



# Shared Investigator Platform

## DCRF Jaarcongres 2019

*Marc Janssens (Senior Manager Clinical Operations - Amgen BeNeLux,  
Transcelerate Country Lead Belgium)*

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**TransCelerate:**

# A Not-for-Profit Entity Created to Foster Collaboration

## Our Shared Vision:

To improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies.



**Ideation started from  
shared need**

# Disparate, Duplicate Processes for Site User ID Management and Feasibility Surveys

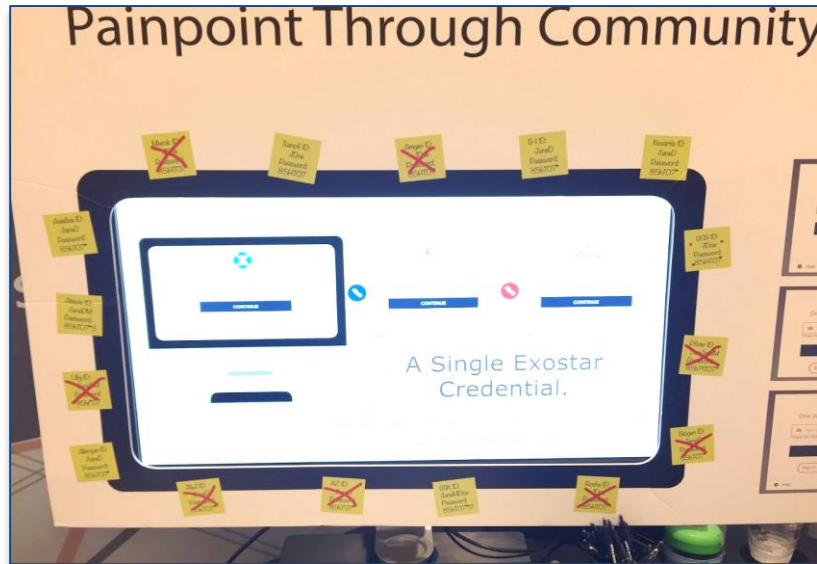


Photo courtesy of Exostar

It is time consuming and cumbersome for clinical trial sites to use many different websites, each requiring unique login credentials to communicate and collaborate with Sponsors.

## Study 1

- Do you have a -70° freezer?

## Study 2

- Do you have a -70° freezer?

## Study 3

- Do you have a -70° freezer?

## Study 4

- Do you have a -70° freezer?

## Study 5

- Do you have a -70° freezer?
- How long are your IRB turnaround times?
- Do you have a monitoring system for cold storage?
- How frequently does your IRB meet?
- Do you have an X-ray?

Site personnel are continuously asked to input the same information on their feasibility surveys when working on a different study or with a different Sponsor.

# Well known pain points from a clinical trial site perspective

Pain points	SIP Solutions
Too many passwords & websites; logging in and out of many portals	
Too many staff hours spent on providing site and site personnel data,	
Multiple competing priorities	
Redundant training	
Provide the same information and documents repeatedly	
Visibility for potential trial opportunities	
Regulatory documents are hard to track and send securely	
Sponsors do not consider Site input when developing new systems	
Every Sponsor “does it differently”	



# How does SIP address sites' pain points?

Pain points	SIP Solutions
Too many passwords & websites; logging in and out of many portals	<b>Single point of access</b> with One User ID & Password across Sponsors; links to systems; SSO work in progress
Too many staff hours spent on providing site and site personnel data,	After initial set-up of profiles, <b>information is reused</b> across platform; <b>allow more time for trial execution &amp; patient care</b>
Multiple competing priorities	Consolidated view of study tasks & surveys by due date; <b>prioritize and manage workload across studies</b>
Redundant training	<b>Centralized history</b> of GCP training; training <b>recognized by multiple Sponsors</b>
Provide the same information and documents repeatedly	Generate an e-Signed CV; upload common documents; <b>profile data accessible by all SIP Sponsors</b> ; can be exported to use outside of SIP
Visibility for potential trial opportunities	Sponsors search <b>Facility &amp; User Profile data for trial opportunities</b>
Regulatory documents are hard to track and send securely	Document exchange allows for <b>easy access, secure exchange &amp; tracking</b> of regulatory documents
Sponsors do not consider Site input when developing new systems	TransCelerate <b>consulted with a Global Site Advocacy Group</b> to develop functionality
Every Sponsor "does it differently"	<b>Harmonization of delivery of content</b> ; Study workspace & user experience consistent across Sponsors

# Shared Investigator Platform



## UNMET NEED

Clinical trial sites must use many different websites, each requiring unique login credentials to perform clinical trial responsibilities and communicate with their Sponsors. Site staff repeatedly prepare and provide the same information to each of their Sponsors. This is time consuming, cumbersome, and often difficult.



