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ORIGINAL ARTICLE

Race in clinical trials in Sweden: How regulatory and medical standards in clinical research trump the post-racial discourse

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Abstract

The post-racial discourse that permeates many Western European countries depicts society as having moved beyond race concepts and classifications. This article focuses on Sweden, a country that, in line with the post-racial thinking, declares race to be an offensive and unscientific concept. The article investigates what happens when this post-racial discourse meets clinical research standards that encourage, if not demand, the collection of data on patient race. Through an analysis of the reporting of patient race in 76 multinational trials with at least one study site in Sweden, and a review of the regulatory and medical standards and trial documents that direct the collection of patient race in trials, we show how race classification is kept intact in trials despite conflicting with post-racial norms and conventions. Notably, our findings diverge from the way racialisation is typically assumed to work in Sweden and related countries. We argue this is possible because the two incompatible understandings of race are 'distributed' (Mol, 2002, The body multiple: Ontology in medi-

Abbreviations: CDISC, Clinical Data Interchange Standards Consortium; CSP, Clinical Study Protocol; eCRF, electronic Case Report Forms; EUCTR, EU Clinical Trials Register; ICH, The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; SAP, Statistical Analysis Plan.

cal practice, Duke University Press) among different social worlds. The distribution, we propose, is upheld through the paucity of major debate on why and how race classification should be carried out in clinical trials in Europe as this allows contradictions to remain unspoken.

KEYWORDS
clinical trials, ethnicity, Europe, post-racial, race, standardisation, Sweden

INTRODUCTION

> Race was a word that was very rarely heard in Sweden after the world wars and until a few years ago [when it was reintroduced by some social scientists] … There was talk of horse and dog races [i.e. breeds], but when it came to humans, it was mainly in extremely obscure environments on the far right where the word race was used … No, there are no races, and it is not an expression of an opinion, but it is the biological knowledge that exists today, about what human variation looks like.
>
> (Hagerman, quoted in Sandberg, 2016; authors' translation)

The above quotation is from an interview with Maja Hagerman, historian and author of a well-received book (Hagerman, 2015) on the infamous Swedish race biologist Herman Lundborg (1868–1943). The quotation aptly summarises the dominant understanding of race in present-day Sweden, which holds that the notion of racial differences became politically indefensible and scientifically obsolete after the Second World War. Indeed, except for one strand of Sweden-based critical race scholarship (e.g. Brännström, 2018; Hübinette & Lundström, 2014)—referred to in the quotation as 'some social scientists'—the consensus among concerned academics and policymakers is that 'race' should not be used to describe human groups. Reflecting this, in 2014 a broad parliamentary consensus put forward that race ('ras') should be eliminated from the law and public policy, because the idea of race was offensive and without support from contemporary science of human differences (SOU, 2015).

In this article, we conceptualise the discourse that publicly refutes the existence of human races as 'post-racial' (Goldberg, 2009; Lentin, 2020). It should be stressed, however, that this public rebuttal of race does not mean that Sweden *is* effectively post-racial. On the contrary, research shows that notions of race, and of racial differences and hierarchies, linger on in Sweden, albeit under other names (Bradby et al., 2019; Mulinari & Neergaard, 2023; Schclarek Mulinari & Keskinen, 2022). In many arenas, for instance in the legal arena (Brännström, 2018), but also in medicine (Mulinari & Bredström, 2022), the concept of race has been replaced by, or incorporated into, the concept of ethnicity. An illustrative example is the removal of the 'racial origin' personal data-collection checkbox from the research ethics application form in late 2020, a change in policy that followed on Swedish lawmakers' elimination of the word 'race' from the law. In response to a direct question from the authors about this change, an Ethical Review Authority representative argued that the removal was *not* intended to affect the possibility of collecting or analysing any particular kinds of personal data in research, that is, data on race

(personal communication to authors). Indeed, the representative explained that if applicants wished to collect information on people's race in Sweden, they should probably check the 'ethnic origin' box, which remains in the ethical application form.

Yet, that ethnicity is used as a replacement for race does not contradict the dominance of a post-racial discourse. Ethnicity, it is argued, connotes sociocultural rather than biological differences and therefore lacks the negative historical and political connotation associated with race (SOU, 2015). Other Western European countries opposing the use of race display similar trajectories (Möschel, 2011; Oltermann & Henley, 2020), including Switzerland (Boulila, 2019), Germany (Juang et al., 2021) and France (Beaman & Petts, 2020)—the latter even reported to uniquely limit race as well as ethnicity data collection in clinical research by law (Guerrier et al., 2017). In this regard, these countries differ from several Anglo-Saxon contexts where race is used (alongside ethnicity) in everyday discourse as a sociocultural category (Lentin, 2020).

In this article, we ask the following question: what happens when this post-racial discourse which publicly refutes race on political, scientific and moral grounds meets international regulatory and medical standards in clinical research that encourage, if not demand, the collection of data on patient race? The outcome is not certain from the outset. Indeed, in his influential work on the development of the 'inclusion-and-difference' paradigm in US biomedicine, Epstein (2007, p. 275) stressed that it was unclear to what extent Europe would follow the US example of routine collection and analysis of race-based data in clinical trials.

