Revolutionizing Site and Sponsor Communications through the Shared Investigator Platform & Investigator Registry

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SCRS Our Voice.℠ Our Community. Society for Clinical Research Sites

European Site Solutions Summit

Faculty Disclosure

In compliance with ANCC Guidelines, I hereby declare:

I do not have financial or other relationships with the manufacturer(s) of any commercial service(s) discussed in this educational activity.

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Presentation Objectives

- **Provide an overview on the Shared Investigator Platform along with a description of the site user's experience and the support and materials available to the user.**

Shared Investigator Platform

The Shared Investigator Platform (SIP) will facilitate interaction between investigators and multiple clinical trial sponsors, enabling study planning, study start-up, and study conduct activities while reducing the administrative burden on site staff.

What is the vision?

Reduce the burden on investigative sites by providing them with a single point of access, harmonized content and services, and streamlined interaction with participating clinical trial Sponsors.

Accomplishments

- ✔ Selected and contracted with Systems Integration partner.
- ✔ Engaged external site users (SCRS Site Advocacy Group) to partner in solution design and testing.

Upcoming Plans

- First release to be adopted by some Member Companies on a rolling basis.
- Enhancements and new functionality in Release 2 and future releases.

Shared Investigator Platform

Benefit to Sites

1. The Shared Investigator Platform was developed with sites, for sites.
2. The Platform increases efficiency, reduces burden on investigators and site personnel in planning and conduct of clinical studies.
3. The Platform streamlines interactions and data exchange with participating Study Sponsors through a single application with centralized access.
4. Aligns and harmonizes data and processes for interacting with participating Study Sponsors.

SIP Highlights

Selected Member Companies Decided to Adopt

Selected, Licensed Key Service Components

Selected Cognizant as SI Partner

SIP Highlights

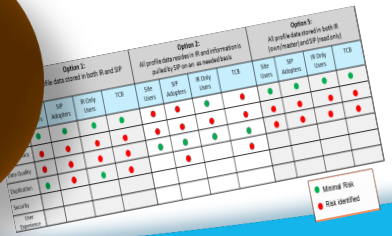
Integrated Investigator Registry (IR) Solution

Partnered with SCRS SAG to Design SIP

Finalized R1 Requirement - working on R2 concurrently

Cognizant

PRESS RELEASE
24 July



Investigator Registry (IR)
Master data for SIP profiles are assigned unique identifiers & stored in the IR.

SIP Roadmap – www.SharedInvestigator.com

Release 1

- Single Sign On
- User Profile
- Facility Profile
- Training
- Feasibility Surveys
- Study Workspace
- Document Exchange
- Tasks, Alerts & Notifications
- Dashboards and Reporting
- Search capabilities

Release 2

(Proposed functionality)

- Document Management (e.g., versioning, workflow, e-signatures, Integration to sponsor eTMF
- Safety Letters
- Surveys -new types, analysis
- Enhanced functionality
- Expanded Reporting

Release 3

(Future proposed features)

- PI/Sponsor Collaboration
- Online FAQ
- Discussion Boards
- Online Meeting
- Investigator Payments
- Non-drug supply ordering
- Drug supply ordering/IWRS

