Benefits of Including a Diverse Population in Your Study

Including a diverse, representative cohort of study participants that reflects the population you are trying to help can be a challenging goal to reach, but the benefits are clear:

- With a more diverse group of participants, research results will be applicable to a broader spectrum of people with MS.
- Including large enough samples of specific ethnic and racial minorities may make it possible to uncover differences in biology, genetics, disease progression and presentation, and treatment responses that underlie the heterogeneity of MS, and enable personalized health care.
- Today more funders are including requirements for diverse recruitment in research design.[39]

Suggested Practices for Successful Recruiting

Recruitment practices that work well in one community may not be as effective in another. Tailoring outreach and recruitment efforts can help. Here are some insights and suggestions for greater success in recruiting study volunteers from diverse communities:

- **Work with the Communities.** Take the time to identify the community or communities you would like to engage in your research. Reach out early in the study process to the trusted individuals and organizations that represent these communities. They can often help you understand the priorities, motivations, and concerns of the people you want to reach, help you find people who may be a good match for your study, and become a partner for sharing resources.[20,40,41]
  - MS organization chapters and support groups, as well as organizations that work with patients and health care professionals from minority communities can help you better understand and reach different communities. The local chapters of some of these organizations may also help you identify community leaders who can advise your team and help with outreach.
  - Reach out to MS organizations, including our Network Partners, the Accelerated Cure Project for MS (www.acceleratedcure.org), the National MS

Society (www.nationalmssociety.org) and the MS Society of America (www.mymsaa.org), as well as other MS organizations such as the Consortium of MS Centers (www.mscare.org), and the International Organization of Multiple Sclerosis Nurses (http://iomsn.org).

- Our Network Partners, the National Hispanic Medical Association (www.nhmamd.org), the National Black Nurses Association (www.nbna.org), MANA, a National Latina Organization (www.hermana.org), and National Minority Quality Forum (www.nmqf.org), as well as other organizations such as the Black Women's Health Imperative (www.bwhi.org), and the National Medical Association (www.nmanet.org) are good places to begin.
- Local community advocates, churches, local policymakers, and business leaders may also be helpful resources for advice and outreach. Holding community meetings has been identified as a useful and preferred method for learning about research.[30]

- **Be There for the Long Haul.** Once you have established foundational connections with the relevant communities, invest the time and effort in maintaining these relationships and demonstrate your commitment to improving health.
  - Engage in regular, two-way dialogue with these communities to continue understanding their needs and desires. Share your ideas, and identify where your interests overlap with theirs.
  - Build partnerships focused on addressing the disease area and overall health (within which your study – and future studies – would be included) rather than a "one-off" interaction built around a single study.
- **Design Studies with Participants in Mind.** It is becoming common practice to involve patient and consumer advocates in the study design process, as well as inviting them to participate on Institutional Review Boards (IRBs) and panels that make funding decisions.
  - Consider including minority community members in the study design and planning process, including study focus, design, recruitment materials, and dissemination plans. The study will be more attractive to that community and the individuals may be able to promote or assist with recruitment into your study as an ambassador or navigator.
  - Be flexible and respectful of study participants' schedules, mobility and transportation issues, and responsibilities. For people with financial

constraints and/or multiple obligations, evening and weekend visits, telephone and online check-ins, and reimbursement for travel, accommodation, food, and time can go a long way to making the commitment easier to keep.[42]

- **Speak the Right Language.** A commonly reported concern among potential research participants is that they have trouble understanding the study, its goals, the consent forms, and what is expected of them.
  - **Health literacy & Lay Language.** For most people, science and medicine are foreign languages. Not only are the words unfamiliar, but some of the concepts around the scientific method and research design may be new, or at least long forgotten. It is important to prepare recruitment, informed consent, and informational materials that are understandable and relatable to your potential participants. Use terms they can understand and images that look like them.[34,37]
  - **Translation and Cultural Competence.** To reach more diverse participants, such as people from Hispanic/Latino and Asian groups, creating accurate, culturally relevant materials is key. Even if they speak English, many people may feel more comfortable and more confident listening to or reading recruitment materials, screening questionnaires, consent forms, and other study materials in their native language. Enlist a professional translator or bilingual research coordinator to help communicate with participants for whom English is not their first language.[43]
  - **Use the Teach-Back Method. T**o ensure your patients understand the information presented, have them state it back to you in their own words.[44] Find information on the method on the Agency for Healthcare Resources and Quality website.
- **Set and Meet Expectations.** Building trust is vital to recruitment and retention success for clinical trials, and transparency is an important component. Avoiding misunderstandings by ensuring that volunteers have a realistic understanding of what will happen in the study can help build and maintain trust.
  - Explain the study questions, goals, and what will be involved, using plain, easy-to-understand language. Communicate why the study matters, and how it may contribute to our understanding of MS and help people with MS.
  - Help participants understand what results (if any) they can expect to receive, and approximately when they would receive these results.

