

**June 2023**

# **CLINICAL TRIALS, TRUST & MINORITY GROUPS**



**SökerData Ltd**



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# FOUNDER'S MESSAGE

Today marks a significant milestone in our journey towards a future where trust and hope intertwine in the realm of healthcare. I'm filled with both gratitude and determination, as we launch our research on community perceptions and trust regarding clinical trials, with a specific focus on Black and ethnic minority groups.

In this pivotal endeavor, we embark on a path that resonates deeply with the knowledge that for far too long, disparities in healthcare access and outcomes have persisted, and it is time we confront them head-on.

When we think of medical research, we know that trust is the lifeblood that courses through our veins. It is the foundation upon which we build bridges of hope, connecting scientists and communities, caregivers and patients. Yet, we cannot ignore the painful truth that trust has been eroded in certain communities, especially among our Black and ethnic minority communities.

Each of us, in our own unique way, carries within us the imprints of experiences that shape our perceptions. We have witnessed skepticism, heard whispers of uncertainty, and felt the tremors of doubt. The trust between communities and the medical world has been tested, strained, and at times, shattered.

This research is our effort to understand the fears, hopes, and aspirations that swirl within our communities. We strive to listen, truly listen, to the whispers of those who have felt forgotten and overlooked. We endeavour to lend a voice to their concerns, fears, and doubts. In doing so, we hope to rekindle the flickering flames of trust.

# FOUNDER'S MESSAGE

We will hold space for the frustration, the skepticism, and the valid concerns that have taken root in the hearts of those who have felt excluded, marginalised and betrayed. For only through genuine understanding can we begin to rebuild what has been fractured; remembering that behind every statistic, every data point, lies a life lived, and a story told.

As we unpack the findings of our research, let us embrace the truth it reveals, regardless of its complexities. Let us foster open dialogue and constructive discourse, recognising that it is through the amalgamation of diverse perspectives that we uncover the most profound insights. And let us remember that the transformational change we seek requires not only the expertise of scientists and researchers but the collective will and collaboration of communities, patients, and advocates alike.

We have the opportunity to create a new narrative where Black and ethnic minority communities no longer fear, but embrace the possibilities that clinical trials hold. Together, we can forge a path towards equal representation, where every voice is heard, every concern is addressed, and every life matters.

I am profoundly grateful for each and every one of you who has joined us on this extraordinary journey.

With boundless hope and enthusiasm,

Dr. Elsa Zekeng  
Founder



# EXECUTIVE SUMMARY

The COVID-19 pandemic has challenged several ways of working including how we conduct research, who we include in the process, how we ensure that communication is inclusive and engagement is sustained. This has been even more crucial with minority ethnic groups who were disproportionately affected by the COVID-19 pandemic. This group however, has been historically easy to ignore and have developed long standing trust issues with companies and institutions. This was evident during the pandemic with the vaccine rollout with vaccine hesitancy.

The insights from this study show that the patterns seen during the pandemic are not isolated. These can be observed in everyday access to healthcare and certainly clinical trial engagement. Some of the reasons for this are highlighted below. It is worth noting that these are steeped in decades of negative lived experience with medical institutions, pharmaceutical companies and even with Governments on an individual level and collectively on a community-wide level. The responsibility remains with these institutions and companies to rebuild engagement and trust with these specific communities.

**01** **Decrease in Trust**  
We are leaving the pandemic with less trust in science and its processes than we did entering the pandemic. This affects access to everyday healthcare as well as clinical trial participation.

**02** **Lack of Information around Clinical Trials**  
Communities are concerned about their safety and adverse events when thinking about clinical trial participation. A key concern is that they will not be supported if they had adverse reactions from clinical trial participation in the future.

# EXECUTIVE SUMMARY

**03**

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## Inconsistent Community Engagement

Communities expressed that engagement was inconsistent when it concerned issues that were specific to their community e.g., maternal death.

While the road ahead may be long, we believe using creative ways to continuously engage with these communities is key to rebuilding trust and representation in data used for the development of safer novel therapies, vaccines, treatments and devices.

# **INTRODUCTION**

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As the WHO announced the end of the COVID-19 pandemic, on May 5th, 2023, it was a relief to some and to others, life was 'back to normal'. Businesses were experimenting with policies around days to return to work in an office and healthcare systems were addressing patient backlogs, at an attempt to address the impact of the pandemic.

Several feelings bubbled to the surface over the course of the pandemic. Some may argue that these issues have always been present but there had been a lack of courage and momentum to discuss these issues on a national scale.

Examples of some of these issues include employee's preference to work from home to save time on commuting (1), healthcare workers non-satisfaction with their rewards (2), and levels of mistrust between minority groups (women, Black and ethnic minorities) and healthcare systems (3).

