



Implementing Cognizant[®] Shared Investigator Platform: Lessons from the Field

A major cancer institution shares best practices from its own experience.

Cognizant Shared Investigator Platform (SIP) is designed to streamline clinical trial site selection, start-up and operational management. When selected by a clinical trial sponsor, Cognizant SIP can be used to enable investigator sites to have a single point of access to multiple resources across multiple studies and sponsors. This significantly increases site

efficiencies and synergies across various sponsors and clinical trials. Hundreds of large academic medical centers have implemented Cognizant SIP globally. Such large, matrixed organizations span across hundreds of physician-investigators (PIs) and dozens of departments.

One leading oncology healthcare system and research institution has recently successfully implemented Cognizant SIP and shares, in this paper, its best practices around planning for and implementing Cognizant SIP given such a large footprint.

Establish a single point of contact or team to manage the Cognizant SIP implementation.

Have a single person or single team organize the implementation of and communication about Cognizant SIP to help ensure a streamlined, well-coordinated transition to the platform. That designated person or team should be the single point of contact for all planning, communication and training related to the platform implementation, including sponsor queries. This person or team should be a part of an institution's or clinical research enterprise's leadership team to ensure that person or team can speak on behalf of the institution and make decisions about the implementation of Cognizant SIP. This helps ensure a unified and cohesive plan for how the institution will manage Cognizant SIP.

When the oncology institution committed to Cognizant SIP, one person in the clinical research operations department was positioned to coordinate and manage the entire implementation as project manager. Other institutions have formed task forces or teams.

Create a systematic implementation framework.

Planning is critical to identifying potential issues and mitigating actions to achieve a smooth implementation. The research institution's Cognizant SIP project manager developed a comprehensive framework for implementing the platform before taking any implementation actions. This framework spelled out time frames for communications, training, registration deadlines for staff and a go-live date. It defined what "go-live" meant to the institution and allowed the project manager to communicate this to sponsors before that date. It also detailed which individuals at the organization needed to be registered in the platform first, how other individuals requiring registration would be identified and how PIs would be registered and onboarded.

Developing the framework at the outset helped organize the effort and eased tensions both internally and externally because concrete steps had been decided before the implementation was under way and could be communicated clearly.

Create a centralized communication system both internally and externally.

Assign one person or e-mail address as the communications point of contact and filter all communications about implementing Cognizant SIP, both internal and external, through that person. Internally, this makes it easier for staff and PIs to know who to contact if they have questions and helps centralize decision making. Similarly, by assigning one contact to handle external communications, this prevents the rest of the institution from spending time and effort fielding questions about the platform from



sponsors or CROs. A single contact also provides a unified response from the institution to all sponsors and CROs, reducing confusion about timeline and actions.

The implementation project manager was also assigned by the institution to be the primary communications point for questions about how the institution was implementing Cognizant SIP. Institution staff were told to forward all questions directly to this point of contact and not respond themselves. The point of contact also informed all sponsors and CROs not to contact staff about the platform. This created a very controlled communication environment that protected staff from additional emails and provided sponsors and CROs with the most up-to-date and accurate implementation information.

Centralize the organization's "build" in Cognizant SIP.

According to the research institution, it is essential that the project manager collaborate with the Cognizant SIP onboarding team to set up the organization, including the organization profile managers and facility profile manager roles. The project manager also recommended that this be the first step in the roll-out plan. It is critical that the platform accurately reflect an institution's structure from the outset so that sponsors and PIs can easily connect with each other.

The research institution had a complex departmental structure and multiple physical facilities set up in Cognizant SIP. It turned to Cognizant for assistance on determining the best build that would address all the nuances of the institution. Getting the structure correct before any individuals registered helped ensure staff and PIs are associated with the appropriate facilities. This is key to ensuring accuracy when the institution needs to reuse data.

The institution noted that before centralizing the build, many individuals created different departments and added different information to the facility's setup in the platform. This led to inconsistencies and confusion, resulting in redundant work. Similarly, the institution

suggested that organizations who attempt a quick implementation of the platform by onboarding participants under an incomplete organizational structure are likely to enter incomplete data and miss trial opportunities.

Ask sponsors to review the organizational build.

