

Front & Center

Trial Collaboration Without Barriers

Investigator-facing SaaS platform provides shared benefits for sites and sponsors.

One of the challenges to leveraging technologies in clinical trials is the administrative burden they add, which manifests itself differently for sites and sponsors. For example, something as simple as sending documents via email requires completing a series of manual checks. Sponsors must confirm the correct recipient, ensure the proper version is shared, and follow up to ensure receipt. Meanwhile, sites have to perform the same checks, but within a different system for each sponsor, meaning they receive a barrage of emails related to each protocol coming from different places: administrative inquiries, regulatory information, and alerts from various sponsors' systems. Locating the correct version of a file requires scouring inboxes, and any errors introduce risk and reduce protocol compliance. The result is additional work for each party, which prevents investing time in more critical tasks.

"Sponsors tell us they want to solve these problems and reduce the burden on their study teams and the sites," according to Larissa Comis, Product Lead for the Cognizant Shared Investigator Platform (SIP). "They're looking for

ways to gain efficiencies, both within their study teams and with the sites with which they work."

This paper explores the benefits of a system that connects more than 100,000 clinical researchers across sites and sponsors via a single-sign-on clinical trials technology, one that harmonizes key workflows across sponsors, and includes tools to remove redundancy and increase efficiency.

Redefining the Site-Sponsor Relationship

The proliferation of new digital technologies and devices has often increased administrative efforts at sites, forcing site staff to log into dozens of different systems to conduct clinical trials. Therefore, it is critical that sponsors actively seek out technology to decrease the burden on researchers and sites. Cognizant SIP, the result of a collaboration between many of the world's largest biopharmaceutical companies, provides a better way for sponsors to collaborate with researchers, addressing this gap.

Cognizant SIP redefines the relationship between sites and sponsors, placing investigators at the center of the ecosystem. With Cognizant SIP, users can expect something novel—standard processes across sponsors and protocols. By creating a central hub for completing diverse tasks, Cognizant SIP helps unify essential trial activities. Communication is harmonized, providing robust messaging, document sharing, and video call capabilities in support of new, decentralized ways of working. Site staff configure their Cognizant SIP facility profile once, which all Cognizant SIP sponsors access to ensure that documents can be shared quickly with the correct person at a site. Sponsors can automatically send and receive documents through configuration with a sponsor eTMF, or they can upload them manually. In a future release, sites will be able to automate the flow of documents from Cognizant SIP to their electronic investigator site file (eISF) technology.

Redundant administrative activities are also eliminated. Frequently required documents, such as an investigator's CV and 1572, are generated from the SIP User Profile and are accessed by all SIP sponsors. Cognizant SIP training is mutually recognized across the platform, so users do not need to conduct many redundant trainings each time they work with a new sponsor.

A scalable and open platform, Cognizant SIP easily integrates with other systems, such as pharmacovigilance systems, eTMF, Study Start Up, and

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CTMS. Bi-directional flow of documents between sponsor eTMF systems and Cognizant SIP is enabled via integration. Study information housed in a CTMS can be transferred to Cognizant SIP to synch up the two systems. This automation decreases the manual effort of sending and uploading files, streamlining the process and ensuring records are uploaded on time.

Cognizant SIP leverages single sign-on technology that reduces the number of usernames and passwords users must remember. By providing access to over 70 clinical platforms that can be accessed in a single session, less time is spent logging in to various systems.

Providing Value for Sites and Sponsors

With more than 20,000 clinical research facilities across 84 countries, Cognizant SIP has the body of evidence to show that, once a site is set up and conducting multiple studies in the platform, the benefits of using Cognizant SIP for both sites and study teams are evident. Sponsors assessed the experience of PIs who have participated in multiple studies to date, comparing

their first Cognizant SIP study experience with subsequent study experiences, and the results show that continued use of Cognizant SIP provides concrete value across sites and sponsors.

Results from a large biopharmaceutical company as a Cognizant SIP Early Adopter include:

- 29% reduction of average time from sponsor sending study invite to PI accepting it
- 3 hours of PI training savings due to mutually recognized training in SIP
- Sponsors receive site study data (study staff, shipping info, etc.) 36% faster
- CV generation and distribution activities time savings of 1 hour/site/study
- 5.6 days faster for survey completion
- 7.5 days faster for study acceptance

Changing the Narrative

When developing clinical technologies, investigators and researchers are as essential a stakeholder as sponsors, but

for too long, the focus of new clinical trial technologies has been defined by sponsor requirements. Over half of principal investigators participate in only one study at a time due to the administrative tasks required. 40% of investigators only participate in one clinical trial in the course of their careers. Since Cognizant SIP reduces the administrative burden for investigators and sites, there is a higher propensity for repeated participation in future trials.

Further, with the momentum increasing behind decentralized trials, remote monitoring, and the changes brought about by the COVID-19 pandemic, it is more important than ever for sites, CROs, and sponsors to have clear, consistent, and efficient communication and collaboration, remotely.

As the use of technologies expands, sponsors and investigators will need to cooperate strategically to ensure workloads are reduced or automated wherever possible. Removing redundancies and duplication, shortening the startup process, and returning researchers to clinical tasks and more time with patients, are vital elements to accomplishing this goal.