May 2024

Addressing inequalities in clinical trials

National Voices

Contents

Introduction

The lack of diversity of participants in clinical trials has long been recognised as a significant challenge. While the data is imperfect, it is widely accepted that the majority of trial participants are white, British and affluent; this is not representative of the diverse range of people affected by the conditions for which medications and procedures are usually being trialled. It is also recognised that there are other aspects of exclusion from clinical trials including geographical and financial exclusion and that these are based on both health status and practical circumstances.

Fortunately, there is growing interest in, and commitment to addressing these barriers among pharmaceutical companies, researchers, regulators, patient groups and others. And work is underway in a number of organisations to identify effective ways to improve the representativeness of clinical and research participants and to ensure that more people have the opportunity to participate in clinical and research trials.

To inform this work, National Voices undertook a consultation among its members and Lived Experience Partners during February and March 2024, to identify key barriers to participation in clinical and research trials and potential ways to address these.

This report sets out the key insights identified through this work and sets out some areas for future action based on these. It is set out in three sections; Barriers to participation in clinical trials; Potential solutions; and Taking action.

Methods

- National Voices consulted with its members and with people with lived experience through workshops and interviews conducted during February and March 2024
- 18 people attended a National Voices online workshop – a mixture of professionals working in health charities and people with lived experience of long term health conditions and/or disability

- A further five people were consulted individually in follow up conversations
- Of the discussion participants, five had been involved in a clinical trial; 15 had not been involved in a clinical trial; one had been involved as a researcher but not a participant and two did not know or did not provide information
- Of those who offered more information about their participation:
    - One had been involved in a clinic trial with diabetes and cardiovascular
    - One had been involved in clinical trials around HIV
    - One had been involved in an implementation trial

Part I - Barriers to participation in clinical trials

In our discussions we acknowledged that the barriers to participation in clinical trials were different for different people, in different places, with different conditions and in different personal circumstances, *and* in relation to different trials.

The dynamics of exclusion, how they impact and the extent to which they matter, will differ depending on what is being trialled, by whom and when.

However, we identified three overarching themes in relation to the ways in which different groups could find themselves excluded from opportunities to participate in clinical and research trials, which were common across groups and which arose in relation to a range of different trials. These barriers were: attitudinal; communication; and practical.

Attitudinal barriers

Attitudinal, emotional and psychological barriers to participation can particularly affect different groups within the population. It affects their interest in taking part in research when asked, and can mean they do not feel eligible to take part in trials, or that the trial is really going to benefit them and their communities.

Fear and mistrust

Participants highlighted that many people from minoritised communities are less likely to participate in clinical trials, did not trust medical professionals and had a range of fears about the potential impacts of getting involved in clinical trials which stemmed from issues such as stigma, poor translation or past experiences of racism.

For example, participants highlighted the very recent (in living memory) experience of some minoritised ethnic groups of racist practice in clinical trials. This included the experiences of Roma people during the Holocaust, and the

Tuskegee Syphilis Study in the USA. These participants were clear that these lived experiences created a significant climate of mistrust among these communities which required focused and proactive work to address.

Concerns around confidentiality were also noted by several participants as well as fear that the trial may impact their ongoing treatment or wider health.

"Stigma around mental health can be a huge barrier as well, both in terms of assumptions about capacity that I've just mentioned, but also people's anxieties about wanting to take part in a trial that's related to mental health."

"There's a real lack of trust of medical professionals and establishments within some parts of the trans community. Hence the need for someone to almost say 'we've vetted [the professional] and they're ok'."

"Basically, there was no interpreting. The husband knew a little bit of English… but very little. And on the day they did not have an interpreter and the doctor tried to explain things, but they've heard the word 'testing'… and they said 'No'. [They told me] 'we're very scared, they want to test something on us. I don't want people to test something on me.'"

"There's often a lot of anxieties around how the information provided on clinical trials is going to be used as well and some lack of trust around that for completely understandable and valid reasons."

"They feel that filling surveys and doing research could either make their mental health worse or it could affect their care, their treatment that they're already going through."

"There is a genuine concern about clinical trials and about trials in general from the Roma people because it's still in our kind of living memory of tests being done on us without our consent for various reasons. We've seen, for example…cases as early as 2004, 2007 with Roma women being forcibly sterilised in Czech Republic, Slovakia. So, although some Roma are aware that the trials are happening… there is that huge distrust of things being done... in a respectful way with respecting people's rights and so on."