The Shared Investigator Platform - developed with sites, for sites

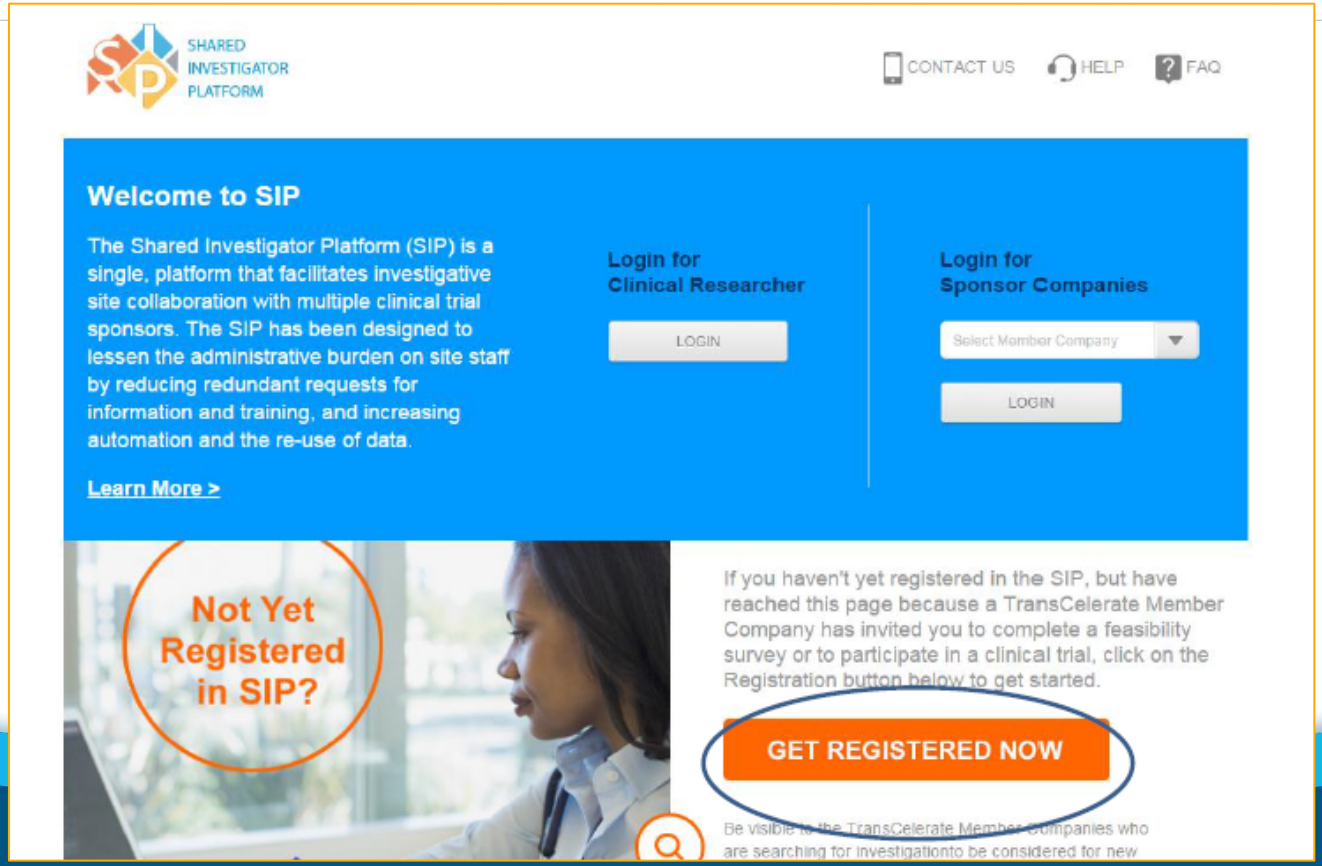
Collaborative Development

- Society for Clinical Research Sites (SCRS) and TransCelerate partnership.
- Site Advocacy Group (SAG) members have been working with the SIP development team.
- SAG members have participated in the development process. Their insights and feedback have guided development to ensure value for investigative sites.

SIP Release 1 Functionality

1. **Single Sign On**
   Secure Access across Sponsors and Studies
2. **Study Workspace**
   Sponsor specific workspace for each study
3. **User Profile**
   Centralized Site staff information; re-used across studies
4. **Facility Profile**
   Centralized facility information; re-used across studies. User associates to facility
5. **Feasibility Survey**
   Survey creation, distribution, completion & response management
6. **Training**
   Centralized Training History; GCP training (mutually recognized)
7. **Document Exchange**
   Share, Post and Retrieve documents
8. **Task, Alerts, and Notifications**
   Consolidated reminders & information across studies
9. **Home Page**
   Dashboards ,News, Links, Reports & Metrics

