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How a dedicated medical affairs team drives site engagement with a dynamic clinical trial collaboration platform

The Cognizant® Shared Investigator Platform (SIP) was built as a cross-industry solution (initially as an initiative from TransCelerate, which is a consortium of 20+ major pharmaceutical companies) designed to enhance efficiency during clinical trial planning and execution, and improve collaboration between sites, sponsors and other stakeholders. Pharmaceutical companies chose to adopt SIP to increase engagement with investigative sites and decrease the need to develop and maintain company-specific portals for site engagement.

Challenges faced by sites in adopting SIP

Given the extensive breadth of offering and functionalities envisioned in SIP, there had been periodic rollouts of new features starting from release 1.0 and most of the requirements for these features were driven by the adopting SIP sponsors, who came together as part of the consortium.

Clinical research sites spread across the globe were gradually introduced to the platform by their respective sponsors, based on trial needs. As a result, in the early days, sites were mostly catching up on the features and trying to learn as they were setting up their profiles and studies in SIP on-the-fly.

With sites also facing typical challenges around their workforce management, understandably, it was not easy for them to get started on a platform that had such broad-based offerings and functionality.

In summary, the following factors contributed to historical challenges faced by sites during SIP adoption:

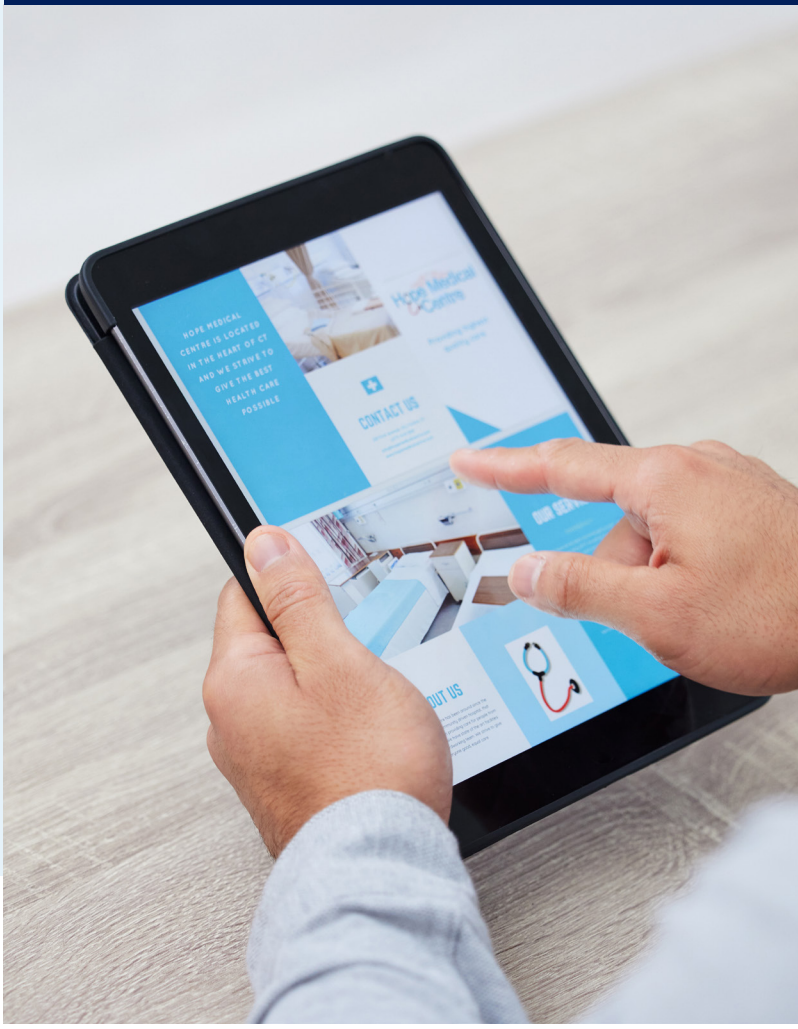
- Lack of site awareness about problems SIP was designed to solve
- No formal consortium or group for sites, who can become the pivotal point of driving Site requirements or disseminating necessary knowledge about SIP
- Lack of proper guidance and training on basic profile setup and other key functionalities
- Varying processes and requirements at sites based on individual needs as well as regional mandates
- SIP roadmap primarily driven through sponsors
- Sites not up-to-date with the functionalities available for them with every release
- Identification of central teams or individuals at sites who will assume the responsibility of managing institution profiles in SIP

Cognizant medical affairs team and establishing site engagement channels

With multiple global pharmaceutical companies onboarded on the platform, SIP has grown exponentially and supports a huge volume of data exchange since its first release in 2016 and given the fast-paced adoption of the platform globally, Cognizant realized the need for expanding its outreach and training about SIP to sites globally.

