What are the causes for the underrepresentation of African and Caribbean populations in clinical trials in the UK and what must be done to tackle this issue?

by

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A dissertation submitted in partial fulfilment
of the requirements for the degree MSc Drug Discovery and Pharma Management

of

University College London

Acknowledgements

Foremost, I would like to express my deepest gratitude to my supervisor Dr Duncan Browne, for his patience, supervision, and continuous feedback that helped to shape my work.

I would also like to extend my sincere thanks to Dr Lia Hunter, who is a mentor and a friend. Her invaluable knowledge and willingness to share it with me, allowed me to write this work.

Special thanks to Garima Limbu for her endless moral support and late-night feedback sessions.

My greatest thanks go to God for allowing me to complete this dissertation. His guidance allowed me to get through the struggles and to persevere. I will continue to trust in You.

Abstract

Introduction: Clinical trials are a well-established procedure for weighing up the risk-benefit ratio of new medical treatments for human subjects. Nonetheless, there is a notable underrepresentation of African and Caribbean people in clinical research in the UK. This paper investigates the factors contributing to the low enrolment of Black participants in clinical trials and addresses potential solutions to rectify this inequality.

Methods: An extensive literature review was conducted, encompassing both UK- and US-based studies and data. Additionally, an interview was carried out with an expert on racial diversity in scientific research. Both approaches offered insights into the underlying causes and consequences of the deficiency of diversity in clinical trials.

Results: The analysis unveiled a stark statistical incongruity between the representation of White and Black individuals in clinical trials. In addition, a clear correlation between a shortage of Black personnel in clinical research and insufficient Black participants in trials was identified.

Discussion: This paper concludes that pharmaceutical companies might not perceive the increased enrolment of Black participants as commercially viable. Therefore, study populations in the UK do not adequately mirror the demography of the African and Caribbean population. To mitigate this issue, there must be concerted efforts to improve the relationship and trust between the Black community in the UK and the scientific community. This will foster a more heterogeneous participant pool and it will allow accurate and applicable medical insights for diverse populations. Suggestions for future studies to understand physiological distinctions amongst racial groups are also provided.

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Plagiarism and responsible use of AI statements

The work reported in this report was carried out under the supervision of Duncan Browne in the UCL School of Pharmacy from June to August 2023.

I, Marie-Therese Bultmann, confirm that the work presented in this dissertation is my own. Where information has been derived from other sources, I confirm that this has been indicated in the dissertation.

I have read and understood UCL's policies on use of AI technologies and confirm that I have abided by them in this report.
I acknowledge the use of ChatGPT/OpenAI (https://chat.openai.com) to modify the abstract, which is included in my dissertation.

Signature: 

Marie-Therese Bultmann

Date: 30.08.2023

Introduction

Note: Throughout this dissertation, when referring to *Black people*, this refers to African, Caribbean and Afro-Caribbean populations and these terms may be used interchangeably. The term *ethnic minorities* includes all minority ethnic groups in the UK, such as Asian, Black and Mixed groups, but excludes White minority groups like Gypsy, Roma and Irish Traveller.

The underrepresentation of Black people in clinical trials has been a recognised issue since the dawn of modern medicine. This is an issue that is prevalent throughout the entire scientific community worldwide. There are various suspected reasons for the low enrolment of Black people in clinical trials, such as: a mistrust in scientific research, unwillingness to participate in studies, as well as an inadvertent or a planned exclusion by pharmaceutical companies (Redwood and Gill, 2013). This research aims to determine the reasons for the lack of African and Caribbean clinical trial participants in the UK, and solutions that can be implemented to increase diversity in clinical research. In this chapter, the research topic is introduced by firstly exploring the background and context of the subject matter, and then moving on to the significance of this paper, which will be followed by its limitations.

Historically, there has been a maltreatment of Black people in scientific research. The most infamous case example of this is the 1932 Tuskegee Syphilis Study conducted at the Tuskegee Institute in the US. The full name of the study was the "Tuskegee Study of Untreated Syphilis in the Negro Male" (Tuskegee University, 2019). The study aimed to explore the pathological progression and consequences of untreated syphilis in Black men. The sexually transmitted disease is caused by the bacterium Treponema Palladium which can be transferred through close contact with an infected person's genitals, rectum, mouth or open sores (www.peacehealth.org, 2023). If left untreated, the disease will progress into tertiary syphilis which is fatal (www.nhsinform.scot, 2023). The majority of participants were vulnerable, uneducated men incentivised and manipulated by the offer of free medical care from the researchers. However, the treatment they would endure through partaking in the study would be deemed as highly unethical by today's standards. Out of the 600 African American men enrolled in this study, 399 had latent syphilis - a form where no obvious signs or symptoms of the disease are present (www.cdc.gov, 2022). The research team failed to inform the participants of their diagnosis and instead would subject the men to painful spinal

taps that served no therapeutic benefit, deceitfully advertising the procedures as their “last chance for special free treatment”. For the entirety of the study, data was published to the medical community and participants were denied the right to leave the study even when penicillin was introduced as the first line treatment for syphilis. This led to 128 men dying from syphilis and associated complications by 1972 when the study was ended. 19 of the participants’ children were born with congenital syphilis and 40 of their wives had been infected (Wikipedia Contributors, 2020). The study led to the reputation of clinical trials and scientific research being damaged in the African American community in the US. Only in 1996 were the concerns about the harm of the study to the mental wellbeing of African Americans addressed through the work of the Tuskegee Legacy Committee. This resulted in a formal apology from President Clinton in 1997 and the publishing of the Belmont report in 1979 that outlines ethical principles and guidelines for the protection of human subjects in research (Office for Human Research Protections, 2018). Nevertheless, the trust in clinical research was tarnished and this study is presumed to be a major factor in the scepticism that is seen in Black people, specifically in the US.

However, this is not the only cause for the scarcity of Black people in clinical trials. A study by the National Institute for Health and Care Research (NIHR) found that in 86 studies that were published in their journal library, an average of 4% of the study participants were Black (National Institute for Health and Care Research, 2022). This was echoed in COVID-19 vaccine trials in the UK, where approximately 5% of the study population were Black (Jethwa, Wong and Abraham, 2021). It is not uncommon for more than 80% of a study population to be White, meaning that results are extrapolated to fit Black people. There are multiple reasons for this, such as recruitment for clinical studies being inadequate in areas where deprivation is paramount and these are often regions where ethnic minorities prevail (Saul, 2020). This is a disservice against Black patients, as there are physiological differences in responses to the medicinal treatments in different racial groups. If there are an insufficient number of Black people present in trials, this means that therapeutic responses and adverse reactions are established at a late stage, once a drug is in phase IV and real-world clinical data is collected. Therefore, important clinical indications that could endanger Black patients may only be discovered once the medication is already released onto the market, even though this could have been hindered.

To help with the recruitment of Black people in scientific research, some initiatives have been put in place, such as a roadmap for better serving underrepresented groups in research by the NIHR (National Institute for Health and Care Research, 2020) and a practice guide by the National Health Service (NHS) to help with communicating with them (NHS England, 2023a). However, existing initiatives are not solely focused on the recruitment of Black people in clinical trials and fail to lay out specific solutions to overcome this issue. Furthermore, the lack of studies that examine the differences in therapeutic responses in diverse racial groups, causes researchers to have insufficient knowledge in the presentation of diseases and clinical outcomes of treatments in Black people. Ultimately, this causes Black patients to be at a disadvantage.

This paper will contribute to the body of knowledge on solutions that must be implemented to truly engage with African and Caribbean populations and to adequately increase the enrolment of them in clinical trials in the UK and worldwide. This is of importance to pharmaceutical companies and any research staff that aim to have clinical results that are representative of the wider population.

This dissertation has some limitations. I have tried to remove bias in studies and papers that were chosen for analysis; however, as I am Black woman who is passionate about increasing diversity not only in patients but also in research staff, there may be some prejudgment present in this paper. Another limitation is that due to a lack of data and resources available, conclusions from US data about African Americans was sometimes extrapolated to African and Caribbean people in the UK.

In chapter one, the research topic has been presented. An overview to the background of the paper has been described, as well as the importance of the research, and its shortcomings.

Chapter two identifies the proposed hypothesis and the justification of the dissertation topic. The aims and objectives are also laid out.

In chapter three, the methodology is described. Planned approaches that were not implemented are also mentioned.

The fourth chapter analyses relevant literature, whilst discussing the findings and the implications of selected data. This is split into seven sections, with each exploring a different area of the impact of low enrolment of Black participants in clinical trials.

In the fifth chapter, there is a summary of the key components of the paper. This is followed by a recommendation of work that could be conducted in the future.

Hypothesis

A lack in the inclusion of Black participants in clinical trials positively correlates to decreased trust amongst Black patients in the healthcare system and the pharmaceutical industry. This decreased trust further leads to substandard clinical outcomes for Black patients, as well as deficient knowledge of the genetic and epidemiological differences in various racial groups.

Justification

Ethnic minorities are frequently under-represented in clinical trials. This leads to ethnic groups, especially Africans and Caribbeans not receiving the best possible treatment that they can, as results from studies are usually extrapolated from findings in White males. The findings from this thesis will help researchers and practitioners to understand the causes for low enrolment of African and Caribbean people in clinical trials in the UK and what can be done to raise those numbers, to allow a more diverse and representative study population in the future.

Aims

Given the lack of Black participants in clinical trials, this paper will answer if this is due to: a planned exclusion from the scientific community or pharmaceutical companies, an unintentional exclusion, a lack in the participation from Black people, a lack in the engagement with scientific research groups, a combination of these factors, or different reasons.

Objectives

1. To establish the importance of racial diversity in clinical trials
2. To compare and contrast ethnicities represented in UK clinical trials
3. To identify who is at fault for the underrepresentation of Black people in clinical trials
4. To evaluate the impact that a lack of diversity in clinical trial populations has on clinical outcomes
5. To determine what steps can be taken to tackle this issue

Methods

To obtain the data that was needed for the completion of this project, I carried out an extensive literature review, as well as an interview with an expert in the field of racial diversity in clinical research.