On the one hand, there are reasons to believe that race categories may be kept intact in trials across countries regardless of local norms and conventions, given that trials are highly standardised to enhance consistency and comparability in research. Over the last decades, demands for international standardisation have increased as the scientific testing of pharmaceuticals has become a global enterprise dominated by large companies that conduct multinational trials (e.g. Petryna, 2009; Thiers et al., 2008). This corporatisation and globalisation is particularly evident in late-stage clinical trials, that is, 'phase-3 trials', conducted to meet regulatory authority demands for obtaining approval to sell drugs. There are various reasons why companies recruit patients across multiple countries in phase-3 trials, including to satisfy the regulator demands in different countries, ensure enough patients in the trial, nurture international research and commercial networks and limit costs by recruiting some patients from 'cheaper' countries (e.g. Glickman et al., 2009). Despite their many advantages, multinational, or multi-regional, trials challenge companies (ICH, 2017). One such challenge is that some regulators could question the relevance of 'foreign' patient data because of possible differential treatment effects across populations, for example, due to genetic variation that might influence drug absorption and breakdown in the body (Khin et al., 2013). Importantly, to address the question of differential treatment effects across populations, companies and trialists often use patient race as a proxy for a range of genetic and other potentially relevant factors (Huang & Temple, 2008).

On the other hand, there are also reasons to believe that race categories might *not* be kept intact across countries. In particular, notions and classifications of race (and ethnicity) differ markedly between European countries and from those in the USA (Farkas, 2017), suggesting that a rejection will occur at least in some countries, possibly involving the translation of race categories into ethnicity categories. In line with this, a previous European study of translations of English-language race concepts and categories in officially approved prescribing information for pharmaceuticals showed a strong tendency to translate race into ethnicity in Swedish, German, Finnish and French (Mulinari & Bredström, 2022). More generally, there are plenty of examples in the literature of how actors can ignore clinical research and regulatory standards (e.g. Davis & Abraham, 2013; McGoey, 2012), showing that standardisation efforts are not always successful.

The first aim of this article is therefore to examine this issue empirically through a systematic analysis of the reporting of patient race in multinational phase-3 trials with at least one study site in Sweden. While there is a long-standing scholarship concerning the racialisation of clinical trials in the USA (Epstein, 2007; Fisher, 2020; Kahn, 2012; Merz & Williams, 2019), similar scholarships addressing its European manifestations is scant (Mulinari & Bredström, 2022; Mulinari et al., 2021); and to our knowledge, no one has investigated the racialisation of clinical trials in a country with strong post-racial norms and conventions such as Sweden. As will be shown, our analysis reveals that patient race is routinely reported in such trials also in Sweden and in European countries in general—suggesting that clinical trials standardisation trumps the post-racial discourse. To deepen our inquiry, our second aim is to explore how, more precisely, standardisation influences the collection and reporting of data on patient race. To this end, we next analyse how guidelines and standards that govern the use of race categories in clinical trials are incorporated into trial documents that standardise the research practices on the ground. In doing so, we also respond to long-standing calls in the medical sociological scholarship on race for more studies of how standards travel internationally to influence racialist medical research practices across the globe (Epstein, 2007).

RESEARCHING STANDARDS AND RACE IN CLINICAL TRIALS IN SWEDEN

Our analytic focus on standards and standardisation in clinical trials is inspired by work in sociology and Science and Technology Studies (STS) which have called attention to how standards (e.g. rules, databanks, forms and protocols) that seek to ensure stability across different domains—what Timmermans and Epstein (2010, p. 72) call 'a defining aspect of modern life'—are shaped by social and cultural factors and can be contested and subjected to negotiation across social worlds (Bowker & Star, 2000; Timmermans & Berg, 2003). Timmermans and Epstein (2010, p. 71) also point out that there is a 'fuzzy line separating the domains of standards with that of norms and conventions'. This fuzzy line is particularly relevant when the standards pertain to contested meanings and terminology—such as in our case where race standards in clinical research confront local post-racial norms and conventions.

In STS, it is also common to use the notion of a 'boundary object' to capture the flexibility and integrity of specific objects that have different meanings in different social worlds—race being a key example (Shim, 2002). A boundary object is 'stable enough' to be recognised as one and the same in different contexts, yet 'loose enough' to be filled with different meanings in different contexts (Bowker & Star, 2000, p. 15). In *The Body Multiple*, Annemarie Mol (2002) explores this 'multiplicity' focusing on the plural ways in which atherosclerosis is enacted in a hospital setting. What is especially helpful with Mol's approach for our purposes is how it centres on how different and sometimes conflicting, definitions, terms and meanings can coexist in medicine. In our case, this is illustrated by how the explicit use of race and race categories manage to coexist with contradicting post-racial norms and conventions. In Mol's view, an important aspect of the analysis is to capture the ways in which multiplicity is 'coordinated', and in the final discussion, we will highlight forms of coordination that may sustain race classification practices in clinical trials.