In 2021, Cognizant became a Global Impact Partner of SCRS (Society for Clinical Research Sites) and formed a dedicated Site Advocacy Group (SAG) for the Shared Investigator Platform. The SAG was composed of multiple site KOLs (key opinion leaders), research directors, clinical trials managers and others from sites who, for the first time, came together to form a common site forum for the Shared Investigator Platform. The key expectations from the SAG members:

- Share their current processes at sites and brainstorm on how SIP, as a global solution, can help support those processes
- Validate and review the early prototypes of upcoming features in the platform
- Provide feedback and suggestions on SIP UX/UI, intuitiveness and ease of use of the system
- Provide feedback on training materials and knowledge repositories



The first SCRS SAG workshop was conducted in Q1 of 2022 with 12 site KOLs. Multiple SCRS SAGs followed that year which helped in refining and enhancing SIP features aligned with site processes and addressing site pain points. Based on site needs identified in the workshops, dedicated site-facing capabilities could be prioritized in the SIP roadmap for the upcoming releases.

Recognizing the acknowledgement from sites of the effectiveness of SCRS SAGs and eager participation in shaping the SIP roadmap, Cognizant realized that sites were looking for greater collaboration and support, and decided to invest to nurture site relationships globally.

To support the need and take the relationship from executional to strategic, in early 2023, Cognizant formed a dedicated Global Medical Affairs Team (GMAT) for SIP, which is a group of life science professionals who collaborate across various functional teams to improve communications, and support medical professionals and site staff around the Shared Investigator Platform and its offerings.

The GMAT's goal is to serve as the life sciences industry's external earpiece, gleaning insights from interactions with the site ecosystems that drive investigators' and end-users' needs and opinions. The team ensures impactful and meaningful discussions by speaking the language of the KOLs, investigators and research directors to help represent their concerns around SIP and available technology.

Cognizant Global Medical Affairs team has two divisions that work in close coordination with each other:

- Site Success Managers, who are board certified medical affairs Specialists
- Product SMEs (subject matter experts), who are part of the site engagement/ onboarding teams for SIP

Enabling the voice of sites

To ensure strategic relationships as a trusted partner of sites using or considering SIP, Cognizant's GMAT established multiple channels of engagement, as listed below, with sites to ensure maximum outreach to sites and their needs and issues heard:

- SCRS Site Advocacy Groups.
- Regional Site Advocacy Groups.
- Strategic partnerships with site networks and organizations (e.g., SCRS Global Impact Partnership).
- Collaborative presentations and panel discussions in industry conferences and events, focused on sites. e.g., SCRS Global Site Solutions Summit.
- Customized site workshops and webinars for specific needs.
- Regional SIP Task Force, jointly with site-facing sponsor PoCs. This has been subsequently expanded to include key sites and site networks like AACI (Association of American Cancer Institute) and SCRS, where representatives from sites can also take part and share their needs and feedback.

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1100+

Research sites supported globally

10

Industry events/conferences speaker opportunities

900+

Site meetings conducted based on customized needs

70+

Site webinars/workshops conducted (incl. in person)

	(5) Very satisfied	85%
	(4) Moderately satified	13%
	(3) Neutral	2%
	(2) Poor	0%
	(1) Very poor	0%

Total number of site responses = 102

Site satisfaction survey, based on focused and tailored sessions with Cognizant GMAT

Extremely valuable, insightful feedback and pain points were shared by sites during the SAG workshops, across different functionalities and workflows in SIP.

Sites began to directly advise on future developments of the SIP with valuable feedback and improvement suggestions as indicated below:

- Need for simplification of the registration process
- Easier document exchange
- Centralized institutional oversight
- Streamlining of study staff management
- System performance improvement
- Need for seamless integration with site systems
- Ability to swiftly work on sponsor assigned actions on the go
- Reduce login needs using credentials

What happens next?

