Optimize your safety notification process with the Cognizant® Shared Investigator Platform (SIP) Safety Exchange module

Sponsors can improve efficiency and reduce the administrative burden on sites by adopting Cognizant's SIP Safety Exchange module.

Safety notifications are a critical aspect of clinical trials. Regulatory agencies mandate that sponsors promptly notify their principal investigators (PIs) of adverse events that may be related to the investigative new drug being studied. If a sponsor does not promptly and adequately inform the PI of a safety event, and the PI subsequently fails to implement required changes, there could be serious consequences. Sponsors carry the burden of proof to ensure PIs are notified in a timely manner and, in turn, many require PIs or their staff to acknowledge receipt of each safety notification.

Due to its vital importance, most sponsors take a very conservative approach to this process, over-reporting safety events to PIs and requiring acknowledgement of receipt, which creates a significant administrative burden for sites. This burden is compounded by the myriad methods sponsors use to send the notifications, ranging from overnight mail to bespoke online portals that facilitate electronic distribution and acknowledgement, increasing the number of portals and logins that sites have to manage, complicating their day-to-day trial operations.

The Cognizant SIP Safety Exchange module enables clinical trial sponsors to:

- Better target investigators and eliminate over-reporting by setting up distribution rules
- Help ensure accuracy of safety notification recipients
- Electronically distribute safety notifications to sponsors and track site acknowledgement
- Improve your operational efficiency by integrating Cognizant SIP with your existing safety system

Cognizant SIP helps alleviate this burden by allowing sponsors to distribute critical and non-critical safety notifications to the right PIs and site staff within required timelines and providing the ability to track site acknowledgements. Cognizant SIP has already helped facilitate the distribution of more than 55 million safety notifications.

Cognizant SIP puts sites and investigators at the center of the clinical trial ecosystem by eliminating the "different sponsor, different system" burden for sites. The SaaS-based, single sign-on (SSO)

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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 across 144,000+ users and 28,000+ sites

- Modernizing site-sponsor virtual collaboration with video conferencing, chat, training and remote review of documents

- 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

- Optimizing the safety notification process, improving efficiency and reducing the administrative burden on sites

The Cognizant SIP Safety Exchange module offers the following benefits: Sponsor benefits:

Better target investigators and reduce duplicative reporting (over-reporting) by setting up distribution rules

- Define global and country distribution rules to automatically send safety notifications to sites based on selected criteria

- Set up distribution rules for each compound type (e.g., IMP, Comparator and Placebo), type of safety notification (e.g., SUSAR, DSUR, etc.) and country

- Start and stop safety notification distribution at a site based on site-specific events—e.g., if a site has not enrolled any subjects and the site is placed on hold

- Easily identify which specific countries, studies and sites need to receive the safety letters, in which language, and distribute translated versions accordingly

Help ensure accuracy of safety notification recipients

- Ensure that the right individuals receive safety information by leveraging the site staff maintained directly by sites in Cognizant SIP

  - Ensure that PIs receive all safety notifications

  - Designate select site staff to receive safety notifications per the sponsor's safety distribution rules

- If needed, track safety notifications that were delivered via courier, fax, alternate email or by other means in Cognizant SIP

Electronically distribute safety notifications to sponsors and track site acknowledgement

- Define the sponsor roles whom you want to receive safety notifications as part of your distribution rules

- Allow sponsor study team members and CROs to receive safety notifications conveniently in their sponsor user inbox

- Enable site-facing personnel to view safety notifications, confirm appropriate distribution and track site acknowledgment status

Improve your operational efficiencies by integrating SIP with your existing safety system

- Leverage the ability to integrate SIP Safety Exchange with your safety systems as needed

  - Set up SIP Safety Exchange to receive and distribute safety documents from your safety system and import distribution rules from your system as needed

Leverage reports and dashboards for better tracking

- Leverage dashboards and reports in SIP Safety Exchange to track distribution and acknowledgement of safety notifications

Site benefits:

Easily locate critical safety information

- Access a single view of all safety notifications across all SIP studies and SIP sponsors

- Easily search for and locate safety notification documents by using various study and sponsor specific filters

- Communicate urgent safety information via email and via pop-up as soon as a site user logs in

Improve operational efficiency at the site and save time

- Designate the appropriate site staff member to acknowledge safety notifications—with a single click

- Bulk download all safety notifications as needed

Reduce the number of duplicative safety notifications a site receives

- Better target sites based on distribution rules and reduce over-reporting

- Eliminate duplicate notifications by sending only one safety notification for all studies under a single compound

Learn more about the Cognizant SIP Safety Exchange module and how it will enable your organization to easily and effectively distribute safety notifications to your research sites. For more information, please visit www.cognizant.com/shared-investigator-platform.

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), digitize interactions between sponsors and investigators across every phase, helping the industry subtract time from clinical development and add it to patient lives. To learn more, visit cognizant.com/life-sciences.

About Cognizant

Cognizant (Nasdaq-100: CTSH) is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Headquartered in the U.S., Cognizant is ranked 185 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn how Cognizant helps clients lead with digital at **www.cognizant.com** or follow us @Cognizant.

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