while genetic drift and endogamous practices due to social restrictions have produced high degrees of internal heterogeneity. Such statements quickly transmute into the racialised language of the non-European or the heterogeneous Caucasian, characterised by both ancestral ties to European populations and a uniquely diverse population substructure. Indians' ancestral identity as predominantly Caucasian indicates their fundamental biological proximity and metabolic compatibility with European populations while the diversity of other genetic markers allows drug developers to test a new substance in a heterogeneous population with variable clinical phenotypes. Of course, drug developers are interested in genetic heterogeneity but only as long as it occurs within the limits of sameness at the higher-level categorical matrix. Since they have, as outlined earlier, no principal interest in population differences as such, *too much* diversity may confound their aim of broad applicability. This means that genetic diversity is valuable as long as it does not destabilise the fundamental sameness on which multi-regional research rests. In other words, biomedical researchers must carefully calibrate difference and sameness in their selection of sample populations.

Some critics assert that the presence of what Indian CRO Pharm-Olam characterised as 'all major racial groups' (Chapter 1) facilitates comparative ethnic or pharmacogenomics studies in India (Sunder Rajan, 2006). In contrast, I propose that it is this genetic 'unity in diversity' that attracts biomedical experimentation to the country. Genetic diversity is a major attraction for drug research, and both Indian companies and state actors pitch the country's "advantage of having 6 out of 7 genetic varieties" (Singh, 2012: n.p.). However, none of my respondents had performed distinct subgroup analyses engaging with this genetic diversity. All but few asserted that Indians were genetically diverse but nonetheless similar enough to defy further subdivisions. Specific subgroup analyses were seldom requested by Indian regulators, and pharmaceutical companies themselves, as I have shown, are rarely inclined to explore internal variations. As global clinical trials in India are usually performed as part of multi-regional research in which the compatibility and commensurability between multiple study populations is sought, subpopulation differences are rendered insignificant. Unity in diversity offers advantages to biomedical experimentation that is characterised by both the need for bodily equivalence and a principal interest in genetic diversity.

Some of my informants suggested entirely new framing devices to capture this intrinsic duality of diversity and similarity. Dr Kunal Chopra, who heads the medical operations in India for Mayer Group, a Germany-based but globally operating pharmaceutical firm, proposed the concept of "Indiasian" in a personal email preceding our telephone interview, emphasising India's exceptional geographical and genetic position. Dr Shifa Abbasi, medical head of Clintech's Asia-Pacific operations based in Mumbai, equally spoke of the need to understand Indian biology in terms of a unique "South Asian genome". Indians were, she specified, "not *fully* Caucasians, but more Caucasian than actually similar to Chinese or Japanese genomes". Her categorical choice was based on the advent of genetic admixture as a distinct characteristic of Indian genetic constitutions which differentiated them from Caucasians of other origins.

Whether or not such categorisations will eventually turn into useful classificatory devices for biomedical studies depends, as this chapter has suggested, not only on their genetic accuracy but on a plethora of scientific, economic and political factors involved in shaping systems of classification. At present, the scientific and political authority of the concept Caucasian appears irrefutable, and although modifications

may be made to accommodate for genetic variation between subpopulations, these have so far not precipitated a reconsideration of the broader categorisations across which comparisons are made. Even though the heterogeneity of Indian populations and the prevailing uncertainty over their precise genetic constitutions puts the cogency of 'Caucasian' as a racial category under immense analytical stress, its multivalent character presumptively rooted in genetic evidence continue to endow it with scientific and cultural authority. Scientific, economic and political narratives postulate Indians' biogenetic similarity to Caucasians in perpetuity.

6.6 Conclusion

This chapter began by outlining the pharmaceutical industry's disinterest in ethnoracial variation, proclaiming a fundamental genetic similarity across populations central to the performance of multi-sited trials. This disinterest notwithstanding, I have shown that clinical studies in India are fundamentally premised on naturalised understandings of genetic populations—yet on the *sameness* rather than the *difference* between them. I have drawn on St Louis' work to argue that race not only operates through the promotion of difference but equally manifests in affirmations of Indians' similarity. My wish was not to adjudicate on the facticity of genetic ideas about ethnoracial variability but to consider why such accounts are used or appear useful. I have suggested that it is the amalgamation of scientific, economic and political factors that recuperate Indians as almost white, but not quite.

While genetic homogeneity between populations is preferable to their heterogeneity, such similarities by themselves do not render human bodies adequately commensurate for biomedical experiments. In the next chapter, I will ask how other variations are translated and standardised to conform to global study protocols and seemingly universal ideas about biomedicine and bodily norms.

Chapter 7: Global trials, local bodies: Making comparable research subjects

> Our patients don't look, don't look and also don't behave like anybody in the US. Why should they? (Professor Tista Nayak, pharmacologist, ethics committee member at a public hospital, India, March 2015))

> Now when you go to different, multi-country trials, . . . parameters start to differ, so a range of normal clinical parameters in the US or Europe may be different from what you would call normal in India. . . . I believe it may have to do something with all these, you know, ethnicity, genetic makeup etc., plus, everything changes right, you have to define a different range, different parameters, because that's the very basis of declaring, or accepting patients into clinical trials (Dr Lokesh Oberoi, pharmacologist, multinational pharmaceutical company, Switzerland and India, August 2014).

> When it comes down to patients, one would assume that they are like any other Western patient, but we are not, actually (Dr Arun Bhatt, physician and CEO of CRO ClinInvent, India, March 2015).

Positing Indians as genetically proximate to Caucasians, though informing the selection of study populations, does not make them adequately commensurate for the production of comparable study results across multiple geographical sites. Ethnoracial variation in clinical research does not only denote variability in genetic traits but biomedical researchers must also assess a plethora of physiological, social and cultural variables (see Chapter 5). For research results to be reliable, reproducible and representative, the influence of these factors must be cautiously managed, 'harmonised' and often attenuated as much as possible. Research participants need to be void of or abstracted from the specificities of what Margaret Lock and Patricia Kaufert (2001), writing about differences between menopausal symptoms in North American and Japanese women, term "local biologies" that

result from the continuous feedback relationship between biology and culture. In the context of globalised biomedical practice, Lock and Nguyen also assert that local biologies are fundamentally incongruent with ethnoracial categories but denote the "local entanglements among historical and cultural activities, technoscientific interventions, and the biology of individual ageing" (2010: 83).

In other words, study participants need to be *made* comparable across geographical boundaries without relying on entrenched notions of ethnoracial similarity and difference. Based on the premise that, as cultural anthropologist Marilyn Strathern writes, "comparability is not intrinsic to anything" (Strathern, 1991: 53) but needs to be carefully produced, I explore in this chapter the efforts of Indian investigators and clinical research executives to render Indian clinical trial participants comparable with other populations. This occurs through adherence to a variety of scientific, operational and classificatory standards as part of a globally uniform study protocol aimed at flattening ethnoracial variation. It is only through such processes of standardisation and "commensuration", transforming "qualities into quantities" and reducing and simplifying "disparate information into numbers that can easily be compared" (Espeland and Stevens, 1998: 316), that clinical data from India acquires translocal applicability.

However, the implementation of standards and the production of comparability or commensurability are not merely technical processes but rather modes of power. Medical sociologists Stefan Timmermans and Steven Epstein (2010) point to the nature of standard setting as a subtle or not-so-subtle means to regulate and discipline life. Standards can function as instruments of power that erase local practices and flatten social diversity. Aiming to render a plethora of social phenomena and structures functionally equivalent, they inevitably raise important questions about the organisation of modern society. The outcome of social work requiring the labour of various stakeholders, standards are rarely politically neutral (Berg, 1997; Bowker and Star, 1999; Engel and Zeiss, 2014; Montgomery, 2017; Simpson and Sariola, 2012)

As such, examining the implementation of standards and processes of commensuration, especially when they fail, offers insight into existing asymmetries in offshored clinical trials beyond the often sensationalist critiques of ethical misconduct. Respondents such as Professor Nayak, cited in the epigraph of this chapter, raise crucial questions as to whether their patients conform, or *should*

conform, to a specific global standard or protocol. Her avowal not only contests the notion of bodily universality but also points to intrinsic inequalities in global research collaborations that seek to iron out local peculiarities. This is not to claim that the local exists independent of, or can be neatly separated from, the global but to illustrate the tensions generated when they are assumed to be too easily reconcilable. In the space of this chapter, I argue that the management of ethnoracial variation in global clinical trials is a question of (postcolonial) power dynamics wherein Indian investigators frequently struggle to adhere to protocols predominantly designed elsewhere and often incommensurate with their own as well as their patients' ethical, social and biological realities. Needless to say, the relocation of clinical trials to India, like many contemporary forms of biomedical travel, traverses well-worn paths of historically salient routes and patterns of colonialism and conflict (Thompson, 2011)

In short, the aim of this chapter is twofold. First, I illustrate that comparable research subjects need to be made, not enrolled, through multiple processes of commensuration that aim at transcending the local biologies and cultural specificities of research participants and sites. The concrete, territorial locality where research is conducted, and the materiality of the actual bodies subjected to experimentation, cannot easily be abstracted or ironed out. And second, I demonstrate that India's performance of outsourced, contractual work implies that the burden of translating, managing and regulating undesirable variation disproportionately lies with Indian investigators who must negotiate an array of epistemic traditions, cultural identities and personal allegiances between global standards and local value systems. As such, I aim to make visible what I call *translational labour*, a conceptualisation I have developed to explain the labour expended by Indian practitioners, and the epistemic and often material violence that processes of translating and comparing scientific practices entails.

With this objective, each of the subsequent sections explores a specific bodily metric, population classification or cultural phenomenon, designated as ethnoracial variation by my interviewees which they themselves have identified as impeding the smooth functioning of multi-regional trials. Though seemingly disconnected, perhaps, they all point to different processes of commensurating Indian local biologies with standardised, translocally applicable biomedical formats. Each case examined serves to substantiate my argument that not only must Indian trial

participants be made comparable, but that this process involves significant labour by local clinical staff, which often remains overlooked (but see Montgomery, 2017; Simpson and Sariola, 2012).

The first section explores the concept of the normal body at the core of biomedical research and the institutional challenges researchers face when encountering deviations resulting from local culture or biology. Section 7.2 moves to describe how researchers translate requirements for population categorisation that may be non-sensical in their respective contexts. Section 7.3 discusses the challenges of documenting and managing ethnic variation beyond the confines of racial genetics and the pharmacokinetics of drug response. Next, I focus on the streamlining of diets for clinical trial participants to show how the adherence to global standards may compromise local cultural and religious sensibilities. Last, section 7.5 problematises the very idea of the independent, transparent research subject to demonstrate how cultural norms around gender and kinship jeopardise the autonomous individual and *vice versa*. Taken collectively, this empirical data illustrates some of the persistent difficulties in responding to human diversity in global clinical trials outside the lab, and the enduring tensions between standardisation and local adaptation.

7.1 "We do find a little more difficulty with these global trials": Challenging the 'normal body' in clinical contract work

Contemporary biomedical research is fundamentally predicated on representations of the normal body (Foucault, 2003). Such representations, according to anthropologists Lock and Nguyen, allow "people to be sorted into standardised groups and populations because their biology is assumed to be the same" (2010: 176). Particularly in multi-regional clinical trials, only the assumption of standardised groupings and the functional equivalence between them provides the ground for meaningful comparisons. However, conducting clinical research across multiple sites presents significant challenges to the very concept of bodily normality and its relation to health. Dr Oberoi, for instance, explains:

> So, for example if you define a normal, let's just take the simple example of normal haemoglobin levels, so there's a range by which you will define a person as anaemic. . . . So, there's a normal range and if a

> person is within that range it's normal, if you're less or more than you're defined as [having] some sort of clinical condition. Now when you go to different, multi-country trials, with sites in the US, in Asia . . . these parameters start to differ, so a range of normal clinical parameters in the US or Europe may be different from what you would call normal in India. . . . I believe it may have to do something with all these, you know, ethnicity, genetic make-up etc., plus, everything changes right, you have to define a different range, different parameters, because that's the very basis of declaring, or accepting patients into clinical trials. . . . So, if there's a particular level of haemoglobin but you don't know what the background of the patient is, you may say that this is anaemic but no, no, this comes from this . . . and it is normal! (Dr Lokesh Oberoi, pharmacologist, multinational pharmaceutical company, Switzerland and India, August 2014)

Likewise, Dr Ahmed expresses concern about deploying standardised biomedical concepts of the body, using the same example of differing haemoglobin levels. He notes:

> How do you even define a healthy volunteer? [In India] I have seen a number of studies where the subjects have been healthy by definition, but . . . their haemoglobin is lower than normal. . . . Actually, they are healthy, but are we taking too much blood, or are we using the wrong criteria to assess what's acceptable? So, the quality of the data may be fine . . . but I'm worried about the effect on the people. . . . I think it's partly nutrition, but again, it could just simply be . . . that we're applying the wrong normal ranges, you know, that actually their haemoglobin isn't low, you know, if you live on a predominantly vegetarian diet, the chances are your haemoglobin levels are a bit lower (Dr John Ahmed, senior director, clinical pharmacology, multinational pharmaceutical company, UK, August 2015).

Variation in laboratory practices, methodologies and reference ranges is itself a major concern for multi-regional trials. Central laboratories have been set up, and

uniform standard operating procedures, reporting systems and IT platforms have been introduced to facilitate the consistency of clinical data across multiple sites (Taboada and Sharad, 2015). However, what respondents address here goes beyond the focus on data quality and consistency: they problematise the very idea of universal bodily norms, for example laboratory ranges, and a standardised definition of health applicable across multiple sites. Pointing to key cultural or religious differences such as vegetarian diets, resulting in the creation of local biologies, they expose the normal body produced by the statistical nature contemporary biomedical research as highly contextually specific.

The interviewees aptly suggest that reference intervals used in global clinical studies are frequently based on European or US-generated values that may not apply to other populations or individuals. Though it is recommended that labs establish their own, local intervals, researchers often draw on values extrapolated from European or North American populations. As laboratory reference values go hand in hand with drug effects and toxicity gradings, access to locally established and corroborated databases is crucial for correct diagnoses (Zeh et al., 2012). However, Indian researchers often fail to generate their own reference intervals given the lack of resources available to them. Creating and validating such databases takes a tremendous amount of time and a strong research infrastructure, often prohibiting robust research in countries of the Global South where these are not accessible. Indeed, most diagnostic labs in India use established intervals from scientific literature, textbooks or adopted from Western cohorts even though several studies have reported significant differences in, as mentioned above and elsewhere, haematological markers for Indian patients (Sairam et al., 2014).

I do not wish to assert expertise in evaluating the actual risk for Indian patients ensuing from the lack of local databases. Of note here is that Indian patients' physiological qualities are measured against biomedical standards that are considered universal but often reveal a fundamental bias towards Euro-American patients, not least due to existing inequalities in healthcare budgets. In this way, too, the pre-eminence of normal distributions reproduces the Euro-American body as the 'standard human' against which Indian patients are compared and assessed, making human diversity appear inherently pathological (Canguilhem, 1991). The presence of evaluative notions around what constitutes a normal or healthy body makes the biologically normal not only an issue of statistical averages but also an

issue of value. Indeed, sociologists Wendy Nelson Espeland and Mitchell L. Stevens (1998) argue that processes of commensuration always also contain moral judgements as they imply that the value of two things is not comparable. Nayak's provocative query in the epigraph points to dominant expectations around the 'proper' or 'appropriate' comportment of bodies in clinical research, exposing the production of comparability as a subtle but powerful disciplinary technique. Of course, her own groupism ('Indian bodies') warrants equal critical scrutiny since, at the genetic level, humans are all individuals. Yet, the point here is that variation from established norms, or the refusal to comply with them, is subject to disciplinary measures rather than a reflection on the global portability of biomedical technologies.

This is not to vilify the standardised body that has become indispensable for contemporary biomedicine but to destabilise that which is assumed to be universal or natural by embedding and contextualising bodily characteristics in time and space (Lock, 2013: 296). My research shows that medical practitioners struggle to develop and adhere to universally valid concepts of the body that would not only make their own patients appear fundamentally deviant but also put their health and safety at risk. Of course, health is a relative condition for which a universal definition is hard to establish. It is a highly elusive concept that transcends clinical measurements, rooted in subjective somatic experiences and contingent upon culturally specific understandings of the body, healing and suffering. However, multi-regional trials are, by definition, conducted under the umbrella of a single, uniform study protocol and fundamentally rely on such standardised and standardising definitions. Representing bodies in an internationally comparable, legible and *legitimate* format requires significant effort by local investigators, effort that often remains overlooked.

Some, though not all, respondents have indeed found it arduous to adjust globally standardised protocols for local variations. The following excerpt from the interview with Nayak illustrates this well. Having heard her speak at a clinical research industry conference as an ethics committee representative, I met Nayak in her office in the clinical pharmacology unit at a large public hospital in southern Mumbai. Though I was quite nervous before our interview given her status as a renowned expert in the field, I felt a profound sense of relief when I was immediately ushered into her spacious, air-conditioned office. This was in part the

result of sheer physical exhaustion after a long trek in Mumbai's midday heat. I was also relieved because I, as a *videshi* researcher from London, was not asked to wait with what must have been dozens, if not hundreds, of ailing Indian patients filling every inch of the hospital ward, hunched in various states of pain and sickness. Entire families, including infants, were lingering outside Nayak's office, presumably awaiting admission to one of the many research studies she was overseeing at the time in exchange for free medical treatment. Her description of the discrepancies between the objectives of global clinical studies and her concern for her own patients could not have been illustrated more vividly. She argues:

> You know if you insist on some changes. . . . They [global drug companies] are very recalcitrant, they do not want change, 'this is a global study, it's been approved in the US, you should approve it!' But you know they don't seem to understand that we are looking at *our* patients. . . . They're not the *same sort* of patients, they live in different circumstances. So, we do find a little more difficulty with these global trials (Professor Tista Nayak, pharmacologist, ethics committee member at a public hospital, India, March 2015).

The main target of Nayak's critique was her unmet demand for changes in the informed consent process, for example translating information and consent forms into local languages or audio-recording the consent process, but the statement illustrates that global drug companies frequently refuse to make necessary adjustments. Adapting a global trial protocol to account for Indians' local biologies or cultural sensibilities is often met with resistance as multi-regional studies imply uniformity in patient selection criteria, definition of clinical endpoints and the consistent traceability of results.[31] In other words, the portability of data derived from Indian sites takes primacy over concerns about patient wellbeing as the objective of clinical trials is the creation of surplus value rather than the fostering of health (Sunder Rajan, 2006).

[31] Note also that, in Nayak's example, it is not only a *global* protocol that is to be followed but one 'approved in the US'. Given the economic weight and scientific authority of US-based drug companies, this installs a further incentive to comply with the standardised trial design.

Anthropologist Adriana Petryna asserts that global clinical research is characterised by a fundamental variability wherein research methods are modified to fit local contexts (Petryna, 2005a), but the quest for uniformity for the purpose of comparison also warrants critical scrutiny. Though Petryna is primarily concerned with the questionable ethics of conducting trials in impoverished countries that lack adequate healthcare facilities, which I share, there is also considerable pressure for Indian researchers to adhere to globally uniform protocols that may not always be applicable to, or beneficial for, their own patients' circumstances, though this has largely remained unacknowledged in the literature on offshored clinical trials (for an exception, see Montgomery, 2017). As Nayak's statement illustrates, local physicians are concerned with their patients' variable biological constitutions, cultural expectations and socio-economic contexts that may not be adequately factored in given that comparability is the underwriting logic of global research. Her example thus illustrates some of the tensions and effects that are brought about in specific local settings where standardised biomedicine is used for the purposes of research or care (Lock, 2013). As Nayak explains, Indian researchers struggle to bring their patients' specific constitutions and circumstances across, and to adjust what is considered a globally valid protocol in accordance with them. This exemplifies that the demand for commensurability is often a tool of the powerful, here global drug companies, that works not through coercion but through the more elusive power of discipline and manufacturing consent (Espeland and Stevens, 1998).

The onsite management of trials by local, often inexperienced CROs with clear commercial incentives further complicates the insistence on local particularities over the compliance to a global protocol. Nayak goes on to explain:

> The difficulty is actually with these companies which are small companies, smaller companies. . . . They don't know the circumstances, you know, so they come up with some CROs, and the level of information and knowledge they have, and their presentation and that depends, it falls short a bit sometimes, compared to larger companies who have a presence here already, or [more] experience. . . . There are problems. There are good CROs, and there are not so good CROs

> [laughs] (Professor Tista Nayak, pharmacologist, ethics committee member at a public hospital, India, March 2015).

What Nayak calls "not so good CROs" may primarily refer to so-called floater sites, ephemeral contract research organisations that are less concerned with achieving specific regulatory standards and are thus willing to take on trial work considered dangerous or harmful (Petryna, 2005b). According to Petryna, their main pursuit is to make easy money and, in contrast to major multinational firms such as Novartis and Pfizer who have had a long presence in India, they often disappear from the clinical research landscape after a few lucrative jobs. But even established CROs have been accused of gross misconduct. For example, a scandal broke in 2012 when it emerged that two local CROs accepted a trial protocol for Vioxx, an anti-inflammatory drug that had been withdrawn from the market for severe safety concerns. The malfeasance was publicised by two investigative journalists for the American television network NBC.[32] When this and other stories of ethical malpractice became public, the government began to investigate such "not so good CROs" and pledged to set up a central register to properly regulate clinical research in the country.

Respondents remained highly doubtful, however, that the register was comprehensive and that CROs were ever rigorously vetted given the lack of resources and the close affinities between the Indian government and the clinical research industry. Nayak herself criticises:

> I am not sure I have, as an investigator, a choice of whom to work with. If a company comes to me and unless I have clear cut evidence that the CRO is unethical, there's very little I can do (Professor Tista Nayak, pharmacologist, ethics committee member at a public hospital, India, March 2015).

India's status as a newly emerging and rapidly growing clinical trial site often means that little institutional recourse is available for clinicians. This lack of accountability leaves plenty of room for ethical variability (Petryna, 2005a, 2009) but the opposite may also be the case. Many newly founded CROs have not yet been

[32] The full documentary is available online: http://www.nbcnews.com/video/dateline/46615550 [last accessed 12.03.2017]

audited for their adherence to quality standards; for instance, the US Department of Health reported that the FDA inspected clinical investigators at less than one per cent of foreign sites for the year 2008 (Levinson, 2010).

Newer CROs with increasingly rigorous standards are eager to prove their professionalism and compliance with international experts as any objections are likely to jeopardise India's privileged position in the global trial market, especially after the negative media coverage since 2011. CRO Quintiles' Dr Shoibal Mukherjee, a highly regarded and experienced clinical research expert, confirms in an interview with the *Hindu Business Line* that "[i]t is not difficult to replace these (Indian trial) sites in other countries" (in Datta, 2013) should multinational companies face excessive opposition in India. This is precisely what occurred in 2013: the government's hold on active trials over ethical concerns meant that most multinational companies withdrew their trial operations and moved elsewhere. After the Supreme Court's decision, the number of applications for trials dropped sharply from 480 (with 253 approved) in 2012 to 207 (with 73 approved) in 2013 (Nair, 2015).[33] Given excessive market pressure, as well as the ease with which capital travels in a postcolonial, globalised world, the prospect of losing valuable research funding and treatment opportunities functions as a constant reminder for Indian investigators to conform to standardised protocols even though their effects may be harmful.

7.2 Lost in translation: (how) do ethnoracial classifications travel?

One of the most immediate ways in which populations are made comparable in global research is the use of standardised population descriptors, not least those mandated by the FDA. Though classifications are not conceived of in any deterministic sense (see Chapter 5), identifying research participants' race or ethnicity is no mere box ticking exercise either. Rather, investigators need to carefully dissect and interpret the categories available to them such that they gain analytical value for their specific research questions and socio-cultural contexts. Negotiations about patients' ancestries or ethnic identities take place between investigators, patients, sponsor companies and regulatory authorities; the effort

[33] Please note that Ravindran and Ved (2013), whom I have cited in Chapter 1, present different figures for the year 2012 but none for 2013, hence I am here citing a different account that makes visible the downward trend in trial approval after 2012.

that goes into them illustrates some of the additional work required by local researchers to present their patient populations in a biomedically valid, globally amenable and transnationally comparable format.

In India, asking patients to racially or ethnically self-identify is an uncommon practice, especially given the postcolonial state's commitment to abolishing social distinctions, primarily related to caste. Unlike in the US, no official survey or census has recorded any such stratifications until recently (Banerjee, 2014). More, since ethnoracial identities are often conflated with ancestral origins and genetic constitutions, many biomedical researchers opine it was up to the scientific expert to determine them, especially since patients seeking medical care or financial benefits through research participation were rarely well educated. Dr Sonali Mishra, for instance, a clinical research consultant with a PhD in biotechnology based in Mumbai, elucidates:

> Me: does the PI define the ethnicity?
>
> SM: So, the PI would enter the data. I don't think there would be a conflict between what the PI and the patient would say. I trust he would be asking the patient for input, but he would be the one entering the data. Now is he trained to do a scientific analysis on that? I doubt. I doubt . . . [but] in India, in clinical trials, a lot of the patients are not really educated, they would usually be below the poverty line or lower income groups, they may have no idea if you ask them 'are you an Asian or are you a Caucasian or an x, y, z' (Dr Sonali Mishra, consultant for the pharmaceutical industry, India, March 2015).

