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Lost Along the Way? Searching for the Inclusion-and-Difference Paradigm in Pharmaceutical Research and Regulation in Sweden

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Abstract

This article examines how the U.S. 'inclusion-and-difference paradigm' translates to the Swedish context. According to Steven Epstein (2007), this paradigm combines health equity arguments for racialised minorities and women with a biological understanding of racial and gender differences in medicine. Drawing on interviews with experts, policymakers, and clinicians involved in international clinical trials in Sweden, we argue that critical elements of the U.S. paradigm – notably the 'categorical alignment' of race-and-ethnicity taxonomies between the social worlds of medicine, government bureaucracy, and political discourse – are absent in Sweden and, more generally, Europe. Consequently, there is no coherent framework for interpreting the existing 'niche standardisation' of certain medicines based on race and ethnicity, such as racialised treatment recommendations. In conclusion, we discuss possible future scenarios and highlight a recent collaboration between the pharmaceutical industry and EU institutions. Despite the challenging context, this collaboration aims to establish a European standard for race and ethnicity data in clinical trials. However, we argue that such attempts warrant caution: with racism being so widespread in contemporary Europe, emphasising racial differences in medicine may unintentionally reinscribe harmful notions of race.

Keywords: Race; racialisation; pharmaceutical regulation; common-sense; Germany

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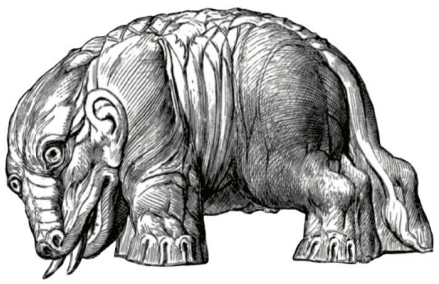

Introduction

Recent research has shown how practices of collecting and analysing clinical trials data based on racial and ethnic categories have spread from the United States to European countries. In 90% of all Phase-3 trials – the trials designed to demonstrate product safety and efficacy – conducted in Europe 2019, the race of the participants is recorded using U.S. racial categories (Mulinari/Bredström, *in press*). This research has also demonstrated how the spread of racialised clinical trial practices to European countries is underpinned by supranational and national regulatory guidelines and standards that strongly incentivise – if not require – the collection and analysis of data by race (Mulinari/Bredström 2024b). Several U.S. regulatory policies have been key for advancing pharmaceutical research on racial differences, including definitions of key concepts adopted by industry and regulators globally. Foremost among these is the 2005 U.S. Food and Administration's (FDA) Guidance document, *Collection of Race and Ethnicity Data in Clinical Trials,* later revised in 2016 (FDA 2016). This document outlines the FDA's expectation that drug companies collect and report information regarding the race and ethnicity of individuals participating in clinical trials and it recommends a common format for obtaining this information for both U.S. and international trials, to be submitted for regulatory review to the FDA.

Sociologist Steven Epstein (2007) has explained how such U.S. regulatory policies should be understood as part and parcel of an "inclusion-and-difference" paradigm that has been dominant in U.S. biomedicine since the 1990s. This paradigm emphasizes the importance of *inclusion* of members of racial and ethnic minorities, who are often considered to have been underrepresented previously as subjects in clinical studies, followed by the measurement of group *differences* in treatment effects, disease progression, or biological processes. Critically, the paradigm is based not only on the idea that race (alongside ethnicity, gender, and age) is a vital variable in understanding biological differences, but also that the "one-size-fits-all" approach to medical treatment ignores therapeutically important biological differences between races and therefore may propagate health inequalities. Thus, a significant aspect of the inclusion-and-difference paradigm is the fusion of social justice arguments with biological concepts of race (Epstein 2007; Kahn 2012).

Epstein introduces two central concepts for understanding the inclusion-and-difference paradigm: "categorical alignment" and "niche standardization". Categorical alignment refers to the use of the *same* demographic categories, such as Black and White, across the different social worlds of medicine, social movements, and state administration. This alignment helps make the use of racial categories appear neutral, natural, and normal. The other concept, niche standardisation, refers to standardisation at the level of specific social groups instead of a single standard. Thus, clinical recommendations and assessments may differ between, for instance, Blacks and Whites.

