Report to B'Me and University College London

Participation in Clinical Trials and Early Phase Trials

Views of Black and Minority Ethnic Communities

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Dedicated to the memory of Dr Rose Thompson

Acknowledgements

The author of this report would like to thank the participants who contributed their valuable time to this project. The information provided has been fundamental in its preparation and production, and to the shaping the recommendations. The information will be used to inform the development of resources and materials for the next phase, centred on engaging Black African and Black Caribbean communities in discussions about clinical trials and early phase trials, and barriers to them.

As always, the voluntary sector plays a crucial role supporting a range of projects that seek to engage communities. They share contacts, time, and meet external requests to bring groups of people together, in addition to delivering their core services.

Finally, the author would like to thank the health care professionals at University College London and B'Me who commissioned this report and actively supported it.

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Executive Summary

Background and context to the inquiry

University College London and B'Me commissioned Dr Sophia Skyers of CIBS IQ Research to undertake an inquiry into the participation of Black African and Black Caribbean people in clinical trials and early phase trials. The inquiry was carried out between January and December 2023 and its methodology was structured around an online survey and five focus groups, three in the East Midlands (Nottingham and Leicester), and one in the East region (Ipswich). To maximise the participation of younger people, two focus groups took place online, drawing nationally but predominantly from the East Midlands. The areas were chosen for their urban and rural locations. A total of 51 participants took part in the focus groups and there were 211 responses to the survey. The aims of the inquiry were to:

a) Conduct a rapid appraisal of the existing evidence on clinical trial participation in Black and Minority Ethnic communities.

b) Examine the views of Black African and Black Caribbean people on clinical trial participation.

c) Explore interpretations and meanings attached to the term clinical trial among Black Africans and Black Caribbeans.

d) Make recommendations on practical initiatives that are relevant to increasing participation and identifying barriers to participation in clinical trials.

Health Inequalities and the use of ethnic categories in research

There are major concerns about health inequalities in the distribution of disease and this is being heavily researched. The concerns centre on the social, economic, and biological determinants of disease, and inequities in access to services and support. A focus on health inequality, and strategies to address it, gained traction following the outbreak of COVID-19, a pandemic that is without precedent in living memory. While diseases affect almost everyone in the population at some stage during the life course, there are disparities in the incidence and prevalence of certain diseases among people from Black and Minority Ethnic groups, compared with the population generally. As an illustration, these include multiple myeloma, a cancer of the blood plasma, and prostate cancer, where, in the case of both diseases, the risk for people of Black African and Black Caribbean descent is double that of the population generally (see for examples, reports by the Basil Skyers Myeloma Foundation, B'Me, and Prostate Cancer UK).

Ethnic categories are employed in medical research as well as in social policy areas across a range of institutional sites such as housing, employment, and so forth. It needs to be made clear however, that they are artificially constructed, imprecise concepts, not biological ones. They are also dynamic, changing over time, and how they are conceived and applied differs between countries, and across continents. In fact, using the UK as an example, the dynamism in the deployment of

ethnic categories on official indices has included some seismic shifts within the last 40 years on who is included in which category and who is not.

The use of ethnic categories is nontheless useful in understanding health disparities and health inequalities, and our understanding of recruitment patterns to clinical trials. These patterns of inequality are however based on shared social attributes as well as individual and collective experiences that may have biological consequences. Thus, understanding patterns of inequality is critical to the framing, understanding, and contextualizing risk and health disparities. It is also important to be clear that while some people in continental groups have particular polymorphisms, these frequencies do not correspond, map onto, or align with socially constructed policy determined race or ethnic categories. The 100,000 Genomes Project mapped the entire human genetic code and demonstrated humans share 99.9% of their DNA, and that the 0.1% remaining, is not attributed to race. There is actually more variation within groups that share similar physical attributes than is the case across groups.[1]

What is a clinical trial?

Clinical trials enrol individuals as volunteers and provide vital evidence in evaluating the safety and efficacy of novel therapies to secure improvements in future patient care and outcomes. While ingesting pills or taking injections is the type of trial in the popular imagination, a clinical trial is in fact much wider than this and includes the testing of medical devices or medical procedures. Clinical trials thus fall into two categories, both of which are governed by the Medicines and Healthcare Products Regulatory Agency (MHRA) and come within the NHS Research and Governance Framework. They are known as Clinical Trial of Investigational Medicinal Product, and Non-Clinical Trial of Investigational Medicinal Product, or CTIMP and Non-CTIMP trials.

The early phase 1 and phase 2 trials look at safety and mainly tend to be run by pharmaceutical companies developing a specific medication. The majority of phase 3 trials are non-industry sponsored and are for drugs that have already been licensed. There is a phase 4 trial period known as 'post market surveillance' and is of no fixed duration once a drug is available on the market to monitor side effects and benefits over a long time. The risk of teratogenicity with the drug Thalidomide, which is routinely used today in the treatment of the blood plasma cancer multiple myeloma, only became apparent in the 1950s after the drug was actually on the market and was being used treat pregnancy associated emesis.

[1] A public dialogue on genomic medicine: time for a new social contract, Ipsos MORI, Genomics England, Sciencewise, UK Research and Innovation, 2019
Dr Sophia Skyers, 100,000 Genomes Project: Black African and Black Caribbean Communities: A Qualitative Exploration, Genomics England, BMe Cancer Communities, 2018

Findings on Cancer Trials and Early Phase Trials

The following is a summary of the results of the survey with the public, focus groups with the public, and interviews with healthcare professionals. This focus included early phase cancer trials. The results are set out under the theme headings arising from the inquiry:

Views of the public

a) Views on what a clinical trial is: The inquiry found that participation in a clinical trial is seen as voluntary, and is seen as a scientific or medical experiment involving treatment or the ingestion of an active agent. A clinical trial is also seen as being underscored by risk, and one where the outcome is unknown, and potentially could involve death.

b) Views on taking part in a clinical trial: The inquiry uncovered a reluctance to taking part in clinical trials due to the perceived risk of side effects. The reluctance also centers on concerns about documented scientific and medical historical abuses of the black body.

c) Notional of control groups in clinical trials: The inquiry found that the idea of a control group is understood in very general terms. However, the notion of randomisation is seen as something of a concern whereby patients may, by chance, be put into a group where they receive no active treatment. This shapes decisions about participation as it is seen as a risk in clinical trials.

d) Concerns about clinical trials: The inquiry found that, while articulating a reluctance to taking part in clinical trials due to a lack of trust, they are still seen as important. The scientific community is also seen as not really wanting to engage with the Black community, and as making little effort to engage. This is compounded by clinicians and scientists not being visible in clinical and scientific research settings.

e) Clinical trials and engaging with the NHS: The inquiry found that interaction with the NHS and the overall patient experience is seen as important in the context of raising awareness about clinical trials. Where patient engagement is poor, this has an effect beyond the specific service. It is also compounded by the invisibility of Black people at higher levels in medical settings, as well as in the general medical and research literature.

f) Locating information about clinical trials: The inquiry found there is a lack of knowledge about where to go to get information about clinical trials, and a view that information is sometimes deliberately withheld. However, some people who took part in the inquiry did have prior knowledge, either through their work in the NHS, or through their participation in previous clinical trials. There is an interest in more information about clinical trials being placed in local in local libraries, via social media platforms, through videos and audio podcasts, and through What's App groups. The church is seen as having a key role to play through its leaders and the many opportunities it can offer for engagement. The survey data overwhelmingly pointed to email as being the best medium for communicating information to the public about clinical trials.

Views of healthcare professionals

g) Ideas of race and ethnicity in clinical trials and biological research: The healthcare professionals stated that it is important to have 'real world data' in oncology, and that representation and inclusion is important for ethical reasons. There was correspondence with the views of healthcare professionals and the survey and focus group participants.

h) Underrepresentation in clinical trials: In reference to early and late phase clinical trials, the reasons are seen as multifactorial. They include the following: not being approached by consultants; there being no incentive to diversify trials where participation is already high; a lack of awareness that their underrepresentation is an issue among those running trials due to the social location principal investigators; patients not being part of active networks, as well as language and cultural barriers. The there was correspondence between the survey respondents, focus group participants, and healthcare professionals.

i) Access to information: Patient information is lengthy and too detailed, making the content impossible to absorb. This is particularly so at a time when patients are dealing with the impact of their diagnosis. Moreover, the approach to making patient information accessible is always reactive and not proactive. The inquiry also found issues around clarity of information and lack of access, and the lack of participation as being due to unwillingness, and the lasting effect of historical abuse.

j) Making patient information accessible: No one size fits all. As well as written information, the inquiry found that there is a need for information in visual or audio format, and for information to be available for those more proficient in a language other than English. Addressing barriers to accessibility will raise barriers for everyone, for example, written information can act as a barrier to those who are sight impaired and availability in other formats addresses this. There was correspondence between the views of healthcare professionals and qualitative data. The survey data overwhelmingly regarded email as the most important way of informing the public.

Conclusions and recommendations

This inquiry examined the reasons for the underrepresentation of Black African and Black Caribbean people in clinical trials using a mixture of focus groups, and a survey with the public, and interviews with healthcare professionals. There was correspondence between the views of focus group participants, survey respondents, and healthcare professionals on the multifactorial issues relating to clinical trials and participation. These centred on reluctance due to fears arising from past historical abuses, a lack of trust in the scientific fraternity, being keen to participate but not being asked to do so, complicated patient information, a lack of clarity around what the clinical trial is, and a lack of time due to the rhythms of family life. While the study did not explore this specifically, these multifactorial issues may also be the case for other segments of the population generally.

There is a need for a greater understanding of race as a social construct, not a biological category, and how it is important in understanding inequalities in health and health outcomes. These inequalities are based on shared social attributes and experiences and shared connection by

geographic ancestry, not race. There seems to be a view that Black bodies are somehow different, and this needs to be addressed given that the 100,000 Genomes project has shown that we share 99.9% of our genetics, that there is more diversity within groups defined using the social construct of race than across them, and that we share a common humanity.

a) An interactive event should be organised engaging voluntary and community sector patient organisations clinicians, principal investigators, data managers, medical historians, and academics. This should mark the start of a continuing dialogue to inform the development of resources.

b) The concept of cancer care should be explained clearly to patients, given that many cancers have high survival rates and are curable.

c) Work with Black and Minority Ethnic groups to develop materials/information to clearly explain early phase trials, why they are needed, how patients might benefit, and to provide assurance that such patients are very carefully looked after.

d) Select some prime examples of early phase trials, what they showed and how they later became standard of care and changed clinical practice.

e) Use clear and easy-to-read language that simplifies the scientific aspects of these trials given that patient information sheets are complex and off-putting.

f) Drawing on current research findings and data from the 100,000 Genomes Project, clear and concise information in a range of accessible formats should be put together on the historical evolution of race and ethnicity as a social construct, and why it is important in adding to our understanding of health disparities, health inequalities, and recruitment patterns to clinical trials.

g) There is a need to think about the long-term relevance of the socially constructed categories being used in clinical trial recruitment, and how they will change as the population changes, particularly given that, since 2002, the fastest growing ethnic category, is the Mixed group.

h) A constructive dialogue is needed, alongside an acknowledgement of historical abuses that have taken place. There is an existing and emerging literature that provides documented evidence of a factually based mistrust.

i) Resources should be developed to explain the various kinds of clinical trial, using concrete examples, and a clear explanation of what the various clinical trial phases mean. This should include an explanation of the difference between CTIMP and non-CTIMP trials.

j) The resources should clearly explain the concept of randomisation, and what this means in terms of access to new therapies, patient safety, and clinical trial recruitment. It should also be explained that being randomised does not mean patients are given no treatment.

k) Short videos should be produced and disseminated via social media, taking account of diverse communication styles, and health forums developed where information on clinical trials and clinical research can be disseminated, and questions answered.

l) This report should be disseminated to organisations with key influence such as National Institute for Health and Care Excellence (NICE), the ICR (Institute for Cancer Research), the Wellcome Trust, NHS Trusts, and other public health and voluntary sector agencies.

m) All of the participants that took part in the inquiry should be given a copy of this report, and feedback given on how their contributions have helped to shape it, its recommendations, and how it will help to shape clinical trials agenda going forward.

n) More engagement is needed with the African community to find out their views as this population, though having a younger age profile than the African Caribbean population, is ageing.