It is suggested that Indian trial participants' lower socio-economic status went hand in hand with their inability to describe their own ethnic or racial identities in internationally recognised formats. As the investigating physician may not be trained to determine actual ancestries either, practices of ethnoracial profiling are pragmatically accepted. In a similar register, Dr Manoj Mehta, a medical director at Quintosh in Mumbai, argues that a lay person would find it very difficult to identify their own race or ethnicity, and only the medical professional would, quite literally, "see" the difference.

Though patients declared their ethnoracial belonging on the enrolment forms handed to them, physicians would later convert these statements into the "correct" categories needed for international documentation. They did so either by subsuming indicated ancestral, geographical, religious or caste identities under the higher-level ethnic, racial or continental category specified in the protocol or by labelling the patient themselves. In this way, phenotypical presentations may well be conflated with genetic constitutions, long established to be fallacious associations.

Such medical paternalism brings the practices of self-identification and Indian social conventions into sharp relief. Not only has the meaning of ethnic and racial categories emerged from distinct historical trajectories and socio-political environments; the practices of classification are highly culturally specific, too. Ascribed emancipatory potential in the US and used to avoid more invasive and often costly measures such as sampling each patient's individual DNA (Bliss, 2012), ethnoracial categorisation can be ostensibly sensitive in other contexts. In India, they may well evoke the pernicious history of colonial anthropology wherein ethnoracial and caste-based communities were counted, conscripted and sharply delineated from one another as scientists-cum-administrators of the Empire established clear-cut boundaries between relatively fluid and dynamic groupings (see Chapter 4). Today, a similar authority is bestowed upon biomedical elites, summoning techniques of governmentality and control, and unmasking the Euro-American bias in standards of classification.

Categorical systems laid out, for example, by the US OMB need to be interpreted and reworked if they are to have any practical applicability in global trials. Though some investigators surmised this was a purely bureaucratic endeavour, others explained how they had to carefully test and decipher standardised population categories to make sense of a specific trial design or safety warning. FDA guidance provides the option to use more detailed categories in case report forms so long as they are traceable to those stipulated by the FDA, but the issue is more complex. Professor Chan, who regularly conducts international trials in Singapore comparing the city-state's Indian, Malay and Chinese populations, explains it thus:

> To them [FDA], Asia is everything outside of the US and to the East, right? So, we don't know how to translate them when they say, when

> they make a recommendation 'we need to be careful with Asians'. What does that mean? . . . So, how do we look at this and translate this decision or this consideration that is made by the US, or these guidelines that are made by the US FDA, how do we translate that to our local contexts? (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

FDA recommendations for Asian patients convey no specific meaning for Chan who studies metabolic differences between at least *three* Asian populations. The category does not signify, in any unmediated way, a clearly delineable group but is 'lumping' an entire range of populations under a single group (Hochschild, 2012). Practices of lumping are certainly not new or surprising, but interesting is how practitioners negotiate the categories' analytical vacuity in their everyday research practices.

Chan's choice of the term translation is intriguing in this regard. The concept of translation has occupied a plethora of theorists in STS as well as in cultural theory. Though their approaches differ, both stress that, as Judith Farquhar (2012: 155) writes,

> even the most universalist abstractions, the most self-evident facts, the most natural entities, emerge in unique histories, develop in localised communities, are claimed by interested political actors, and travel in particular networks, . . . but they travel, and root themselves in foreign soils, only with difficulty.

As such, the globalisation of prominent scientific concepts and classifications requires *translation*—in Chan's example, of an incongruous conceptual framework for population classification. His task involves constructing "a domestic representation of a foreign text and culture" (Venuti, 1995: 10), or interpreting an unfamiliar concept in a way that renders it intelligible for the specificities of his local circumstances. As such, much of the effort put forth by local investigators to make their contexts fit with established standards can be described as *translational labour* without which both the central principles of biomedical research and the value created through offshoring and outsourcing would be compromised. Exercising their intellectual and affective capabilities to realise both the use-value of adequate and safe healthcare and the exchange-value of a potential new drug,

Indian physicians' translational labour is core to the functioning of contract clinical research.

Chan explains these processes of translation in more detail:

> First of all, it requires some insight into what the issues are. . . . [If] the FDA says 'there's an Asian problem', then we want to look at that a little bit more closely and see what's their basis for saying that's Asian data? Where was this source of the data? If the source of the data comes from the UK and we know that in the UK Asian means South Asians, then we might say 'maybe this only applies to the Indian population and does not apply to a Chinese or Malay population'. And we want to look at that a little bit more closely and say 'is there any evidence that in Chinese in particular there is a problem?' . . . So, we try and translate that and develop the evidence that will help make our own regulatory decisions and say 'do we apply this to all Asians or do we see this as specific to one particular group?' and maybe we need to be careful about how we apply this across the board (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

As the quote illustrates, there is no domestic equivalent to 'Asian' that Chan could utilise for his research. Rather, the category is broken apart for more precise information about its source and the sample population on which claims about Asian patients are based. In other words, Chan engages the category's cultural origins, semantic contexts and historical conditions of possibility; viable interpretations of 'Asian' as describing Indian, Chinese or Malay patients are weighed against each other and additional research is conducted to determine whether a statement is applicable across these populations. In a process reverse to the one described in Sofia Coppola's well-known drama about two Americans in Tokyo in which complex meaning is literally lost by their interpreter's single-sentence translations, Chan's labour lends the concept more depth, meaning and content than it initially conveyed. This also reflects his active role in shaping these concepts: Translation is no transparent, technical mechanism of establishing

equivalence between two formally commensurable entities but has a political quality in that the interpreter is core to constituting the putative unity of both the original concept and its translation (Solomon, 2007; Venuti, 1995).

Though comparison always involves more than translation and *vice versa*, it is a necessary step in rendering patients and population groups functionally equivalent. Chan's description of the translation process, and his own active involvement in it, comprises the selection of specific markers, population characteristics or sampling criteria that correspond to 'Asian' and can be deployed for comparative analysis. This is precisely what Strathern points to when arguing that comparison is not an act of identifying things that are similar or different to then correlate them. Rather, by virtue of its selectivity, comparison itself *creates* such connections; it is the act of comparing, translating and relating specific phenomena which produces relations and associations (Strathern, 1991).

The production of similarities and differences is thereby never merely a neutral description but "configure[d] in hierarchies of dominance and marginality" (Venuti, 1995: 18). Farquhar (2012) is attuned to this, arguing that the conceptual and bodily violence involved in the transplantation of foreign knowledge forms is primarily visited upon those bodies or populations denounced as deviant, non-compliant or uncomprehending. In this sense, there resides an inevitable epistemic violence in the processes of translation, comparison and harmonisation of bodily and socio-cultural constitutions across borders; the very purpose of translation and commensuration is the removal, or at least the containment, of local difference through the various commensurating methodologies of clinical research. Processes of translation and comparison are ensnared in global power dynamics. They do not constitute operations of relay or equivalence but assume a vital role in shaping social realities. As such, filtering global populations through a constricted cluster of choices for categorisation is generative of particular modes of conceptualising and acting on human diversity.

Making comparability also has concrete, material consequences for those conducting and participating in experimental research. In subsequent sections, I will illustrate how bodily variability is being conveyed and acted upon by Indian investigators. In particular, I demonstrate the affective dimensions of their labour,

not only translating differential bodily characteristics but also negotiating a plethora of identifications and social positions in the process.

7.3 "Only in the West we have a formula": Managing the fuzziness of clinical judgment

Though Indians are assumed to be at least genetically related to Caucasians, they do exhibit certain variations considered to be ethnic. For instance, Dr Kamireddy explains:

> For example, again, BMI and height, typical BMI varies, typical weight also varies. And the amount of what is given to the, say, Caucasian population, cannot be directly translated to the Indian population. For example, take a simple drug like Paracetamol, which has been used for the last 30 years, 1g of Paracetamol is very well tolerated in the US and Europe but in Indians, they cannot tolerate 1g of Paracetamol. The maximum dose of Paracetamol is 650[mg]. So, these kinds of changes should be considered in terms of safety, whether the dose that has been selected is really safe for the Indian population (Dr Suresh Kamireddy, CEO of CRO ClinSync, India, March 2015).

Besides variations in body weight and height, some differences are also directly shaped by genetic polymorphisms, for example in the liver enzyme CYP2D6 that variously expresses in distinct poor, extensive and hyper-extensive metabolising phenotypes. Scientific studies have estimated the rates of slow metabolisers at five to ten per cent in Caucasians, up to five per cent in Indians and only one or less than one per cent in East Asian populations (Frackiewicz et al., 2002; Kitada, 2003). Yet other variations, biological and clinical, are less well studied and often harder to validate through experimental research. Nayak notes:

> There is actually something I haven't been able to put my finger on, because you don't find it in the literature, [that] is that if you look at many of our drugs, we start in India with lower doses, we require lower doses to produce the same effect, it's not only about the weight. They [Indian patients] just seem to be more sensitive . . . and this has got

> nothing to do with genetics, it's about the sensitivity of the receptors. We need to do more data, we need literature to show this (Professor Tista Nayak, pharmacologist, ethics committee member at a public hospital, India, March 2015).

Nayak's longstanding experience as a clinician suggests that Indian patients are more perceptive to specific drug classes not because of obvious genetic mutations or differences in body weight but from increased receptor sensitivity, or the pharmacodynamic mechanisms responsible for variable drug actions. Whereas pharmacokinetics (PK) refers to the relationship between the drug dose and the resulting tissue or plasma concentrations, pharmacodynamics (PD) describes the relationship between drug concentration and its effects (Roden and George, 2002). This means that, as Nayak observes, patients may have identical drug concentrations, but their response can nonetheless vary significantly.

In contrast to the relatively mature science of studying genetic variants in the proteins that accomplish drug metabolism, methods to evaluate pharmacodynamic differences such as, here, the sensitivity of drug receptors or target molecules, are less systematically standardised (ibid.). Respondents confirmed that PK differences were better known as they were more amenable to experimental testing, and Nayak's description of these observations as something she cannot "put her finger on" implies the dearth of research available on PD effects, especially in Indian patients. As such, Nayak's identification of variation is based on her experiential, observational knowledge rather than the often automated and overly abstract knowledge produced by Evidence-Based Medicine (EBM). Though the two approaches are not irreconcilable, EBM is still in a nascent stage in India due to its inherent complexity and prevailing misperceptions, its absence in the medical curriculum and the unawareness of practicing clinicians (Agarwal et al., 2008). Not least, limited resources and biomedical infrastructures mean that systematic reviews are yet to realise their benefit in many countries in the Global South that are subject to imminent public health crises (Feierman, 2011).

Given the increasing dominance of EBM and its hierarchisation of knowledge that favours some form of evidence over others, observational or non-experimental claims may find it harder to convince an international clinical research audience which, as shown, is often recalcitrant to approve changes in global study protocols

such as different dosing requirements. As experimental research is a recent introduction to the Indian medical infrastructure, the evidence base of local researchers' claims is often observational, but forms of data not informed by what is considered defensible science are regarded as biased, less internally valid and difficult to standardise. Dr Arun Bhatt, CEO of CRO ClinInvent in Mumbai, aptly sums up the issue at stake:

> One would assume that they [Indian patients] are like any other Western patient, but we are not, actually! But we don't have so much data in India to say [with certainty] whether the patients are behaving differently (Dr Arun Bhatt, physician and CEO of CRO ClinInvent, India, March 2015).

Indian clinicians tacitly know that their patients' responses vary but there is limited or 'inadequate' data to prove this hypothesis. While in the Global North, information and biomedical knowledge continuously flow between research settings and clinical practice, Indian doctors often have fewer possibilities for comprehensive clinical research. Interest in addressing this lacuna appears limited given the primary objective of Indian trials to add value to Western drug markets (Sunder Rajan, 2006).

Despite the problems of EBM and its illusion that, as historian Steven Feierman (2011) argues, one can eliminate the fuzziness of clinical judgements, the limited evidence on differential drug reactions available in India means that Indian patients' biological characteristics are either compared against datasets extrapolated from European populations, as shown earlier, or that Indian doctors make use of other, 'good enough' evidence to predict a specific response. Dr Khan in Hyderabad recalls the challenges he faces when determining ideal doses of drugs (study drugs as well as co-drugs and controls), here the anticoagulant warfarin, for Indian patients:

> In the West, we have a good amount of infrastructure to genotype for a few drugs. For example, there is [the] drug called warfarin, the blood thinner. Right now, we do a genotyping, before giving a dose, we do a genotyping of each individual. Because the concern is intracranial bleeding. . . . So, some of the very critical drugs we do individualise based on ethnic disposition as well. . . . [But] only in the West we have a

> formula which is being computed, so what we call nomograms, n-o-m-o-g-r-a-m-s, where we do consider the genotype of a subject, for dosing such drugs. Because genotyping comes with its cost. So, we can find out the patients' body height, body weight, genetic disposition, it becomes easy to give a dose like that. But it cannot be done everywhere, every subject across the globe. . . . [In India] we do have a form, without doing a genotyping, because it's only the dose titrations, dose titrations are just like, I will not use the word 'trial and error', I will not use the word 'trial and error', it is [hesitates]—learning how do they respond. So, based on that, the physician gives the dose. But the point is, it is, I will use the word, 'a calculated risk'. The physician has to take a calculated risk for providing these type of blood thinners (Dr Mansoor Khan, clinical pharmacologist, multinational pharmaceutical company, India, March 2015).

In contrast to the precise algorithms for the individualised and safe calculation of warfarin doses available to clinicians in the West, Indian doctors are forced to treat their patients with much less sophisticated biomedical technologies at hand. Though, as I will explore in Chapter 9, Indian pharmacogenomics start-ups are working towards developing various genetic tests specifically for the Indian population, so far physicians need to take the "calculated risk" of triggering an intracranial haemorrhage, a serious and potentially fatal medical emergency. As Khan emphasises, this is not the result of bad will or lack of expertise but of the questionable applicability of specific technologies to the Indian context and the limited resources available to Indian researchers. Here too, physicians need to painstakingly discover their patients' responses rather than drawing on verified empirical data. Making existing databases work for their own patients' clearly is an emotionally taxing endeavour given the potential risk of failure that may, at worst, result in a patient's death. Respondents therefore stress the need for more evidence tailored to local disease conditions and bodily constitutions rather than operating with biomedical technologies approved for patients elsewhere.

Of course, the consistent administration of drug dose regimens is a core concern in harmonising processes and the selection of sites. Respondents emphasised that from

the early planning stages, the assessment of standards of care is incorporated into the design of multi-regional studies. Countries deviating from an established standard may be excluded. However, as the examples above suggest, this poses a dilemma for Indian researchers who insist on their patients' need for varying doses. They struggle to back up their claims with 'acceptable' evidence, illustrating the collision of varying epistemic regimes—though, of course, these cannot be neatly mapped onto a global/local binary. Khan's example demonstrates that the biotechnological infrastructure to provide identical and/or appropriate diagnostics and treatment may simply not be there, precipitating a professional and emotional impasse for local investigators. Again, physicians need to weigh the necessity of obtaining research funding with their patients' needs as well as their own ethical commitments.

I cannot elaborate on the predicaments of implementing Evidence-Based Medicine in India within the scope of this chapter (for a more comprehensive discussion see Feierman, 2011; Greenhalgh et al., 2014; Wenzel Geissler and Molyneux, 2011). Neither am I able to expand upon the lack of evidence about pharmacodynamic variability or other observed variations described as ethnic. Rather, the point here is that the management of human variation in global clinical trials is no straightforward technical process but fundamentally a question of (postcolonial) power dynamics and hierarchies in knowledge production. The cross-regional comparison of ethnically diverse patient cohorts in hugely disparate socio-economic settings significantly challenge the notion of bodily commensurability and operational comparability. Moreover, the burden of establishing such comparability largely lies with local investigators who translate and negotiate differential value systems and existing standards. The examples in this section deal a blow to the notion that established biomedical knowledge is both *available* and *applicable* to everyone. The concepts and technologies supposed to seamlessly circulate across the globe are not immutable mobiles (Latour, 1987), as I move to illustrate, but are modified, transformed and hybridised in the process. Their standardisation requires the labour, I argue, of a variety of on-site actors.

7.4 Immutably mobile? The politics of meat consumption and the hybridisation of science

One of the most significant extrinsic determinants of variable drug responsiveness is food intake (see Chapter 5). Though the standardisation of diets is exceedingly difficult beyond the confines of the clinic, Phase I and bioequivalence studies carefully monitor their participants' dietary patterns. As the nutrient and caloric contents of different foods as well as their temperature and volume can significantly alter a drug's transit time, dissolution and availability, an essential component of most early phase studies is the collection and comparison of dietary histories (Frackiewicz et al. 1998: 72). Uniform diets are administered and regulatory agencies such as the FDA recommend the use of high-calorie and high-fat meals (FDA, 2002). Here, meals should ideally derive around 150, 250, and 500–600 calories respectively from protein, carbohydrate and fat; as an example, the FDA describes a breakfast consisting of two eggs fried in butter, two strips of bacon, two slices of toast with butter, four ounces of hash brown potatoes and eight ounces of whole milk (FDA, 2002: 5).

The standardisation of dietary regimes across trial sites appears a straightforward process, but performing such studies in India entails unforeseen complications for medical researchers and patients alike. Food, as argued in Chapter 5, cannot be reduced to its chemical content but is embedded in and shaped by myriad social and cultural practices. As described, eating and feeding are inherently contingent and culturally specific processes that do not easily transcend the plethora of boundaries characteristic of multi-regional clinical research. Dr Marthak of Lambda, for example, recalls a recent bioequivalence study he conducted for an FDA submission when we sat down for a (vegetarian) breakfast in leafy Powai, an affluent, upper middle-class neighbourhood in northern Mumbai. Though making me feel equally out of place, the five-star hotel in which we met provided a stark contrast to Nayak's overcrowded public hospital, demonstrative of Marthak's financial success in the lucrative clinical research sector and the discrepancies between local healthcare infrastructures and industry-sponsored biomedical research. Speaking to the challenges his company faced with standardised trial protocols, Marthak especially emphasises the administration of uniform diets:

> In Gujarat, [the] majority of the population is strictly vegetarian. And USFDA recommends a particular kind of breakfast, which is 60% high protein, 20% high fat, and 20% carbohydrates, and that will include essentially the non-vegetarian diet, with beef inside. And, you know, the population who is only vegetarian, they cannot take that diet, so they replace it with the equivalent calories coming from [a] vegetarian diet. And until now, USFDA was accepting it, but now, for certain products, they are not accepting it [anymore]. They want the similar breakfast as the Americans eat. That will include sausages, ham, etc., so that is why some of the companies, they insist that we should give the breakfast as recommended by the USFDA that includes sausages (Dr Kiran Marthak, CEO of CRO Lambda, India, March 2015).

Though FDA guidance (2002) declares that substitutions in the test meal are acceptable if they provide comparable amounts of calories in the required breakdown, in Marthak's experience the agency increasingly insists on specific foods to be administered, including non-vegetarian items such as sausages. More specifically even, as he smirks, *specific kinds* of sausages are prescribed:

> And that is a Canadian sausage which is, I don't know whether [a] Canadian sausage differs from [a] US sausage [or] differs from German, I have no idea! Because I don't eat sausage, so [laughs]. But they insist on it [shrugs his shoulders]. So now slowly they have been sending letters to companies saying that this time we're accepting it, but subsequent molecules please insist on the American breakfast, so that it matches what the Americans eat, so that they can see how that product will behave when the Americans take their breakfast or American food and not the Indian food (Dr Kiran Marthak, CEO of CRO Lambda, India, March 2015).

His tongue-in-cheek acknowledgment that he himself did not consume any non-vegetarian foods, much less could differentiate between Canadian, US-American or German sausages, exemplifies the out-of-placeness of such foods in India, and especially the north-western state of Gujarat. Gujarati culture upholds strong

adherence to a pure vegetarian lifestyle,[34] a result of the presence of both large Hindu Brahmin and Jain communities but also of local Muslim saints (*pir*) (Ghassem-Fachandi, 2011: 94). Spiritually-motivated vegetarianism as part of the doctrine of *ahimsa* (non-harm of any life form) is core to these communities, and the administering of non-vegetarian foods is strictly forbidden. Writing on the mobilisation of vegetarianism and animal sacrifice for *Hindutva* politics in Gujarat, cultural anthropologist Parvis Ghassem-Fachandi argues that this means that "one can easily encounter members of groups . . . reacting with a cringing face recoiling from the mere mention of meat consumption" (ibid.).

Dr Marthak himself did not appear to find the incidence particularly noteworthy, but considering the state's bloody history of intercommunal violence which resulted in the murder of at least 2000 people in the 2002 massacre alone (Jaffrelot, 2003), the recommendation or consumption of non-vegetarian foods is certain to be a source of conflict between sponsors, investigators and patients. Meat, in Gujarat, is not an inanimate, indifferent substance but very much alive through a plethora of significations and meanings that inform an equally diverse array of actions and reactions. As Ghassem-Fachandi (2011: 91) puts it, "the affect of disgust for meat has become an important cultural relay in the vegetarian politics of the state". The disgust for or rejection of meat consumption is an expression of a sensitivity that is increasingly conceived as an indicator of non-violence, and therefore also of Gujarati identity and citizenship itself. Though Marthak's example does not neatly map onto the sectarian violence between the state's Hindu and Muslim populations, the charged symbolics of meat consumption looms large in the offshored clinical trials he manages.

The ethics and politics of vegetarianism are crucial to the biomedical practices of Gujarati researchers themselves. The compliance to FDA dietary standards does not imply the mere imposition of unfamiliar cultural regimes on Indian patients but interferes significantly with local scientific practices, too. Marthak explains:

> In our Ahmadabad unit, we do not give non-vegetarian at all, even if the sponsor insists, we decline the study in Ahmadabad, because the

[34] Pure vegetarianism is a slightly ambiguous term that usually refers to a vegetarian lifestyle that also abstains from consuming eggs, and often onion, garlic as well as root vegetables and potatoes. In Jainism in particular, the principle of *ahimsa* extends to the non-harming of microorganisms that may be injured when uprooting onions or root vegetables.

> owners of the CRO they are from [the] Jain religion, and they are very strict about something like this. We also have a temple in our institute, in our building, so being a so-called religious place, they do not want to administer the non-vegetarian diet to our subjects. So, what we do, in our Mumbai unit, it is a unit which is in a business building, we occupy only two floors out of the thirteen floors, so there is no temple or anything like that. So, recently, just about a year ago, we started taking those studies, those products for which they want to give the non-vegetarian diet, and in Mumbai you can find a number of people who eat non-vegetarian, so we take such studies to our Mumbai unit, we don't take it up in our Ahmadabad unit (Dr Kiran Marthak, CEO of CRO Lambda, India, March 2015).

As this quote shows, the Ahmedabad clinic is owned and run by Jain doctors whose ethical principles are trampled on by the prescription of 'American breakfasts'. Such regulations compelled the doctors to decline studies requiring the consumption of animal products, and therefore to choose between exercising their profession and adhering to their religious and ethical beliefs. The clinic in Mumbai, in contrast, faced fewer ethical quandaries and problems recruiting non-vegetarian participants. Its location in a commercial building, as Marthak concludes, made it a 'secular' and therefore a more 'appropriate' space for biomedical experiments aligned to US-American standards.

The relocation of such trials to secular clinics or trial units requires not only substantial logistical efforts. It also asks of doctors to renegotiate the limits of their ethical beliefs, and to reconsider the relationship between their moral, political and religious objections and professional obligations. This, of course, is a longstanding debate in healthcare delivery. A study conducted amongst US-based physicians found that 63 per cent of doctors agree with the statement that it would be ethical for a physician to describe their moral objections to a specific procedure or treatment to their patients (Curlin et al., 2007). 71 per cent opined it was permissible for the doctor to refer the patient to someone who does not share these objections. Though the study was conducted in the United States, it is likely that a majority of doctors share a commitment to maintaining their ethical integrity when confronted with religiously or morally objectionable practices. In Marthak's case

though, referring patients would have meant to reject the study itself, possibly implying the physicians' loss of their livelihoods, had they not been able to move the study to the subsidiary in Mumbai. Their case is akin to Nayak's example in that the choices available to them were limited to conforming to existing standards laid out in the protocol or opting out of the study altogether, potentially resulting in the lack of valuable research funding and career opportunities. When global protocols contravene local value systems, it is resident doctors who bear the brunt of negotiating, translating and managing potential discrepancies—and face the consequences if they do not.

The example also illustrates the intrinsic entanglement of science and religion in India, an intersection often perceived as threatening medicine's secular logic. Modernity's project of banning the mythic, the religious and the spiritual from the scientific realm has meant that, as James A. Boon argues, "religion gets safely tucked away—restricted theoretically to 'meaning' rather than power" (Boon, 1998: 245 in Whitmarsh and Roberts, 2016: 204). This neglects the character of medicine and religion as co-constitutive rather than mutually exclusive, and often serves to project religiosity onto those who endorse other cosmologies while retaining medicine's appearance as secular science (Langford, 2016; Whitmarsh and Roberts, 2016). The Jain doctors' refusal to compromise on religious conventions portrays their interpretation of biomedicine as fundamentally incongruous with the principles of experimental science. The Jain clinic appears as the antithesis or as disruptive of modern biomedicine that requires study sites and human biologies to be 'neutral' and essentially exchangeable. Though Marthak did not state this explicitly, it can be assumed that the doctors' religious and ethical commitments were not exhausted by their refusal to handle non-vegetarian foods but also blended other spiritual elements into their practice.

