Solution Overview

# Optimize your trial operations with the Cognizant® Shared Investigator Platform (SIP) Document Exchange module

## Securely exchange critical study documents among site and sponsor teams with Cognizant's SIP Document Exchange module

The global pandemic has compelled the life sciences industry to reimagine how to proceed with clinical research and development in an environment stymied by emergency restrictions. Despite unprecedented obstacles, the industry survived and thrived, accomplishing in approximately 12 months what has historically taken years. However, life sciences organizations still have to contend with the perennial challenge of reducing the cost of bringing therapies to market while shortening the time

### The Cognizant SIP Document Exchange module enables clinical trial sponsors to:

- Securely exchange study documents between sites and sponsors
- Efficiently collaborate with stakeholders using workflows, task management and appropriate user permissions
- Minimize study startup time with document packages and activity and site trackers
- Effectively track study document collaboration through robust reporting and document audit trails
- Reduce manual sharing of documents through integration between Cognizant SIP Document Exchange and sponsor and site systems

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between discovery and regulatory approvals. In fact, the emerging landscape has placed heightened expectations on organizations for speed to market and operational efficiency in addition to cost pressures.

The clinical trial process requires effective collaboration and exchange of critical documents between sponsors and sites, such as CVs, financial disclosure forms, the investigator brochure and the study protocol. While the process is critical, many sponsors and clinical investigators still default to manual methods for sharing documents with sponsors, including email, mail courier services and faxing. These methods are burdensome and costly, lead to hours being spent searching for documents, pose potential security risks, are difficult to track, and hinder collaboration.

Cognizant® Shared Investigator Platform (SIP) helps alleviate this burden with its robust Document Exchange module. Cognizant SIP Document Exchange enables seamless collaboration between sponsors and sites for management and exchange of critical study documents. It provides sites a consolidated view of all document tasks, requests, workflows and notifications across multiple sponsors and trials in one central location. Cognizant SIP Document Exchange helps stakeholders get comprehensive visibility into document status, simplify document distribution, and optimize overall trial operations, ultimately helping accelerate the development of new therapeutics.

Cognizant SIP puts sites and investigators at the center of the clinical trial ecosystem by reducing the "different sponsor, different system" burden for sites. The SaaS-based, single sign-on (SSO) platform alleviates operational inefficiencies and administrative tasks for sites, and it transforms collaboration and communication with sponsors by:

- Enabling seamless end-to-end workflow and key clinical trial document exchange
- Unifying management of critical components of clinical trials across industry stakeholders
- Providing sites with a single point of access to dozens of clinical trial technologies and standardized processes across all sponsors

## The Cognizant SIP Document Exchange module offers the following benefits:

**Securely exchange study documents between sites and sponsors**

- Effortlessly manage documents with stakeholders
- Leverage filter, view, export, copy and move capabilities
- Easily upload new documents, including automatic assignment of document details and notification of CRAs
- Streamline workflows and data mapping across studies and sites
- Download documents individually or in bulk using drag and drop
- Conduct document search, including by compound, study, study country, facility or department, document name or based on document content
- Create and distribute placeholders to quickly build your document folder structure
- Edit and provide comments for easy document review
- Compare documents and maintain version control

**Efficiently collaborate with stakeholders using workflows, task management and appropriate user permissions**

- Enable document access based on the roles individuals are assigned for each study
- Initiate workflow actions to send documents to site or sponsor users along with a task to track the completion of the work, including review and acknowledge, review and comment, review and edit, review and sign, and request site document

- Enable site users receiving the tasks to review and electronically sign the document[1] and track its audit trail. Alternatively, the platform also allows the recipient to submit a document with a "wet signature" and captures relevant metadata

**Minimize study startup time with document packages and activity and site trackers**

- Create logical groupings of documents, referred to as document packages, to streamline document distribution and tracking
- Generate document packages to address specific clinical processes or milestones, which can be reused across study sites within the same study or across studies
- Document package types include sponsor packages, compound packages, study packages, country packages and study country packages
- Track and manage site activity completion by creating flexible site checklists that comprise lists of activities, documents and document packages
- Use for study startup, protocol amendments, site close-out, or any other event for which multiple activities or documents are required
- Define your own activities and build a library of activity trackers over time, which can be reused across studies, countries and sites
- Automatically create site checklists for each site based on the applicable study or country checklist template

**Effectively track study document collaboration through robust reporting and document audit trails**

- Closely manage the progress of your study documents with key reports
- View audit trails for a complete history or log of activities that were performed on a document and identify each step the document went through
- Export your audit trails into a human-readable format, including Excel and PDF
- Create study startup dashboard reports based on data selected, including activated sites by region and study startup status

**Reduce manual sharing of documents through integration between Cognizant SIP Document Exchange and sponsor and site systems**

- Sponsors who already utilize an eTMF or other study startup systems can configure workflows and generate document tasks automatically and continue to perform all of their activities directly in the eTMF or study startup systems
- Sites who already utilize an eISF can integrate with Cognizant SIP Document Exchange to automatically file relevant study documents in their reference site binders

For more information on Cognizant SIP, please visit www.cognizant.com/shared-investigator-platform

[1] **Part 11 Qualification.** Cognizant has initially qualified the Software Service for consistency with standards for electronic records and electronic signatures under 21 C.F.R. Part 11 - "Electronic Records; Electronic Signatures" ("Part 11"), and European Union Annex 11 ("Annex 11"), and has a quality management system which includes change management and internal monitoring to verify that the Software Services are maintained. You are required to perform additional validation and confirmation of the Software Services as implemented and used by you to comply with applicable regulations and standards.

## 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 improving patient outcomes. To learn more, visit **www.cognizant.com/life-sciences.**


Cognizant (Nasdaq-100: CTSH) engineers modern businesses. We help our clients modernize technology, reimagine processes and transform experiences so they can stay ahead in our fast-changing world. Together, we're improving everyday life. See how at **www.cognizant.com** or **@cognizant.**

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