- Describe any benefits that the study may provide to racial and ethnic minority communities or other subgroups of participants. For example, "We want to include people of different races and ethnicities in this study so we can understand whether the treatment works differently in different groups."
- Encourage volunteers to ask questions and address any possible concerns or challenges up front. Be ready with answers about side effects and long-term risks, treatment in the control group if there is one, funding and financial conflicts (especially related to pharmaceutical companies), and who else might be participating as both researchers and volunteers.
- Explain the reasoning when a volunteer cannot be accepted in a study and, if possible, direct them to other options. Being disqualified for a study without being told the reason why can deter a volunteer from seeking other research opportunities.[38]

- **Seek Truly Informed Consent.**
  - Use the consent document as a communication tool when talking to potential volunteers about the study. Provide copies to read and refer to sections in the document during your meeting.
  - Explore alternative models of informed consent, such as electronic consent options that present the required information in a more user-friendly format than a lengthy paper document. Companies such as Sage Bionetworks have developed mobile-friendly, modular consent platforms that allow the participant to consent to specific parts of the study, but not to others. Consider splitting up the informed consent process into two meetings so people have time to read the materials, think about them, and ask questions before enrolling.
  - Make absolutely clear that participation is voluntary and they can leave the study at any time.
  - Understand that in some communities, such as the Hispanic community, family members are often included in decisions concerning medical care and research participation. Be available and prepared for an informed consent process that includes a wider family group.

- **Choose the Right Channel.**
  - **Health Care Professionals.** Patients report a preference for hearing about research opportunities from their physicians. However, information about studies isn't always easy to find for busy clinicians. Reach out and supply informational materials – patient flyers, brochures, fact sheets, and contact information – directly to the MS clinics, neurologists, and pharmacists in the areas where you want to reach patients. National and state medical societies for MS health care professionals and minority health care professionals may be another good conduit. See here for a list of specialty and minority professional organizations.
  - **MS Organizations.** Organizations for people with MS are another source of information about clinical trials that people with MS trust.[33] These organizations may post links to current research opportunities, share information about them in newsletters, emails, and social media, and even be able to recommend people to serve your research team as an advisor. See here for a list of MS patient advocacy organizations.
  - **Institutions, Centers, and Clinics.** Reach out to health care professionals in your institution and/or other MS centers, clinics, and pharmacies.
    - Talk with physicians, nurses, and other health professionals about the study and the patients you are looking to recruit. Consider hosting a meeting or grand rounds on the topic.
    - Post information about your study in institutional newsletters, emails, updates, and the like, as well as flyers and waiting rooms
    - If available, work with your Institution's programs or offices that are aimed at increasing minority research recruitment and/or patient advocates.
  - **Websites, blogs, and social media.** Look for websites, bloggers, and social media groups that cater to people with MS from different racial and ethnic backgrounds.
    - Contact the site or group owner and ask to share information with their audience or followers or, if the group allows public posts, upload an appealing message. Social posts with an image are more likely to be read.

- **Keep Participants in the Loop.**
  - Offer to share information that will help participants. In a study conducted among patients with MS, patients noted that they would like to receive useful information about MS as part of their participation in the study. They also noted that they would like receive information about the research they participated in when the study is complete. Some noted that this was a factor as to whether they would participate at all, as they don't want to feel like the benefit of their participation is a one-way value proposition.
  - When people volunteer for clinical research, they care about their contribution and want to know what was learned. In fact, learning the outcomes of a study generally ranks as a top reason people participate.[45,46]
  - Yet very few actually do learn the results, and fewer still in language that is meaningful to them.[45,47] This can make participants feel undervalued and used, and can create a barrier against future participation.[48]
  - The Declaration of Helsinki[49] considers dissemination of study results to participants a moral obligation, and the FDA requires researchers to enter data into the ClinicalTrials.gov registry.[47] However, professional tools such as registries, even though publicly available, are often not easily understood by the lay public.
  - Developing a summary of the relevant findings in clear lay language is an effective way to communicate results to study participants.