Such hybridisations of scientific practice, the "postcolonial provincializing of 'universal' reason" (Anderson, 2002: 643), considerably challenge the assumption that science is an immutable mobile (Latour, 1987). When biomedical practices move between and across different usages, cultural settings and geographical locations, they come to bear the imprint of their specific social and political environments. Though they are mobile, their meaning or structure is not fixed. It emerges through multiple contingent and relational processes, informed by the embodied and contextual practices of researchers themselves. In the example of the

Jain clinic, the doctors' synthesis of spiritual and scientific elements is generative of a hybridised form of biomedical practice that is not easily compatible with a trial protocol that prescribes consistency and uniformity across different sites. Protocols need to be carefully modified to accommodate for local peculiarities, or, if not possible, declined and moved elsewhere. This means that their cross-cultural and cross-regional comparability, and the compatibility of the specific bodies they produce, is not a given but requires the concrete logistical, cultural and often emotional labour of calibration, negotiation and translation. Here, it also requires the identification of concrete study sites and bodies deemed most suitable to epitomise 'American' bodies: to state the obvious, the objective is not to make these bodies comparable as such but to align them with presumably homogeneous American ones (see also Chapter 6). The task for Indians is to resemble or *mimic* (Bhabha, 1994) these as closely as possible.

Though I do not wish to suggest a one-way relationship in the way scientific practices travel from the 'centre' to the 'periphery' where they are absorbed to a greater or lesser degree (Prasad, 2010), it is important to bear in mind that India's primary function in global drug development processes is to deliver data that is directly expendable for Euro-American markets. India's transformation from manufacturing generics to conducting contract work has meant that its role in and for global pharmaceutical capitalism is largely limited to the provision of experimental bodies. Indian philosopher of science Ashis Nandy notes, albeit in a different context, that "the role of Indians is to collect and package the data. In societies that have gone through that kind of socialization, it is difficult to define yourself as a theorist" (2006: 120). Adapting Nandy's intervention for the context of biomedical contract research: Indian practitioners' function is largely to collect and deliver clinical data rather than drive fundamental decisions over the design of global clinical trials. This means that the way clinical research travels to India is often a more unidirectional process than expected, and much work by local experts goes into translating and adjusting local conditions to global protocols.

7.5 "Let the wife go": Gendering the abstract subject of clinical research

While the focus of this chapter is not the ethical challenges of conducting cross-cultural research *per se*, attending to the ways in which the idea of the standardised

human subject is translated, or fails to be translated, to Indian contexts also offers interesting insight into the management of human diversity in multi-regional trials. Chapter 5 has shown that cultural factors are explicitly seen as being part of the conglomerate constituting ethnoracial diversity for my respondents. The notion of the human subject is thereby perhaps one of the most important concepts illustrating biomedicine's "universalizing rhetoric" (Jasanoff, 2005: 15) and, as such, key to the comparability of datasets across sites. However, it has also been found to reflect Anglo-American rather than universal values (Lederer, 2004), and to have little significance in, for example, Buddhist societies that reject its individualised conception of the human (Sariola and Simpson, 2011). Here, I shall look more closely at the challenges that local conventions around gender and cultural propriety pose to the autonomous subject, stressing the effort that goes into making Indian patients compatible with operational and ethical standards in multi-regional clinical research.

The idea that medical research participants should be autonomous and freely consenting, codified in international guidelines such as the Nuremberg Code and the Declaration of Helsinki, was set out to safeguard individuals from the power of medical institutions and the state. In the aftermath of World War II, never again should medical researchers be complicit in atrocities comparable to those committed by Nazi physicians. But humans rarely exist in isolation, and the governmentalities attached to the (neo)liberal, autonomous individual foreground the complex entanglements of biomedicine and power. More specifically, they point to the ways in which particular subjectivities emerge within specific regimes of power and thus call attention to the importance of place and context. As bioethicists Salla Sariola and Bob Simpson argue, "subjectivities are locally specific and situational, pointing to the need to understand context-specificities when analysing the construct of 'the subject'" (2010: 517).

During my fieldwork, I have come across multiple examples in which doctors and investigators formally embraced the conception of the human subject but cited several cases that highlight its incongruity with their specific research contexts. Dr Mishra, for instance, recounts:

> Also, from a social, cultural perspective, you might have certain criteria in the protocol. For example, . . . audio-video consent. . . . Women may

> not want to be videotaped. And a lady in a burka may even be more averse to that. Or you ask questions around pregnancy tests etc., some parts of the community may be most unhappy about such questions being asked though it's being asked from a scientific perspective. Definitely those cultural issued may be factored in (Dr Sonali Mishra, consultant for the pharmaceutical industry, India, March 2015).

Also consider this incidence recalled by Dr Nath:

> We've had quite a few women who were pulled out of the studies by their husbands. In one of the Phase I studies, we were administering, some hormone was involved, I can't recall, this was about 7 or 8 years ago, so this lady had to stay at our Phase I facility overnight and we conventionally ask the spouses to come along, see the place where they're staying etc., etc., so that there is a comfort. We don't have to, but you let them in. So, everything was fine, this lady has consented etc., 11 o'clock the husband came and said, 'I don't want her to stay here'. So, the site was under security and all, there were investigators, doctors etc., there was no standard procedure what to do if a spouse comes and says, 'let the wife go'. The wife was asked, and she said, 'no I don't want to go back' and the spouse called police. So, [the] police also didn't know what to do. . . . I think about 2 hours later, maybe 1:30 am, the investigator decided, send the woman home (Dr Prashant Nath, CEO of CRO, India, March 2015).

In both cases, the fundamental philosophical principle of biomedical experimentation, the choice-making, self-governing and freely consenting individual, is jeopardised by cultural expectations around gender and religious propriety. The second incidence especially illustrates the husband's socially-sanctioned authority over his wife's participation in the study. Though she had formally given and confirmed her consent to take part—notable itself given the large number of Indian women who decline participation as they did not feel in a position to make independent choices (Gitanjali et al., 2003)—the spouse was given the final word in the decision. In the absence of a standard procedure, the principal investigator turned to culturally entrenched criteria that frequently continue to

privilege men's views over women's and discharged his patient against her will. Of course, I do not wish to argue for the existence of what feminist scholar Chandra Talpade Mohanty refers to as "Third World Difference", a "stable, ahistorical something that apparently oppresses most if not all the women in these countries" (1984: 335). However, the incidence reflects, to some extent, what Turkish feminist Deniz Kandiyoti calls "classic patriarchy" (1988: 278) to denote the often patriarchal nature of decision-making in South Asia and elsewhere.

Two points are of note. First, most sociological and bioethical research has focused on gender norms impeding on women's autonomy to give informed consent in the first place due to their embeddedness in male-headed households and extended families (Lomelino, 2015; Pratt et al., 2013; Sariola and Simpson, 2011). Here, however, the female patient had consented to participate, perhaps engaging in acts of what Kandiyoti (1988: 275) refers to as "patriarchal bargains" to describe women's agency and the ways in which they strategise within a set of concrete societal constraints. However, she was denied participation *ex post* by the patriarchal bond between husband and investigator. This means that ethnographic analyses of the obstacles to responsible research should not be limited to the consent process but engage the myriad ways in which specific gender roles inflect the research process as a whole. And second, the nature of the specific trial itself may have amplified the tensions between presumably universal biomedical principles and local gender regimes. Though Dr Nath did not recall the precise molecule under study, the fact that "some hormone was involved", as he says, suggests it was a study related to women's reproductive capacities. As female reproduction has always been a central site for patriarchal and biopolitical control— feminist theorist Jana Sawicki (1991: 193) argues that reproductive technologies constitute "a disciplinary technology of sex that was developed and implemented by the bourgeoisie at the end of the eighteenth century as a means of consolidating power"—the two men's authority over the woman's body is reiterated by a long trajectory of sexual domination.

The cases demonstrate that the autonomous subject which biomedical research promulgates does not necessarily connect to local values and concerns. Though international guidelines exist and the investigators involved in clinical trials work hard to standardise procedures within global frameworks, subjectivity is not, as Sunder Rajan (2005: 150) puts it, a "placeless" concept. Rather, subjects are shaped

and actively constructed by the concrete particularities of location, power, and history. In South Asia, it is often the extended and male-headed family, not the individual, that is the locus of decision-making. As a Sri Lankan clinical research professional interviewed by Sariola and Simpson (2010: 517) proposes, South Asian bioethics should be more "family-centred", incorporating responsibilities and duties towards others rather than framing the consent process as a matter of individual rights. Such demands are only reasonable as the family occupies a central status in ensuring the material well-being of women and is often the only form of 'welfare' or social insurance given the absence of state-sponsored social securities. Especially in socio-economically deprived settings, the allocation of scarce resources inevitably requires the family's involvement. However, giving more weight to collective decision-making also compromises on the principle of the autonomous human subject.

Let me illustrate this point with another example. The following excerpt is from the same interview with Nath:

> Another situation, this happened quite a few times, Muslim women in burqa, in veil, they don't want to show that they're the same person who is participating in the trial. Sometimes they would come in jeans and . . . next time when they come, they're having some male accompanying them. There are no jeans, there are no T-shirts, they're in veil! [First, they agree] and on visit number three, some male is accompanying them, so, you lose a patient suddenly. . . . And the woman wanted to participate even on visit three, but she didn't want to show her face, so the investigator said, 'I don't know you as a patient' (Dr Prashant Nath, CEO of CRO, India, March 2015).

A similar logic is at play in this example though the woman is not directly coerced into withdrawing from the study. In fact, she even challenges existing, gendered (religious) norms by dressing in jeans when unaccompanied and by insisting on her right to participation. Ultimately, however, the unidentified male family member escorting her exerts control over her dress code to ensure it conforms to local norms around religious and cultural propriety. Though she was officially allowed to participate in the trial, the Islamic custom of wearing a burqa prohibited the male

investigator's ability to identify her as his patient such that she was discharged from the clinic.[35]

This example also illustrates the tensions between abstract biomedical principles and local value systems and practices. The woman's adherence to an Islamic dress code in the presence of the investigator, though not entirely voluntary, can also be read as a refusal of the biomedical gaze that is also always a *colonial* gaze claiming unmediated access to and control over her body. As postcolonial scholarship has shown, the colonial gaze has always been obsessed with lifting the veil that limits the reach of its power (Yegenoglu, 1998: 62). In Frantz Fanon's words, "it was the colonialist's frenzy to unveil the Algerian woman, it was his gamble on winning the battle of the veil at whatever cost" (1965: 46–7). Here, the biomedical/colonial gaze seeks to, quite literally, unveil the woman; however, it does so not through coercion but through biomedicine's more subtle claims to rationality, effectivity and care (Miller and Rose, 1993). The investigator's statement, 'I don't recognise you as a patient', works to discipline the woman's conduct through the evocation of biomedicine's authority. Participation in the modern project of clinical experimentation is granted only upon the submission to its desire for transparency and surveillance. The female patient's autonomy to participate is thus compromised by the domination of the patrilocal family, religious conservatism as well as the penetrating gaze of modern biomedicine. Again, my intent is not to proclaim a homogeneous notion of oppressed women in India, or the Global South more broadly, but highlight some of the challenges to global clinical trials engendered by local social practices and value systems.

Shedding light onto the non-linear entanglements of Indian culture and global biomedicine, I also wish to problematise the proclamation of some unbridgeable rift between a universal science and deviating Indian practices. The investigator's multiple positionalities and allegiances—as a man, an Indian, a physician, perhaps a brother and husband himself— complicate notions of clear-cut, binary antagonisms between the global and the local. What the empirical examples stress is that it is precisely the generalisation of scientific practices and bioethical standards that produces local variability (Petryna, 2005a). As Sunder Rajan (2005: 150) aptly

[35] Many Indian women of all religious affiliations cover their hair as a symbol of modesty; wearing a headscarf or veil is often a cultural rather than a religious custom. Here though, Nath clearly identifies the veil as a burqa and thus an Islamic (cultural or religious) garment.

argues, "the replication of an epistemic system, in which the science is resolutely the same whether performed in India or the United States" must inevitably lead to incongruent manifestations of subjectivity in the two contexts. It often does so "in ways that allow one (Indian) to be conceived and written of as particular, localized, contingent, and 'empirical', and the other (American) to be conceived and written of as general, subscribing to epistemic rationality, placeless and 'theoretical'" (ibid.).

The multiple and complex entanglements of experimental science and culture mean that substantive effort must be made to negotiate, translate and accommodate a whole variety of factors for clinical trials to travel successfully across sites. Clearly, such processes are messy and often contradictory. The examples in this chapter question the assumption of a seamless distribution of scientific and ethical principles in trials around the globe. Nonetheless, this does not imply, as Petryna (2005) rightly points out, that variability or particularity mean to evoke cultural relativism, and medical anthropologists have repeatedly warned of the potential dangers to the very people and practices they have sought to understand by retreating to a protection of cultural difference (Farmer, 1999). Any blind defence of local culture against universalist principles may make itself complicit in, here, the marginalisation of women and the further entrenchment of inequality. My aim was merely to emphasise the frequent incongruity of the notion of an autonomous research subject with local ethical principles, and the effort needed to make Indian trials compatible with established standards of clinical research in offshored contract work.

7.6 Conclusion

This chapter has illustrated through empirical data that multi-regional clinical research cannot merely harness the intrinsic comparability of experimental bodies. Rather, it needs to produce them as similar or compatible through the day-to-day implementation of a range of formal or informal standards in transnational scientific collaborations. Such standards often reflect the social and biocultural specificities of those with the power to determine international scientific agendas. As such, they do not always connect with local value systems and may not be appropriate or applicable to the specificities of local biologies. Though modern biomedicine derives much of its power from its claims to universality, much effort goes into the

translation and harmonisation of bodies and practices in order for clinical trials to travel across different sites. I have proposed that comparable research subjects need to be made, not simply enrolled, and that the processes of making bodies and research participants comparable render visible the concerted, and often unsuccessful, translational labour by investigators on the ground. In the next chapter, I build on these arguments to discuss the overlapping and sometimes contradictory representations of and interests in Indian diversity by the multinational pharmaceutical industry and Indian public genome research, illustrating existing discrepancies between the objectives of multi-regional clinical trials and public health.

Chapter 8: Public health genomics meets Big Pharma: Indian DNA between genomic sovereignty and biopiracy

> India actually is the ideal genetic milieu, is ideal for clinical trials, ideal for drug response measurement, because it has an enormous genetic diversity that almost covers the world diversity (Professor Samir K Brahmachari, biophysicist and medical geneticist, public sector, India, February 2017).

> Ethnicity is not important for my work because I only focus on India (Dr Shifa Abbasi, medical head, multinational pharmaceutical company, India, March 2015).

While the Indian population is construed as *almost* Caucasian for the purpose of global clinical trials, Indian geneticists foreground its internal heterogeneity. In 2008, the Indian Genome Variation Consortium (IGVC), a government-sponsored network of six prominent laboratories under the purview of the Council for Scientific and Industrial Research (CSIR), announced the first findings of its five-year research project. Mapping the country's genetic substructure, the IGVC eliminated, once and for all, the idea of a homogeneous Indian population. In fact, its founder Professor Brahmachari declared in the Indian business newspaper *Livemint* that the very concept of 'the Indian' was a "misnomer in population genetic studies, as it indicates the population to be homogenous. This is evidently now untrue" (in Koshy, 2008: n.p.). The focus of the IGVC was thereby both to understand India's vast genetic diversity and mobilise it for the creation of a predictive population database to facilitate research on differential disease susceptibilities and drug reactions in the Indian population (Hardy et al., 2008; Seguín et al., 2008b). Similar to other pharmacogenetic research initiatives in resource-poor settings, the genetic diversity of the Indian population was heralded as harbouring the potential to contribute relevant information for public health.

In this chapter, I juxtapose the perspectives, aims and objectives of the international pharmaceutical industry I have previously explored (see Chapters 5 and 6) with

those advanced by the IGVC as the so far largest, publicly funded genetic research initiative on Indian population diversity and public health. Drawing on published materials, policy documents and additional primary data from a personal interview with Brahmachari, I explore not only their potentially contrasting accounts of Indian diversity, but also the different (bio)political projects driving them.[36] In other words, I am interested in the differing kinds of populations and publics (Hinterberger, 2012b; Reardon, 2007) outsourced drug research and national biobanks envision, and what these can tell us about the specific ways in which the Indian population's biological properties are mobilised in new forms of genomic sovereignty. By foregrounding national, publicly funded initiatives to harness Indian genomic diversity, the chapter not only extends the prior discussion of global clinical trials but also contributes to a deeper understanding of the value of Indian DNA in both the symbolic and material sense.

The chapter illustrates that while the IGVC can be seen as an expression of genomic sovereignty claims, it shares with other governmental and private actors the explicit aim of promoting India as a global player in the bioeconomic arena, mobilising Indians' unique genetic qualities in complex and often contradictory ways. In doing so, it cooperates with the multinational industry conducting clinical research in India, often compromising its claims to national ownership of DNA and its aims to foster social cohesion. Drawing on Ong's (2001) formulation of graduated sovereignty, I argue that India's version of genomic sovereignty is *graduated* in that it significantly overlaps with global market flows, often mobilising different populations and their molecular qualities according to rational economic calculations. As Ong argues, the model of graduated sovereignty allows us to abstain from positing the market and the state as adversaries and to focus on their dynamic interactions instead. Considering these multiple politics of life (and death) contributes to a more nuanced assessment of the intersections of the postcolonial state, novel biotechnologies, global markets and the enduring appeal of Indian population diversity.

The chapter proceeds as follows. First, I will introduce the IGVC against the larger backdrop of emerging human genome research in the Global South. I then place it

[36] I initially sought to secure additional interviews with four other, prominent IGVC geneticists via skype or phone. Yet, despite their agreement to be interviewed and my repeated attempts at setting up a concrete date and time, only Brahmachari eventually granted me a one-hour interview via telephone (see Chapter 3 for a discussion of the limits of this research).

in conversation with the aims and objectives of the global drug industry to discuss the numerous ways in which Indians' genetic properties are procured as a valuable and highly versatile resource. Section 8.3 moves to discuss the IGVC's ambitions to foster national cohesion, illustrating the contributions of genome research in shaping novel forms of genomic sovereignty and bionationalism. Having assessed the differential biopolitical objectives driving research on genetic variation and the globalisation of clinical trials, section 8.4 will argue that we need to recognise the inherent tensions in how the Indian population is mobilised between the postcolonial pursuit of scientific autonomy and the vectors of global biocapital. I propose that the rhetoric of and policies around genomic sovereignty are graduated since the state and India's biomedical elites make available the country's often vulnerable population groups for corporate biomedical research because of their genomic qualities. The simultaneity of strategies of 'making live' and 'letting die' challenge the assumption that contemporary biomedical technologies aim exclusively at fostering life beyond race, class, caste and nation.

8.1 Mapping the Indian population: the IGV predictive database

In line with similar studies on genetic diversity such as the International HapMap Project and the HUGO Pan Asian SNP Consortium, the IGVC set out to uncover the genetic structure of the Indian population. During a telephone interview in February 2017, Samir K Brahmachari, the renowned IGVC founder and former secretary of the Indian Department of Scientific and Industrial Research, explained to me that social groupings do not calibrate with scientific findings on population substructure. Nonetheless, the IGVC was explicitly motivated by the concern over the lack of adequate South Asian samples in the HapMap Project. India's vast genetic diversity, Brahmachari argues, could never adequately be represented by the 30 samples that HapMap had allocated to Asian populations; therefore, participating in the HapMap with 30 samples "did not make any sense to us". Shortly before the completion of HapMap in 2005, the Consortium announced the creation of its own database (hereafter IGVdb). This database was based on research on validated SNPs in over a thousand genes through sampling 15,000 individuals based on ethno-linguistic and geographical criteria (IGVC, 2005).

The findings of the IGVC eliminated, once and for all, the idea of a homogeneous Indian population. Through sequencing multiple candidate gene loci in a diverse sample, researchers identified and validated 420 SNPs that were then typed in 55 Indian populations selected through linguistic, geographic and socio-cultural factors (IGVC, 2008). The results revealed, for example, that large, Indo-European speaking populations and castes significantly differed from Indo-European tribal populations, possibly due to the antiquity and relative isolation of many tribes. Fewer differences were found between geographically distant groups. This confirms earlier findings based on frequencies at blood group and enzyme loci (Piazza et al., 1980) and suggests that tribal versus nontribal identity as well as linguistic and geographic criteria are the major determinants of genetic affinities between different Indian population groups. Overall, the IGVC suggested that the four main linguistic families of Indo-Europeans, Dravidians, Tibeto-Burmans and Austro-Asiatics reliably map onto genetic groupings.

According to the IGVC, diversity and endogamy make India the ideal ground for gene-association studies for many common complex diseases and clinical research on drug response. Isolated populations facilitate gene mapping and research in predictive medicine due to genetic homogeneity. IGVC researchers emphasise that the relative isolation of Indian subpopulations, considered more homogeneous than even the Icelandic population for certain genetic markers, offers an immense opportunity for gene-disease mapping (IGVC, 2005). At the same time, haplotype diversity is highly variable *between* subpopulations, providing an equal opportunity to replicate findings in other groups that are genetically similar. This means that the "genomic diversity of the Indian ethnic groups coupled with an underlying genomic unity" (IGVC, 2005: 3), or its "unity in diversity", as Brahmachari puts it, makes the Indian population uniquely suited for biomedical research.

Focusing on candidate genes as opposed to deploying GWAS technologies, the IGVC was not envisioned as a mere population genetic study but also sought to create a map of common genetic markers predisposing Indian communities to differential disease risks and adverse drug reactions. Brahmachari explains:

> We did not only want to get a neutral marker. We believed that all the markers and all the SNPs that are associated with various diseases will be important so that thereby we can also create a genetic landscape

> associated with various disease markers. Because it was not a pure population genetic study, it was also a disease genomic study (Professor Samir K. Brahmachari, biophysicist and medical geneticist, public sector, India, February 2017).

As previous research has pointed out, resource-poor countries increasingly look to the field of genomics to address inherent shortcomings in their healthcare infrastructure (Acharya et al., 2004; Aggarwal and Phadke, 2015; Hardy et al., 2008; Kumar, 2012). Genomics and resultant technologies can support existing healthcare systems by foregrounding prediction and prevention, and by decreasing the cost of healthcare through early detection and diagnosis as well as improved treatment and management regimes. The IGVC as an initiative of public health genomics clearly envisions Indian citizens, particularly those who may not be able to afford often exceedingly expensive treatments, as primary beneficiaries of this research.

IGVC researchers propose explicit links between India's diverse population and differential disease risks and drug reactions. For instance, they found that the frequency of a particular mutation of the CCR5 gene, CCR5Δ32, which is said to protect individuals against HIV infection, is around 5.8 per cent in Indo-European groups (as compared to sixteen per cent in Caucasians) while virtually absent in some Dravidian, Austro-Asiatic and Eastern populations. This suggests a high-to-low gradient from north to south (IGVC, 2008). Moreover, the efficacy of salbutamol, a drug popular for the treatment of asthma, is known to vary according to a mutation in the receptor ADRB2 (Kukreti et al., 2005). Though the differentiation is not high, the study shows that the frequency of the mutation of the ADRB2 gene differs between Indian populations, requiring in-depth studies of differential drug response. Overall, it is estimated that up to thirteen per cent of North Indian populations may not respond to 30 essential drugs (Hardy et al., 2008), and IGVC researchers have begun investigating these findings further through experimental and computational studies.

Given this procurement of Indian genetic diversity that contrasts the global pharmaceutical industry's emphasis of Indians' relative homogeneity as Caucasians, it is important to understand the political background of the IGVC, set up with the explicit aim of establishing India as a credible player in the global bioeconomic market. Two years before the launch of the IGVC, its participants had declined to

contribute samples to the HapMap Project, arguing that, besides the lack of adequate genotyping facilities, Indian geneticists "did not want only to supply samples" (Jayaraman, 2005: 493) but become equal partners in the project. Commentators presumed that Indian donations to HapMap would fall within the purview of international trade agreements, *de facto* preventing Indian geneticists from future claims to intellectual property or profits (Knoppers et al., 1997; Reddy, 2013). Though Brahmachari himself refuted such assumptions, arguing that he had sensed from the beginning that the HapMap database would be made publicly available free of cost, he nonetheless admitted that the IGVdb had had to be protected through exclusive licencing in its initial stages:

> In the beginning, we wanted to exploit it ourselves, and we did not want others to exploit it and come up with their stories that this caste is related to that caste and this and that, we did not want people to misuse it. And that is why we had to take registration of the database and people had to register to access the database. Now we have made everything open and people can come and look and utilise it (Professor Samir K. Brahmachari, biophysicist and medical geneticist, public sector, India, February 2017).

