

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

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Eli Lilly and Company



@TransCelerate

# 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



Sponsors

Quality, streamlined processes, regulatory compliance, capacity



Costs for training, document Exchange, Support /Help desk  
Startup time



Investigators

Productivity (via reduced redundant tasks & streamlined processes); access to information



Study startup time, redundant training



Regulators

Streamlined electronic audit process, insight into trial, harmonized information model



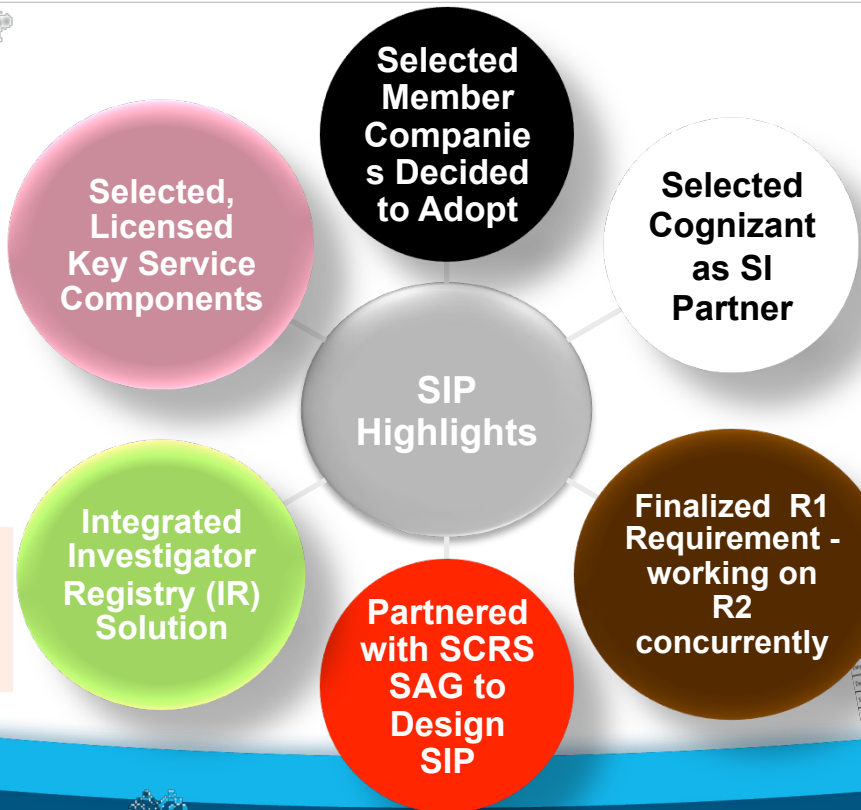
Startup time

# Benefit to Sites

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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



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

	Option 1: No data shared in both R1 and R2			Option 2: All profile data (except IR) and information provided by SIP are shared in both R1 and R2			Option 3: All profile data shared in both R1 and R2		
	SIP Adapters	R1 Only (SIP)	R2 Only (SIP)	SIP Adapters	R1 Only (SIP)	R2 Only (SIP)	SIP Adapters	R1 Only (SIP)	R2 Only (SIP)
Availability	●	●	●	●	●	●	●	●	●
Flexibility	●	●	●	●	●	●	●	●	●
Security	●	●	●	●	●	●	●	●	●
Cost	●	●	●	●	●	●	●	●	●
Integration	●	●	●	●	●	●	●	●	●

● Minimal Risk  
 ● Risk Identified

# SIP Roadmap – [www.SharedInvestigator.com](http://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)*

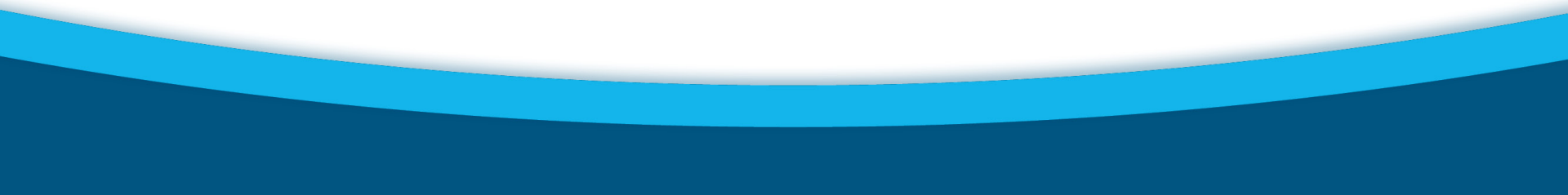
- PI/Sponsor Collaboration
- Online FAQ
- Discussion Boards
- Online Meeting
- Investigator Payments
- Non-drug supply ordering
- Drug supply ordering/IWRS

The Shared Investigator Platform - developed with sites, for sites



# Collaborative Development

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- 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

**SHARED INVESTIGATOR PLATFORM**

CONTACT US HELP FAQ

## Welcome to SIP

The Shared Investigator Platform (SIP) is a single, platform that facilitates investigative site collaboration with multiple clinical trial sponsors. The SIP has been designed to lessen the administrative burden on site staff by reducing redundant requests for information and training, and increasing automation and the re-use of data.

