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COVID-19: A Catalyst for Technological Change in Clinical Research

True technological change occurs over long periods of time and even then, adoption is typically segmented between early and late adopters. The same is true in clinical research, where the shift to innovative technologies, including decentralized and hybrid trial models, has been slowed for reasons including the cost to implement and support training staff and lack of trust.

Resistance to changing technology cannot be sustained. For example, the adoption of social media as a marketing tactic among many businesses did not happen overnight. Instead the shift happened over many years once the old way of doing things was rendered obsolete in the wake of the digital era. Rather than being left behind, many companies evolved out of necessity.

The Current State of Clinical Research

The far-reaching effects of COVID-19 have led to changes in the ways we interact and how patients are cared for within clinical research. Since January, the pandemic has caused nearly half of all disruptions (over 1,100) in clinical trials [*CenterWatch 5/18/2020*]. 67.3% of clinical trial disruptions are reportedly due to suspension of enrollment. Of these trials, 14.7% are experiencing slow enrollment; within this segment, 20.7% were specifically attributed to the availability of sites and principal investigators (PIs) [*Global Data, 7/1/2020*].

Considering the situation, the FDA released new guidance covering site-less tests, virtual IRBs, and patient monitoring, all while stressing the importance of trial participant safety. Because of this shift, many sponsors that have been slow to adopt decentralized or hybrid trial models are now actively seeking these solutions in order to get trials back on track while enabling the safe conduct of enrollment for study startup, interventions, and trial participant data-gathering without the need for in-person visits at clinics or hospitals.

How Is COVID-19 a Catalyst for Change?

As mentioned above, decentralized or hybrid trial models have been met with resistance. However, these proven solutions can take on many challenges sponsors and CROs currently face. Chiefly, decentralized trials provide secondary benefits such as engagement and the potential to increase diversity among trial participant populations as this model alleviates many of the logistical burdens participants face, making it easier to participate through remote solutions including virtual visits or telehealth services.

The ability to provide decentralized solutions has become more critical today — and will continue to be so moving into the future. As travel restrictions, social distancing, and the overall strain on the healthcare system continue, a full range of decentralized trial methods, including hybrid clinical trials and trials including both site-based and remote activities, will be needed.

What Are the Benefits of Decentralized or Hybrid Trial Models?

According to Oracle's 2019 Market Research Report: The Use of Virtual Components in Clinical Trials, the use of technology in decentralized trials delivered value, particularly when it came to data quality, increased patient retention, and increased patient enrollment [***Oracle, 2019***]. These tech-enabled models are successful because they take research to the patient, making participation more convenient by removing many of the travel concerns while enabling more control, convenience, and comfort for the participant — all of which improve engagement and outcomes.

By extending the reach of clinical research, decentralized and hybrid trials can also:

- Alleviate the administrative burdens placed on sponsors and PIs
- Improve study quality, data integration, and integrity
- Facilitate faster recruitment, accelerate therapy development, and reduce costs
- Shorten timelines and facilitate faster study startup
- Provide opportunities for home administration or home use of the investigational medicinal product (IMP), which may be more representative of real-world administration and post-approval use

Who Are the Decentralized or Hybrid Trial Experts?

As the pandemic began to unfold, Elligo's healthcare-enabling approach enabled rapid response to challenges presented by COVID-19. As early adopters of tech-enabled, decentralized, and hybrid trial models, the company was able to immediately support and staff COVID-19 test sites while also maintaining support for ongoing trials across their network. A leader in managing integrated trials, Elligo has developed proprietary, technological solutions that provide sponsors, physicians, and trial participants with the expertise, technology, and processes needed to make research as seamless as possible. Elligo's preparedness to facilitate change combined with its capability and flexibility to enable the transition of a trial from in-office or traditional trial models to a decentralized format allow it to keep trials on track with the infrastructure needed to support the shift.

Elligo's technologies and data science capabilities were developed with patients, physicians, and sponsors in mind to allow the conduct of more efficient research. The company's System of Accelerated Research (SOAR®) is a GCP-compliant, decentralized, site-less clinical trial under a single, central PI. This not only mitigates risk but complies with regulations and improves data quality while decreasing resource requirements and costs associated with clinical research.

Developed to keep the patient and physician at the heart of its design, this technology-enabled service is adaptable and flexible enough to support completely decentralized, hybrid, and traditional randomized clinical trials. Formulated around CDISC standards, Elligo's system ensures quality and standards-based data are integrated from the start with the ability to safely gather informed consent while managing data collection from all participants at once. The benefits of this model are:

- Results in months rather than years
- Greater control and data integrity
- Greater patient centricity than a traditional trial

Partnering With Elligo for Innovative Trials

Having established the industry standard in technologies, Elligo provides essential information to sponsors, physicians, and trial participants. From improved 24/7 source data visibility to remote monitoring, transparency to real-time insight into the patient journey, and data interoperability for sponsors, Elligo creates a transparent environment that makes it easy for sponsors to monitor and maintain every trial type, including decentralized and hybrid.

Only Elligo provides the technology, data science, service flexibility, and experience needed to help ensure patients and physicians gain access to clinical research while sponsors have the confidence born of efficient trials and quality data. Utilizing decentralized and hybrid trials will become more common in the wake of COVID-19 as trials will need to:

- Facilitate research with fewer trial-participant and monitor visits to the site
- Embrace technology that allows data to be remotely accessible
- Carry out prudent measures to keep trial participants and staff safe
- Enable the sharing of best practices among participating sites

During the pandemic and beyond, Elligo will continue to support research by bringing solutions and insights to meet the real-world needs of sponsors, physicians, and trial participants as well as strategies that mitigate risk in order to ensure ongoing data integrity, visibility, control, and safety for successful research.

About Elligo Health Research®

Elligo Health Research, a healthcare-enabling research organization, uses electronic health records and the trusted patient and physician relationship to ensure all patients have access to clinical research as a care option. Powered by our *Goes Direct*® approach and novel IntElligo® Research Stack clinical technology, our team provides access to the best healthcare experts, patients, and research technologies. We engage physicians and patients who otherwise would not participate in clinical research and accelerate the development of new pharmaceutical, biotechnology, and medical device and diagnostic products. Learn more at ***elligodirect.com***.