The SIP Homepage



User Profile – Create & Manage, Download CV

SPONSOR USER

SITE USER

SITE USER: CREATE USER PROFILE / UPDATE & MAINTAIN

- Create user profile manually or by uploading SQT Abbreviated CV
- PI can delegate data entry

SITE USER: GENERATE CV

SPONSOR: CAN DOWNLOAD UPDATED CV FOR STUDY START UP

- Sponsor downloads are documented in user profile

Basic Details

Facility association

Education Details

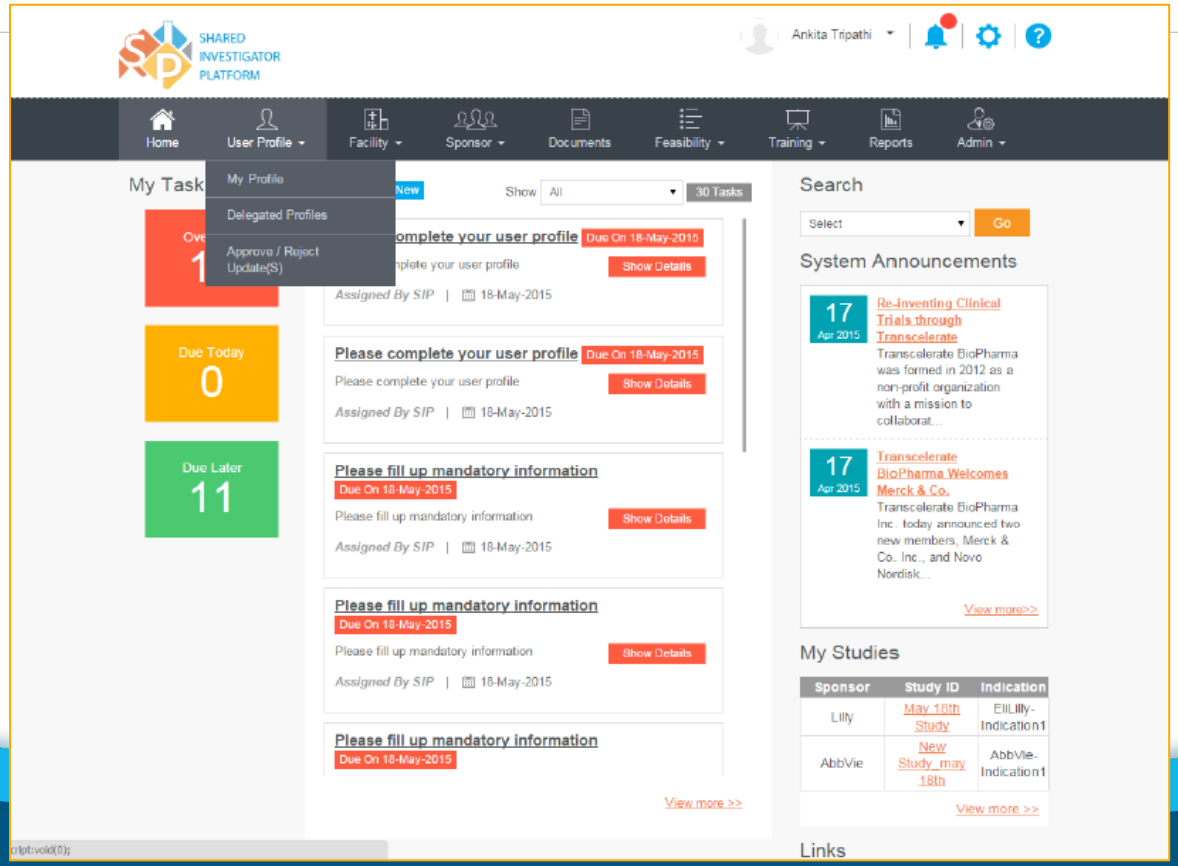
Professional, Research Experience

Journals, articles published

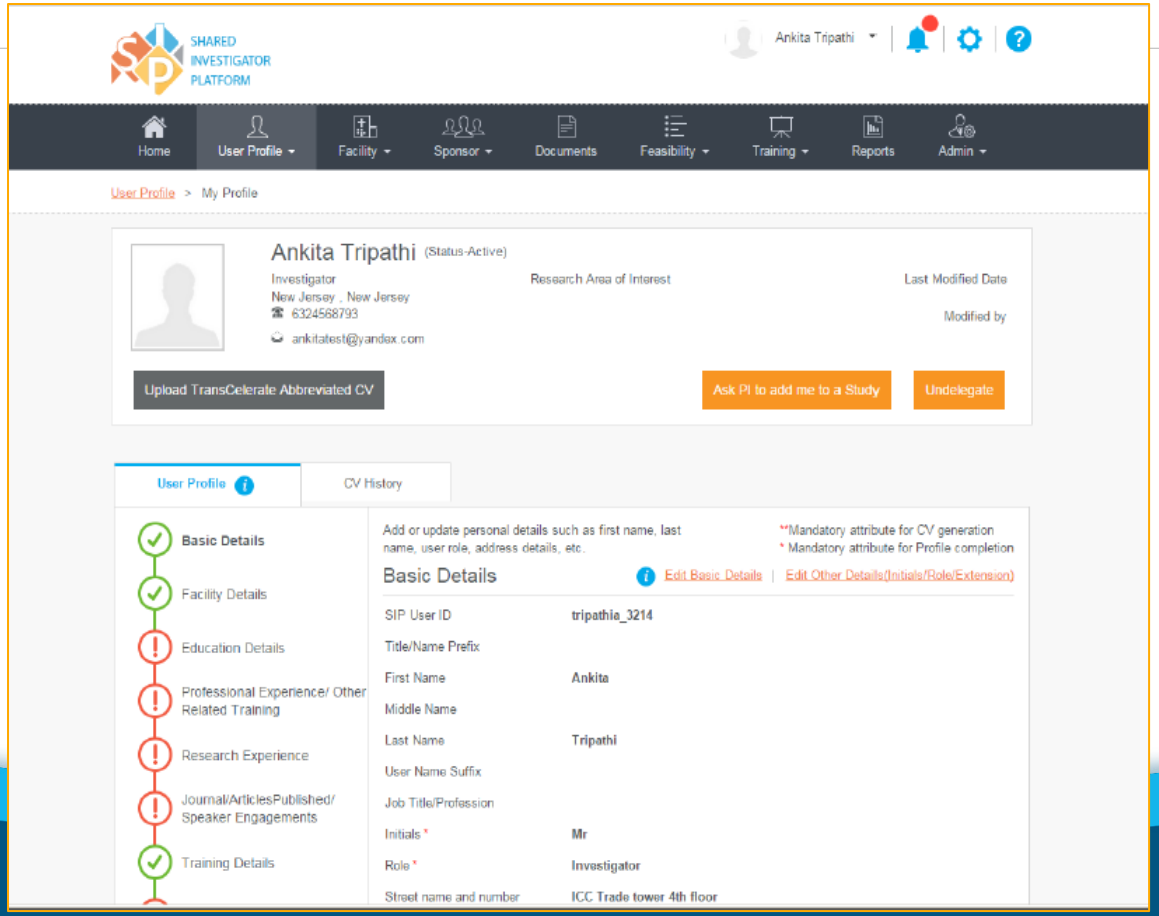
GCP Training

Medical License

The SIP User Experience



The SIP User Experience



Create & Manage Facility Profile

SITE
USER

ADMIN

SITE: CREATES A FACILITY

- If the facility is not already in SIP, creates a new facility
- Selects Facility information owner(s) who will update / maintain information