Against this backdrop, our research explores the racialisation of pharmaceutical research and regulation across countries—specifically, how race and ethnicity become important to drug testing and evaluation in the context of globalised clinical research. This racialisation of drug testing reinforces, in

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turn, specific taxonomic frameworks and concepts that facilitate racial profiling and prescribing in clinical settings (Mulinari et al. 2021). In the U.S., the inclusion-and-difference paradigm provides a framework that underpins racialisation processes, aided by widely available standards, discourses, and paradigmatic examples related to race and ethnicity in medicine. Yet, Epstein (2007, 275) noted the uncertainty surrounding whether Europe would follow the U.S. example due to distinct differences in conceptions of race and ethnicity. However, as noted above, collecting and analysing race-based data has become routine also in European countries, particularly in late-stage clinical trials.

This article critically explores the fate of the inclusion-and-difference paradigm within the challenging context of Sweden, where the concept of race is widely viewed as unscientific, as well as politically and morally objectionable (see e.g. SOU 2015). The sociology of scientific knowledge clearly shows that translating scientific concepts and practices across various contexts is complex and often requires significant conceptual power (Carpenter 2014) and boundary work (Bowker/Star 2000) by different actors. Such translations may also lead to local adaptations and transformations, exemplified by the varying interpretations of race and ethnicity categories across national boundaries (Panofsky/Bliss 2017; Smart/Weiner 2018; Mulinari/Bredström 2024a).

Importantly, in EU member states like Sweden, key aspects of pharmaceutical regulation, such as drug approval and withdrawal, are primarily managed at the EU level through the European Medicines Agency (EMA), ensuring harmonisation across the EU. The EMA also approves "drug labels", or Summaries of Product Characteristics, aimed at providing uniform information on a drug's properties to prescribers across the EU member states. However, our research has documented significant adaptations in translating concepts of race and ethnicity from English to other languages in such drug labels (Mulinari/Bredström 2024a). Additionally, each EU country retains substantial authority over clinical research regulation and ethics. Critically, this includes country-specific clinical trial policies, decisions to approve or reject specific trials, and oversight, despite the 2022 EU Clinical Trials Regulation, which began harmonising the evaluation and supervision of multinational trials through joint assessments by national authorities.

Methods

To trace the translation of the inclusion-and-difference paradigm in Sweden, we conducted semi-structured interviews with 26 key stakeholders and experts in pharmaceutical research and regulation, including clinical researchers, research nurses, regulators, pharmacists, and industry professionals (Bredström/Mulinari in press). Using qualitative coding (Silverman 2016), we categorised condensed meanings both inductively and deductively. A limitation of our study is the relatively small sample size, which prevents us from drawing definitive conclusions about variations in how race is articulated across medical fields or expert roles. However, our earlier research on race and ethnicity discourses during COVID-19 suggests that

professional differences may exist, especially between public health and clinical medicine (Bredström/Mulinari 2022).

Moreover, this study does not include views from patient groups or representatives of Sweden's migrant or ethnic minority communities, such as Afro-Swedes, Sami, Muslims, Jews, or Roma, whose perspectives may differ due to distinct historical experiences. For example, Sami and Roma were subjected to violent eugenics policies in the 20th century, leading their representatives to express concerns about any state-sanctioned data collection based on ethnicity or race (Sveriges Television 2015). In contrast, Afro-Swedes' representatives have been more open to using these categories to measure social inequality (McEachrane/Diakité 2018).

In this article, however, we specifically focused on interviews with stakeholders and experts in pharmaceutical research and regulation, examining codes related to the inclusion-and-difference paradigm: (1) the inclusion of patients in clinical trials based on race and ethnicity; (2) how ethnic and racial differences are conceptualised; (3) the categories used for race and ethnicity, and their alignment across medical and social and political spheres, and (4) niche standardisation according to race and ethnicity. Before analysing our interview data, we will contextualise the global spread of racialised clinical trial practices from the U.S. to other countries in recent years.

The Inclusion-and-Difference Paradigm: International Ripple Effect

In this section, we identify two major factors driving the international proliferation of racialised clinical trial practices: the continued institutionalisation of the inclusion-and-difference paradigm in the U.S., and the increasingly globalised nature of clinical research in the context of U.S. hegemony in this area.

The first factor is evident through a series of FDA policies and practices that have often been shaped in response to explicit political demands for ensuring that racial differences in treatment responses relevant to the U.S. population are addressed by pharmaceutical companies. Political and budgetary frameworks in the U.S. following the Prescription Drug User Fee Act (PDUFA) of 1992 have empowered Congress to wield substantial influence over the FDA (Davis/Abraham 2013). Since 1992, Congress has reauthorised the FDA's ability to collect "user fees" from pharmaceutical and subsequently medical device companies every five years through a new legal Act, which increasingly funds the FDA's product review and approval processes. Although each subsequent Act requires the FDA to be more responsive to industry concerns, the five-year budgetary cycles also provide opportunities for Congress to direct the FDA in other areas. For instance, the 2012 FDA Safety and Innovation Act (FDASIA), which marked the fifth reauthorisation of user fees, mandated that the FDA evaluate clinical trial participation and the inclusion of demographic subgroups in safety and efficacy data, including race and ethnicity (Mulinari et al. 2021). FDASIA further required the FDA to publish a report on demographic diversity in trial participation, analyse demographic differences in medication efficacy and safety, and develop an

Action Plan for enhancing the collection and availability of subgroup data, particularly for race and ethnicity.