These are all sentiments we have perhaps heard in passing from families and friends but we may have not fully grasped the weight of these feelings. Over the last 3 years, we have come face to face with these realities in various forms and have been forced to reckon with them individually, as a community and on a systemic level.

The results from this research and therefore this article will focus on the levels of mistrust between minority groups (women, Black and ethnic minorities) and healthcare systems.

# CONTEXT

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As the COVID-19 pandemic unfolded, we witnessed the statistics highlighting the higher risk Black and ethnic minority groups had to contract COVID-19 infection (4). This led to an increase in engagement of these communities upon the roll-out of the vaccine. However, we observed a lower vaccine uptake in these groups as we heard the terminology 'vaccine hesitancy' used often (5). Organisations sought to understand the reason behind this, and amongst many reasons, mistrust in healthcare systems bubbled up to the surface.

As engagement with these communities on the vaccine uptake ensued, several questions around the ethnic makeup of participants in COVID-19 clinical trials began to surface. It is with this in mind that the SökerData team set out to conduct a research study in honour of world clinical trials day to understand Black and ethnic minority community perceptions in the UK on engagement with clinical trials as well as the effects of COVID-19 on clinical trial engagement.

The research was carried out over a 5-week period, engaging members of Black and ethnic minority communities across ages and gender. In the end, 3 focus groups were held, participants were equally distributed across age from 18-60 and included 45% male alongside 55% female. 32.4% identified as Black African/Black British, 13.6% as Black Caribbean, 21.6% as Asian British, 24% as White British and 8.1% as other ethnic group. Overall, 67.6% of participants identified as Black and Ethnic Minority.

The research started by exploring perceptions around COVID-19. The insights highlighted key factors which could be considered as the tipping point into a decrease in trust between these communities and health systems during the COVID-19 pandemic. This includes trust in health systems delivering primary care (e.g., the NHS) as well as organisations developing strategy around delivery of care (e.g., Government). Some of these factors are highlighted below in the COVID-19 related research insights.



# TRUST TIPPING POINT DURING COVID-19

**01**

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## Communication & Engagement

84% of participants stated communication was 'confusing', constantly 'contradictory' and further described it as 'fragmented and disconnected' with feelings of anxiety leading to mistrust

**02**

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## Accessibility to Routine Treatment

56% of women stated a main challenge they faced was inaccessibility to a primary care giver

**03**

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## Government Officials' behaviour

'What brought it home was when Boris Johnson caught COVID-19 and they made a big deal about it. We realised that they really do not know what is going on. They were having a party, clapping their hands, it all became a bit of a pantomime.'

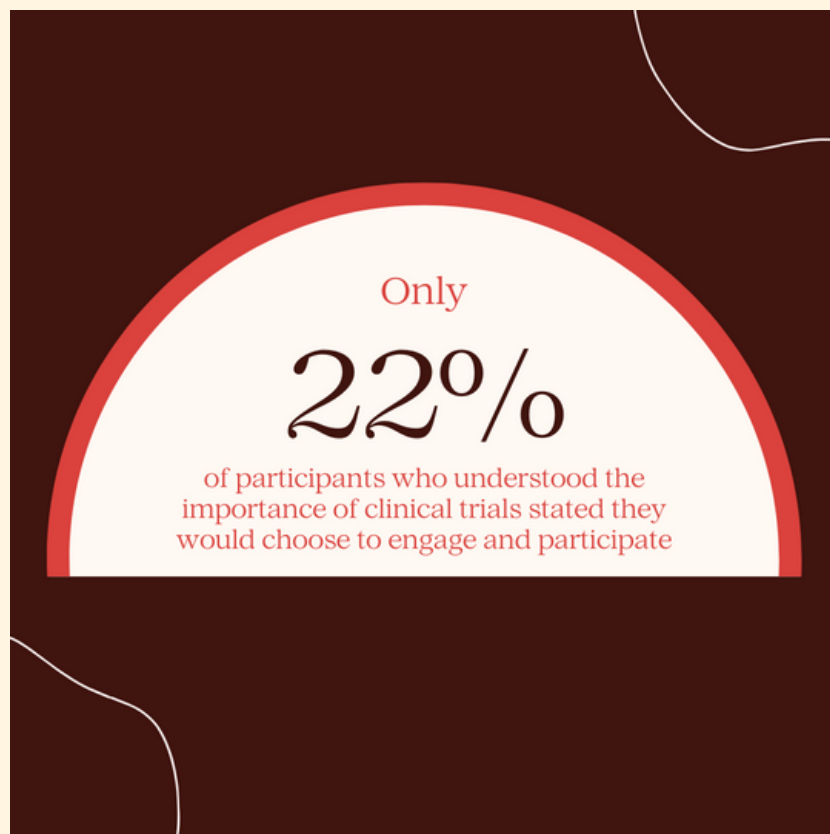
– White female participant

**These factors led to a decrease in Trust in the Government as participants stated a 26% decrease in trust in the Government compared to pre-pandemic levels**

# CLINICAL TRIAL RELATED INSIGHTS

Among many reasons for 'vaccine hesitancy' on the COVID-19 vaccine in Black and ethnic minority communities, a key question asked by many was 'what was the ethnic diversity inclusion in the COVID-19 vaccine clinical trial'. At the time of the vaccine rollout, this data seemed opaque to some and insufficient to others.