Brahmachari emphasises his team's efforts to prevent sensationalist interpretations of the data leading to social stigma through the reification of social categories. Clearly, the IGVC seeks to address the broader social and political implications of genetic research. Careful not to break the social fabric of the Indian society, IGVC researchers refused to disclose the origin of their samples to avoid any social backlash caused by genetically reified communities. In this sense, Brahmachari and his team advance arguments similar to those concerned about the molecular re-inscription of race for the genetic reification of caste and regionally specific populations. This reflects Benjamin's suggestion that genetic diversity maps not only function as a "'naturalizing' cartography of the nation" that chart the genetic inheritance of a people but also as "social maps for contemporary anxieties about social fragmentation and future cohesion" (2009: 344).

Securing intellectual ownership of the database, Brahmachari and his colleagues also wished to maximise its utility first and foremost for their own scientific and political objectives. IGVC researchers not only took a strong stance for India's

scientific autonomy but also laid claim to India's biological properties, determined to avert their capitalisation by global corporations. An expression of genomic sovereignty, emerging policies and practices through which postcolonial countries frame their increasing investment in genomics for national regeneration and public health (see Chapter 2), the IGVC exercised a kind of protective ownership of India's genetic diversity against its appropriation by global biocapital. Indeed, Brahmachari himself expresses a strong ethical commitment to questions around the ownership of tissue samples and intellectual property in the context of global scientific collaborations. When queried about his association with the United Nations Expert Group on Human Rights and Biotechnology Commission, he notes:

> I was an activist, I used to, that time, say 'no, fauna, flora belong to the nation' . . . and the people who own the land should have stakes, ownership, so you cannot just take away samples. . . . India has adopted that with a ten per cent of economic return. I, whatever money we received during many, many research collaborations and studies, we made sure that ten per cent of the money goes back to the free service, to the community. . . . There was an effort by multinationals to create a . . . genomic database, material database, by leaching immortal cell lines of quarter million Asians, and that's where I protested and said 'no, there is a right of the patient because it's he who says I have asthma, I have a problem, it is the patient and who captures it, [and] then the doctor'. So, the first intellectual property, copyright, is generated by the patient with the help of doctors. So much before those samples are analysed and genomics studies are done. So, therefore there is a right of the patient, that's what I stood for (Professor Samir K. Brahmachari, biophysicist and medical geneticist, public sector, India, February 2017).

The IGVC evidently positions itself against potential forms of biopiracy through the commercialisation of animals and plant life (Shiva, 1997) as well as of human tissue and clinical data by foreign companies (Dickenson, 2005; Lock, 2001; Reardon, 2005). This way, his claims of sovereignty over genetic materials work to insert ethical considerations into the operations of global biocapitalism, especially in postcolonial contexts marked by histories of conquest, exploitation and violence

(Hinterberger and Porter, 2012). Imbued with postcolonial sensibilities, the nation is seen as exercising a kind of custodianship over the genetic resources of its people and regulates or restricts foreign use as much as possible. Limiting access to the IGVdb and emphasising that genetic resources "belong to the nation" illustrate Brahmachari's conviction that Indian genetic resources and populations needed protection or preservation from expropriation by biocapital.

His evocation of a kind of public ownership of data contrasts the practices in the corporate world associated with the commodification of bodily tissues and the exploitation of human research participants (Hayden, 2004). The ownership arrangement envisioned by the IGVC, making data publicly available and returning ten per cent of any economic benefits to "the community", exemplifies a critical and reflective engagement with the currencies of national genomic databases and the potentially exploitative practices of biomedical research (Hayden, 2007; Parry, 2005). As Hinterberger and Porter (2012) argue, sovereignty claims by historically marginalised actors seek to reorganise sharing practices in global scientific networks to accrue benefits back to those from whom the biological resources were initially extracted. This protectionist stance around the creation of the IGVdb suggests a strong link to the Indian government's larger projects of genomic sovereignty and bionationalism to which I will return later in the chapter.

8.2 "A cocktail of the entire Indian population": Indian genomic diversity as a versatile resource

The IGVC's approach to the creation of a medical genetic database has been centrally informed by a new perspective in public health that seeks to repurpose existing generic drugs and tailor them to patients' genetic profiles. The repositioning of failed, out of patent or generic drugs has become an increasingly common strategy to tackle the skyrocketing costs of developing new compounds (Nosengo, 2016). Researchers seek to identify the molecular similarities between diseases through novel biotechnologies in ways that may significantly disrupt Big Pharma's business model. Rather than focusing on the genetics of disease progression though, Brahmachari and his team envision tapping into the country's rich genetic diversity, seeking to repurpose generic drugs that have failed to show efficacy in one population for treatment in another:

> I personally believe that it is very important that if a drug has not worked on the Tibeto-Burman populations, the Japanese, the Chinese . . . it is worth trying to see whether it works in [the] Dravidian population. And based on the genetic data information, and that is the key thing to do now, look at the adverse drug reactions of a particular drug—can we repurpose the drug for a smaller population? That's still a large population! In India, a small population will still be around 300 million people. So that's, I don't think that has been done so far, and I think this is the most challenging research project at the moment. How do you repurpose drugs for a subpopulation, thereby removing all adverse reactions? (Professor Samir K. Brahmachari, biophysicist and medical geneticist, public sector, India, February 2017)

Seeking to mobilise genetic research on the allelic variability between India's main genetic clusters, Brahmachari's approach to personalised medicine runs counter to the aim of customising treatment as conventionally understood. He hopes that the IGVdb will ensure that affordable, generic drugs will not be side-lined as safe and efficacious options in resource-poor settings. Instead of replacing them with significantly higher priced, innovation-based treatments, he seeks to validate their efficacy if given to the right patient; put differently, the aim here is not to find the right drug for the patient, but to find the right patient for the drug. This explicit link to tangible medicines and therapeutics is crucial for genomic sovereignty rights, patent claims and other appropriations of nature, as science scholar Sheila Jasanoff argues: to make proprietary claims about biological specificities and for such claims to gain traction in society, they have to materialise in concrete products "just as money historically achieved circulation through embodiment in shells, feathers, precious metals, and other products of nature" (2012: 172).

However, Brahmachari also mobilises insight into the differences between populations rather than individuals. Each of them is seen as still large enough to form a valuable patient or consumer pool. In this way, Indian diversity becomes a central resource for postcolonial genomics *and* the creation or recirculation of specific biomedical products under the aegis of public health. Ethicists Abdallah S. Daar and Peter Singer (2005) argue that in order to fully realise the benefits of pharmacogenomics, countries such as India need to consider not just genetic

variations between individuals but also between population groups. Rather than focusing on the pharmaceutical industry's "boutique 'personalized' medicine", scientists must carefully define differences between population groups and "the ethical ways of using emerging genomics knowledge to develop drugs and improve health" (Daar and Singer, 2005: 241; also Seguín et al., 2008). In this vein, Brahmachari pragmatically deploys his research findings on allelic variations between India's genetic populations to identify possible treatment options. If and to what extent genetic screening technologies will be available to identify the precise characteristics of a patient, or if more conventional means will be deployed to determine genetic belonging, remains unclear. This leaves open the possibility of the politically precarious and medically questionable geneticisation of India's myriad populations, as I will discuss shortly.

While Brahmachari and his team procure the country's genetic heterogeneity for public health, respondents working in the multi-regional clinical trials sector eschew any engagement with this heterogeneity, unless explicitly required to do so by regulatory authorities. Though IGVC scientists have elsewhere expressed hope that the predictive database would contribute to India's competitive edge by further reducing the time and cost associated with clinical trials through improved patient stratification (Hardy et al., 2008), none of the clinical research executives I spoke with had engaged with its findings. As Dr Bhatt at ClinInvent explains:

> If they plan to do an analysis of different ethnic groups, then they might be able to say something more. . . . [But] none of the protocols are designed to look at differences. They're only designed to look at the overall data of x number of patients (Dr Arun Bhatt, physician and CEO of CRO ClinInvent, India, March 2015).

Despite the aims of the IGVC to transform India into a prime location for biomedical research by sharing its findings, the multinational industry has, at least so far, defied applying data on India's population heterogeneity efficiently.

The lack of engagement with India's ethnic diversity comes despite the explicit hope by the IGVC and a recommendation by the DGC(I) itself to distribute trials equally across the country in order to explore the drug effects of India's genetic heterogeneity. Though the Indian regulator usually approves new medications without substantive testing in Indian patients, recent regulatory changes include an

expectation to distribute trials equally across the country to consider potential ethnic differences in drug response. Dr Kamireddy in Hyderabad explains:

> Also, geographical distribution. . . . This is also linked with ethnicity, India is a diverse site, North Indians are significantly different from South Indians, the Eastern population is different from the rest of the country. . . . So, for example, if I have to have ten sites, we were open to have the ten sites in a single state, or in a couple of states, but now it is mandatory that it has to be geographically distributed, like across the North, if you have ten sites, two sites in the North, two sites in the South, two sites in the East and two sites in the West, and two sites in the central part of India. It has to be at least, if not exactly, but uniformally distributed (Dr Suresh Kamireddy, CEO of CRO ClinSync, India, March 2015).

Though the government recommendations on geographic distribution remain somewhat vague, they mirror the IGVC's assertion that geography is a key driver of India's ethnic diversity and that this diversity can significantly impact individual drug responsiveness. The endorsement of analyses of potential subpopulation differences closely resembles other national moves for inclusion and participation. This is in order to examine the causalities of differential disease burdens and drug reactions, and to broaden access to potentially life-saving medicines for marginalised populations (see Chapter 2).

However, at the time of writing, the geographical distribution of trials to capture diversity was officially expected, but this recommendation had neither been codified into law, nor was it rigorously followed in practice. Kamireddy explicates:

> In terms of the clinical trial operations, like for connecting Phase II to Phase IV, yes, there is some impact, because, it is challenging, it's not easy to identify the good sites with the good insights, quality of the data. . . . In terms of the geographical distribution of sites, yes, it's challenging (Dr Suresh Kamireddy, CEO of CRO ClinSync, India, March 2015).

Like Kamireddy, other respondents stressed the challenges to implement this new expectation. This was due to the concentration of biomedical infrastructures in a few urban centres (such as Ahmedabad, Mumbai, New Delhi and Bangalore) that made the equal distribution logistically impossible, and the very methodologies of clinical trials that demand large enough populations to yield statistically significant results. But, as I will illustrate, this is also the result of the lack of interest on the side of the industry to engage population differences unless necessary, and its relative authority to enforce its interests (section 8.4). As the 2012 investigation into the DCG(I)'s practices by the Parliamentary Standing Committee on Health and Family Welfare has shown, almost one third (28 per cent) of newly approved drugs had *not* been tested in India before receiving marketing approval. Ethnic representation is also rarely considered when approving trial sites (Department-Related Parliamentary Standing Committee on Health and Family Welfare, 2012). This suggests an explicit tension between the IGVC, the DCG(I) and global trials in the country with regards to their specific valorisations of Indian genetic diversity. As shown in Chapter 6, a key reason for pharmaceutical companies to relocate their trials to India is the genetic structure of its population, considered diverse but similar enough for the purpose of drug testing.

At the same time, Mumbai in particular has emerged as a hub for global trials, not only because of the cheap labour force set free by the mass closure of the city's textile industry (Sunder Rajan, 2006), but also because it is widely regarded as a genetic melting pot. As Nayak says:

> India is a potpourri of people and that's why Bombay is a good place to do clinical research because we get the mix of patients. . . . We don't have only *Marathis*, you know, people from this region, we get people from everywhere, it's a melting pot really (Professor Tista Nayak, pharmacologist, ethics committee member at a public hospital, India, March 2015).

And Brahmachari notes:

> Most of the clinical trials are done in Bombay, and in one slum area called Dharavi, which contributes the largest number of clinical trial subjects. But that Bombay, that Dharavi is a cocktail of the entire Indian

> population. So, therefore when you go to Bombay and go to Dharavi and you sample random, you will end of with most of the Indian population represented there. So that's why Bombay has become the hotspot for clinical trials (Professor Samir K. Brahmachari, biophysicist and medical geneticist, public sector, India, February 2017).

In Brahmachari's assessment, it is not Mumbai itself that is seen as a melting pot but Dharavi—Asia's largest urban shanty town that has inspired innumerable books and films and became infamous worldwide after unwittingly providing the scenery for the blockbuster *Slumdog Millionaire*. Exemplifying the conjuncture of long-established inequalities and new biocapitalist markets, Dharavi is now heralded as the ideal site for experimental research. Of course, this poses crucial questions to the ethics of testing medicines on impoverished populations; worth noting too is that, as Brahmachari says, almost every Indian community is represented in Dharavi, providing bitter evidence of the millions that have come to Mumbai from across the country in the hope for a more prosperous life. We must also ask if the socio-economic differences between the slum dwellers of Dharavi and the future drug consumers, predominantly middle-class Indians and Euro-Americans, as well as the prevalence of comorbid infectious diseases in the neighbourhood, may not undermine the very grounds of biological comparison on which globalised biomedical research is based (Lock and Nguyen, 2010).

Yet, what is most striking in the context of this chapter is how Brahmachari himself posits the biological properties of Dharavi's populations as universal for the purpose of global clinical trials while foregrounding genetic distinctions as part of his own research on the genetics of drug response.[37] As Yulia Egorova (2010: 44) aptly observes, an enduring paradox characterises the representation of Indian diversity that constructs Indian communities as genetically *distinct* for the purposes of categorisation, as *unique* compared to the rest of humanity to establish forms of genomic sovereignty, and as *universal* for the purpose of global clinical trials. This paradox must not be a contradiction though. Rather, such multiple and diverging representations are fully internal to the logics and polyvalent nature of scientific

[37] This also neglects that trial populations in global studies have already been 'pre-filtered' qua their location in predominantly urban settings such as Dharavi. These rarely include the country's tribal or indigenous communities who, respondents suggest, often remain marginalised from or sceptical towards allopathic medicine. As such, most sampling strategies which target urban populations exclude groups deemed most genetically distinct, *de facto* engineering out potential variations.

discourses about human diversity. As I have pointed out in Chapter 5, ambiguity and contradiction can have multiple purposes for bioscience, and part of the flexibility of population descriptors is that they move almost seamlessly between distinct levels and registers of analysis. In other words, the ambivalence of genetic categories and their relation to social groupings or phenotypical markers is not prohibiting but rather fuelling scientific classifications of human heterogeneity (also see Panofsky and Bliss, 2017). This way, human diversity becomes a highly versatile and multivalent resource that can be mobilised for manifold and often seemingly opposing projects.

The ability to shift between different scalar levels and physiological descriptors means that the Indian population can be described as similar at the aggregate level of statistical medicine while foregrounding internal heterogeneity in smaller-scale or specialised studies of differential drug response. While Brahmachari and colleagues devise public health interventions based on India's genetic heterogeneity, such diversity, as the quote by Dr Abbasi in the epigraph to this chapter illustrates, plays no major role in global clinical trials. For Abbasi, Indians are homogeneous enough to act as proxies for the (presumably equally homogeneous) population of future drug consumers.

This especially holds for the conduct of so-called rescue studies, studies that begin in one location but shift to another halfway through the research, often with a new company or organisation taking over responsibility. Usually studies need to be rescued due to poor recruitment numbers leading to delays in trial timelines, out of which Indian CROs have carved a niche market for themselves. For oncology trials in particular, the range of tumour types expressed in diverse Indian patients means that CROs can be certain to quickly enrol the required number of the precise kinds of patients needed for a study. Here, genetic diversity is not the dazzling array of new opportunities to enhance the vitality of India's poor but the very backbone of mundane, outsourced contract work in the service of global biocapital.

Indeed, the notion of India as a rescue country resonates with the common representation of the country as the "back office" of the global IT revolution, taking over the "support functions" or "back office type activities" for clinical research, as Amit Wadia, a pharmacologist and diversity officer at Quintosh, puts it. Indeed, I suggest that the burgeoning field of clinical research is modelled after India's successful IT and call centre industries. Overlaps in personnel—at the ISCR annual

conference in 2015, I counted numerous managers or CEOs of CROs whose careers began in the software or call centre sector—and industry self-descriptions clearly mirror the representations and economic optimism of the *India Shining* campaign.[38] At the conference, catchphrases such as "today, the winter for clinical research is over" or "the wind for clinical research is changing" were applauded vigorously by the audience. The conference theme, '*achhe din* [Hindi for 'good days'] for clinical research' was even a direct nod to the most recent campaign by the Hindu nationalist Bharatiya Janata Party (BJP). The current BJP government was elected in 2014 with the slogan *achhe din aane waale hain* ('good days are coming'), promising to restore the country's ancient glory and create the conditions for a prosperous future, not least through a significant increase in spending on research and biotechnology. One presenter explained that the theme was chosen to directly "reflect what the Prime Minister has promised the nation", hoping that now-Prime Minister Narendra Modi's neoliberal vision of a slim and effective state would streamline existing regulations and speed up the application and licensing processes for clinical trials in the country. As Sunder Rajan astutely notes, such representations are "very much in keeping with a post-1990s ideology of economic liberalization that has been prominent in Indian elite and policy circles whose idea of India is as India Inc" (2006: 68), illustrating strong ties between the surge of nationalist sentiment and India's clinical research and biotechnology sectors. In this sense, Indian population diversity is both a resource for improving public health and a convenient vehicle to promote the vision of India as an economic superpower to reckon with.

8.3 Unity in diversity: Mobilising genetics for national cohesion

Unlike the primary aim of global clinical trials to foster health and vitality *elsewhere*, the IGVC's commitment to patient rights and giving back to the community is engrained in its very research methodologies and objectives, the representations of its findings and forms of public engagement. The Consortium explicitly moulds social ideals and values with genetic research and mobilises its findings in the

[38] *India Shining* was a central slogan popularised in the 2004 general elections by the Hindu nationalist BJP. Used widely in marketing campaigns and economic analyses, the idiom represented a general feeling of economic upswing and political progress, associated with the neoliberal restructuring of the country and the boom of the IT and BPO industries.

service of national cohesion and development. As mentioned earlier, a major objective of the IGVC was to prevent the creation of any data that may break what Brahmachari describes as the fabric of Indian society, namely unity in diversity. More than just a powerful political mantra, behind the slogan lies the assumption that Indian population groups can be neatly separated through centuries of endogamous practices. The social practice of intra-group marriage maintains the diversity of the gene pool, preventing its hybridisation through genetic admixture. In contrast to other national genetic projects such as the Mexican Genome Variation Project that foregrounds the hybrid nature of a *mestizo* nation and increasingly portrays hybridity as a positive asset (Schwartz-Marín and Restrepo, 2013; Schwartz-Marín and Silva-Zolezzi, 2010; Wade et al., 2014a), Indian geneticists are keen to point out that Indian communities have stayed socially and thus genetically separate. Both narratives of heterogeneity, however, marshal existing national imaginaries about biological and cultural affinity and are testament to the inherent tensions between, and potential political implications of, linking genetic and social groups.

Keen to avoid the language of caste, IGVC researchers devised a sampling strategy guided by multiple ethno-linguistic and geographical criteria. Conscious of the ways in which anthropological categories may contort research outcomes, Brahmachari, apparently an ardent supporter of English football, explains his methodology thus:

> You can always come up and say, 'you are a United Manchester [Manchester United] supporter, you are a Chelsea supporter' and do a genetic analysis and come back and say that 'Chelsea supporters are more aggressive than the United Manchester', but it will be very meaninglessly conclusive, right? So, the reason is, if you start with neutrality, you will get truths (Professor Samir K. Brahmachari, biophysicist and medical geneticist, public sector, India, February 2017).

Despite this care and commitment to objectivity, the use of linguistic criteria stands in a long tradition of anthropological research that draws on theories of grammatical structure to demarcate ethnoracial groupings. As Chapter 4 has shown, language has served as a prime lens for the study of human variation ever since Max Müller's assumption that the nature and essence of human diversity first and foremost manifests in language. Though without the explicit value judgments

common to eighteenth century science, the mobilisation of linguistic markers is no neutral and truth-making strategy either. Rather, associating ethno-linguistics with biological constitutions risks geneticising Indian populations, inevitably re-inscribing differences between them based on differential allelic frequencies. Though boundaries are fluid, regional, linguistic or national identities are increasingly understood as biological affiliations that can be detected or revoked through genetic testing. Schwartz-Marín and Restrepo (2013) rightly argue that national initiatives to preserve the genetic heritage of specific populations, or the nation as a whole, may harbour emancipatory ambitions, but the creation of genetic identities and attendant schemes to protect them inevitably buttress essentialised, and often racialised, human groups. Despite its commendable effort to avoid the reification of caste-based identities, the IGVC nonetheless reifies linguistic and geographical populations and imbues them with new meaning at the nexus of colonial continuities, national governmentality projects and public health objectives.

The links between the mapping of India's unique genetic structure and recurrent or novel forms of nationalism are not only exemplified by the incessant reiteration of former Prime Minister Jawaharlal Nehru's popular mantra of unity in diversity.[39] Brahmachari also recounts that his effort to maintain national cohesion earned his research a place in a national museum, namely the Indian Museum in Kolkata:

> That's why the IGVdb has appeared in the national museum in Calcutta [The Indian Museum], in the Department of Anthropology, there is a picture of the landscape of genetic variation, because there we are not talking about caste. We are not, we are just saying 'community' (Professor Samir K. Brahmachari, biophysicist and medical geneticist, public sector, India, February 2017).

Here, avoiding the language of caste is perceived as politically responsible and conducive of national harmony. Of course, this also stands in a long trajectory of the Indian government's refusal to acknowledge caste-based discrimination (Reddy,

[39] In an interview with *The Telegraph India* (Mudur, 2008), Brahmachari also said the study results stirred his memories of the 1920 poem *Bharat-tirtha* and others by India's most prominent national poet, Rabindranath Tagore, which reads: "Here came the Aryans, the non-Aryans, here came the Dravidians, the Chinese –/The Saks, the Huns, the Pathans, the Mughals–/and all got merged into one body…" (in Ray and Kundu, 2008: xiii).

2005). Yet, interesting here is how the research by the IGVC is directly utilised to promote national cohesion wherein deploying the inclusive concept of community is favourable to that of caste. Given national museums' representational roles in nation building processes and civic education (Knell et al., 2010), this illustrates the key role genetic research is assigned in devising a novel and decidedly collective Indian bioidentity. Especially the Indian Museum, the oldest museum in South Asia established by the British in 1814, stands in a long trajectory of fostering national identity through (bio)scientific research and representation. It is also the very same museum that played a prominent role in the categorisation, organisation and display of diverse Indian racial types since the peak of anthropological and phrenological research (as discussed in Chapter 4). Today, museological presentations of genomic unity as a form of public engagement suggest that bioscience is increasingly brought into the public realm to affirm, transform or rewrite constructions of collective national identities. As such, the Consortium addresses Indian communities as both beneficiaries of and actors in the project: in conjuring specific populations, the IGVC also assembles specific publics whose engagement and inclusion may ultimately enhance the legitimacy of the project. Such publics, as Hinterberger (2012) notes, hold significant discursive and symbolic appeal for narratives of national belonging.[40]

Seeking to put genomics in the service of promoting national cohesion, the IGVC also deploys the popular slogan *vasudhaiva kutumbakam*, Sanskrit for 'the world is a family'. Arijit Mukhopadhyay, for example, in a paper in *Science and Culture* writes that "India is globally known for its hospitality and for spreading the message of VASUDHAIVA KUTUMBAKAM. . . . This central theme also unites the entire country across all social and cultural borders" (2011: 4). As Deepa S. Reddy (2013) keenly observes, the Sanskrit idiom has been used for decades to mobilise popular support for scientific projects, most prominently blood donation. Indian medical institutions are well aware of the imbrications of giving blood with ideas and

[40] Whether it will succeed in assembling such publics and promoting cohesion remains more doubtful though. The museum remains a somewhat alien cultural model in India, whose role in popular education and fostering national unity regularly eludes its visitors. Mark Elliott (2003) describes how Indian museum goers often engage with its exhibits in ways deemed highly inappropriate by staff, blurring the boundaries between museum space and religious site by removing shoes before entering, draping exhibits with flower garlands and kissing statues' feet (also Bhatti, 2012). This brings to the fore some of the tensions between the metropolitan model of the museum as a bastion of culture, as well as a technology of power, and local idiosyncrasies refusing to be governed in specific ways.

feelings about community and citizenship (Waldby and Mitchell, 2006). As is well known, blood has long been tied to the symbolic of racial and national imaginaries, and its circulation as gift is key to forming collective relations amongst those imagined as legitimate members of the community. Especially those possessing blood that is considered rare or unique are often seen as imbued with a particular social responsibility to donate. As Titmuss suggests, "because one's blood is rare or unique", some individuals might be made to feel a "particular responsibility to make it available to others who may need it" (1970: 263).

IGVC researchers' mobilisation of the mantra of political unity and their call for voluntary donation to spark support for their own research demonstrates how they seek to bind Indians' biological constitutions to a collective national project in the name of genomic sovereignty. In line with the IGVC's objective of transgressing caste divisions and fostering cohesion, invoking the unifying rhetoric of blood ties functions to bridge the social boundaries of race, class, caste, gender and generation.[41] It works to incorporate the marginalised Indian citizen into the body of the nation (Cohen, 2001), transcending any notion of blood impurity, untouchability or contamination (Titmuss, 1970). In particular, the shared uniqueness of their blood, diverse yet unified, places the onus on potential Indian donors to make their biologies available to an imagined but biologically, socially and culturally distinguishable community. Here, Indians' genetic heterogeneity is ingrained with an exceptional kind of value, the exclusive benefits of which need to be harnessed for a greater cause.