Common to these STS perspectives is that they emphasise the importance of analysing how certain definitions, terms and meanings might take a more solid or durable form if they find their way into *standards*. Epstein's (2007) work on inclusion of diverse social groups as research subjects in the USA does this in an eloquent way. He shows how the racial standards used in

medical research and policy stem from successful 'categorical alignment' through the superimposing of categories used in identity politics, biomedicine and bureaucratic administration in the USA. This includes the categories 'Hispanic or Latino' for ethnicity and 'American Indian or Alaska Native', 'Asian', 'Black or African American', 'Native American or other Pacific Islander' and 'White' for race. This alignment makes these categories seem natural and inevitable. It also allows for easy intertwining of arguments about social inclusion and biological differences in the USA, which, in turn, allows attentiveness to biological differences to be framed as central to both health equity and anti-racism in this country (Bliss, 2012).

In our analysis below, we will show how the outcome of this categorical alignment in the USA trickles down to the Swedish, and European, context which differs markedly from the context described by Epstein. Indeed, the way in which race is enacted in contemporary clinical trials *conflicts* with identity labels and state-sanctioned categories in numerous non-English speaking European countries, like Sweden, that explicitly avoid the use of race and race categories (Farkas, 2017). This avoidance can be seen as part of a broader trend across a number of Western societies, a trend that has been framed by critical race scholars through the concept of *post-racialism* (St Louis, 2015). In political discourse, post-racialism is used to describe that society has moved beyond racism and that race therefore is no longer a major structural factor in society. Importantly, the post-racial discourse in Sweden emphasises that race is a meaningless, non-scientific concept, often drawing on the academic argument that race and categories are socially constructed (Ahlberg et al., 2019; Hübinette & Lundström, 2014). Critical race scholars, however, argue against the idea that racism and thus race is obsolete, and instead propose that the post-racial discourse is an effective mode of *disguising* the continuities of racial thinking and practice. For instance, scholars such as Lentin (2020) and Goldberg (2009) have contributed to detailed analyses of post-racial discourses internationally, exploring, for example, how notions of culture, diversity and secularity sustain racial orders. Likewise, researchers in Sweden have argued that notions of cultural otherness, in which migrants and especially asylum seekers are constructed as racialised 'others', serve as the dominant discourse through which race is produced in a Swedish context (Schierup & Ålund, 2011). To capture this process, the concept of racialisation (Miles, 1989) gained a foothold as early as the nineties (Molina, 1997) and constitutes a key perspective within critical race studies in Sweden today (Mulinari & Neergaard, 2023). However, while there are an increasing number of studies that interrogate the intersection of whiteness and Swedishness (e.g. Hübinette & Lundström, 2014; Mulinari, 2017), most studies tend to focus on the ways in which the concept of ethnicity, or sometimes migrant or foreigner, function as proxy for race, and how presumptions of culture have replaced ideas about biological differences in racist discourse (Schierup & Ålund, 2011). By contrast, few studies consider an *explicit, routine* use of race in contemporary Sweden as the present study does.

More broadly, this literature on 'racialisation without race' in Sweden can be connected to the sociological and STS literature on the enactment of race in the European scientific and medical context, and in which race is often characterised as an 'absent presence'. As M'charek et al. (2014, p. 462) put it, active attempts to remove 'the tabooed object of race' have not been completely successful, and 'race keeps surfacing in various European societies', albeit often under other names. For example, in the context of UK blood stem cell transplantation, Williams (2018, p. 26) drew on this idea to explain 'how race felt like it was always there, and yet nobody really used the term'. By contrast, Smart and Weiner's (2018) study of how US census categories were transformed in the context of UK hypertension prescribing guidelines did point to explicit uses of race, and so did Mulinari et al.'s (2021) study of approved English-language drug prescribing information. But what this will be like in non-English speaking countries is

unclear, particularly in countries that officially reject the use of race. Moreover, it is unclear what room there is for local transformation and resistances to US census categories in clinical trials, which are even more internationally standardised than biobanks, and prescribing guidelines and information.

DATA AND METHODS

To investigate the racialisation of clinical trials in Sweden, we use two sources of publicly available data: (1) clinical trial report summaries and (2) key regulatory and trial documents.

Existing regulations require that clinical trial sponsors (i.e. the organisations responsible for trials) always report summaries of the results of the main analyses of clinical trials in public registries no later than 1 year after study completion (Davis et al., 2021). The EU Clinical Trials Register (EUCTR)[1] contains trials with one or more study sites in the EU or the European Economic Area (EEA). The US ClinicalTrials.gov contains, among others, trials with one or more study sites in the USA, as well as any purely non-US trials but for which the US Food and Drug Administration (FDA) has approved the testing of the drug in people. Notably, both EUCTR and ClinicalTrials.gov contain patient demographic data fields where sponsors (e.g. companies) can specify the number of patients of different 'races' and 'ethnicities'.

We collected reports of all phase-3 trials in EUCTR (www.clinicaltrialsregister.eu) that matched the following criteria: had at least one study site in Sweden, were completed between 2017 and 2020 (based on the global end-of-trial date), recruited adults (because rules for paediatric trials may differ) and had reported their results (to ensure access to the final analysis).

