Clinical trials and underrepresented populations

A conversation guide for healthcare professionals

Biogen

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Addressing concerns about clinical trials in underrepresented populations

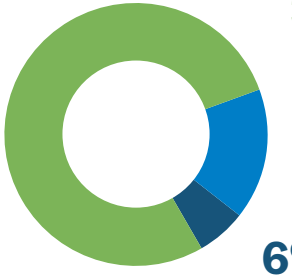
Please note: While this terminology is commonly used to refer to race, we acknowledge that the way people identify varies. And people may refer to themselves in many ways not used in this document. Always defer to individuals on how they identify.

Accurate representation of participants in clinical trials not only helps fight health disparities and inequities, it's just good science. That's why it's critical that participants accurately represent the populations that potential medications are designed to treat.

But many people may not be well represented in clinical trials.

CLINICAL TRIAL PARTICIPATION IN THE UNITED STATES[1]

BY RACE

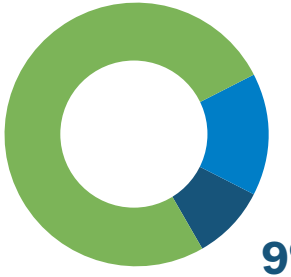


78% White

16% Black and/or African American

6% Other Races

BY ETHNICITY



76% Not Hispanic and/or Latin American

15% Hispanic and/or Latin American

9% Not Reported

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The impact of the data gap

This data gap isn't just a research problem. It's a social justice problem. Fair access to healthcare and treatment options persist at the research level.

When medical products and diseases aren't studied in diverse populations, researchers may not have the information they need in order to understand how they may affect certain groups.

This may lead to diseases going underdiagnosed, untreated, or treated with medicines that may not work as well for certain people.

So, why aren't people of color accurately represented?

For many people in these populations, certain barriers are believed to systematically prevent participation in different ways.

Things like language, work schedules, family dynamics, and mistrust of the medical system (to name a few) should be considered when discussing research opportunities.

Beyond these barriers, or perhaps because of them, many people from communities of color are simply not being approached about potentially participating. So, while talking about a clinical trial is always a nuanced conversation, the specifics of a trial itself should never be the only consideration.

Here's how you can help

You have the opportunity to introduce clinical research early on and in a way that is approachable and give patients a safe space to ask candid questions.

These personal conversations can help them understand the importance of participating and help them better understand if a clinical trial could be right for them.

Barriers of trust

For some communities, a lack of participation in clinical trials runs much deeper than lack of awareness. It's important to understand and talk about the historic injustices communities of color have faced in the name of medical progress.

With the extreme ethical violations of the Tuskegee Study* still top of mind for many on top of persisting health disparities, people may have a deep mistrust of clinical research in general.

This conversation guide

The following learnings were compiled through community ad boards and discussions with patients, participants, advocates, and community members. These talking points are certainly not comprehensive of the barriers underrepresented populations face—nor are they blanket statements for everyone. However, we hope they'll help you proactively address concerns with people considering clinical trials as we work to close the data gap and better develop potential medicines for all.

*For more on the Tuskegee Study, visit **history.com/news/the-infamous-40-year-tuskegee-study**.

Addressing mistrust

- [ ] Listen carefully to potential participants' concerns. Acknowledge their lived experiences and speak to their specific questions and hesitations
- [ ] Whenever possible, involve families/loved ones in these discussions. Not only do they often help make medical decisions, but their support can make a huge difference in participation and retention
- [ ] Discuss personal safety measures and layers of ethics, transparency, and safety approvals are all in place for research participants to ensure clinical trials are conducted safely
- [ ] Personal data and identifiable information are protected and not shared with third parties

Addressing mistrust

Mistrust can seem like an overwhelming problem, and unfortunately, there aren't any quick fixes. The good news is that the work can start right away.

Along with having context for this mistrust, building relationships with community members and organizations in your community is key. Here are some ways to get started.

- ☐ Make sure your staff is representative of your community, including language. Recruit staff from community job fairs, local high schools, and community colleges in your area
- ☐ Implement ongoing cultural competency training for your staff
- ☐ Continuously build relationships with community-based organizations (like community centers and places of worship). Consistency is important here. Show up often and be a visible presence supporting your community, listening to its needs, and advocating for its health

"Someone who is a medical person but also a member of the community will be more trusted than if you just bring Doctor XYZ in and not only does he not look like us, but we don't know him. … We don't see him at church. We don't see him at community gatherings. He doesn't know us. … But he comes here when he wants us to try his medication or something. We're not doing that."

– Patient

Misinformation

Beyond a mistrust of the medical system, some people are unclear about what clinical research actually means. Ask questions to gauge understanding of clinical trials and be prepared to address misconceptions.

- ☐ Challenge the perception that clinical trials are a last resort. Clinical research can happen for any condition and even healthy people may be eligible to participate
- ☐ Many people are hesitant to participate because they don't want to be used as a "guinea pig" or feel out of control of what happens to them and their health. Discuss safety measures, the extensive research that happens before people are allowed to join clinical research, and the voluntary nature of clinical trials
- ☐ People may be suspicious of intentionally being assigned a placebo or that they may be given other experimental products without their knowledge. Discuss randomization and the approval process for study designs

How health is protected

Historic injustices and misconceptions about clinical research can make people understandably hesitant to participate. If people are new to clinical trials, they may be unfamiliar with the ethical measures in place to protect participants.

“A lot of times people don’t know the steps that happen before this drug actually gets to clinical trials. So that’s the part that makes it scary.”