Failure to signal inclusion

Participants noted that unless trials proactively communicated their inclusivity, people from marginalised and underserved communities would be very likely to self-select out of these trials. Simply publicising trials would not be enough to support a diverse range of participants to get involved. Participants told us that awareness was particularly low among some groups within the population and that some people assumed they would not be eligible for trials.

"Unless research says it's for people who are trans then people assume it's not for them. I imagine this applies to lots of different groups."

"Specifying 'we particularly encourage people from [x, y, z groups] to take part; The representation shown in any literature or adverts, do people see themselves represented? Inclusive forms - would a non-binary person feel able to fill in the form? Sharing requests through trusted organisations within the community, co-production and PPI - helps make sure that the research is sensitive to people's needs and info has FAQs answering the concerns from specific communities."

"A big barrier that we've noticed is self-selection bias. We run focus groups with people who have lung conditions but it's almost always full of white middle-class women and we believe it's due to ethnic minorities and people living in deprived communities not feeling that it's something that is relevant to them."

Failure to design trials with diverse communities

Participants highlighted that one of the reasons that trials were not able to attract diverse participants was because they had not been designed to address questions of interest to these communities, and to operate in ways which facilitated their engagement. This was underpinned by a lack of capacity for, and commitment to, co-production with communities across pharmaceutical companies and within the research profession.

"Whilst the Government has recognised the need for a people-centred approach in some of their policy documents that they've been putting out recently and tasked NIHR with delivering training for that…[but] at the moment trials [do not have] the expertise to build them in an inclusive and people centred way and fundamentally if they're not being built with that

understanding at the forefront, then they're not going to be able to reach out to those communities that they need to."

"They need to understand co-production and engagement processes and have those within their teams."

"There has to be co-production, [and] in terms of research options that isn't happening."

Lack of feedback and results

Another key issue was the failure to ensure that people who participated in clinical trials were updated on what happened as a result of the trial, a process which some felt would go some way to overcome attitudinal barriers. Participants also highlighted that where more diverse pools of participants were recruited, information on any differences observed between different groups was not reported at the end of trials.

Our participants were clear that this lack of feedback impacted people's motivation to participate in trials and enforced the disempowerment of trial participants.

"We need this level of representation to be able to draw meaningful results from the trial that then will affect how the drug is prescribed and available to people and what we know about side effects and all of that. We need to see that information being reported on. But there is also how do you feed back to people?"

Additional barriers for people from minoritised ethnic communities

While many of the barriers noted were common across many different groups, additional barriers faced by minoritised ethnic communities included a lack of cultural sensitivity and diversity within research.

Participants described a failure to adapt trial protocols and environments to meet people's cultural needs. One participant explained how a lack of attention to their dietary requirements and preferences and preferred music made the experience of being part of a clinical trial alienating, saying, *"Britney Spears is more accepted than Bollywood music."*

Several participants highlighted a lack of diversity within the research community and at the top table of pharmaceutical companies. Some pointed out that this was potentially less of an issue at a global level, but that in meetings with senior researchers in the UK it was rare to find people from minoritised ethnic communities and particularly Black people. Participants argued that this lack of representation had significant impacts on the appropriateness of research design and on people's willingness to participate.

"I think we have a fundamental elephant in the room that we're not actually talking about, which is actually the racism around research. We have all white research associates, research offices, everybody's white from top to bottom. How do you expect to look after people like myself who are in these kind of clinical research places properly, if you don't understand a single thing about our culture? I think research on the whole needs to change and I think we need to actually employ more Black and Asian minority ethnic people within our services so that they can actually help us and support us."

Communication barriers

Participants told us about a range of challenges relating to communication including:

- How opportunities to engage in clinical trials were communicated
- Requirements around language and literacy for those participating in clinical trials
- Communication during clinical trials.

Participants highlighted that communication challenges could particularly impact blind and partially sighted people; people with dementia; people with learning disabilities; and people who do not speak English as a first language.

While some trials now offer translated materials, the communication barriers faced by people do not speak English as a first language are not always resolved by simply translating written materials.

"In some South Asian languages, there's no word for dementia, it's not understood necessarily. It's changing over time and with current generations, but it's… been seen more as an inevitable part of ageing rather than as down to underlying disease that you can do something about and therefore that you might want to take part potentially in research to change and to know more about et cetera."