ADMIN: APPROVES FACILITY / NOTIFIES SITE

SITE USERS: ASSOCIATE (LINK) FACILTY WITH USER PROFILES

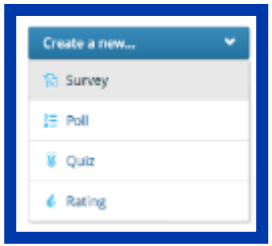
SITE USERS: ASSOCIATE (LINK) LAB/ IRB, ETC. WITH FACILTY

Feasibility Survey

SPONSOR USER

SITE USER

SPONSOR: CREATES A NEW SURVEY



- Sponsor can create a new survey using template or copying an existing survey. Creates recipient list
- Sends survey and recipient list to internal reviewers

SPONSOR: SENDS SURVEY TO SITE USERS

SITE: COMPLETES THE SURVEY

- PI reviews study documents; can submit a question, complete the survey, or delegate survey, a question or survey sections
- Confirms user and facility profiles are accurate
- Submits completed survey

SPONSOR: REVIEWS SURVEY RESPONSES

- Sponsor manages incoming responses
- Exports survey results for analysis and decision

SPONSOR: REVIEWS SURVEY & RECIPIENTS

SPONSOR USER

Create a Study Workspace

SPONSOR: CREATES STUDY WORKSPACE

SPONSOR: CREATES POTENTIAL INVESTIGATOR LIST

- Sponsor can search existing SIP users, upload or copy from an Excel list, or manually add names

SPONSOR: IDENTIFIES SHORTLIST

SPONSOR: SELECTS/ NOTIFIES SITES FOR STUDY

Participate in a Study

SITE USER

SITE: RECEIVES AND ACCEPTS INVITATION TO PARTICIPATE IN STUDY

SITE: PI ASSOCIATES FACILITY TO STUDY SITE

- Can associate a new facility or additional IRB / Local lab

SITE: ASSIGNS SITE STAFF TO STUDY

- Can search and select site staff / assign to the study
- Can accept / process site staff request to be added to the study

SPONSOR USER

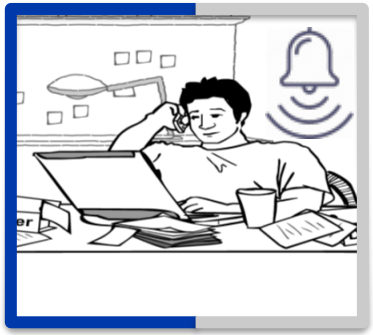
SITE USER

Document Exchange

SPONSOR / SITE: UPLOADS DOCUMENT

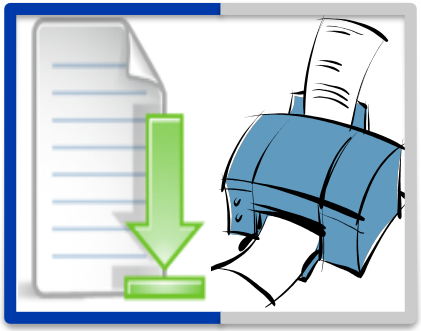
- Selects the recipients who access the document
- SIP notifies recipients