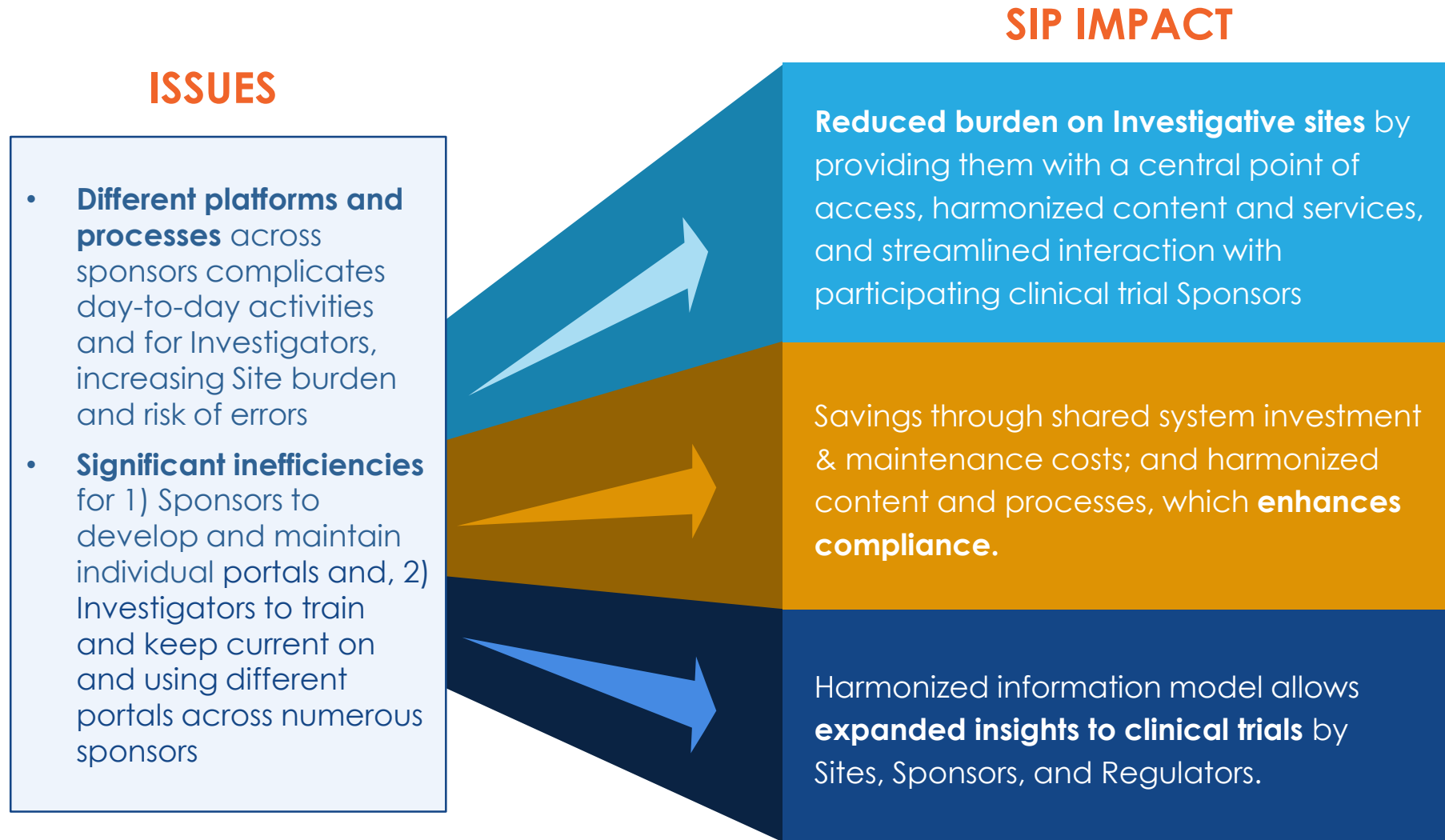
## OBJECTIVE

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

*What is the Shared Investigator Platform?*



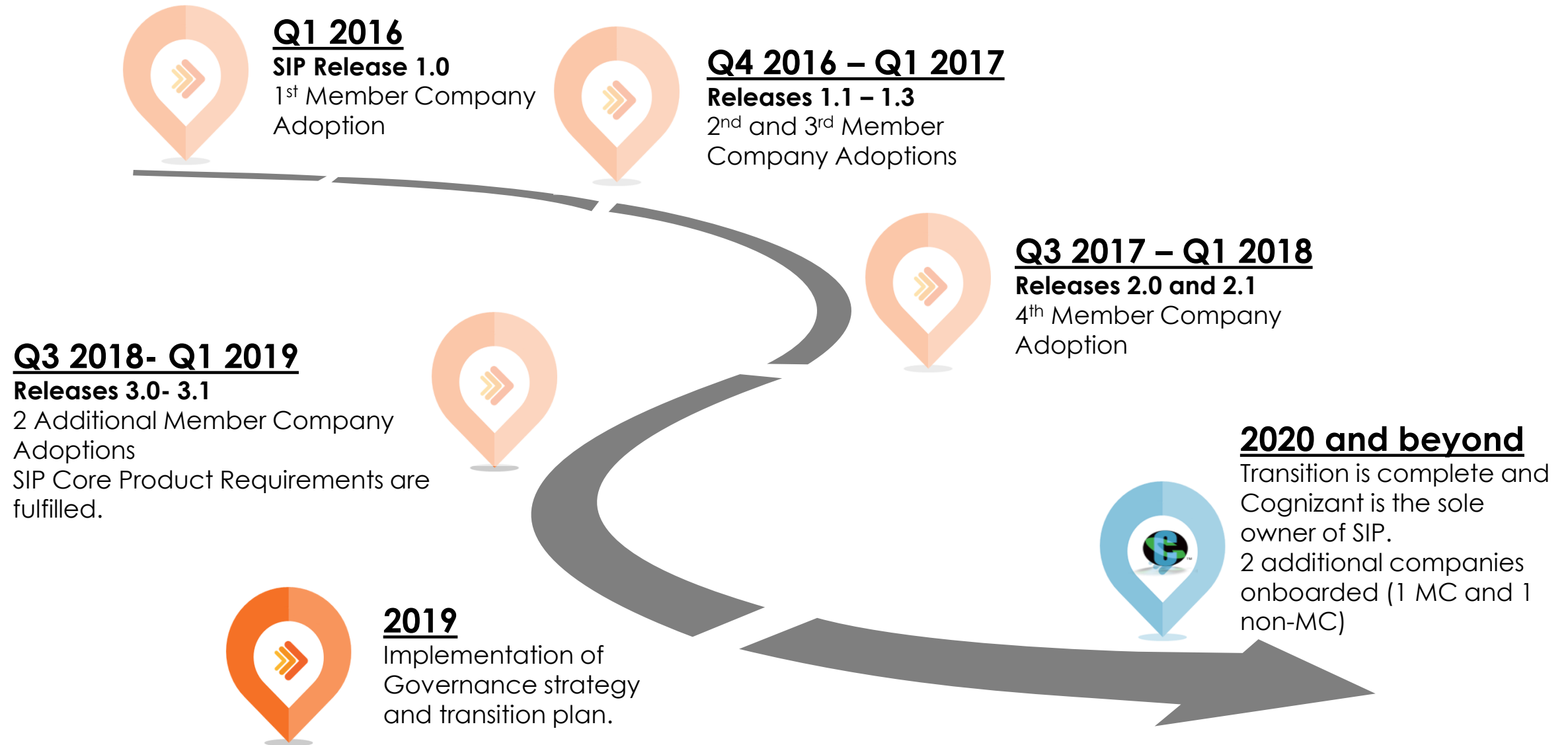
# SIP Value Proposition



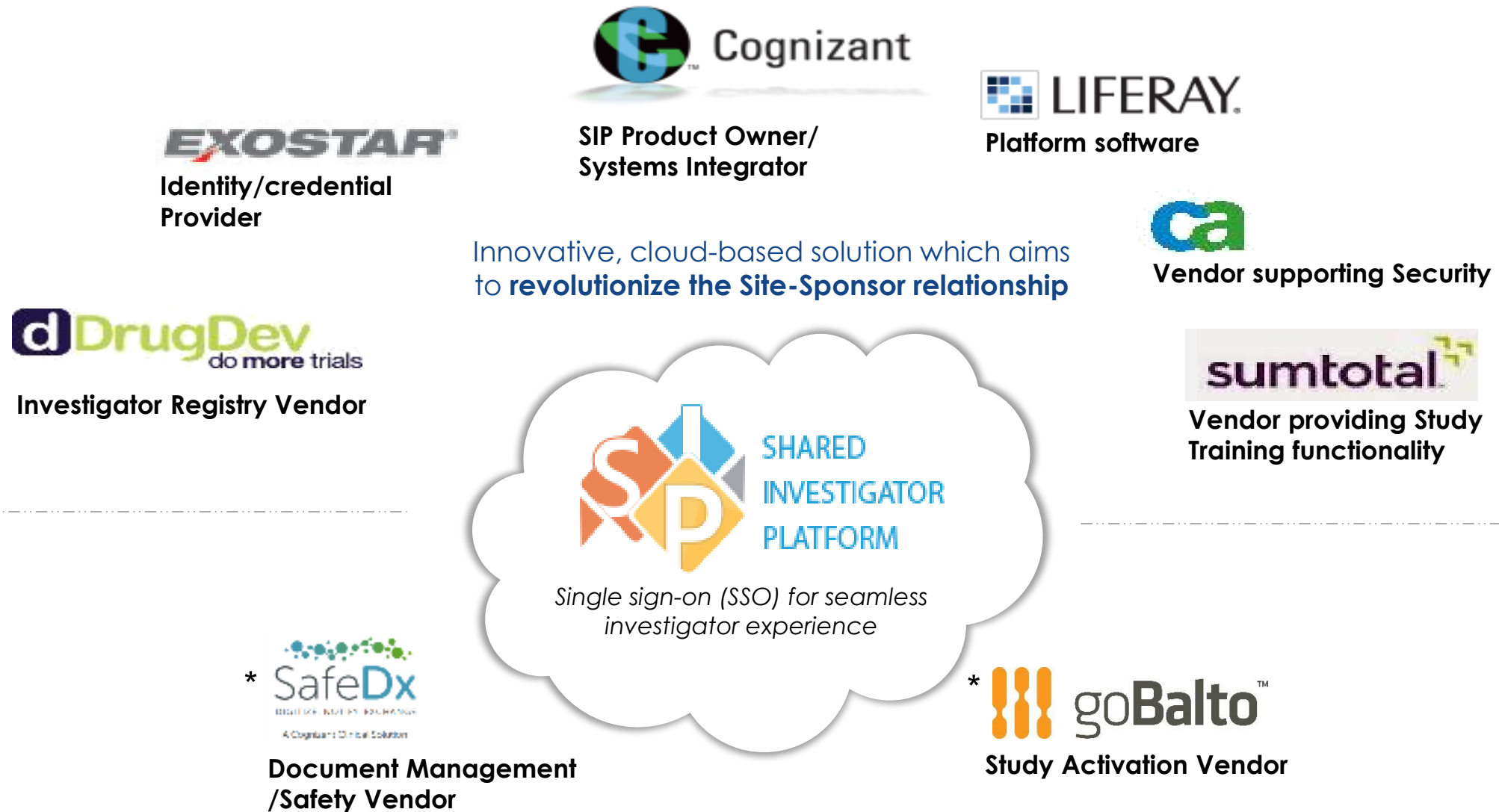


# SIP Concept to Reality

# SIP Journey

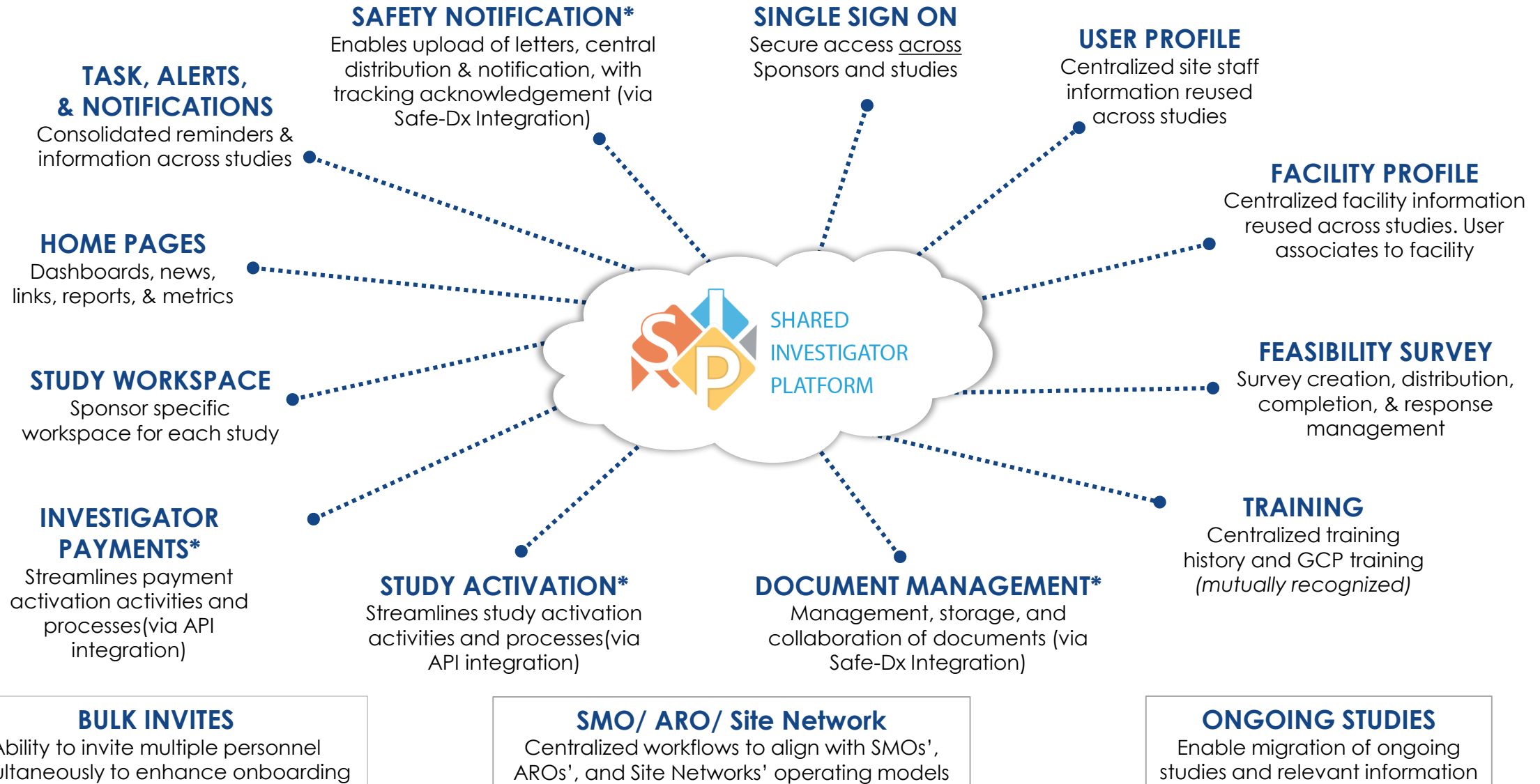


# What is the Shared Investigator Platform?



\* Open, public APIs delivered for use with any vendor of choice