"The lack of widespread adoption of the Accessible Information Standard is another barrier to participation. The same can be said of the Reasonable Adjustment Flag."

"Quite a high chunk from [some] communities are functionally illiterate, for example. So even if they are able to read a text, they have very low abilities to really understand the content of that text, […] Just, for example, interpreting a leaflet, it doesn't mean that the communication barrier has been met."

Lack of outreach and awareness

Communication issues were compounded by poor communication with certain communities about clinical research. Participants cited a lack of awareness of the opportunity to be involved in clinical trials in general, and of the specific trials that may be relevant for an individual.

Participants highlighted that whether or not people were offered the opportunity to participate in trials often depended on them being lucky enough to be supported by a clinician that was proactive in relation to trials (or directly involved in research) or having the resources to do their own research to seek out opportunities to get involved.

"There's a lack of information and awareness about clinical trials, particularly in the groups I work with - South Asian communities"

"The clinical trial units… and the researchers don't reach out into the communities as well as they should do, so they don't have awareness of where to go, how to reach those communities that they need to."

"MND is a slightly rarer disease, which means sometimes when people go out to their neurologist or clinicians and they may not have seen MND before, this can limit them getting involved in the clinical trial because the neurologist or clinician doesn't really know about the clinical trials that are happening. And then the onus is then put onto the person to go out and try and find a clinical trial to get involved in rather than them actually being told about the opportunities that are available."

Clinician capacity challenges

While most participants wanted clinicians to be more proactive in linking people to appropriate trials, they recognised that lack of capacity – in terms of time, and expertise – was a barrier for some clinicians communicating new research trials to their patients.

"Some hospitals, some clinicians are very research focused, they're very keen to get people onto trial. […] So in some areas they will have the time, it will be standard practice to be talking to their patients about clinical trials from day one and they will find the time to ensure that the right decision is made. For others, it's not necessarily the same picture. The healthcare system is extremely stretched right now. So those conversations may well be deprioritised by health professionals."

"I think often people have really good intentions by maybe having a clinical trial notice up in a waiting room, but then they won't have a conversation with people. So [it would help] if you made it everyone's responsibility while seeing people in that particular clinic to have a conversation, have you read this leaflet? Here's a leaflet. I think there's a reality around time as well. So, if a clinic is overrunning, there is no time to talk about all of the other stuff."

Digital exclusion

As information about trials is increasingly shared online, there are growing barriers for people who are digitally excluded whether due to a lack of access to digital hardware, connectivity, or digital skills and confidence. Digital exclusion was also highlighted as a practical barrier to people being able to involve themselves in trials run on digital platforms.

"Lack of information about opportunities for research is huge. I think there have been steps to try and publicise these a little bit more for mental health related clinical trials, but often they're sort of put up on websites or on apps and so if people are digitally excluded, it's still continuing to exclude a lot of people from taking part."

"If we rely too heavily on digital inclusion, that does exclude a lot of the elderly, particularly if they are vision impaired. If we are looking at digital exclusion that has a social-economic relevance as well. If you are really struggling, you are not going to have great Wi-Fi links at home, if any at all, and those people will be excluded."

Practical barriers

Participants highlighted a range of practical barriers that may make it harder for some groups of people to get involved with clinical and research trials. We identified barriers faced by people on lower incomes, those who were carers, people living in rural areas, plus barriers that arose due to the way trials were designed. All of these issues interlink with digital exclusion too, discussed above.

Participants identified that some demographic groups – such as women, and people from minoritised ethnic communities – may be more likely to experience these barriers. In this way the exclusion was compounded. For example, one person said: *"Lots of different aspects to [accessibility]. So, one is about being able to understand and know about what research is available. Another is about where it's taking place and being able to get to it. Also things like being able to do stuff digitally on your own obviously improves access. So yeah, time factors, travel factors are all issues, [and] cost with that as well."*

One participant crystallised the practical challenges by saying: *"There's the clinical side of things that might rule people out of trials and then there's the social side of things."*

Financial barriers

Several participants highlighted concerns around the cost of involvement in clinical or research trials, explaining that trial participants were not always compensated for expenses incurred, and that even where they were, there could be delays in receiving payments.

"Travel is a huge issue, but so is finance. People can be out of pocket for ages and asked to fill in loads of forms to get their money back."