– Patient

Informed consent process

- ☐ Before participants can join a clinical trial, their study team will explain everything that will happen and all known risks and potential benefits during the informed consent process
- ☐ Involve family and loved ones in this process. They often help make health decisions and their understanding and support is invaluable to participation
- ☐ Remind patients that the informed consent document is not a contract. Participants are free to leave a trial at any time with no impact to their usual medical care
- ☐ When talking about a specific trial with a patient, talk about the phase of that trial and what research has been done to get the study medication to that point
- ☐ Remind patients about the voluntary nature of clinical trials. They can leave at any time and still receive their usual medical care
- ☐ Discuss randomization and the possibility of placebos
- ☐ If placebos are used, explain the role they play in research

How health is protected

Safety

- [ ] Participants' health is closely monitored throughout the trial. If their health gets worse, the study team will discuss their options with them. This might include leaving the study early and returning to their usual care
- [ ] Discuss the role of internal review boards in ensuring the study is generally safe and ethical before anyone is allowed to take part

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Addressing access barriers

While the following items may be provided when participating in clinical trials, confirm with the sponsor which are available before discussing a trial with potential participants.

Opportunities such as access to childcare may be available and could mean the difference between participating and not, so ensure these opportunities are discussed with a potential participant.

Community involvement

- ☐ Encourage potential participants to discuss the possibility of joining a clinical trial with their loved ones as family and community support are essential for retention during the trial
- ☐ In some studies, study partners (family members or people who spend considerable time with the participant) take part in the study itself and are important contributors to clinical research

Travel*

- ☐ Travel to study visits may be compensated or provided
- ☐ Stipends may be available for participants and study partners for their time in attending study visits

Childcare*

- ☐ Childcare may be provided or compensated when needed

"These trials don't provide enough support or compensation to help with things like missed work, travel, and childcare. … It's good [to talk] about these barriers."

– Patient

*Confirm accuracy before discussing this topic with potential participants.

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Addressing access barriers

Informed consent process

- ☐ In the United States, health insurance isn't required to participate in a clinical trial
- ☐ Study-related tests and study medications are provided at no cost to participants
- ☐ Participants are generally responsible for medical costs for tests and procedures that would happen, whether or not they are in the study

Office hours*

- ☐ Flexible clinic hours may be available to accommodate work schedules and responsibilities

Language*

- ☐ Multilingual study staff and/or an interpreter may be able to help with visits and interact with families and loved ones
- ☐ Study materials may be available in multiple languages

Privacy

- ☐ Participants' health information, personal data, and study data are confidential and follow a secure process
- ☐ Only their study team, people hired to perform or manage the study, will see their personally identifiable data
- ☐ Only study data that is de-identified will be shared with the company conducting the study

Immigration status

- ☐ Immigration status is generally not collected in clinical trials and will not be collected in any Biogen clinical trial

*Confirm accuracy before discussing this topic with potential participants.

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The scientific need for representation

Many potential participants may be unaware that disparities in research exist—and how that data gap can impact the development of medical products.

- ☐ Discuss with potential participants about how their contributions to a clinical trial extend beyond themselves to potentially help others

- ☐ Talk with potential participants about how certain diseases affect groups of people at different rates. In addition, different genetic makeups can also cause medications to work differently in different people.[2] Because of this, it's vital that potential medications are researched in a representative sample of the population

Participants have the power to contribute to the greater good of medicine

Although taking part in a clinical trial is a highly personal decision, discuss with your patients how their participation matters. By providing their unique and important health information, they have the power to help contribute to the health of their community because the more we learn about diseases, the better we can potentially help patients.

“It doesn’t make sense that a lot of the medicines that will be treating these people are not tested with these people.”

– Patient

We want to learn from you

At Biogen, we are committed to continuously learning from patients and partnering with community physicians to dismantle barriers to participation and help make medical research more representative and equitable. You know your patients better than anyone.

The insights you have about your community can help us develop practical support and tools for potential participants.

If you have ideas of ways to better support your patients through clinical research, contact Biogen at **clinicaltrials@biogen.com**.

Representation in research matters

While clinical research has come a long way in inclusivity and accessibility, we recognize we still have a long way to go. Dismantling barriers to participation must happen structurally within our organizations and in the medical world as a whole. But by taking the steps to have meaningful and productive conversations early on and actively engage with communities, we can begin to make clinical trials, and medicine as a whole, more equitable.

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Build your knowledge

Talking with patients about their potential participation in clinical research is an important step toward more equitable healthcare, but it's not the only one. We encourage you to continually build your knowledge of issues facing underrepresented populations and ways you can help close the data gap to make medicine for the greater good.

For further reading and resources, visit **www.minorityhealth.hhs.gov**.

About Biogen

Where science meets humanity

Biogen is a global biotechnology company. Since 1978, our mission has been to discover, develop, and deliver innovative therapies that improve the lives of patients globally—starting in your community. Each individual who participates in one of our clinical trials contributes to our understanding of the disease and has the potential to benefit patients around the world.

We are committed to the power of diversity—in our organization and among our patients. Every day we work toward helping close the access gap in both clinical trials and the healthcare system.

References: 1. U.S. Food and Drug Administration. 2015-2019 drug trials snapshots summary report: five-year summary and analysis of clinical trial participation and demographics. Published November 2020. Accessed December 2, 2020. https://www.fda.gov/media/143592/download **2.** Bierer BE, White SA, Meloney LG, Ahmed HR, Strauss DH, Clark LT. Achieving diversity, inclusion, and equity in clinical research guidance document. Multi-regional Clinical Trials Center: The MRCT Center of Brigham and Women's Hospital and Harvard. Published August 6, 2020. Accessed December 2, 2020. https://mrctcenter.org/diversity-in-clinical-trials/

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