There is a wealth of information about the demographics in clinical trials in the US, as it has been of interest to the scientific community for decades. Before starting my literature review, I wrote six questions that were based on my title. These would help me to focus my research to ensure only relevant articles would be selected. These questions were:

1) What is the history of ethnic minorities in clinical trials and is there mistrust? If so, where does it stem from?
2) What is the importance of racial diversity in clinical trials?
3) Are there differences in ethnicities represented in clinical trials?
4) What impact does the low enrolment of minorities have on results and clinical outcomes?
5) Who is responsible for the under-representation of ethnic minorities in clinical trials/what is contributing to it?
6) What can be done in the future to increase enrolment?

The databases that were used to undertake my literature search were Google Scholar, Google and PubMed. Sentences that were written into the search bars of Google Scholar include *APBI statistics on race and ethnicity*, where I obtained 428 results, *ethnic minorities in clinical trials* with 19200 papers and *clinical trial enrolment* with 26700 articles found. To enhance my search, I set the custom range of articles to the years 2000 to 2023, as I needed current data to obtain a view of what clinical trial demographics and issues have been like in this century. To ensure only relevant papers were chosen, I only included papers that were written in English and excluded any that solely looked at ethnic minorities that were not Black, African or Caribbean. When deciding on which articles to read, I chose the ones that included data on ethnicity or had the words *Black, African, Caribbean, Afro-Caribbean, BAME (Black, Asian and minority ethnic) and BME* (Black and Minority Ethnic) in the title or in the preview on the start page. I then proceeded by scrolling through the entire article or page and skimming through it to see if there was any data that would answer one or a few of my six questions. If

this was the case, then I would read the abstract of research papers or the introduction of other articles. I also looked for any available quantitative data, specifically a breakdown of ethnicities, any graphs and figures of interest. Some research papers also cited other relevant research papers in the reference list, which I would use to build my database for the literature review. The articles and papers I had found were then ranked on their trustworthiness based on how current they were, if the individuals or companies that had written them had any conflict of interest in the topic, and how credible the source was. I would then extract relevant data and analyse data in forms of graphs and figures.

The interview that was undertaken was with Dr Lia Hunter, who has over 20 years of experience working in the pharmaceutical industry, is the director of CGX Training- a clinical trial specialist provider, and is an advocate for increasing the presence of Black people working in clinical trials and participating in them. The interview consisted of open-ended questions such as “What can we do to increase the number of ethnic minorities in clinical trials?”, as this allowed for a conversation to occur and follow-up questions to be based on the interviewee’s answers.

I had further planned to prepare a questionnaire with open questions about thoughts and feelings towards clinical trials, that I wanted to distribute to African and Caribbean people in order to gather some original data. However, as I would have to identify the race of the participants, which is a protected characteristic, this would have needed approval of the ethics committee at UCL and this did not fit into the timescale for this dissertation. I had also planned on gathering data on the ethnicities of participants in trials at UCL, however I was informed that this information was not recorded for participants until recently, therefore there was no data that could be shared with me.

Results and Discussion

I have conducted an extensive literature review, as well as an interview with Dr Lia Hunter who is an expert on racial diversity in healthcare in the UK. As a result, data was gathered to aid in the understanding of the causes and implications of the underrepresentation of African and Caribbean people in clinical trials. Current initiatives to tackle this issue were also highlighted.

Differences in ethnicities represented in clinical trials in the UK and US

Black people make up 4% of the population in the UK, equating to 2,409,278 people as per the 2021 Census. These include people who identify as Black, Black British, Black Welsh, Caribbean and African (Wikipedia, 2023).

In the UK, there is a lack in recording the ethnic background of participants in clinical trials. It is therefore challenging to gather information on the ethnicity of participants from online sources and from clinical trial sites, which leaves a lot of room for speculation and not much room for hard facts. This was emphasised by Dr Hunter who struggled to find literature that described the clinical trials, their location, and recruitment of Black participants in the UK. "*There is a lack of data, meaning that we often extrapolate from US data"* (interview with Dr Hunter, 2023). This issue was reiterated when contacting the clinical trials unit at UCL, who disclosed that information on the ethnicity of the participants in their studies has not been collected up until recent years.

A study by the NIHR (*Figure 1a*) looked at the number of studies from the years 2007 to 2017 that were published in their journals library. This study showed that only 58% of the 148 published studies had a breakdown of the ethnicities of their participants (National Institute for Health and Care Research, 2022).

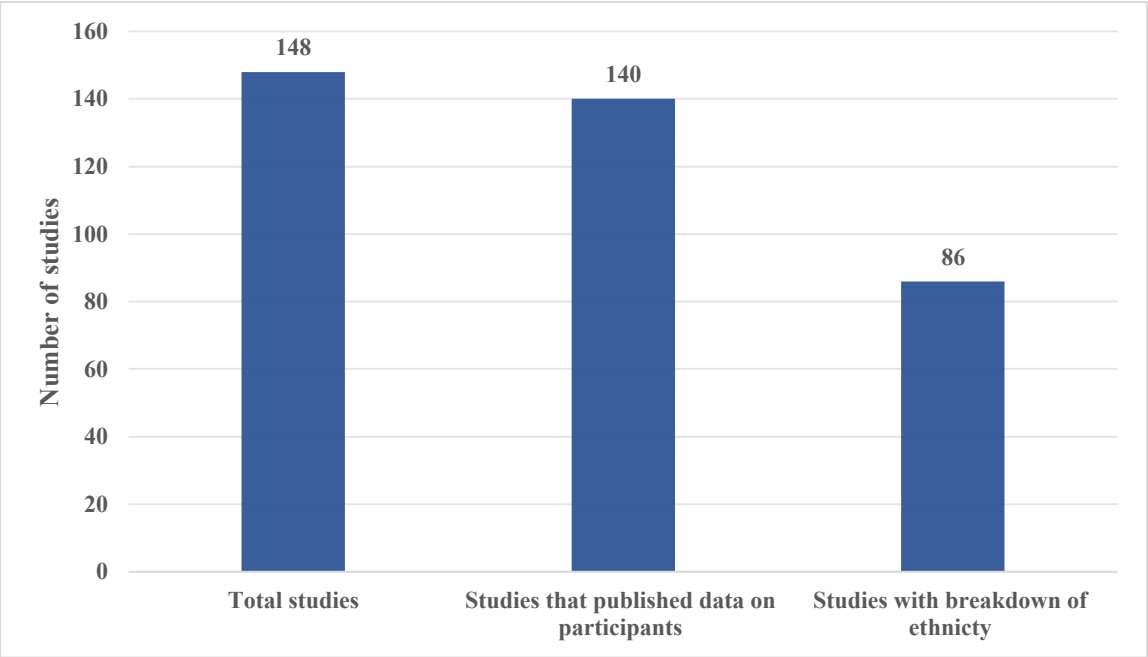

Figure 1a. *This bar chart displays the Randomised Clinical Trials (RCTs) in England and Wales from the years 2007 to 2017 that were published in the NIHR Journals Library. The NIHR conducted an analysis to increase their understanding of their patient population. 140 of the 148 published studies were taken forward, as they contained participant data. 86 studies, which is equivalent to 60% of the 140 studies that were analysed, contained data on the ethnic breakdown of their participants (National Institute for Health and Care Research, 2022).*

Upon further investigation of the analysed NIHR studies, the underrepresentation of Black people is shown in *Figure 1b.* In 86 studies, 4% of the participants were Black, compared to 86% of the participants being White. As the population of Black people in the UK is 4%, it may be argued that the enrolment of 4% of Black people in clinical trials is representative of the UK population. However, due to the absence of ethnicity data in 42% of the published NIHR trials, we cannot be sure that 4% of Black people were present in all or even most clinical trials. According to a study in America that reviewed 50 new clinical trials, the percentage of Black people in clinical trials does not correspond to the percentage in the general population (PMLive, 2021). Furthermore, for a study sample to be representative of a population of more than 1,000 people, 10% of individuals are required (St Olaf College Education, n.d.). Therefore, if the population of Black people within a disease area exceeds 1000 people, 10% of the Black disease population must be enrolled in the trial to say that it is representative. To get a statistically meaningful result, the vast majority of statisticians insist that at least 100 people of a studied population should be tested to get valid results that allow conclusions to be made from (Tools4dev, 2013). This may not be achievable for phase I studies, which usually recruits 20-80 people. However, once phase III trials are conducted, it

is common for more than 3000 participants to be enrolled. Therefore, it is crucial to have at least 10% of the population represented in this phase. Therefore, many conclusions that are made about Black people in trials are not statistically significant and generalisable.