From each record, we extracted the following information contained in specific data fields: (1) EUCTR and ClinicalTrials.gov unique identifiers; (2) end of trial date; (3) name of trial; (4) sponsor; (5) number of recruited patients in Sweden, EEA and globally; (6) race and ethnic categories reported, if any and (7) number of patients in each category. We cross-checked this information with ClinicalTrials.gov, because in a few cases the demographics of a trial were reported in only one database, but for most (61 of 76) trials the records matched.

To be certain that we considered only trials in which Swedish patients' race was *verifiably* recorded, we also analysed, separately, the subset of trials matching our inclusion criteria *and* in which (a) any discrepancy between recruited and reported patients was smaller than the number of Swedish patients (i.e. the study must have verifiable Swedish patients), and there were (b_1) no uncollected or unreported cases of race or (b_2) fewer unrecorded or unreported cases of race than the verifiable number of Swedish patients. This approach excluded any trial with the *possibility* that no Swedish patient's race was recorded; however, it is certainly possible that all unrecorded cases represented patients from other countries, and hence that every Swedish patient had their race recorded in the phase-3 trials. In the results section, we report data descriptively alongside examples of illustrative trials.

With respect to the regulatory and trial documents, we sought to review, first, the key international regulatory guidelines and standards that have cemented expectations that patient race should be routinely collected (see Kahn, 2007; Kuo, 2008). Second, we sought to identify how these regulatory guidelines and standards are translated into the trial documents that standardise the collection, tabulation and report of race (and sometimes ethnicity) in clinical trials. Notably, in ClinicalTrials.gov, but not EUCTR, the sponsor may attach key trial documents that contain more details of the trial: the *clinical study protocol* (CSP) and *statistical analysis plan* (SAP). We reviewed the process of developing and using the CSP and SAP, including how they sometimes

include explanations of how patients' race and ethnicity are planned to be recorded in *electronic Case Report Forms* (eCRF) and tabulated and included in the *Clinical Study Report* to be submitted to regulators and in scientific publications (Pocock, 2013).

FINDINGS

Race in phase-3 trials in Sweden

We found 76 clinical trials matching our inclusion criteria. This should be considered a subset of phase-3 studies completed in Sweden, as the pharmaceutical industry estimates that around 50 phase-3 studies start each year in Sweden (LIF, 2021). All 76 studies were multinational, only two had patients only from EU/EEA countries, and all were conducted by, or on behalf of, pharmaceutical companies.

Sixty-six of 76 trial records (86.8%) reported the 'race' or 'race/ethnicity' of the study population, and 42 also included a separate 'ethnicity' classification. The 66 clinical trials had 25 different company sponsors: Novartis sponsored seven studies, followed by AstraZeneca and Gilead with five each. Together, the 66 trials recruited 96,884 patients of whom 36,263 (37.4%) were in EU/EEA countries and 1539 (1.6%) in Sweden. The median number of patients in a trial was 643.5 (range, 49–11,016; interquartile range [IQR], 740.5). The median number of patients from Sweden was 8.5 (range, 1–172; IQR, 29). However, for 19 trials, not all recruited patients were included in the analysis, for example, because some patients abandoned the trial before it started. Of 96,884 recruited patients, 94,907 (98.0%) were ultimately included across all 66 trials.

Across the trials, the US race and ethnicity standard strongly dominated: most patients (98.3%) were categorised as White (71.8%), Asian (15.3%), Black or African American (3.5%) or Black (1.4%), American Indian or Alaska Native (1.5%), Native Hawaiian or Other Pacific Islander (1.0%), belonging to more than one race (1.2%) or of unknown or not reported race (0.6%). In the 42 trials that included a separate 'ethnicity' classification, it was always the US classification: Hispanic or Latino (23.2%), or not (68.3%) or of unknown or not reported ethnicity (7.9%). Interestingly, five trials (7.6%) reported that some patients' race was not collected because of local regulations ($n = 559$; 0.6% of patients across all 66 trials). In addition, in 39 trials (59.0%), at least one patient's race was categorised as either unknown, not reported, missing, not collected or not otherwise specified, for a total of 665 patients (0.7%). However, it is impossible to judge how many of the uncollected or unreported cases (in total 1.3% of all patients) were from Sweden, or from any other country, since study demographics were aggregated across all countries in the trials.

Among the 66 trials, we were able to identify 38 studies (57.7%) in which all or some Swedish patients' 'race' or 'race/ethnicity' was *verifiably* recorded ($n = 884$ patients; 57.4% of all included Swedish patients across the 66 trials). We provide three illustrative examples.

1. AstraZeneca's study 'A Randomised, Double-Blind, Placebo-Controlled, International, Multicentre, Phase III Study to Investigate the Efficacy and Safety of Ticagrelor and ASA [acetylsalicylic acid] Compared with ASA in the Prevention of Stroke and Death in Patients with Acute Ischaemic Stroke or Transient Ischaemic Attack' (the THALES study) included 11,016 patients in 28 countries, including 157 patients in Sweden across 10 study sites. All 11,016 patients were classified based on the US race standard: White, 5921; Black or African American, 53; Asian, 4692; Native Hawaiian or other Pacific Islander, four; American Indian or

Alaska Native, 341 and Other, five. Furthermore, according to the trial report published in the *New England Journal of Medicine*, 'race was determined by patient report', but in the published study, Native Hawaiian or other Pacific Islander, American Indian or Alaska Native and Other are combined into the 'Other' category (Johnston et al., 2020).

