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Solution overview

Optimize your trial operations with the Cognizant Shared Investigator Platform Document Exchange module

Enable secure and streamlined exchange of study documents between sponsors and sites through automated workflows, audit trails and real-time status tracking. The Shared Investigator Platform mobile app further enhances efficiency by allowing site users to review, e-sign or acknowledge documents anytime, using convenient biometric login and signature capabilities.

Life sciences organizations are under increasing pressure to deliver safe, effective medicines, therapies and medical devices faster, at lower cost, and with fewer resources. As expectations rise, operational efficiency for both sponsors and sites has become essential.

A critical part of trial execution is the timely, secure and efficient exchange of essential documents from study startup through closeout. Yet many sponsors and investigators still rely on manual processes (email, courier services or document collection during onsite monitoring visits) leading to delays, confusion and avoidable administrative burden.

The **Cognizant® Shared Investigator Platform (SIP) Document Exchange** module replaces these manual workflows with a streamlined, automated and compliant solution that benefits both sponsors and sites by:

- Reducing administrative effort
- Eliminating the risk of delayed, misplaced or misdirected documents
- Increasing transparency across the study team and preventing duplicate requests
- Enhancing traceability to support rapid, accurate responses during audits or regulatory inspections

The platform supports document exchange at every trial stage:

- Study startup: Protocols, investigator brochures, CDAs and startup packages
- Site selection and activation: User-level CVs, licenses, GCP certificates; facility-level IRB and lab documents; Form FDA 1572; site information sheet
- Study management and monitoring: Monitoring visit follow-up letters, updated IBs, protocol amendments
- Study closeout: Closeout checklists, IRB closure letters, CSR reports and EDC archival acknowledgements

While safety documents can be exchanged through the Document Exchange module, SIP also offers a dedicated safety notifications module for safety-specific workflows.

Document exchange features in SIP:

- Automated workflows and tasks: Configurable by document type with due dates, delegated roles, action tracking
- Document library: Advanced search, sorting, filtering, favorites
- Placeholders: Created manually or via integration for sites to upload required documents
- Annotations and comments: For informed consent templates and other collaborative documents
- Document packages: For startup, protocol amendments or milestone-based bundles
- Version control and audit trails: Complete document history with comparison tools
- Bulk actions: Bulk upload/download, bulk acknowledgment, bulk printing

Benefits for sponsors:

- Unified and secure workflows across all studies and sites
- Lower administrative effort and reduced operational burden
- Faster site activation and improved overall trial efficiency
- Enhanced collaboration and transparency across study teams

- Continuous inspection and audit readiness supported by robust reporting
- Seamless bidirectional API integration with eTMF and study-startup systems, enabling:
  - Automatic filing of site documents directly into the sponsor's eTMF
  - Automated workflow configuration, task generation, document distribution, and site document request management—allowing sponsors to work within their existing systems while SIP drives end-to-end automation

Benefits for sites:

- Centralized dashboard for document tasks across multiple sponsors
- Ability to reuse profile documents across studies and sponsors, with automated workflows that instantly share these documents when a new study invitation is accepted
- Multiple workflow options including e-signature and biometric authentication via mobile app
- Supports a variety of site operating models—from small independent sites to large networks
- Integration with eISF for automatic filing

About Cognizant Life Sciences

Cognizant's Life Sciences business unit partners with biopharmaceutical and medtech companies to develop strategies and solutions for healthcare challenges across the value chain. Our services and products, including SIP, digitize interactions between sponsors and investigators, helping the industry subtract time from clinical development and add it to improving patient outcomes.

Learn more about SIP: www.cognizant.com/life-sciences-technology-solutions/shared-investigator-platform

For more information, visit: www.cognizant.com/life-sciences-technology-solutions

World Headquarters
300 Frank W Burr Blvd
Suite 36, 6th Floor
Teaneck, NJ 07666, USA
Tel: (201) 801-0233

European Headquarters
280 Bishopsgate
London
EC2M 4AG
England
Tel: +44 (01) 020 7297 7600

India Corporate Office
Siruseri-Software Technology Park of India (STPI)
SDB Block – Ground floor North wing
Plot No H4, SIPCOT IT Park
Chengalpattu District
Chennai 603103, Tamil Nadu
Tel: 1800 208 6999

APAC Headquarters
1 Fusionopolis Link, Level 5
NEXUS@One-North, North Tower
Singapore 138542
Tel: +65 6812 4000

WF4214150