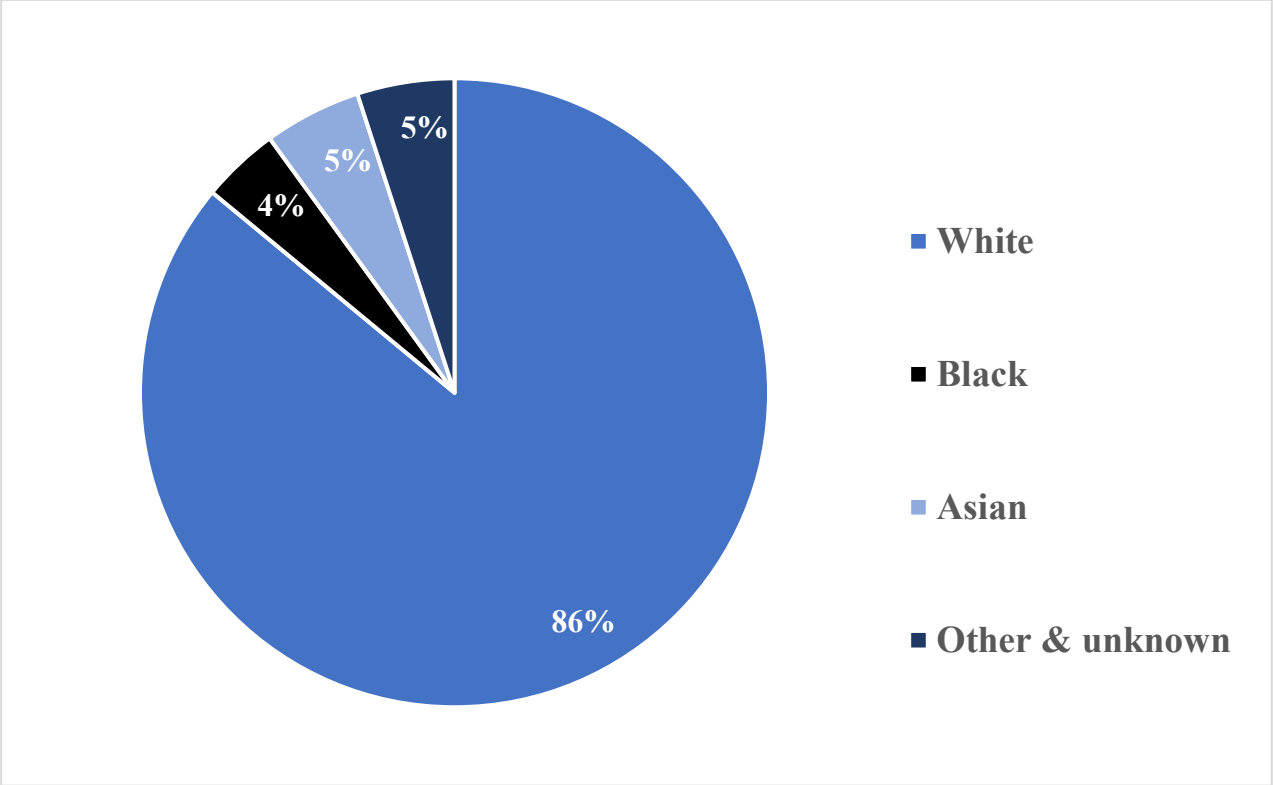

Figure 1b. *This pie chart looks at 86 RCTs that were published in the NIHR Journals Library from the years 2007 to 2017 that had a breakdown of ethnicity. It shows that the majority of participants were White with 86%, followed by Asians with 5%, then others and unknown ethnicities with another 5% and Black participants with 4% (National Institute for Health and Care Research, 2022).*

A further issue that is faced when trying to analyse data on ethnicity in clinical trials in the UK is that ethnic minorities are often grouped together. The term BAME meaning Black, Asian, and minority ethnic is still used in research papers to this present day. This umbrella term for ethnic minorities does not allow for interpretation of data of specific racial groups. Many papers and websites use the term 'mixed' and 'other minority background' in their published data. They often do not define these terms, making it difficult to ascertain which racial and ethnic groups were being tested.

The most amount of data is found in US clinical trials, as US pharmaceutical companies and clinical research organisations have a higher percentage of recording the different ethnicities of their participants. The US census in 2021 revealed that 12.1% of Americans identify as

African American, which makes up a sum of 40.1 million people (Office of Minority Health Resource Center, 2021). Two studies (*Table 1*) that were carried out by T. Bebi and Johns Hopkins Medicine looked at the enrolment of Black patients and the distribution of ethnicities in participants in oncology trials in the US. They found that the enrolment of Black people in various oncological studies was as low as 2.1% in a study in bladder cancer and not representative of the African American population suffering from the diseases.

Therapeutic area	Percentage of Black patients enrolled (%)
Oncology	8.5%
Lung cancer	8.1%
Breast cancer	11.4%
Bladder cancer*	2.1%

Table 1. *This table shows the percentage of Black patients from a cohort of 434,700 participants, that were enrolled in interventional clinical trials from the years 2010 to 2021 for the first three columns (Bebi, 2022) and 1994 to 2021 for the invasive bladder cancer (Johns Hopkins Medicine, 2022) in the last column. This table shows that the enrolment of Black people ranges between 2.1% to 11.4% of participants in those oncology clinical trials.*
** BCG-unresponsive, non-muscle-invasive bladder cancer*

The low percentage of Black people in clinical trials is frequently justified by saying that Black people are not interested in partaking in clinical trials. Dr Hunter stated that "*there is a historical feeling that clinical trials are genuine pig experiments to test drugs on Black people that will be used on White people once approved"* (interview with Dr Hunter, 2023). Even though there is a blatant mistrust of the entire clinical trial process which has been reinforced by the Tuskegee Syphilis trial, an exhaustive literature review by D. Wendler that looked at more than 70,000 clinical trial participants in 20 studies in the US found that there were no significant differences between African Americans, Hispanics, and White people's willingness to participate in clinical trials (Wendler et al., 2005).

Takings from COVID-19

The Coronavirus pandemic (COVID-19) started in 2019 and by the 16th of August 2023 had claimed the lives of over 6,955,141 people (World Health Organisation, 2023). The mortality risk is between 10-50% higher in ethnic minorities in the UK and US (Ekezie et al., 2020), with Black men being more than four times as likely to die from the virus compared to White men in the same age range, as displayed in figure 2. Similarly, Black women are 4.5 times more likely to die compared to their White counterparts (Office for National Statistics, 2020). This is often due the living conditions that many Black people face in the UK, specifically living in overcrowded areas and multi-generational households, which facilitates the fast spread of the virus. It has also been noted that there are increased rates of pre-existing health conditions such as cardiovascular diseases and type 2 diabetes in Black people in the UK and US, which can intensify the symptoms and outcome of the virus (Murali et al., 2023).

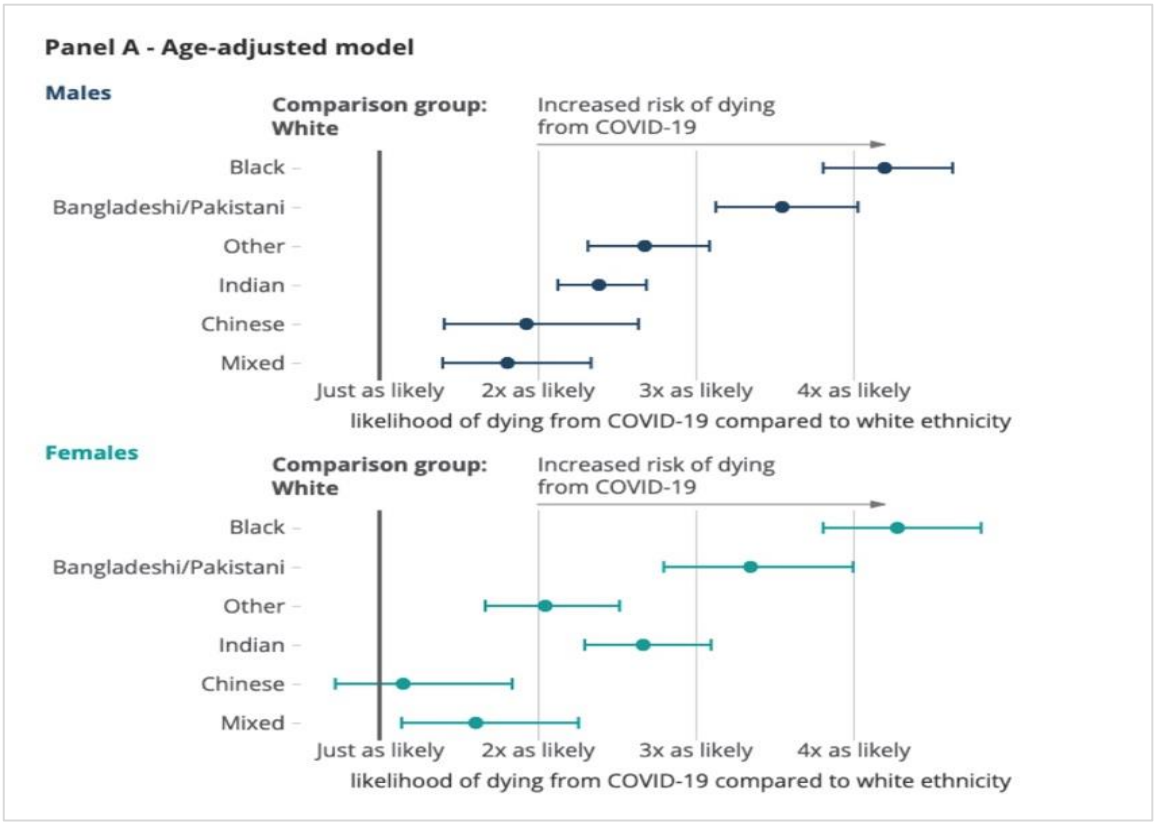

Figure 2. *This graph compares different ethnic minorities in the UK grouped by sex, to the likelihood of dying from COVID-19 in relation to their White counterparts in the same age group. Scheme is taken unedited from (PMLive, 2021).*

As COVID-19 has disproportionally affected and carries more risks for Black people, an adequate number of Black people would be expected to have been included in clinical trials for COVID-19 vaccines, so that data for vaccine efficacy can be applied to those individuals.

In reality, only 1,509 out of 622,978 participants in COVID-19 vaccine trials in the UK were ethnic minorities (Black, Asian and mixed). This was established in a report by the National Institute of Health Research, who also found that only 5% of individuals in the COV002 phase 2 study for the Oxford vaccine had people from an ethnic minority background participate in the trial (Jethwa, Wong and Abraham, 2021). This does not correspond to the 18% of the population in the UK that make up ethnic minorities as stated in the 2021 census (Commons Library, 2023).

A study by M. Murali conducted a systemic review and meta-analysis to look at ethnic minority groups in COVID-19 trials in the UK. The criteria used to filter the search in MEDLINE and Google Scholar were: studies published between January 2020 and May 2023, studies conducted in the UK, and studies with more than 50 adult participants. Out of the 5,319 studies identified, only 30 were analysed due to the others not meeting inclusion criteria, being duplicates or not being randomised clinical trials (Murali et al., 2023). The analysis of the 30 studies is shown in figure 3.