2. Novo Nordisk's study 'Efficacy and safety of oral semaglutide versus placebo in subjects with type 2 diabetes and moderate renal impairment. A 26-week randomised, double blind, placebo-controlled trial' (the PIONEER 5 study) included 324 patients in eight countries, including five patients in Sweden. All 324 patients were classified based on the US race standard: Asian, one; Black or African American, 13; White, 310 and all other categories, zero. The study was published in *Lancet Diabetes & Endocrinology*, in which patient race was similarly reported (Mosenzon et al., 2019).
3. GlaxoSmithKline's study 'A Multi-Centre, Open Label, Single Arm, 32-week Treatment Study in Subjects with Severe Eosinophilic Asthma Not Optimally Controlled With Current Omalizumab Treatment Who Are Switched From Omalizumab To Mepolizumab 100 mg Subcutaneous' (the OSMO study) included 145 patients in nine countries, including three patients in Sweden. The study used an unusual categorisation for all patients: Asian—Central/South Asian Heritage, two; Asian—East Asian Heritage, one; Asian—South East Asian Heritage, two; Black or African American heritage, 11; White—Arabic/North African Heritage, four; White—White/Caucasian/European Heritage, 124 and Multiple—Black/African American and White Heritage, one. This unusual categorisation implies that while the US census categories strongly dominate, there remains some possibility to eschew the hegemony of the US taxonomy. However, when the OSMO study was subsequently published in *Allergy* (Chapman et al., 2019) and *Respiratory Research* (Liu et al., 2021), the various heritage categories were collapsed into four explicit standard race categories: Asian, Black or African American, White and Mixed.

In sum, evidence shows that at least for the largest studies that often inform regulators' decision to approve drugs, racial concepts and categories travel across national borders and give rise to a racialised practice regardless of local norms and conventions. Worth noticing is that the clinical studies considered took place across several other European countries that exhibit similar 'paradoxical' relations to race (Sayyid, 2017). This includes, for example, France where there are regulations uniquely restricting the collection of race data (Guerrier et al., 2017). Still, there were French patients in several trials in which *every* patient's race was verifiably recorded. For example, the THALES (Johnston et al., 2020) and OSMO (Liu et al., 2021) studies discussed above had 444 and 31 patients from France, respectively. That is to say, officially 'opposing' race does *not* mean that race data cannot and will not be routinely collected in the context of clinical trials.

Regulatory guidelines and standards related to race data collection

After having established empirically that the collection and report of 'race' or 'race/ethnicity' is commonplace in late-stage clinical trials in Sweden, and Europe in general, we turn now to the question of how this research practice is stabilised across countries.

Previous research has pointed to three key guidelines and recommendation documents which have been crucial for crystallising a discourse on the nature, causes and consequences of racial and ethnic differences in drug trials, including definitions of key concepts adopted by industry and regulators globally (Kahn, 2007; Kuo, 2008; see also ICH, 2017). First, in 1998, as

part of an international effort by industry and regulators in the EU, the USA and Japan to harmonise technical requirements for pharmaceutical development and regulation, that is, the ICH, the regulators in the three jurisdictions adopted a common guidance: *ICH-E5 Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data* (ICH, 1998). This document is among 20 harmonisation guidelines adopted by the ICH on clinical trial design, conduct, safety and reporting. The stated purpose of ICH-E5—consistent with the ICH mission—is to reduce barriers to registering medicines in the different jurisdictions 'by recommending a framework for evaluating the impact of ethnic factors upon a medicine's effect' which included racial differences understood in genetic terms (ICH, 1998, p. 1). However, Kuo (2008, p. 500) described ICH-E5 as 'one of the most troublesome points of contention in the history of the ICH' due to clashes between the country representatives' divergent concepts of race and ethnicity, including the fact that the EU representatives did not want to 'overemphasise diversity' between 'racial groups'. As an outcome of these negotiations, ICH-E5 nonetheless suggested that 'ethnic factors' could be studied at the level of the three 'major racial groups', that is, 'Asians, Blacks, and Caucasians' (ICH, 1998, p. 12).

The second guideline is the FDA's 'Demographic rule'—also adopted in 1998 (FDA, 1998). Although FDA recommendations regarding demographic subgroup analyses have existed since the mid 1980s, the 'Demographic rule' was important in emphasising FDA expectations that companies collect and analyse clinical data based on race. Notably, the 'Demographic rule' was issued against the political backdrop of federal mandates emphasising the issue of diversity in US clinical research, the outcome of US social and political mobilisation around gender and minority health rights (Epstein, 2007). These federal mandates include the National Institutes of Health (NIH) Revitalisation Act of 1993, which required the NIH to establish guidelines for including women and minorities in research, and—most relevant to the FDA—the FDA Modernisation Act of 1997, in which Congress directed the FDA to examine issues concerning demographic diversity and inclusion in clinical trials of new drugs.

