Solution overview

Seamlessly connect site and sponsor systems for enhanced collaboration

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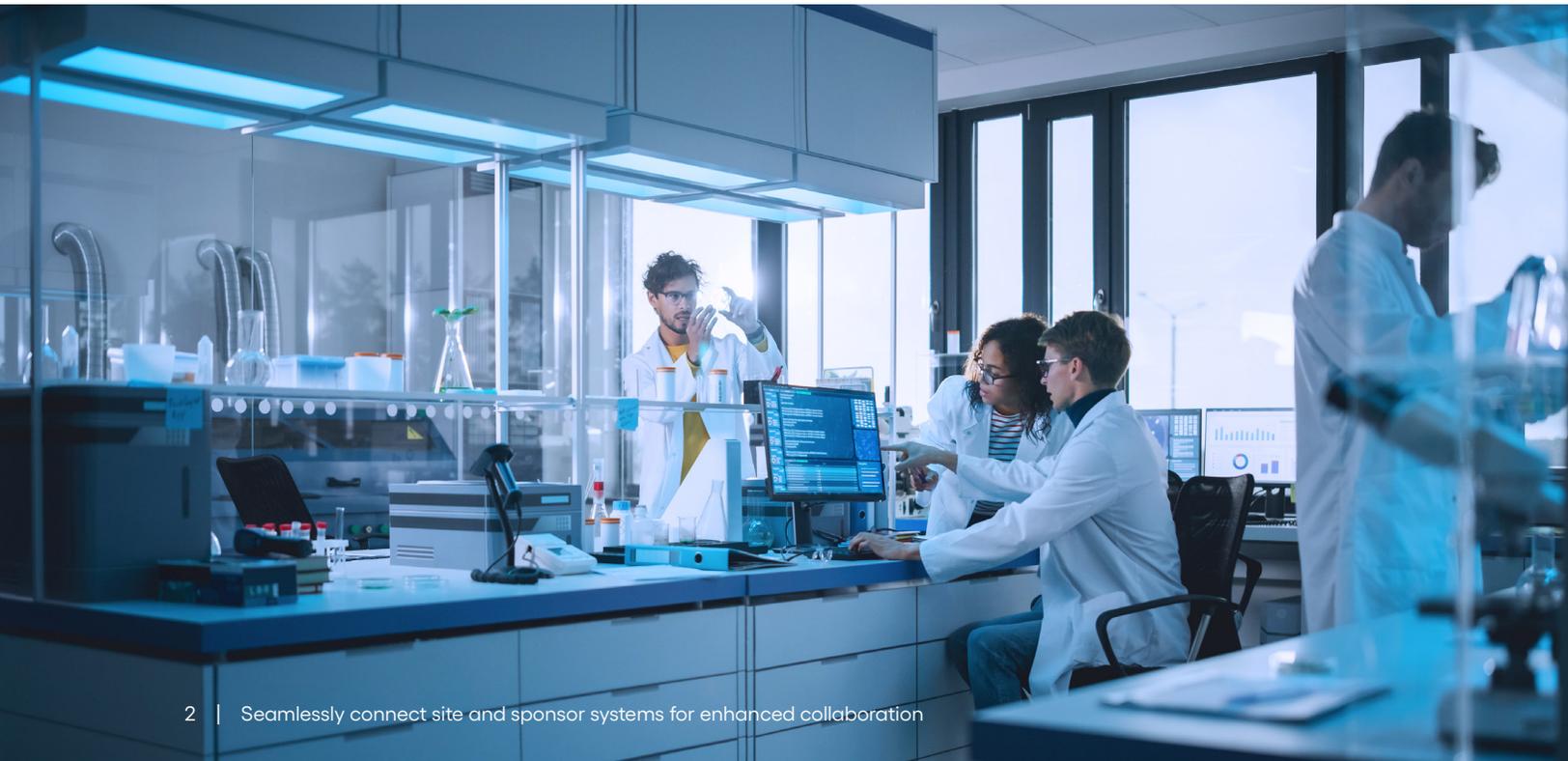# Now available through Cognizant Clinical Systems Connector

Conducting effective clinical trials depends on seamless and continuous exchange of records, documents and data between sponsor study teams and research sites. This exchange requires clinical research site staff to update and maintain numerous key documents, data management systems and site information throughout a clinical trial, including CVs, FDA Form 1572 and users' training records and safety notifications, among others. While many research sites, including large academic medical centers and mid-size organizations, have invested in their own systems to manage their records, they must also manage and track all the records and documents to be exchanged with their various sponsors. In many instances, the documentation provided by clinical study sites is the same from sponsor to sponsor and requires site staff to upload and send the same records and documents to multiple sponsors.

Sponsors, on the other hand, use many different systems and portals when conducting clinical trials. These systems and portals require sites to electronically upload documents and populate various sponsor systems with significant amounts of data. Even when sites have digital platforms to manage their clinical trial records and documents, each site must still regularly manage multiple digital uploads and record transfers to multiple sponsor systems. With no single pathway or link between site and sponsor systems, the task of managing the continuous transfer and exchange of clinical trial data and records is time consuming and complicated.

Challenges

Both sites and sponsors face similar challenges when attempting to share and streamline the exchange of documents, records and data for clinical studies:

- Given the plethora of clinical study sites sponsors must work with, integrating site systems on an enterprise scale is costly and time-consuming

- The same thing holds true for clinical trial sites—daily and continuous efforts to connect with multiple sponsor systems and assure accurate and complete uploads of a sites' records, documents and data is a time-consuming struggle

Solution

Cognizant® Clinical Systems Connector (the "Connector") is designed to help address these challenges. By leveraging standard REST APIs, the Connector acts as an integration hub that allows the seamless and bi-directional exchange of records, data and documents from site systems to sponsor systems, and vice versa.

Benefits of Clinical Systems Connector

- Accelerates study start-up times by providing a direct means of linking site systems to sponsor systems, empowering sites to initiate study start-up tasks as quickly as possible

- Improves efficiency and may reduce costs through streamlined system-to-system connections

- Reduces the burden on sites that maintain their own records and data management systems by minimizing delays in transferring data to sponsors

- Eliminates the time and effort of logging into multiple systems for sponsors and sites

Greater efficiency through streamlined processes

- Enables rapid and secure exchange of records and data between site systems and sponsor systems by automating repetitive exchanges

- Expedites document review and approval processes by automating the transmission of documents immediately to the appropriate reviewer system

- Syncs document status updates and versions

Clinical Systems Connector Partner Program

The Connector is designed to help clinical study sites and sponsors minimize time-consuming tasks, repetitive efforts and other challenges faced when managing connections between the multiple sponsor systems and site systems required for the efficient and effective exchange of clinical trial data and records.

While Cognizant and the Clinical System Connector cannot solve for the additional challenges faced by sites that don't have access to digital systems for managing site records, we have developed a Clinical Systems Connector Partner Program to facilitate the integration of existing, commercially available systems like eISF and eTMF platforms.

The partner program is a pre-integration service, designed to help minimize the effort required by sponsors and sites to establish and integrate their systems using the Clinical Systems Connector. The program allows third-party system vendors to establish and test the integration between Clinical Systems Connector and their systems.*

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.

* Pre-integration does not validate the vendor system itself, nor is Cognizant endorsing use of a particular vendor to provide specific functionality for the site or sponsor.

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