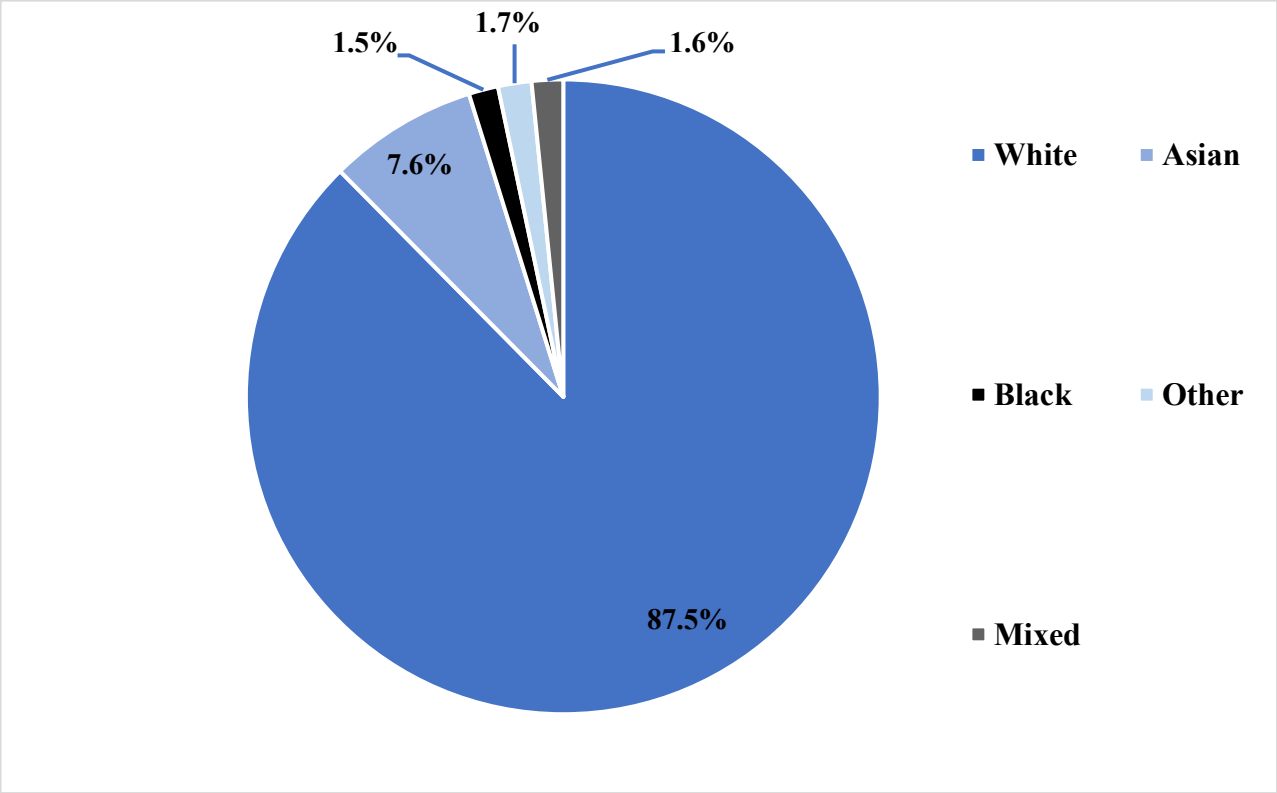

Figure 3. *This pie chart shows the enrolment of 118,912 participants in 30 UK COVID-19 trials broken down by ethnicity from the time period 1st of January 2020 to 4th of May 2022. Overall, there were 98,362 White participants in the trials equating to 87.5%, 2559 Asian participants equating to 7.6%, 764 mixed participants equating to 1.6%, 2559 others equating to 1.7% and 317 Black participants equating to 1.5%.*

The findings from this study shows that even though the disease severity is worse in Black COVID-19 patients and there are gaps in the understanding of the causation of this, the recruitment of Black people was extremely low in UK COVID-19 trials, as only 327 out of 118,912 participants were Black. Murali also documented that Black participants were underrepresented in these trials by 0.6-1.5% compared to the rates of 3.3% that were noted in the Office for National Statistics. This again, is much lower than the population averages of Black people (Murali et al., 2023).

There are multiple speculated reasons for the low enrolment rates of Black people in COVID-19 trials: many Africans and Afro-Caribbeans thought the vaccines were developed to eradicate Black people, that they may contract COVID via the vaccines, or that they may be shunned their local community for taking part (Ekezie et al., 2020). W. Ekezie conducted a qualitative investigation with three focus groups consisting of 17 people of African and Afro-Caribbean descent. The investigation further uncovered fears of vaccine side effects, inadequate support if complications occurred, and language barriers further contributed to low enrolment rates.

Nevertheless, it is crucial to recruit participants from ethnic groups and geographical areas where diseases are more common or have a higher mortality rate, such as COVID-19 for Black people. This allows researchers to better understand the disease, as well as differences in responses to treatments, which ultimately leads to better care for patients of all races, as treatment schedules and dosing may need to be adjusted for an optimal outcome.

The importance of racial diversity in clinical trials and its impact on clinical outcomes

The COVID-19 pandemic was an opportunity for the NHS to exercise its plan of tackling inequalities in healthcare. As of now, clinical trial data in the UK is mostly based on the "*White male genetic makeup, physiology and statistics"* (interview with Dr Hunter, 2023). This is a disservice to ethnic minorities who are underrepresented in clinical trials, as patients who take part in clinical research have better health outcomes, as well as better management and monitoring of their diseases (Hussain-Gambles, Atkin and Leese, 2004).

It is critical that there is racial diversity in clinical studies so that therapeutic responses can be optimally targeted, specifically in groups where there are differences in disease patterns (Taylor and Wright, 2005). Due to demands from funders to quickly recruit participants in trials, many studies have a homogenous population, as this leads to less variance in results (Witham et al., 2020). Clinical trials must account for the physiological differences between different races; a wide range of ethnically diverse participants will allow for results to be more generalisable to the wider population. Recruiting individuals from ethnic minority background is the only way of collecting data to weigh up the risks, benefits and effectiveness of the treatment for that specific group (National Institute for Health and Care Research, 2020). How diseases present themselves in Black patients differs to their presentation on lighter skin tones. Research such as the work of Malone Mukwende, the co-author of 'Mind the Gap'- a clinical handbook detailing the appearance and symptoms of diseases on black and brown skin- brings awareness to this often overlooked phenomenon.

After breast cancer, lung cancer is the second most common cancer in the US. When comparing the mortality rates in ethnic groups, African Americans have the highest and the greatest number of lung cancer cases. A US study by K. Mitchell looked at non-small cell lung cancer (NSCLC), by profiling the transcriptome to find coding and noncoding differences in RNA in African American and European Americans. The aim of this was to determine if there is any clinical relevance to racial differences in miRNA and gene expression in lung tumour biology. The data could then be used to help with predicting prognosis, having accurate methods of diagnosis, and treating cancer. After collecting the specimen of human lung tumour tissues from NSCLC patients who lived in Maryland, they were macroscopically dissected and then analysed. It was found that in 9.9% of African

Americans the lung tumours had an abundance of invasion pathways and stem cells compared to 4.5% in European Americans. Adversely, 4.5% of European Americans have lung tumours that are enriched in proliferation pathways, cell cycle, and mitosis, compared to 0.1% African Americans. African Americans also had a considerable amount of M1 and M2 macrophages, gamma delta T cells and follicular helper T cells, which was much lower in European Americans. This study also found an overexpression in cytotoxic T-lymphocyte associated protein-4 that was higher in African Americans than in European Americans, which is a protein that is targeted in immune checkpoint inhibitor drugs such as Yervoy. The differences that were found in the differential miRNA expression and gene expression indicate that there may be clinical differences. When resistance and drug sensitivity is predicted, there is a possibility that African Americans and European Americans may not benefit from treatments in the same way. This study concluded that further clinical trials will have to be carried out to understand the impact of racial differences in lung tumour biology, as this will lead to better health outcomes for both populations and a lower mortality rate (Mitchell et al., 2017).

Other studies have also shown that race may contribute to differences in pharmacokinetic parameters. A study by Krecic-Shepard looked at the clearance of the calcium channel blocker nifedipine in different races. The high-affinity CYP3A substrate has been shown to have inter-patient variability in clearance through a previous study (C M Hunt- Effect of age and gender on the activity of human hepatic CYP3A). 138 Black participants and 88 White participants with coronary artery disease and hypertension were enrolled in this study. These participants were being treated with sustained release nifedipine and their oral clearance was estimated using a nonlinear mixed effects population model (also known as NONMEM). This is a software program that analyses pharmacokinetic and pharmacodynamic data, as well as estimating parameters and interindividual variability (www.sciencedirect.com, 2022). The first model that was made with NONMEM had no covariates and subsequent models had covariates like race and coronary heart disease and the final model equation included interindividual error. This study found that clearance was considerably lower in Black patients (8.9 ± 0.7 mL/min/kg) when being compared to the White participants (11.6 ± 0.8 mL/min/kg). Therefore, racial differences may lead to disparities in therapeutic responses, specifically in oral drugs that undergo CYP3A clearance (Krecic-Shepard, 2000).

Commercial considerations

The decision of who gets recruited in clinical trials mainly lies in the hands of pharmaceutical companies. These companies strive to enhance the quality of life for sick individuals by introducing new treatments or optimising existing ones. However, it is important to note that ultimately these are businesses that are competing with each other and their main goal is to make as much profit as possible.

