

Preparing for a New Era of Clinical Research

Since January, COVID-19 has caused nearly half of all disruptions in clinical trials, totaling over 1,100 as of May 2020 — of which oncology trials have been the hardest hit [*CenterWatch 5/18/2020*]. The effects of the pandemic, including continued social distancing, have transformed how researchers carry out routine trial operations, fundamentally impacting patients. As COVID-19 continues to disrupt clinical research, the consequences are poised to be devastating for sponsors, physicians, patients, and worldwide health.

Getting Your Trial Back on Track

Although decentralized (DCT) or hybrid trials are not new, the industry has been slow to adopt these models — until recently. As many sponsors and CROs are rushing to get their studies back on track in the wake of COVID-19, DCTs are being actively sought. Elligo Health Research® was immediately capable of providing solutions for ongoing trials within their network and can provide a successful model for restarting and starting clinical research successfully.

As sponsors require solutions that mitigate risk to patients and practitioners, Elligo is uniquely situated and experienced to support the continuation of effective clinical research. This is accomplished by offering industry leading, tech-enabled solutions; fully understanding real-world needs of sponsors, physicians, and patients; and providing the mitigation strategies that ensure ongoing data integrity, visibility, control, and safety.

Expert Guidance for a New Era of Trials

As the leader in managing tech-enabled and integrated trial models, Elligo has developed proprietary, first-in-class solutions perfected over the past five years that make research as easy and seamless as possible. In a case where a trial needs to transition from a traditional in-office model to a decentralized, virtual, or hybrid model, Elligo can seamlessly facilitate the change within their platform.

The capability to transition to a decentralized model is paramount. Elligo partners with sponsors to conduct efficient and cost-effective trials to accelerate and optimize the process of bringing products to market. As a healthcare-enabling research organization, their network, including a range of physicians and healthcare communities, seamlessly integrates clinical trial execution into current physician workflows and provides the infrastructure and expert personnel needed for support.

Making the Transition to a New Research Environment Seamless

Using the *Goes Direct*® approach and novel IntElligo® Research Stack, Elligo provides access to the best healthcare experts, patients, and research technologies available. Powered by their advanced technology platform, IntElligo, including ResearchConnectSM for feasibility and patient identification, Elligo makes it feasible to employ electronic health record (EHR) data and leverage EHRs to bring more patients clinical research as a healthcare option. Elligo better matches sponsor study criteria with patient data access, which automatically prepares data for submission and regulatory compliance, ultimately optimizing the process while saving valuable time and resources.

Having established the industry standard in technologies, Elligo provides essential information to sponsors, physicians, and patients. For sponsors, this improves visibility, remote monitoring, transparency for real-time insight into the patient journey, and data interoperability while creating an environment that makes it efficient and easy to maintain transparency and control over every trial aspect. For physicians, Elligo's tech-enabled solutions simplify trial oversight and remote reviews while easing data access and tracking to provide the support needed to seamlessly integrate into workflows. Partnered with Elligo's expert staff, these advantages ensure patients have access to clinical research as a care option and physicians have the opportunity to bring clinical research into their practices.

Only Elligo offers the technology, data science, flexibility, and firsthand experience needed to seamlessly transition to decentralized or hybrid models, ensuring sponsors have the confidence of efficient trials and quality data, and more importantly, that patients and physicians have access to clinical research.

Access to Tech-Enabled Solutions

State-of-the-Art Technology

IntElligo Research Stack offers verified, cutting-edge solutions for streamlined data collection from patient identification to study close. The proprietary technology collects data at the right point of care and automatically checks for regulatory compliance and study operational management. Through this technology, Elligo makes sure that study sponsors can see real-time views of management information and that patients receive their stipends promptly. Everything within the platform bolsters Elligo's mission to protect the integrity of the trusted patient and physician relationship, safeguarding it throughout the process.

Innovative Data Science Tools

The proprietary data science technology, ResearchConnect, supports protocol feasibility assessments through direct links with EHR data across the Elligo partner network. The expert data science team conducts routine searches for screening and rapid enrollment of qualified patients. Through this, Elligo makes it possible to use real-world data to boost clinical trial performance while supporting regulatory decision making, surveillance, sophisticated data analytics, and decentralized or hybrid trial models. ResearchConnect ultimately enables physicians to bring more study opportunities to their practices while securely protecting patients' data privacy.