1. The background and context to the inquiry

1.1 This report is an account of the views of Black African and Black Caribbean communities on participation in trials and early phase trials which is an emerging area of exploration in the UK. In January 2023, Cancer Research UK & UCL Cancer Trials Centre, Cancer Institute, and B'Me commissioned this inquiry into views on clinical trials among Black African and Black Caribbean people.

1.2 The inquiry commenced in January 2023 and concluded in December 2023. It was centred on a series of focus groups and an online survey, as part an ongoing national programme of patient engagement. The aims of the inquiry were to:

a) Conduct a rapid appraisal of the existing evidence on clinical trial participation in Black and Minority Ethnic communities.

b) Examine the views of Black African and Black Caribbean people on clinical trial participation.

c) Explore interpretations and meanings attached to the term clinical trial among Black Africans and Black Caribbeans.

d) Make recommendations on practical initiatives that are relevant to increasing participation and identifying barriers to participation in clinical trials.

1.3 The geographical areas for inquiry were structured around locations based on the residential patterns of the Black population. The inquiry areas selected favoured those less well represented in inquiries of this nature, and because they were in the former industrial regions comprising an urban and rural makeup. The areas were, Nottingham and Leicester in the East Midlands, and Ipswich in the East. To maximise the participation of young people, and to include those for whom travel might have posed a problem, two online focus groups were held with participants drawn from a range of areas but principally, those who took part were from the East Midlands where B'Me operates. The focus groups drew from a broad age range and a wide range of occupations, and the convenience sample included a total of 51 participants. The below table sets out some of the key demographics for the chosen areas.

1.4 A national survey was also undertaken and there were 211 respondents drawn from and including but not limited to the following areas, the North East (East Lincolnshire) South Yorkshire (Sheffield), North West (Manchester, Salford, Merseyside), West Yorkshire (Leeds), East Midlands (Derby, Nottingham, Leicester, Northampton) East of England (Luton, Essex, Hertfordshire), the West Midlands (Royal Leamington Spa),the South East England (Milton Keynes, Surrey, Ipswich, West Sussex, Berkshire), South West (Wiltshire, Bristol) London (Croydon, Lambeth), and Wales.

Key Demographics of the Inquiry Areas	
Nottingham 1 Focus Group	**Population Data**
Population	The population of Nottinghamshire is estimated to be in the region of 832,000 and the City of Nottingham 323,632.
Black and Minority Ethnic groups	42.7% of the population is from a Black and Minority Ethnic group. This is an increase from 34.6% in 2011. The Asian groups comprises Pakistani 6.7%, Indian, 3.6%, Bangladeshi 0.7% and Chinese 1.3%. The Black group comprises African 5.8%, Caribbean 2.9%, and other Black, 1.3%. The largest population group is the White group at 57.3% and the second highest group being White Other, 7.4%.
People in 65+ range	38,000 people, an Increase of 6.9% since 2011 Census
Languages	Languages other than English spoken include Polish, Urdu, Arabic Punjabi, and Polish.
Leicester 1 Focus Group	**Population Data**
Population	The population of Leicester is estimated to be in the region of 1,053,486 and the City of Leicester 566,000.
Black and Minority Ethnic groups	57% of the population is from a Black and Minority Ethnic group, with the largest being the Asian population of 43%. Leicester has a very young population with the median age 33.9. The White group comprises 41% of the population.
People in 65+ range	Leicester has a relatively young population and people 65`~+ represent 12% of the population.
Languages	Leicester has around 90 languages, making it one of the most linguistically diverse and after Gujarati, English is the most commonly spoken language in the City. Other languages include Panjabi, Polish, Urdu, Arabic, Chinese, and Bengali.
Ipswich 1 Focus Group	**Population Data**
Population	133,384
Black and Minority Ethnic groups	17,1% of the population of Ipswich is Black and Minority Ethnic.
White groups	90.5% of the population of Ipswich is White, 3.9% South Asian, and 2.1% Black.
People in 65+ range	In Ipswich, 23.8% of the population is estimated to be in the 65+ age range.
Languages	Portuguese, Romanian, Polish, Bengali, Kurdish, Lithuanian, Arabic.
Online Focus Groups x 2	Participants drawn from Nottingham, Bristol, London, and Reading

2. Health inequalities

2.1 **The distribution of disease and cancers:** Concerns about health inequalities in the distribution of disease, its social, economic, and biological determinants, and inequities in access to

services and support, are fields that are being heavily researched. The focus on health inequality, strategies to address it, and research to support stratified medicine, gained impetus following the outbreak of COVDI-19, a pandemic that is without precedent in living memory. While diseases affect almost everyone in the population at some stage during the life course, there are disparities in the incidence and prevalence of certain diseases among people from Black and Minority Ethnic groups. These include, for example multiple myeloma, a cancer of the blood plasma, and prostate cancer, where in the case of both diseases, the risk for people of Black African and Black Caribbean descent is double that of the population generally. If we look in more granular detail at prostate cancer, the second most common cancer in men, we get a more vivid illustration of inequalities. While nationally, 1 in 8 men in the general population will be diagnosed with prostate cancer at some stage, for Black men of African and African Caribbean descent, it is 1 in 4, the highest risk of any ethnic group. The median onset age is also on average five years younger, and the mortality rate is 30% higher in Black men compared with the mortality rate for White men.[2]

2.2 A further fine-grained illustration of health inequalities can be seen in the incidence of T-cell malignancy, one of a group of aggressive non-Hodgkin lymphomas which is higher in the Black population, particularly Black women. It can also be seen in Hodgkin lymphoma and mature B-cell malignancies in the South Asian population. There is a disproportionately higher incidence among men in the South Asian group as a whole, and within that group, a significantly higher proportion among Pakistanis compared with Bangladeshis.[3] A recent study found that Black people were more likely to be diagnosed with stomach and liver cancers, people of south Asian descent more likely to be diagnosed with liver cancer, and people of South Asian and African and African Caribbean decent, more likely to be diagnosed with gall bladder cancer.[4] It should be noted however that cancer incidence is lower overall in the Black and Minority Ethnic population. This explanation may be partly due to its younger age structure, although the profile will change as the Black and Minority Ethnic population increases, and as it ages, as cancer is largely a disease of ageing.[5]

2.3 **Social constructions of ethnicity in health research and tackling health inequalities:** While ethnic categories are employed in medical research and social policy areas, it needs to be made clear that they are artificially constructed, imprecise concepts, centred around a hierarchical set of beliefs. They are also dynamic, changing over time, and are geographically contingent. The dynamism in the deployment of ethnic categories has included some seismic shifts in who is included in which category. As an example, in the UK Census, the Black category included South Asian people at one time, but those categories have now been disaggregated. The UK Census now defines ethnicity by colour in Black people, and with reference to an entire continent in the case of South Asian people. The Chinese group is defined by reference to ethnicity and included in the overall Chinese category is the culturally distinct Vietnamese group. Added to variations and changes in definition are also

[2] See Prostate Cancer UK http://prostatecanceruk.org/prostate-information/what-is-my-risk/a-Black-mans-risk
Mortality from Prostate Cancer, National Cancer Intelligence Network, 2012.
'Hear Me Now', BME Cancer Communities, 2013.
'Hear Me Now One Year On', BME Cancer Communities, 2014.

[4] Christine Delon, Katrina F. Brown, and Jon Shelton, et al, Difference in cancer incidence by broad ethnic group in England, 2013 – 2017, British Journal of Cancer, 126, 1765-1773, 02 March, 2022.
[5] Listen Up! Multiple Myeloma in Black Communities: An Unequal Risk Burden, The Basil Skyers Myeloma Foundation, 2017.

variations by country.[6] In the US, the Census has an Asian category, as is the case in the UK but in the US, the South Asian and Chinese population are included under that category as a single group. It also needs to be understood that science is not neutral given that scientists and clinicians are part of society and absorb prevailing ideas, as do we all. They are shaped by time and place and are informed by prevailing ways of thinking about the world, and our place in it.

2.4 As assigned arbitrary and fluid categories, it is also the case that how individuals choose to identify, or whether they choose to do so changes with time as notions of identity and the expression of it change.[7] There is an added layer of complexity in practically applying broad ethnic constructs given that the 200,000-year history of humans has been one of constant migration and the coming together of people spanning numerous geographical continents. In this scenario, infinitesimal diversity cannot be reduced to a few ascribed groupings that are assigned an official imprimatur.[8] Importantly, a social construction of ethnicity has important implications for the way it potentially shapes and informs clinical trials and medical practice. It brings with it, methodological constraints on data collection; comparisons between and within groups; comparisons between continents, and critically, how patients themselves identify or not. The key point it is important to reiterate here is that ethnic classifications do not denote inviolate biological or naturally occurring categories within the genetic script of individuals or groups sharing physical and or social attributes. As socially constructed, imprecise concepts, they have a long, variegated, and contested history.[9] This needs to be understood by clinicians and those engaged in clinical research so that categories are not adopted uncritically.[10]

2.5 **The relevance of ancestry:** While race and ethnicity are not biological categories, the terms are nevertheless valuable in medical research as broad social constructs. They add to our understanding of patterns of health disparities and health inequalities, and our understanding of recruitment patterns to clinical trials. These patterns of inequality are however based on shared social attributes as well as individual and collective experiences that may have biological consequences. Thus, understanding patterns of inequality is critical to the framing, understanding, and contextualizing of risk and health disparities. It is also important to be clear that while some people in continental groups have particular polymorphisms, these frequencies do not correspond,

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[6] To illustrate these points further, the UK Population Census has a number of ethnic categories. This includes the White group and the Black group, both of which are defined principally by colour. The South Asian group by contrast is defined not by colour, but by reference to an entire continent. The Chinese group is defined by reference to an ethnicity and included in the overall Chinese category is the culturally distinct Vietnamese group. This is a radical departure from the 1991 UK Population Census, which as illustrated by the Office of National Statistics, A Guide to Comparing 1991 and 2001 Census Ethnic Group Data, which had different categories of ethnicity in the two periods, and different questions were asked in England, Scotland, Wales, and Northern Ireland during this same period. In terms of other variations by country, in the UK, the Asian and Chinese groups are distinct Census categories whereas in the US, the Asian Census category includes the South Asian and Chinese population in one group.

[7] See for example JRF and Manchester University, Dynamics of Diversity: Evidence from the 2011 Census, ESRC Centre on Dynamics of Ethnicity, March 2014 which, through anonymous records linking responses to 2001 and 2011 Census, was able to track how individuals express their ethnic identity across time, with significant proportions choosing a different ethnic group in 2011 to the one they selected in 2001.

[8] Annabel Sowemimo, Divided: Racism, Medicine and Why We Need to Decolonise Healthcare, Profile Books, 2023.
David Reich, Who we are and how we got here: New science of the human past, Oxford University Press, 2018.

[9] Angela Saini, Superior: The Return of Race Science, 4TH ESTATE, 2019.
Annabel Sowemimo, Divided: Racism, Medicine and Why We Need to Decolonise Healthcare, Profile Books, 2023.

[10] A patient from Jamaica for example, who has Indian or Chinese ancestry, will share an identity as an African Caribbean, or Black Caribbean. Therefore, group based notions or probabilities should not be employed in making judgments about individual patients on the basis of group membership because individuals do not confirm to group assumptions.

map onto, or align with socially constructed policy determined race or ethnic categories.[11] The 100,000 Genomes Project mapped the entire human genetic code and demonstrated humans share 99.9% of their DNA, and that the 0.1% remaining, could not be attributed to race. Moreover, there is more variation within groups that share similar physical attributes than is the case across groups. The same conclusion was reached by studies in previous decades, using a variety of genetic and molecular methods.[12]

2.6 It is continental ancestry that has relevance and nowhere is this seen with greater clarity than, for example, in the Human Leukocyte Antigen (HLA) typing that is used to match stem cell donors to patients. HLA is a protein or marker found in most of the cells in the human body. The immune system uses HLA markers to determine which cells belong in a particular body and which do not. HLA matching is important in allogenic bone marrow transplantation to prevent graft rejection and other serious complications. Ancestry is pivotal to this because according to clinicians and the African Caribbean Leukaemia Project (ACLT), patients are more likely to find a match among potential donors from their own ancestral group. For this reason, Black and Minority Ethnic patients in the UK for example, face more obstacles in finding suitable donors. This is because of their smaller numbers in the donor pool, and because they are under-represented on the donor registry. Moreover, patients who are of dual heritage, for example, African and European or other ancestry, have a rarer HLA variation and therefore have an even smaller chance of finding a suitable stem cell donor.