Annually, the pharmaceutical industry makes a turnover of more than £40.8 billion in the UK (ABPI, 2020). However, there has been a significant decline in the number of clinical trials that are carried out by pharmaceutical companies in the UK from the years 2017 to 2021. There has been an observed decline of 41% of clinical trials, as more pharmaceutical companies are doing their trials in countries like Australia and Spain. This pushed down the UK's global ranking in phase III clinical trials, to 10th place in 2021, whereas it had classed as fourth place in 2017. This decrease in clinical trials in the UK has meant that less patients have been enrolled in clinical studies, as there were 50,112 participants in the years 2017-18, which decreased by 44% to 28,193 participants in 2021-22 (Mahase, 2022). This is of concern to the UK, as it is one of the world leaders in clinical trials and with the global clinical trial market size *(figure 4)* having an anticipated compound annual growth rate of 6.9% over the next seven years, the turnover potential for pharmaceutical industries is huge. As the UK has a large influence on how clinical trials are run in other countries, if the UK were to set a precedent of recruiting a set percentage of Black people in clinical trials, this practice may be adopted and implemented globally once beneficial outcomes are yielded.

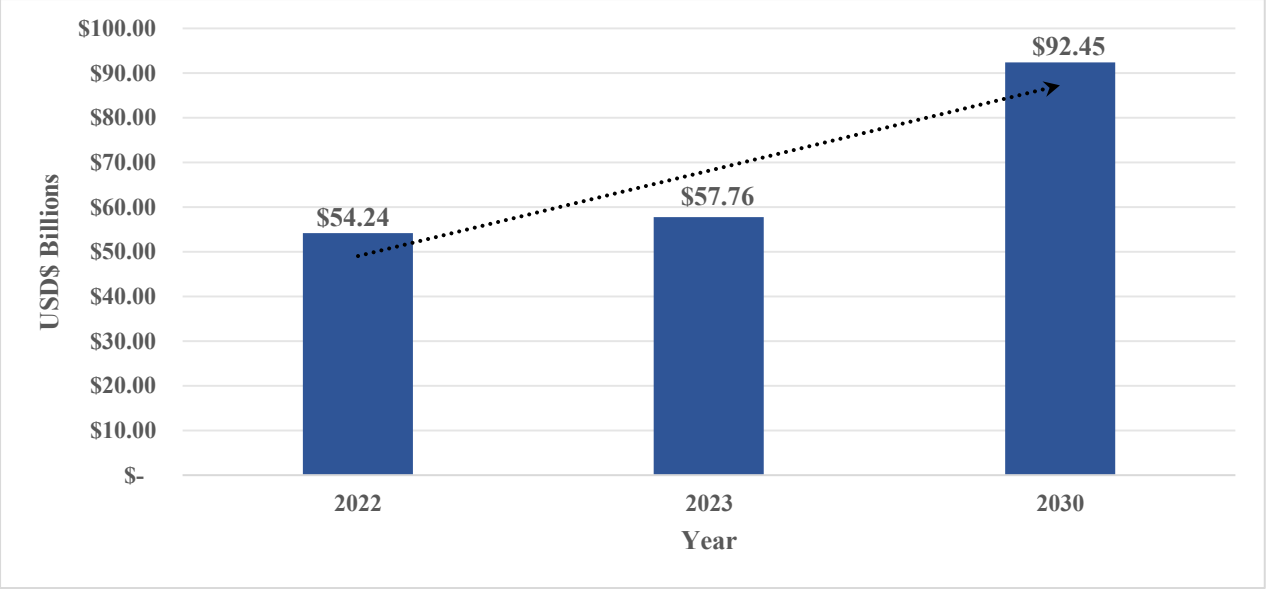

Figure 4. *This bar chart shows the global clinical trial market size from the years 2022 to the predictions for the years 2023 to 2030. There is an expected growth from $57.76 billion in 2023 to $92.45 billion by 2030, measuring an anticipated compound annual growth rate of 6.9% (www.fortunebusinessinsights.com, n.d.).*

A study by the NIHR that looked at the recruitment of patients across the UK has shown that geographical locations where disease burden is high, have the lowest number of patients partaking in research. Furthermore, regions where deprivation is highest and annual income is the lowest had the least recruitment into clinical research. For recruitment to match the disease prevalence, 90,000 more participants would have to be recruited from the identified postcodes that were underrepresented. Diseases where this was particularly prevalent were mental health issues and diabetes (Saul, 2020).

More than 422 million people worldwide are living with diabetes, one of the leading causes of death (www.who.int, n.d.). Type 2 diabetes is the most prevalent type of diabetes, as 90-95% of people with diabetes have this form of the disease. This is when the body does not respond to the hormone insulin in order to regulate blood glucose levels or when resistance is built towards insulin. In the US, Black adults are twice as likely to get diabetes compared to their White counterparts. However, the lowest prevalence of diabetes is recorded in African nations like The Gambia and Benin. In the whole of Africa, less than 2% of the entire continent's population have diabetes, which equates to 23.6 million adults (Moro, 2023). A forecasted doubling to 55 million adults with diabetes in Africa by 2045, makes this a very lucrative market for pharmaceutical companies to take an interest in. The diabetes market size is expanding from $29.81 billion in 2021 to $61.60 billion by 2030 as shown in figure 5.

If studies were to be carried out in Black participants to fully understand why there are discrepancies in the prevalence of diabetes in African Americans and Africans, this would allow better preventative measures to be established. Moreover, the cost of treating diabetes is expected to cost the NHS £16.9 billion in the next 25 years, which is 17% of the NHS budget (University of York, n.d.). Studies have to be conducted to explore why Black African and Black Caribbean ethnicities are two to four times more likely to have diabetes than White populations (Diabetes UK, 2023). This is a win-win situation for the pharmaceutical industry and patients, as better understanding of disease epidemiology could lead to improved treatments made by pharmaceutical companies, which will improve the quality of life for patients. This is also an opportunity for medical innovation, as improved comprehension of a disease in Black people could lead to the development of novel medications with a more precise target.

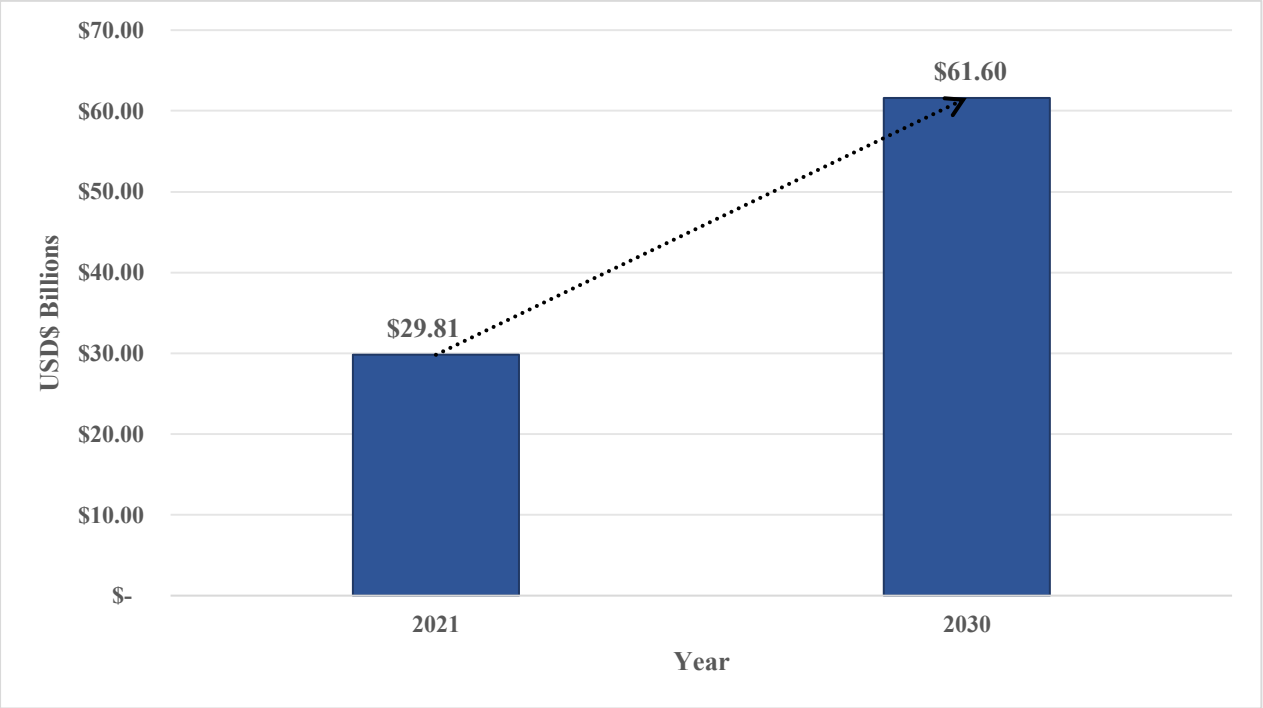

Figure 5. *This graph shows the global type 2 diabetes market size from the years 2021 to predictions for the year 2030. There is an expected growth from $29.81 billion in 2021 to $61.60 billion by 2030 (World Pharma Today, n.d.).*

Historically low recruitment levels of Black people may be attributed to concerns of additional costs associated with: transport, translators (to overcome the issue of language barriers), and abiding to regulations by the ethics committee like a translated information sheet (Murali et al., 2023). However, having a more diverse set of participants in clinical

trials leads to decreased costs in the long term. Investing more into the UK's life science sector can decrease the burden of disease by 40% (Mahase, 2022). Furthermore, the effectiveness of a treatment in different racial groups can be established in early phases instead of recalling the product or discovering differences in side effects further down the line. For example, Black people are more susceptible to grade 3 and 4 adverse events from the antiretroviral medication Efavirenz that is used to treat human immunodeficiency virus (HIV)/AIDS. This is due to the CYP2B6 enzyme variant that is present in African people, but this was only discovered once the medication was introduced in African populations (i-base.info, 2006). This caused the World Health Organisation to recommend the use of the safer antiretroviral Dolutegravir, meaning that the pharmaceutical company Bristol-Myers Squibb lost many sales on Efavirenz. Therefore, more diversity in clinical trial participants allows stronger data to be collected that is representative of a larger population, as well as satisfying regulators' demands and increasing profits for the companies, as drugs can get onto the market much faster (www.mantellassociates.com, 2022).