Building on these efforts, the 2022 Food and Drug Amendments (the seventh reauthorisation of user fees) required the FDA to "ensure clinical trials are representative of diverse populations" by compelling drug and medical device manufacturers to submit clinical trial diversity action plans early in product development. Anticipating this directive, the FDA issued draft guidance to the industry in April 2022 on developing a "Race and Ethnicity Diversity Plan" for each product. The plan must outline rationales and strategies to "enroll representative numbers of participants from underrepresented racial and ethnic populations in the United States" in clinical trials. It should also describe how companies plan to explore potential safety and effectiveness differences across the product life-cycle, not just during pivotal trials or studies.

Despite originating in the U.S. context, these FDA policies and practices exert substantial international ripple effects. This influence is linked to the second factor: the globalised nature of pharmaceutical research and development. Companies typically conduct extensive clinical trials across multiple countries and submit international results to regulators worldwide, including the FDA, for product approval. Even when trials are run outside the U.S., companies must meet FDA requirements if they plan to use those trials for submissions to the FDA. The global reach of clinical trials – and its significance in spreading racialised practices to Europe – is highlighted by aggregated data on trials and demographics published by the FDA (2020). Of the 231 products approved between 2015 and 2019, only 10.3% were based exclusively on U.S. data, and 5.4% relied solely on non-U.S. data. In total, 35% of the 292,766 clinical trial participants were from U.S. sites and 65% came from non-U.S. sites. Notably, Europe contributed more clinical trial participants than the U.S. for these 231 products, with approximately 1% of participants coming from Sweden (FDA 2020).

Categorical Misalignment Instead of Categorical Alignment

The focus now turns to an analysis of the experiences of our Swedish interviewees in relation to the categorisation of clinical trial participants according to race and ethnicity. One of Epstein's main arguments is that the inclusion-and-difference paradigm builds critically on the 'categorical alignment' between the worlds of medicine, state administration, and social movements. Among other things, this alignment enables targeted recruitment efforts that seek to enrol historically underrepresented social groups in clinical trials in the United States (Epstein 2008). We therefore begin our analysis by focusing on the use of racial and ethnic categories in recruitment and research and their overlap with those used in wider Swedish society.

Our participants represent a wide spectrum of expertise in pharmaceutical research and regulation, ranging from conducting drug trials to policy-making and regulatory oversight. Those involved in international trials were accustomed to U.S.-based standards that require recording participants' ethnicity (Hispanic/Latino or non-Hispanic/non-Latino) and race (American Indian or Alaska Native, Asian, Black or African American, Native

Hawaiian or Other Pacific Islander, and White). However, interviewees with experience in exclusively Swedish clinical trials, without international ties, reported that these studies never categorise participants by race or ethnicity. They also confirmed that Sweden lacks guidelines on ethnic and racial diversity and inclusion in trials. While Sweden's health authorities occasionally advise on ethnicity-related issues, such as the importance of medical screening for asylum seekers, there is no designated body monitoring or promoting minority inclusion in clinical research. In their references to trial participant categorisation by race and ethnicity, our interviewees consistently cited FDA requirements but were unaware of any similar requirements from the EMA or the Swedish Medical Products Agency.

Although categorising research participants by race and ethnicity was viewed as mandatory in international trials to meet FDA requirements, our interviewees had no knowledge of targeted recruitment strategies based on these criteria. This contrasts sharply with the efforts of the "recruitmentology" industry that Epstein (2008) described in the United States. This doesn't mean interviewees considered current recruitment methods optimal. Several highlighted concerns about biases in Swedish patient samples and expressed the need for increased diversity across gender, ethnicity, and socioeconomic class:

> It is very important [to reach other groups]. It is difficult to include them in studies, in research. The less educated don't understand the issues and don't want to participate because they don't understand, they can't take a stand. We have too few minorities in the studies. And we would need many more. We also have too few women.
>
> — Clinical researcher, Heart specialist

However, there were no explicit strategies to address demographic biases, but interviewees pointed to barriers that reduce minority participation, such as language requirements for understanding consent forms and treatment instructions. Recruitment practices also weren't adapted to monitor or increase diversity, as race and ethnicity of patient populations weren't systematically recorded in registries, hindering targeted recruitment efforts. One interviewee even criticised reliance on morning newspaper advertisements for participant recruitment, which could disadvantage minorities and less-educated groups.

