

Decentralized clinical trials: A more patient-centric approach

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Patients with chronic, progressive diseases like systemic sclerosis must contend with limited treatment options, poor survival statistics, and debilitating symptoms that drastically reduce quality of life. These patients desperately need new treatments, but their disease makes it difficult to participate in clinical trials for promising new treatments.

Andreas Reiff, SVP of Inflammation and Immunology at Parexel, and Kristina Reeder, the company's Associate Director of Innovation, say that decentralized clinical trials, where portions of a study are conducted outside a traditional trial site, offer new opportunities — and new hope — for patients struggling with inflammatory conditions, and for organizations eager to develop new treatments.

Systemic sclerosis is an autoimmune disease that causes tightening and thickening of the skin, as well as scarring and inflammation of internal organs. It is a progressive and often painful disease with generally poor outcomes. “In my opinion, this is probably one of the most difficult autoimmune diseases from the patient's and the physician's perspective,” says Reiff. He explains that as skin hardens, mobility becomes limited and painful. Lung scarring creates breathing difficulties, and as the intestinal tract thickens patients must contend with stomach pain, acid reflux, malabsorption, constipation, and other digestive issues. “It has a huge impact on quality of life,” Reiff says.

“Most scleroderma patients have multiple specialists on their medical teams, which can become quite burdensome, both physically and mentally,” says Karen Gottesman, Director of Pharma & Biotech Engagement for the Scleroderma Foundation, an advocacy group. “Participating in clinical trials oftentimes becomes prohibitive due to the additional burden placed on the patient. Streamlining that process is essential not only for participation and compliance, but ultimately success of the trial.”

The nature of systemic sclerosis creates a challenging Catch-22 when it comes to drug development. There is a great need for new therapies to treat the disease and its symptoms, but those very symptoms lead to discomfort, exhaustion, and pain that make it difficult to participate in these clinical trials.

Reiff and Reeder believe decentralized clinical trials (DCTs) provide a new opportunity for these patients. DCTs are different from standard trials in that some or all of a study is conducted remotely.

“The most simple description of a DCT is that you are taking the study to the patient as opposed to taking the patient to the study,” says Parexel’s Reeder. “When you do that, you’re making clinical trial participation as easy as possible.” For patients managing systemic sclerosis, that might mean completing assessments via an iPad, using a wearable electronic device to conduct functional assessments, or bringing health care providers to the home to conduct study-related activities such as exams and blood draws.

DCTs improve access to trial participation for systemic sclerosis patients in several ways. Patients don’t need to travel to distant trial locations (Reiff estimates that 70 percent of trial participants live more than two hours from a research site), spend less time juggling family and work obligations, and are less likely to withdraw from a study due to poor health. “If you’re participating in a trial and you miss a few visits you’re often excluded from continuing,” Reiff says. “With systemic sclerosis you have good days and bad days, and sometimes you just don’t have the energy (to travel to an appointment).”

Reiff notes that systemic sclerosis patients most often participate in what are known as hybrid trials. “Certain treatments can’t be administered at home, and you can have logistical challenges delivering medications or scheduling home visits,” he says. “Between a traditional trial and a fully decentralized trial, there is often a hybrid middle ground.”

Finding that middle ground often involves aligning trial activities with other parts of a patient’s treatment. “It could be happening at a local hospital or infusion center where they are receiving other treatments,” says Reeder. “You weave the study participation into the care they’re receiving, so you’re not adding another trip. It’s about meeting patients where they are”

Reeder and Reiff say meeting patients where they are is all about connecting with them directly, whether through patient advisory councils, or advocacy groups like the Scleroderma Foundation.

“The first step in building a truly, patient centric study is to understand the patient, and what their life is like with the disease and how they may perceive certain aspects of a studies design,” Reeder says. “You can ask them what feels encouraging, or what might help them feel supported in their study participation, and likewise, what might feel disruptive. You can then use those insights to create really patient-centric protocols and operational plans.”

Gottesman, of the Scleroderma Foundation, agrees. “Scleroderma patients have very unique challenges not seen in other diseases,” she says. “Learning what those needs and challenges are is essential to developing new therapeutics in scleroderma.”

Actively seeking patient input can yield interesting and sometimes unexpected insights. “When you deal with serious diseases, your medical team becomes your family,” Reiff says. “You travel with them for many years through the ups and downs of their illness. They really become a part of your life, and you don’t want to lose that connection.” Planning for flexibility in patient-centric solutions becomes paramount to being able to participate for some patient populations, like those with systemic sclerosis.

Reiff believes that finding new and better ways to connect with patients can guide the industry toward designing more human-centric trials, empowering them to pursue new treatments. “They (pharma companies) recognize that we all need to become more innovative in searching for new solutions,” Reiff says. “DCTs are definitely part of that solution.”

But he says that ultimately, it comes down to providing hope to a group of patients who are in real need. “We need to be flexible and creative in providing the systemic sclerosis population with solutions that work,” says Reiff. “They have a high interest in clinical trials. If there’s anything new that shows promising results, we must try it.”

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