2.7 As researchers begin to formulate views about the complex relationship between our genetic endowment and what happens to us during the life course through understanding more about the interaction of complex biosocial variables: genetics and genetic inheritance; epigenetic and epigenetic inheritance; environmental signals; the contours of response, response variation and so forth, a different set of questions arise that correlate with the social categories of ethnicity, as well as other groupings such as social class. These have implications for the collection of epidemiological data, and the future of stratified medicine.[13] This is important given the underrepresentation of Black and Minority Ethnic communities in for example, NHS Clinical Genetics Services, and their underrepresentation in clinical trials, including representation in disease areas such as multiple myeloma, and prostate cancer, where, as already stated, Black people have a disproportionate incidence of diagnosis, and a higher mortality rate.

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[11] Karama C. Neal, Use and Misuse of 'Race" in Biomedical Research, Online Journal of Health Ethics, 5(1) http://dx.doi.org/10.187585/ojhe.0501.08.
Catherine Lee, "Race" and "ethnicity" in biomedical research: How do scientists construct and explain differences in health? Social Science and Medicine, 68 (2009) 1183 – 1190.
[12] Foster MW, Sharp RR. Race, ethnicity, and genomics: social classifications as proxies of biological heterogeneity. Genome Rs 2002; 12:844-850.
Anglea Saini, The return of race science, 4th Estate, 2019.
Lewontin R C. Evol Biol. 1972; 6:381–398.
[13] Epstein, Steven, Op. Cit. 6.
Marmot, Michael, The Health Gap: The Challenge of an Unequal World, Bloomsbury, 2015
K Dimopoulos, P Gimsing and K Grønbæk, The role of epigenetics in the biology of multiple myeloma, Blood Cancer Journal, 2014, 4.

2.8 **Socially constructed concepts of race and ethnicity:** The case for the application of socially constructed definitions of ethnicity within a socially responsible framework, is an inclusive agenda, and it is important ethically to include all social groups in clinical trials. This is because recruitment from a diverse population pool where the specific experiences of groups and individuals influence their health and health outcomes, can potentially bring benefits in terms of enlightenment and acuity in understanding more about disease aetiology and disease pathogenesis. Clinical trials encompass a whole constellation of interventions as the definition of clinical trials outlined in paragraph 3 below of this report makes clear. An inclusionary approach can therefore potentially generate ideas for service design and accessibility and add to the existing armamentarium of therapies.

2.9 **Representation in clinical trials:** There are several studies that evidence the underrepresentation of Black and Minority Ethnic groups in clinical trials. It cannot be overstated that this is the case across a range of disease areas, including those where Black and Minority Ethnic people have a disproportionate risk.[14] The Covid 19 pandemic, still within our purview shows this. While Covid 19 posed a greater risk to Black Minority Ethnic people, at the time of writing, only six of the 1,518 Covid 19 trials registered on ClinicalTrials.gov collected data on ethnicity. Moreover, of the 270,000 people who signed up to the NHS vaccine Registry to participate in COVID 19 vaccine trials, only a fraction were from Black and Minority Ethnic groups.[15] The largest prostate cancer trial, the PROTEC T study that reported its results in 2016, enrolled very few Black patients, despite the increased risk of prostate cancer in Black men.[16] Furthermore, the global registration trial data for ASPIRE and ENDEAVOR which tested Kyprolis for refractory multiple myeloma revealed that Black African and Black Caribbean people, had very low rates of trial enrolment at 2.9% and 2% respectively, despite having double the risk of myeloma and a higher mortality rate.[17] Asian women were significantly underrepresented in the PROCAS study on predicting the risk of breast cancer at screening, and Black African Caribbean and Black African women were also underrepresented.[18]

2.10 There are a number of reasons put forward to explain this, including Black and Minority Ethnic people being uninterested in clinical trials for historic reasons; perceptions that Black and Minority Ethnic participants may not stick to research protocols, and unconscious bias in design of clinical trials and recruitment. There are also studies that show Black and Minority Ethnic people

[14] Sophia Skyers, Campbell Kerr and Pauline Johnson, Count Me In! Exploring the future of personalised medicine from bench to bedside, The Basil Skyers Myeloma Foundation, 2017
Sophia Skyers and Vivienne Kendall Listen Up! Multiple Myeloma in Black Communities: An Unequal Risk Burden, The Basil Skyers Myeloma Foundation, 2015.
Rose Thompson, Hear Me Now: The Uncomfortable Reality of Prostate Cancer in Black African and Black Caribbean Men, 2013.
[15] Ending the Diversity Gap in Research, Innovative Trials undated
[16] Freddie Hamdy et al, 10 Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer, New England Journal of Medicine, October 13, 2016: 375: 1415-1424.
[17] A.K Stewart and Vincent Rajkumar et al.; Carfilzomib, Lenalidomide, and Dexamethasone for Relapsed Multiple Myeloma, New England Journal of Medicine 2015: 372:142-152 and Meletios A, Dimopoulos, Philliple Moreau, et al., Carfilzomib and dexamethasone versus bortezomib and dexamethasone for patients with relapsed or refractory multiple myeloma (ENDEAVOR): a randomized, phase 3 open-label, multicenter study, Lancet Ocol. 2016; 17:27-38.
[18] D. Gareth Evans and Anthony Howell, Can the breast screening appointment be used to provide risk assessment and prevention advice? Breast Cancer Research (2015) 17:84.

are as interested in participating in clinical trials as the population generally but lack information about how to go about taking part.[19] This inquiry explores these issues.

3. What is a clinical trial?

3.1 Clinical trials enrol individuals as volunteers and provide vital evidence in evaluating the safety and efficacy of novel therapies to secure improvements in future patient care and outcomes. While ingesting pills or taking injections is the type of trial that is in the popular imagination, a clinical trial is in fact much wider than this and includes the testing of medical devices or medical procedures. They fall into two categories, both of which are governed by the Medicines and Healthcare Products Regulatory Agency (MHRA) and come within the NHS Research and Governance Framework. They are known as Clinical Trial of Investigational Medicinal Product and Non-Clinical Trial of Investigational Medicinal Product, or CTIMP and Non-CTIMP trials.

3.2 The randomised trial or CTIMP is generally regarded at the unassailable gold standard. It is seen as the centrepiece of evidence for testing that safety and therapeutic efficacy is due to a particular intervention rather than to chance, or to some unrelated cause, through statistically representative samples of research participants. The second category non-CTIMP trials encompass studies that do not use investigational medicinal products as defined by the MHRA. Non-CTIMP trials cover a broad spectrum and include for example, the trialling of a medical shampoo or a surgical procedure. As an illustration, cornea grafts were experimental and largely unsuccessful in the 1960's but are now carried out routinely and successfully. As well as surgical procedures, non-CTIMP trials also include tests, scans, studies exploring risk, genetic studies, screening, the psychological or social impact of disease and so forth. Both CTIMP and non-CTIMP trials can be sponsored by a variety of organisations, and these include universities, charities, NHS Trusts, NHS Healthcare Foundation Trusts, pharmaceutical companies, biotechnology companies, and companies in the medical devices and diagnostics industry. Furthermore, there are powerful patient-led organisations that engage with statutory agencies and industry, and actively campaign to increase access to clinical trials across specific disease areas for the communities they represent.

3.3 The early phase 1 and phase 2 trials look at safety and mainly tend to be run by pharmaceutical companies developing a specific medication. The majority of phase 3 trials are non-industry sponsored and are for drugs that already have a license. There is a phase 4 trial period known as post market surveillance and is of no fixed duration once a drug is available on the market because some risks are only discovered in long term trials. An example is the risk of teratogenicity, the possibility of causing defects in unborn babies, with the drug Thalidomide, which is routinely used today in the treatment of the blood plasma cancer multiple myeloma. This risk only became apparent in the 1950s after the drug was actually on the market and was being used to treat pregnancy associated emesis.

[19] Ref Race. Ed, May 7, 2021, University of Edinburgh.
Op.Cit 15

3.4 In terms of patient confidentially and ethics approval, the requirements for CTIMP and non-CTIMP trials are largely the same but there are some additional requirements for CTIMPs. CTIMP studies must receive Clinical Trials Authorisation to proceed and are subject to mandatory inspections. While, as stated, it is the CTIMP studies involving the testing of new drug therapies, medicine, and the use of placebos that people tend to be most familiar with, in this study, the term clinical trial will be used to mean CTIMP and non-CTIMP.

4. Approach to carrying out the inquiry

4.1 The approach to the inquiry involved a rapid appraisal of some of the emerging UK literature on the subject of clinical trial participation, and interviews with a convenience sample of staff at the Cancer Research UK & UCL Cancer Trials Centre, Cancer Institute and B'Me Against Cancer. They were as follows:

Rapid Appraisal Interviews	
Professor Allan Hackshaw	Director Cancer Research UK & UCL Cancer Trials Centre
Lyndsay Thompson	Chief Executive Officer, B'Me Against Cancer Executive Officer, B'Me Against Cancer
Jack Allen	Media and Patient Communications Lead, Cancer Research UK & UCL Cancer Trials Centre
Esther Arthur-Darkwa	Trial Manager, Cancer Research UK & UCL Cancer Trials Centre CTC
Isabella Rattigan	Data Manager, Cancer Research UK & UCL Cancer Trials Centre
Dr Giulia Pellizzari	Lecturer & Education Lead, Cancer Research UK & UCL Cancer Trials Centre
Rhianne Beveney	Trial Manager, Cancer Research UK & UCL Cancer Trials Centre
Dr Uma Mukherjee	Registrar in Oncology, Clinical Research Fellow, UCL

4.2 The inquiry was structured around a survey and five focus groups, two of which were virtual focus groups using Zoom. The survey was online and was promoted widely through partner organisations and community networks. The process was supported by staff at UCL Cancer Trials Centre, Cancer Institute, the Board of B'Me Against Cancer, and other Black and Minority Ethnic patient organisations who collectively advised on the shape and content of the questions. The focus groups recruited a convenience sample of 51 participants in total and a total of 211 respondents completed the online survey.

4.3 The focus group participants comprised 43 first, second, and third generation Caribbean women and men, and 8 African first generation men and women. The focus group facilitator asked participants' permission to make a digital recording and gave guarantees of confidentiality and anonymity. It was also made clear to participants that they were free to leave at any time and could

omit answering any question if they wished to do so, without explanation. The focus group themes were informed by a rapid appraisal of some of the emerging grey literature on clinical trial participation, and the rapid appraisal interviews with healthcare professionals. The facilitators were mindful of the effect of particular lines of inquiry, and this meant being empathetic in exploring issues at all times. The researcher made clear that as well as having specific lines of inquiry to inform the study, the issues participants themselves saw as relevant were welcome for inclusion. In line with best practice in qualitative research, the lines of inquiry were continually refined as the research proceeded and new questions arose. This ensured that the process remained exploratory, and focused. The focus group participants were given an incentive of £40, and the survey had a hamper prize as an incentive.

4.4 The focus groups, were transcribed immediately where logistics permitted, or within two days of being carried out. A system of framework analysis was used to identify and categorise emerging themes and in conjunction with the analysis of the survey, is the process that has informed the production of this report. The classification headings generated for the rapid appraisal interviews and the focus groups are set out in section 6 below, and under these headings, all of the information was accounted. The survey went live on 21 October 2023 and ran until 11 December 2023 and the results are presented in the following section 5.

