

Best Practices for Facilitating Clinical Trial Participation

Researchers rely on patient participation in clinical trials to better understand the natural progression of neuromuscular diseases or test potential therapies. But some patients are hesitant to take part.

What are common barriers to patient participation in clinical trials? How can providers address these challenges and facilitate patient participation? For insights, we talked with Leann Lewis, MSGC, and Jeanne Dekdebrun, MS. Both are Senior Human Subjects Research Coordinators with the Neurology-Neuromuscular Disease Center at the University of Rochester.

Common barriers to patient participation

The reasons patients cite most frequently for declining participation in clinical trials are related to time, money, and travel logistics. Some patients can't take time off from work. Others can't afford to participate, particularly when a trial's stipend won't cover the cost of travel. Still, others are concerned about the logistics of getting to and from the trial site.

"A hesitation might be, 'I can't ambulate very well; it's going to be uncomfortable for me to figure out how to get there and then maneuver around the site,'" Dekdebrun says.

Other barriers are less common but still impede patient participation. For example, some patients aren't aware of opportunities to participate in clinical trials because their providers don't share them. This is more likely if patients see primary care providers rather than neurologists.

At many research sites, the same handful of patients volunteer for studies, but researchers need greater diversity. To attract new patients, researchers send email blasts, share details through MDA channels, and post notices in the community, such as in churches and libraries.

Some patients are hesitant to join clinical trials studying new medications because they may not trust the safety of the drug. Others may be intimidated to participate because they don't know what will happen during the trial.

"Demystifying what some of these activities and procedures are should help take away some of the unknown," Dekdebrun says. "It would be easy to get that information out there without destroying the study design. We tend to do the same things at every visit, no matter what the trial is. For example, we need to measure muscle strength, take some blood, and probably take a muscle biopsy."

For general education on clinical trials, researchers can refer patients to MDA's [Clinical Trial Finder](#), which includes definitions of trial types and FAQs, and MDA's [Clinical Trials 101](#) guide for individuals and families.

Managing the biggest roadblocks

Solutions that address the most common roadblocks — time, money, and travel concerns — make it easier for researchers to recruit patients.

Grants and stipends may cover the cost of travel for patients and, in some cases, a caregiver. Individual programs may pay for travel upfront or reimburse patients for travel expenses. Generally, the pharmaceutical company or organization sponsoring the clinical trial will provide funding for travel stipends, in addition to stipends for daily expenses, to relieve the financial burden on the participants.

“It helps alleviate some of the stresses that might come with participating in a study,” Lewis says. “We can’t reimburse participants for time off from their jobs, but we can at least tell them, ‘We’ll pay for your plane ticket, your hotel, your meals, and we’ll take care of you while you’re here.’”

Since the start of the pandemic, some researchers have offered remote or in-home visits for certain aspects of clinical trials. Questionnaires; reviewing medical history, medications, and side effects; and pregnancy testing for women of childbearing age can all be done remotely. Researchers may get reliable data via Zoom, with patients inputting data on researcher-provided tablets. Some trials also employ home health nurses who can perform simple procedures at the participant’s home, such as electrocardiograms, blood draws, and collecting urine samples.

“It can be more convenient for them and reduce the burden of travel,” Lewis says. “But they have to come in if they’re getting a drug infusion.”

Who should get tested?

Genetic testing is an option for any at-risk relative of a person with an identified pathogenic variant or mutation.

“The decision to have genetic testing is a personal one, and at-risk relatives should meet with a genetic counselor to discuss the benefits and limits of testing,” Kelly says. “Some genetic diseases also have associated medical risks that have available screening, such as cardiac disease risk. Genetic testing would allow for earlier screening for those individuals.”

Limitations to genetic testing include reduced penetrance in certain diseases, meaning not everyone with the mutation or the pathogenic variant will develop the disease. In these cases, being identified as having the mutation could cause unnecessary psychological distress.

Addressing accessibility

Some clinical trial organizers partner with patient logistics companies, like [Clincierge](#) or [Colpitts Clinical](#), to manage patient travel arrangements. Others designate someone on staff

to be the travel liaison.

“It’s a lot of logistics and trying to find out how to accommodate people who have different assistive devices,” Lewis says of her role. “Do you need a roll-in shower? Do you need to be close to the elevator or on the first floor? I can make those requests. It’s the customer service part of my job, making sure that patients are taken care of and not exhausted and in a bad mood by the time they get to the trial.”

Clinical trial organizers also need to manage on-site transportation for patients who may have walkers, braces, or other devices that make walking challenging.

“We have a contract with a hotel that has a shuttle that can accept wheelchairs and walkers; it’s easier to maneuver in and out of than, say, a taxi or an Uber,” Dekdebrun says. “Once they get to the hospital, we have a drop-off site with hospital golf carts that could help take them to the researchers if it’s a long walk.”

Lewis advises creating an Advisory Board that includes experts and stakeholders to review protocol feasibility and advise on all the logistical aspects. This board could include experts in the field of study/disease, participating patients, and study staff members.

Lewis points out that it’s important to take the next step and implement the advice given by these experts and stakeholders. “They have a lot of knowledge and personal experience with lessons learned to share to help make future trials successful,” she says.

CALL TO ACTION

MDA’s Medical Education Team established the Clinical Trials Awareness program to promote national-level/multi-center clinical trial programs looking to find potential participants. To promote an upcoming or ongoing clinical trial or research study, complete the submission form [here](#). For questions, email meded@mdausa.org. Find a list of actively enrolling clinical trials [here](#) and share them with your patients.