To this end, this research went on to explore participants understanding of clinical trials, their likelihood to participate in clinical trials, likelihood of engagement and reasons for engagement or non-engagement. After explaining the importance of clinical trials alongside the reasons why they are conducted, participants were asked if they understood the importance of clinical trials and if they would participate in clinical trials.



Participants were asked to select from a list of 7 reasons that would hinder their participation with clinical trials. The most selected reasons are highlighted below;

## Key reservations with engaging in clinical trials

### 50% stated a lack of knowledge around clinical trials

*'I do understand the need for clinical trials however, I am uncertain about the adverse effects trials may have. This is my biggest fear of taking part'*  
- Black, female participant

### 27.8% stated challenges with access to trials

*'I may still not participate in trials, however, access to trials is a key factor. Usually, clinical trials happen in big cities and transport is not reimbursed.'* - Asian female participant

*Another participant chimed in with similar concerns stating, 'I may participate but I would require further support with childcare and that may not happen.'* - White female participant

### 16.7% were sceptic around companies' attitudes & beliefs for carrying out clinical trials

*It will depend on the motives of company running the trial. If it is a non-profit, I will be happy to do that for example with insulin. However, if it is solely for pharma's profit, I'll review their motives and most likely wouldn't participate.'* - Black, male participant

### 16.7% stated a lack of trust

*'Young people do not get taken seriously because they are young and told 'you're not old enough for this condition. A group that are gaslighted by medical professionals wouldn't want to get involved in clinical trials.'* - Asian, female participant

### 5.57% stated logistical and practical issues

*'I feel like clinical trials are impractical as they require a lot of follow up sessions'* - Black, female participant

Another key theme that was evident across focus groups were the concerns around safety and adverse events. Participants expressed concerns on whether their personal health will be prioritised over the success of the clinical trial. Others highlighted a need for more communication through post, TV, social media, emails etc. Emphasis was made on pharmacovigilance monitoring of side effects and transparency in the availability of results to ensure people 'can have the full picture.'

A trend that seemed to appear was that participants from a White demographic were concerned about logistics and personal inconveniences while participants from Black and Ethnic minority communities were concerned about trust in motives, safety and adverse events. That being said, insufficient data was collected to emphatically state this.

This highlights some of the main concerns these communities have when considering participation in clinical trials. It also suggests a gap in communication around clinical trials from pharmaceutical, biotech companies, CROs and/or generally clinical trial sponsors.

Participants went on to suggest strategies and ways to increase engagement and participation in clinical trials from communities that are easy to ignore. Unsurprisingly, the most common suggestion was education in a tailored format that included deeper insights into safety and adverse effects detailing what participants can expect and/or sharing what other participants have experienced. While some of the participants stated they understood this may be challenging due to confidentiality, they still maintained that creative ways can be developed to meet members of the community halfway.

These insights were shared at an event; Special dialogue: Inclusion of data from minority groups in clinical trials. This event was in honour of world clinical trials day 2023 and expert opinions were sought on the lay of the land on community engagements post COVID-19 and what strategies should be considered in rebuilding this engagement. This event was chaired by Dr. Elsa Zekeng, Founder of SökerData Ltd.

# EXPERT OPINION

In honour of world clinical trials day 2023, a virtual event with expert panels representing the private sector, public sector, primary care delivery, community champions and subject matter experts was held.

In continuation with the community research, their opinions on the research insights gathered were sought and a discussion ensued on how to shape a more inclusive world when taking data from minority groups into consideration in clinical trials and every day healthcare

SÖKERDATA

## Special Dialogue: Inclusion of Data from Minority Groups in Clinical Trials

In Honour of World Clinical Trials Day



Panelist

### Dr. Syra Madad

Epidemiologist in Infectious Diseases and Special Pathogens, NYC Hospital



Panelist

### Dr. Virginia Acha

Associate VP, Global Regulatory Policy, MSD



Panelist

### Dr. Sarah Tade

NHS Primary Care Dr, Health Equity Advocate



Panelist

### Emma Lowe

Head of Research Policy, Department of Health and Social Care



Panelist

### Lee Chambers

Founder, Essentialise Workplace Wellbeing



Dr. Madad highlighted that the research insights are currently similar with what is being observed in the USA. She stated that the lack of trust in science is glaring and we are leaving the pandemic with less trust in science than when we entered the pandemic. Given this context, the results of the study do not surprise her. However, as we talk about pandemic preparedness, to ensure that we are all ready for the next outbreak, it is important that we have a much better communication strategy from the message and messaging standpoint. This should be reflected in communication around clinical trials as we develop new therapies and vaccines.

