Increasing Diversity in Clinical Trial Participation: An Exploration of Clinical Trial Site Engagement

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Introduction

Because of the profound lack of diversity in clinical trials, large gaps exist in understanding how diseases and treatments affect the health outcomes of Black, Indigenous and people of color (BIPOC), who represent approximately 39% of the US population and only 2%-16% of clinical trial participants.[1] As a result, treatments coming to market are not tested on a significant portion of the population, exacerbating healthcare bias, reinforcing institutional racism, and thwarting equitable care delivery.

Increasing the diversity among clinical trial participants requires awareness, commitment, and change at multiple levels, including clinical trial sites. There may be high levels of variability in what sites know, are doing, and are willing to do to ensure clinical trial participation matches the disease population being studied.

Methodology

- Avidity surveyed its clinical trial sites to better understand where it stands and what it is doing to increase diversity in muscular dystrophy clinical trials
- Sample
  - 92 investigators and research staff from 36 sites invited
  - 43 respondents
- Data collection
  - A brief online survey including open-and closed-ended questions was conducted
  - Items focused on awareness of the problem, actions taken at the individual, clinic and institutional level, impact of actions, feasibility of specific activities, and ideas for next steps for their own site
- Data analysis
  - Descriptive analysis including frequency distributions for closed-ended questions
  - Qualitative data were analyzed using thematic analysis to reveal common themes and identify trends in perspectives

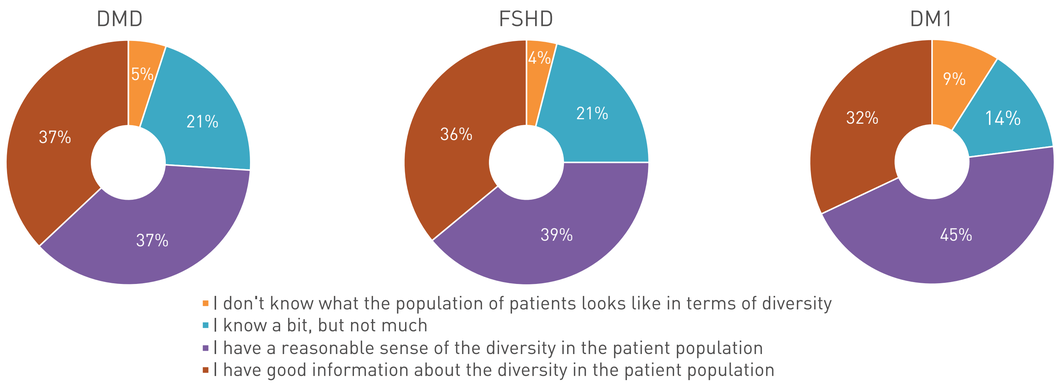
Results

The respondents work in Duchenne muscular dystrophy (DMD), myotonic dystrophy type 1 (DM1), and facioscapulohumeral muscular dystrophy (FSHD) disease states in nearly equal proportions with the majority of respondents (61%) working in more than one disease. The respondents included a nearly even split of investigators (n=20) and coordinators (n=22) with 1 research administrator.

Table 1: Percentage of Respondents' Work in Each Disease Area

	Number of respondents	Percentage
DM1	5	12%
DM1, FSHD	9	21%
DMD	3	7%
DMD, DM1	2	5%
DMD, DM1, FSHD	11	26%
DMD, FSHD	4	9%
FSHD	9	21%
TOTAL	43	100%

Figure 1: More Than 74% of Respondents Reported They Have a Reasonable or Good Sense of What Diversity Looks Like in the DMD, FSHD, and DM1 Patient Populations



A diversity, equity, and inclusion (DEI) policy is a fundamental requirement and first step for diversity in clinical trial participation.

Respondents were asked whether their institution has a DEI policy and 62% (18/29) of respondents indicated their institution does have a policy while 38% (11/29) reported their institution does not have one or they were unaware of whether their institution has one.

Overall, 90% of respondents report being somewhat or very familiar with the concept of clinical trial diversity (CTD).

Table 2: Eight Actions Were Identified as Mostly or Very Feasible to Promote Diversity in Clinical Trials by at Least 80% of Respondents

Of the 11 activities provided that could potentially promote diversity, more than 80% of respondents identified 8 actions.