In order for us to see actual change, the recruitment of Black people in clinical trials needs to be perceived as commercially viable. A planned strategy may need to be implemented by pharmaceutical companies that lays out the enrolment metrics that would be required for regulatory approval of a clinical study.

Black representation in healthcare and research

Subconsciously, as emphasised by the mere-exposure effect phenomenon, humans tend to feel more comfortable towards things and people they are familiar with (Wikipedia Contributors, 2019). This also translates to race and ethnicity. Patients often feel more comfortable when they are around people who they can identify with. In the UK, when looking at the NHS, only 7.4% of the workforce are Black (*Figure 6*). This means that the 2,409,278 Black people that live in the UK are often not exposed to healthcare professionals that look like them. "*Not having the representation in doctors or nurses that look like them makes Black people think that clinical trials are not for them"* (interview with Dr Hunter, 2023). This may contribute to Black people feeling uncomfortable or unwelcome in healthcare settings, research and clinical trials. A survey by the black equity organisation showed that most Black people in UK face discrimination from healthcare staff. The aims of this survey were to better understand the experiences of Black people in the UK and to tackle systemic racism in health care systems. It found that nearly two thirds of respondents indicated that they had encountered prejudice from doctors and other staff in healthcare settings. When solely looking at the Black respondents from the ages 18 to 34, this increased to 75% (Iacobucci, 2022).

The NHS has gained more employees from diverse ethnic backgrounds at board levels; however, the representation of ethnic minorities is extremely low in senior positions. The long-term plan for the NHS is to have more ethnic minorities in senior positions, as this should reflect their entire workforce (NHS England, 2023b). When looking at the split of the NHS workforce in 2022 (*figure 6),* it is apparent that there is an underrepresentation of ethnic minorities. Whilst White people made up 74.3% of the workforce, Asians made up 12.5% and Black employees made up 7.4% of the workforce in 2022 (www.ethnicity-facts-figures.service.gov.uk, 2022).

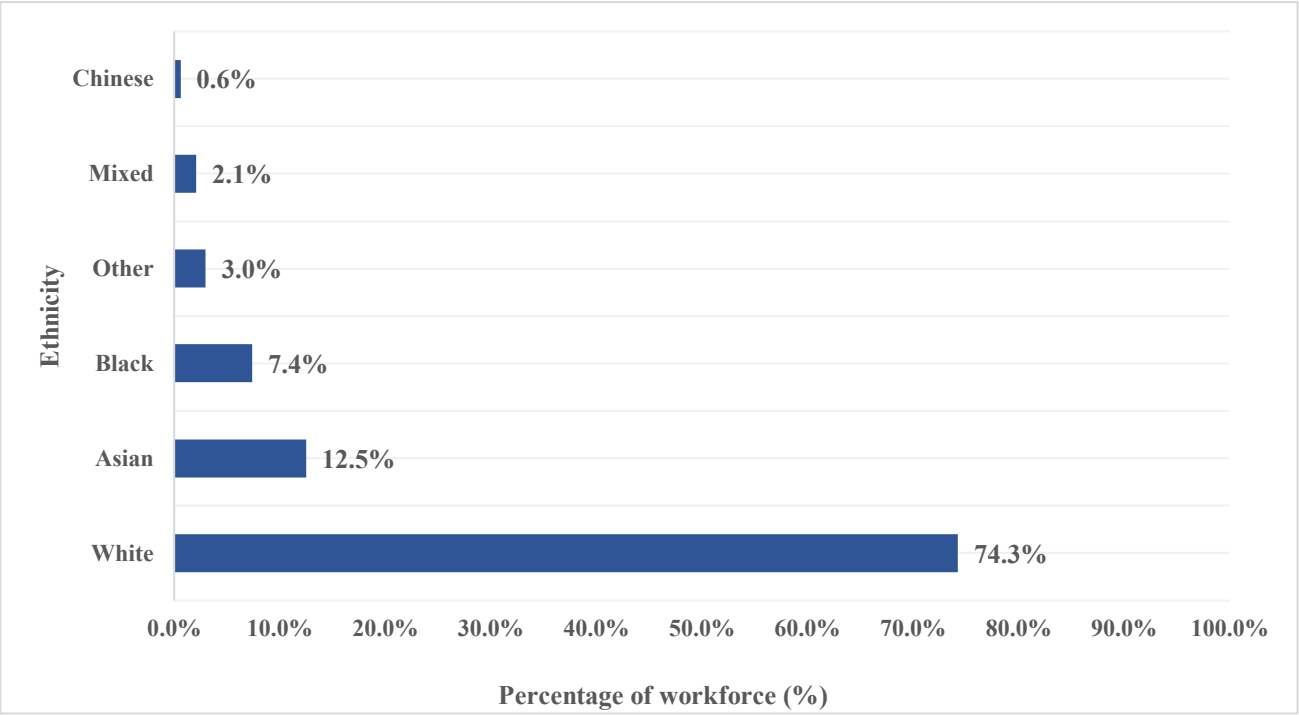

Figure 6. *This bar chart shows the percentage of the NHS workforce broken down by ethnicity in 2022. The NHS as of 2022 is mostly made up of White employees making up 74.3% of the workforce, whilst Black employees make up 7.4% of employees (www.ethnicity-facts-figures.service.gov.uk, 2022).*

A report by the NHS recorded the experiences of NHS staff in 2021. It was revealed that 29.2% of ethnic minorities reported harassment compared to 27% of White employees. As all ethnic minorities were grouped together (Black, Asian, Chinese, mixed and other), it is not possible to distinguish the specific experience for each racial group. 27.6% of ethnic minority staff experienced bullying compared to 22.5% of White staff. A discrepancy is seen when analysing the NHS staff beliefs towards their trust providing equal opportunities for career progression, as 58.7% of White NHS staff believed this, compared to 44.4% in ethnic minority staff in 2021. Furthermore, the NHS is 1.54 times more likely to hire White shortlisted applicants compared to ethnic minorities (NHS England, 2023b).

Globally, there is an underrepresentation of Black employees in pharmaceutical companies. As shown in *table 2,* the percentage of Black employees in some of the major pharmaceutical companies hovers around 10%. When looking at senior leadership roles, this number decreases drastically.

Name of pharmaceutical company	Global percentage of Black employees (%)
Glaxosmithkline (GSK)	12%
Bristol-Myers Squibb (BMS)	9.7%
Merck	10.5%
Johnson & Johnson (J&J)	10.3%

Table 2. *This table shows some of the major pharmaceutical companies' demographics. With more than 99,000 employees, GSK has less than 12,000 employees that identify as Black or African American. BMS with more than 30,000 employees has only 2,910 Black employees. Merck with more than 74,000 employees has 7,350 Black employees. J&J with more than 134,500 employees has around 13,853 Black employees (www.zippia.com, 2022).*

It is of great importance to have a diverse workforce in pharmaceutical companies, because this relates to diversity in research and clinical trials. It was noted by the Tufts Center for the Study of Drug Development at Tufts University School of Medicine that there was more ethnic and racial diversity in participants that were enrolled in studies when the research staff was more diverse. A diverse workforce will allow better care for patients, as they may be able to relate to some of the experiences of patients more and may be able to identify and categorise issues for their racial group quicker. The current workforce should be trained on reducing implicit bias and cultural appropriateness, so that they know how to work with people of different ethnic backgrounds (dperreault, 2023). For a more diverse workforce, there need to be more opportunities for people from different ethnic backgrounds. Dr Hunter emphasised that many Black people do not feel that they can work in clinical research as they do not see many people who look like them in the workforce (interview with Dr Hunter, 2023). This may be off-putting to them and could lead Black individuals to think that a career in scientific research is not attainable. A way of tackling this would be by encouraging Black students who have a passion for science and healthcare, by making them aware of the vast opportunities that they have. Also, offering online courses where the fundamentals of ethics, the protection of patients, and regulatory requirements are taught may also give people from minority backgrounds the confidence to pursue a career in clinical trials.

Current initiatives

There are various initiatives that have arisen to tackle the underrepresentation of ethnic minorities in clinical research and healthcare settings. One of these initiatives is the NIHR-INCLUDE project. The NIHR is a leading funder for clinical trials in the UK and the INCLUDE project that was authorised in 2017 aims to improve the health and care for patients by having more inclusive research (National Institute for Health and Care Research, 2020). Guidance was issued after gathering information through three different strands. The first one being three stakeholder meetings with regulatory bodies, patient groups and practitioners amongst other contributors, where the outcome was that research should be more patient centred and appropriate for the group that is being targeted in the real world. The second was a comprehensive literature review of barriers to inclusion for under-served groups and the third strand was surveys for stakeholders and participants that are involved in the delivery of research. The guidance for researchers and healthcare professionals includes a roadmap that explains means of increasing inclusion, as well as a framework of questions for researchers and funders to consider when designing research proposals. These questions acknowledge the demographics of the population for which the research is being done, as well as inclusion and exclusion criteria for participants of studies that correlate to the population that will be served with the research.

The roadmap *(figure 7)* aims to provide guidance to researchers on how to better serve under-represented groups in clinical trials, such as how to tackle barriers which they may face.