Cognizant Global Medical Affairs and SIP Product teams laid out a prioritization plan for all Site feedback in the SIP Product Backlog and by Q4 of 2023 most of the feedback had been addressed either via new features or enhancements to existing functionalities.

Following are the impactful changes for sites which have already been implemented in SIP:

- Simplification of new site user registration process eliminating almost all manual data entry
- Automatic access to relevant Studies based on pre-configured setup, immediately after account creation, thereby reducing multiple steps and dependency on PI (Principal Investigator) or other staff
- ~ 90% improvement in system performance across different screens and actions
- Flexibility with individual site users to manage their own notification settings
- Biometric-enabled SIP Mobile app to help respond to pending actions and access SIP without the need of explicitly providing username and password for login
- Quick access to study documents following contextual links in emails hence reducing dependency on searching
- Bulk actions enabled for sites for easy access to all study documents, eliminating the need for downloading or acknowledging single document one at a time
- Centralized control with site and network managers to administer and oversee site staff accesses and along with many other usability improvements

More enhancements and feature additions to the platform are currently being evaluated for 2024 and beyond, which will further simplify site users' experience, eliminate their redundant actions and improve intuitiveness.

What sites are saying now

The impact? Clinical research sites are now coming forward with testimonials attesting to their enhanced user experience with SIP and valued relationship with the Cognizant Global Medical Affairs team.

The same sentiment is also reflected in the SIP Annual Survey for 2023, along with acknowledgment from Sites around benefits of using SIP as a single operational tool for their Sponsor trials.

Site testimonials

By Q4 of 2023, multiple voluntary testimonials have been received from sites globally. Click on the below links to check out some of the site testimonials:

- Alliance for Multispecialty Research (AMR)
- Pioneer Clinical Studies
- Total Research Group (TRG)

Snippets of some additional site testimonials:

"All our contacts are automatically applied to each study, and SIP has been a game changer"

"The time Cognizant specialists spent with us, helping us in getting everything setup as we needed it was amazing"

"It is really nice that by logging into SIP portal you have all your study documents that you had uploaded onetime and then you have links to portals that you may need for that specific clinical study"

"The other piece that really excited me was engaging the medical affairs and the site engagement team that are coming out to sites and actually talking and listening to them rather than imagining/ assuming what our problems might be"

"In a bigger site, you could have more than just a coordinator be involved in the SIP, and that was fantastic because where you have your trial assistants that do a lot of the documentation and admin work, they could do their job. The coordinators could do their bit, and managers like myself could go in and look for feasibility and perform higher functions that are also embedded within the system"

"With the safety reporting, it was a massive boon because we could do safety reports in bulk. It eased a lot of pressure from us, PIs as well"

"What I really appreciate about Cognizant is that they listen to my feedback. They ask for feedback continuously. They understand that SIP is a portal that sites use, and they want to make it better for the sites"

SIP Global Annual Survey for 2023

- Net Promoter Score (NPS) score from sites has improved by more than three times in 2023, compared to 2022
- Number of promoters/supporters* from site standpoint is more than eight times that of 2022
- A resounding majority of site respondents* (55%–56%) have shown they have received help from their engagement with the Cognizant Global Medical Affairs team

*Number of survey respondents = 4023

The survey also shows that there are still a considerable number of sites (32%–34%) who are yet to interact with Cognizant's Global Medical Affairs team.

As we look forward to 2024 and beyond, we intend to expand our Cognizant Global Medical Affairs team across strategic countries and continue with our engagement channels, to support our sites globally, so that that we can build a truly single consolidated operational platform which is beneficial for all stakeholders.

Epilogue

The clinical research industry is at a juncture and the time has come to completely rethink in terms of how sites and sponsors we work together. sites upset or frustrated with sponsors/CROs due to their lack of knowledge about how sites work, too much technology, complex budget negotiations, etc. have become quite common.

Going beyond a single technology platform, the Cognizant Global Medical Affairs team for SIP aims to get sites' voices heard and disseminate their message to other stakeholders to ensure there is a healthy collaboration and relationship built among all.

Let's remember sites, sponsors/CROs and technology providers are all intricately intertwined, and we all need each other to ensure we deliver for the patients.

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