Unparalleled Decentralized/Hybrid Trial Experience

Elligo has worked with the FDA and National Institutes of Health (NIH) over the past few years on projects centered around the use of real-world data for regulatory decision-making. The company has firsthand experience in decentralized and hybrid trials, having developed their technology to be flexible and adaptable, with the patient and the physician at the heart of the design. Through their System of Accelerated Research (SOAR®), Elligo is able to offer technology-enabled services which not only mitigate risk but ensure adherence to regulations and improve data quality to decrease resource requirements and costs associated with research.

Understanding the Real-World Needs

As previously mentioned, when COVID-19 began to disrupt trials nationwide, Elligo was able to immediately provide solutions for ongoing trials within their network. They achieved this task by mobilizing across their network to gather information from physicians and patients.

Methodology

Practice staff and their patients were surveyed regarding trial experiences with Elligo, specifically about satisfaction and areas for improvement. Questions included how they were coping with the pandemic and about their needs, among others. These survey results provided Elligo with an understanding of how to support continuing clinical research post-COVID-19 and brought to light a number of ways in which Elligo could strengthen existing capabilities, refine services, and optimize research during this time. Following are some of the insights these surveys provided:

Practice Survey Results

- Most respondents (66%) said they desire to do more research than they are doing currently; “We have plans to do much more”
- Many practices noted that while research poses many difficulties because of COVID-19, they would like more communication on which studies are available and how to participate
- Others mentioned the need to utilize more physician and clinical staff engagement, in addition to the coordinator, in order to conduct research more effectively
- Practices said they had updated their mitigation protocols several times, following CDC guidance
- Of those surveyed, all were using telemedicine, many for the first time
- Every practice reported making significant changes in response to COVID-19, including remote screening, contactless check-in, staggered office hours to reduce the number of waiting patients, mask requirements, temperature checks upon arrival, questionnaires, increased sanitizing/routine cleaning, checkouts from the patient rooms, no cash transactions, and telemedicine options
- Some reported limited surgeries and mentioned drive-thru centers and curbside visits

Patient Survey Results

- Many patient participants in Elligo-enabled trials reported extra caution when coming into the office for regular visits for several reasons
- Some have childcare issues caused by the pandemic and cannot leave young children unattended at home and could not bring them along to their visits
- Others don't have time because of working extra hours
- Many patients are still wary of venturing out of the house, sharing concerns about bringing home COVID-19 to an elderly relative
- A few participants cited that they would rather wait until the pandemic passed before feeling comfortable coming in
- Across the board, most patients are interested in participating in clinical research when appropriate, once positive COVID-19 cases in their area have declined and medical offices have more safety measures in place

In cases where the study drug is a lifeline, many patients have mixed feelings about whether to miss their dose or go to the office. Some patients with respiratory ailments such as COPD, for example, were uncomfortable leaving quarantine, even to visit the doctor's office. However, patients still wanted to get the monthly study drug administered. Likewise, a few patients said that the pandemic has helped them realize how important research is, whether it's for COVID-19 or any other indication. To see the Elligo Mitigation Report with recommendations for safely conducting clinical trials during the pandemic, [click here](#).

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The Results Are in — Physicians Survey Summary

- All respondents said their practices use telemedicine
- No universal telemedicine platform is used by more than three respondents (20%)
- Just five of the respondents (33%) believe their use of telemedicine will be a standard for initial consultations and/or certain types of visits
- Only two respondents (13%) said they were using new technologies to assist in caring for patients remotely
- Thirteen respondents (87%) have incorporated telehealth or increased its utilization because of COVID-19; practices are also doing more office cleaning and limiting the number of in-person patient visits
- Eleven respondents (73%) expect to increase the number of hours they are open once business and social distancing measures are relaxed

Providing Mitigation Strategies: a Partner for the Path Forward

In the past few months alone, Elligo has successfully started, restarted, and continued to conduct ongoing trials driven by their commitment to continue ensuring patients have access to research as care. Elligo has communicated a range of key directives for practices backed by recent research carried out with physicians and patients across their network.

Key risk mitigation strategies include:

- Ensuring the most recent FDA/CDC/state/local protocols and guidance are followed to ensure safety for practice staff and patients
- Following best practices including updates to layout, SOPs, and scheduling
- Employing remote monitoring and telemedicine capabilities when possible
- Practicing under the assumption that all patients are potentially infected

Elligo will continue supporting successful research today and into the future in practices where research has continued despite the pandemic. The company is dedicated to helping others prepare for startup as soon as local circumstances allow, during the pandemic and beyond, through their significant capabilities in industry-leading, tech-enabled solutions; real-world insights; understanding of the needs of sponsors, physicians, and patients; and strategies for mitigating risk, ensuring data integrity, visibility, control, and safety.

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.