Even if a strategic attempt would have been made to recruit participants based on demographic categories, success would be uncertain. This issue lies in what we argue is a categorical *misalignment* between socio-political spheres and clinical trial standards in Sweden. Interviewees noted that race and ethnicity categories used in trials often don't align with their understanding of relevant demographic categories. Some respondents humorously highlighted the lack of Native Americans in Sweden, while others noted that those who could be categorised as Black in Sweden don't necessarily share the genetic origins of African Americans, for whom the category was designed. The clinical trial categories are also incongruent with Sweden's bureaucratic lexicon, which rejects the concept of race and instead employs categories based on country of birth or migration (Swedes, immigrants),

while political discourse emphasises official national minorities (e.g., Roma, Sami, Jews) and religious identities (e.g., Muslims). A clinical researcher reflected on these discrepancies when asked about the FDA's call for inclusion:

> I jumped a bit at those words actually, this... race and ethnicity. And race, I think it was someone who explained to me, this is in the U.S. It's kind of like this in these forms. It must be included, and I'm more interested in the country of birth, that you include which country you were born in and so on. But you want to increase the number of foreign-born people, because 20 percent are born abroad and in [city], 59 percent are first or second generation. So, to be representative, we must be better at including them [foreign-borns].

For a 'diversity plan' modelled on FDA draft guidance to succeed in Sweden, U.S. categories would have to be replaced with more contextually relevant terms such as Swedes, migrants, foreign-born or Muslims. If every country adopted its own system, however, companies and researchers would face multiple taxonomic systems that don't overlap systematically. This would be practically challenging in international research and would also undermine the feasibility and face validity of statistical analyses of group differences – the inclusion-and-difference paradigm's second pillar.

Ontological Ambiguity Regarding Racial and Ethnic Differences

Indeed, in the U.S., the imperative of inclusion of minorities in clinical trials works in tandem with strong ideas about the existence of important differences between groups. A key example is differential hypertension drug treatment for Black versus nonblack patients in the U.S. – that is, angiotensin-converting-enzyme inhibitors should not be prescribed as initial antihypertensive therapy for Black patients. Another example is common algorithms for estimating physiological parameters, such as lung function, that 'correct' for race. Significantly, the niche standardisation in both cases has its historical and conceptual roots in century-old racial science in the U.S., which emphasises innate and robust biological differences between races – although the current biopolitical imperative stems from the inclusion-and-difference paradigm (Savage/Panofsky 2023; Braun 2014).

In addition to examining interviewees' thoughts and experiences with categorising clinical trial participants by race and ethnicity, another critical analytical entry point for our research is their understanding of the 'essence' of racial and ethnic differences, that is, the ontologies of race and ethnicity. Given the pervasiveness of a post-racial discourse in Sweden that rejects concepts and categories of race (Mulinari/Bredström 2024b), it was predictable that some interviewees attempted to distinguish between 'unacceptable' racial categories with a biological ontology and 'acceptable' ethnic categories with a sociocultural one. However, there were numerous instances where this distinction was inconsistently applied or not applied at all when probed

further. For example, ethnicity was sometimes discussed as a biological category, and ethnic/national classifications were equated with, or folded into, racial ones. This is illustrated by the following excerpt, where the category 'Swedes' is conflated with the racial category 'Caucasian':

> We never talk about race in Sweden [...] We've never used that word, but we have perhaps said... Talked about ethnicity, that you have a... That you are Caucasian, that's something that occurs quite often and that becomes relevant in this environment because we are Swedes and so on.
>
> — Policy and regulatory specialist, pharmaceutical company.

There was also frequent uncertainty about the scientific rationale for routinely collecting race and ethnicity information. For instance, a research nurse who regularly registers patients' race and ethnicity reflected on her own uncertainty, having asked why the company collects race and ethnicity data without receiving a convincing explanation:

> Y: And I don't really know. I haven't gotten a good answer to that question. I've asked and everyone says something like this, 'it's about the metabolism and how you absorb drugs and so on.'