The research institution recommends asking several sponsors to review organization and facility data in Cognizant SIP to ensure they understand it. The institution did this because some of the platform setup queries ask for "yes/no" responses, and they wanted to ensure they had interpreted and answered these accurately. Taking this step helped prevent unnecessary requests for clarification and data.

Take a layered approach to internal communications.

The institution recommends tailoring information distribution about Cognizant SIP to the specific activities and deadlines of internal participants. Once the institution was fully set up within Cognizant SIP, the project manager communicated about the implementation with all the managers of operations staff who support PIs. PIs were not included in this initial communication. The institution's goal with this approach was to minimize PI concern about using a new tool.

Have managers handle investigator registrations.

Managers are typically in the best position to identify which of their operations support staff members will work with Cognizant SIP and should provide that information to the project manager. The institution's project manager delegated registration decisions to managers. Once those names were received, the project manager used the platform's bulk registration feature to send an invitation to approximately 200 operations staff to register. Using the bulk feature vs. creating individual invitations streamlined the process.

Customize Cognizant SIP training to the roles of the audience.

Ensure training information aligns with institutional workflows as well as how support staff and PIs use the platform. Using training videos created by Cognizant, the institution developed an internal training program for its operations staff. The institution augmented the videos by creating slides with information specific to the implementation and made them available on the organization's intranet. In addition, Cognizant hosts regular training webinars to support continuing education for site users.

Onboard physicians last.

The institution's implementation plan called for onboarding the PIs as the last step. The operations managers were tasked with informing their PIs about Cognizant SIP and then onboarding them. The institution deferred to each service on how they wanted to inform and onboard these PIs. All investigators were informed that they were required to register in the platform and could delegate that action as appropriate. The building of profiles was left to the operations support staff. The goal was to have the PIs do as little data entry as possible.

Set a go-live date deadline.

It is recommended that each organization customize and define what going "live" means. Not every PI and member of staff needs to have their profile created in order to be "live" in Cognizant SIP. For this institution, the go-live date was determined as the date on which sponsors could begin to contact study teams directly and request specific participants to be registered, and the institution would comply with the sponsor requirements. Past this date, study groups could register in the platform as they needed to. The organization did not require all PIs to register in the platform before this date as some groups had not commenced work with a sponsor using Cognizant SIP. The go-live date was established so that the institution would be open to receiving all communication and requests regarding the platform.

Take advantage of sponsor assistance as appropriate.

Sponsors recognize that setting up Cognizant SIP requires administrative effort, and many are prepared to assist. The research institution is using one sponsor's assistance in creating PIs' profiles using their CVs. The CV fields require extensive amounts of data, but once captured, that data will populate surveys from multiple sponsors and forms, and can be used to complete the FDA's Form 1572 for the sponsor's submission.

Use all available technical help from Cognizant.

Working with Cognizant, the institution learned it had more options for configuring its organizational structure in the platform than originally understood. The Cognizant SIP onboarding team helped the institution align its organization and facility design in the platform with internal policies, such as accepting drug shipments at just one physical location for distribution to other investigation sites.

Implement Cognizant SIP soon.

The institution chose to be one of the first to implement Cognizant SIP, providing valuable insight and feedback to assist Cognizant in shaping future programming and development for institutional use. Cognizant is continuing to evolve the platform and relies on users and organizations to help develop features and functions that are important to PIs and clinical trial sites.

Additional resources

Cognizant offers investigator sites a comprehensive set of training materials as well as customized assistance. There are no fees for sites to use Cognizant SIP.

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, visit [cognizant.com/life-sciences](https://www.cognizant.com/life-sciences).



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World Headquarters

300 Frank W. Burr Blvd.
Suite 36, 6th Floor
Teaneck, NJ 07666 USA
Phone: +1 201 801 0233
Fax: +1 201 801 0243
Toll Free: +1 888 937 3277

European Headquarters

1 Kingdom Street
Paddington Central
London W2 6BD England
Phone: +44 (0) 20 7297 7600
Fax: +44 (0) 20 7121 0102

India Operations Headquarters

#5/535 Old Mahabalipuram Road
Okkiyam Pettai, Thorajipakkam
Chennai, 600 096 India
Phone: +91 (0) 44 4209 6000
Fax: +91 (0) 44 4209 6060

APAC Headquarters

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