However, the 'Demographic rule' did not specify what racial and ethnic categories should be used by companies or the standards for collecting these data. These gaps were addressed in the 2005 Guidance document for industry and FDA staff, *Collection of Race and Ethnicity Data in Clinical Trials* (FDA, 2005). Updated in 2016, this Guidance recommends a format for obtaining race and ethnicity information for both US and international clinical trials to be submitted for regulatory review to the FDA. Specifically, the Guidance outlines the FDA's recommendation that the Office of Management and Budget (OMB) race and ethnicity standard should be used for data collection in clinical trials. That is, the minimum choices are 'Hispanic or Latino' for ethnicity and 'American Indian or Alaska Native', 'Asian', 'Black or African American', 'Native American or other Pacific Islander' and 'White' for race. It is strongly recommended that the assignment should be based on self-identification, and that there should be the option of selecting one or more racial designations. However, the FDA also cites the caveat that race and ethnicity categories 'are social-political constructs and should not be interpreted as being scientific or anthropological in nature' (FDA, 2005, p. 9). Similarly, the FDA states that it 'recognises that the recommended categories for race and ethnicity were developed in the USA and that these categories may not adequately describe racial and ethnic groups in foreign countries' (FDA, 2005, p. 11). Nonetheless, the FDA requires companies that choose more detailed characterisations of race and ethnicity in foreign countries to allocate individuals to US racial and ethnic categories before submitting data or analyses to the FDA, with the exception that 'Black' should be used instead of 'Black or African American'.

Crucially, as a consequence of these regulatory guidelines and recommendations, pharmaceutical companies must carefully consider the issue of race when designing, executing and

analysing their trials, especially if their aim is to include a trial in a marketing application to the FDA (Bierer et al., 2021). As explained above, many late-stage trials are multinational, partly to ensure that the trial population is diverse enough to satisfy regulators in different jurisdictions. Drug companies, or their contract research organisation agents (i.e. companies specialising in clinical trials), often engage local doctors to recruit and treat patients and collect patient data based on study-specific instructions from the pharmaceutical company to ensure the compatibility of data across study sites.

Providing study-specific instructions to participating doctors across the study sites is enabled by a set of global trial documents, especially the CSP and SAP (Pocock, 2013). These documents thus constitute the key link between the regulatory guidelines and the classificatory practice. They are written by the drug company and are either formally approved or discussed by the regulators in the concerned countries before the start of any study. For example, since 2016 the FDA has requested that companies submit a plan for formal discussion with the FDA addressing the inclusion of 'clinically relevant subpopulations,' including racial and ethnic ones, before any phase-3 study starts (FDA, 2016).

Significant for the purpose of this article, both the CSP and SAP will include information about the patient variables to be collected, often including race to meet the regulatory expectations described above, and may also include information on how this data will be summarised and analysed—for example, whether racial subgroup analyses will be conducted (study size is often a limitation here). Specifically, race (alongside ethnicity) is commonly presented as one among several *standard variables* that may influence treatment effects, alongside factors like age, sex, geographic region (e.g. Europe, Asia and North America), smoking status, prior medical treatment, diverse diagnoses and baseline physiological parameters and other biometric measures.

Illustratively, the SAP for AstraZeneca's THALES study, mentioned above, specifies the comparison of the drug's efficacy across the racial categories of White, Black, Asian and Other, along with 15 additional subgroup variables (AstraZeneca, 2019). Similarly, in the context of Boehringer Ingelheim's 'EMPERIAL—preserved' study, which investigated the impact of the anti-diabetic drug empagliflozin on exercise capacity in chronic heart failure patients, the SAP outlines the comparison of empagliflozin's efficacy across 13 variables, including 'ethnicity' (Hispanic/Latino and Not Hispanic/Latino) and 'race' (White, Black/African American, Asian and Other including mixed race) (Boehringer Ingelheim, 2019).

Additionally, the CSP and SAP may include information about how race will be used as a covariate for estimating physiological parameters such as kidney and lung function in accordance with existing (albeit increasingly contested) race-based standards (Vyas et al., 2020). For example, to be included in Novo Nordisk's PIONEER 5 study, the company's CSP (Novo Nordisk, 2018) specified that patients had to have 'moderate renal impairment', calculated for each patient using the standard equation for measuring kidney function (the CKD-EPI equation) which 'corrects' for race, suggesting better kidney function for anyone identified as Black by a factor of 1.159 (Inker et al., 2021; Levey et al., 2009). The same race-based correction equation was employed in Boehringer Ingelheim's EMPERIAL-preserved study (Boehringer Ingelheim, 2018, p. 51). Consequently, the CSPs instructed the participating study clinics in the eight countries involved in PIONEER 5 and the 11 countries involved in EMPERIAL-preserved, including Sweden, to collect and utilise patient race data due to its perceived significance as a proxy for kidney physiology.