### **Dr. Syra Madad**

Pathogen Preparedness Expert, Epidemiologist in infectious disease, NYC

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Emma Lowe reflected on the fact that pandemic preparedness should be baked into how we do things normally. She stated that in the pandemic, we reaped the positive benefits of 'normal' ways of working. For example, we could conduct clinical trials and deploy vaccines speedily. However, the negative aspects around specific community engagement were also highlighted for example, vaccine hesitancy. She stated she was not surprised about the decrease in trust but was encouraged that people will be open to participating. However, while we talk about pandemic preparedness, we need to ensure that these new ways of working become the everyday 'norm' in access to healthcare.

### **Emma Lowe**

Head of research policy, Clinical Research and Growth at Department of Health and Social Care, UK

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Dr. Tade stated that she was not surprised at the data, specifically the percentage of participants who will not participate in clinical trials. However, for context, she shared that this is both as a result of historical and present mistrust. She cited examples such as the Tuskegee experiment in the USA and more recently the Pfizer scandal in Nigeria with Meningitis. This brings to question why these institutions should be trusted. She went on to highlight that mistrust is not isolated to healthcare, especially when we look across the pillars of society; education, policing, social care etc. Constantly seeing inequalities in other pillars of society, will inevitably be reflected in healthcare as a result of social structures that discriminate. Nonetheless, she was encouraged by the willingness to carry out this research and have these conversations as it is a step in the right direction to develop equitable strategies.

### **Dr. Sarah Tade**

NHS GP trainee, Health equality advocate, NHS Race & Health Observatory



Lee Chambers followed on a similar thread to Dr. Tade highlighting that systemic inequities that exist within all institutions and pillars of society collaborate to create an atmosphere of distrust that is difficult to address in isolation. Collaboration across different facets and factors can bring about a change but from a community perspective, people feel like they have had promises broken. They feel like the world is changing and maybe becoming more equitable. However, they do not see the action behind some of the words. He concluded with that the data doesn't surprise him but there needs to be action taken behind the promises.

### **Lee Chambers**

Award winning founder, Essentialise Wellbeing

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Last and certainly not the least, Dr. Acha followed on from Lee stating that once you have lost community trust, it is a long road back. She restated the Nigerian example, Dr. Tade highlighted stating that this happened in the late 90s; however, that is what people remember. Unfortunately, communities seem to be unaware of what guidelines regulators have implemented since then limiting chances of a reoccurrence. She went on to highlight the work the FDA is currently doing on clinical trial inclusion requirements; reporting requirements that ensure representation in clinical trials. For their company [MSD], they currently have 50% of participants from previously neglected communities participating in clinical trials and this is progress. However, little is known about these developments as there is too much information that is not curated or substantiated from various sources. In communities, sponsors can make a bigger effort in engagement, e.g., in COVID-19, they deployed mobile labs that went out to engage with communities. This is one example that doesn't solve the whole trust challenge, but it can certainly build momentum.

### **Dr. Virginia Acha**

Associate Vice President - Global Regulatory Policy, MSD

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The results from the research and the viewpoints from the experts within this field are aligned as it is clear that we have a long way to go to build trust between underrepresented and marginalised communities and institutions at the helm of scientific innovation, clinical trial development, and healthcare systems at large.

More importantly, engaging with communities and patients in a way that is akin to 'everyday healthcare' is crucial in preparation for the bigger moments such as epidemics, outbreaks, clinical trials and the event of another pandemic. At SökerData, we are committed to this cause.

# SÖKERDATA'S COMMITMENT

**01**

## Engaging with Communities & Patients

We are committed to engaging with communities and patients to increase education and build trust while placing their concerns at the centre of the decision making process; thereby, ensuring patient-centricity.

**02**

## Supporting Companies and Organisations

We are committed to supporting pharmaceutical companies, biotech, CROs, clinical trial sponsors and Governments as well as Non-Governmental organisations to engage with these communities in a sustainable manner that increases trust.

**03**

## Bridging the Gap between these Stakeholders

Our role is to bridge the gap between these communities and institutions, with the goal of increasing trust, increasing engagement and accelerating the inclusion of data (molecular data and lived experiences) from these communities in clinical trials.



# ACKNOWLEDGEMENTS

We would like to thank:

- Our expert panel for their time and for sharing their insights
- Cheyenne Ritfeld, acting as project co-ordinator through the conception of this research to execution of the event
- Dr. Eldrid Herrington, for her support as advisor and brainstorming prowess
- Our focus group participants for their time. Without them, this research would not be possible

**We thank you for your continued support in our efforts to increase representation of data from minority groups in clinical trials**

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