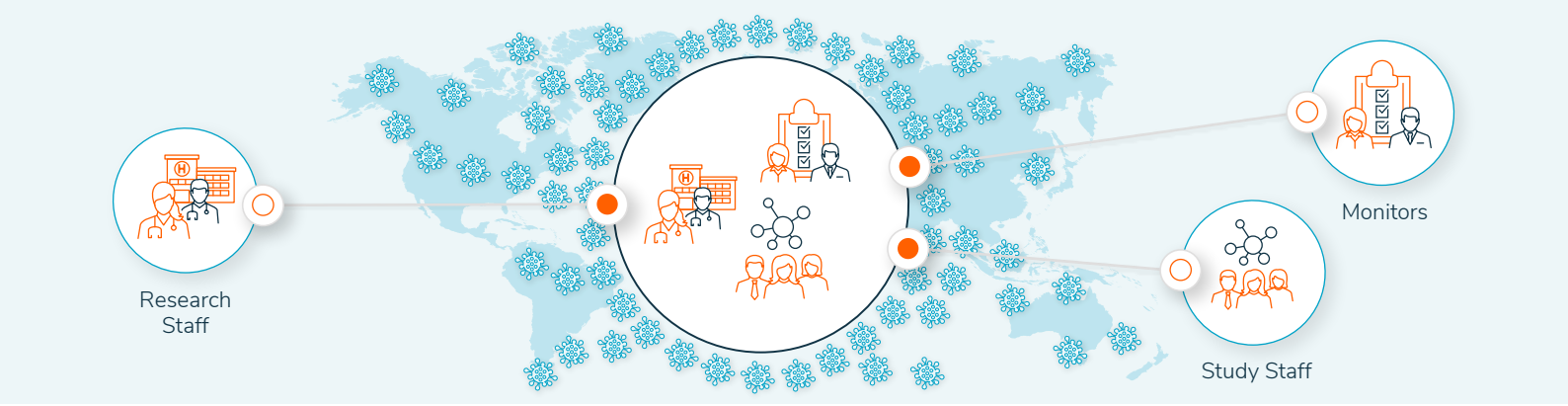
Accelerating Infectious Disease Research in Response to COVID-19

When it comes to infectious disease clinical research, it is a race. Now, in the midst of a global pandemic, there is immense time pressure to find a solution for COVID-19. In response, sponsors, with support from regulators, health authorities and governments are starting clinical trials at record pace.

Accelerating infectious disease trials requires a new level of coordination and communication among research staff, sponsors and monitors to balance speed, safety, data quality and integrity. The use of paper-based study documents and onsite monitoring are not practical in fast-moving infectious disease trials – and right now with COVID-19 neither are even possible. Personal Protective Equipment (PPE) is hardly conducive to consulting a protocol in a binder or a desktop portal. The challenge is to adapt, while moving quickly and minimizing errors.



Time is precious and speed is critical, which means research staff and monitors need:

- **Immediate Answers:** Current study information needs to be readily accessible when and where research staff and monitors need it. They also need to be confident that it is truly the latest, approved study information, as protocols are quickly amended in infectious disease trials. Current study information is critical for proper enrollment and fewer deviations.
- **Real-Time Communication:** Communication to sites and monitors should be consistent, continuous and streamlined. For example, site staff need to know cohort status so they know if they should stop screening patients. Likewise, safety alerts about adverse events need to go out immediately. Best practices and what's working should be shared among sites to increase the probability of trial success.
- **Timely Guidance:** Coaching can help sites to enroll the right patients and to limit deviations. For example, visit reminders can help ensure staff understand procedures and sample collection requirements. Additionally, data entry is challenging given how quickly data comes in. This is where reminders such as data entry timeframes or upcoming interim analysis database lock can help site staff not fall behind on data entry.

Accelerating Clinical Trials with Teckro

Teckro clinical trial software connects research sites, monitors and study teams so that only the most current study information is guiding decisions during infectious disease trials. Through their smartphone or any digital device, current study documents are always immediately on hand for doctors and nurses, study coordinators and monitors.

