



Cognizant[®] Shared Investigator Platform

Accelerating clinical trials: The new and future normal

Cognizant[®]

Keeping clinical trials operating efficiently during the COVID-19 pandemic is forcing the life sciences industry to adopt new working practices. Supporting these with the right collaborative technologies will help ensure a long-term and positive impact on streamlining clinical trial set up, execution and results.

Momentarily, everything and everyone stood still, pausing to consider how to move forward in the face of a pandemic. That was the initial impact of COVID-19 on many existing and planned clinical trials, with the possible exception of oncology trials through which many cancer patients receive treatment.

Now that trials are resuming and new trials are commencing, sponsors and sites are required to follow the Centers for Disease Control and Prevention's (CDC) health safety guidelines, including social distancing. This new normal requires them to find new ways to work. We expect many sponsors to continue these practices even after the pandemic recedes because these modern, digital ways of completing work can increase productivity.

Based on the current landscape, Cognizant anticipates that key changes in clinical trial management and operations are likely to continue. These new practices include:

- **Rapid onboarding practices.** Sponsors launched COVID-19 studies in weeks vs. the months it typically takes to conduct clinical trials. This rapidity can carry over to other trials, especially when investigator and site information

is shared across sponsors. Some examples of rapid onboarding practices include:

- Using shared trial documents to leverage data and information from sites that have previously enrolled in trials
 - Harmonizing document workflows because trial sponsors have agreed to standardize key clinical trial processes and share certain trial documents, so sites only have to learn and support one way of working for the more than 900 studies on SIP
 - Maintaining up-to-date contacts with investigators and clinical trial sites, which is critical. Sponsors participating in the Cognizant® Shared Investigator Platform (SIP) have access to over 75,000 clinical researchers in more than 18,500 sites across the globe. Included in the Investigator profile is the investigator's specialty, professional experience and clinical trials previously conducted.
 - **Virtual trial management.** Fewer clinical research associates (CRA) are making site visits because of the CDC's recommendation to curtail nonessential air travel. Instead, CRAs are making virtual visits, mainly via video conferences. We expect these virtual visits and remote site management to continue and increase, in part because air travel is likely to be fraught until the coronavirus is better contained. The longer term impact is that less travel could prove more cost-effective and productive: instead of traveling for a day to spend a couple of hours at a site, one CRA could potentially "visit" several sites in a day while working from home.
- That said, in the short term, this abrupt move to virtual management might seem inefficient: the volume of emails and calls is likely to seem overwhelming. With Cognizant SIP, however, CRAs can use the platform's capabilities to more easily find the correct site contacts. In turn, site leads can use the platform's reports and dashboards to manage investigators' workloads and results. Contacts may be made through the platform, which provides clear audit trails. CRAs may also use Cognizant SIP to monitor the volume of activity at an investigative site to understand how much the site has been affected by COVID-19 and to evaluate site readiness.

• **Widespread video and rich content use.**

As trial management steadily becomes virtual, sponsors and sites will adopt more video and collaboration tools, such as digital whiteboards, for enriching conversations and delivering protocol-specific and more general study training. Video tools may be used to carry out virtual site evaluation visits and required interviews. Rich media will enable sponsors and sites to maintain strong, safe connections. These capabilities can enable sponsors to rapidly adopt fully remote interactions to reduce or replace many of the required in-person visits and training.

