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Clinical Trials Need More Subjects

Patients are unaware or reluctant to participate, delaying new medicines' development

Studies show as many as 40% of all clinical trials don't meet enrollment goals and as few as 3% to 5% of cancer patients join a clinical trial. *PHOTO: ISTOCK*

By LAURA LANDRO
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Researchers conduct clinical trials to test new drugs and medical treatments, but the rate at which they are able to recruit and retain patients is at an all-time low.

Studies indicate that fewer than 10% of Americans participate in clinical trials, and only 3% to 5% of patients sign up for trials of new cancer therapies. Patients often aren't aware that trials are an option, and their doctors may not suggest them.

Some patients mistrust the research process and fear being a guinea pig, but for patients who do want to volunteer, complicated protocols and eligibility requirements can be discouraging. About 40% of clinical trials don't recruit enough patients to meet their goals.

“The challenges of identifying, recruiting and retaining volunteers for clinical trials drive up the direct and indirect costs of drug development and significantly delay the introduction of new medical interventions,” says Ken Getz, an associate professor at Tufts University School of Medicine’s Center for the Study of Drug Development and board chair of the nonprofit Center for Information & Study on Clinical Research Participation.

Carlos Calderon has participated in a clinical trial of a drug for multiple sclerosis. He is currently pursuing a college degree and likes to deejay in his spare time. *PHOTO: CARLOS CALDERON*

Now, federal regulators and research groups are proposing changes that speed up and enhance the way clinical trials are conducted and overcome barriers to participation.

Last month, the National Institutes of Health, working with the Food and Drug Administration, released a proposed new format for researchers to use when preparing study protocols for certain drugs that they submit for approval. It includes clearly stating the purpose, risks and benefits, recruitment and retention strategies, and time required for participating patients. Federal agencies are also collaborating on modernizing and strengthening existing research protections for patients, including simpler informed consent documents that clearly state the details most relevant to a patient’s decision to participate in a clinical trial.

“Too often scientists are focused on designing a perfect clinical trial to answer a scientific question, but ignore the importance of attracting patients to that study,” says Neal Meropol, chief of the Division of Hematology and Oncology at University Hospitals Case Medical Center in Cleveland. The center offers patients a Web-based interactive computer program called Pre-Act, for Preparatory Education About Clinical Trials, with 28 short videos to explain different aspects.

A study Dr. Meropol led, published online in December in the Journal of Clinical Oncology, showed that patients who viewed the program before their first oncology visit improved their knowledge and attitude about participating in trials. The Pre-Act videos are available free on the American Society of Clinical Oncology’s Cancer.net website.

Dr. Ann Bass, president of Neurology Center of San Antonio, often suggests clinical trials to her patients, helping them sort through the pros and cons and navigate consent documents. *PHOTO: ANN BASS*

The Clinical Trials Transformation Initiative, or CTTI, a public-private consortium co-founded by the FDA and Duke University, is preparing to issue new recommendations urging researchers to work closely with every "stakeholder" involved in clinical trials, including patients, disease-specific advocacy groups, community organizations and local doctors who act as investigators on trials.

Patients for example, should be asked what study questions are important to them, how many procedures such as blood draws they would be willing to tolerate, and how to improve written consent forms. "We want to create trials that everyone involved can champion, and that doctors can feel good about engaging their patients in," says Jamie Roberts, senior clinical project manager for the CTTI Recruitment Project.

Studies have found that trust in a physician is a main reason patients decide to participate in clinical trials. Many patients are swayed by a desire to help advance the cause of research for their disease. Researchers are also beginning to use social media to recruit patients.

Carlos Calderon, 30, was working installing home security systems with his brother in San Antonio in 2012 when he was diagnosed with multiple sclerosis, an immune system condition which disrupts transmission of signals between the brain and spinal cord and other parts of the body. In the relapsing forms, which are most common, attacks of symptoms such as fatigue, muscle weakness and cognitive difficulties are followed by periods of recovery.

His doctor, Ann Bass, president of Neurology Center of San Antonio, suggested a trial of a promising new drug, ocrelizumab, from Roche Holdings AG's Genentech unit, which acts to reduce damage to the central nervous system and disability progression with a low rate of serious side effects.

Because Mr. Calderon has a highly active form of relapsing MS, she felt he would be a good candidate for the trial, comparing the drug to an existing medication, Rebif, in a so-called double-blind, double-dummy trial. Dr. Bass, an investigator for the study, often suggests clinical trials to her patients, helping them wade through consent documents and pros and cons.

After the blinded phase of the trial ended last year with successful results, Mr. Calderon and Dr. Bass learned that he had been receiving ocrelizumab. He entered a new extension phase of the trial that gave study patients the option to continue on the drug. "It's been a very encouraging and positive and optimistic experience, not just for myself, but to see advancements for all MS patients," he says.

Oakland, Calif.-based health care system Kaiser Permanente, with over 10 million members, is using electronic medical records to help its doctors quickly identify patients who are good candidates for trials. Kaiser also launched a website were its members can locate trials and elect to receive emails about those for which they may be eligible. Dr. Louis Fehrenbacher, medical director of Kaiser Permanente Oncology Clinical Trials, says the "secret sauce" is Kaiser's ability to enroll patients in trials in their own communities, where doctors and nurses focus on building trust and relationships. In recruiting, staffers make it clear that patients are doing researchers a favor.

Yolanda Johnson, 58, a Kaiser patient in Sacramento, initially declined to participate in a clinical trial that was offered to her after she was diagnosed last year with triple negative breast cancer, a form that isn't driven by the three most common receptors that drive tumor growth. She says she was in a state of shock, and her family felt it wasn't right for her. But subsequent tests showed the cancer had spread to her lung, and when a nurse again presented the option of a clinical trial, she was more receptive.

"She took the time to explain what it was all about," Ms. Johnson says. "The way it was presented made me feel more comfortable and at ease and there was no pressure at all." The study compares an immunotherapy drug to a placebo when both are used in combination with chemotherapy. Ms. Johnson at first felt it was unfair that some patients got a placebo, but understood that was how participating in research helps advance treatment. Since she has to undergo chemotherapy as part of her regimen, whether or not she gets the study drug, "if there is something that can be gained, I have nothing to lose," she says.

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