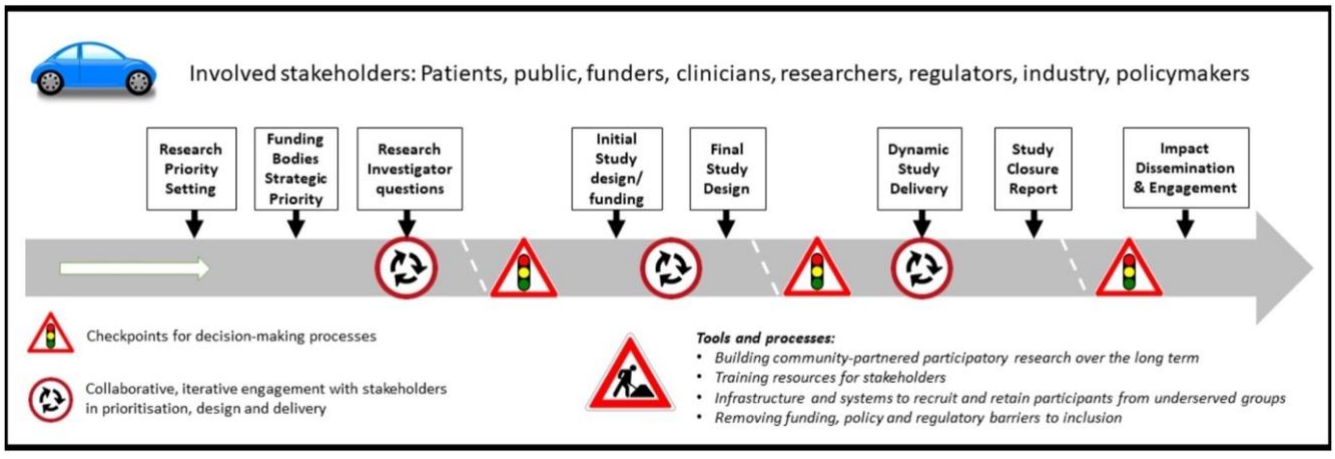

Figure 7. *A roadmap by the National Institute for Health Research to improve trial delivery for under-served groups. The boxes display what points must be acknowledged when designing a study, to ensure that it is inclusive and serves the chosen underrepresented group. Scheme is taken unedited from (Witham et al., 2020).*

Another UK initiative that has been brought about by the company Innovative Trials- a clinical trial patient recruitment company- aims to increase the representation of Black communities in clinical research. The company uses methods such as diversity focussed mapping and they ensure that sites have the ability to recruit people from diverse ethnic backgrounds by asking specific questions and examining the sites' prior work. Innovative trials then collaborates with the sites to recruit enough patients to make it representative of the population of the target disease. The initiative 'The Road to Equality taskforce' increases diversity in UK clinical trials, as has been seen in a Phase III Active Systemic Lupus Erythematosus study that saw a 63% boost in the diversity of patients (PMLive, 2021). This has been created in collaboration with creative health engagement agency COUCH Health, who strive to increase inclusivity in studies.

The NHS has also published a 36-page practice guide for researchers and other healthcare professionals for communicating with underrepresented groups. The guide includes reasonings on some of the causes of low participation and suggestions on how to increase the presence of underrepresented groups in research. A two-step process was used to create the guide. The first one being a literature review of current resources in this field from the UK and the US to gather more background information and to better understand the participants. The second step involved reaching out to six underrepresented groups in research that were reported by the National Institute for Care and Excellence in 2022 and discussing what barriers they face with them. One of these groups were Black African and Black Caribbean people living in South London with dementia and diabetes. Experienced social health researchers took on the roles of "trusted advocates" to carry out this discussion (NHS England, 2023a).

The literature review identifies three main reasons for the underrepresentation in research. These are language barriers, accessibility and mistrust. Language is often an exclusion criterion that causes underserved groups, such as people from African and Caribbean backgrounds to not take part in research, as English may not be their first language or it may not be of the standard required to partake in the research. Overly technical or scientific terminology may be used when communicating with ethnic minorities which not only hinders comprehension, but also increases scepticism in regard to participating in scientific research. No access to translation services is also of disservice to participants with different ethnic backgrounds and another barrier that was pointed out is the culturally inappropriateness of

some explanations that were given by researchers. There is also the issue of some staff not feeling comfortable discussing topics such as race, as they fear the repercussions and may not know how to communicate sensitive data, so they prefer not to discuss it at all. Lastly, to overcome the issue of language barriers, family members or friends may be used to help with translation, but they do not always feel comfortable consenting for the other person.

In the practice guide, the term 'accessibility' refers to the ethnic minorities' ability to join research. Some of the reasons for the lack of accessibility include the cost and time of travelling. Partaking in research may be time consuming, subtracting from the time needed for working or looking after dependents. The demands of the study may also be too much for the participants, such as coming to the facility multiple times a week or study periods that are very long. When travel is involved and this is not reimbursed to participants, this may deter them from partaking in research. Travelling may also not be an option for participants who need a carer to do so or have some physical limitations. Accessibility is also reduced by poor trial promotion. If prospective participants do not know about the study, they cannot take part in it and as seen in the commercial considerations section above, recruitment is often low in areas where disease prevalence is high. As many ethnic minorities live in income-deprived neighbourhoods, this is often not where pharmaceutical companies reach out to doctors to inform them about trials, meaning that this information cannot be relayed to patients. Promotion also includes incentives, which may not exist for specific trials or participants are not made aware of these incentives. Lastly, there is a lack of accessibility and inclusivity when very narrow inclusion criteria are used.

The final reason for underrepresentation in research that was identified in the practice guide is a lack of trust. Some participants do not trust the entire clinical trial process, as they do not understand what is happening at every stage and feel that there is a lack of transparency. Some also voiced concerns of the procedures that will be carried out and what negative effects this may have on them, as well as their thoughts and opinions not being valued by research staff. Other concerns of trust include prior unfavourable encounters with health services and not wanting to come to terms with their disease. Lastly, there may also be religious and cultural barriers that prohibit the participation in scientific research.

This guide has been useful as it is available online for anyone who is interested in research, specifically research staff, which will allow them to better understand the difficulties that are

faced by ethnic minorities and what perceptions they may have towards scientific research. Solutions can then be found to address these, to help with the enrolment of African and Caribbean populations.

The Food and Drug Administration in the United States have published a guidance draft in April 2022, which is provisionally called the “Plan” and will be known as the ‘Race and Ethnicity Diversity Plan’ once it has been implemented. This is to encourage more inclusivity in clinical trials and is a push towards a more representative cohort of participants with adequate Black and African American participants in trials. There are five categories in the plan, which include defined targets for the enrolment of ethnic and racial groups that are underrepresented in clinical trials for the disease that is being researched, as well as a detailed plan on the steps that will be taken to recruit and enrol ethnic minorities. Once published, the guidance will also emphasise how there may be differences in the effect that covariates have on pharmacokinetics and pharmacodynamics in different populations. Therefore, exposure-response analyses may need to be carried out in the patient population of interest to find a suitable dosing regimen. Furthermore, data on the safety and effectiveness of the drug in different races should be collected throughout the entire life cycle of the drug (Russell et al., 2023).

Further steps that must be taken

The aforementioned initiatives aim to help with the recruitment of more Black participants in clinical trials. However, there are still many areas that need to be modified to be able to truly get a statistically significant number of Black people in each clinical trial and to increase the trust those Black people have in the entire clinical trial process.

Engagement

"To truly improve engagement with Black people, networking with lupus and sickle advocacy groups, as well as Black people who actually live with the diseases needs to occur" (interview with Dr Hunter, 2023). To understand the experiences of Black people in scientific research and how negative experiences can be improved, open conversations are vital. This may also reveal if the research topic of interest is relevant to the Black community (NHS England, 2023a). Some disregarded factors that fuel the low clinical trial enrolment in African and Caribbean populations may also be identified. One way of tackling this is by going to the communities where disease prevalence is high and enrolment is low and talking to valued members of that community (PMLive, 2021). This has been seen to be beneficial at the University of California, San Francisco where research staff actively engage with Hispanic communities to build trust and relationships (dperreault, 2023). This should also be done with African and Caribbean communities in the UK and preferably around the world. Building strong relationships can be done in person, through leaflets and posters that are distributed at GP surgeries or online through forums such as Facebook groups. The steps that will be taken to ensure that proper engagement occurs should be outlined in the research proposals and protocol of the study (NHS England, 2023a). It may also be useful to have Black researchers or other Black staff speaking to communities, as patients may identify with them more and therefore feel more comfortable talking about preconceived conceptions about clinical trials or other issues. Furthermore, it is vital that the feedback and new knowledge that is gained from these discussions is taken on board and acted on.

Neglected diseases

Many diseases that are prevalent in African and Caribbean people are neglected in scientific research to this day. Malaria, which is a life-threatening infection that is spread by mosquitoes, is most common in the South of Africa (Prevention, 2020). 10% of people who

are infected with HIV also preside in the South of Africa (Wikipedia, 2023b). It is not until these diseases spread to the West until much attention is paid to them, as was seen with the Ebola epidemic when it spread to the US and the UK between the years 2014 to 2016 (www.cdc.gov, 2020). Active recruitment for clinical trials in these diseases should occur, so that new and improved treatments can be offered at lower costs, with the aim of increasing treatment accessibility to populations in the poorer parts of the world. This may require more funding for research and recruitment, which could be provided by the government or charities that are devoted to increasing inclusivity in scientific research.

Promote transparency and unified reporting

The scientific community, as well as pharmaceutical companies need to be much more transparent about the research they are conducting. This includes releasing the research brief and organisations they are working with to prospective participants, as this is of interest to many of them (NHS England, 2023a). This will allow participants to feel informed on the entire clinical trial process and what awaits them if they decide to participate. Publishing regular reports and what is being done to increase diversity in research on public platforms also promotes transparency and should be conducted by all pharmaceutical companies.

It is also important to be transparent and acknowledge the history of the abuse of Black people in clinical trials, such as the Tuskegee syphilis trial. In today's society, many people fear talking about race and ethnicity, as this is a sensitive topic for some. However, ignoring it is the real injustice. Dr Hunter recalled her experience working at one of the largest pharmaceutical companies globally, where she wanted to speak about the history of Black people at a panel meeting. This was not permitted by the company, as they believed this may be too controversial (interview with Dr Hunter, 2023). It is crucial that pharmaceutical companies do discuss such topics and remove the negative connotations that are associated with talking about race and ethnicity.

To increase transparency, data on the ethnicity of patients should be gathered at every stage of the clinical trial process and this information should be made available once the trial has been completed. For accurate collection of data that can be shared and compared amongst trials, there must be uniformity in the classification of ethnic groups globally. There should also be an effort to not place all ethnic minorities in one group, but to place them in their own

individual groups, so that data can be collected accordingly. For this to occur, guidance may need to be provided to investigators and sponsors (Hussain-Gambles, Atkin and Leese, 2004). Once this has been established, a mandatory number of Black participants enrolled in clinical trials should be enforced by ethics committees and regulatory bodies as one of their requirements to carry out a study (www.mantellassociates.com, 2022).