5. The research findings (The Survey)

5.1 There were 211 respondents to the survey. 152 respondents selected their ethnicity of whom 15% (23) said they belonged to the African group; 75% (114) the Black Caribbean group; 3.0% (4) the Mixed African Group, and 7.0% (11) the Mixed African-Caribbean group. 68% (102) of the respondents were women; 32% (48) men, and 0.0% (0) identified as non-binary. The respondents covered the entire spectrum of ages, with the majority in the 32% (60) in the 60-69 age range, followed by 29% (44) in the 50-59 range. The representation of age ranges is set out in the table below:

Age Breakdown of Survey Respondents		
Age	**Numbers**	**Percentage**
16 - 29	12	8.0%
30 - 39	8	2.0%
40 - 49	19	12%
50 - 59	44	29%
60 - 69	50	32%
70 - 79	18	12%
80 – 89	3	2.0%
90 and over	0	0.0%

5.2 The survey asked about employment status. 154 people responded of whom, 38% (59) said they were employed full time, 12% (18) part time, 6.0% (9) said they were unemployed, and 5.0% (9) worked on a volunteer basis. 13% (20) indicated they were self-employed, and 26% (40) were retired. This table below sets this out:

Employment Status of Survey Respondents		
	Numbers	Percentage
Employed full-time	59	38%
Employed part-time	18	12%
Self-employed	20	13%
Unemployed	9	6.0%
Retired	40	26%
Volunteer	8	6.0%

5.3 The survey asked whether respondents were cancer patients; whether they cared for someone with cancer; whether they were a cancer patient and cared for someone with cancer, or whether they were neither a cancer patient nor a carer for someone with cancer. 211 people responded and of those, 12% (26) said they were a cancer patient, 7.0% (14) cared for someone with cancer, 1.0% (3) were a cancer patient and that they cared for someone with cancer, and 80% (168) were neither a cancer patient nor a carer for someone with cancer. The table below sets this out:

Carer and/or Patient		
	Numbers	Percentage
Cancer patient	26	12%
Care for someone with cancer	14	7.0%
Cancer patient and care for someone with cancer	3	1.0%
Neither carer nor patient	168	80%

5.4 The survey asked respondents whether they had ever taken part in a clinical trial; if a clinical trial had been offered to them but they had declined to take part; if they had never been offered a clinical trial; if they wanted to take part in a clinical trial but were unable to do so, or whether they had no idea what a clinical trial was. 193 people responded and of those, 17% (33) said they had taken part in a clinical trial, 13% (25) had been offered a clinical trial but had declined to take part, 51% (99) had never been offered a clinical trial, 7.0% (14) wanted to participate in a clinical trial but were unable to do so, and 11% (22) had no idea what a clinical trial was. The table below sets this out:

Participation in Clinical Trials		
	Numbers	Percentage
Taken part in a clinical trial	33	17%
Offered but decided not to take part	25	13%
Never been offered a clinical trial	99	51%
Wanted to but was unable to	14	7.0%
I don't know what a clinical trial is	22	11%

5.5 The survey asked respondents to select a statement they agreed with, vis-à-vis, whether they viewed taking part in clinical trials as important; unimportant, or whether they viewed taking part in clinical trials as neither important nor unimportant. 161 people responded and of those, 87% (140) regarded taking part in clinical trials as important, 0.0% (0) no one indicated they were unimportant, (21) were neutral. The table below sets this out:

Importance of Clinical Trials		
	Numbers	%
Taking part in a clinical trial is important	140	87%
Taking part in a clinical trial is not important	0	0.0%
Taking part is neither important nor unimportant	21	13%

5.6 The above question included and open-ended component and respondents overwhelmingly said that they regarded clinical trials as important to, moving forward the research agenda, finding cures for diseases, the development of more effective treatments than exist currently, supporting future generations, and personal benefits for their children and grandchildren. They were also seen as a route to receiving better care through close monitoring, and providing vital understanding about how diseases present on different skin tones. At the same time, concerns were expressed about racism, and this was linked to a lack of trust resulting from historical experiences, and as already stated, deep fears the experimental nature of clinical trials, unforeseen risk, and adverse outcomes. As selection of the comments made are set out in the table below:

Comments on Importance of Clinical Trials
'Taking part in a clinical trial ensures that we have representation of all ethnicities that ensures we are able to treat all'.
'I work in the clinical research environment and understand the importance'.
'Clinical trials can help to develop the right treatment or detect illnesses early therefore it is important'.
'Without trials we don't know which treatment works'.
'If it's gonna help with community, then I think it is important to take part in clinical trials'.
'I am glad some people have the courage to take part in clinical trials. I feel they are important but personally wouldn't'.
'It depends, what it is for and risk factors'.
'To improve understanding and you might receive extra care'.
'I've taken part in several trials that were relevant to me'.
'I'm neutral on this question as not enough is known about them and the long term effect on the body'.
'It is important but trust issues about who is conducting these and for what purpose'.
'I had read something very negative about clinical trials and at the time I decided not to take part'.
'I'm worried of racism hence get frightened to visit the clinic'.
'Hold no faith participating in clinical trials. Much convincing will be required that no risks are involved'.

5.7 The survey asked whether respondents had ever been offered a clinical trial but had decided not to participate. 161 people responded and of those, 18% (29) said they had been offered a clinical trial but had decided not to participate, and 82% (132) said they had not been offered a clinical trial. The table below sets this out:

Offered A Clinical Trial		
	Numbers	%
Yes	29	18%
No	132	82%

5.8 The respondents to the survey who indicated that they had been offered a clinical trial but had decided not to do so, were asked why. This was an open-ended question and a sample of responses providing an overall view is set out in the table below. The responses range from, other issues to contend with, ethics, distance from location of the trial, costs, concerns about side effects, and a lack of clarity about the trial:

Comments on Non-Participation in Clinical Trials
'At the time I had too many issues to deal with'.
'I was busy so wasn't sure if I wanted to know the answer at the time'.
'Private company researching hypertension. I didn't' feel I could afford the time'.
'Was not ready, dealing with personal issues'.
'I was worried about the side effects'.
'I was a bit nervous because of all the negative comments about medical trials'.
'The trial details were unclear'.
'Too overwhelming for me relating to my own case'.
'I have been offered a cancer test and I never accepted the offer'.
'Sometimes it's wrong trial or violates my values and not ethically correct for me'.
'It was in London and they weren't willing to pay my expenses'.
'It was for blood pressure medication for pregnant women but I decided I didn't want to take any risks'.
'The information wanted was too intrusive and on face value did not relate to the knowledge the study was seeking'.
'Was offered but there was no clear explanation of what was expected to come out of the trials. I thought it was risky after seeking stories on the news and social media'.

5.9 The survey asked respondents who had taken part in a clinical trial, whether it related to drugs, surgery, or radiotherapy. There was also an 'other' category. 30 people responded, and of those, 10% (3) said their trial they was about drugs, 7.0% (2) surgery, 3.0% (12) radiotherapy, and 80% (24) indicated Other. The table below sets this out:

Nature of the Clinical Trial		
	Numbers	%
Drugs	3	10%
Surgery	2	7.0%
Radiotherapy	1	3.0%
Other	24	80%

5.10 The above question included and open-ended component asking respondents to provide additional details of the nature of the trial. The table below sets out all of the responses.

Nature of the Clinical Trial
'Bowel cancer'.
'CT scan on brain to support university studies'.
'Blood test'.
'Galleri cancer trial'.
'I took part in the Summit Study where smokers were tracked to help the NHS develop a blood test for lung cancer'.
'New test to detect cancer in the blood'.
'To try two methods of treating Wilms tumors in children'.
'Genetic testing'.
'To see if cancer can be detected early'.
'Hypertension'.
'Was offered a trail for HIV drugs and did not take the offer'.
'Sexual function'
'Nicotine gum'.
'New test to detect markers in the blood cancer, tell us whether or not we're likely to have cancer'.

5.11 The survey asked whether the experience of taking part in a clinical trial was a positive, negative, or neutral. 36 people responded and of those, 36% (13) said it was a positive experience,

8.0% (3) said negative, and 56% (20) said it was neither positive nor negative. The table below sets out these responses:

Experience of Clinical Trials		
	Numbers	%
Positive	13	36%
Negative	3	8.0%
Neither positive nor negative	20	56%

5.12 The above question included an open-ended component, where respondents were asked to provide additional details on their positive, negative, or neutral experiences. The following table sets out a selection of the responses.

Positive, Negative or Neutral Experiences of Clinical Trials
'Feedback was shared on the trial and the drug was later put on the market'.
'The trials that I have been involved with have been positive'.
'Good explanation about the trial'.
I got lots of information about it beforehand and felt comfortable with the procedures and that my information was dealt with correctly'.
'They have found some abnormalities so it has been helpful to identify problems before they become life-threatening'.
'I was given the results and I found this reassuring'.
'Effortless, turn up for mobile MRI and 2 yearly poo in the post'.
'It was something unpleasant but it had to be done'.
'Wasn't given information as to why and what the information investigated'.
'It confirmed that I can't stand chewing gum and it did nothing to encourage me to stop smoking'.

5.13 The survey asked those who had not taken part in a clinical trial, whether they would participate if one were offered. 142 people responded and of those, 69% (98) said they would take part if one was offered, and 31% (44) said they would not. The table below sets out these responses:

Participation in Clinical Trial if Offered		
	Numbers	%
Yes	98	69%
No	44	31%

5.14 The above question included an open-ended component where respondents were asked why they had indicated they would or would not take part. The responses included, clinical trials being important in discovering treatments and alternative treatments, an interest in science and learning, the potential long term benefits of participation for society, the importance of understanding more about the Black body, and where guarantees can be given that there will be no long term negative effects. Those who said they would refuse cited lack of trust, a fear of the unknown, being a guinea pig, and the historical misuse of Black people by science and medicine. There were some who said while they would refuse to participate in a trial involving ingesting medicine or injections, because of the potential for physical harm, they would take part in a lifestyle or purely observational study which was seen as safer. The responses are set out in the following table:

Participation in A Clinical Trial Among Those Who Have Not Taken Part
'I believe we have to be part of trials if we want to look at alternatives'.
'Yes, I would love to take a clinical trial if am offered it because I like finding out about new things'.
'Depending on the fact that it would benefit me in the long run'.
'Possibly if I thought its purpose was genuine'.
'If I knew all it would entail and I felt comfortable with it then yes'.
'I wouldn't mind taking part in any trial that may potentially cure diseases'.
'Maybe if I know the details of the process'.
'We need to do these so they have more Black people to study'.
'Perhaps if I was guaranteed that there would be no risk to my health'.
'I think on reflection it was a missed opportunity to refuse to take part in a trial'.
'How can we as a community shout out if we don't or don't challenge when we are not included'.
'I would if important to me'.
Perhaps if it was explained plainly, the benefits, how long it will take and what to expect from it'.
'I don't know what it is'.
'Don't trust'.
'Fear of the unknown'.
'Depend on the type of trial'.
'There is a long history of Black people being used as medical subjects without informed consent. Even with the Indian people and radioactive chapatis in the UK in the 80's'.
'Yes, I would like to support my community with health conditions that mainly affect us and be part of a wider trials to support all and those of mixed heritage'.
'I would consider participating in a clinical trial if my health or life is not placed at risk. I will directly benefit for example, providing a blood sample for a bio-resource study. A breakdown of the results of the nutrients in my blood etc'.

5.15 The survey asked whether they had any idea why Black African and Black Caribbean people were underrepresented in clinical trials. The question was an open-ended one and respondents offered varying explanations including, historical abuses of Black people, poor experiences with the NHS, not understanding clinical trials and the reasons for them, negative views circulating about clinical trials, lack of visibility of Black scientists, not being offered a trial, fear and superstition, and again, lack of clarity. The responses are set out in the table below:

View on Reasons for Underrepresentation in Clinical Trial
'Mistrust of the system, historical evidence of abuse, lack of knowledge'.
'We have been let down so many times before by clinicians, Doctors etc. The people that is meant to look after you'.
'Hesitancy and mistrust in the healthcare system'.
'Mistrust of treatment and care needs for Black people not always great'.
'We are offered the opportunity, we are too superstitious, we fear damage to our health'.
Don't trust the establishment'.
'No trust in medical professional due to historical reasons'.
'Perhaps we are not fully informed/don't understand the importance'.
'Too many negative things being said in the Black communities about clinical trials'.
'Because not enough of us are offered and/or taking part in clinical trials'.
'I guess we may be scared to go. I'm not really sure'.
'Not given the opportunity to participate, reluctant to engage in experimental drugs'.
A scepticism around medical research as a result of past negative experiences individually or wider African community'.
'Surveys do not reach us. We are so conditioned to thinking someone else is doing the work. Too many old fashioned ideas about drugs used as tracking devices'.
'I think that with mistreatments to our communities and undervalued in all areas in our lifestyle, education, and scientists of our race are few, financial help also plays a part and backers who are committed, even we ourselves to come forward to assist'.

