Site Advocacy Group and Cognizant Medical Affairs: A collaborative effort to align SIP Roadmap to Site needs

Overview of Shared Investigator Platform (SIP)

For years, multiple pharmaceutical companies noted that clinical trial sites were heavily burdened by using many different platforms, each requiring unique login credentials, unique technology training to perform clinical trial responsibilities and communicate with their sponsors. In addition to the high costs and redundant efforts involved in developing and maintaining individual sponsor portals, the existence of disparate processes and tools within these portals increased both risk of error and support needed for site users. 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 address these challenges and ultimately enhance efficiency during clinical trial planning and execution. Pharmaceutical companies chose to adopt SIP to increase engagement with investigative sites and eliminate the need to develop and maintain company-specific portals.

SIP is offered free of cost to clinical research sites and site organizations.

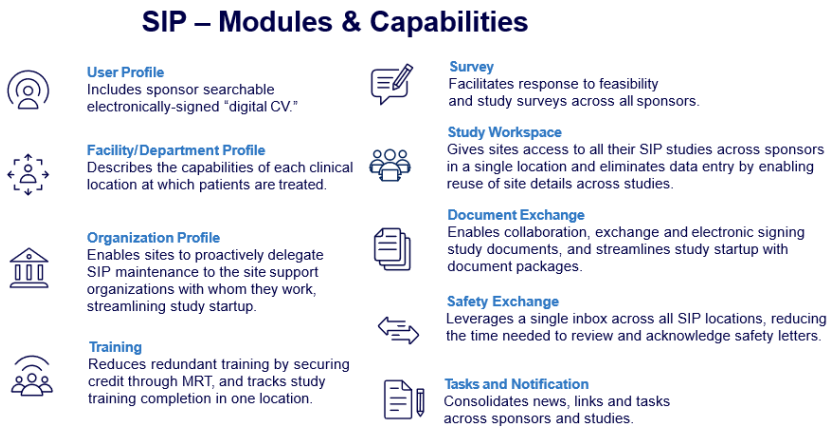
With multiple global pharmaceutical companies onboarded on the platform, SIP has grown exponentially and supports a huge volume of data exchange since its first release in 2016.

Following are the some of the recent metrics, as of December 2023:

- **302K**+ Site users active in SIP, across **114** countries
- **35K+** clinical research locations / sites registered in SIP
- **13000+ Feasibility Surveys** sent to Sites
- Approx. **180K Training (e.g., GCP) requests** raised by Site Users for Sponsors' review
- **1460+** active Studies running in the platform across all SIP Sponsors
- **118+ million Safety Notifications** distributed to sites globally
- **10.9+ million TMF documents** uploaded in platform

Challenges faced by Sites in adopting SIP

Given the extensive breadth of offering & functionalities (refer below snapshot) being envisioned in SIP, there were periodic rollouts of new features starting from Release 1.0.



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 introduced to the platform gradually by their respective Sponsors, based on trial needs. As a result, Sites were mostly catching up on the features and trying to learn as they were setting up their profiles & studies in SIP on-the-fly.

Unlike Sponsors, there was no formal consortium or group for sites, who can become the pivotal point of disseminating necessary knowledge about SIP. Additionally, sites' processes & requirements vary based on their individual needs as well as regional mandates.

With sites also facing typical challenges around their workforce management, it was not easy for them to get started on a platform whose offering is so broad-based.

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

- Lack of training on profile setup.
- Lack of site awareness about problems SIP was designed to solve.
- No forum for sites to directly share feedback and their requirements.
- SIP roadmap primarily driven through sponsors.
- Lack of appropriate guidance from sponsor/CRO POCs who were interacting with sites.
- Sites not up to date with the functionalities available for them with every release.
- Identification of central teams / individuals at Sites who will take up the responsibility of managing Facility or Department profiles in SIP.

The Initial Steps

To address the challenges faced by Sites, Cognizant took the strategy of onboarding a Medical Advisor in SIP team, one having extensive medical & clinical trials experience.

Dr. Lestter Cruz Serrano, as an industry expert, joined the SIP leadership team in 2019, with the responsibility of orchestrating Site discussions and nurturing Site relationships globally.

Subsequently a Site Onboarding team was established, under Dr. Lestter Cruz Serrano, with the objective of helping new sites setup their profiles in SIP. With the Site Onboarding team in place, an initial pilot was

rolled out with top 100 Sites in USA. The Site needs and processes were studied in detail by Cognizant's Site Onboarding team, necessary handholding was provided to Sites, and optimal structure was setup for each Site based on their alignment.

SIP Sponsors had also formed a SIP Task Force which had representatives from site-facing Sponsor POCs, mostly from the USA. Cognizant's Site Onboarding team joined them, and the SIP Task Force eventually became a forum where sponsors and Cognizant (as the technology vendor) came together every week to share updates and best practices on how to best onboard sites and tackle any issues/challenges that were presented with SIP adoption and implementation at a particular site.

The SIP Task Force has subsequently expanded to include local, regional, national & international key sites and site networks like AACI (Association of American Cancer Institute) and SCRS (Society for Clinical Research Sites), where representatives from sites can also participate and share their needs and feedback.

Introduction of SCRS Site Advocacy Group (SAG) for SIP

Given the pace and volume with which the Shared Investigator Platform was expanding globally from late 2019, Cognizant realized the need for expanding the outreach to sites across the USA and even more beyond, globally.

With the sudden global, Covid-19 pandemic in early 2020, clinical research stakeholders realized the relevance of digitized methods of conducting clinical operations and necessary collaborations, e.g., remote monitoring, document exchange, etc. which would help reduce turnaround time.

