

# Critical Considerations: Using Decentralized and Traditional Trial Models Interchangeably in a New World

## Our challenge now

The world has changed in fundamental ways. The far-reaching effects of COVID-19 have transformed how we act, how we interact, and how we care for patients. When it comes to clinical research, the pandemic has already exacted a huge toll. Between March and April 2020 alone, approximately 440 studies involving as many as 200,000 patients had been suspended because of the outbreak. About a quarter of these studies were for cancer treatment. [NPR 4/11/20] As the pandemic disrupts clinical research, the implications are potentially devastating for sponsors, physicians, patients, and human health worldwide.

## Leadership response

Fortunately, there are proven solutions that can overcome challenges and help sponsors and CROs get studies back on track. With industry-leading, tech-enabled, and integrated trials, Elligo Health Research® has long been able to provide solutions for virtual clinical trials. Elligo's commitment to bringing clinical research directly to healthcare — and the innovative solutions we offer to accomplish this — provide a successful model for restarting and starting clinical research successfully.

Elligo is uniquely experienced, equipped, and situated to provide solutions that help mitigate risk and support continuation of successful clinical research. The company accomplishes this in three ways: by offering industry-leading, tech-enabled solutions; by fully understanding real-world needs of sponsors, physicians, and patients; and by providing the mitigation strategies that ensure ongoing data integrity, visibility, control, and safety.

*“Elligo is already built for clinical research of the future.”*

## Expertise in what the present world demands

Elligo is the leader in managing tech-enabled and integrated trials, a model the company has been building and perfecting for almost five years. The company developed proprietary, first-in-class solutions to make research as easy and seamless as possible for sponsors, physicians, and patients. For example, if there's a need to transition a trial from in-office to decentralized, Elligo has the flexibility to facilitate that change within our platform. Now more than ever, these capabilities are crucial. Elligo works with sponsors to conduct efficient and cost-effective trials to help accelerate and optimize the process of bringing products to market. As a healthcare-enabling research organization, Elligo's growing network includes a range of physicians and healthcare communities to seamlessly integrate clinical trial execution into current workflows with the infrastructure and expert personnel needed for faster startups.

*“The ability to provide decentralized solutions is more critical now — and moving forward — than ever before.”*

## Benefits of Elligo offerings for sponsors, physicians, and patients

Using the *Goes Direct*<sup>®</sup> approach and novel IntElligo<sup>®</sup> Research Stack, Elligo provides access to the best healthcare experts, patients, and research technologies available. Their advanced technology platform, IntElligo, including ResearchConnect<sup>SM</sup> for patient recruitment, makes it possible to utilize electronic health record (EHR) data and leverage EHRs to bring more patients clinical research as a healthcare option. With patient data access, Elligo can better match sponsor study criteria. This also makes it possible to automatically prepare data for submission and regulatory compliance, a streamlined process that ultimately can save valuable time and resources.

Elligo has established the industry standard in technologies providing essential information to sponsors, physicians, and patients. For sponsors, some of the benefits include improved visibility, remote monitoring, transparency to real-time insight into the patient journey, and data interoperability. All of these create an environment that makes it easy for sponsors to maintain visibility and control of every trial.

For physicians, benefits of Elligo tech-enabled solutions include easier oversight, remote reviews, reduced tracking, easier access to data, and support for healthcare.

These benefits, along with Elligo staff expertise and support, are to help ensure patients have access to clinical research as a care option and physicians have the opportunity to bring clinical research into their practices.

As we transition to a new research environment, only Elligo offers the technology, data science, flexibility, and experience to help ensure patients and physicians gain the access to clinical research they need and sponsors have the confidence of efficient trials and quality data.

## Innovative tech solutions

### Technology

Elligo's proprietary technology, IntElligo Research Stack, offers innovative, proven solutions for streamlining data collection from patient identification to study close. IntElligo collects data at the point of care, then automatically uses it for regulatory compliance and study operational management. In addition, Elligo technology ensures that patients receive their stipends promptly and study sponsors can see real-time views of management information. This all supports Elligo's mission to ensure that the integrity of the patient and physician relationship is maintained throughout the process.

### Data science

Elligo's data sciences platform, ResearchConnect<sup>SM</sup>, supports protocol feasibility assessments through direct links with EHR data at Elligo practice partners. Elligo's data sciences team conducts expert searches for screening and rapid enrollment of qualified patients. Elligo makes possible the use of real-world data (RWD) to augment clinical trials and support regulatory decisions, surveillance, decentralized trials, sophisticated data analytics, and other means of streamlining and enhancing clinical research. Ultimately, ResearchConnect enables physicians to bring more study opportunities to practices while securely protecting patients' data privacy to maintain the trusted physician and patient relationship.

