



Solution Overview

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.

Cognizant SIP helps alleviate this burden by allowing sponsors to distribute critical and noncritical safety notifications to the right PIs and site staff within required timelines and providing the ability to track site acknowledgements.

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

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

- Better target investigators and eliminate over-reporting by setting up distribution rules
- Electronically distribute safety notifications, help ensure accuracy of recipients and track site acknowledgment
- Improve your operational efficiency by integrating Cognizant SIP with your existing safety system
- Leverage reports and dashboards for better tracking

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

Electronically distribute safety notifications, help ensure accuracy of recipients and track site acknowledgment

- 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
- Allow sponsor study team members and CROs to receive safety notifications conveniently in their sponsor user inbox, confirm appropriate distribution and track site acknowledgment status
- If needed, track safety notifications that were delivered via courier, fax, alternate email or by other means in Cognizant SIP

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

For more information on Cognizant SIP, 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 improving patient outcomes. To learn more, [cognizant.com/life-sciences](https://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](https://twitter.com/cognizant).

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