Directed communication alerts monitors and site staff to specific study changes relevant to them. Unlike other conventional impromptu communication channels, Teckro is compliant with industry regulations, including FDA 21 CFR Part 11. Communication is centralized within Teckro, which helps with continuity regardless of staff turnover. And your regulatory and clinical trial team members can export individual messages, or in bulk, for inclusion into your TMF.

When site staff have immediate access to critical study information, they enroll the right patients faster and have fewer deviations. Here's how Teckro helps with clinical trial operations for infectious diseases:

- **Immediate Answers:** From any digital device, answers from the protocol and other study documents are immediately available to anyone involved in the study. Users simply type a query into the Teckro search bar and relevant answers are returned in seconds by analyzing all of the study documents in Teckro. This is particularly useful for common searches about eligibility and visit schedules. Documents are always the approved, current version for each site, so as protocols are amended, only the current version is in the hands of research staff and monitors. Study managers have visibility into what is being searched, which can help identify the need for clarification or potential safety risks. Search activity is also a good indication of site engagement with the trial.

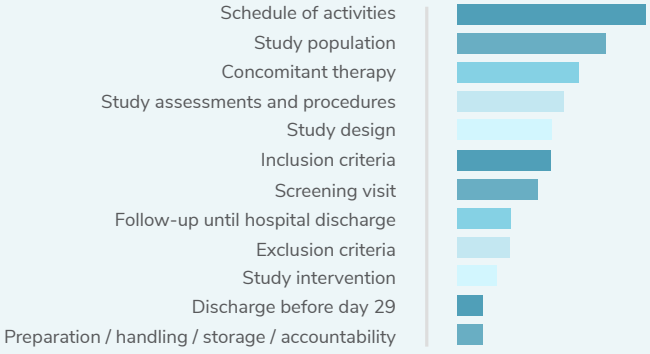
- **Real-Time Communication:** Direct communication alerts monitors and site staff of specific study changes relevant to them. Study managers can be granular in who they target, selecting the audience by individuals, roles, sites, or even countries. Teckro flags the message for users through push notifications to their mobile devices to make sure users know they have an important update. Teckro also gives study managers visibility into who is opening their messages, so they can be sure critical updates, such as safety holds, are reaching site staff and monitors.

- **Timely Guidance:** Teckro can help study teams coach research staff in carrying out procedures correctly. Useful tips and clarifications can be added to Teckro and shared broadly or targeted to specific sites, monitors, or both. Teckro also supports quick surveys of study stakeholders to capture immediate feedback, which can be used by study managers to target areas where site staff or monitors need help. Site staff and monitors can also initiate messages back to study teams to get answers and guidance beyond what is available in the study documents.

With many COVID-19 trials already live on Teckro, study teams are working at incredible pace. For example, here's a snapshot of a Top 10 Pharma company's COVID-19 trial that is being conducted in eight countries across 32 sites.

Unprecedented Speed: Within three weeks, the trial was configured in Teckro and rolled out to all sites and monitors. This included a recent, rapidly approved protocol amendment. Within two days of training, all study monitors were active on Teckro. Within a week, the majority of site staff were active on the platform.

Immediate Answers: Research staff need immediate answers when they are with a patient. Mistakes in screening and enrollment may jeopardize an entire cohort. Below is a sample of searches across all of the sites in the first week the study was live for this Top 10 pharma company's COVID-19 trial.



Teckro is cloud-based software, which means trials in infectious diseases can be fully operational very quickly. Sponsor's study teams provide details of the site personnel and monitors they wish to have access to the study. Users have the choice to access Teckro with a dedicated mobile app, downloadable from their usual app store. Alternatively, they can access Teckro from any device through a secure website. New users register their accounts with Teckro in a couple of simple steps, while users already using Teckro can simply switch between studies.

Given the extraordinary challenges with COVID-19, we have added some new capabilities to allow study teams to quickly provide specific guidance. Our team of experts will work with you to determine how to best set up Teckro to support your infectious disease trials.

Have a question about your clinical trial? Teckro the answer.

For more information, please submit a request on **our website** or email us at **info@teckro.com.**