View on Reasons for Underrepresentation in Clinical Trial
'Fear, uncertainty about the efficacy and a belief that Black people can be guinea pigs in trials that would not serve them, but maybe others'. Because we're not offered plus, we know very little about them so that cycle will continue unless we start to do these trials'.

5.16 The survey asked whether the term 'random' or 'randomization' in the context of a clinical trial had any meaning. 154 people responded of those, 45% (69) said they understood the term in the context of a clinical trial, and 55% (85) said that they did not. It is important to point out that the question did not ask respondents to define what the terms 'random' and 'randomization' meant to them and therefore it could be the case that some of those who answered yes, may not have understand, and likewise, those who stated that they did understand, might not have done. The table below sets out the responses:

Understanding of 'Randomisation'		
	Numbers	%
Yes - understand randomization	69	45%
No – do not understand randomization	85	55%

5.17 The above question had an open-ended component, and responses included, randomization being akin to a lottery, a name being picked out of a hat, the use of placebos against a control group, and not being able to predict whether you would get a drug or not. Randomization was also compared to what happens at airport security when they search bags randomly. The views of focus group participants corresponded with those of survey respondents:

Understanding of the term Randomization
'I suppose you pick a random selection of people from the trials'.
'Are some people given the drug/other being trialed whilst others are given a placebo'.
'Choosing out of sequence'.
'It being unpredictable'.
'It means people are selected randomly. There is also a control group in addition to those receiving the trial treatment'.
'Random suggests the choice is not 'directed' but 'chance' however I hear this all the time at airport security'.'
'No process of selection just luck of the draw in terms of the group you are placed in'.
Don't fully know random in clinical trials'.
'Does this mean that it is informal?'
'I am not familiar with this area of clinical trials'.
'You ae not the mainstream, you are a name picked of a hat'.
'Means you are selected by chance like flipping a coin'.
Blind testing given placebos or the real thing'.
'I don't associate the word random with a clinical sense because it's a word that means without reason or method'.
'I have not heard of the word randomization before and the term doesn't mean anything to me'.
'Having no systematic approach so not controlling the research participants for race, age, etc. Just having those who want to take part'.
'This means the decision about which treatment each participant in a randomized controlled trial receives is made at random – based on chance, rather than decided by the doctor or participant'.

5.18 The survey asked if respondents knew where to find information about clinical trials. 153 people responded of which, 24% (36) indicated they would know where to find information about clinical trials, and 76% (117) indicated that they would not. This following table sets this out:

Finding Information About Clinical Trials		
	Numbers	%
Know where to find information	36	24%
Do not know where to find information	117	76%

5.19 The above question had an open-ended component where respondents were asked to explain their answers. They included Google searches, social media, via their consultants of general practitioners, cancer research websites, medical journals, hospital noticeboards, ClinicalTrials.gov, NHS websites,, the National Institute of Health Research website, and BMe Against Cancer.

Finding Information About Clinical Trials
'Not sure but would probably Google it'.
'Doctors/specialists/cancer research website'.
I can go to WHO International Clinical Trials Registry Platform (CTRTP) website'.
'Medical journals, hospital and GP noticeboards'.
'I don't have much knowledge'.
'They don't target my community it's not written anywhere it's not on the radio or publications'.
'No knowledge of this'.
'I am working with CRUK, BHF, Astra Zeneca'.
'Not specifically. I am signed up to a site that sends me emails inviting me to apply for non-medical ones. I wouldn't know where to go specifically to find out about them'.
'BMe Against Cancer'.
'ClinicalTrials.gov and NHS website'.
'Trials can be found on the National Institute of health research website'.
'Internet, NHS, GP Surgery'.
'Social media'.
'Via my research and clinical colleagues, wider networks, newsletters from CRUK, PCUK, and other funders, trial registers e.g Cochrane.

5.20 The survey asked if respondents would be interested in more information about clinical trials. 146 people responded of which, 71% (106) said they would be interested in more information about clinical trials and 29% (43) said they would not. This table below sets this out:

Further Information About Clinical Trials		
	Numbers	%
Yes – interested in further information	106	71%
No – not interested in further information	43	29%

5.21 The above question had an open-ended component. Those who were interested in receiving further information were asked the formats they would prefer. A sample of responses is set out in the table below and include, email, and this was very popular among the overwhelming majority, as well as information by post, through social media, and TV dramas.

Desired Format for Information on Clinical Trials
'I would like to receive information by email'.
'By post or email'.
'By email, text, letter'.
'Social media'.
'I would want to know about being anonymous I would prefer email'.
'Social media such as X and LinkedIn'.
'Videos on social media, stories, dramas e.g. Eastenders'.

6. The research findings (Qualitative)

6.1 The following presents the findings from the analysis of the focus groups and the views of healthcare professionals who took part in interviews. The overall headings used are Views of the Public, and Views of Healthcare professionals.

Views of the public

6.2 The information from the focus groups with the public is set out under the following classification headings:

a) Views on what a clinical trial is.

b) Views on taking part in a clinical trial.

c) Notions of control groups in clinical trials.

d) Concerns about clinical trials

e) Clinical trials and engaging with the NHS

f) Locating information about clinical trials

6.3 **Views on what a clinical trial is:** The focus group participants, for the most part saw a clinical trial as a novel medical investigation, experiment, or scientific research in which a member of the public voluntarily takes part, often for payment, and which, may come with a considerable element of risk to health. For the most part, a clinical trial was seen as involving the ingestion of a medicine, the injection of a drug, or any form of treatment to test for efficacy. Due to it being seen as experimental in nature, where the outcome could not be determined, those who participated in clinical trials were seen as 'human guinea pigs', voluntarily subjecting themselves to the unknown where *'you might die, or you might not'*. The potential for adverse impact was seen as enormous and for this reason, the majority of focus group participants said they would be extremely wary of participating in a clinical trial, particularly if they were enjoying good health. The following remarks typify those that were made,

> 'I have always been wary of the word clinical trial because that in itself makes you think OK, you're not experimenting on me for whatever reason. So that's my conception of the word clinical trial. Makes you think experiment on a guinea pig' (Female Participant).

'When doing clinical trials, the people won't necessarily have the ailment that the drug is for but maybe they're looking to see, on a healthy population, whether there is any side effects to these drugs. They've done all the theory you know, maybe tested on animals, but in practice, will it cause any other effects I guess' (Male Participant).

'You don't, as a rule of thumb, I'm guessing, you don't know what sort of reaction your body will have, let's say if it is a health clinical trial, you don't know what reaction your body will have to it' (Male Participant).

'I think it's at what stage you feel. I mean, if I'm healthy and well and they're going to ask me I think that's different, but I wouldn't put myself out there. You're a guinea pig' (Female Participant).

'The thought of being used as a guinea pig almost, being tested on and not sure what effect it will have on me and also whether it will work on someone else' (Female Participant).

6.4 There were a significant number of participants however who saw a clinical trial as data collection and as encompassing a far wider spectrum than either medicines or injections. In addition to testing drugs or medicines for efficacy, clinical trials were also seen as involving experiments that were less risky and less invasive than those in the popular imagination. They were seen as including behavioural and psychological studies, the taking of blood and genetic samples, as well as novel medical procedures that might bring symptom relief. As this topic was being discussed, it also became a light bulb moment for those who had previously had a much narrower interpretation of a clinical trial. As was explained,

'I did one for breathing, for lung capacity as well, and I think it was about over two or three months so you just had to breathe in, and they would analyse it. I didn't really get any feedback from it but obviously they did a cross section of age groups and ethnicity, so I have done that. And then I think we touched on another one where the genes for cancer, but I didn't do any tests, but it was for the Genomes project, so I've done that.' (Female Participant).

'I had bowel cancer, and they had this new treatment, and they said they were trying a treatment' (Male Participant).

6.5 **Views on taking part in a clinical trial:** Asked whether they would participate in a clinical trial, the majority of participants who said they would not take part in a clinical trial explained their views in a variety of ways. The reasons ranged from, in one case, having been approached but being unclear about the purpose of the trial, being fearful of side effects unknown to those conducting the trial, others who were concerned about the past history of experimentation on Black people, those who were concerned about a loss of control of their bodies, and others who said they would take part, but only in circumstances where there were absolutely no other options. The following comments typify those that were made,

'I didn't feel comfortable in doing it. Maybe if they had explained fully what they wanted to do. I didn't understand what they wanted to do so no. I read the paperwork but saying that I don't think clinical trials are useless, they do serve a purpose' (Male Participant).

'I would probably say no because there are so many side effects. If it's a clinical trial that means all of these side effects haven't been found yet, are not listed, so anything can happen' (Female Participant).

'I think if it was like a government issued one, I think that would always be no for me. I know that might sound really harsh, but I just think that there's a very murky history, even recently like hearing about, not too long ago where the NHS has given like South Asian people like chapati's and they were like radioactive or something so I'm like, "yeah, no". But I think if it was for something potentially more behavioural because I think those ones are a bit less invasive, like the side effects I don't imagine to be something that's physically out of my control that maybe therapy couldn't fix. But something where it's like medical it's too many unknowns and things that are potentially irreversible' (Female Participant).[20]

'I think like if I had a terminal illness, I would be willing to take a gamble' (Male Participant).

'I would sign up for a clinical trial if it was life or death. If I was very poorly and every other option of medicine or treatment had been used up and there was no other option and they say, "I've got this clinical trial, do you want to try it?" I probably would; to try and save my life but I think that would be the only time' (Female Participant).

6.6 The majority of participants said however they would be willing take part in studies as long as they *'didn't involve taking anything.'* A few referred to this inquiry, and explained they were willingly participating because it had come to their notice via a trusted network. There were others who said they would be willing to participate in clinical trials more generally if they were getting something out of it, including being clear about the contribution they would be making, and receiving feedback on outcomes. It was stated that one of the reasons for non-participation was because in consultations more generally with the community, there was often no feedback, and ties were always severed completely once researchers had "got what they wanted". Participants also explained there was a mistrust based on evidence of historical medical abuses of Black people whom scientists had been experimented on, without their consent. At the same time, there were others who, due to ongoing chronic or acute health issues, felt they had learned a considerable amount about clinical trial protocols, had congenial relationships with their clinical team, and were absolutely confident about taking part in a clinical trial if offered. The participants put it in this way:

'I wouldn't just accept anything. If it's about them wanting to get statistics or information from me as opposed to putting stuff in me and making me take a tablet, then that's different because I wouldn't take a tablet. But I might offer you some information about me, I might let you take my weight, my height or whatever so it depends' (Female Participant).

[20] This refers to calls for a recent inquiry into a 1960's study carried out on 21 Asian women in Coventry, identified by a GP. The women who were unable to give informed consent were given chapati's containing radioactive isotopes as part of a research trial in 1969 into iron deficiency in the South Asian population.

'I may be cynical, but I would say no way, not trying on me. They tried on my ancestors they're not trying on me so ignorance I suppose. It depends on who's asking. Like today, with people reaching out to us that we're close to, and asking, we said "yeah, we'll do it", but before when we've had from our other group, it's "no sorry". So it depends on relationships and trust and who's asking as well' (Female Participant).

'There has been an echo of distrust in society but from a country point of view so I'm from Nigeria…. We had a situation 20 years ago where we had this infamous scandal where they experimented with some kids in northern Nigeria and its them lost their lives. Massive distrust for anything that western medicine to this day the people who lost their lives were predominantly Muslim' (Male Participant).

'I definitely would do it without any hesitation because of what I know now because I feel I'm capable to question them enough to decide whether I want to do it or not and I think in the past ignorance I would say, "no, no, no, you're not trying nothing on me". But because of what I know now…. I've got prostate cancer (Male Participant).

6.7 The focus group participants who had taken part in a clinical trial, and in some cases, more than one trial, saw it as something routine that did not need detailed consideration, as the following participants make clear:

'I had experienced having a stroke back in 2017. I was pregnant with my son and I got regular testing for blood because that's the first time I've experienced blood clots in my body so once I'd had him, the blood testing team had asked me if I would sign up to be part of a clinical trial and all it was, was they wanted to take like a tube of my blood and test it to see if I had something called haemophilia which is something like a blood clotting disorder that presents more in ethnic minorities and yeah, that was it. I signed the document and that was the end of that really' (Female Participant).

