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AACI Commentary

Simplifying Clinical Trials

Using Technology to Improve Operations

By the AACI Shared Investigator Platform (SIP) Task Force

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Commentary Overview

- Cognizant's Shared Investigator Platform (SIP) is a single information technology solution that facilitates investigative site collaboration with multiple clinical trial sponsors.
- The goal of the SIP is to address common challenges facing clinical trials offices by reducing the time it takes to initiate a trial and streamlining information exchange, document flow, and data access.
- AACI convened a SIP task force to identify and address challenges that AACI members have encountered during implementation of the SIP.
- In a recent meeting with industry champions, participants considered how industry and AACI cancer centers can develop realistic expectations for implementing the platform.

The complexities and inefficiencies of clinical trial operations can overwhelm even the most successful academic medical center. Reducing the time it takes to initiate a trial; facilitating relationships between industry and investigators; and streamlining information exchange, document flow, and data access are just some of the persistent challenges facing clinical trials offices.

The Shared Investigator Platform (SIP)—a concept developed by TransCelerate Biopharma Inc., and now managed by Cognizant—aims to make clinical trials management more efficient for trial sites and sponsors. The SIP is a single information technology solution that facilitates investigative site collaboration with multiple clinical trial sponsors. Such a system can reduce redundant requests for information to qualify investigators and trial sites when participating in industry-sponsored trials.

AACI SIP Task Force

The **Association of American Cancer Institutes** (AACI) convened a SIP Task Force to identify and address challenges encountered in SIP implementation. Task force members were selected through recommendations from AACI's **Clinical Research Innovation** (CRI) Steering Committee.

Academic medical center trial sites conduct multiple studies and work with numerous sponsors at the same time. For academic cancer centers, implementing the SIP requires fundamental changes in clinical trial workflow at the cancer center and university level.

At its first meeting in February 2019, the task force discussed the challenges of SIP, such as identifying funding or staffing to cover the costs for SIP implementation requested by various trials sponsors. An option to address this unfunded mandate is to seek reimbursement from sponsors by adding costs to the trial's budget. Another challenge revolved around establishing appropriate points of contact at the cancer center or university, the SIP's compatibility with other cancer center information systems, assignment of physician delegates, working with a wider range of industry sponsors not currently using SIP, and using the SIP for trials conducted at network sites.

SIP Implementation: A Challenging Process

The AACI SIP Task Force identified four major SIP implementation challenges:

1. SIP is designed to be used by an entire university and not just an academic cancer center. Setting up multi-level profiles in the system is time-consuming and requires ongoing maintenance by the trial site.
2. Resource outlays for clinical trials offices are daunting. Trial start-up work requires a time investment that is compounded by staff managing both an existing system and the new SIP. For SIP implementation, cancer centers would need to set user access and enter an electronic curriculum vitae for each investigator and feasibility criteria.
3. SIP does not integrate into existing systems.
4. Determining the appropriate level of detail is exacerbated by inconsistent guidelines from pharmaceutical companies regarding information to enter into the SIP. For example, some companies require detailed information, while others seek high-level overviews.

Engaging Industry Champions

The task force also met with representatives from Cognizant, who outlined a plan for SIP implementation, and industry sponsors who had been selected to participate in the first phase of the SIP rollout for 2019. Cognizant addressed the limitation of physician delegates and made the requested updates to SIP. Future plans include implementation of SIP with additional pharmaceutical companies as well as contract research organizations.

A task force conference call with SIP champions from Bristol-Myers Squibb, Genentech, Lilly, Merck, and Pfizer covered the companies' plans and the expectations of trial sites working with initial SIP implementation. This meeting highlighted some of the resources that the companies are making available for the trial sites to use for implementation. Task force members reported on the importance of identifying a key contact who manages SIP for each cancer center.

A meeting convened by the task force during the annual AACI CRI meeting in Chicago was led by Theresa Werner, MD, chair-elect of the **CRI Steering Committee**, and included AACI leadership and representatives from Bristol-Myers Squibb, Genentech, Janssen R&D, Lilly, Merck, and Cognizant. Participants considered ways to allow both industry and AACI cancer centers to operationalize the implementation of the SIP and to develop realistic expectations.

With respect to individual progress with the SIP implementation, understanding "pain points" for trial sites has led to bidirectional learning for industry and the sites. Industry representatives recognize that SIP implementation is daunting, and are willing to assist sites with the process. Cognizant offered to provide on-site training, explore options for batch uploading of documents, develop an application platform interface to allow transfer of documentation, and create a roadmap for industry to use to standardize the information for the SIP.

What's Next?

Next steps for the task force include continuing discussions among the task force, Cognizant, and industry partners. Cancer centers have indicated that they would like to work with Cognizant directly, instead of individually with pharmaceutical companies, to ensure the process is streamlined and university leadership at academic medical centers should be engaged early in the implementation process.

The task force is now considering a range of potential solutions, such as weighing the benefits of implementing SIP across the university or health system, not just at the cancer center. Other measures that may prove beneficial include requesting organizational training for start-up and maintenance; financial help from industry to support needed resources; staggered start-up schedules organized by disease team or new trials launched only with integration over a reasonable timeline, perhaps spanning a 12-month period; providing an interface that works with cancer center existing platforms and eRegulatory systems; and creating the ability to personalize the SIP implementation to better suit individual sites' needs.

The AACI SIP Task Force welcomes feedback on future discussion topics.

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Our Mission

Representing 98 of North America's premier academic and freestanding cancer centers, the Association of American Cancer Institutes is dedicated to reducing the burden of cancer by enhancing the impact of leading cancer centers.

About AACI Commentary

To promote the work of its members, AACI publishes Commentary, an editorial series focusing on major issues of common interest to North American cancer centers, authored by cancer center leaders and subject matter experts.