"There would be travel and accommodation, there would be things like having to take time off work, particularly affecting those in low social demographics, and childcare - all of those kinds of things. The practical logistics of getting yourself out of your normal day-to-day circumstances to be in hospital all day."

"Reimbursement should be in advance/immediate, rather than making people chase up their reimbursement payments two months later!"

Geographical barriers

Another key barrier was the fact that most trials required participants to regularly attend appointments in major hospitals, usually in cities, making access a challenge for those living in other parts of the country, and particularly in rural communities. They also highlighted that many trials were only available in some places, and not across the country. Several participants acknowledged that moves were being made towards more decentralised trials, however these approaches were not yet the norm.

"I think the financial and geographic aspects are probably the things that we hear most [concerns about]. So, in blood cancer, as I'm sure with many other conditions, there are hubs in inner city specialist centres where most of the trials are situated. People from elsewhere in the country, rural areas, et cetera, find it much harder to find a trial that's accessible to them."

"My biggest barrier is where I live in Devon and it's a financially deprived area."

"Not a lot of research is happening in primary and community care settings. Often a lot of research is taking place in hospital settings."

Lack of support for carers

Participants highlighted that there could be significant barriers for carers in getting involved in clinical trials, because of a lack of appropriate support for their caring roles. Carers also face additional barriers due to the need to avoid anything which may impact their ability to care.

"What's the impact on me in terms of caring, can I devote the time, and will there be the right support for them/us if we need it? They also need to be able to trust this support. For some people, they've been consistently let down in terms of support - so if it's assured or promised, it has to happen."

"Because they're responsible for somebody else who quite significantly relies on them, [people will be] really worried about [whether the trial] will affect their ability to care?"

Carers may also face barriers in helping the individuals they care for to take part in research due to a lack of established mechanisms for handling issues around confidentiality and consent.

Barriers in trial design

A common concern among participants was the ongoing use of blanket exclusion criteria which often ruled key groups out of trials. These included exclusions around age, and comorbidities. While participants recognised that some exclusions were made with good reason, and that progress was being made towards a more sophisticated approach to exclusion criteria – for example using frailty scores rather than age to inform exclusions – many highlighted ongoing concerns around these criteria.

For example, we heard that people with learning disabilities were often excluded from clinical trials due to concerns around ability to consent and ability to tolerate trial conditions. This was a particular concern where it led to a failure to test medications for conditions common among people with learning disabilities on this population. For example, a failure to test epilepsy drugs on people with learning disabilities despite people with learning disabilities making up a substantial proportion of the overall population with epilepsy.

"Very little of our research has been done with the biggest group of people who live with epilepsy and lots of that is around assumptions, around capacity assumptions, so that might be mental capacity and decision making. But […] there's this broad sweep of exclusion [from the belief] people won't be able to tolerate the trial rather than looking at it on a different, more individual basis of what will it mean to be part of this."

Participants highlighted that people may also make assumptions about their eligibility for trials.

'If I see something coming up for a clinical trial that's not trans-specific, I assume that I'm probably counted out because aspects of my biology or being on hormone therapy treatment or things like that would count me out. And the reason it's an issue is because it just adds to the lack of research base around trans people's healthcare."

They also noted that even where trial criteria may be designed for inclusion, clinicians may apply blanket assumptions to people when choosing whether to flag up trials to their patients.

"You can go to a conference and you find people crying because they never knew something existed for their community. And then you think, well actually that's because people have made lots of assumptions about people like, you are hard to reach, so we won't bother reaching you."

Participants highlighted that the processes of consent for trials could often be particularly complex and that there was insufficient attention paid to the need to make adjustments for people who were supported by carers or who may have learning disabilities or cognitive issues. Without specific thought to the design of consent processes, these could lead to people being excluded who

could otherwise benefit from participation and whose participation would provide valuable data.

"There are high proportions of people with Down's syndrome that develop dementia and of course that's another consent issue that needs to be considered and how we make sure that we don't neglect them."

Lack of equality data

We recognised that efforts to address inequalities in clinical trial participation can be hampered by a failure to collect data which would support monitoring. In particular, participants highlighted that data on ethnicity is still not routinely collected in clinical trials. However, it was noted that there are now moves to improve this, including through the creation of more standardised reporting systems.

Participants noted that, depending on the nature of the trial, it may be necessary to collect data around other characteristics and circumstances that may be relevant to the trial outcomes.