'I've been involved in a couple of clinical trials, probably because I've got the time to do it because I'm retired now. I was involved in a gout study, uric acid. I was refused a couple of studies because I no longer fit the criteria' (Male Participant).

6.8 There were likewise other participants who said that they were pleased to have taken part in a clinical trial which they saw as their way of contributing to medical knowledge and which, engendered a sense of pride in them. The view of clinical trials being important to the advancement of knowledge was also shared by focus group participants who had not taken part in a trial but nonetheless, regarded them as important to enhancing medical knowledge. In this context, the legacy of the past was seen by some as something clearly in the past:

'We have to look forward. No point in looking backward towards what has happened in the past' (Male Participant)

6.9 There were those who spoke of an added personal dimension in relation to clinical trials informing answers to family illnesses. The response from the following participants exemplifies this:

> 'I didn't have any issues. I was pleased to have been picked but I think I was only picked because kidney cancer is a cancer that affects older people and at the time, I was 48 so I was young…. I then went onto another trial drug and that was the one that took my melanin and my colour from me. But I don't have problems with trials. I think you have to participate because I think without participation there's no change. You can't improve. So, I was pleased to be involved' (Female Participant).

> 'I think mine was a selfish thing and at the time, my Dad had just died, and I thought you know, he had prostate cancer, but he died of a heart attack….so I thought I'd go along and find out if it was a family thing. It was to do with heart condition. My Mum died of a heart problem she had a heart bypass in 1990 she didn't survive so I joined in just to really find out for the rest of the family' (Female Participant).

> 'People want something that is going to benefit them so if you have a trial, as Black people or as a woman or as a young man you feel it's going to benefit you whereas as older man if you don't see the benefit, not the financial side, if there was a direct benefit for you, it's going to make you grow hair, you could start having an Afro again. So for me, it would be like "Oh, I can get an Afro back". So I would probably take part because I know it's going to benefit me' (Male Participant).

6.10 There was general agreement about the importance of participation where it might help a family member or help others as part of our shared humanity. Some of the participants who had never taken part in a clinical trial and who had said they were fearful of doing so, also said they would take part if they were offered one for an existing treatment or illness, or if it would help their family member. The important point, more generally, was participants felt the relationship with healthcare professionals needed be underpinned by trust, and that diversity in clinical trials could reveal important things about the human body and the presentation of diseases:

> 'If it was part of my illness or part of my family, or just so that they can do the research and get the data so that we could move forward because I think not just different cultures, I think different bodies heal differently and that's the reason…. I was on blood pressure tablets which is supposed to be very mild…people's bodies work differently going through illness and repairing itself' (Female Participant).

> 'If it was fully explained to me and particularly for my family and other members of the community, but the person or the organisation who is asking for that information is important and who I see as the face is important as well. So the information share is important knowing what they're going to do but also having the trust in who's asking for it' (Female Participant).

'Depends on is very much the key. Whilst we all want to feel that we're contributing to society to development, especially when you hear they're calling out for donors from the ethnic minority. I think I'm the wrong age but if I was the right age, would I (laugh)? is another thing. But I do feel that I would want to. It does depend on what it is I think if its more specific to something that I've got, then you're more willing to but not only do you want to give relief to yourself, but you want to give relief to others and even if it doesn't work for you, I don't want someone else to go through what I'm going through. So, I think if it was something pertaining to what I'm suffering with then I would give it serious consideration' (Female Participant).

'It is always good to go across a conscious effort and go across as many groups as you can when it comes to medical stuff which is why I think there are issues where some groups like you know in cancer for example, people are taught that it looks like this on White skin for example so they're going to go to the doctor quicker, Black people might not even know what skin cancer looks like on their skin and might not even believe they get it so, I'm just saying that'. (Female Participant).

6.11 A recurrent theme in the focus groups was on the one hand, the notion that Black people's bodies are somehow different, that Black bodies work differently to the bodies of other ethnic groups, and on the other hand those who were of the view that Black bodies were not different but were seen as different. As a consequence, drugs were seen for some as potentially working differently in different groups of people, and within that context, the importance of recruiting Black bodies was so that they could be used a test bed. Thus, clinical trials involving the Black body was seen as part of a learning process that did not have benefits to Black people as an objective:

'It has come to my attention in recent years that the medication that we take, a lot of it has been tested on Europeans, Caucasians race and there's very few studies done with our race, so I just feel it's important that the drugs, because I know for a fact that it's really killing our people its unsuitable for them' (Male Participant).

'Most of the NHS is kind of borderline they base everything off White people and I've actually been told that by a consultant in the NHS because they don't have trials on us. So, when we go into the NHS and we're taking drugs and were ticking all those boxes, its actually, they're not actually looking at us and how that would have an effect on our body make up our DNA. You have not really looked at us and how our body reacts to things so you're basically giving us stuff that you know has been already tried on middle aged White men so to speak and nothing has been done on us so when we go in there, those types of things are going to create more damage in us than actually healing us' (Female Participant).

'…biologically, are we that much different? Is the makeup inside of a Black person completely different to an Indian person, a White person? I do believe there are differences, you know, we have different metabolic generally speaking but then you can get a Black person from Jamaica, a Black person from Nigeria and a Black person from Australia and they might just be different anyway because of environment, because of the food they eat.

So it's not that simple. Not all Black people are the same. What works for one Black person isn't going to work for another Black person and what works for that one Black person could work exactly the same for a White person so really and truly, medication in itself is a hit and miss' (Male Participant).

'I personally think that quite a lot of times when you go in the trials, I don't know what it's for and I think sometimes being a Black person as well, I think there's a lot of testing that's done on us that we almost don't always reap the benefits of and obviously, historically there's been times in our past where they've used us in clinical trials and created certain diseases so to speak so that's part of my reasoning' (Female Participant).

6.12 There is a need for a clear understanding about race as a social construct, not a biological one, to counteract current misinformation as for some, notions of race, and notions of the peculiarity of Black bodies and learning from them, may go some way to explaining why there is distrust, particularly given the history of scientific experimentation. The resources should make this clear, using information from the 100,000 Genomes project, and set clinical trial participation within the framework of continental ancestry, involving a wide group of people, centred on bringing greater acuity and perspicacity to diseases that occur in all of us, and that have biological consequences.

6.13 There were some focus group participants who talked about financial inducements for taking part in a clinical trial being persuasive, particularly at a time when finances are on a negative spiral and it being a positive thing financially. By contrast there were those who said they had looked at what clinical trials were available at a time when their funds were low, but were too afraid to pursue it because of the unknown, and specifically because they might be opening themselves up to abuse:

'I found myself cash strapped so there's a place…. where they had different programmes where they do studies on you, for example, swallowing a capsule, you actually become a resident of that place, so you become a patient for a weekend. Like being in a hospital but you're not in a hospital, you're free to get up and dress and walk around and so on. But, they are taking blood samples regularly, every six hours or whatever it is, day and night. They actually wake you up get your blood and so on, so I actually did that. That was to earn money, and it was well worth it' (Male Participant).

'I find it interesting and know it's needed and did consider it and one time it was about £5,000 but then I think to myself what is it going to test on me? The top and bottom line for us as Black people is the fear factor, what they did to us in history…They want to find what makes us tick and they're going to put whatever it is inside us like Frankenstein. It's very, very scary. Very scary' (Female Participant, Nottingham).

'Sometimes it's about the money to be honest. You think, I could do with a bit of money, but I've always sort of been that not for me, maybe because for some of them you had to go away, maybe for a couple of days, and it was work and all of that. But I would want to know

do they understand and are they considerate of my needs as a Black person and the differences there may be depending on what the trial is' (Female Participant).

'We have to be careful because of past history. Clinical trials have taken part in the community without our consent, so you know, there is still that discrimination element of it. It's still there, you know and the fear that we're all showing in this room, there's an element of fear there as to why people want us' (Male Participant).

6.14 A clinical trial was not always seen as a deliberative process where a study is conceived, designed, and executed. It was also seen as part of ongoing cancer treatment where drugs had been through a clinical trial process. It is clear that some participants understood post-market surveillance, or stage 4 of a clinical trial, where drugs are licenced and in use, and data are being continually collected on efficacy, side effects and so forth over a time frame extending in perpetuity:

'As cancer patients, we are more or less constantly part of the clinical trial because the breast cancer sufferers, we have to take medication for five years, hormonal if your cancer's hormonal for five years and really they can't give an answer as to what happens at the end of the five years. So I think they're testing us to see if you survive within that and if you don't. Maybe they know that medication for hormonal breast cancer doesn't work for certain people' (Female Participant).

6.15 **Notions of controls groups in clinical trials**: The idea of a control group in clinical trials was understood in general terms by those who had previously participated, as well as those who had not. Moreover, for some, the notion of random selection was a term they had heard of. One participant mentioned a clinical trial he had volunteered for, the Galleri blood test. However, he lacked certainty about risk and appeared hesitant that if anything was detected, he would actually be informed if he was part of a control group. As he stated:

'I think it is called the Galleri, the blood one, a new form of detecting cancers from a simple blood test. They can now identify a lot of different cancers, so I signed up for that one. I don't know whether I'm in the control group or not, but essentially they fed back to me there's no problem, there's nothing negative feedback of anything found in my blood sample as such. I *suppose* if they did find something, they would tell me' (Male Participant).

6.16 Participants tended to have some familiarity with the term placebo and understood this to mean:

'Something that doesn't have a medical component in it but your belief in it working can actually have it to work and there's many trials that have proven that over and over again. If someone believes that a sugar pill can work, it will actually heal them because of their belief, more than actually what is in the pill' (Male Participant).

'I think it's to mean that you might take something and believe it's working but it could be water' (Male Participant).

> 'When you are doing a clinical trial and you are trying to find out whether a drug actually works, the placebo has none of the active drug in it, people are randomised to a point where they get the drug, people are randomised where they get a placebo, but they don't know. So people all assume they get the drug. Only the people doing the trial know who is on placebo which is nothing, and who is on the drug so they can actually have a comparison' (Male Participant).

6.17 The concept of randomisation in the context of a clinical trial does need to be explained clearly so that there is absolute clarity that randomisation does not mean patients with life-threatening or other illnesses taking part, are left untreated. It also needs to be explained that if something is found, they will receive the full package of care. The confusion is reminiscent of the Tuskegee experiment which was raised by participants in the focus groups, and Henrietta Lacks, where concerns were expressed about the way in which Black bodies had been used historically, *'first holding them down, cutting them open'* and *'They have no respect the establishment for our Black bodies'*.

6.18 Randomisation seen in this context, shaped decisions to participate or not in clinical trials. In explaining randomisation, the notion of risk and the safety of the drugs being tested needs to be clearly explained using concrete examples. It also needs to be made clear that when patients agree to participate in a trial, this is the route for them to access newer treatments before they are licensed or have gained regulatory approval. It should also be explained, using concrete examples, that where patients decide not to participate in a clinical trial, that there is absolutely no risk of them not receiving treatment but that the basis for comparison is that the best available current licensed treatment will form the basis for comparison with the trial drug, not the absence of active treatment or a placebo.

6.19 **Concerns about clinical trials:** There was no clear separation in any of the focus groups between those who expressed fears and concerns arising from past experimentation, as well as risk, and the view that clinical trial were important. Overwhelmingly, participants held both views simultaneously. They were aware of Black and Minority Ethnic underrepresentation in clinical trials and put forward a number of reasons, in addition to those already cited, to explain this. There were those who were of the view that the rhythms of work and family life meant people did not have the *'luxury of time to take part'*. There were others who were of the view that researchers generally *'do not want to engage with Black people or reach out to the community'*, although there were avenues to do so, because *'they are not interested in the views of Black people'*. They stated that the community lacked awareness about clinical research and clinical trials, and this was also a reason why Black people were not engaged. The following participants explained it in this way,

> 'When people are doing the research, they walk past you. Unless it's for you to give money, they walk straight past you because they don't want you. They don't think you'll be interested or that the research is for you. The whole world is mixed and therefore we should form the basis of all research' (Female Participant).

'When they are advertising, a lot of the time, they're not advertising to Black people so they might advertise in, it might be through a newspaper and the percentage of Black people reading that newspaper is going to be very small. Sometimes, they don't want Black people to take part in trials or as we found out previously, at the very end of a trial they might think, "Oh, we might need a few Black people to make this more diverse". So um, yeah' (Male Participant).

