Continuing Clinical Research Innovations After COVID-19

Historically, the clinical research community has been slow to adopt technological changes that could benefit trial operations. The resistance to changing technology is not a new phenomenon across industries; it often arises when such progress threatens to render old ways of doing things obsolete. Take the transition from steam power to electricity in the late 1800s, for example. Until the advent of electricity, factories were built around the use of steam-powered technology. Although electricity would have served as an immediate catalyst for change in manufacturing processes, it wasn't until decades later that electricity's potential was maximized. Why? Because factories were entirely built around steam technology and maximizing electricity's potential necessarily meant redesigning processes and rebuilding facilities.

The same can be seen in the clinical research industry where full adoption of innovative technologies, including those used in decentralized and hybrid trial models, has been slow to materialize in the last five to ten years. However, the COVID-19 pandemic has highlighted the importance of these solutions and, of necessity, accelerated their adoption. NPR reported that between March and April 2020 alone, approximately 440 studies involving as many as 200,000 trial participants were suspended because of the outbreak. The traditional pre-COVID model primarily required trial participants to visit sites for study interventions and data collection, and required CRAs to travel to monitor clinical data and safety. COVID-19 constrained traditional methods.

In response, the FDA released guidance stressing the importance of trial participant safety, noting that sponsors, investigators, and IRBs all play key roles in continuing studies while balancing a new risk to trial participants. This shift has sponsors and sites desperately searching for technologies that will enable them to safely conduct interventions and gather trial participant data without traveling to clinics or hospitals. Fortunately, decentralized and hybrid trial models are proven solutions that can overcome the many challenges sponsors and CROs face in getting back on track without having to rebuild.

> *"Risks to subjects are minimized [and] ... must be reasonable in relation to anticipated benefit to participants (if any) and the importance of the knowledge that may reasonably be expected to result."*
>
> *21CFR56.111(a)(1) and (2) IRB Criteria for Approval*

Clinical Trial Models for the Real World

The ability to provide decentralized solutions is more critical today — and moving into the future — than ever before. COVID-19 has made the benefits of the full range of decentralized trial methods, including hybrid clinical trials — trials that include both site-based and remote activities — even more apparent as travel restrictions, social distancing, and the overall strain on the healthcare system has become more evident. Importantly, decentralized trials provide secondary benefits such as the potential to increase trial participant population diversity and engagement as this model alleviates many of the logistical burdens trial participants face, making it easier to participate through remote solutions including virtual visits or telehealth services.

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According to Oracle's 2019 Market Research Report: The Use Virtual Components in Clinical Trials, technological solutions such as decentralized trials are not only more convenient for patients but can also increase retention. The key to these trials' success is taking research to the patient. By remaining patient-centric, the participant has more control, convenience, and comfort — all factors that improve engagement and outcomes.

Decentralized and hybrid trials extend the reach of clinical research and can also provide the following benefits:

- Reduced administrative burden on sponsors and principal investigators (PIs)
- No compromise in study quality or data integrity
- Faster recruitment: accelerated therapy development and reduced costs
- Shortened timelines
- Opportunity 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

"Pragmatic and hybrid clinical trials, including decentralized trials that are conducted at the point of care — and that incorporate real world evidence (RWE) — can help clinical trials become more agile and efficient by reducing administrative burdens on sponsors and those conducting trials, and can allow patients to receive treatments from community providers without compromising the quality of the trial or the integrity of the data that's being collected."

Scott Gottlieb, M.D., FDA Commissioner, January 2019

Expertise in Innovative Trial Models

Elligo's healthcare-enabling approach was able to respond rapidly to the challenges presented by COVID-19, effectively supporting and staffing COVID-19 test sites while also maintaining support for ongoing trials across its network. As the leader in managing integrated trials, the company has developed proprietary, first-in-class solutions that provide sponsors, physicians, and trial participants with the expertise, technology, and processes needed to make research as seamless as possible. Elligo's capability, flexibility, and preparedness to facilitate change enables transitioning a trial from in-office to decentralized with the Elligo infrastructure in place.

Elligo has developed a continuum of technologies and data science capabilities to enable patients, clinicians, and sponsors to conduct more efficient research. The System of Accelerated Research (SOAR™) is a GCP-compliant, decentralized, site-less clinical trial under a single, central PI. The system not only mitigates risk but adheres to regulations and improves data quality while decreasing resource requirements and costs associated with clinical research.

Developed to be adaptable and flexible, with the patient and physician at its center, this technology-enabled service can support completely decentralized, hybrid, and traditional randomized clinical trials. Based on 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:

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

Benefits of Partnership With Elligo

Elligo has established the industry standard in technologies providing essential information to sponsors, physicians, and trial participants. This includes improved 24/7 source data visibility, remote monitoring, transparency to real-time insight into the patient journey, and data interoperability for sponsors. All of these create a transparent environment, making it easy for sponsors to maintain visibility to control and monitor 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 the clinical research they need and 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:

- Conduct research with fewer trial-participant and monitor visits to the site
- Utilize technology that allows data to be remotely accessible
- Implement prudent measures to ensure trial participant and staff safety
- Share best practices among participating sites

Elligo will continue to support research during the pandemic and beyond, bringing solutions and insights to meet the real-world needs of sponsors, physicians, and trial participants along with strategies for mitigating risk 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.