"There's very little data around who is coming forward for clinical trials, who's being referred. Ethnicity for example, isn't collected as standard at hospitals across the UK before going onto clinical trials. So, it's very difficult to benchmark where we are now. We know it's low but developing that benchmark would be a really useful recommendation for the future."

One participant noted positive steps being taken to address this data gap within trial design: *"In any clinical trials that we are going to go on to fund, there will be a set of protocols developed to ensure that things like ethnicity data, collected as standard, will be part of the condition of that funding. […] And then would be looking to identify impact and then share impact to try and do influencing across the sector and the pharma space as well to improve practice there."*

Part II – Potential solutions

Our participants suggested a range of approaches which could be taken to widen participation in clinical and research trials. Many of our participants had been involved in implementing some of these approaches but recognised a need for them to be taken up more widely. There was also a call for collective effort to address barriers in the round, rather than relying on piecemeal action in relation to individual trials, conditions or groups.

Seven key solutions were identified, these were: Demystify research, Use a range of communication tools; Work with the Voluntary, Community and Social Enterprise (VCSE) sector and community groups; Address bias and discrimination; Give people a fair deal; Shift the power dynamics; and Commit to co-production.

These seven solutions are discussed in more depth below.

1. Demystify research

Participants felt that there was work to be done to demystify the whole area of research and clinical trials for members of the public in general and particularly those from groups who are often excluded. While many VCSE organisations are already engaged in this work in relation to their specific conditions or communities, several participants thought that more could be done at a cross-cutting level.

Work is needed to explain the research process to people and a key part of this would be to open up more conversations about research. Several participants discussed the expectation from people with cancer to be involved in clinical research and how this practice could be transferred to other conditions.

Part of this communication needs to encompass *why* people may get involved in clinical and research trials. This is particularly important where people may be given a placebo. Creating a sense of a wider community around research was felt to be important.

> "I think somewhat we put the onus on participants to kind of clue themselves up on what clinical trials are and expect them to have some prior knowledge and join. But I think we need to be better [both] in the charity sector but writ

large across the public sector of government at demystifying the whole nature of clinical research and clinical trials… using simple, easy to understand, easily accessible language that's inclusive, to allow people to make their own decisions about whether or not they want to be involved in clinical trials."

"I think there's something about really making clear the case for why research really matters and what does it lead to, why does it need to be done? And just making that information really clear and accessible to everyone."

"It is this sort of idea that research is a part of your care, and you should expect it - How do we get that message out to others and replicate the cancer model in all areas of health and disease?"

"[We need to have] advocates in spaces that can really support people to understand the offer. Promoting, I think the concept and idea that if there's a health footprint that every conversation… would include a conversation about a clinical trial."

"I feel part of a community so often I feel like if I'm taking part in research, it's not going to benefit my life, but it might benefit the lives of people who are born with the condition I have. So, for me that gives me hope because I want to help people with my health condition even though it doesn't directly benefit me."

2. Use a range of communications tools

A key area for improvement in encouraging and enabling wider participation in clinical trials was in improving the communications surrounding all stages of clinical trials, from having initial wider-reaching conversations, to focused recruitment, and then ongoing communication with trial participants.

Several participants highlighted the need for trial information to be provided in a wide range of formats, including translation into other languages, easy read, and audio and video versions.

Participants recognised that regulatory requirements currently presented barriers to the provision of accessible information, but many pointed to positive work that had been done already, often through partnerships between researchers and VCSE organisations.

One person gave the example: *"With the INCLUDE study I was involved in that what we did was we took the patient information sheet and produced five video podcast information in different language in the South Asian languages as a way to make it more accessible to reach those communities."*

Participants highlighted the need for communications materials to be developed in line with accessible communication standards in place across the NHS. This means people should not be presented with leaflets as the only option.

Similarly, it was felt people should be offered a range of ways to engage in further conversations about clinical trials – including opportunities for face to face and telephone discussion. People highlighted the need for people to be able to follow up and access further information, and for support around understanding information that has been shared. It was felt that better training for health professionals to see research as part of their job would help improve the way people hear about trials. and then decide to take part.

"Every health professional needs to see research and promoting research as part of their job too."