[Learn More >](#)

### Login for Clinical Researcher

LOGIN

### Login for Sponsor Companies

Select Member Company

LOGIN

**Not Yet Registered in SIP?**

If you haven't yet registered in the SIP, but have reached this page because a TransCelerate Member Company has invited you to complete a feasibility survey or to participate in a clinical trial, click on the Registration button below to get started.

**GET REGISTERED NOW**

Be visible to the TransCelerate Member Companies who are searching for investigators to be considered for new

# 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

**My Task**

- My Profile
- Delegated Profiles
- Approve / Reject Update(S)

**Task List:**

- complete your user profile** Due On 18-May-2015  
Assigned By SIP | 18-May-2015
- Please complete your user profile** Due On 18-May-2015  
Please complete your user profile  
Assigned By SIP | 18-May-2015
- Please fill up mandatory information** Due On 18-May-2015  
Please fill up mandatory information  
Assigned By SIP | 18-May-2015
- Please fill up mandatory information** Due On 18-May-2015  
Please fill up mandatory information  
Assigned By SIP | 18-May-2015
- Please fill up mandatory information** Due On 18-May-2015  
Please fill up mandatory information  
Assigned By SIP | 18-May-2015

[View more >>](#)

**Search**

Select

**System Announcements**

- 17 Apr 2015** [Re-Inventing Clinical Trials through Transcelerate](#)  
Transcelerate BioPharma was formed in 2012 as a non-profit organization with a mission to collaborat...
- 17 Apr 2015** [Transcelerate BioPharma Welcomes Merck & Co.](#)  
Transcelerate BioPharma Inc. today announced two new members, Merck & Co. Inc., and Novo Nordisk...

[View more >>](#)

**My Studies**

Sponsor	Study ID	Indication
Lilly	<a href="#">May 18th Study</a>	EIL Lilly-Indication1
AbbVie	<a href="#">New Study_may 18th</a>	AbbVie-Indication1

[View more >>](#)

**Links**

# The SIP User Experience

The screenshot displays the user profile interface for Ankita Tripathi. At the top, the 'SHARED INVESTIGATOR PLATFORM' logo is on the left, and the user's name 'Ankita Tripathi' is on the right, accompanied by notification, settings, and help icons. A dark navigation bar contains icons for Home, User Profile, Facility, Sponsor, Documents, Feasibility, Training, Reports, and Admin. Below this, a breadcrumb trail shows 'User Profile > My Profile'. The main profile card features a placeholder for a profile picture, the user's name 'Ankita Tripathi (Status-Active)', and fields for 'Investigator', 'New Jersey, New Jersey', '6324588793', 'ankitaltest@yandex.com', 'Research Area of Interest', 'Last Modified Date', and 'Modified by'. Action buttons include 'Upload TransCelerate Abbreviated CV', 'Ask PI to add me to a Study', and 'Undelegate'. A tabbed interface shows 'User Profile' (active) and 'CV History'. The 'Basic Details' section includes a checklist of profile categories (Basic, Facility, Education, Professional Experience, Research Experience, Journal/Articles, Training) and a table of personal information.

**SHARED INVESTIGATOR PLATFORM**

Ankita Tripathi

Home User Profile Facility Sponsor Documents Feasibility Training Reports Admin

User Profile > My Profile

**Ankita Tripathi** (Status-Active)

Investigator  
New Jersey, New Jersey  
6324588793  
ankitaltest@yandex.com

Research Area of Interest  
Last Modified Date  
Modified by

Upload TransCelerate Abbreviated CV Ask PI to add me to a Study Undelegate

User Profile CV History

**Basic Details**

Add or update personal details such as first name, last name, user role, address details, etc. **\*\*Mandatory attribute for CV generation**  
**\*Mandatory attribute for Profile completion**

**Basic Details** Edit Basic Details | Edit Other Details (Initials/Role/Extension)

SIP User ID	tripathia_3214
Title/Name Prefix	
First Name	Ankita
Middle Name	
Last Name	Tripathi
User Name Suffix	
Job Title/Profession	
Initials *	Mr
Role *	Investigator
Street name and number	ICC Trade tower 4th floor