Decentralised trials

Clinical trials are becoming much more decentralised, meaning that some procedures are no longer taking place at the conventional clinical trial site, but rather at laboratories that are nearby or even at patients' homes (Research, 2023). This can be utilised for the recruitment of Black participants, as "*many Black people do not have the time to leave their children and take out hours of their day to travel to clinical trial facilities"* (interview with Dr Hunter, 2023). Therefore, site staff could travel to the patients and be more accommodating to the schedules of the participants, which would be an enticing incentive for many participants who would otherwise struggle to partake in trials.

Furthermore, there needs to be more involvement of Black participants in the early stages of clinical trials, such as the clinical trial design. This allows studies to be patient-centric, as participants can voice their thoughts and opinions on the proposed plans for the study. As a result, the trial is more appealing to the participants and their overall retention time is increased, ultimately optimising trial outcomes (www.medicalnewstoday.com, 2021).

Digital recruitment and the use of AI

"Clinical trials are not in mainstream media. We often only hear about them when something has gone wrong" (interview with Dr Hunter, 2023). This paints the image of clinical trials in a negative light for lay people, in turn dissuading their enrolment. To combat this, successful news about clinical trials need to be shared on various online platforms. This is a form of digital recruitment and as social media is becoming more present in the life of many people, this information may be directly read by prospective participants or information can be passed on by word of mouth (NHS England, 2023a). Additionally, artificial intelligence (AI), can also play a role in increasing the accessibility of information on clinical trials through its role in the translation of study documents. The translation of protocols, informed consent

forms and patient leaflets can be very costly, but with the rise AI, this can be done with online AI systems. This saves money for the companies and it allows participants to read documents in their native language and therefore understand the research better.

Conclusions & Future Work

The main causes for the underrepresentation of African and Caribbean populations in UK clinical trials were established throughout the paper. The reasons that were identified through a comprehensive literature review and a discussion with Dr Hunter are: a mistrust towards scientific research that evolved through the historic mistreatment of Black people, inadequate efforts for the recruitment of Black participants that is mandated by pharmaceutical companies, and a lack in the representation of African and Caribbean employees in research staff.

The key research findings are that the number of Black people enrolled in clinical trials are so low that they are often not statistically significant and not representative of their disease population, meaning that it is difficult to draw accurate conclusions. There have been various instances, such as recent studies in COVID-19 vaccines where researchers had the opportunity to show progress in the scientific and medical community by enrolling more Black patients, but they failed to do this. My work also highlighted the monetary gains that are associated with the recruitment of a more diverse patient population in clinical trials and the pharmaceutical industry's responsibility to do better by the patients they are serving.

Future work that can be conducted are pharmacoepidemiologic studies for new and existing treatments. Specifically, these should be carried out in Black populations to determine differences in therapeutic responses. Furthermore, universal policies could be enforced which lay out a required percentage of Black people that must be enrolled in clinical trials to allow the start of a study.

This research emphasised that the next step that must be taken, is to increase the representation of Black people in healthcare and clinical trial staff. As well as this, there must be an active push to engage with Black communities so that in the next 5-10 years there will be a 10% representation of African and Caribbean populations in every study population in the UK.

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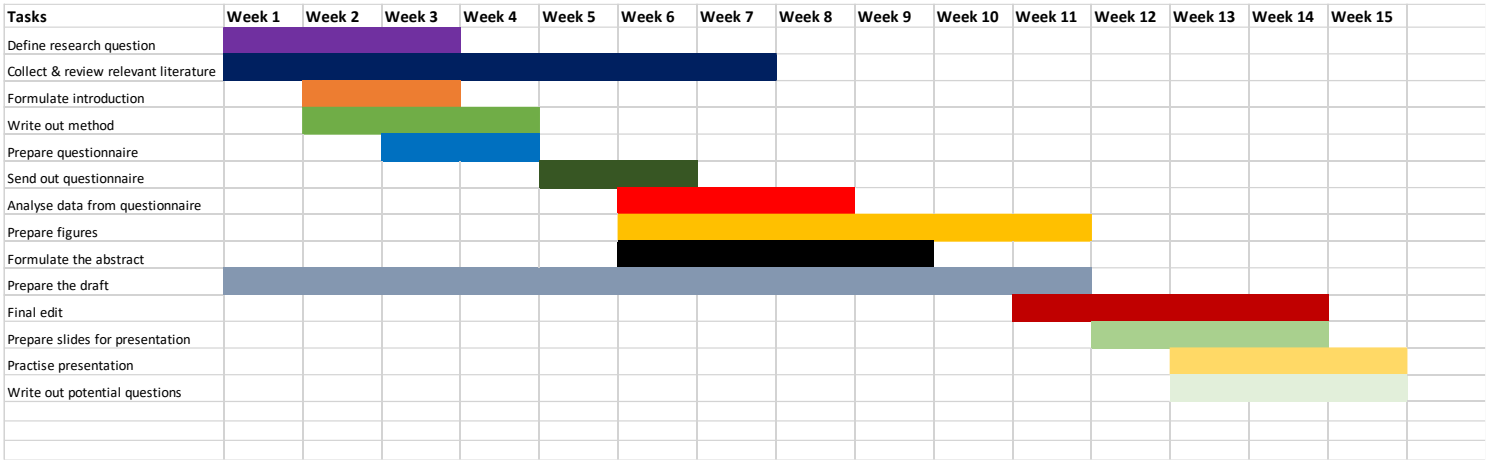
Appendix

1. Gantt chart



2. Use of AI

I did not use AI in any other sections than the requirement for its use in the making of the abstract. This includes the use of AI for getting ideas, improving language, writing text or any other way AI may be used.

3. Use of AI for the abstract

a) Initial version of the abstract

Introduction Clinical trials have been used for thousands of years to weigh up the risk-benefit ratio of new medical treatments for human subjects. In the UK, there is an underrepresentation of African and Caribbean people in clinical research participants. This paper investigates the causes for the low enrolment of Black people in clinical trials and addresses the solutions that must be offered to combat this issue.

Methods An extensive literature review of UK and US based studies and an interview with an expert on racial diversity in scientific research were conducted. These determined the causes and outcomes of a lack of diversity in clinical trials.

Results The analysis unveiled a discrepancy in the statistical significance of White and Black people represented in clinical trials. In addition, a correlation between a shortage of Black staff in clinical research and Black participants in trials was identified.

Discussion This paper concludes that pharmaceutical companies do not see the enrolment of more black participants as commercially viable, which causes the study sample of African and Caribbean people in UK clinical trials to not be representative of their population. Furthermore, there must be more attempts to better the relationship and trust between the Black community in the UK and the scientific community to get a heterogenous study population. Suggestions for future studies to fully understand physiological differences in racial groups are also provided.

b) Prompts entered to the AI chat bot

"Give me feedback on how to improve my abstract and how to better my language?" (OpenAI, 2023)

c) Version of the abstract produced by AI

Introduction: Clinical trials have long served as a crucial tool for assessing the risk-benefit balance of new medical treatments for human subjects. Nonetheless, a notable deficiency exists in the representation of African and Caribbean individuals in clinical research within the UK. This study investigates the factors contributing to the low enrolment of Black participants in clinical trials and explores potential solutions to rectify this disparity.

Methods: Employing an extensive review of literature encompassing UK and US-based studies, along with insights gathered from an expert interview focusing on racial diversity in scientific research, this study elucidates the root causes and consequences of the underrepresentation of diversity in clinical trials.

Results: The analysis reveals a stark statistical incongruity between the representation of White and Black individuals in clinical trials. Additionally, a noticeable correlation emerges between the scarcity of Black personnel in clinical research and the limited presence of Black participants in these trials.

Discussion: This paper posits that pharmaceutical enterprises might not perceive the increased enrollment of Black participants as economically viable. Consequently, the composition of study samples in UK clinical trials inadequately mirrors the demography of the African and Caribbean population. Mitigating this issue necessitates concerted efforts to cultivate a more trusting relationship between the Black community in the UK and the scientific realm, fostering a heterogeneous participant pool. Furthermore, this study underscores the urgency of delving into physiological distinctions among racial groups, thus offering suggestions for future research directions.

Conclusion: The underrepresentation of African and Caribbean individuals in clinical trials within the UK demands attention and rectification. By addressing the underlying causes and advocating for increased inclusivity, we can ensure more accurate and applicable medical insights for diverse populations. (OpenAI, 2023)

d) Version of the abstract adapted and improved by the student.

Introduction: Clinical trials are a well-established procedure for weighing up the risk-benefit ratio of new medical treatments for human subjects. Nonetheless, there is a notable underrepresentation of African and Caribbean people in clinical research in the UK. This paper investigates the factors contributing to the low enrolment of Black participants in clinical trials and addresses potential solutions to rectify this inequality.

Methods: An extensive literature review was conducted, encompassing both UK- and US-based studies and data. Additionally, an interview was carried out with an expert on racial diversity in scientific research. Both approaches offered insights into the underlying causes and consequences of the deficiency of diversity in clinical trials.

Results: The analysis unveiled a stark statistical incongruity between the representation of White and Black individuals in clinical trials. In addition, an apparent correlation between a shortage of Black personnel in clinical research and insufficient Black participants in trials was identified.

Discussion: This paper concludes that pharmaceutical companies might not perceive the increased enrolment of Black participants as commercially viable. Therefore, study populations in the UK do not adequately mirror the demography of the African and Caribbean population. To mitigate this issue, there must be concerted efforts to improve the relationship and trust between the Black community in the UK and the scientific community. This will foster a more heterogeneous participant pool and it will allow accurate and applicable medical insights for diverse populations. Suggestions for future studies to understand physiological distinctions amongst racial groups are also provided.