Learning Disability England flagged its work to develop new mechanisms for consent – including a process called "staged consent", where people are offered simple information and given opportunities and avenues for follow up. Its representative said: *"So you give the kind of summary of the study in the first leaflet, but you make it clear that there's more to come and there are places you can look for more information."*

"Leaflets can be helpful to take with you to discuss options and participation with friends/loved ones/GPs. But should be part of a broader 'suite' of materials."

"So, I think I would say 30% of written information supports people making a decision. The rest of it is, I suppose the exposure to the opportunity. People in those settings, advocating, supporting, conversation around."

"I know people are being sent letters or leaflets and so on, but joining that letter or leaflet with a conversation with face-to-face or even over the phone, [to ask] 'Have you received that leaflet? Did you have the time to look over it? Do you understand? Do you have any questions about it?' and so on. That also makes a huge difference for people."

"Providing the alternative to have face-to-face discussion, not just the via digital or through letters. And if people have been asked to fill in forms for example, then providing that support to fill in that form."

3. Work with the VCSE sector and community groups

Several participants from medical research charities working on specific conditions highlighted the work that they had been doing to support people from their communities to engage with clinical trials, and to diversify the pools of people participating.

Examples of action being taken by VCSE organisations included:

- Working with pharmaceutical companies to encourage them to engage in outreach / provide outreach support
- Developing specific recruitment campaigns – for example a campaign developed by Diabetes UK and Egality Health to support young people to become involved in a trial
- Developing a support offer for people interested in participating in clinical trials
- Developing programmes with community organisations embedded in under-represented communities
- Building additional requirements around participant diversity into trials they fund

"MNDA is starting to build a network of specific MND research nurses… who will go out into the more rural communities and things like that to highlight and

help access to clinical trials and make it a little bit more equal if we can for everyone."

"We were regularly hearing from people who had heard about clinical trials but weren't really sure about what that meant and just wanted more information and people who were struggling on clinical trials, all of those kinds of things […] So for that reason, we set up a specific service called our clinical Trial Support Service, which is staffed by haematology research nurses."

Participants also highlighted the enormous potential of working with community groups embedded in those communities who are under-represented in trials. They pointed out that these organisations had existing networks and established trusting relationships and could therefore act as vital intermediaries.

"It's about pharma companies actually being courageous and going out and working in that different way and having the right people to go out and do it."

"You have to go and find someone in the community to coordinate those kinds of groups because you have to build trust."

"We have a race equality and research programme in which we're developing community-based events to invite people from the South Asian community, from the black community and we're working with them to increase the level of trust, which I think is obviously a big issue amongst these communities when being involved in research to break down some of those barriers."

However, participants highlighted the tendency for community groups to be expected to undertake this work as a matter of goodwill. They argued clearly that this work needed to be valued and remunerated adequately.

"A lot of the medical charities and other bigger organisations, because they don't have the reach, they expect this goodwill of providing free services and that goodwill has run out, so we need to be adequately resourced if they want to do proper effective engagement with those communities."

4. Address bias and discrimination

Our participants told us that there was significantly more work to be done to break down damaging biases and to address discrimination across research. Improving cultural competence and cultural understanding, and providing training on discrimination and bias for those working around clinical and research trials, was seen as a priority.

We also heard that more trials needed to be designed around the real lives and real experiences of disabled people and those living with long-term conditions. This would help address concerns that the research might not be beneficial to them and would encourage more personalised approaches in recruiting to clinical trials to reduce the use of blanket exclusions. As the population lives longer but often with more complex multimorbidities one participant said: *"There's this idea of the perfect patient [for research] and that just doesn't exist."*

A longer-term planned approach is also needed to diversify the workforce.

"One of the things we hear from lots of people with learning disabilities is even when some physical adjustments are made to include them, they don't feel respected equally, they feel patronised often."

"There needs to be a mindset change in the workforce in terms of prioritising this to be action rather than just words. We heard horror stories of researchers not really discussing trials with some group of patients because they were seen as hard to recruit or hard to retain on a trial."

"It's about upskilling those representatives to be more aware culturally, et cetera. They might not look like you but at least they understand how to relate to you better."

Another way of overcoming bias would be to ensure more health professionals have the skills and capacity to talk to people about clinical trials. These would allow professionals already working with potential participants, and therefore more likely to have established trust, to explain the role and benefit of trials.

"Linking to the professionals that already work with them together I think is really important."