SIP sponsors also started onboarding more global trials in the platform, leading to more sites adopting SIP globally.

In 2021, Cognizant became a Global Impact Partner (**GIP**) of SCRS 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 were to

- Share their current processes at sites and brainstorm on how SIP, as a global solution, can help support those processes
- Validate & 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 SIP roadmap for the upcoming releases.

The Site Advocacy Groups had a unique, well-rounded mix of CEOs, Investigators, Site Operations Managers, Trial Coordinators, Regulatory experts etc. which ensured that feedback was collected from all strata of Site stakeholders.

Cognizant Medical Affairs team and expansion of SAGs

Recognizing the acknowledgement from sites of the effectiveness of SCRS SAGs and their eager participation in shaping the SIP roadmap, Cognizant took the initiative to conduct Site Advocacy Group workshops across all regions, with Sites globally, who voluntarily want to share their feedback & improvement suggestions.

With the help of regional sponsor POCs, Cognizant reached out to numerous clinical research sites across all major regions (US (United States), Europe, LATAM (Latin America), Canada, Asia-Pacific, Japan) in 2022 with the objective of conducting regional SAG meetings to ensure country and region-specific needs were also heard and taken into consideration.

Cognizant realized the unmet need of sites, where sites were looking for greater collaboration & support, and decided to invest to nurture site relationships globally. To evolve its engagement from executional to strategic, and not only just disseminate evidence but also lead evidence generation activities that can inform the real-world use of this platform, Cognizant invested in a **Global Medical Affairs Team (GMAT)** for SIP, in early 2023.

This team's goal has been to serve as industry's external earpiece, gleaning insights from interactions with the sites ecosystem that drive investigators and end-users needs and opinions. The team ensures impactful and meaningful site discussions by speaking the language of the KOLs, investigators and research directors and represents the voice of the end-users within industry around SIP and its offerings.

Cognizant's Global Medical Affairs Team is a board-certified group of life science professionals who collaborate across various functional teams to improve communications and support medical professionals and non-clinical staff. Working closely with sites and sponsors' clinical operations team, this team enables streamlined & easier collaboration for sites, and enhance site user experience during technology platform adoption.

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

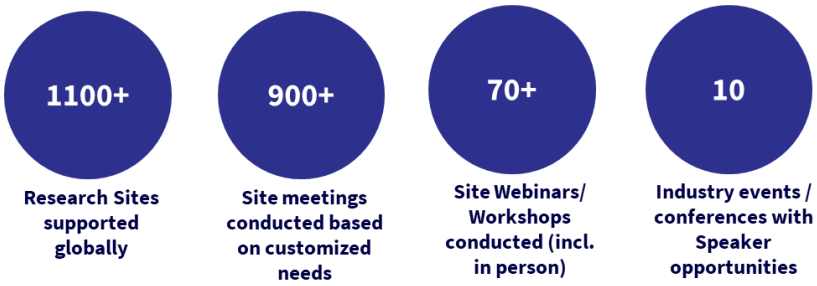
1. **Site Success Managers**, who are Board Certified Medical Affairs Specialists
2. **Product SMEs (subject matter experts)**, who are part of the Site Engagement/Onboarding Team

To ensure strategic relationships as a trusted partner of Sites, Cognizant's GMAT team utilizes the following key channels of engagement:

- **SCRS Site Advocacy Groups**
- **Regional Site Advocacy Groups**
- **Strategic partnerships with site networks and organizations** (e.g., SCRS Global Impact Partnership)
- **Collaborative presentations & 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

As an outcome of these key engagement channels, over 2023, there has been significant outreach made to Sites across all regions and key Site relationships have been established.

Following illustrations capture the **Key Statistics & Coverage** *(as of end December 2023)* for Global Medical Affairs team in 2023:



Site Satisfaction Survey, based on focused & tailored sessions with Cognizant GMAT

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

Total number of Site responses = 102

Key Outcomes from SAG workshops

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 influence the development of the SIP, starting with key **feedback** like

- 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 & 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 & Network managers to administer & oversee Site staff accesses

and along with many other usability improvements.

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

What Sites Are Saying Now

The result? 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 recently concluded SIP Annual Survey for 2023, along with acknowledgment from Sites around benefits of using Shared Investigator Platform as 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 one-time and then you have links to portals that you may need for that specific clinical study"

"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"

"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"

"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"

"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 & listening to them rather than imagining / assuming what our problems might be"

SIP Global Annual Survey for 2023

- Net Promoter Score (NPS) score from Sites has improved by **more than 3 times** this year, compared to 2022.
- Number of promoters/supporters from Site standpoint is **more than 8 times** that of 2022.
- A resounding **majority of Site respondents (55% - 56%)** have indicated they have benefited from their engagement with the Cognizant Global Medical Affairs team.

Introduction of the region-specific Medical Affairs / Site Engagement team has been beneficial for me	
Agree / Strongly Agree	56%
Not Applicable	32%
Disagree / Strongly Disagree	12%

Medical Affairs / Site Engagement team has helped me use SIP in a more efficient & effective way	
Agree / Strongly Agree	55%
Not Applicable	32%
Disagree / Strongly Disagree	13%

Medical Affairs / Site Engagement team has been able to address my issue(s) in a timely manner	
Agree / Strongly Agree	55%
Not Applicable	34%
Disagree / Strongly Disagree	11%

Survey Respondents from Sites = 4042

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 & beyond, we intend to expand our Cognizant Global Medical Affairs team across strategic countries and continue with the Site Advocacy Groups, to support our Sites globally, get their voices heard and spread their message to other stakeholders so that we are able to build a truly single consolidated operational platform for all – which will eventually mean Sites having more time to focus on critical tasks and patients.