This uncertainty extended to the ontology of, and the distinction between, race and ethnicity, as seen in the following dialogue from a group interview with five pharmacists:

> A: However, studies must be carried out on the different [groups]. Because we know that there can be differences. African Americans... Asian, is that a race? I don't understand, is it the equivalent of white and black and Asian?
>
> B: Well, Asian, I think that's just to go into enzymes directly. You don't have to say that the Asian population has a worse effect. Because they have worse enzymes. Then you don't even have to mention Asians. You can just say that people with reduced enzyme activity have this. Or do you have to mention that?
>
> C: Yes, you have to. Asians and Asians, there are many different ones. It's not just molecules, it's a lot of other things too.
>
> D: It could be an ordinary drug. Then they shouldn't have to enzyme-test the person.
>
> E: That's the future.
>
> F: But ethnicity and race, I may be completely wrong, but I think I recall that the indigenous people of Greenland are very different, are they a race or an ethnicity?

Thus, in addition to the misalignment of demographic categories across medical, political and social spheres, the interviews highlighted an *ontological ambiguity*, where differences were variously associated with race and ethnicity, but with little clarity about their nature or meaning.

The Prospects and Perils of an Inclusion-and-Difference Paradigm in Europe

In this text, we have argued that the expansion of racialised trial practices to Europe is driven by the institutionalisation of the inclusion-and-difference paradigm in the U.S., alongside the global nature of clinical research and the sustained U.S. dominance in pharmaceutical research and regulation. In Sweden (and likely other European countries), however, racialised trial practices seem disconnected from this paradigm —that is, from the framework of "ideas, standards, formal procedures, and unarticulated understandings" that would make such racialised practices intelligible (Epstein 2007,17).

Importantly, the reach of the inclusion-and-difference paradigm extends beyond the collection of race-based data in clinical trials. It is also evident in how pharmaceutical companies are increasingly submitting race-based data to the European Medicines Agency (EMA) (Smith et al. 2022). Furthermore, European drug labels, such as those for the cancer drug Nerlynx (neratinib) and the statin Crestor (rosuvastatin), include demographic subgroup analyses, with some even providing niche-standardised recommendations based on race and ethnicity (Mulinari et al. 2021; Mulinari/Bredström 2024a). However, our interviews with Swedish experts reveal a lack of awareness regarding these cases, underscoring the gap in the conceptual and policy framework concerning race and ethnicity in medicine in Sweden.

Looking forward, the increasing emphasis on inclusion and difference in the U.S. – most recently seen in the FDA's draft guidance to industry on developing a "Race and Ethnicity Diversity Plan" – could eventually lead to a consolidation of a similar conceptual and policy framework in Europe. A first step in this direction may involve creating and adopting demographic categories in clinical research that more accurately reflect the European context. A notable sign of such a movement is the recent allocation of €66.85 million to a major public-private partnership project aimed at promoting "inclusive clinical studies for equitable access to clinical research in Europe" (European Commission 2024). Jointly funded by the EU and the pharmaceutical industry, this initiative seeks to define what diversity means in European clinical trials, driven in part by the FDA's new guidelines on clinical trial diversity.

Specifically, this European partnership project aims to develop definitions and measurements for concepts like 'underserved populations' while exploring the social and cultural factors that contribute to underrepresentation in clinical trials across Europe. Crucially, the project also aims to establish, for the first time, unique demographic data standards for Europe—including race and ethnicity—through collaboration with regulators, which pharmaceutical companies will be expected to apply consistently.

Thus, even though our interviews did not reveal a clearly recognisable inclusion-and-difference paradigm in Sweden, there is now a well-funded, collaborative effort between European institutions and the pharmaceutical industry to create a distinctly European version of this paradigm. However, our research highlights the challenges of this effort, given the persistent misalignment of demographic categories across medical, bureaucratic and political spheres in European countries.

More critically, Epstein's analysis of the U.S. inclusion-and-difference paradigm shows that categorical alignment and the emphasis on reliable data standards can obscure underlying tensions between conflicting understandings of race. Indeed, the ontological ambiguity around race and ethnicity—whether understood as social or biological categories—that emerged in our interviews is similarly present in the U.S. For example, while the FDA routinely treats racial categories as biological, it paradoxically maintains that racial categories "are socio-political constructs and should not be interpreted as scientific or anthropological in nature" (FDA 2016, 1). However, partly as a result of FDA policies, racial categories have been operationalised and naturalised in in the U.S. in ways that obscure their socially constructed nature, thereby reinforcing biological notions of race (Roberts 2011).

In today's Europe, where explicit racism is prevalent, placing emphasis on racial categories and data standards in clinical research could carry similar risks, potentially reanimating harmful biological concepts of race. It is crucial that social studies of race and medicine in Europe remain vigilant to these developments and their possible consequences.

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