Solution Overview

Seamlessly connect site and sponsor systems for enhanced collaboration

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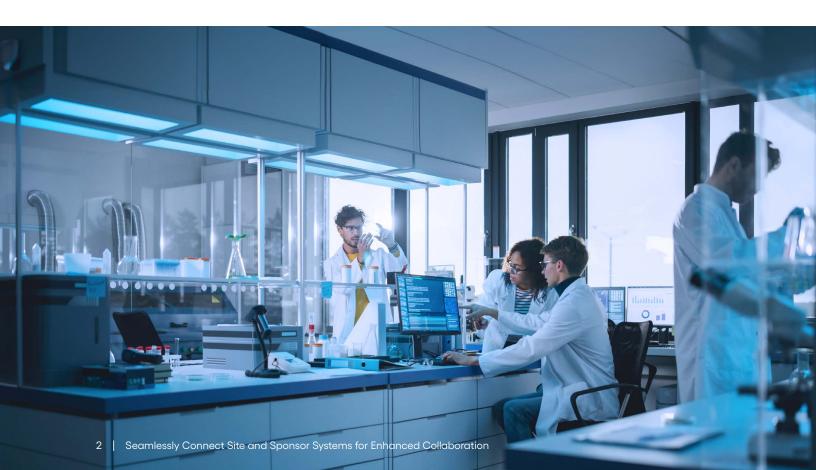# Now available through Cognizant® Clinical Systems Connector

Conducting effective clinical trials depends on seamless and continuous exchange of documents, data and information between sponsor study teams and research sites. This requires clinical research site staff to work on and maintain numerous key documents, data management systems and site information throughout a clinical trial, including CVs, FDA Form 1572, users' training records and safety notifications, among others. Many sites, whether large academic medical centers or mid-size organizations, have invested in their own systems to manage these documents, but in many instances, the site must still manually manage data uploads and document exchange with their various sponsors. Often, the documentation provided by clinical study sites is the same from sponsor to sponsor requiring duplicative efforts by the site staff.

Sponsors on the other hand use various systems and portals when conducting clinical trials that require sites to physically and electronically upload documents and populate various sponsor systems with significant amounts of data. Even for sites with contracted or their own internal systems for managing clinical trial records, multiple manual uploads to sponsor systems is still fairly typical.

Both sites and sponsors, therefore, face a similar set of challenges when attempting to collaborate and streamline the exchange of records, data and information for clinical studies:

- Given the plethora of clinical study sites that sponsors need to work with, integrating site systems on an enterprise scale is a costly and time-consuming endeavor.

- The same thing holds true for clinical trial sites – daily struggles with integrating into multiple sponsor systems that require accurate and complete upload of site records, data and other key site information.

Cognizant Clinical Systems Connector is designed to help address these challenges by leveraging standard REST APIs. Clinical Systems Connector serves as an integration hub that allows for the seamless and bi-directional exchange of documents and metadata from site systems to sponsor systems, and vice versa.

Benefits of Clinical Systems Connector

- **Accelerate study startup time** by providing sites with the convenience of using their own systems thus empowering them to initiate and take charge of startup tasks.

- **Improve efficiency and reduce costs** through streamlined system connection.

- **Alleviate the burden on sites** by reducing points of friction and hand-off delays.

- **Eliminate logging into multiple systems** for sponsors and sites.

Greater efficiency through streamlined processes

- Enable rapid and secure exchange of documents with sites by leveraging the Connector capabilities.

- Help expedite document review and approval processes by automating the document exchange.

- Sync document status updates and versions. 21CFR Part 11 compliant.*

Clinical Systems Connector Partner Readiness Program

In order to facilitate the seamless roll-out of Clinical Systems Connector API functionality, Cognizant is launching a Clinical Systems Connector Partner Readiness Program. This program is a pre-integration service that allows external third-party system vendors to integrate between Clinical Systems Connector and their systems, like eISF and eTMF.** This pre-integration service is designed to help minimize the effort required by sponsors and sites to integrate their systems using the Clinical Systems Connector. Sponsor and site organizations that are already using Cognizant SIP will be able to leverage Clinical Systems Connector to further enhance their collaboration.

Why Cognizant?

From discovery to post-market, life sciences companies are increasingly looking to digital to drive efficiencies and open new growth opportunities. Whether it's driving process improvements to clinical operations, increasing sales effectiveness or enhancing drug safety, Cognizant is at the forefront of helping our clients transform their businesses through end-to-end digital solutions that combine consulting, process operations and technology services.

* Records held for a few days to allow time for download.

** Pre-integration does not validate the vendor system itself or that Cognizant is endorsing use of that vendor to provide specific functionality for the site.

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