Part 2: Better Clinical Care Driving Transformative Change in 2021

How a Pandemic-Inspired Model for Clinical Trials Will Impact Research in 2021

Ready or not, the COVID-19 pandemic ushered in a new era of clinical research, the biggest advantages of which are just beginning to surface. In 2021, the life sciences industry will see more remote trial designs adopted by a larger and broader group of sponsors, sites, and patients. As a result, patient access and participation will rise to rates never seen before, more real-world evidence will be captured to enable better outcomes for more indications, and dramatic trial efficiency gains will enable more life-saving therapies to reach more people faster and for less.

The second of this two-part feature details the impact of a decentralized clinical trial (DCT) model on patients and how this will dramatically change healthcare in 2021…and beyond.

Virtual Tools Will Expand Patient Access to Clinical Trials Tenfold

Historically, access to clinical trials has been one of the greatest hindrances to study speed and success. By the end of 2021, many more pharmaceutical companies will leverage a decentralized model, which will not only open doors to more patients but will also reduce racial disparities in healthcare and improve overall outcomes.

Across the US, there is tacit acknowledgement of a two-tier system: those who have access to quality healthcare and those who do not. The difference between the two often tips the scales in terms of population representation in trials. DCTs improve access by bringing the trial to the patient and removing the burdens of travel and distance to make trials feasible across demographics. DCTs can also capture real-world data from patients “in the moment,” dramatically improving the quality of information.

This is not theoretical. The National Center for Biotechnology Information (NCBI) found that a decentralized trial model recruited three times as many patients three times faster than the traditional model. Urban and rural areas were also better represented by the patients in the decentralized model. These benefits are particularly important for rare diseases, as trials are few and far between and patients may be spread across wide geographic areas.

Greater Awareness of Social Injustices Will Ensure That Diversity is No Longer an Afterthought

As we continue to open our eyes to social injustices, more pharmaceutical companies will engage in real conversation about equality and will have another important reason to embrace a decentralized approach to trials. But this is just the start. From New Year's Day 2021 onward, trial sponsors will not only embrace DCTs to expand access but will also engage more people of color in protocol development. Diversity and racial equality will be first-order priorities at the beginning rather than a reverse-engineering "rescue" exercise well into the trial design.

Study teams, too, will become more diverse so that all demographics have better representation. They will bring vital insight into cultural and communications differences that can impact trial design and outcomes. Already, people of color may be less inclined to take an approved COVID vaccine even though they are a more vulnerable group; this could be overcome with better communication and education.

Expect to see diversity increasingly built into study protocol design and product development throughout 2021 and beyond. This will extend beyond people of color to include different genders and ages. We will see patients from all backgrounds involved in the study process from the start. Patients in Patient Advocacy Councils (PACs) can range in age from 20 to mid-70s, and mix female and male and minority members to inform product development and trial design – not on the back end, but at the beginning, when they can make the biggest impact.

Improvements in Patient Care Will Minimize Fear of the Unknown for Research Sites

The COVID-19 pandemic turbo-charged the use of virtual tools and a decentralized model for clinical research. But as life "returns to normalcy," the pharmaceutical industry must continue its pace of adoption of decentralized clinical trials (DCTs). Investigator sites stuck between the "fear of missing out" and "fear of the unknown" will cautiously push forward with DCTs as they see patients receiving better care.

It will not happen overnight. But sites will slowly grow less wary as they see the positive impact that a decentralized approach has on patient care. DCTs allow patients to stay safely in their homes and still have physician-monitored access to potentially life-altering new therapies. And because patients' health can be surveilled continuously using wearables, electronic diaries, virtual check-ins, and other tools, they receive premium care because sites can respond in real time and engage directly with patients more often.

Real-world data from in-the-moment patient accounts (before memory-muddled experiences are recounted at the next in-person visit weeks later) will also improve data quality and could lead to better outcomes. In addition, with greater trial access across all demographics, study data will be more comprehensive and lead to greater insight into developing new treatments. Improvements in trial speed will also drive more novel drugs to patients faster and for less cost.

DCT adoption will steadily increase through 2021 as improvements in patient care, data quality, and trial outcomes assure sites, sponsors, regulators, and patients that there is nothing to fear.

Patients Will Be at the Center of Every Aspect of Clinical Research

The recent expansion of decentralized clinical trials will have the unintended effect of holding a mirror in front of a life sciences industry that ironically has had a longstanding lack of focus on patients. In 2021, several factors will inspire companies to make substantive changes to how they operate to put patients at the center of everything they do.

In the last decade, the life sciences industry was distracted by a turbulent environment where blockbusters were replaced by niche innovations, globalization became the norm, and regulatory change was the only constant. New technologies have helped companies manage these changes but social injustices, growth in personalized medicine, and a global pandemic will turn the conversation back to patients in 2021.

Building patient relationships requires sponsors, sites, regulators, and technology partners to break down the silos that have hindered collaboration. We do not need a wrecking ball to do this – just trust and transparency. Patient advocacy groups are key to building trust, and advanced technology platforms that enable transparency across every stakeholder will cement these pivotal relationships.