'I don't think they really want our views, I don't think they want to reach out to us that's why, to a certain degree, most of us don't really know enough because there's been enough Black community workers, even in our city and I suppose if you look in other cities, pastors, churches, we've got various you know, church people. Nobody contacts the church if that's what they wanted to do even if there is a distrust element but they're not even trying' (Female Participant).

6.20 There were others who continually revisited the issue of trust in the medical and research establishment as a means of explaining the underrepresentation. There was a strong view that Black people has been forced or tricked into taking part in research, by a medical and research establishment, that Black people had been disrespected Black people, and that the scientific research community did not represent Black people. The following participants explained it in this way:

'You've got the past history where people were falsely given injections and given syphilis. Then you've got the Henrietta Lacks, so there is all this distrust in history that shapes people's decision and plus they don't really approach us, you know. It's not like you seeing somebody that looks like you, it's somebody that is a White professional or an Asian person but it's not somebody that you relate to' (Female Participant).

'As you were talking, it did make me think of experimentation and then I cast my mind back to history and that Black woman, she had a humungous bottom, but I can't remember her name, but they displayed her body for years, in France, even up until recently and toured with her body because whatever it was about the shape or whatever but again it made me think of that, it's a trust thing' (Female Participant).

'I've turned down a few (clinical trials) to be honest. Just from like the information I was getting off my peers, my family, and obviously how I've educated myself and certain situations that's been coming out and I feel like a lot of people have been under these trials or whatever without their permission. So yea, I feel like sometimes when they ask you, I mean other times they could be putting you under a trial without you even knowing. So, if I ever have opportunity I will always say no, but I always try and look and avoid it' (Male Participant).

6.21 The reference above to the Black woman was to Saartjie (Sara) Baartman, who features prominently in the emerging literature of clinicians, and historians exploring links between colonialism, slavery, and medicine. Sara Baartman was a South African Black woman (circa 1789– 29

December 1815), whose sexual organs were exhibited across Europe as a freak show attraction, under the banner Hottentot. In 1994, President Nelson Mandela made a formal request that she be returned to South Africa to be laid respectfully to rest. This did not happen until 6 March 2002. She is now buried at Hankey in the Eastern Cape Province. While the full details could not always be recalled by participants, this information is freely available on the web and has an impact on participants who, while keenly interested in moving the research agenda forward, are concerned that past history may also inform current clinical research practice.

6.22 It was stated by participants that pharmaceutical companies were interested in research only for profit with *'no real interest in people'* but to *'line pockets rather than for people's benefit*'. As well as being available on the web, there is an emerging and accessible literature on medicine, slavery, and colonialism written by scientists and clinicians who have an interest in the history of medicine. There is a high level of awareness about this literature and much of it can be accessed via popular bookstore chains, particularly in London where the majority of the Black population live. It can also be accessed easily on smart devices. A further reason for underrepresentation also stems from trust in terms of not knowing how data will be kept, how it will be used, and/or whether it will be used *'for or against Black people'*, concerns about *'what the after-effects might be'*, and concerns that clinical trials are not there to improve the health of Black people '*but to use Black people'* because *'they do 'trials on Black people but not for us*'. The fact that experimentation and abuse of Black bodies occurred is incontrovertible and the resources developed need to acknowledge this history openly in order to move the discussion forward. Not to do so positions underrepresentation in a way that is utterly devoid of context and the historical factors and forces that have shaped where we are today, and therefore positions Black people as being unwilling without foundation.

6.23 In one of the focus groups, there were two participants who referred to the various trial stages, stating that people had varied views on clinical trials due to a lack of information about the testing process and a view that clinical trials involved testing completely novel treatments in circumstances where scientists had no idea what the outcome might be:

> 'People tend to get involved in clinical trials at phase three when safety has been met and then they start looking at testing in the human population. So, sometimes people's misunderstanding of clinical trials is that they don't realise that before they are tested in the population, they've gone through, hopefully, quite a few years of study. So I suppose clinical trials take all forms and it's about being informed about clinical trials. People are not informed about clinical trials hence why a lack of the Black population taking part' (Male Participant).

> 'Sometimes, some clinical trials they are only rolled out in a certain part of the area based on funding so for example, my daughter's a diabetic and I know that when they run certain trials, for example, at the moment, she's using artificial pancreas system but that's not rolled out in the country, but she is part of the trial, its already been tested, it already works, but they just want to get the data' (Female Participant).

6.24 **Clinical trials and engaging with the NHS:** All interactions with healthcare professionals are important and clinical trials must be seen in the context of the patient experience along the care pathway. There were focus group participants who talked of all the health care they received as being part of a clinical trial and cited poor experiences when engaging with the NHS. These poor experiences have an effect beyond a specific service. Moreover, poor experiences are compounded by a lack of representation at higher levels in clinical settings, and in the general medical and research literature. The following participants explained it as follows:

> 'I am aware of, may have had treatment but not aware whether the treatment is part of a clinical trial because I wouldn't have known, there's a problem to begin with, you know?' (Male Participant).

> 'I remember years ago I was in my early 20s and the skin on my face suddenly just stopped shedding naturally, so it went Black and cracked so it was almost like scaly, and I remember going to the doctor and a White doctor, and I'd been with him for years but there was a lack of understanding of my skin and even, you look in the medical books and it's still an issue, you don't see yourself in the medical books. And I remember he gave me some steroid cream, made it worse and he called his brother in who was a doctor there also and they literally stood there chatting about it and laughing about it and almost like I wasn't there and looking in the book, and trying to work out what they could treat me with and I remember that I was just like, "they can't help me" and I went to a herbal shop and spoke to them and they said try this oil and my skin was as beautiful as it is today' (Female Participant).

> 'I think when you start dealing with those everyday interactions, then you might get somewhere where people start having the trust to put their, what feels like put their bodies on the line or health in a vulnerable place even if that isn't what it is, building relationships with GPs and medical professionals' (Female Participants).

> 'I would say that when you go to a GP, you are on trial anyway because when you go there, they are looking in the medical book and they say, "we think it is this, let's try this and if that doesn't work, we'll try something else". So technically if we're in an NHS environment, it's still always a trial so to speak anyway' (Female Participant).

6.25 For some focus group participants, clinicians that looked like them engendered more trust because, *'they have our back if you like because we are like them'* and therefore there was seen to be less risk of *'mistreatment'*. At the same time, there were some focus group participants who took the view that the concern was not exclusively whether a doctor was Black or not, albeit agreeing that there should be more Black doctors, but that doctors, wherever they are from, should engage everyone on an equal basis. It was stated that the reason for the lack of engagement of Black people in clinical trials was not because of a problem located in Black people, but a problem located in the institutions, and this translated into the majority of participants stating that they would only take part in a clinical trial if they were gravely ill, and there were no other potentially better options

available to them, *'when there was nothing to lose'*. To the question of more Black doctors, participants summed it up in this way:

> 'That sounds absurd, you've got people in positions. We shouldn't have to say we need African doctors. We've got people in positions who have to reach out to all of us regardless of where they're from, but we do need African doctors or Black doctors, we need them, but we shouldn't do but the problem really is not here, not this side, the problem is that side, the other side' (Male Participant).

> 'Now you want us to trust clinical trials when you've got doctors who wouldn't do what the (Black) doctor did for his mother has done or a doctor that went extra. So it's not us it's the professionals not reaching out to us because they don't want to' (Male Participant).

> 'My main view if the team is probably predominantly White the issue with that is, its gonna sound bad but, I feel that when you have a diverse team, they naturally think of everyone. Like for me, I think what about South Asian people, Latino people what about men, women, different age groups because I have to think like that every day what do people think of me. But I think when you have a team that, maybe is just predominantly middle class White men and maybe one White woman, you might have the woman maybe speak and say OK, but you haven't included any women, but diversity wise it goes very much further than that. So I think that's why there's a problem and its always the afterthought of "Oh my gosh, we've got a week to the deadline, and we need to get someone whose ethnic'. That's what it might be so that's my process of under representation really' (Female Participant).

6.26 In order to move forward in a relationship of trust and understanding, the resources developed as part of a programme of awareness-raising should be targeted at clinicians as well as at the general public. This is important because scientists, doctors, and other healthcare professionals are also part of the general public. They live, as indeed do we all, at a particular historical moment, and may not always understand the wider context in which horrific and unjustifiable experiments have been carried out in the name of science, or the historical links to prestigious institutions. There are numerous resources to support this work through for example, the Wellcome Collection, as well as through the Medical Science Collection at UCL, and a range of other organisations working at the intersection of science, medicine, and society. There must be trust and this is one way of building it. Furthermore, the point cannot be overstated that a clinical trial from the public perspective, is not something set apart, but is inextricably linked with every interaction within the healthcare system. All interactions therefore need to be positive ones. The following comment sums this up aptly:

> 'I am happy to take medication if the doctor says "try this". If my doctor says that and I have a good relationship with my doctor, I'll try something and take it and get back to them and say, "this is how it worked, this is how it didn't work", but there's got to be a trust thing there' (Female Participant).

6.27 **Locating information about clinical trials:** The majority of participants stated that they would not know where to go to get information about clinical trials unless they were directly

approached, although some stated that they had seen posters for recruitment drives on buses, and had seen information on the web by Googling, and through US dramas. The prevailing view however was that unless you are directly involved with healthcare agencies or have had the experience of being in a clinical trial, *'you wouldn't know'*. The question was even posed *'how are they missing us?'* There were some participants who thought that in some cases, information about clinical trials was deliberately withheld from Black people, and also withheld from Black scientists. The suggested concealing of information was also underpinned by what was seen as a reluctance among agencies to engage with Black people because it is regarded as too resource intensive requiring significant time and financial commitment:

> 'Where do you look? Because obviously I think I've seen now and then in a magazine, clinical trial for such and such and that's about it but how do they reach out to certain communities to say there is a trial and we need certain people from a certain community? If you've got a leader in that community, that person can go out and talk to their community but if they don't have nobody, no Black people will go because they don't know. And then it's the trust thing again. It goes back to history, from what they did to us in history, so you look back and you think…I don't know what the younger ones now are thinking' (Male Participant).

> 'So whereabouts are these clinical trials~? Where do you come into contact…could be the reason they haven't done it is because they don't know anything about it' (Male Participant).

> I think we're suspicious anyway, if someone says let's test you, trust is a massive thing
> But people are not given the choice to take part or say yes or no because they don't know anything about them or where to go for them' (Female Participant, Leicester).

> 'We are not hard reach. We live in the same town. It's those people not working hard enough to reach the community' (Male Participant).

6.28 The focus group participants on the whole associated information about clinical trials exclusively with CTIMP trials, that is, the ingestion of medicine, or the taking of blood for example, or body parts, and essentially as being about *'white coats'*. As already explained above, when the discussion turned to Non-CTIMP trials, very few participants had prior knowledge of them, and some expressed surprise. It was then that their responses changed, in some instances, from categorically not wanting to take part, to wanting to learn more, and to receive feedback. The following remark illustrates this:

> 'If it was more physical without taking medication I probably would try but the jury is out on it, and I think the lady hit the nail on the head. It's trust from our community again because you've got to have people in your own community coming to you because what I find as well, there's so many things they talk about Black people, but you never know the result, and does it get filed? What's been done? Because you never hear what's been done so why are they studying us so hard, and you don't get no result? Is it just a tick sheet it's filed away in the cupboard and that's it?' (Male Participant).

6.29 There is a need to move beyond the notion of the clinical trial that is in the popular imagination, and to inform people of the much broader spectrum. It was suggested that this needs to begin at school, that communication needs to be clear, and that people taking part in clinical trials should receive feedback to avoid fuelling suspicion, leaving people, and particularly patients feeling as if they have been treated casually and discarded once the trial ends.

6.30 All of the focus group participants said that they would be interested in more information about clinical trials, and that it should be readily available. Some of the focus group participants stated that the patient information sheets they had seen contained too much information to absorb, and that they needed to be condensed dealing with a cancer diagnosis, and reams of information, was too much. It was suggested that information about clinical trials should be available in local libraries, on all social media platforms, through streaming, visually through videos, and via audio through podcasts, as well as messages and information via What's App groups. An important vehicle was seen as the Black church on 'Saturday's, Sunday's or on Wednesday evenings during midweek prayer. The church was seen as a readily available audience for engaging with the wider community, and for discussions about clinical trials becoming part of the norm. It is clear that one approach will not suit everyone as is the case for the population generally, and there is a need to adopt different approaches. Nonetheless, there are specific Black networks that professionals, can access in order to do this.