At the same time, it is not only the nation, but mankind as a whole, that Indian citizens are made to feel responsible for *qua* their unique DNA. Though Mukhopadhyay interprets *vasudhaiva kutumbakam* as denoting unity across the country, clearly the saying postulates humanity as such being connected through kinship ties. Later in the article, Mukhopadhyay acknowledges India's special relationship to the world as harbouring numerous "people and their cultures which

[41] A recent example is the One-World-One-Blood camp in 2015 during which volunteers from over 25 countries donated their blood as part of the Global Youth Peace Fest. Indian media particularly highlighted the contribution by Pakistani youth who joined the camp in the city of Chandigarh near the Pakistani border. In times of "strained relations between nuclear-armed neighbours", as *The Times of India* writes, blood flows across the border not only promise hope for Indian patients but also symbolise the fraternity of the two nations. As one of the organisers opines, the camp "will help to strengthen the message of unity of mankind and Indian ethos of 'Vasudhaiva Kutumbakam'" (The Times of India, 2015).

resembles different parts of the world" (2011: 4). Similar to Brahmachari's description of Dharavi's genomic advantages, this evokes a commitment to a global community of biological citizens connected through the unifying fabric of DNA and the progressive potentials of genomic science. As Dwaipayan Banerjee (2011) astutely observes when writing about novel biocapitalist markets, while the 1980s and 1990s witnessed representations of Indian scientific practices and epistemological traditions as sites of radical alterity, India's entry into the global biotechnology market also requires new forms of relational enquiry. As the country joins the global life science industries, it is no longer enough to postulate internal unity, but Indian biological properties also need to be aligned with global market forces. As such, the IGVC represents Indians' genetic characteristics not only as unified but perhaps even as *universal*, rendering their prospecting not only an ethical necessity but also an economic opportunity.

8.4 Graduated genomic sovereignty

Brahmachari's commitment to and enthusiasm for enlisting genome research for socio-political purposes and national empowerment stands in sharp contrast to how respondents describe India's journey from independent drug manufacturer to service provider for multinational companies. In particular, critiques of the Drugs Controller and accusations of its collusion with the industry, rather than the protection of the Indian public, abound. This is ascribed to both the inexperience of Indian physicians and health policy makers as clinical researchers and their implicit orientation around the aims and objectives of the global pharmaceutical industry. Dr Nath, for instance, who helped rewrite Schedule Y ahead of the 2005 WTO deadline (see Chapter 1), recalls that the reformulation of drug policy was a rather bumpy road to success:

> The journey was a merry go round, so you have some people who wear the hat of an expert, they will be having adequate halo around them, they will be experts in their own field, but [good] clinical research sadly has not been the effect. Clinical research has not been around in India for very long as we know it now. Even our organisation was only doing Indian clinical trials until about ten years ago, when the new law came

> into being. . . . Here were some doctors, who, because of the expediency of the situation, were given the cap of experts in clinical research. [But] being a doctor and being a clinical research professional, these are two very different things, actually, I sometimes believe they are opposite to each other! A clinician is actually trained to follow a standard protocol for treatment whereas a clinical researcher essentially is going beyond the standard protocol and is trying to do something new (Dr Prashant Nath, CEO of CRO, India, March 2015).

Given the virtual absence of innovative drug research before 2005, it was mainly Indian primary care physicians and medical specialists who were summoned to revise Schedule Y of the Drugs and Cosmetics Act when India became signatory to the TRIPS Agreement. Describing the revision process as a "merry go round", Nath lays out that the revisions were decided upon under considerable time pressure and advisors often lacked the necessary expertise in experimental research. When I queried him why they agreed to the task in the first place, Nath suspected "ego-boosts" and, somewhat implicitly, a culture of corruption as some of the main reasons.

Other commentators have gone even further in their criticism of the DCG(I). In a recent study of clinical trial governance (Lada, 2016: 141), an Indian ethics committee member explicitly identified the source of existing problems as the regulatory authority's corrupt practices and political affiliations:

> DCG India is the first gatekeeper, who is understaffed and extremely corrupt. The reviewers for DCG have conflicts [of interest]. . . . [There is a lack of] sincere effort to protect our people. The government talks only about market potential, but not about protections of the people.

From their perspective, the DCG(I) is not aligned with the interests of the Indian public but of the global market. Many view CROs, the pharmaceutical industry and India's regulatory authorities as sharing a strong interest in building a clinical trial infrastructure and promoting the country as a prime destination for global research (Sunder Rajan, 2007). The ethicist's critique of corrupt practices is echoed by two anonymous representatives of sponsor firms. In the Indian newspaper *Business Today*, they accuse the DCG(I) of breeding a culture of corruption and inefficiency:

> A small clearance takes months unless you pay money. . . . A bio-study clearance takes time while a clinical trial clearance takes a lot of time. For a new drug, we are asked all kinds of irrelevant questions. At both the central and state levels, there is a cadre of clerks always on the lookout for ways to make money (in Sharma, 2015: n.p.).

It is well beyond the scope of this chapter to adjudicate on the facticity of these accusations. The point here is that the DCG(I) neither appears to have the expertise and resources to enforce existing regulations and recommendations, not least on where to conduct studies and what kinds of populations to include. Nor does the regulator seem to have the determination to alienate the pharmaceutical industry that is crucial in driving India's success in the global bioeconomic market.

Even if such a determination existed, informants interviewed by Shashank Tiwari and Sujatha Raman (2014) who conducted research on stem cell governance in the country claim that there exists a significant asymmetry between different regulatory authorities themselves as well as between the DCG(I) and the industry. One policy maker states that "[o]ur FDA is not that strong" (in Tiwari and Raman, 2014: 421), suggesting that the Drugs Controller was uncertain about the reach of its powers given that it was only nominally on a par with the FDA as the globally most influential agency. A clinician interviewed for the research expressed similar concerns, arguing that violations of existing guidelines were rarely ever persecuted due to this power relation. "Even if you go to the Drug Controller of India", he notes, "he says, what can I do . . . when I don't have powers to crush you, even if you don't follow the guidelines why should I bother you?" (ibid.). This reflects a certain laissez-faire attitude permitting pharmaceutical companies and CROs to circumvent existing regulations and exert undue influence over shaping the Indian clinical research landscape. Though I find the notion of a new colonialism (Nundy and Gulhati, 2005) to be somewhat imprecise to describe global companies' flocking to India for clinical research purposes—as I hope to have shown throughout this thesis, the story of clinical trials in India is far more complex than merely Western companies exploiting Indian patients—the new impositions by the WTO have certainly given global corporate elites great power over national economies. They restrict the Indian state's ability to formulate legislation that is conducive of its pursuit of national health and economic development, and have transferred

decision-making power, at least partly, to non-state actors such as pharmaceutical industry bodies (Chaudhuri, 2005; Joseph, 2016).

Considering these and other dilemmas, it remains uncertain whether the DCG(I) will be successful in enforcing existing recommendations and guidelines, not least on genomic diversity and the (commercial) exchange of human biological materials. As Billie-Jo Hardy and colleagues (2008) note, though extensive legislature exists to protect Indian communities and patients from the harmful practises of bioprospecting or even biopiracy, multinational companies conducting research in India have long been able to circumvent these guidelines. The DCG(I)'s lack of political will and the significant economic potential global studies entail continue to grant pharmaceutical companies and CROs a relative degree of freedom over the design of clinical trials, including the *de facto* inclusion and exclusion of specific populations. Marginalising populations that may deviate excessively in their genetic makeup, for example by focusing on geographical areas where they are scant, ensures cleaner data and firmly aligns the research with global market interests rather than local public health. Even if the DCG(I) had an interest in procuring the genetic diversity of the country, either for commercial or public health purposes, it is improbable that global trials would contribute to India's bionational project. Added to restrictions in data sharing caused by the industry's proprietary models, the engineering out of variation through the exclusion of specific populations advances a dynamic of exploitation wherein multinational corporations harness only those genetic properties most closely aligned to, or most valuable for, the objectives of global pharmaceutical markets.

If both quests for genomic sovereignty and the extraction of surplus value for global pharmaceutical capital exist within the procurement of Indian genetic heterogeneity, how are we to understand this conjuncture? I suggest that the simultaneity of empowering and exploitative practices in the procurement of Indian DNA is no contradiction but the result of the shared objective by local biomedical and political elites to secure India a place amongst the key actors in the international biotechnology arena. As explained earlier, despite the IGVC's claims to foster national empowerment and its arbitration of global biocapitalism, amongst its primary aims is to establish Indian genome research on a par with the world's leading research locations. In an interview with Hardy and colleagues (2008), some IGVC members explicitly expressed hope their research would contribute to

driving India's status as a global biotechnological player by allowing for patient selection and stratification for global clinical trials, and some have ventured into other areas in the hope for commercially successful genetic applications and international collaborations. Brahmachari himself, I was told, is a scientific mentor and shareholder in a molecular diagnostics company called *Dhiti Omics*, seeking to commercialise genetic research findings for an Indian and international audience.

As such, though we undoubtedly witness claims to genomic sovereignty wherein Indian scientists and government authorities rework existing population descriptors through genomic science and emerging biotechnologies in the hope of enhancing the nation's health and economic prosperity, it is perhaps more befitting to describe it as a form of *graduated* genomic sovereignty. Ong (2000) has developed the concept of graduated sovereignty to describe the changes in governmental practices to treat populations, instituted by the penetration of formerly developmental states and planned economies by global markets. She asserts that, first, some governments work to differentially treat segments of the population in relation to rational market calculations, thus intensifying the fragmentation of citizenship along the lines of race, ethnicity, class, gender and region; and, second, that state-transnational interactions are flourishing wherein increasing aspects of state power are taken up by foreign corporations. Writing primarily for the context of South East Asia, her insights nonetheless have much to offer both to understand the DCG(I) and other government institutions' dynamic relations with multinational industries, and the variable mobilisation of Indian DNA for different bioscientific projects.

The juxtaposition of postcolonial genomics and global trials illustrates that India's genetic heterogeneity represents a resource that has multiple currencies, material and symbolic, and the state's quest for bioscientific progress sometimes firmly aligns these with global market forces. Though they are the target of extensive genomic and public health technologies, India's impoverished populations simultaneously figure as experimental subjects *qua* genetic make-up and economic deprivation as these qualities help promote India's attractiveness for foreign investment (also see Chapter 6). In other words, claims to genomic sovereignty overlap with and mediate global market flows to attract international biomedical technologies, expertise and capital, often in seemingly contradictory ways. The model of graduated sovereignty, as Ong (2001: 72) explains,

> shows that it is not so much a question of the market versus the state, but that market society at our particular moment in history means that there are certain areas in which the state is very strong and its protections very significant, and certain areas where it is near absent, because these zones must be flexible vis-à-vis markets.

The required flexibility of specific zones or, here, *bodies* points to the simultaneity of neoliberal market rule and governmental technologies, marking what are often the very same populations for state protection in one instance, and capitalist exploitation in another. And while middle-class Indians are increasingly being envisioned as future biomedical consumers (see Chapter 9), the fragmentation between them and purely bioavailable research subjects may well increase, proceeding firmly along the lines of caste, class and socio-economic status.

Furthermore, Ong also highlights that practices of graduated sovereignty may well calibrate governmental technologies and pastoral care with military repression and violence when deemed necessary for the protection of the state or national development. Indian state actors' and bioscientists' proclaimed will to foster the vitality of the poor through public health genomics stands in sharp contrast to instances where the same populations appear as, at best, unproductive for, or, at worst, hindrance to capitalist development. Their involuntary insertion into various biomedical projects, though sometimes with the potential of individual benefit as in the case of clinical research, resembles other cases of (state) violence and injury through which the rights and protections of India's poor are bypassed in the name of (bio)capitalist transformation and development. For example, one could think of the thirteen villagers in Orissa's Kalinganagar area who were killed for protesting the enclosure of their lands for the construction of a new Tata steel factory in 2006, or the fourteen peasants killed in the West Bengal village of Nandigram in 2007 as they resisted the acquisition of 14,000 acres of agricultural land for the establishment of a Special Economic Zone (Chatterjee, 2007).

What these, more directly violent, forms of dispossession share with clinical experimentation is not only the exploitation of otherwise 'unproductive' spaces and bodies, rendering them bioavailable for global capital, but also the legitimation of such acts in the name of (bio)capitalist transformation, development and progress (Chakrabarty, 2000; Limki, 2015). To draw on Raman and Tutton's work (2010) again, rather than assuming a linear progression from the population to molecular

level and from sovereign to biopower, one ought to recognise that contemporary biopower equally permits the illiberal management, and killing, of unruly individuals and groups. As such, some have aptly questioned if the politics of life itself (Rose, 2001) is a useful conceptual trope for the analysis of biopolitics outside the West (Bharadwaj, 2008; Cohen, 2001; Greenhalgh, 2009). Not only does the biopolitics of *population* still loom large, but the politics of life is often accompanied by a politics of *letting die* in the name of (scientific) progress that periodically requires state support and intervention.

Biomedical projects have long been a way through which constitutively marginal, subaltern subjects have been promised some form of modern participation in the nation state while at the same time being made available for global capital (Cohen, 2001). Both genome research and global drug trials promise partaking in the inclusionary, quasi universalist projects of bioscience and the state while their shared agenda of advancing the Indian bioeconomy enables research participants' exploitation. This might well be unwilling or unwanted but is the outcome of the *de facto* protection of global corporate interests. This means that neither the lenses of genomic sovereignty nor of biopiracy capture the contemporary procurement of Indian genetic diversity well. Though the notion of genomic sovereignty offers much to understand how the mapping of genetic heterogeneity is used for claims to ownership over national genetic properties while also rebranding national populations as ethnic niche markets, it has yet to grapple with the multifaceted interrelations between nation states and local and global corporate elites. Charges of biopiracy, on the other hand, fail to account for the complexities of national bioeconomies and the new biopolitics of genomic research that is not only rooted in the negative, murderous face of biopower but simultaneously in its life-affirming dimensions.

8.5 Conclusion

This chapter has contrasted the diverging interests in Indian genetic diversity by two major stakeholders in India's bioeconomy, the global pharmaceutical industry and the government-sponsored IGVC, as well as their respective practices to procure it. I have argued that while the research by the IGVC is put in the service of fostering national cohesion and development, the pharmaceutical industry aims

to harness those, and only those, genetic properties of the Indian population that are most closely aligned with global market interests. The simultaneous existence of these multiple and seemingly contradictory practices suggests that we cannot straightforwardly characterise the Indian governments' approach to the national genetic heritage as genomic sovereignty. I have proposed, following Ong (2001), that it better be described as graduated genomic sovereignty, overlapping with and mediating, as well as being mediated by, global market flows. This means that Indian bioscientific and governmental actors sometimes grant specific populations special rights and protections while at other times mobilising their molecular qualities according to rational economic calculations.

The concluding chapter turns to India not only as a site of drug testing but also an emerging pharmaceutical market. Despite the operational segregation of CRO-driven clinical research and biomedical consumption, the two are nonetheless part of the same logic of pharmaceutical value creation. While existing research has, if at all, explored this nexus by focusing on the monopolist business models and patent regimes that make access to medicines an increasingly arduous endeavour (Sunder Rajan, 2017), I am interested in the ways in which conceptions of Indian population heterogeneity, or homogeneity, are mobilised to facilitate the creation of new markets for drugs and devices within India.

Chapter 9: Race to the market? Genetic medicine and national vital value(s)

> Companies want to get in there, they see it as a market for the future! So, for example, if you see the diabetes rates are going up like this, you want to get in there, because when the drug gets marketed, it's gonna be a big proportion of your sales [that are] gonna come from India then. The sooner you get in, the better (Dr Alice Friedman, global head of clinical sciences, multinational pharmaceutical company, Switzerland and India, August 2014).

> Indians differ from other populations in terms of body build, genetic origin, and disease presentation. Hence, India needs more clinical trials in diabetes to develop more suitable and effective treatment options for the Indian population (Dr Vyankatesh Shivane, physician, India, June 2016).

Thus far, this thesis has primarily considered the production of pharmaceuticals through biomedical and genetic research in India. In this last chapter I turn to the (actual or anticipated) consumption of such biomedical technologies. India is not only a preferred location for drug development, but it is also considered a core future market for drugs and attending diagnostic services by multinational and local corporations alike (Gupta, 2016; Sunder Rajan, 2017). Of course, the markets that *really* make a difference for patent-protected drugs remain in the Global North (Ecks, 2008), and stark contradictions between the economic and therapeutic benefits of clinical trials in India persist. Nonetheless, as Friedman's statement in the epigraph illustrates, few companies seeking to expand their consumer base can afford to ignore India's large patient population, particularly for non-communicative diseases that often require lifelong therapy. For diabetes alone, global drug companies are competing for a slice of India's growing diabetes

treatment market currently worth 12 billion Indian rupees, or 143 million pounds (Gupta, 2016). A sizable market dominated by local biotech and pharmaceutical companies has also emerged, offering diagnostic services in clinical genomics for everything from disease risk to drug insensitivity.

Considering India as a site of consumption is crucial to understanding the transnational field of clinical research as a more complex geography of provision than existing accounts of biomedical exploitation surmise. India's commercial potential lies not only in its current patient population waiting to be enrolled in trials but also in its growing consumer pool for drugs and medical devices. As Sunder Rajan (2017: 11) writes, though we usually treat them as two discrete domains, the conduct of global clinical trials and the ambivalent status of India as a therapeutic market are both "a function of logics of global capital touching down in India". Despite the distinct institutional spaces they occupy, the different discursive modalities informing them, and the varying actors forging their emergence, their trajectories are part of structurally interconnected biomedical and political economies (ibid: 35).

While Sunder Rajan focuses on conceptualising the broader structures of global pharmaceutical political economy as manifest in the confluence of clinical experimentation and the institution of monopolist patent regimes, in this chapter I use my empirical data from interviews and online materials (press releases, newspaper clippings, advertising and promotional materials as well as conference documentation) to explore how specific populations are mobilised in the realm of biomedical consumption. I find that, as physician and diabetologist Dr Vyankatesh Shivane's account above demonstrates, Indian researchers advance scientific arguments about Indian ethnicity and genetics to imbue their quest for more clinical research and thus the prospect of targeted therapies with ethical legitimacy and popular support. Not only must effective treatment for diabetes reflect the specificities of 'the Indian population', but the research essential for the development of such treatments should be carried out on Indians, too. Similarly, I will demonstrate through the case study of Jai Heart, a risk assessment tool for coronary heart disease developed specifically for Indians, that many of the diagnostic products currently on the market advertise their products by reference to the uniqueness of the Indian gene pool. Both discourses mobilise explicitly ethno-national markers for the creation of value as both the profits to be made and

the ethical significance they hold for the promotion of public health. Attending to these debates will allow me to stress the pivotal status of the nation as a reference point for arguments about population differences, and craft a more nuanced assessment of how such differences are variably used in drug development, biomedical consumption and contemporary genealogies of the nation.

My aim in this chapter, then, is twofold. First, turning to India as a potential market for targeted biomedical technologies rather than merely a site of research, I wish to challenge core assumptions prevailing in the literature that picture a unidirectional service provision in which "the West exploits the rest" (Parry, 2015: 33). Narratives of unambiguous exploitation (Cooper and Waldby, 2014; Fatima, 2014; Fisher, 2007; Jennifer Kahn, 2006; Nundy and Gulhati, 2005; Vora, 2015) tend to paint a somewhat dualistic image that contrasts unethical or even illegal experiments in India with the life-augmenting technologies prevalent in the West. My empirical data contests such depictions: I will show that existing narratives tend to disregard that data collected outside a specific national jurisdiction is not deemed as valuable as data from within, which also challenges the precedence given to racial classifications at the expense of national markers. Moreover, these narratives ignore that Indian biodata are increasingly seen as loci of biovalue themselves rather than merely contributing to the amelioration of health elsewhere, and that Indian research participants are scarcely the homogeneous, destitute patients that some journalistic and even theoretical accounts tend to emphasise. Such representations, as sections 8.1 and 8.2 will elaborate, obscure the multiplicity of narratives, stakeholders and subject positions in the field as they unify them under the header of a "racialized global underclass" (Epstein, 2008: 803).

As respondents' accounts demonstrate though, for any value to be realised from their genetic properties, Indians need to be brought into the realm of neoliberal governmentality and 'empowered' to become consumers of their own health. In sections 8.3 and 8.4, I draw on the story of Jai Heart to illustrate that the ethical and commercial potentials of genetic medicine are predicated upon Indians' biological citizenship under the aegis of private corporations. I ultimately argue that India's potential as a lucrative market for new biomedical technologies rests upon Indians' successful inclusion as conscious consumers, and that existing struggles to conjure a pro-research and pro-corporate citizenry exemplify the country's ambivalent configuration between the promises of consumer capitalism

and postcolonial development. Recent efforts to summon a self-conscious consumer class may bring *some* health benefits to *some* Indians, but they further depoliticise the already profoundly divided healthcare infrastructure in India. In other words, I argue that though a plethora of corporations, researchers and entrepreneurs strive to transform India into a profitable marketplace for biomedical technologies, often genetically reifying the national population, the structural constraints imposed by postcolonial capital prohibit any tangible benefits to be derived from such technologies.

9.1 "We're getting less and less successful in getting Blacks into trials": Foregrounding national anxieties in drug regulation

There can be no doubt that India's status as a preferred location for clinical trials is firmly rooted in the historical relationships of colonialism and its material and symbolic forms of exploitation. The continued expropriation of biological resources, from cotton, tea and spices in the eighteenth century to today's extraction of tissues and genetic information, must remain subject to profound ethical scrutiny. The enrolment of unsuspecting patients into medical experiments, often those who have already suffered innumerable losses at the hands of multinational corporations from the East India Company to Union Carbide, reproduces all too familiar dynamics of abuse and neglect. My intention in this chapter is by no means to trivialise these dynamics and attendant experiences.

What I do wish to show, however, is that the description of Indian trial participants as a destitute, 'racialised underclass' eclipses important intra-group distinctions. It also overlooks the ways in which trial participants and patients themselves emerge as potential loci for the creation of biovalue as Indian researchers increasingly look to the ethical and economic potentials of biodata derived from studies in India, for India. I argue that although global clinical trials undeniably contribute predominantly to the biovalue realised on US-American and European markets, the value of genetically diverse data collected inside and outside specific national jurisdictions differs significantly. At the same time, Indian scientists and healthcare entrepreneurs increasingly seek to valorise the biological properties of *Indian* bodies for *Indian* citizens themselves. This illustrates the enduring role of the nation as a

reference point for arguments about ethnoracial populations and their potentials for the creation of new biomedical markets.

US-American regulators, for example, have raised concern about the effects of transnational research on the ethnoracial configuration of trial populations and their representativeness of the US citizenry as mandated by NIH policy. When queried about the challenges resulting from the globalisation of trials, Dr Bull of the FDA's OMH confirms:

> It's a concern from the standpoint of adequate inclusion of US populations going back to our policy statement that the clinical database in applications should reflect the likely patients that will use the drug in the United States (Dr Jonca Bull, FDA, USA, September 2015).

For her, the relocation of pharmaceutical trials significantly compromises on the applicability of clinical data to the US population, failing to mirror its physiological properties. This is well in line with longstanding federal efforts for population control through racial enumeration that seek to curb, as Bliss (2005: 332) writes, the wanton incorporation of 'foreign' data without due consideration of its effects on the local population. Bull's colleague at CDER raised similar issues. Consider the following statement by Dr Temple:

> The main problem [with global trials] is, we're getting less and less successful in getting Blacks into trials because more and more trials are moving offshore, so if you do a trial in India, you will not have any Blacks. Or China. And in Eastern Europe, not too many. So, the percentage of patients who are Black in our trials has fallen somewhat from about twelve or thirteen per cent on average down to about seven or eight per cent. Although it's been pretty consistent within the United States, but we have more and more people from other parts of the world, where there are not a lot of Blacks. . . . We do want them [drug companies] to be more conscious of trying to find components of the Black population, especially where the disease is particularly prominent in that population. But it's hard to do with a lot of trials outside of the US. Big problem (Dr Robert Temple, FDA, USA, September 2015).

Asked about the significance of the globalisation of trials for assessing ethnoracial variation, Temple not only echoes Bull's hesitation about the applicability of foreign data but also illustrates that a prime concern of North American regulatory policy lies with ensuring Black or *African* American representation in trials. Some respondents emphasised that this was scientifically unfounded as variations in East Asian and Asian American populations occurred at similar frequencies. Indeed, it has been suggested that the federal focus on African ancestry is not purely the result of scientific deliberation but also of where debates around inclusion and diversity in biomedical research originated, the availability of resources and, crucially, a particular interest in remedying the legacies of transatlantic enslavement (see Chapter 2).