Similarly, GlaxoSmithKline's (2017) SAP for the OSMO study specifies that lung function (FEV1) measured with spirometry will adjust for 'collected race' with reference to race/ethnicity standards described by Quanjer et al. (2012). Spirometers used to diagnose and monitor

pulmonary disease often use correction factors for persons labelled Black (10%–15% reduction) or Asian (4%–6% reduction) versus White (Braun, 2014). Specifically, the GlaxoSmithKline's study used different standards for South East Asian, North East Asian, African-American (including any patient of 'Black or African-American heritage'), Caucasian and other. Another illustrative case in our trial sample is Vertex's VX17-445-102 study, which evaluated the effect of the company's drugs on patients with Cystic Fibrosis. In this study, the SAP provides explicit instructions to categorise patients into race groups, including Black, White and Other, and to use these race categories in the lung function equations where 'white is reference race in the equations and assumes 0 values for all race coefficients in the GLI [Global Lung Function] Initiative equations (Vertex, 2019, p. 38)'. Again, this means that clinics across all international study sites need to apply these race-based standards because of assumed important physiological differences between 'races'.

Instructions in the CSP and SAP are operationalised in another key study document, the eCRF, which are the standardised electronic forms completed by local doctors about each patient and that together comprise the study's 'raw data'. Significantly, if the CSP and SAP state that patient race is to be recorded, then the eCRF should include data fields for race. In other words, it is realistic to assume that in all 66 studies analysed above, the eCRFs instructed the local doctors across countries to collect data on patient 'race' or 'race/ethnicity' and occasionally 'ethnicity'. Frequently, these data fields will be constructed using the consensus-based, standardised collection format developed by the Clinical Data Interchange Standards Consortium, a global standard-setting organisation for clinical research (CDISC, 2019). The CDISC standard is required for electronic submission to regulatory authorities in the USA and Japan and is recommended by regulators in Europe and China. Regarding race, the CDISC standard defines race as 'an arbitrary classification based on physical characteristics' and endorses the use of the FDA-requested racial categories (i.e. the OMB standard) either using a direct question (i.e. 'Which of the following five racial designations best describes you?') or indirectly using 'expanded categories' such as Arab or White South American that are 'collapsible' into the US categories, such as White, to be reported to regulators (CDISC, 2019). An example illustrating this is GlaxoSmithKline's OSMO study, in which the subcategories 'White—Arabic/North African Heritage' and 'White—White/Caucasian/European Heritage' were subsequently combined into the explicit race category 'White' (Chapman et al., 2019; Liu et al., 2021).

Finally, regulatory guidelines and clinical trial standards not only direct the collection and reporting of race in clinical trials internationally, but are also central for translating this race-based data into regulatory and academic science that stabilise the idea of race as a key biomedical variable. Thus, once a study's data collection is completed, the pharmaceutical company should conduct the statistical analyses as specified in the SAP (Pocock, 2013), including any analyses with demographic variables, and the main analyses and the relevant trial demographics should thereafter be reported in the public trial registries in accordance with the regulations. In addition, if the study is relevant to a company's marketing application or to an existing drug authorisation, the company should submit detailed analyses to regulators in the form of a Clinical Study Report, which is a standardised document presenting the most complete record of the planning, execution and results of the clinical trial (ICH, 1995). For marketing applications, the company should also provide a draft of the so-called product label intended for communication with health-care professionals, and this will often include statements about demographics and subgroup analyses based on 'race' (Mulinari et al., 2021). The company may also choose to write one or more scientific publications if it believes this will help advance commercial or other goals. Significantly, both regulatory submissions and scientific publications are standardised when it

comes to presenting race and ethnicity data and analyses, for example, tables with patient demographics and plots showing subgroup analyses (Furler et al., 2012).

DISCUSSION

Our study is the first to demonstrate that clinical trials performed in Sweden make use of race categories despite the otherwise dominant post-racial discourse in society—a finding that also applies to several other European countries, and that divergences from the way racialisation is typically assumed to work in Sweden (e.g. Ahlberg et al., 2019; Schierup & Ålund, 2011).

As shown above, the proximal cause of the extensive use of race classification in this context lies with the drug regulation and testing regime, which is underwritten by supranational and national regulatory standards (e.g. issued by ICH and FDA) *and* medical standards (e.g. physiological algorithms) that strongly incentivise, if not demand, the collection and analysis of data by race. While it is safe to say that both the elaboration of and demands related to regulatory (Epstein, 2007) and medical (Braun, 2014) standards largely concern US history and politics, the endorsement and use of race-based standards across the world by regulators, companies and researchers reflect their broader international and institutional acceptance (Mulinari et al., 2021). This is also evident from the various regulatory and company documents reviewed here and from the databases and publications consulted and searched. The demands for international standardisation in evidence-based medical research and practice thus work to stabilise race categories and concepts in clinical trials in Europe even in countries that simultaneously discard race as a scientifically inappropriate concept.