6.31 The information needs to be channelled through avenues that are relevant, and its visual content and images made relevant. Indeed, focus group participants said clinical information does not reflect Black people and how Black people look in real life. It was suggested that there is also a need for health events held in local community venues, and deliberative approaches such as focus groups. In fact, attendance, and participation at the focus groups for this project shows that communities will engage where trusted people are doing the recruiting, and even those who are reticent will participate. Community radio it was suggested is a good place to transmit information, as well as community educators and individual pastors in faith organisations. There is no single organisation that can do this, but forming coalitions of organisations as this project has done with UCL, B'Me and other community organisations is the model that has made the production of this report, and other reports, possible. It offers the opportunity to pool experience, working across professional and organisational boundaries, enabling us to look beyond our immediate horizons, and to challenge the assumptions we take for granted. The importance of this is encapsulated in the following remarks:

> 'Personally, I'd like it to be written, as much information as possible. If it was written like an email, it could have a video attachment as well as an explanation, that would be handy' (Female Participant).

> 'You have to go through the trusted people, and they can help you break those barriers, involve the local community and those in high esteem like the religious leaders' (Male Participant).

'Maybe the researchers looking for this information, they're not aware or they don't know who to approach, they call it hard to reach groups and it's not necessarily hard to reach because they don't know how to engage with certain types of people so the engagement side of it' (Male Participant).

'I would want more information, yes. I don't know if I would want it written because if I wanted to ask any questions, I'd like the answers to them so I could ask questions regarding it' (Female Participant).

'I would like more information on clinical trials because as you said, it doesn't just involve medication but a wide range of things so if I was to get that information I'd like it written so I get the full information and then possibly a video, if there's a video attachment via email, as long as I get more information and more in depth information as well, I'd be interested' (Female Participant).

I think we have a responsibility to the next generation to get the information so that when we're no longer here, they're questioning, they're learning. So, our sons daughters need to be part of the discussion, not only us our 60s and 70's. They need to be having this discussion because we are now developing own health problems' (Male Participant).

Views of Healthcare Professionals

6.32 The information from the interviews with healthcare professionals is set out under the following classification headings:

a) Ideas of race and ethnicity in clinical trials and biological research.

b) Underrepresentation in clinical trials.

c) Access to information.

d) Making patient information more accessible.

6.33 **Ideas of race and ethnicity in clinical trials and biological research:** The healthcare professionals interviewed as set out in Table 4.1 above, stressed the importance of having *'real world data'* in oncology, and within that, the importance of carrying out clinical trials representative of the entire population. It was seen as important from an ethical perspective, and crucially, in terms of being able to extrapolate data around the prevalence of diseases in different parts of the world. The Director of CRUK & UCL Cancer Trials Centre, put it in this way:

'There is an assumption in some disorders that genetic make-up makes you respond differently which is related to ancestry biological adaptations and it could be differential outcomes because of people's adherence to drugs. There might be something there.' (Director Cancer Research UK & UCL Cancer Trials Centre).

6.34 **Underrepresentation in clinical trials:** The healthcare professionals were aware of the significant under representation of visible Black and Minority Ethnic patients in clinical trials. It was

pointed out too that this includes early and late phase trials, and for NHS Trusts providing services in geographical locations where there is significant ethnic diversity. The reasons for this are seen as multifactorial, among which is the view that visible minorities are not always approached by their consultants, as well as patients themselves being unaware of clinical trials that are relevant to them. It was suggested, by contrast, patients who are from Black and Minority Ethnic groups may not be part of networks such as Facebook forums and What's App groups that have been set up specifically to advocate patients' behalf. As a result, those who are engaged will be more in the know. In circumstances where Black and Minority Ethnic patients are aware of social forums, they may still not be accessible to them due to language and/or cultural barriers. These barriers were seen as being linked to other potential and inherent biases, where clinicians might not include Black and Minority Ethnic patients because of perceived language or other access issues. Indeed, clinical trials can essentially be seen as a mirror of barriers to healthcare more generally as the following remarks make clear:

> 'One of the major barriers as far as I am aware and one of the key problems, is to reach out to the communities, to be able, in the first place, to provide them with access to information. Even before research, there are issues in accessing care and I see this in the same way'. (Education Lead for the Cancer Trials Centre).

> 'We see in many studies that there is a low uptake, and ours particularly, because they tend to be early phase experimental drugs of combinations that don't exist, rather than Phase three trials. Many early Phase trials don't go anywhere, but many have treatment benefits and effects and there is usually a lack of participation because the way they are explained takes more time' (Director Cancer Research UK & UCL Cancer Trials Centre).

6.35 In circumstances where the number of patients on a clinical trial is high, it can also be a barrier to widening participation as there is no incentive to diversify recruitment. Added to this is the further disincentive of additional resources that will be required to improve recruitment practice, weighed against continuing with existing practice that delivers the numbers. It was pointed out that principal investigators may not consider underrepresentation as an issue because they may not actually be conscious of it. The following remark illustrates these points and refers to the Altogether haematology clinical trial which has approximately 200 people enrolled in it in the UK, and a further 1,000 people across the EU. However, while date on aged, weight, height and sex are collected, there are no data collected on ethnicity:

> 'There is different access to recruitment and there are different media for different groups and these things need to be considered and the demographic for different populations. From what I know, trials are not diverse in terms of Principal Investigators and there are blinders in that sense because as White people, they are not considering there are any differences. How can you fix something if you don't know what is going on? Now we are starting to collect data for trials but only age, weight, height, and sex' (Cancer Trial Centre Data Manager).

6.36 Taking part in a clinical trial it was said, requires time, commitment, flexibility, and resources. It requires for example, people attending clinic each week, and in circumstances where travel costs are not refunded, the costs of travel can be prohibitive for those not living close to a trial centre. This is in addition to not being *'in the know'* where clinical trials are concerned.

6.37 **Access to information:** The team carrying out the recruitment to clinical trials explained that patients are required to complete lengthy recruitment information sheets, and that these are not always available in an accessible format nor in the required format. As an illustration, the example was given of an Arabic speaking patient the oncology team wanted to put forward for a clinical trial. The information was not available in Arabic, so the team spent three weeks arranging for the document to be translated, after which, the patient turned out to be ineligible for the trial. In fact, not having patient information sheets in the required or accessible format was highlighted as a recurrent issue and because of this, the approach adopted was always reactive rather than proactive. The clinicians and clinical trial managers interviewed made it clear that not everyone will want to or will be able to read pages and pages of detailed clinical trial information. This is compounded at a time when patients may not be psychologically in a place where they can give the level of focus required while dealing with a devastating diagnosis, or at a time when they may be running out of options.

6.38 **Making patient information more accessible:** The healthcare professionals made clear that there is no one size that fits all in terms of patient information. There are patients who may welcome content in a visual or audio format, and others who will prefer written information. In cases where English is not their principal language, patients may require all formats in their parent tongue. The challenge in recruitment is making information that is often couched in dry, academic terms, accessible. The Communications Manager explained that a failure to take account of diversity, from the outset is a barrier that skews the population towards those *'more in the know'*. Referring to a lung cancer screening study among patients. It was explained in this way:

> 'When the trials are set up what they need to do is explain it to the people in terms of making information accessible. A lot of information is generated, but it is not always generated in the most user-friendly way when it comes to taking part in trials. We are now working on a follow up to the lung cancer screening study in London which involves people diagnosed and taking some of their tumour sample and getting them analysed. The study was a great success but if you look when it was set up, the patient information was a Black and white Word document, and even though it went on to be a success and was expanded, it was not good in reaching the people it should have reached. So, this time around, they have gone to great lengths to try and produce easy to read booklets and have put together a video for it too and they ensure while the research is taking place, they have the means to update people on how things are doing' (Communications Manager).

6.39 There is an urgent need to move away from an exclusive reliance on complicated paper formats, towards presenting written, visual, or audio information in, a clear accessible way so that it can be understood by as many people as possible. The point was made that from an equality and diversity perspective, raising the bar on accessible clinical trial information will enhance accessibility

for a range of groups currently facing barriers including sight impaired, and d/Deaf patients, and will include patients from those groups who are Black African and Black Caribbean, as well as other groups. Giving someone a lengthy document while at the same time, dealing with a diagnosis underlines the need for clear concise information. A barrier to clearer information is seen to relate particularly to clinical trials run by drug companies and their concern with the avoidance of litigation and ensuring the relevant boxes are ticked, rather than information starting from the perspective of the information needs and requirements of patients.

7. Conclusions, synthesis, and recommendations

7.1 This inquiry examined the reasons for the underrepresentation of Black African and Black Caribbean people in clinical trials and early phase trials, using a mixture of focus groups, a survey, and interviews with healthcare professionals. There was correspondence between the views of focus group participants, survey respondents, and healthcare professionals on the multifactorial issues relating to clinical trials, with a lack of participation centring on reluctance due to fears arising from past historical abuses, a lack of trust in the scientific fraternity, being keen to participate but not being asked to do so, complicated patient information, a lack of clarity around what a clinical trial is, and a lack of time due to the rhythms of family life. While the study did not explore this specifically, these multifactorial issues may also be the case for segments within the population generally.

7.2 There is a need for a greater understanding of race as a social construct, not a biological category, and how it is important in understanding inequalities in health and health outcomes. These inequalities are based on shared social attributes and experiences and shared connection by geographic ancestry, not race. There seems to be a view that Black bodies are somehow different, and this needs to be addressed given that the 100,000 Genomes project and other research has shown that we share 99.9% of our genetics, that there is more diversity within groups defined using the social construct of race than across them, and that we share a common humanity.

a) An interactive event should be organised engaging voluntary and community sector patient organisations clinicians, principal investigators, data managers, medical historians, and academics. This should mark the start of a continuing dialogue to inform the development of resources.

b) The concept of cancer care should be explained clearly to patients, given that many cancers have high survival rates and are curable.

c) Work with Black and Minority Ethnic groups to develop materials/information to clearly explain early phase trials, why they are needed, how patients might benefit, and to provide assurance that such patients are very carefully looked after.

d) Select some prime examples of early phase trials, what they showed and how they later became standard of care and changed clinical practice.

e) Use clear and easy-to-read language that simplifies the scientific aspects of these trials given that patient information sheets are complex and off-putting.

f) Drawing on current research findings and data from the 100,000 Genomes Project, clear and concise information in a range of accessible formats should be put together on the historical evolution of race and ethnicity as a social construct, and why it is important in adding to our understanding of health disparities, health inequalities, and recruitment patterns to clinical trials.

g) There is a need to think about the long-term relevance of the socially constructed categories being used in clinical trial recruitment, and how they will change as the population changes, particularly given that, since 2002, the fastest growing ethnic category, is the Mixed group.

h) A constructive dialogue is needed, alongside an acknowledgement of historical abuses that have taken place. There is an existing and emerging literature that provides documented evidence of a factually based mistrust.

i) Resources should be developed to explain the various kinds of clinical trial, using concrete examples, and a clear explanation of what the various clinical trial phases mean. This should include an explanation of the difference between CTIMP and non-CTIMP trials.

j) The resources should clearly explain the concept of randomisation, and what this means in terms of access to new therapies, patient safety, and clinical trial recruitment. It should also be explained that being randomised does not mean patients are given no treatment.

k) Short videos should be produced and disseminated via social media, taking account of diverse communication styles, and health forums developed where information on clinical trials and clinical research can be disseminated, and questions answered.

l) This report should be disseminated to organisations with key influence such as National Institute for Health and Care Excellence (NICE), the ICR (Institute for Cancer Research), the Wellcome Trust, NHS Trusts, and other public health and voluntary sector agencies.

m) All of the participants that took part in the inquiry should be given a copy of this report, and feedback given on how their contributions have helped to shape it, its recommendations, and how it will help to shape clinical trials agenda going forward.

n) More engagement is needed with the African community to find out their views as this population, though having a younger age profile than the African Caribbean population, is ageing.