By extension, this also means that the FDA encourages adequate representation of African *Americans* in trials rather than of patients with African ancestry more broadly. Though, as Chapter 6 has shown, the occasional pooling of (often racially defined) populations is usually accepted, respondents in the pharmaceutical industry also emphasised that, when possible, they aimed to meet FDA requirements for inclusion and diversity in trials conducted within the United States. Dr Ahmed of Clintech, for instance, insists:

> You would include, make sure that you've included appropriate groups in the US to meet the US requirements rather than going abroad. An example of that would particularly be Africa. And this is partly, probably largely infrastructure-driven, but you know, the evidence for efficacy and safety in a Black population for America would have to come from American African people. Not from Africa. . . . [And] if you wanted East Asian data in America, you would just make sure you'd do studies on the West Coast (Dr John Ahmed, senior director, clinical pharmacology, multinational pharmaceutical company, UK, August 2015).

While the FDA officially allows pharmaceutical companies to file applications based on data solely obtained abroad, this has not led to the *de facto* acceptance of data from such trials or the global recruitment of study participants according to NIH inclusion criteria. Regulatory pressure is put on sponsors to adequately represent US-American minorities rather than ethnoracial diversity as such. While global research is undoubtedly *represented* through a system of racial classifications

pertinent to the US-American context, as Bliss (2012) argues, the effect has not been a wholesale incorporation of foreign-based data on a par with local study results. Dr Caroline Smith, an NIH spokesperson responsible for implementing the Institutes' inclusion policies, confirmed that that the NIH aimed to ensure diversity across its research portfolio rather than in individual studies. Resonating with Bull's emphasis on the need for flexibility, research outside the United States contributed to addressing knowledge gaps in particular disease areas and may be exempted from requirements about inclusion and representation.

Pharmaceutical firms thus rarely jeopardise their marketing applications due to insufficient or the 'wrong kinds' of ethnoracial representation. As Ahmed explains further:

> We actually have not been terribly successful in persuading the US to accept those packages [of trials done predominantly outside the US]. It's only happened once or twice. . . . The US will say 'well, how does that apply to the American population? Oh no, we want to see data in Americans'. . . . I mean I'm not saying there's not some logic in that, because they have, you've got this whole environment thing, but at the same time it's also a little bit narrow minded. You know, a little, this 'not done in my backyard' (Dr John Ahmed, senior director, clinical pharmacology, multinational pharmaceutical company, UK, August 2015).

In a cynical twist on the popularised slogan expressing opposition to land developments, Ahmed explicates that regulatory agencies still preferred data collected "in their backyard", or their own national jurisdictions. The metaphor of the backyard thereby perfectly illustrates the sustained link between what Zygmunt Bauman (1992) describes as the postulates of nationalism, namely soil, blood and identity, latent in such regulatory requirements. For centuries, blood has been the substance through which collectives were formed and ideologies of descent were imagined. Such ideologies, as Bob Simpson (2000) writes, did not only provide the basis of the symbolic unity of a people but equally buttressed claims to territory and land. While the rise of genetics recast the metaphor of the blood in the new vocabulary of DNA as *the* marker of shared identity, strong links are still being forged between specific biologies and national imaginaries. Evoking, quite literally,

the national soil from which clinical data is to be extracted, Ahmed's statement exemplifies how such regulatory guidelines carry forward familiar ideas of nationhood and imbue them with new legitimacy. Despite the FDA's commitment to "think, act, and engage globally", as its then-Commissioner Dr Margaret Hamburg (FDA, 2013) states, Professor Chan equally finds:

> I am also doubtful that there is a commitment to trying to resolve some of these problems, because regulatory authorities do what is required for their own domestic needs, they don't necessarily look at it from a global point of view, so I am not sure a consensus on something like that is possible (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

These statements confirm that despite the increasing harmonisation of regulatory policy and efforts to standardise ethnoracial variation across regions, regulatory authorities' prime interest continues to lie with ensuring the safety of 'their' populations. Though somewhat parochial, this was no crude nationalist reflex but very much reasonable, as Ahmed was quick to add, given not only their political mandate to protect the national population but also due to the significance of extrinsic factors such as medical practice and environmental influences shaped by professional conventions and distinct geographies.

The FDA's insistence on the representation of its own population also contests propositions of a new scientific and commercial interest in race as a transnational and deterriorialised category evoked by much research on race and genomics (see Chapter 2). My respondents' statements are striking in that they highlight crucial differences *within* a group presumptively characterised by racial sameness, putting the cogency of racial explanations under enormous analytical duress. Though FDA guidelines specify that for peoples of African origin, "the racial designation is African American in the United States, whereas it is Black for studies conducted in foreign countries" (FDA, 2005: 6), these categories are not simply metonymic and interchangeable. Respondents made clear that for their own requirements, as Bull puts it, to "call someone Black who is in a trial from South Africa is not the same as a Black person in the United States". Research participants' citizenship status and location critically impact on whether they are suitable for studies seeking to emulate the respective population. Regulators do not propose an unmediated link

between genetic populations, but a significant distinction exists between the biological properties of those inside and outside the jurisdiction wherein marketing authorisation will be thought. As Chapter 5 has shown, which populations are included in research is often contingent on the bioeconomic imaginaries of the nation state, moulding scientific findings with political projects into seemingly coherent narratives.

The sociological concern with the reification of race in genomics (e.g. Bolnick et al., 2007; Fullwiley, 2007a; Inda, 2014; Kahn, 2012; Roberts, 2012; Whitmarsh and Jones, 2010) tends to ignore such intra-racial distinctions *qua* citizenship or region that question the salience of explanatory frameworks drawing solely on race. The prominence of national markers and economic considerations stratifying presumed racial groupings should caution us to assume race to be the prime, or even the only, factor for population classifications in post-genomic medicine. Perhaps, as Gilroy surmises, the "attempt to make 'race' always already a meaningful factor, in other words to racialise social and political phenomena, may be itself identified as part of the 'race' problem" (Gilroy, 1987: 116). The postulation of group-ness glosses over distinctions with considerable symbolic and material consequences. Concepts of racial kinship continue to linger in the description and mobilisation of India as an ideal trial site, but citizenship and location, though undeniably tied to racialised descriptions of specific nations and geographies, are crucial in the assessment of clinical trial data. They determine the representativeness of specific populations and the value derived from them. Put differently, to understand the global dynamics of clinical research in the current era, we need to be attentive to the ways in which citizenship and notions of national belonging continue to inflect the delineation of and potential value derived from specific populations. That is, we need to focus not only on the discrepancy between 'racial' life within and outside the lab (Benjamin, 2016a), but also within and outside the nation, especially within and outside the United States where race-specific research and the social concern with race is particularly popular. In this sense, I now turn to the Indian context to explore evocations of the Indian population to summon support for clinical research.

9.2 Indian biodata for Indian patients

Existing work (Cooper and Waldby, 2014; Petryna, 2009; Prasad, 2009; Sunder Rajan, 2017, 2006) has convincingly demonstrated and sharply criticised the asymmetries between those upon whom research is performed and those who will eventually benefit from its results. My own research confirms this discrepancy—though only partially. When I queried Dr Bhatt in Mumbai, for example, about the benefits of global trials for Indian patients, he replied with astonishing candour:

> If you look at somebody with a rare disease, yes, there is an impact, because most of them require a trial for a new drug. If you look at maybe advanced cancer, yes. But the large number of people in India, I am talking about this as a doctor, I don't think it matters if the trials are not there. . . . Okay, so through trials they are getting free treatment for some time, but not around [before and after the trial], [and] not everybody's getting it, I mean we have such a huge population in India with so many problems. . . . So yes, from the point of view of innovation, we need trials, but for the patients I would question that. Personally, I am not sure (Dr Arun Bhatt, physician and CEO of CRO ClinInvent, India, March 2015).

The statement supports existing critiques that for the majority of Indian trial participants, the therapeutic benefits of participation such as access to better medical care is quite limited and temporary at best. This is so because the post-trial availability and affordability of drugs continues to be highly uncertain. Global clinical trials promote scientific innovation and bioeconomic growth but often remain ostensibly distinct from Indian doctors and their patients' immediate concerns.

This ethical dilemma notwithstanding, Bhatt also stresses that for patients with rare and non-communicative diseases, trials may offer the lone chance of innovative and potentially life-saving treatment. The patient narratives I will explore below illustrate that especially for India's growing middle-class with similar disease profiles to patients in the West, participating in clinical research constitutes an increasingly interesting prospect. In addition, the regulatory reorganisation of clinical research in India appears to have resulted in a gradual shift in researchers'

attitudes to benefit-sharing and making research results available for the local population, if only due to mounting public pressure. Indian researchers vocally reject the accusation of being accomplices in a neo-colonial project by drug companies and vigorously proclaim their commitment to harnessing research results for local medical needs.

Professor CS Pramesh, chief thoracic surgeon at the prestigious Tata Memorial Hospital in Mumbai, for instance, states in an ISCR press release for World Cancer Day 2016 (ISCR, 2016a: n.p., emphasis added):

> When we look at medical research over the last decade or so, I think we have made some major advances. But when you look at the conversion of these major medical advances into what has actually reached the patients, we have not fared too well. We need to focus our research and resources on finding treatments for the more prevalent cancers in India—head and neck, breast, cervical and gall bladder. As a country, we have a moral obligation to participate in clinical research and a responsibility to our patients. Institutions such as ours have made a lot of investments in clinical research to address the unique needs of our patient population. Clinical research *by the country* and *for the country* is the way forward.

Admitting serious shortcomings in making study results available to patients, his almost theatrical, patriotic plea for "research by the country and for the country" reveals not only research professionals' ethical predicaments given their occupation that has recently attracted much negative attention by the press, and their resultant eagerness to signal a new direction in Indian clinical research. Stressing the need for more investigator-initiated studies, the results of which can be immediately harnessed for the improvement of local public health, Pramesh also foregrounds doctors' moral obligations to their patients as well as, although somewhat implicitly, of Indian citizens to each other. In doing so, he conjures an imagined Indian community of shared ties and responsibilities, "conceived as a deep, horizontal comradeship" strong enough "for so many millions of people, not so much to kill, as willingly to die for such limited imaginings" (Anderson, 1983: 48).

While arguing for contemporary inclinations for self-sacrifice in the name of the nation may seem exaggerated, in the context of biomedical research this is perhaps

not far-fetched at all. The mutual responsibility Pramesh evokes is also one of assuming the potentially lethal risks of undergoing experimental treatments. While Indian doctors have an obligation to conduct clinical studies, Indian patients have the (vastly riskier) duty of posing as experimental subjects, exposing their bodily integrity and even lives to biomedical trial and error. The sacrifice expected from them resonates with familiar interpretations of nationalism as created by state or, here, biomedical elites, functioning to capture the masses' approval of their governmental practices. A process that Bauman (1992: 675) describes as "the self-constitution and the self-separation of new elites legitimizing their status by reference to superior knowledge and culture", nationalism not only promotes the formation of new allegiances beyond communal affiliations but also forges the unassailable loyalty of formerly antagonistic forces. Invoking the nation as an imagined community, Pramesh's account works to secure popular support for clinical research activity in the country and conjures new forms of biological citizenship that evoke political collectives based on shared biological criteria and pathological conditions.

Of course, whether such efforts will translate into actual improvements for Indian patients remains to be seen. To state the obvious, industry bodies and allied researchers have a vested interest in rectifying their tarnished reputation, and building a pro-corporate citizenry is a core vehicle in doing so. Nonetheless, the customary narrative of 'the rest servicing the West', suggesting a largely unidirectional dynamic of exploitation, brushes over significant distinctions. As Bronwyn Parry (2015) rightly notes, though there can be little contention over the broad thrust of these narratives, closer analysis can serve to demonstrate crucial distinctions and shifts within and between different sectors in the global bioeconomy. Writing about reproductive services in India, Parry argues that assessing their exploitative potential needs a more in-depth exploration of the conditions *in situ* than the dominant, homogenising account affords. As I wish to demonstrate in this chapter, neither are Indian physicians and investigators silent witnesses to or intentional accomplices in projects of biomedical exploitation, nor are trial participants always the destitute patients that many commentaries propose. Again, the description of global research as a new form of colonialism deserves closer attention to internal contradictions, and portraying Indian patients as a

homogenous, subjugated underclass risks reiterating colonial imageries of India as the world's poorhouse.

Particularly interesting about the effort to make clinical research more viable for the local context is how arguments about Indians' genetic properties are mobilised to strengthen popular support. Dr Shivane's statement cited in the epigraph to this chapter and taken from an ISCR press release on World Diabetes Day in 2016 (ISCR, 2016b) exemplifies this well. Shivane proposes that the Indian population was distinct from others in its physiological, genetic and pathological qualities such that it warrants more clinical investigation into specific susceptibilities and treatment regimens. The invocation of uniqueness works to evoke a common identity through a shared sense of exclusivity, feeding seamlessly into prior narratives of Indian nationhood that portray Indians as guardians of a special genetic heritage.

Similarly, ISCR President Suneela Thatte emphasises that "[g]iven the high incidence of diabetes in India, clinical research will also help identify which medicines work best for *our genetic disposition* which is critical to managing *our* growing diabetes burden" (ISCR, 2015: n.p., emphasis added). Thatte's emphasis of an Indian *disposition*, somewhat distinct from the more fluid *predisposition*, the expression of which is always contingent on environmental, social and cultural conditions, construes a fixed, timeless character of the Indian population that warrants special consideration for the amelioration of gaping health disparities. The explicit inclusion of herself serves as a powerful reminder of the shared membership in this imagined "genetic community" (Simpson, 2000: 5), and, as such, functions to gather allegiance to her organisation's objectives. In some sense, Thatte, and others like her, may be described as what Brubaker (2002) calls "ethnopolitical entrepreneurs", invoking and *evoking* ethnic or national groups to "stir, summon, justify, mobilize, kindle and energize" (2002: 166). When they are successful, the unified group can be powerfully realised in practice, crystallising in a sense of belonging, mutual solidarity and collective political goals. However, clinical researchers here neither centre on Indians' somatic proximity to Caucasians nor on their internal differentiation but on the presumably distinct features of the nation. Their own groupism, conflating biological descriptions and political realities, summons the national population as an internally homogeneous and externally

confined collective to legitimate their campaign for further clinical research in the country.

Recent epidemiological research has indeed proclaimed Indians' higher propensity to diabetes and other non-communicative diseases (for examples see Abate and Chandalia, 2001; Bhopal, 2013; D'Costa et al., 2000; Gholap et al., 2011). Rapidly growing rates across the world have become a major public health concern. However, the particular moment at which arguments about Indian genetic uniqueness re-surface in discussions about clinical research in India warrants scrutiny. Naturally, techno-scientific phenomena such as new medical knowledge about South Asian propensities for, here, diabetes rarely emerge in isolation. Chan, for instance, suspects that national claims to genetic specificity in clinical research settings do not solely stem from scientific deliberations, as discussed earlier (see Chapter 5) but are often advanced to mask other motives. He argues that:

> My impression is that this is particularly so [regulatory agencies demanding additional local studies due to ethnic or genetic differences] when there's a domestic market they're trying to look after, and so, again, this is just off the top of my head, my feeling is that there is a lot of national interest, some of these regulatory agencies are trying to protect; and the decision-making is not necessarily based on scientific evidence, so, this is as much as I can say I think without slaughtering anybody [laughs] (Professor Ben Chan, Professor of clinical pharmacology at a public university, Singapore, April 2016).

While his qualifier "off the top of my head" serves to distance himself from such lines of argumentation, Chan proposes that it was economic protectionism and national interests rather than robust scientific evidence that drove the demand for clinical data in local populations. Additional studies constituted an effective barrier to pharmaceutical imports that may have significant effects on local biotechnology and pharmaceutical industries. Though one should not, as Kelly and Nichter (2012) warn, overestimate protectionist doctrines at the expense of other social and cultural meanings, Chan's insights are decisive as they disclose that the mobilisation of ethnic or genetic particularity rarely stems from scientific concerns

alone. Instead, he stresses the centrality of political, social and economic dimensions for the emergence of new knowledge claims about specific population groups.

Other respondents such as Dr Connors equally find that formal or informal regulations about the inclusion of local populations due to ethnic or genetic specificities often result from larger political or economic considerations. She notes:

> They [regulators] quite clearly do this because they want to have clinical trials in their country. That helps their country because it takes away their burden to treat patients. So, they want trials. . . . Russia wants trials, Russia put in that you have a to have a certain amount of Russian patients in your trials, otherwise, they're a bit like the US now, otherwise they wouldn't approve, and they really try to enforce this. And that's because they want, first of all it's a stimulation, there's always money involved here, and it also helps patients' access to the drugs early on (Dr Sylvie Connors, regulatory expert, multinational pharmaceutical company, Switzerland, July 2015).

According to Connors, too, arguments about ethnicity are mobilised to advance other aims and objectives. Foregrounding population characteristics works to advance the function of clinical trials as a substitute for healthcare, not only boosting bioeconomic growth through foreign investment but also granting patients prompt access to potentially life-saving drugs and unburdening the state from delivering medical care. This illustrates that ethnoracial arguments in drug research have become convenient vehicles for meeting other, often distinctly political, targets. Framing specific inclusion criteria through the lens of ethnoracial variation appears to offer regulatory authorities a language to couch their otherwise potentially problematic political economic considerations in unassailable terms. Indeed, medical sociologist John Abraham (2002a) confirms that regulatory science is bound to draw on broader social interests and political dynamics, disillusioning assumptions of scientific value-neutrality and disinterest. Scientific and policy judgments intermingle, and decision-making processes are as much informed by scientific facts as by wider public concerns.

A notable distinction to Abraham's account is that, here, it is Indian industry executives rather than drug regulators currently advancing such politico-scientific

claims for the need of research. This exemplifies sustained tensions between industry and government with the latter forced to distance itself from its pro-industry stance by the 2011 Supreme Court decision and consequent public uproar over clinical exploitation. As such, claims to ethnoracial uniqueness also work against the government's effort to tighten regulations and its verdict to significantly limit the number of trials conducted in the country. They come at a time when mounting pressure from media, civil society and the Indian judiciary urges the industry to demonstrate palpable benefits of its research to the local population. Foregrounding genetic properties not only works to attract global pharmaceutical capital interested in India as a future market but also functions to legitimate the need for research that will ultimately augment the health of the nation through the identification of targeted therapies. Robust evidence is hard to come by given the political sensitivity of these debates, but it is safe to assume that claims to ethnoracial uniqueness emerge out of a plurality of sociocultural, political and economic deliberations. These include the potential economic gains to be harnessed from the Indian gene pool as much as the symbolic value of fostering Indian vitality.

9.3 Ill-informed and destitute? Indian clinical trial participants as treatment activists

As Indian clinical investigators increasingly claim to devise research strategies and develop treatments that yield immediate and long-term benefits for their own patients, the role of these patients must also be critically reassessed. Just like narratives of neo-colonialism do not always do justice to the complexities of the field, the description of Indian clinical trial participants as a homogeneous, destitute and voiceless underclass misses emerging accounts of patient activism for tighter regulations *and* pro-corporate campaigns for clinical research, especially among India's affluent middle-classes. True, the experts I spoke with believed that most participants—estimates ranged from 50 to 75 per cent—are recruited from the lower socio-economic strata given the incentive of access to otherwise unavailable medical care. The recruitment of patients with few alternatives for accessing treatment poses intrinsic ethical challenges, not least regarding questions of justice and the fair distribution of the burdens and benefits of research.

However, Bhatt's explication earlier in the chapter that trials *did* make a difference for patients with rare and non-communicative diseases points to another, yet to be illuminated, side of clinical research in India. While much attention has been paid to civil society organising for better protection of participants and stricter ethical oversight (Sama, 2013; Sunder Rajan, 2017; Terwindt, 2014), patient testimonies online as well as at professional meetings and industry conferences suggest that for those possessing the cultural capital and socio-economic privileges to navigate the involved risks and benefits, research participation offers otherwise unavailable opportunities. Focusing on present or future possibilities for drug marketing, it is important to shed light on how research firms seek to transform India into a market to return to, and to carve out a stable consumer base for themselves. In this context, it is equally important to point to how patients themselves cooperate with industry in delineating research aims and identifying experimental treatments. Of course, this is not always successful given the structural constraints caused by monopolist patent regimes, but such pro-corporate engagement, as anthropologist Stefan Ecks (2008) finds, often exists alongside more traditional forms of health activism.

Consider the example of Suman Bolar, a 45-year old food writer, animal lover and mother of two, suffering from clinical depression. Suman gave a poignant and moving talk at the annual ISCR conference in 2015, describing years of battling depression she likened to "living behind glass", and the relief she experienced from participating in experimental research. Similarly, Ramgopal Vallath, who goes by RamG, turned from successful businessman to motivational author after suffering from Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), a rare and debilitating auto-immune disorder. Like Suman, he advanced a vivid plea for more investment in clinical research infrastructures during his talk. He ended an emotionally engaging and rhetorically skilled account of his condition thus:

> What I want to leave you with is that it is extraordinarily important for people like us to get an option of a treatment. It does not matter that there was a risk in it, and the doctor was very clear in it. He said there's a 2 per cent probability of mortality. If it was 20 per cent I would still have gone for it! Because it was so important to me to get some treatment. I was so, so, so close to giving up in life when I discovered this. . . . It is a patient's *right* to get a treatment. It is the patient's *right*

> to be told the risk and let him decide or let her decide for herself that they can choose the treatment. . . . The problem is in India, it is not available. How many people can spend 150.000 Dollars and go to the US and get a treatment [which he did]? If it was in India, you would have been able to get the same treatment at 5 lakh rupees or maybe 10 lakh rupees. So, can you imagine the number of people we are denying this great thing? So, let us understand that there are people there who have a right to go through treatment, knowing that there is a risk in it (Ramgopal Vallath, patient, India, March 2015).[42]

RamG powerfully stresses patients' autonomy over their bodies and their right to participate in biomedical experiments, evoking the bioethical principle of justice as the equitable access to clinical trials. While often (rightly) interpreted as referring to the unethicality of testing therapeutic interventions on populations unlikely to benefit from subsequent applications, justice also points to the need for fair and objective subject selection (Emanuel et al., 2000). According to RamG, the absence of rigorous research in India infringes upon this principle, denying patients the option to assume the risk of an experimental treatment.

Unlike their representation as passive sufferers of corporate onslaught, Indian patients such as Suman and RamG collaborate with medical practitioners and industry bodies to gain leverage in promoting biomedical research on their specific conditions to gain access to experimental therapies. As medical anthropologists Ann H. Kelly and P. Wenzel Geissler (2012: 5) argue, since the methodology of the randomised controlled trial centrally relies on the representative character of the trial sample, it can also function as a political resource and offers "occasions for new approaches to the production of knowledge and value that rest on the dynamic collaboration of civil society". Of course, such patient narratives are often carefully selected top-down by the industry to support their own objectives and bestow credibility upon them. There can be no doubt that Suman's and RamG's stories were strategically selected by the ISCR for their exemplary character and ability to raise compassion as industry bodies in India make a significant effort to reach out to patients. Moreover, RamG's story, though not Suman's, is distinct from others as

[42] RamG's talk at ISCR is also available on youtube which has allowed me to reproduce it verbatim: https://www.youtube.com/watch?v=wlD1qJyqvr8 (last accessed 8 December 2017).

he advocates for experimental stem cell research rather than drug trials. As Carolyn Heitmeyer (2017) points out, stem cell activists and their organising strategies differ from mainstream health activism in India whose work concentrates almost exclusively on large public health issues involving disadvantaged Indians. While concerns over the stringent regulation of clinical trials have been a priority for most activists, similar concerns around stem cell therapy remain peripheral as only few patients with the financial capacities to pay for the expensive treatment are affected.

I chose to discuss Suman's and RamG's stories nonetheless because I believe they exemplify that Indian trial participants are no homogeneous class of dispossessed patients but are, in fact, quite internally differentiated. They are not, or not all, as Parry writes, mere "victims of a voracious neoliberalism: exploited financially, in unstable outsourced employment, working under oppressive contractual service relationships in the bioeconomy" (2015: 33). It has been widely argued that clinical 'workers' intersect with the lowest echelons of informal service work, marginalised by the decline of Fordist production (Cooper and Waldby, 2014; Sunder Rajan, 2006). Their destitution and financial predicament undoubtedly contribute to the 'India advantage' of fast recruitment and low cost. Important as they are though, such accounts overlook, for example, that the majority of global trials conducted in India are Phase II and III patient studies because first-in-human studies are prohibited for molecules developed outside the country. This *de facto* prevents foreign companies from conducting studies with healthy volunteers, guaranteeing Indian citizens at least some protection from drug candidates whose safety is yet unproven in humans. Of course, later phase trials are no less exploitative simply because they reward participation with medical care instead of monetary compensation, but the proscription of first-in-human studies means that the pool of patients looking to research participation as an alternative means of income is rather limited (also Nadimpally and Bhagianadh, 2017).

Homogenising representations also paint a whole array of lived experiences and subject positions with one brush, erasing often highly personal motives to participate in research. Suman's and RamG's stories illustrate that there is significant variance not only between distinct types of clinical 'labourers' (surrogates, egg and sperm donors, clinical trial participants), as Parry (2015) observes, but also within the presumptively uniform group of clinical trial

participants themselves. Reminiscent of a longstanding sociological debate, the primacy given to Indian patients' national or ethnic identities dismisses internal dissimilarities, especially according to socio-economic background, class and caste. It underplays the hierarchical distribution of Indian patients along these lines and underestimates their differential abilities to negotiate the terms of their engagement in biomedical research. In other words, India not only has an abundance of bioavailable bodies but is also home to a burgeoning, confident consumer class eager to participate in Euro-American lifestyles saturated with pharmaceuticals. To reiterate, my intention is not to downplay ethical wrongdoing or instances of exploitation but to understand them better by complicating the very notion of experimental populations.