All potentially eligible patients invited to consider a clinical trial	100%
Demographic collection to be inclusive of people of color and members of the LGBTQ+ communities	92%
DEI training for all members of research team	92%
Mentoring, internship, and fellowship programs to expand opportunity for BIPOC and LGBTQ+ clinician researchers	88%
Inclusive and accessible educational materials, such as in languages other than English	84%
Informed consent with multi-modal options such as including infographics and/or videos	84%
Cooperation with community hospital(s) in more racially, ethnically, or socioeconomically diverse areas for trial recruitment	84%
Leverage sociodemographic information of screened-out applicants to inform future research and adjust for biases	84%

Results (Continued)

Respondents shared examples of approaches to increase CTD that fell into 4 categories.

Table 3: Examples of Existing Efforts to Increase CTD

Category	Examples
Navigating cultural and language barriers	Fees to use hospital-based translation software have been waived for research projects, and tablets connected to translation services have been provided to all units
	"We always ask sponsors to provide/translate material in Spanish for our Latino patients, who make a good proportion of our patients"
Individual advocacy and intrinsic accountability	Speaking at patient events
	"The single easiest area I feel I have had the most measurable impact is on holding sponsors accountable for providing translated documents in Spanish, at minimum, and other languages when we know we have good candidates in those languages. Internally, I have advocated for and personally hired more candidates from diverse backgrounds to gain new perspectives and insight into cultural barriers that may prevent access. I strive to lead by example and when I have identified potentially sensitive areas, seek to train my staff to watch for cultural sensitivities in the same way we would watch for trip hazards – all are in service to good patient care"
Institution/clinic staffing, accountability, and internal education	*"We have a diversity and equal opportunities leader who is dedicated in ensuring no discrimination in patient recruitment, invitation, and information sharing. The clinical research team consists of people of various ethnicities and representations"*
	"We formed a DEI committee in 2023 to try to increase our DEI awareness in both personnel and study recruitment. We have a lot of ideas from that committee but need funds to implement them"
	"There are several grants just within our department whose sole focus is on increasing trial participation for underrepresented populations"
Recruitment, outreach, and patient education	Increased recruitment and inclusion of all patients in disease-specific databases where clinical trial information is sent to patients to keep them informed of studies. This allows for removal of some bias that may happen if patients are selected on case-by-case approach in clinics
	"We recently hired a bilingual recruitment specialist dedicated to our division who maintains a presence in our clinics and also focuses on creating/expanding our social media campaigns"
	Community outreach to populations not appropriately represented in research

Barriers to existing efforts to increase CTD fell into 4 categories.

Table 4: Barriers to Increasing Diversity Among Clinical Trial Participants

Theme	Definition
Trials are not designed in a way that is inclusive	Existing inclusion/exclusion criteria, study schedules, and participant incentives are tailored toward people who have access to support and flexibility in their obligations. This further increases the likelihood of enrolling a highly privileged select pool from the patient population and further disincentivizes everyone else from study participation
Specific populations have less access to trials	Socioeconomic status, geography, language, and other demographics can negatively impact the access certain groups have to information on studies and even potential participation in a study
Lack of information about who the patient population is	There is minimal evidence identifying the demographics of the true FSHD, DM1, and DMD disease populations. There is a dire need to better understand the ethnic demographics of diagnosed and undiagnosed people living with these diseases so that true diversity within the patient population can be achieved
Historical and ongoing exploitation in research and healthcare	There is a need for more intentional community outreach, education, and relationship building to counteract the compounding evidence that supports the historical and ongoing exploitation of BIPOC and underrepresented groups within research studies

Discussion

- There is a willingness from study staff and investigators to make change and a hesitation in knowing how to take the next steps and whether it is their place to do so
- Work needs to be done at all levels and within all systems in order to make the necessary changes to increase the diversity of clinical trial participants, including sites. At the site level, there is some work already happening and great ideas for what could be happening
- Education and guidance are needed, in addition to clear expectations and roles for each system. Education to level out the understanding and competency around CTD, cultural humility, and appropriate language to use when describing different populations will provide a foundation for implementing the outreach, communications, and support needed to shift the demographic in trials to become more representative

References and Abbreviations

BIPOC, Black, Indigenous and people of color; CTD, clinical trial diversity; DEI, diversity, equity, and inclusion; DMD, Duchenne muscular dystrophy; DM1, myotonic dystrophy type 1; FSHD, facioscapulohumeral muscular dystrophy; LGBTQ+, lesbian, gay, bisexual, transgender, and queer.

1. Giusti K, et al. Addressing Demographic Disparities in Clinical Trials. Harvard Business Review. June 11, 2021. https://hbr.org/2021/06/addressing-demographic-disparities-in-clinical-trials. Accessed July 2023.

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