ELLIGO HEALTH RESEARCH® | Goes Direct®

The Need for Healthcare-Enabling Research Post-Pandemic

First, we would like to commend all the heroes who have stepped up to serve the increased need from patients and others in their communities during this difficult time. To reduce the spread of the COVID-19 pandemic, much of the world was sent home while other businesses, like ours, saw a downturn in activity. We acknowledge that requirements to reinstate halted clinical research activities now necessitate new procedures to deter a resurgence of infection. New daily routines and interactions must also be considered for the foreseeable future.

As a healthcare-enabling research organization, we have supported practices where research has continued despite the pandemic and helped others prepare to enroll patients as soon as local circumstances allow. We have done this by keeping the safety of patients and staff front of mind and mitigating health risk while ensuring regulatory compliance and data integrity. Our staff has been provided instructions on means and methods to mitigate risk for patients and healthcare personnel and about how to communicate appropriately with research patients.

The instructions to our staff have been in accordance with recommendations from the FDA guidance document, "*Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency*," and with the safety of all concerned in mind. Concurrently, it is incumbent upon the entire clinical research industry to redesign research processes with the continued safety of our patients, investigators, study managers, and monitors as an integral concern while seeking ways to improve and streamline clinical research.

The shift of focus to decentralized clinical trials (DCTs) is, thus, not unexpected. Through requirements associated with the *21st Century Cures Act*, FDA leaders have been encouraging DCTs for several years now. They have also been writing recent guidance related to gathering real-world data (RWD) to support regulatory decisions and guidance on *Patient-Focused Drug Development*, encouraging "comprehensive and representative" engagement of patients in all aspects of clinical research; such opportunities are gaining more traction now, out of necessity.

Elligo's Role During the Pandemic

Our study managers have demonstrated their ability to adjust to the pandemic during the past two months, including actively working at COVID-19 testing sites to take samples from individuals who fear they have been infected. Our operations and technology teams have spent this time identifying opportunities to mitigate risks through more efficient research that leverages our proprietary technology (IntElligo® Research Stack) and data science platform (ResearchConnect℠). This technology-based research system streamlines research processes, enables important research operations to safely continue during a pandemic, and backed by our experience, allows for conducting successful DCTs and hybrid trials.

Although this pandemic is difficult, there is opportunity to use innovative technologies and processes to increase the efficiency of clinical research and incorporate more patient centricity. Elligo's technology supports these important objectives and can enable sponsors to take the FDA recommendations related to the COVID-19 pandemic to heart — along with previous recommendations related to DCTs and the use of real-world evidence (RWE) to support regulatory decisions — as we move forward.

Elligo Has Been in the Lead

As *Dr. Scott Gottlieb stated* when he was FDA commissioner, "Efforts to streamline medical product development based on advancing science can be frustrated by legacy business models that discourage collaboration and data sharing, and the adoption of disruptive technologies that make clinical research more effective."

Elligo was founded to stimulate precisely this innovation and industry disruption that clinical research needs now more than ever as we transition into a new environment. Only Elligo offers the technology, data science, and experience to provide these opportunities so patients and physicians gain the access to clinical research they need, and sponsors are ensured efficient trials and data quality.

Technology

Elligo's proprietary technology, IntElligo Research Stack, facilitates remote monitoring with remote source data verification. IntElligo is configured to collect protocol-specific eSource data in industry standard formats and provides flexibility with respect to workflows. Transcription can be eliminated, thus improving data quality and reducing required resources. This proprietary technology maintains patient privacy and adheres to regulations relevant to eSource documentation for research. In addition, patients promptly receive their stipends and study sponsors can see tailored views of real-time management information. This all supports our mission to ensure that the integrity of the patient-physician relationship is maintained throughout the process.

Data Science

Elligo's data sciences platform, ResearchConnect, supports protocol feasibility assessments through direct links with electronic health record (EHR) data at Elligo practices. Our data sciences team conducts expert searches that facilitate patient identification and transfer of baseline information into IntElligo for screening and rapid enrollment of qualified patients. Our capabilities also include the use of RWD to augment clinical trials and support regulatory decisions, surveillance, virtual trials, sophisticated data analytics, and other means of streamlining and enhancing clinical research.

Experience in Decentralized/Hybrid Trials

Over the last few years, Elligo has worked with the FDA and NIH on projects centered around the use of RWD for regulatory decision-making. In addition, Elligo has firsthand experience in DCTs and hybrid trials. Our technology was developed to be flexible and adaptable, with the patient and the investigator at the heart of the design, and allows us to offer technology-enabled services to provide a System of Accelerated Research (SOAR™), which not only mitigates risk, but adheres to regulations and improves data quality while decreasing resource requirements and costs associated with clinical research.

While we all continue to maintain vigilance to react accordingly in the event of any local resurgence of the virus, as the ultimate healthcare-enabling research organization, only Elligo is prepared with the right technology, tools, and experience to provide you with the direct access to physicians, patients, and data you need for your clinical research program to resume trials after COVID-19.

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.