In terms of their socio-economic status, cultural capital and pro-research stance, patients like Suman and RamG are much more aligned with medical travellers and patient activists in the United States than the destitute volunteers typically portrayed in journalistic and even some theoretical accounts. As Epstein suggests, early AIDS activists in the US successfully constructed themselves as active participants in and credible contributors to the production of new scientific knowledge. He pertinently argues that we need to be wary of construing the role of laypeople in science in purely passive terms, as "a resource available for use, or an ally available for enrollment, by an entrepreneurial scientist who is conceived of as the true motive force in the process of knowledge making" (Epstein 1995: 409). The power of science cannot merely be analysed top-down but requires attention to moments of subversion, agency, collaboration and resistance, or, in other words, "the fluxes of power throughout all the cracks and crevices of the social system" (ibid: 412). While Margaret Sleeboom-Faulkner and Prasanna Kumar Patra (2011) highlight that Indian activists rarely assert influence on state policy through official legal or policy channels and more through informal affiliations with scientific and industry bodies, which Suman and RamG's involvement in the ISCR confirms, both perspectives illustrate that patient engagement plays a vital role in devising research priorities and the conditions for creating new scientific knowledge.

It would be an overstatement to speak of a large-scale, organised patient movement around clinical research in the Indian case, but Suman, RamG and others like them are proactive in seeking to change the structural and institutional conditions under which research takes place. Their involvement indicates a status more akin to

"treatment activists" (Epstein, 1995: 410) than experimental subjects, confidently intervening into debates usually reserved for clinical research professionals. The stereotypical and often victimising representation of Indian trial participants misses instances of such conscious, pro-corporate engagement that exists alongside traditional health activism focussed on protecting impoverished Indians from biomedical harm. Ecks (2008) describes similar dynamics between patient groups lobbying for and against stricter patent protection in the infamous Gleevec case wherein pharmaceutical multinational Novartis sued the Indian government over alleged patent infringement for the chemotherapeutic drug used to treat leukaemia. As Ecks stresses though, pharmaceutical companies and local firms often work to build up a faithful constituency of pro-industry activists who cannot but feel indebted to the company, for example through the free provision of medicines. It may well be that Suman and RamG were given 'gifts' or other incentives to present at the conference since pro-corporate patient activism enhances legitimacy and, ultimately, profitability.

I have explained in more depth in Chapter 3 why I have chosen not to conduct substantive research with participants themselves. The stories I have presented here simply serve to substantiate my argument that clinical research is increasingly held to yield health benefits for the local population by both researchers and patients themselves. Neither are Indian clinical researchers victims of, or silent accomplices to, a neo-colonial project by Western pharmaceutical companies seeking to capitalise on India's corrupted healthcare system, nor are all Indian trial participants compliant 'guinea pigs', a representation that prevailing discussions have perhaps inordinately emphasised. Though these accounts are allied to the compelling cause of revealing the structural constraints that, for many, make research participation the only option to access medical care, they do not engage the multiplicity of stories, perspectives and contradictions *in situ*. As such, they cannot comprehensively explain the complex social and spatial dynamics characterising this transnational field. To adapt Parry's critique, the imagining of Indian clinical trial participants as exclusively working to realise the desires of an overwhelmingly white, privileged class of patients in the West offers a generalised analysis of the broad contours of the field but fails to capture significant internal discontinuities and variations (Parry, 2015: 36).

9.4 Biomedical consumption and national vital values

Equally challenging existing narratives of unidirectional service provision, more and more local biotech companies aim to capitalise on the opportunities of the Indian genepool in the age of personalised medicine. Personal genomics services, genetic tests to determine drug insensitivities and wearable technologies are only a few products currently mushrooming in the country (Limaye, 2013). For example, biotech company GeneStore's leading personalised genomics arm, NutraGene, developed a genetic test for Type 2 Diabetes specifically for Indians, positing the Indian gene-pool as a valuable resource for knowledge production and the creation of economic benefits. Anubhav Anusha, director of NutraGene, explains in an interview with the Indian newspaper *Livemint* that the reason he developed the test was that specific genetic mutations may have different effects in Indian than in Caucasian patients. "For instance," he illuminates, "while a particular mutation could translate into intermediate risk of diseases for Caucasians, it could mean high risks for Indians" (in Ray, 2012: n.p.). Dr Sandeep Saxena of Acton Biotech, a biotech start-up based in Pune, equally explains that while a plethora of genetic tests for various common drugs had already been developed, they may not be suitable for the Indian population (in Thangavelu, 2008). This was a crucial gap in healthcare delivery that his company aimed to address through the development of targeted diagnostics, among them a genetic test determining the accurate dosage of the blood thinner warfarin for Indians.

An exhaustive exploration of these emerging markets is well beyond the scope of this thesis. I here utilise the story of Jai Heart, a risk-assessment algorithm and diagnostic tool for coronary heart disease (CHD), to sketch some key dynamics of and limitations to the creation of value from targeted genetic products and services in India. This is not meant to be a conclusive analysis; rather I wish to offer some preliminary insight into the predicaments of transforming India's bioeconomy from mere service delivery for multinational companies to creating biomedical markets and yielding tangible health benefits for its own population. Drawing on the successes and failures of sectors closely related to drug research in the era of personalised medicine will allow me to underscore the limits of the targeted healthcare industry aiming to exploit the genetic properties of specific populations. Not unlike the financial fiasco that BiDil became, Jai Heart and other products often lack the active consumer base keen, or able, to invest in personalised healthcare; this

points to larger dynamics around biological citizenship and promises of what Ecks (2005) calls "demarginalization", the integration into middle-class society through biomedical consumption.

Jai Heart is an excellent example of an innovative technology that seeks to improve public health through delivering personalised healthcare based on Indians' unique genetic and epidemiological properties. Developed by Jai Medica, a Bangalore-based biotech start-up, it combines conventional risk factors such as age, gender, smoking status, blood pressure and cholesterol with an assessment of ethnicity and the allelic status of the 9p21 gene that is strongly associated with cardiovascular diseases and cancer. Jai Medica was founded by British Indian cardiologist Dr Sanjay Kakkar who sought to push into new commercial ventures in India in 2010. Adopting the bioscientific foundations, commercial strategies and governing philosophies of its equivalents in Europe and the United States, the company wished to adapt existing scientific knowledge for specifically Indian needs. Since few prevailing risk scores had been validated in Indians despite their high prevalence of CHD, it aimed to develop a targeted, clinically validated risk estimation tool "specifically for South Asian and Middle Eastern populations" (Kakkar et al., 2013: n.p.). The result of its nested case-control study with 2068 patients from the Indian Atherosclerosis Research Study found that Jai Heart was more appropriate for South Asian populations than existing risk assessment tools such as the widely-used Framingham score. This was due to its incorporation of additional variables prone to inter-individual and inter-population variation, especially the allelic status of 9p21 but also diabetes history, the family history of premature CHD, pre-existing anti-hypertensive treatments and body mass index (ibid.).

Jai Heart initially caught my attention because of its developers' bold claims about the significance of ethnic factors for assessing CHD. Conference documentation I had found online was littered with vague and eclectic references to Indian, Asian, South Asian, Middle Eastern and African populations, seemingly proposing genetic similarities between them that justified the development of a joint risk assessment tool. When I presented CEO Kakkar with this observation, he was more careful, explaining that the databases utilised for the research were already stratified according to race and ethnicity, and admitting that some of the claims about ethnicity were rather imprecise. Statements were based on the national origin of available datasets, and the exploration of possible extrapolations of data from South

Asian to African populations had only just begun. Jai Heart remains interesting nonetheless since it not only foregrounds the specificities of Indian ethnicity for delivering targeted healthcare but also because it demonstrates the practical obstacles in achieving this aim.

From the outset, Jai Heart aimed at improving "the health of the nation", as Kakkar explains. This is even reflected in the product name itself: Jai, literally 'long live' in Hindi[43], not only promises a long life through a healthy heart. It is also reminiscent of the popular slogan 'Jai Hind', meaning 'long live India' or 'hail India', initially coined as a salutation for Indian soldiers during World War II. As the Indian National Army had historically been organised into regiments along ethno-religious lines, the new salutation introduced by a high-ranking officer replaced religion-based, divisive greetings, seeking to unify soldiers and build an integrated Indian nation. Replacing the traditional Hindu greeting 'Jai Ram ki' with the secular 'Jai Hindustan ki', Major Abid Hasan Safrani eventually coined the shortened, catchier 'Jai Hind' as the Army's new battle cry (Gordon, 1990). As the army has long been an epitome of nationalism, the greeting is therefore inextricably linked to the creation and expression of national unity. Without such militaristic undertones, Jai Heart appears to build on this unifying and nationalist momentum, transcending ethnic barriers and putting *India's* health at the centre of scientific investigations and commercial efforts.

Indeed, Kakkar sees the multiplying incidences of CHD as very much a societal issue affecting the Indian population as such. Not only were heads of household dying in the millions, implying a lack of income for entire families. Their deaths also reflected the lack of adequate healthcare, especially in rural areas where even primary care was often unavailable. For Kakkar, CHD is a demographic as much as an economic problem and developing suitable prevention technologies based on the specific ethnic qualities of the population was hoped to provide relief for India's overtaxed healthcare system. Articulating explicit nationalist and emancipatory sentiments, Jai Heart therefore sought to appropriate algorithms established in the West for usage in India, foregrounding entitlements to quality healthcare and

[43] The use of a Hindi idiom reflects this unifying, nationalist momentum as well. Alok Rai describes in his book *Hindi Nationalism* (Rai, 2001) the linguistic battles in northern India at the time of independence, leading to the victory of political Hindutva over the Nehruvian, English-speaking elites and ousting Persian and Arabic words from the language. Hindi was not only 'sanskritised' to help construct a new, unified identity for India, but this identity was formed in explicit opposition to Pakistan where opposite attempts were made to 'persianise' Urdu.

targeted medications as a way of nurturing the Indian body, individual and collective. As such, Jai Heart not only utilises Indians' ethnic characteristics as a key resource for the development of an ethically laudable and economically viable technology but also points to crucial questions about vital rights, as I will return to discuss shortly.

Similar to the statements by researchers Shivane, Pramesh and Thatte explored earlier, Jai Heart thus mobilises the unifying discourse of Indianness, defined *qua* social and biological markers and grounded in both ethical and economic concerns. Unlike the nationalist rhetoric of unity in diversity advanced by government-sponsored geneticists such as the IGVC, the unit of interest is the Indian population, asserting a degree of biosocial homogeneity and conjuring a sense of shared responsibility. This, of course, is also related to questions of market size as centring on minor population differences disrupts the broad applicability of products. As argued throughout this thesis, the explanation for researchers' shuttling between different representations and multiple scalar levels cannot be found in scientific elucidations alone but needs to consider the larger socio-cultural contexts in which they emerge.

In fact, the very rhetoric of Indianness, as Anandita Bajpai (2017) observes, is not just a remnant of Indian secular nationalism but was revived when the Indian state strove to re-invent itself after the coerced liberalisation of its political economy in the 1990s. Multiple nation branding campaigns created a novel image of an 'emerging', 'rising' or 'shining' India to attract foreign investment but also to evoke affective attachments to the nation by Indian audiences both within and outside India. In some sense, the discourses of Indianness explored here are elicited to similar ends: part of a neoliberal discourse of innovation, regeneration and ethical self-fashioning, researchers mobilise biosocial concepts of Indianness to legitimate clinical experimentation and promote India as a future market. They also claim a unifying grammar of Indian genetic constitutions to represent themselves as candid proponents of national health.

The Indian body, then, has emerged as an important source of value. Two things are of note. First, it is a decidedly national body that has become the locus of such value, though of course the algorithm used to calculate Indian CHD risk biologises Indians' propensity for disease and re-inscribes Indianness at the level of DNA. And second, the economic value of specific tissue cannot be disentangled from its ethical

dimensions. Value is an inherently entangled and multiple notion, and etymological considerations (Graeber, 2001; Skeggs, 2013) suggest a decidedly relational understanding of value. Entwined with words and notions that include, but cannot be reduced to, financial transactions, value is a product of economic, legal and cultural processes. This also means that we need to understand the terrain of drug marketing and population-specific technologies not only with regards to the creation of value by capital, but also to their potential for the improvement of health and the amelioration of longstanding disparities. The Indian body emerges as a target of biomedical technologies that seek to both yield economic profits *and* augment its vitality. Unlike the ways in which the Indian body is construed as valuable only when it can be 'recycled' to revive other biologies (Bharadwaj, 2008), here it is at least portrayed as holding significant potentials for the pursuit of public health.

However, as Kakkar alleges in a somewhat essentialising move, Indian culture exhibited a certain fatalism with regards to healthcare: Indians were either in denial of existing problems or reluctant to spend money on preventive technologies. Moreover, interest in Jai Heart by venture capitalists remained low, and after a lucrative offer by a San Francisco-based pharmaceutical company, Kakkar himself eventually set off for new endeavours. Jai Heart failed to come to market, and Kakkar is currently considering its marketisation as a free educational tool without the attendant genetic analysis. Cost may also have been an influential factor in preventing its success: with a purchase price of just under 5,000 Indian rupees (around 60 pounds) per test kit, Jai Heart may not have been out of reach for affluent audiences, but it was certainly pricey for a technology without any immediate benefits. However, I will argue in the following that cost factors alone do not explain its failure.

9.5 Biological citizenship between demarginalisation and consumerist excess

According to Kakkar, what products such as Jai Heart needed in order to deliver on their promise of ameliorating public health was an approach that was consistent with Indians' "inclination" for entrepreneurship: the activation of Indian citizens as conscious consumers. For him, such a strategy constituted a "disruptive" and "empowering" approach that not only circumvented the government's

unwillingness to "deliver anything" but also challenged the traditional model of paternalistic doctors and submissive patients. His vision is one of consumers rather than patients, and a "coaching" rather than "lecturing" relation between healthcare professionals and their customers. This means that Jai Heart not only capitalises on the promises of genetic medicine by purporting a specifically ethno-national risk; it is also fully in line with the neoliberal trust in the market to solve existing health problems, and the concomitant expectation that Indians will take charge of their own health. The well-rehearsed notion of the 'entrepreneur of the self' is strongly echoed in Kakkar's description of ideal consumers that monitor their own health, including their genetic data.

The healthcare model Jai Heart envisages is deeply rooted in a neoliberal vision of individualised consumption, expressive of a shift in the regulation of life from the state to healthcare professionals, the market and self-governing individuals. Jai Heart's commercial failure was precluded precisely by the dearth of such active, self-governing managers of health and the delinking of social identities and genetic predictions. It envisioned a neoliberal citizen who proactively pursues information about his or her risk for future disease and seeks to contain it pre-symptomatically. Indian individuals are thus addressed on the assumption that their main aim was a healthy and long life, and that they freely seek to identify the means most likely promoting this aim (Rose, 2006). In other words, products such as Jai Heart require the activation of biological citizens (Rose and Novas, 2005) that confidently intervene into existing healthcare scenarios. Akin to the responsible citizens Pramesh conjures, gathering around specific health needs or diagnoses to campaign for more robust clinical research, genetic services necessitate active citizens pursuing the best means to promote their long-term health. This vision, however, fails to factor in existing tensions between India as an emerging site of biomedical consumption and its ambiguous configuration on a global playing field that is anything but level.

The concept of biological citizenship has been discussed in two different yet interrelated strands of literature. One is rooted in the resource-poor settings of the Global South in which patient groups and individuals look beyond the state to safeguard their health. Petryna (2004) describes the case of post-Chernobyl Ukraine wherein citizens harmed by the nuclear disaster mobilise their damaged biologies to stake claims for social membership and new forms of citizenship, petitioning for

access to medical care, social equity and human rights. The other model of biological citizenship, as Chapter 2 has introduced it, stems from Foucauldian approaches to molecular techniques of governing the population wherein "a new space of hope and fear is established around genetic and somatic individuality" (Rose and Novas, 2005: 458). With the emergence of personalised genetic testing, new forms of somatic self-fashioning have conjured new biosocial collectives and associated markets, at least in the liberal democracies of the West.

Despite their variable epistemological assumptions and geographical foci, both perspectives are crucial in understanding Indian scientists' effort to mobilise patient support for clinical research, as well as the market failure of products such as Jai Heart. While Rose's articulation of the concept has been accused of glossing over important distinctions within the Global North (Pollock, 2012b) or misjudging political developments outside liberal democracies (Bharadwaj, 2008), a similar critique could be raised regarding Petryna's approach that focuses on the experience of a purportedly homogeneous population of injured and marginalised citizens. The Indian citizens addressed by the promises of pharmaceutical consumption and preventive medicine sit uneasily between either definition. Their conceptualisation as future consumers promises partaking in the consumptive biomedical practices of the middle-classes in Europe and the United States. At the same time, the global geopolitical forces that shape India's ambivalent position as emerging biomedical player *and* postcolonial configuration, reinforced by monopolist pharmaceutical capitalism, prevent the majority of Indians to truly engage in such consumerist projects.

A similar argument has been made in relation to BiDil. Anne Pollock proposes that the drug's commercial failure points to a distinctly American biological citizenship "in which consumer capitalism and racialized deprivation coexist" (2012b: 60). Though it promised inclusion into a specifically American way of life saturated with (overpriced) pharmaceuticals and thus transformed consumption into a civil rights issue, it missed how structurally underserved its target audience was. In the context of what Clarke and colleagues (2003) term 'stratified biomedicalisation', not everyone can partake in consumerist models of citizenship; BiDil failed to be commercially successful as most African American patients simply could not afford it. While, as Pollock concludes, we can object the reification of racial categories for

pharmaceutical profits, we should therefore also acknowledge that BiDil reflects the sustained denial of care to marginalised groups (2012b: 67).

Significant differences between the two cases notwithstanding, Pollock's perspective is crucial to understanding why BiDil, and also Jai Heart, have remained commercially unsuccessful. The analogy is imperfect yet evocative: both technologies illustrate the premium placed on populations previously marginalised from mainstream biomedical markets. As shown, Jai Heart's explicit aim was to serve and "demarginalize" (Ecks, 2005: 242) the Indian population, positing the suffering caused by escalating incidences of CHD as a core social, ethical and economic concern. The promise of demarginalisation through biomedical technologies is often not limited to the specific underlying health condition but to one's social status more broadly. As Kakkar describes, Jai Heart not only sought to improve early detection of CHD risk but also to restore traditional family values by prolonging the life expectancy of the male breadwinner. Demarginalisation means the integration into the models of biomedical consumption and engagement prevalent in the West, the return to socially acceptable kinship norms and the reintegration into the labour market. Moreover, both technologies also highlight that neither African Americans nor Indians, even from socio-economically privileged backgrounds, easily embody the active patient-consumers required for their commercial success. A key hope by NitroMed as well as Jai Medica was that patients were well-versed in the promises of genetic medicine and would absorb the publicity around their products. Yet, as most of my respondents emphasise, awareness of the benefits of genetic medicine remains low even amongst Indian healthcare professionals, and the lack of a feasible healthcare infrastructure and out-of-pocket expenditure present significant barriers. In situations where the majority of people are uninsured and lack access to even basic medical facilities, consuming and advocating for new biomedical technologies is, as Benjamin puts it "an invitation to a roulette game in which, it seems, their number is never called" (2013: 18).

In short, Jai Heart's commercial failure was caused by the misjudgement of the Indian therapeutic context which occupies an ambivalent status between biomedical market and structural deprivation. For any vital or economic value to be realised from the Indian population, not only would the public, as Kakkar suggests, need to be "sensitised" for the significance of genetic susceptibilities and, accordingly,

preventive technologies. I propose it would also, and perhaps primarily, require improved health budget allocations and overall enhanced economic conditions. Not unlike prevailing questions about post-trial access to medicines raised by public health activists, the arduous beginnings of preventive medicine point to the structural constraints caused by the precarious state of Indian public health. The promise of demarginalisation misses, or readily disregards, that Indians scarcely figure as conscious consumers. It ignores, as Bharadwaj (2008: 101) writes, that "the complexities and compulsions individuals and/or collectivities face in emerging neoliberal formations like India seldom produce powerful opportunities to harness or gain anything remotely profitable" from engaging in consumerist models of biological citizenship.

Nonetheless, Indian scientists' efforts into making clinical research results available locally as well as the emergence of a range of new products such as Jai Heart that aim to enhance the health of the Indian population illustrate that the juxtaposition of unethical biomedical practices in India with the life-augmenting technologies prevalent in the West is only part of the story of how novel biomedical technologies travel across the globe. Though indispensable to expose global inequalities, binary oppositions distort the finer intricacies and internal contradictions of growing biomedical markets. Indian patients may not be the active consumers required for biomedical citizenship projects, but neither are they the purely experimental, bioavailable subjects often conjured. Likewise, Indian clinical researchers engage in the representative politics of promoting public health as they seek to shake off the image of conducting ethically flawed experiments. To draw on Parry's critique again, dualistic narratives may only help replicate stereotypical representations of India as the global warehouse for spare body parts, 'wombs for rent' or clinical services without adequately attending to the myriad biomedical technologies currently seeking to penetrate its economic and social spheres.

9.6 Conclusion

This chapter has turned to India as an emerging site of biomedical consumption and has considered how ethno-national descriptors are deployed in stirring support for drug research and in marketing practices. I have argued that India is not only a preferred location for the conduct of global clinical trials by multinational

pharmaceutical companies but that local research firms also mobilise the qualities of the Indian gene pool to legitimate research and the necessity of population-specific products and therapies. While this means that the conventional narrative of a new colonialism by pharmaceutical multinationals eclipses important differentiations, I have also shown that national population descriptors continue to shape which populations are deemed economically valuable. Departing from research on the reification of race in the biosciences, I have argued that the prominence of national markers and economic considerations stratifying presumed racial groupings should caution us to assume race to be the prime factor for population classifications. Put differently, to understand contemporary global dynamics of pharmaceutical production, circulation and consumption, we should be attentive to the ways in which citizenship and notions of national belonging continue to inflect the delineation of and potential value derived from specific populations.

Chapter 10: Conclusion

Given the growing costs of clinical research, regulatory requirements on larger sample sizes and the heightened interest in novel biomedical markets across the globe, core elements of drug development have recently been relocated to countries in the Global South. India, in particular, has emerged as a preferred destination for clinical trials since it became fully compliant with the requirements of the TRIPS Agreement. Researchers and drug regulators vociferously proclaim the numerous benefits of conducting research in the country, including its large and genetically diverse population that offers ample opportunities for biomedical research. Against this geopolitical and economic backdrop, this thesis has examined how the ethnoracial qualities of the Indian population are construed as a locus of scientific, ethical and economic value by various stakeholders. With the aid of a range of primary sources including archival data, ethnographic tools and qualitative interviews, it has addressed two overarching questions. First, how do ethnoracial qualities contour global clinical trial offshoring and implementation? And second, how are specific populations constituted and mobilised by the myriad actors in the field, often for contradictory objectives?

10.1 Key disciplinary contributions

Asking these questions, this thesis has empirically investigated a simple theoretical principle: insisting on the constructionist character of social categories of difference, especially race and ethnicity, not only omits the corporeal effects of embodied difference but must also remain unsuccessful in fully grasping the discursive formations, material structures and institutional arrangements that maintain them. Rather than readily dismissing these categories as scientifically invalid, I have sought to probe the specificities of innovative biomedical technologies, including their epistemic and socio-cultural conditions of possibility, that have bestowed new analytical capacities upon race/ethnicity. I have aimed not to repudiate existing statements about ethnoracial variation in drug response and disease expression as indicators of a naïve reductionism or, even worse, the return of race science, but to analyse when, how and why they come to matter in contemporary biomedical research.

As such, this thesis has made significant contributions not only to the sociology of race and racism *and* to STS investigating the surge of bioscientific research on ethnoracial difference, but also to a growing dialogue between them. The increasing number of biomedical technologies developed for specific populations, from vitamins to genetic tests to drugs, has startled scholars in both subdisciplines to the biological reification of what were believed to be primarily socio-political classifications, potentially paving the way for new forms of social stratification and economic exploitation. Despite an initial divide between both 'camps', equally provoked by STS's overall silence on issues of race, class and gender and sociologists' inability to distinguish between "the analytical wood of STS and some fairly manifest deficiencies in the trees that make it up" (Law, 1990: 2), recent accounts have engaged more fruitfully with the mutual connections between the subdisciplines. While David Skinner and Paul Rosen (2001) aptly criticised STS scholarship almost two decades ago for dropping questions of race, and especially racism, off its academic agenda, current work more successfully bridges STS and critical sociologies of race to investigate not only the meaning but also the materiality and effects of race and racism (Rodríguez-Muniz, 2016; for examples see Benjamin, 2013; M'Charek, 2013; Nelson, 2008;).