As emphasised by Epstein (2007), a key reason why race categories used in clinical trials appear self-evident for many in the USA is because of the successful alignment of categories used in US biomedicine, identity politics and bureaucratic administration. However, while the use of these categories appears to work more or less smoothly in the USA, the opposite is likely to happen in Sweden, as well as in several other European countries, where there is no categorical alignment, and where concepts and categories of race have been varyingly described as 'tabooed' (Maneri, 2021), 'denied' (Boulila, 2019), 'buried' (Balkenhol & Schramm, 2019), 'silenced' (Lentin, 2020) or even 'abolished' (Hübinette & Lundström, 2014). Indeed, from this perspective, the lack of categorical alignment makes it almost peculiar how the whole system of race classification in clinical trials does not burst into pieces.

To explain this stability, Mol's (2002) work on 'multiple ontologies' in medicine provides important cues. Mol (2002) shows how patients, diagnostic manuals, science and health care produce multiplicity through their focus on different aspects of, and by using different approaches to, bodies and diseases. However, multiplicity does not necessarily lead to 'fragmentation' of the body, Mol (2002) argues; rather, multiplicity is *coordinated* in different ways through everyday practice. One way coordination can happen is through *mutual inclusion*, where differences are aligned side by side. Mutual inclusion, we would argue, corresponds with the US context where social and biological arguments regarding race are articulated together, as if there would be no or little friction between the two (Bliss, 2012). The FDA, for example, stresses the importance of using a set of standard race categories to discern genetic differences in drug metabolism, yet simultaneously says that race categories 'should not be interpreted as being scientific or anthropological in nature' and says people can 'choose their identity' and 'belong to more than one group' if they feel this represents them (FDA, 2005).

The Swedish case, however, fits better with what Mol (2002) describes as *distribution*. When multiple understandings are distributed across different sites, possible tensions 'disappear into the background'; and she also emphasises how 'distributions separate out what might otherwise

clash' (Mol, 2002, p. 115). In our case, the different enactment of race concepts and categories, as either acceptable and scientific or unacceptable and pseudo-scientific, are distributed between clinical trials and broader Swedish society. The distribution, we propose, is upheld through the paucity of major scientific or political debate on how and why race classification should be carried out in clinical trials in Europe (Mulinari et al., 2021), as this allows contradictions to remain unspoken. This differs markedly from the USA where such debates have been ubiquitous over the last decades (Bierer et al., 2021; Deloitte Insights, 2021; Epstein, 2007; Kahn, 2012).

Importantly, one reason why European drug regulators may wish to avoid scientific or political debate on the use of race may relate to EU regulations, such as the preamble to the Race Equality Directive of 2000, which stress that the EU 'rejects theories which attempt to determine the existence of separate human races' (Council Directive 2000/43/EC) (Mulinari & Bredström, 2022). Nevertheless, the acceptance of race classification by regulators in Europe could potentially bolster biological race theories (Kahn, 2012). Indeed, drug product regulation and testing undoubtedly exert massive impact on health systems and practices around the world through its influence on medical research, treatment, knowledge and discourse (Carpenter, 2014), so there is strong reason to think that it may influence discourses and practices related to race across countries too. Consistent with this, subgroup analyses of race-based data from clinical trials underwrite the prescribing information for many drugs which arguably transmit a biological understanding of race, including several cases of race-specific prescribing recommendations (Mulinari et al., 2021; Ramamoorthy et al., 2015). An example is the cholesterol-lowering drug rosuvastatin, where European (including Swedish) doctors are instructed to prescribe smaller doses to patients of Asian ancestry (AstraZeneca, 2021). Another example is the immunosuppressant tacrolimus, where doctors are instructed that Black patients may require larger doses than Caucasians (Astellas Pharma, 2007).

Such examples also help illustrate the key point that despite the 'distribution' between the clinical trials and broader Swedish society, eventually the two divergent enactments of race can be expected to meet in clinical practice as doctors (and their patients) should decide on how to react to a classificatory system that clashes with local post-racial norms and conventions (Ahlberg et al., 2019). It is an open question how such conflicts are coordinated. Perhaps the classificatory system is modified or eschewed in favour of some locally accepted world-view (Smart & Weiner, 2018). Or perhaps they continue to be distributed through some compartmentalisation mechanism or, alternatively, the US framework will eventually help (re)introduce an explicit race concept in Swedish, and European, health care and society more broadly (Epstein, 2007). Understanding how clinical trial managers and personnel, health-care professionals and patients navigate these conflicting standards in practice thus seem like an important avenue for future research.

AUTHOR CONTRIBUTIONS

Shai Mulinari: Conceptualization (lead); formal analysis (lead); funding acquisition (equal); writing – original draft (lead); writing – review & editing (equal). **Anna Bredstrom**: Conceptualization (supporting); funding acquisition (equal); writing – original draft (supporting); writing – review & editing (equal).

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CONFLICT OF INTEREST STATEMENT

The authors report there are no competing interests to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in the EU Clinical Trials Register at https://www.clinicaltrialsregister.eu.

ETHICS STATEMENT

N/A.

PATIENT CONSENT STATEMENT

N/A.

PERMISSION TO REPRODUCE MATERIAL FROM OTHER SOURCES

N/A.

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ENDNOTE

[1] In January 2022, the European Medicines Agency (EMA) launched the Clinical Trials Information System (CTIS), which will eventually replace the older EU Clinical Trials Register (EUCTR).

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