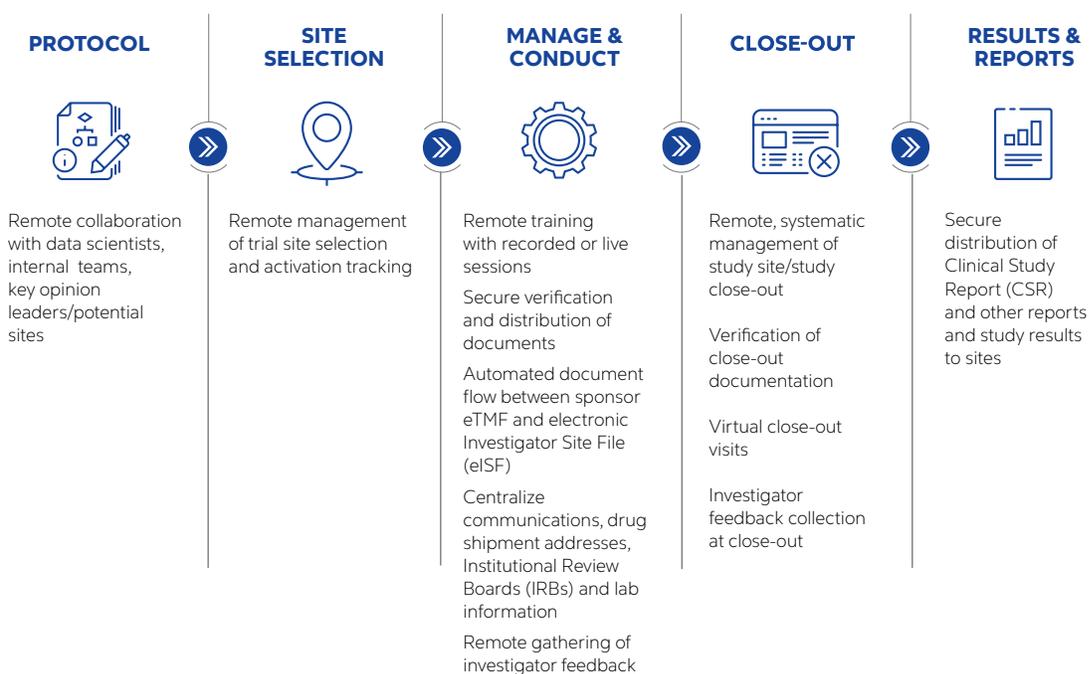
• **Electronic document collaboration.**

To optimize virtual trial management and interactions, eRegulatory Binders may be used to more efficiently track and upload clinical trial documents and data to the sponsor’s clinical data and clinical trial management systems. eBinders may also be utilized by CRAs charged with monitoring clinical site compliance. This move has the initial potential to shift administrative costs, such as charging for copies, to the technological cost of setting up the eBinders. Over time, however, digital access to electronic documents will improve efficiency and lower costs by helping reduce the number of visits to monitor the site and review documents, as well as increase the efficiency of these visits. Cognizant SIP links eBinder technology and site documents with sponsor electronic Trial Master File (eTMF) folders, enabling full collaboration across the document life cycle.

• **Virtual trials.** In the longer term, Cognizant expects homes and retail clinics to become key endpoints for clinical trials as high-quality in-home diagnostic devices shrink in size and price. With trial participants wearing monitoring devices, receiving drug deliveries at home and adhering to guidance from virtual voice assistants, investigators will likely need more support and CRAs will need to follow trial results even more closely. Platforms equipped to streamline data flows and keep contacts up to date will be key components to ensure virtual clinical trials meet protocols and deliver reliable results.

Sponsors will adopt many of these tactics quickly, out of necessity, and become more sophisticated in how they use them. Widespread use of modern trial technologies will be key to business continuity. Right now, we see many life sciences clients diverting internal resources to make COVID-19 a company-wide top priority. We have learned a great deal about the absolute necessity of digitizing all phases of clinical trials because of the deadly and unprecedented COVID-19 healthcare crisis. Digital work practices as well as online and remote clinical trials are now a reality. Cognizant Shared Investigator Platform is at the forefront of this “new normal” and leading the charge to change the face of clinical trials now and in the future.

Key components of remote collaboration across the clinical trial life cycle



About Cognizant Life Sciences

Cognizant's Life Sciences business unit partners with biopharmaceutical and med-tech companies to develop strategies and apply solutions to healthcare challenges across the value chain. Our services and products, including the Shared Investigator Platform (SIP), are digitizing interactions between sponsors and investigators across every phase, helping the industry subtract time from clinical development and add it to patient lives. To learn more, visit cognizant.com/life-sciences.

About Cognizant

Cognizant (Nasdaq-100: CTSH) is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Headquartered in the U.S., Cognizant is ranked 194 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn how Cognizant helps clients lead with digital at www.cognizant.com or follow us [@Cognizant](https://twitter.com/Cognizant).



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