Scitelline

DIA 2021 Reflections

DIA 2021 Reflections

The COVID-19 pandemic brought about many challenges to everyone around the world. People and organizations had to quickly pivot to work and engage in ways never done before. In addition to resiliency and perseverance, technology played a central role in our ability to carry on our work and lives, and clinical trials were no exception.

At the height of the pandemic, thousands of clinical trials were either suspended or stopped all together due to safety concerns from COVID-19 or regional lockdown conditions. Collectively, resources and energy were reallocated towards either COVID-19 studies or mitigating the impact of COVID-19 on existing studies[1].

This disruption posed great challenges to researchers and participants in clinical trials; however, the industry responded in a profound way that will have a lasting impact on how clinical trials are conducted moving forward.

The DIA 2021 virtual global annual meeting in June brought together many key opinion leaders, researchers, and partners across the industry together to discuss how they leveraged novel processes and technologies to continue their work. They shared perspectives and challenges they overcame, as well as key learnings and a path forward. Below are some of the key takeaways from Sciteline's perspective.

Decentralized clinical trial (DCT) technology and processes not only worked; they identified new opportunities

Whether leveraging eConsent or telemedicine, study sites and trial participants embraced and adopted various digital solutions to ensure participant safety and study continuity were maintained throughout the pandemic.

This was evident in sessions held by the FDA and Health Canada, as study sponsors and site staff worked diligently with health authorities and local research ethics boards to adapt DCT processes into their study protocols. These changes ranged from creating COVID-19 specific protocol deviation guidance or leveraging technology to conduct remote visits and assessments using telemedicine. Ultimately, these solutions not only showed that data integrity would be maintained, but also that these shifts provided both study sites and trial participants with more flexible options.

[1] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31787-6/fulltext

A survey conducted by ICON of patients between the ages of 18-75+ revealed study participants want more options[2]

During DIA, several sessions pointed to specific circumstances where DCT technology may have impacted participant retention. In particular, studies with long-term safety follow-up periods leveraged the use of digitized forms (ePROs and eDiaries) and telemedicine to maintain regular participant engagement during the pandemic when in-person visits were less desired or not possible.

Diversity and access to clinical trials

Clinical trials are often carried out by study teams located in specialty clinics or clinics near larger urban centres. This has created a long-standing participant recruitment and retention barrier as many potential participants are not willing to travel long distances to a study site for regular in-person visits.

Only 10% of survey respondents say they would travel one hour or more to participate in a clinical trial[2]

Other reasons for dropping out of a clinical trial early can range from the participants changing life circumstances, relocating, approval of alternative therapies or study fatigue.

We also heard that a large proportion of the population that would be eligible for a clinical trial are *not* participating because they are not being engaged, unaware of a trials' existence, or participation would simply be too inconvenient for them (e.g., too much travel or time away from work).

The implications of these findings are significant, both from a study validity (lack of a study participant pool that represents the broader population) and equal access to potential therapies perspective.

As we learned at DIA, the industry has recognized this gap. Researchers are now looking at addressing this issue into their study design process and looking for new ways to engage with historically underserved populations in clinical research.

Moreover, the pandemic brought to light the power of digital tools to reach populations in rural areas that may benefit from clinical trials but have historically been underserved.

Increasing adoption of DCT technologies is only one component of closing the access and diversity gap. As we heard from panel discussions, community engagement, knowledge-sharing and earning trust will need to be front and centre as we create a path toward equity in clinical research.

[2] https://www.iconplc.com/insights/patient-centricity/patient-voice-survey-decentralised-and-hybrid-trials/

Consider the patient experience and site workflow during study design

DCT is not a one-size fits all approach. Some studies could benefit from certain elements of DCT, such as eConsent, while others would benefit from remote visits via telemedicine. Implementing any sort of DCT technology should consider the patient journey as a *first step*.

A study participant may be averse to technology or may prefer to see their study team in-person. Any DCT technology should be hybrid-ready, meaning that assessments and case report forms can be entered in-person or remotely if preferred with no impact on data quality or user experience.

72% of survey respondents were more willing to participate in a clinical trial using technology, such as wearables and mobile devices in addition to patient diaries[2]

Additionally, almost every session around DCT acknowledged that technology vendors need to be a close partner in the study design process, and the earlier they are engaged in this process, the better the likelihood of success.

The introduction any new technology should consider existing processes and strive to reduce complexities and burden for the study site and participant, not the other way around. This could mean a relatively low learning curve, minimal impact on existing processes and an easy-to-use interface.

Where do we go from here?

Large-scale industry shifts are often in response to either a tragic event or crisis. COVID-19 has undoubtedly accelerated the adoption of technology in clinical trials. As many of us in the clinical research space are realizing, the pandemic will have a lasting impact on how clinical research is conducted.

As we move toward leveraging various technologies, we should be reminded of the most important factor in a clinical trial – that is, the participant. This means that we need to engage early and often, educate in a way that is understood by all, earn trust through transparency, and follow-through on what decades of surveys, research and experience tells us: potential study participants have busy schedules, live and work outside of urban centres, and come from diverse and vibrant communities. It's time to reduce barriers to participation – and DCT technology and processes may be the tool to do just that.

Visit www.sciteline.com to learn more about our patient-centred approach to DCT solutions built specifically for clinical trials.

About Sciteline

Sciteline combines creative thinking, robust research and cross industry leadership experience to develop decentralized clinical trial solutions to help solve some of Canada's most challenging issues facing clinical research. Our mission is to accelerate the generation of new knowledge by enabling researchers to achieve their best work while connecting them with a diverse population of clinical trial participants. We believe that by reducing the patient burden and changing the status quo, we can lower the cost of delivering new treatments and medical devices to patients.

Connect

To learn more about Sciteline's products and services, please visit **www.Sciteline.com**

Subscribe

To receive upcoming thought leadership publications and articles, please follow our LinkedIn page. To subscribe to our blog, please visit **www.Sciteline.com**