5. Give people a fair deal

Participants were clear that there was a need for those running clinical trials to make a more comprehensive offer of varied support to those taking part in trials, as at present participating in trials can be burdensome, especially for people who are living with health inequalities. This might include referral to support from peer groups or VCSE organisations, or enhanced support from clinicians or researchers.

"I've heard people have… set up a kind of info or support line so that if people have any questions throughout [the process] they can get those answered."

Participants were clear that there should be benefits for individuals for taking part in research which should include financial recognition and in particular, clarity around ongoing access to any medications from which they may have benefited during the trial.

Financial support offered to people taking part in trials should *at least* fully cover their costs and ideally *also* offer a reward in recognition for people's time and the value of their participation. Participants recognised that there were ethical concerns raised around incentivisation but felt that these could be worked through in co-production with people from marginalised and under-represented communities.

"We know that taking part in research, they give a lot of time and it's very selfless and we should be allowing them to get something out of it as well so that they can continue to get access [to medicines]… So, things like open label extensions [allowing participants] to receive the treatment after the placebo control."

"I could imagine a lot more people would be encouraged if they said, oh, perhaps it's in say London or Bristol and yeah, we'll pay for you to get a train there. Do you need a carer? Do you need any extra support? And that would probably help get a wider selection of participants."

"The option of reimbursement by gift voucher as a consideration on the impact it could have on people in receipt of benefits."

"I do think incentivisation, which is seen as unethical, so why [are we] not using it in an ethical way? So those with the most need pull down the most resource,

you have to think of really different ways if you want to shift that status quo. And I think incentivising cash reward, all of that kind of stuff can help massively."

Participants discussed the need to close the gaps between under-represented groups and those running clinical trials by bringing trials closer to people, taking the burden away from participants to take time out from their day-to-day lives. This would involve the decentralisation of trials from major teaching centres and allow more trials to be situated in primary care. We also need to be able to deliver trials in settings such as care homes.

6. Shift the power dynamics

We heard a very clear message of the need for a shift in the power dynamics held between people who may want to participate in clinical and research trials and those involved in establishing and running these trials. We heard that gaps in representation will not be addressed without a move to more equal power sharing between all those involved. Rethinking power dynamics requires honesty, relationship-building and a transparent recognition of the value participants bring to research.

We also heard very clearly that we needed to put the onus of addressing these gaps on the researchers and those commissioning research, not the people who are underserved and under-represented. Research teams need to take responsibility for examining their own practice and making changes to enable people to participate. We recognised that the people who may be underserved or under-represented will be different from one trial to the next, so each trial will need a tailored approach.

"The onus should be on the researchers rather than encouraging people to be more involved in research. Actually, the research teams, the institutions, the pharma companies, whoever it is, should be actively considering that in their trial design and even when setting what the research question should be."

"Let's also understand organisations tend to exclude diverse communities because they say we're hard to reach - which is the other way: the institutions are hard to reach and don't want to engage with us."

One participant talked about how they had sought to address the inherent power imbalances within clinical trials by discussing with trial representatives how they were "contracting" with them for their participation. In this framing, the moral responsibility to cover costs and meet support needs is much clearer. It also makes it clear that when people give their time to a trial, they expect in return minimum courtesies such as being kept informed of the outcome of the research.

"Once you're on a clinical trial, I think there's lots of stuff around finance, impact on finance, the psychological adjustment from just having care as usual, to I suppose a more intrusive type of care and what that means. So when I talk to health professionals about 'How are we going to contract working together?', they'll look at me like I'm mad, but I'm like, 'Well this is what I need from you and this is how I need it'. So, there is an inherent power imbalance, and if you start to talk about the power, I think you can start to address some of that stuff."

"We often hear that people from minoritised communities feel that they've given a lot when it comes to research and they've provided their insights and then what's happened as a result of this, what's changed? And so, I think there's something around the transparency around results, what's happened as a result of the research and if it hasn't led to something moving forward, what's the reason for this."

"Even when really good clinical trials research happen, it's kind of like the end that people find out, but you need to give people information and updates as you go along and you need to find out how people want to receive that. So, it could be a text message to say like, 'oh, we've now got to phase two'. It's not hard."

Being honest and open with people is vital. We heard that sometimes researchers made assumptions about the kind of information groups would want to hear, but in reality, most disabled people and people with long-term conditions were clear that they most valued honesty. For example, we heard about a research project in which researchers did not want to include information about the fact that people with learning disabilities die earlier than their non-disabled peers. However, when the information was discussed with people with learning disabilities, they were clear they wanted to know this

information. Making sure processes are robust around issues of confidentiality was also seen as vital to building trust.