### 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. Elligo's technology was developed to be flexible and adaptable, with the patient and the investigator at the heart of the design. This allows the company to offer technology-enabled services to provide a **System of Accelerated Research (SOAR<sup>TM</sup>)**, which not only mitigates risk, but adheres to regulations and improves data quality while decreasing resource requirements and costs associated with clinical research.

*“We listen to our customers so that we can give them what they need to succeed.”*

## Practice Physician's Survey Summary

- **Universal telemedicine usage** – All 15 respondents (100%) said their practices use telemedicine.
- **No universal platform** – No one telemedicine platform is used by more than three respondents (20%).
- **Limited intent to use telemedicine for specific visits** – Just five of the respondents (33%) believe their use of telemedicine will be a standard for initial consultations and/or certain types of visits.
- **Very limited adoption of new technologies** – Only two respondents (13%) said they were using new technologies to assist in caring for patients remotely.
- **Adoption or increased use of telemedicine biggest COVID-19 change** – 13 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.
- **Expected increased hours** – 11 respondents (73%) expect to increase the number of hours they are open once business and social distancing measures are relaxed.

## Understanding real-world needs

### Listening to our customers

As COVID-19 began to disrupt trials nationwide, Elligo mobilized to gather information from physicians and patients. Practices were asked about trial experiences with Elligo, satisfaction, and areas for improvement. Practice staff and their patients were asked about how they were coping with the pandemic and about their needs. The results of these surveys helped Elligo understand how to support continuing clinical research. And it pointed to ways in which Elligo could help strengthen capabilities, hone services offered, and make research in this transitional time successful and efficient. Following are some of the insights these surveys provided.

### Practice survey results

Among physicians, practice administrators, and study coordinators, most respondents said they would like to do more research than they are doing today (66%); comments included, "We have plans to do much more." Several noted that while research is difficult because of COVID-19, they would like more communication on which studies are available and what they need to do to participate. Others mentioned that to conduct research more effectively, they utilize more physician and clinical staff engagement, in addition to the coordinator.

### Adjusting to the pandemic

Respondents reported updating their mitigation protocols several times, following CDC guidance. All practices surveyed were using telemedicine, some for the first time. All have made significant changes in response, including remote screening and contactless check-in, staggered office hours to reduce the number of patients in the waiting room, no visitors, use of masks, taking temperatures of patients upon arrival, questionnaires, increased sanitizing/scheduled cleaning, checkouts from the patient rooms, no cash transactions, and telemedicine. Some said they have limited surgeries. Some mentioned curbside visits and COVID-19 drive-thru centers. To see the Elligo Mitigation Report with recommendations for safely conducting clinical trials during the pandemic, [click here](#).

### Patient responses

Many patient participants in Elligo-enabled trials have been cautious coming into the office for their regular visits for a variety of reasons. Some have childcare issues due to the pandemic; they can't leave young children at home and can't bring them along to their visits. Others are working extra hours and don't have time. Still others are wary of venturing out of the house or are concerned about "bringing home" something to an older relative. A few research patients have indicated they would rather wait until the pandemic has passed before coming in. Overall, most patients are interested in participating when appropriate, once positive COVID-19 cases in their areas decline and medical offices have safety protocols in place.

For some patients in trials, the study drug is a lifeline, and they are torn about whether to miss their dose or go to the office and potentially be exposed to illness. For example, some COPD patients were extremely anxious about leaving quarantine, even to visit the doctor's office, and yet they really wanted to get the monthly study drug administered. On the other hand, some patients say that the current situation helps them realize how important research is, whether it's for coronavirus or any other clinical indication.

## Providing mitigation strategies

### Leading the way forward

As we move through and past the pandemic, Elligo has accomplished starting, restarting, and conducting ongoing trials, and is committed to continuing to do so. Based on research with physicians and patients, as well as the company's significant experience in bringing clinical research directly to clinical healthcare, Elligo has communicated a range of key imperatives for practices. Key points of these mitigation strategies include:

- Ensuring the most recent CDC/state/local guidelines are followed to promote safety for practice staff and patients
- Implementing best practices including updates to layout, SOPs, and scheduling
- Using telemedicine capabilities when possible
- Assuming all patients are potentially infected

As the leading healthcare-enabling research organization, Elligo provides ongoing support to practices where research has continued despite the pandemic, and helps others prepare to enroll patients as soon as local circumstances allow. Elligo will continue to support continuity of clinical research during the pandemic and beyond, bringing its significant capabilities in industry-leading, tech-enabled solutions; insights into real-world needs of sponsors, physicians, and patients; and strategies for mitigating risk in order to ensure ongoing data integrity, visibility, control, and safety for successful research today and into the future.

## 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](http://elligodirect.com).