Though rooted more firmly in the race critical side of this divide, I have aimed to become more versed in STS approaches to further advance such interdisciplinary scholarship. As Duster (2015) pointedly argues, social scientists cannot remain silent on novel scientific debates about race but must engage in an open dialogue with them while also providing a critical framework for evaluating how scientists research and reify race (and often ethnicity) as genetically based. The stakes of being left out of the conversation are too high for sociologists to maintain artificial disciplinary boundaries. As such, Chapter 5, for example, made use of STS critiques of modernist divisions between nature and culture (Douglas, 1986; Haraway, 1997; Strathern, 1992), aiming to think about the relationship between biology and society in less reductionist and more relational terms. Likewise, Chapter 7 drew on STS work on standards and standardisation to underscore the structural inequalities conditioning how global research is conducted and by whom. It also utilised the concept of local biologies to engage more thoroughly with the materiality of embodied difference that often disrupts biomedicine's premise of a standard human. As such, I have challenged the conventional sociological

hypothesis that race is a social construct with little to tell us about biology all the while pushing STS scholarship to engage more fully with the socio-political realities of racialised difference and colonial legacies outside the laboratory or the clinic. Though some scholars, for example Benjamin (2013), have emphasised the social dissonance between the investments made in speculative research and the enduring struggles to access even basic forms of healthcare in both the Global North and South, STS scholarship still tends to privilege the lab as its main, if not its exclusive, site of investigation. Throughout, I have also reiterated the race critical stance that warns of the erroneous inference of genetic causality as well as the ascription of explanatory value to race and/or ethnicity.

Not least, my study has contributed to the expanding literature on clinical trial offshoring and the burgeoning bioeconomies of the Global South. It has engaged with the role of specific populations that figure prominently in both the sites chosen for multi-regional trials and new articulations of genomic sovereignty and national identity. While existing studies have predominantly focused on the ethics and/or economics of such processes, often without recourse to original empirical material, I have enriched them through primary data *and* interdisciplinary labour. To do so, I have drawn on research that locates the global discourses on biological diversity, human or otherwise, within renewed debates about colonialism, exploitation and national sovereignty. As Reardon aptly notes, "[u]nder the header of 'biocolonialism' and 'bioprospecting', many scholars and activists alike observe links between Western exploitative practices, and the production of diversity as a site of informational and commercial value" (2005: 367). Extending these practices from the domain of raw materials to the domain of humans, pharmaceutical and biotech firms stand accused of carrying forward familiar techniques used to oppress and capitalise on communities in the Global South. While there can be no neat partition between the exploitative practices of Western corporations and local elites as they collaborate in transforming, here, India into a prime destination for biomedical research, my data has revealed the finer details and complexities of the relationship between governmental practices both old and new, pharmaceutical capital and the struggle for national bioeconomic independence.

Through my empirical material I have argued that it is an amalgamation of scientific, pragmatic, socio-political, economic and ethical vectors that produce specific populations as central concerns in drug research. Inflected by their

familiarity and common-sense character, the commercial incentives of industry-driven clinical research and the aims and aspirations of local stakeholders in both public health and biomedical entrepreneurship, ethnoracial qualities are enacted in multiple and seemingly paradoxical ways. In particular, I have shown that the vagueness and fluidity of ethnoracial categories more broadly, and Indians' historically ambiguous status more specifically, does not prevent but rather fuel their mobilisation in biomedical practice. Below I present a brief review of my principal arguments.

10.2 Chapter summaries

Based on the hypothesis that biomedicine has turned away from the proclamation of a standard human and turned to the exploration of human (genetic) diversity instead, this thesis has examined the scientific, ethical and commercial value of the Indian population for clinical studies, often declared a "goldmine" (Apte, 2012: 982) for research. Chapters 1 and 2 have set out the empirical and theoretical frameworks in which the arguments of this thesis unfold. I have shown that though many sociologists proclaim the risk of novel, ethnoracially specific biomedical markets disguised by a new interest in life, the economics of and global inequalities in contemporary drug development contest such accounts. I have also proposed that in order to grasp the pervasiveness of ethnoracial arguments in biomedical research and practice, we cannot simply explain them away by social constructionism or buy into their explanatory value as independent variables. Rather, in this thesis I have followed approaches that have sought to carefully document the specificities and particularities of the multiple enactments of race, ethnicity and other categories of difference as they surface in the processes of global clinical research collaborations between multinational pharmaceutical corporations, US-American regulators and Indian researchers on the ground.

In Chapter 3 I have set out the methodological principles that have informed my research as well as some of the practical and ethical obstacles I have encountered during data collection and analysis. I have argued that neither the design of this project nor the reflections I offer can be decoupled from the socio-cultural contexts in which they have emerged. My own situatedness and the fluidity of social identities have significantly inflected my perspective and I claim no prerogative in

interpreting the social worlds unfolding in this thesis. Nonetheless, I have, following Haraway, aimed to 'stay with the trouble' and sought to delineate how ethnoracial diversity is enacted and mobilised in drug research, why and with what effects. The chapter also introduced my research respondents and the archives I visited, described the particulars of these encounters and discussed the limits of both interviewing and archival research vis-à-vis the knowledge claims I made in this study.

Chapter 4 has traced contemporary arguments about Indian population diversity back to their historical origins in nineteenth and twentieth century anthropology and biology. This was not to offer a comprehensive account of the historical record but to ground present-day narratives in their historical conditions of intelligibility. My research revealed that in the period I examined, colonial scientists were intrigued by the opportunities the Indian population structure offered to the scientific study of race, and stunned by what they interpreted as simultaneous similarities and differences to Europeans. Repudiating the primary scholarly focus on the analysis of caste, they emphasised the explanatory value of race concepts for both knowing and governing the Indian population. Throughout, most of them perceived Indians as holding a historical connection to whiteness that had been (temporarily) tarnished by environmental, historical or cultural forces. Nonetheless, racialised discourses about Indians were never hegemonic nor homogeneous but widely contested and variably appropriated by critical voices from the metropole and Indian scholars. The chapter added to existing research focusing on the governmentality of caste and illuminated the exceptional status Indians occupied for race science. Ultimately, I have proposed that contemporary depictions of Indians as similar enough for the purposes of clinical research recuperate their colonial representation as almost white, but not quite.

Chapters 5 and 6 laid out how biomedical researchers and policy makers conceptualise and operationalise ethnoracial variations in contemporary drug development. In contrast to basic research in the lab, for example in genetics, Chapter 5 has found that clinicians must calibrate an entire range of factors shaping human variation along with the political parameters and economic considerations structuring transnational clinical trials. Within these constraints, they resort to racial classifications of human diversity not because they believe in their truth-

making capacities but due to often messy nature of biomedicine as both research and practice as well as the pragmatic quality of decision-making and the bureaucratic expectations of their concrete working environments. For them, race is what I have called an uncertain certainty that promises at least some insight into existing variations, sometimes, though by no means always, provoking further analysis. Clinical researchers' ethically laudable concern with ethnoracial health disparities is tempered, however, by the increasing weight given to genomic analyses often curtailing the study of biocultural interaction, or rather "intra-action" (Barad, 2003), rescinding the prior existence of independent entities. In other words, the growing significance attributed to the environment in the post-genomic era (Fox Keller, 2015) has not done away with defining race through the genome. Attending to the specificities of transnational drug development rather than proclaiming an overall surge in bioscientific studies of ethnoracial variability, through my empirical data I have added to existing sociological research that has predominantly focused on the narrow confines of the United States and/or based its claims solely on materials already in the public domain.

The recurring prevalence of racial as opposed to the relatively volatile parameters of ethnic concepts also means that the Indian population can be construed as genetically affiliated with the actual populations of interest for pharmaceutical capital, namely Euro-Americans. Chapter 6 has challenged prevalent arguments in the sociological literature about the inevitability of ethnoracially-segmented drug markets and established the pharmaceutical industry's concern with locating those populations for research that are genetically similar to the target population, thus promising a cleaner data set, at least when relocating trials to cheaper destinations. Naturally, this does not mean that racial arguments play no role in relocating clinical trials but that, as my study revealed, it is sameness rather than difference driving these decisions. Global biomedical research rests on the assumption that even if variations exist between populations, they can easily be standardised or flattened through the methodologies of the randomised controlled trial—though some populations are considered more readily standardisable than others, often through a racialised lens. The portrayal of Indians as 'brown' or 'heterogeneous' Caucasians not only recuperates historical representations but also "tethers" (Hinterberger and Porter, 2012) biological materials to constructed origins of the nation state.

Chapters 7, 8 and 9 have focused more closely on the specificities of the Indian context. In Chapter 7, I have investigated how ethnoracial variations are dealt with when conducting clinical research that is predicated on the supposition that human diversity can be standardised across an entire range of geographical, cultural and biological boundaries. By way of my Indian respondents' experiences, I have illustrated that not only do the local biologies of Indian research participants defy this supposition; more importantly, the labour of attending to and managing existing variations predominantly falls to local researchers given the global geopolitical configurations that forge India's status as a service provider for multinational pharmaceutical corporations. As assumptions about the world's main genetic populations are being upheld in biomedical science in an explicitly racialised guise, the confounding effects of nationality, culture, gender and variable biomedical standards are ironed out to ensure the smooth functioning of multi-regional trials, frequently to the detriment of local collaborators and patients. In defiance of prevailing concerns with the growth of ethnoracial niche markets, the presupposition of a standard human—a *Caucasian* standard human, to be more precise—still shapes the conception and conduct of clinical research, at least when moving beyond the confines of the United States.

Chapter 8 has juxtaposed the assumption of the standard human with the findings of the Indian Genome Variation Consortium (IGVC), a large-scale, publicly-funded genomic research project. It has described the biopolitical objectives driving both genome research and clinical trials which centre on Indian population diversity, albeit in fundamentally different ways. Though both are key actors in India's burgeoning bioeconomy, I have shown that while the IGVC mobilises its research findings to drive national cohesion and public health, trials conducted by or for the multinational pharmaceutical industry reap only those qualities of the Indian population that are best suited to advance its goals of promoting health elsewhere. This means that the project of genomic sovereignty the IGVC envisions, what we might better characterise as *graduated* genomic sovereignty, is shot through with interests in novel biomedical markets, making Indian populations variably the benefactors and victims of current biomedical research practices. The chapter has illuminated the simultaneity of empowering and exploitative practices in the procurement of Indian genetic properties, rendering them a flexible resource for both pharmaceutical capital and political aspirations.

Chapter 9, ultimately, has turned to India as a site of biomedical consumption. In doing so, I have challenged existing research that has focused on India as either a location for clinical trials or the deprivation of essential medicines and has tended to portray Indian patients and research participants as passive victims of either (or both) of these two biocapitalist regimes. I have proposed, first, that claims of a unidirectional service provision do not do justice to the complexities of the field as at least some Indian patients are more closely aligned with the treatment activists of advanced liberal democracies than the exploited 'guinea pigs' journalistic as well as some scholarly narratives construct. I have detailed, second, the ways in which ethnonational arguments are advanced by Indian healthcare entrepreneurs in the clinical trial and auxiliary sectors to boost their own objectives. Indian genetic properties are mobilised for nationalist arguments about the need for biomedical research and consumption tailored to the local population. The specificities of the (presumably homogeneous) Indian population are put in the service of advancing national bioeconomic growth, but the actual health effects for Indian patients remain highly speculative. Here, too, remains a fundamental gap between the value of specific ethnoracial qualities in the lab or the clinic, and a broader concern with the tenets of social justice and equal access to healthcare.

10.3 Pathways for further research

This thesis has aimed to construct a broader survey of the discourses and practices around ethnoracial diversity in transnational drug development. Though it has used the Indian context as a site to think through some pertinent questions and to review existing arguments in the sociological literature that has predominantly focused on US-American realities, it was not a study of clinical research in India *per se*. This has allowed me to contextualise prevailing, often purely library-based debates through rich empirical data and expand them beyond the confines of the United States, significantly enriching them by addressing the messier realities of pragmatic, industry-funded research, unequal geopolitical configurations and national political ambitions.

However, this aim has prevented me from turning to the finer intricacies of the Indian context, of a particular condition and the search for its treatment, or of a specific trial. As the organisation of global clinical trials is shot through with

various national and/or regional regulations and each drug and the condition it aims to cure are profoundly specific in terms of their underlying pathologies, metabolic processes and socio-cultural significance, I have at times struggled to map *the* international discourse on ethnoracial variability. In fact, as I have argued in Chapter 3, such a discourse did not exist prior to my analytical labour that constructed it as such. This means it would be highly fruitful for further research to focus more closely and examine through empirical data the nitty-gritty of dealing with human variation at the level of a single trial, a specific drug, or a particular location. Needless to say, a variety of empirical contexts promise rich data about the construction of ethnoracial variation through biomedical practice. Not least, these include settings where comparative studies between populations are conducted (for example Singapore), where narratives about hybridity and mixture are particularly prevalent (for example Brazil) or where the histories of white supremacy, racial segregation and/or extinction render the imperative to ethnoracially classify specific populations a profoundly sensitive endeavour (for example Germany or South Africa) (for a rare discussion of the German context see Nieden, 2014).

Furthermore, due to the nature of my study as largely focused on the conceptual level, I have been unable to address more fully the intersections of race and ethnicity with other categories of difference, especially gender. I agree with Karen Barad (2011) in that the concern of critical feminist scholarship is not with women or gender *per se* but aims at developing an explicitly feminist understanding of the political, including through insights from race critical and postcolonial perspectives. To think that the sole contribution feminist research has to offer is to 'add' women certainly derives from an impoverished understanding of social critique. Nonetheless, exploring in more detail how ethnoracial descriptions are gendered and how scientific narratives about sex and/or gender are tethered with assumptions about race and ethnicity constitutes a promising avenue for further research. This is especially so as my research respondents themselves have pointed to the presumed parallels between race/ethnicity and sex/gender. For instance, Dr Herbst at Quintosh argued that nearly 95 per cent of drugs were tolerated similarly across racial groups; when prompted for examples, however, he instanced differences in the expression of the Fragile-X-Syndrome, also known as Martin-Bell-Syndrome, between men and women (the syndrome affected men disproportionately since they only had one X-chromosome). Using the analogy of

sex/gender to explain race/ethnicity powerfully evokes the association of structural similarities between the two, lending both new meaning as biogenetic problems (see Chapter 5; also Stepan, 1986).

10.4 In conclusion: which matter comes to matter?

To conclude, I would like to go back to the beginning—more precisely, to my very first interview that took place at Quintosh Pharma in the summer of 2014. That day, I met with Dr Joseph Obasanjo, an executive for diversity and inclusion at Quintosh with, to my surprise, a background in the humanities and social sciences. Welcoming me with a tongue-in-cheek "you didn't expect to meet someone like me here, did you?", Obasanjo's perspective as a critical scholar *and* an executive for the pharmaceutical industry proved invaluable for my understanding of the industry's key concerns and priorities. As I met him quite early in the research process, we also spent considerable time thinking through my interview questions. Indeed, his line manager Amit Wadia, whom I had actually wanted to speak with, insisted on my meeting with Obasanjo first to "refine my ideas"—presumably to ensure I was not going to waste *his* time. Rather than sleek management speak about the benefits of maximising plurality for the company's return-on-investment, Obasanjo offered precious insight into the complexities of Quintosh's diversity and inclusion mandates.

One of Obasanjo's most valuable propositions was that I refer not to ethnoracial differences in my project description but to ethnoracial *diversity*. Difference, he reasoned, conveyed a too conflictual and confrontational image of human heterogeneity and risked alienating future respondents. Diversity, on the other hand, was more celebratory of existing variations and positively acknowledged the productivity of including a range of perspectives and biological constitutions into the company's research and marketing strategies. More than linguistic nit-picking or misconceived political correctness, his suggestion points to the ways in which naming and classifying human variation is bound up with broader questions about history, justice, and social equality. Feminist and critical race scholar Sara Ahmed (2012) in her acclaimed account of diversity politics in higher education describes how the language of diversity allows its practitioners to invoke human difference without the appearance of criticism or complaint, or the commitment to action or

redistributive justice. In contrast to other analytical frameworks such as (institutional) racism or equity, as Gloria E. Anzaldúa also argues, diversity can sometimes be a "superficial over-lay that does not disrupt any comfort zones" (Anzaldúa and Keating, 2009: 205), or "a coping mechanism for dealing with an actually conflicting heterogeneity" (Bannerji, 2000: 37, in Ahmed, 2012).

Obasanjo's insistence on the neoliberal terminology of diversity suggests that the diversification of biomedical research portfolios and the inclusion of previously marginalised populations does not necessarily imply a commitment to alleviating the structural causes of existing variations in disease prevalence, access to treatment or the global distribution of bioscientific knowledge. The glossy appearance of diversity, and the ease with which it can be circulated, as Ahmed (2012) writes, indicates that it accumulates both affective and commercial value but also conceals a lack of emancipatory potential. As the commercial failure of BiDil, for example, demonstrated, the development of race-specific drugs not only reifies ethnoracial populations but also underscores the absence of engagement with the structural inequalities conditioning the health realities of many African Americans.

The discrepancies between diversification and genuine transformation urge us to ask who or what even qualifies to be recognised as diversity or, as Alana Lentin and Gavan Titley put it, which bodies represent "the right kinds of diverse" (2011: 157). This thesis has illustrated that national regulations and bioeconomic ambitions are central to shaping the value of specific ethnoracial populations, producing certain differences as (clinically) significant while simultaneously glossing over others as they align them with global markets and geopolitical concerns. Indian population stratification, for example, is routinely omitted, especially with regards to those populations that do not have the purchasing power central to pharmaceutical business models.

Stefan Timmermans and colleagues (1998: 203) refer to such practices as processes of differentiation and dedifferentiation: Dedifferentiation means that existing differences are covered up, blurred or removed altogether, while differentiation points to the construction of novel distinctions or the reinforcement of existing ones. While these are central to making successful and practically workable classification schemes in biomedical practice, I argue that which or whose differences are reinforced and whose are covered up or removed is moulded by the unequal global distribution of scientific, political and economic authority. In the

global arena of pharmaceutical experimentation, some differences come to materialise and/or *matter* but not others, always contingent on the postcolonial power relations between pharmaceutical companies, local research organisations and national regulatory authorities. This means that some regulators, for example the Chinese or Japanese, are authorised to claim ethnoracial uniqueness and adopt corresponding policies and regulations while others are not. As Täubel sarcastically notes "they can afford it, they're a rich nation whereas of course the African nations typically don't have any opportunity to be as choosy". African countries, as Miller puts it in an equally cynical tone, are "lucky to get drugs at all".

More than scientific or pragmatic decision-making, which differences become what Bruno Latour describes as "matters of concern" (2004), underlining the values and affective agendas that lead to privileging certain scientific facts over others, thus hinges on a regulator's symbolic, economic and social capital. As Bourdieu (1975) asserts, at stake in the construction of scientific evidence and authority are, in equal parts, technical capacity *and* social power that allow a specific agent to speak legitimately in scientific matters. Scientific authority, he notes, is a particular kind of capital which can, just as other forms of capital, be accumulated, transmitted and even (re)converted into other kinds of capital (Bourdieu 1975, 25). Many African regulatory authorities, as my respondents assert, do not possess these kinds of capital that would give them power over the constitutive mechanisms and foci of globalised drug research, not least due to the contemporary legacies of colonialism and expropriation. As such, it is not only vital for future research to attend to the co-imbrications of race, ethnicity and their larger economic and geopolitical contexts; it is just as crucial to investigate why some populations, but not others, are ascribed value in biomedical projects concerned with ethnoracial (health) disparities.

Appendix 1: List of interviewees

* Please note: the below are pseudonyms when in single quotations marks.

1. 'Prashant Nath', MPharm: Pharmacist, sociology student, consultant to the Drugs Controller General of India and CEO of an Indian CRO located in Gurgaon, India
2. 'Amit Wadia': Clinical pharmacologist and diversity and inclusion officer at Quintosh Pharma, Switzerland
3. 'Alice Friedman', MD: Global Head of clinical sciences, Quintosh Pharma, Switzerland and India
4. 'Lokesh Oberoi', MD: Medical director, Quintosh Pharma, Switzerland and India
5. 'Kaushik Bansal', MD: Clinical head, Quintosh Pharma, Switzerland and India
6. 'Rahul Khanna', MD: Medical director, Quintosh Pharma, New York
7. 'Rainer Mössinger', MD: Pharmaco-epidemiologist and expert in tropical medicine, Quintosh Pharma, Switzerland
8. 'Amit Regal': Manager, Quintosh Pharma, Switzerland
9. 'Joseph Obasanjo', PhD: Diversity and inclusion officer, Quintosh Pharma, Switzerland
10. 'Jean de Boer', MD: Cardiologist, Quintosh Pharma, Switzerland and South Africa
11. 'Sylvie Connors', PhD: Regulatory expert, Quintosh Pharma, Switzerland
12. 'Ralf Herbst', PhD: Mathematician and statistician, Quintosh Pharma, Switzerland
13. 'Sunita Bhave', PhD: Public health researcher and feminist bioethicist, working for a women's rights organisation in New Delhi, India
14. Barbara Bierer, MD: Professor of medicine, Harvard Medical School, and Faculty Director of the Harvard Multi-Regional Clinical Trial Center, USA
15. 'Divya Nayak', MD: Head of pharmacology and member of ethics committee at a public hospital, Mumbai, India
16. 'Sonali Mishra', PhD: Biotechnologist at a consultancy firm, Mumbai, India
17. Arun Bhatt, MD: Physician and CEO of CRO ClinInvent, Mumbai, India
18. 'Tista Dutt': Director of regulatory affairs at Quintosh India, Mumbai, India
19. 'Manoj Mehta', MD: Medical director, Quintosh India, Mumbai, India
20. 'Anandita Rao': Training manager, Quintosh India, Mumbai, India
21. 'Shilpa Reddy', MD: Physician and principal investigator at Santora Therapeutics, Mumbai, India
22. 'Dilip Kapoor', MD: Head of cardiovascular and metabolic diseases, Quintosh India, Hyderabad, India
23. 'Rajesh Aggarwal, MD': Physician and principal investigator at Indian pharmaceutical company, Mumbai, India

24. 'Shifa Abbasi', MD: Medical head and executive director at Clintech India, Mumbai, India
25. Kiran Marthak, MD: CEO of CRO Lambda, Mumbai, India
26. Suresh Kamireddy, MD: CEO of CRO ClinSync, Hyderabad, India
27. 'Mansoor Khan, PhD': Clinical pharmacologist, Quintosh India, Hyderabad, India
28. 'Kunal Chopra', MD: Head of medical operations, Mayer Group, Mumbai, India
29. Jörg Täubel, MD: CEO of Richmond Pharmacology, London, UK
30. 'Irene Miller', MD: Physician and head of ethnopharmacology, Clintech, Sydney, Australia
31. 'John Ahmed', MD: Senior director, clinical pharmacology, Clintech, London, UK
32. Robert Temple, MD: Deputy Center Director for Clinical Science, Office of Drug Evaluation (CDER) and Acting Deputy Director of the Office of Drug Evaluation I (ODE-I), FDA, Washington DC, USA
33. Jonca Bull, MD: Ophthalmologist, Director of the Office of Minority Health, FDA, Washington DC, USA
34. 'Judith Goldstein', PhD: Ethicist and adjunct professor in personalised medicine, Boston, USA
35. 'Yukiko Kobayashi', PhD: Statistician at a large multinational pharmaceutical company, Cambridge, MA, USA
36. 'Ben Chan', MD: Professor of clinical pharmacology at a public university, Singapore
37. Brian Tomlinson, MD: Adjunct professor of medicine, The Chinese University of Hong Kong
38. 'Caroline Smith', PhD: NIH inclusion officer, Washington DC, USA
39. Munir Pirmohamed, Sir, MD: Professor of medicine and NHS Chair of Pharmacogenomics, Liverpool, UK
40. Sanjay Kakkar, MD: Cardiologist and founder of Jai Medica, San Francisco, CA, USA
41. Samir K. Brahmachari, PhD: Biophysicist and medical geneticist, Professor at Indian Council for Scientific Research
42. 'Jonathan Clifford': Statistician at Human Medicines Evaluation Division, European Medicines Agency, London, UK

Appendix 2: Schedule of questions

* Please note: some questions varied according to the specific respondent's professional expertise; reproduced below is the schedule of questions from my interview with Professor Chan.

1. Could you tell me a bit more about the research you do within the context of global clinical trials?

2. In your experience, how (if at all) do race and ethnicity matter in drug development? And how do they matter in your specific field of expertise?

3. What *are* race and ethnicity?

4. I am particularly interested in multi-regional clinical trials: how can the consistency of (ethnic) data be ensured in such trials?

5. What are the considerations when designing a multi-regional trial, especially with regard to potential ethnic variations?

6. What are some of the potential challenges in assessing racial or ethnic differences *globally*? How are these challenges addressed?

7. Do regulatory authorities prefer data from within their own country, and if so (if not), why?

8. I am interested in the case of Singapore which is often celebrated as an ideal place for multi-regional trials due to its ethnic diversity; can you tell me a bit more about how (if at all) this diversity is valuable for drug development?

9. How is ethnicity taken into consideration when selecting participants? What are different sampling methodologies?

10. Could you take me through an example where you saw (clinically significant) ethnic variation? What happened?

11. And finally: what do you think needs to be done to improve the assessment of racial and ethnic differences in drug development? What steps are being taken?

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