"Confidentiality [....] it's a huge concern for people nowadays with all the cyber-attacks and you just don't know where your information is going. So, I think we need to do more to alleviate those kinds of concerns."

7. Commit to co-production

The need for co-production was a powerful message that came through continually in our discussions. Participants talked about a shift towards co-production throughout the entire clinical trial's process. This would include establishing the research topic and questions, designing the studies, developing communications materials through to running trials.

Our participants emphasised that co-production would require time and financial resource and commitment which should be features right throughout the trials process. The first key co-production step would be to recognise and enable patients to be experts in their own conditions and to tap into the existing networks and strengths of these patients.

One participant described how these networks had been vital in the early days of HIV research trials: *"Because my clinical trials were really rooted around really oppressive times, there were lots of peer conversations and information and there was lots of people doing stuff and supporting other people to understand the system and health."*

"Until organisations... make a real commitment to [co-production], and I mean that in terms of a strategic priority that's funded from choosing research questions... to implementation and impact... we're going to keep coming across what you call capacity issues. The reality is until you have the funding as a result of a strategic commitment to co-production from beginning to end, from design to implementation and impact, these issues will continue."

"Let's make a commitment to co-production, research institutes need to do it, universities need to do it, charities need to do it."

A vital element to genuine co-production is taking the time to build "cultural security" for people from marginalised and minoritised communities. This process of building relationships and trust with communities that have previously been excluded from clinical research and trials takes time and energy and therefore needs proper resourcing. Without it, however, co-production with those facing health inequalities will be an ambition hard to achieve.

"It's expensive and it's time consuming to build up those relationships, but at the end of the day it's the relationships that are going to enable a better future, I think, in this work."

"I think there is a lot of needs to be done in terms of building the trust, building the connections with the community between health settings that do such research and so on."

Taking action

There is much to be done to address inequalities in participation in clinical and research trials and to improve inclusion and diversity across the clinical research world.

The key five areas for improvement are as follows:

Build capacity across the system:

- Increase commitment, capacity and skills within pharmaceutical companies and research organisations around engagement, co-design and co-production
- Increase the capacity and skills of the clinical workforce and wider healthcare professions to talk to people about clinical trials, so that a far wider group of professionals are able to flag up opportunities to individuals
- Resource the work already underway within VCSE organisations and with community groups, and accelerate and extend this work
- Commit to a long-term plan to diversity the workforce
- Empower all those involved in research to actively challenge bias and discrimination and take proactive responsibility for diversifying participation

Improve communication around research trials:

- Raise awareness of clinical and research trials across the board and particularly with people from under-represented groups, sharing information to demystify research and engaging more people in talking about research
- Use a wider range of communications channels and modes to engage people in research opportunities and communicate the benefits as well as the individual opportunities

- Provide accessible communications including different media formats, translated versions etc. and alternatives for people who face digital exclusion

Strengthen support for people who engage in research:

- Cover all expenses incurred through participation in research, including the costs of travel and accommodation, lost earnings and backfilling care
- Offer incentives within a clear ethical framework, co-produced with people
- Provide support with the psychological and practical aspects of participation in research trials, whether peer, VCSE or clinical means
- Offer opportunities to participate in trials close to where people live, including offering access to trials through primary care and in care homes

Engage the Voluntary, Community and Social Enterprise Sector:

- Work with patient and medical research charities to tap into their networks, and to offer people a source of trusted advice and information around clinical trials
- Work with community organisations, as trusted intermediaries with groups who may otherwise be excluded
- Remunerate charities and community organisations for their work to support engagement

Shift the power dynamics by committing to co-production:

- Commit to co-production with diverse communities, across the full clinical trials process
- Recognise and value the contribution of clinical trials participants as part of a mutual "contract" between researchers and research participants
- Recognise that patients are often experts in their own conditions and tap into this expertise
- Invest in building relationships and trust, working through trusted intermediaries and adequately compensating them for their time and expertise

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National Voices

National Voices is the leading coalition of health and social care charities in England. We work together to strengthen the voice of patients, service users, carers, their families and the voluntary organisations that work for them. We have more than 200 members covering a diverse range of health conditions and communities, connecting us with the experiences of millions of people.

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