SPONSOR / SITE: RECEIVES NOTIFICATION, ACCESSES DOCUMENT, MARKS AS VIEWED



- SIP notifies the uploader that the document is viewed

SPONSOR / SITE: CAN DOWNLOAD, OR PRINT DOCUMENT



SPONSOR USER

SITE USER

Training – Execute Training/ View Assignments & Training History

SITE USER: RECEIVES ALERT, EXECUTES TRAINING

SITE USER: VIEW, PRINT COMPLETION CERTIFICATE

SITE USER: CAN VIEW TRAINING ASSIGNMENTS & TRAINING HISTORY

SPONSOR: VIEWS TRAINING STATUS

Training – Request Credit / View Training Assignments & History

SPONSOR USER

SITE USER

SITE USER: REQUESTS CREDIT FOR TRAINING MEETING MINIMUM CRITERIA

SPONSOR: REVIEWS/ APPROVES REQUEST

SITE USER: RECIEVES NOTIFICATION OF CREDIT

CREDIT CASCADES TO ALL SPONSORS WHO ACCEPT

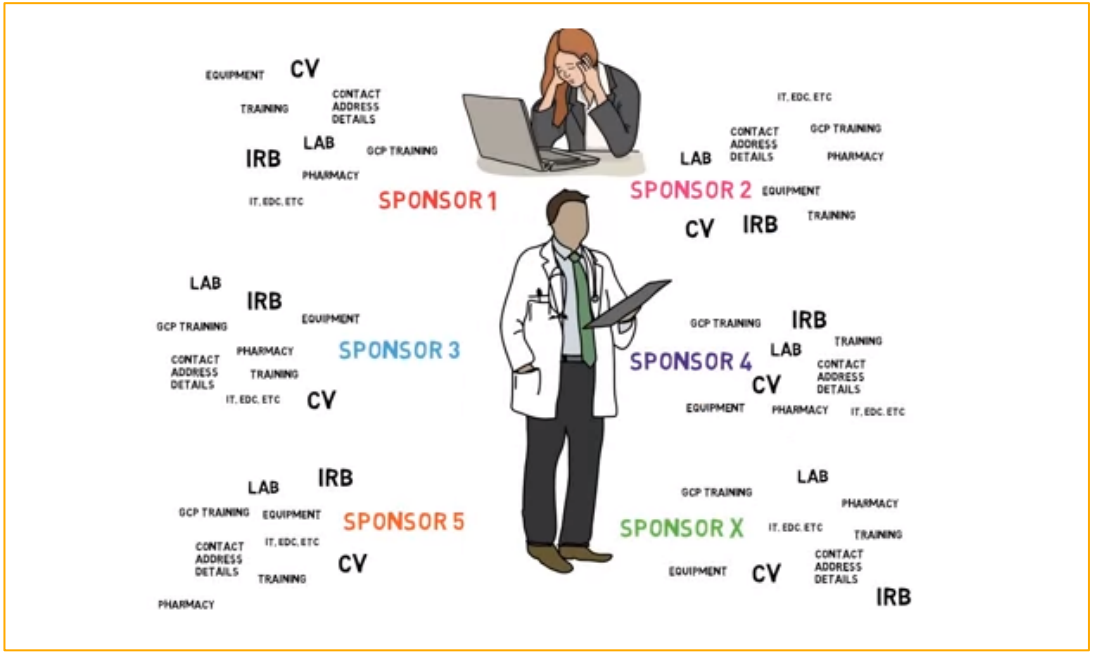
SIP Enables a Site User to:

1. Join the Platform — One login; access to multiple participating sponsors
2. Build a User Profile — Enter data once; maintain your credential centrally for use across SIP sponsors & studies
3. Complete GCP Training — Centralized history. Take GCP training once – credit may be recognized by multiple participating sponsors
4. Prioritize & Manage Your Work — Consolidated view of a site tasks across SIP studies and sponsors

SIP Enables a Site User to:

5	Manage a Facility Profile	Maintain information centrally for use across SIP sponsors & studies. Facility is associated to users & studies
6	Complete Feasibility Surveys	Central visibility to all SIP Feasibility surveys; shorter surveys due to re-use of SIP user & facility profile data
7	Access Your Study Workspace	Interact & collaborate with SIP study teams; SIP study materials in one place
8	Exchange Documents	Post, share and retrieve study documents with SIP sponsors

SIP Fast Facts



Audience Questions…

ACCELERATION
TRUST
PERIENCED
PROCESS INVOLVEMENT
COLLABORATIV
OVATIVE
PROGRESSIVE THINKING
FORWARD
THINKING
DETERMINED
INDUSTRY
RESULTS
NSPARENT
OPEN MINDED
SOLUTIONS
CONSORTIUM
POWERFUL
SIMPLIFIED

Thank you!