# Create & Manage Facility Profile

SITE  
USER

ADMIN

**SITE: CREATES A FACILITY**



**ADMIN: APPROVES  
FACILITY / NOTIFIES SITE**



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

**SITE USERS: ASSOCIATE (LINK)  
FACILITY WITH USER PROFILES**



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

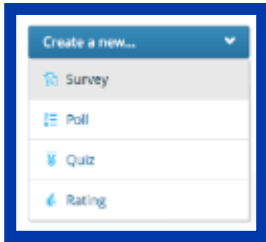


# Feasibility Survey

SPONSOR  
USER

SITE USER

## SPONSOR: CREATES A NEW SURVEY



## SPONSOR: SENDS SURVEY TO SITE USERS



## SITE: COMPLETES THE SURVEY



## SPONSOR: REVIEWS SURVEY RESPONSES



- 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: REVIEWS SURVEY & RECIPIENTS



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



# Create a Study Workspace

**SPONSOR:  
CREATES STUDY  
WORKSPACE**



**SPONSOR: CREATES  
POTENTIAL  
INVESTIGATOR LIST**



**SPONSOR:  
IDENTIFIES  
SHORTLIST**



**SPONSOR: SELECTS/  
NOTIFIES SITES FOR  
STUDY**



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

# 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

# Document Exchange

SPONSOR  
USER

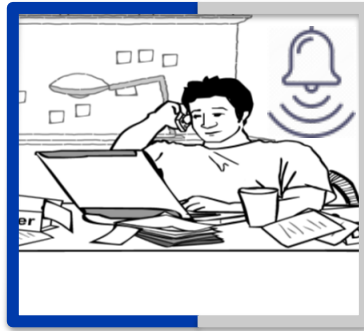
SITE USER

**SPONSOR / SITE:  
UPLOADS  
DOCUMENT**



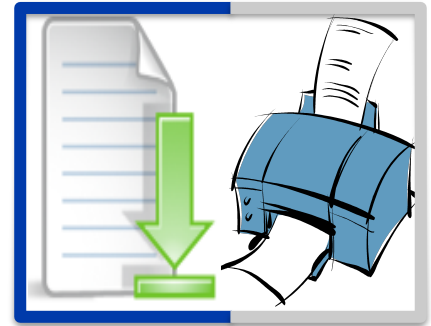
- Selects the recipients who access the document
- SIP notifies recipients

**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**



# Training – Execute Training/ View Assignments & Training History

SPONSOR  
USER

SITE USER

**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: RECEIVES  
NOTIFICATION OF CREDIT**



**CREDIT CASCADES  
TO ALL SPONSORS  
WHO ACCEPT**

# SIP Enables a Site User to:

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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

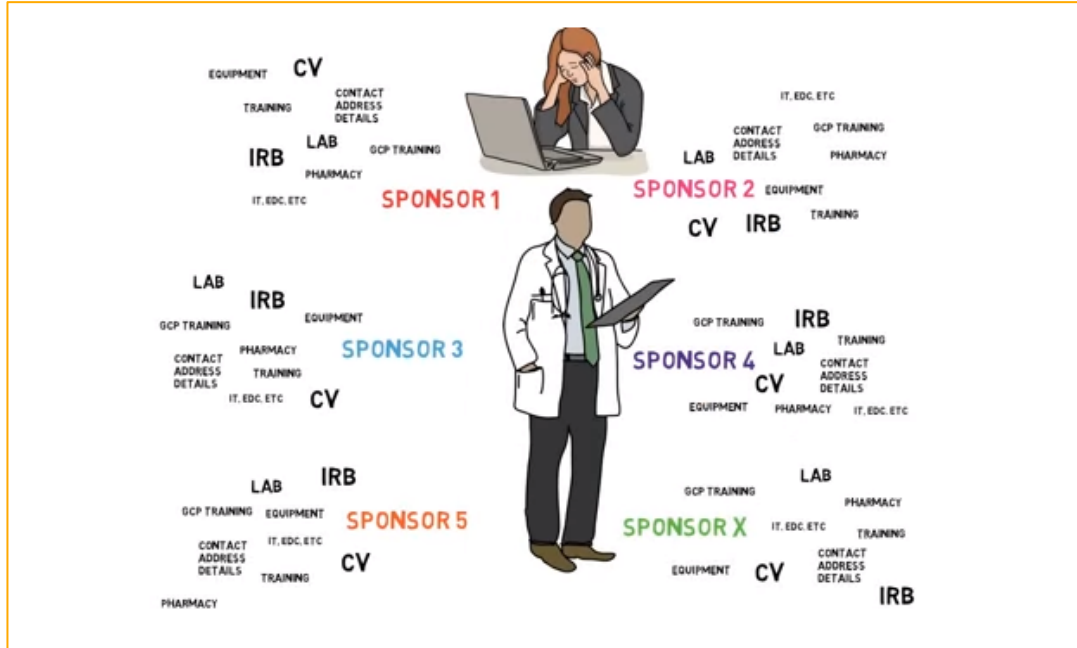
7 Access Your Study Workspace

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...

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**Thank you!**