### **5 Ways to Make Your** Clinical Trial Work at



Without Compromising Quality, Compliance and Integrity

The genie is out of the bottle: clinical trials can go faster. The pandemic showed us that clinical trials can safely move faster – a lot faster. Out of necessity, clinical trial operations around the world modernized virtually overnight in response to the COVID-19 public health crisis. Now is the time to keep momentum for digitally connected clinical trials that better serve innovative research to address health needs today and in the future.

Efficiency creates speed in clinical trials. And herein lies a key limitation of today's siloed clinical trial operations: they are not designed for quick decisions. Silos exist between the people designing the protocol and those in the field conducting the trial; between the study experts intimately aware of the science and those on the ground making eligibility and treatment decisions. Study monitors have the impossible job of being the conduit between multiple research sites and sponsors and cannot possibly provide immediate clinical trial answers.

What if clinical trials were powered by a connected network of stakeholders optimized for real-time decision making? This network would bust the silos and allow speedy enrollment of the right patients, fewer execution errors, and achievement of study milestones on time and on budget. Research would progress efficiently and predictably through study phases, delivering new treatments to market faster.

Here are 5 ways to move clinical trial operations to lightspeed without compromising quality, compliance, and integrity:



Paper is slow. You cannot tell who is using it or what version they are viewing. Whether in traditional paper format or as a PDF, static documents force users to sift through pages, scanning for answers. To keep the files secure, they are inconveniently locked in a room or a portal – away from the clinic where research staff and investigators need instruction the most to inform screening, enrollment, and trial conduct decisions.

The most logical way to support research staff is from their pocket. When your study is digitally connected, site users can easily access content from the devices they already have with them and collaborate with their CRA or the study team through embedded communication tools. Because it works in a tap just like other mobile applications, adoption is easy and seamless.

Digital moves your trials to lightspeed, giving you confidence in your trial performance. A digital protocol ensures every stakeholder references the current, approved version from the convenience of a secure mobile application. No more chasing to find what version is assigned to a given site and no more wondering whether sites are aware of the current version for them. A digital protocol gives you the control to assign the right version to the right site and to ensure that it is delivered straight into their pockets via a secure mobile application.



Today's multimedia world puts a priority on digital engagement. There is a lot that clinical trial managers can learn from applying basic digital principles to content and communication practices. Rather than two distinct elements, content and communication should be tightly intertwined so that your communication strategy directs people to the most topical, relevant content – be it a section in the protocol or multimedia, such as videos. Consider how much more depth you can deliver to inspire and inform your research sites by providing a short podcast from your lead medical experts on the rationale for the trial design. Or the intricacy that can be communicated from a video explaining a complex procedure.

Achieving lightspeed humanizes your clinical trial with modern approaches to content and communication that are truly helpful to your audience. Short tutorial videos accessible alongside the protocol are visual, making the content more memorable to your audience. Ultimately, digitally connected clinical trials open a new world of possibilities for collaboration among sites, monitors and sponsors.

Supercharge Your Site Outreach

You might think it's impractical to regularly coach your research sites. However, digitally connected clinical trials lower the barrier, making it possible to tailor your site outreach. Learning from digital interactions with your trial allows you to better gauge what sites need. For example, a question from one site could prompt you to create and deliver a short video explaining a procedure. You could then time when you share the video to coincide with the visit schedule at your other sites so they have the benefit of the additional guidance.

Site instruction doesn't have to be a static curriculum provided to all sites – it can be a fluid set of tailored course corrections informed by real-time insights. It is bi-directional knowledge sharing at lightspeed that drives participant safety, data integrity, and inspection readiness. Importantly, achieving lightspeed is not about burdening the sites with more communication. Rather, it supports well-orchestrated site outreach with useful tips to help sites enroll faster, best practices to ensure patient retention, and timely instruction for complex procedures. You avoid spam filters and email backlog by delivering actionable communication to sites exactly when and where they need it.

## Open a Two-Way Communication Highway

Traditional forms of communication – email, phone, in-person visits – are slow, generate site burden, and frustrate study timelines and budgets. Let's say a site needs a clarification. First they track down the CRA. Then the CRA needs to track down the right contact at the sponsor. Then the answer goes back to the CRA and then back to the site. It's not hard to understand why clinical trial answers can take hours, days or more. If there is then a further clarification, the painfully slow game of "telephone tag" starts all over again. Digitally connected clinical trials pave the way for a communication superhighway.

Achieving lightspeed means research sites have access to study experts when they need a clarification or reassurance on the right course of action. We know important decisions don't wait for office hours, making it essential that sponsors and CRAs can quickly, easily, and conveniently address site queries when they arise. Communication tools need to be simple, intuitive and mobile to support decisions at the point of care – bridging sites and study experts in just a tap. A modern approach makes manual logs a thing of the past as CRAs and sponsors can easily resolve and automatically capture communications into inspection-ready study files.







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It's impossible to implement corrective action or even an effective communication strategy if you don't know what's going on with your study in real time. What if you could see that a site is regularly searching the protocol but not enrolling any patients? What if an expected toxicity begins to trend in the keywords sites are searching? What if sites are continuing to send queries requiring the same set of clarifications on a new procedure? Digitally enabled clinical trials unlock all kinds of actionable signals that inform cost saving and proactive actions sooner.

Reaching lightspeed means you unlock insights to drive ongoing decisions that improve trial performance, rather than waiting for periodic after-the-fact reports. When your protocol is digitally enabled it becomes the key to valuable insights: who is engaged with your study, who is actively trying to enroll participants, what questions they have, what trending topics may need the attention of your medical experts. Visibility into site engagement and study performance is only accessible when clinical trials are digitally connected. Think of each interaction with your study as a piece of a digital mosaic. As time goes on, each interaction builds a bigger and better picture of what's really going on in the field. It means you can take data-driven decisions for improved patient safety and optimal trial outcomes.

#### **Unlock the Full Potential of Your Clinical Trials**

When clinical trial operations are geared to move at lightspeed, investigators and research staff can spend more time focused on patient care and higher value research insights. Less frustration and friction are important for optimizing site relationships. Digitally enabling and engaging the broad set of clinical trial stakeholders creates new insights and possibilities for the future of research. With a streamlined approach to collaboration, research sites can spend less time figuring out which portal and what password to access trial instruction. In turn, this frees up sites to increase capacity for more research.

There is also an opportunity to expand to newer research naïve sites to improve accessibility to more participants, thereby increasing patient population diversity. New to research, these sites and investigators gain confidence from access to a responsive set of people and resources to guide them for the best decisions. In turn, this creates more opportunities to expand more trials to fully decentralized or hybrid settings without sacrificing quality or compliance. Additionally, more complex trial designs can be successfully executed when content and communication are embedded into digitally connected clinical trials. Digital engagements feed continuous enhancements of timely, relevant communication plans that deliver multimedia resources to assist with trial conduct. The ultimate proof point of digitally connected clinical trials is that trial milestones are met with fewer delays.

# Benefits of a Digitally Connected Trial

1	Increases capacity at current research sites
2	Opens new, "research naïve" sites
3	Expands into hybrid trial settings
4	Supports complex trial design
5	Meets trial milestones with fewer delays

### **Teckro: The Hub for Digitally Connected Clinical Trials**

As the hub for content, communication and insights, Teckro connects study stakeholders with the answers they need, when they need them. By embedding content with communication, you can directly link researchers to specific guidance when it will be most useful for them. It is the "virtual coach" on the shoulder of researchers, giving them the study expert guidance to make the best-informed decisions to safely conduct your trial.

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