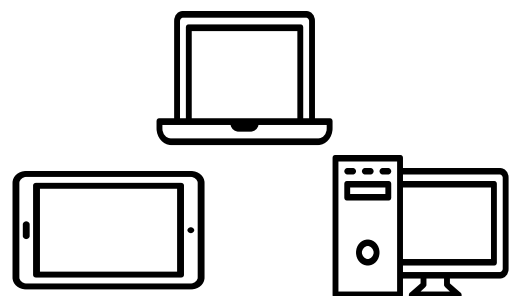
# SIP Functionality



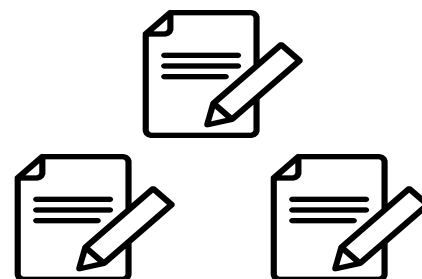
# Key Benefit- Re-use of Site User and Facility Profiles Information across studies

Several hours to provide redundant profile information for each study

## Process without SIP



Log onto multiple portals with varying processes for different Sponsors



Repetitive entry of CV information in various formats for each Sponsor



Completion of feasibility survey takes approx. X time, entering information from beginning to end

~1-2 hours to complete the Profile across studies

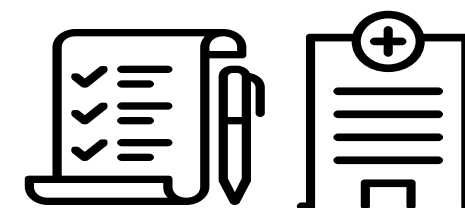
## Process with SIP



Log onto one Platform to manage studies in a harmonized way with participating Sponsors



Complete User and Facility Profiles once, and information can be seen by multiple Sponsors



Pre-population of existing Facility information in the Feasibility Survey means less time (~50% reduction) needed to fill out the Survey



# Key Benefit- Mutual Recognition Training (MRT) Program

## Process without SIP

Investigator must complete GCP Training for each Sponsor



Training Certificate



Sponsor 1



Sponsor 2



Sponsor 3

## Process with SIP

Site User completes a GCP Training under MRT Program



Site User submits MRT Request to Sponsor



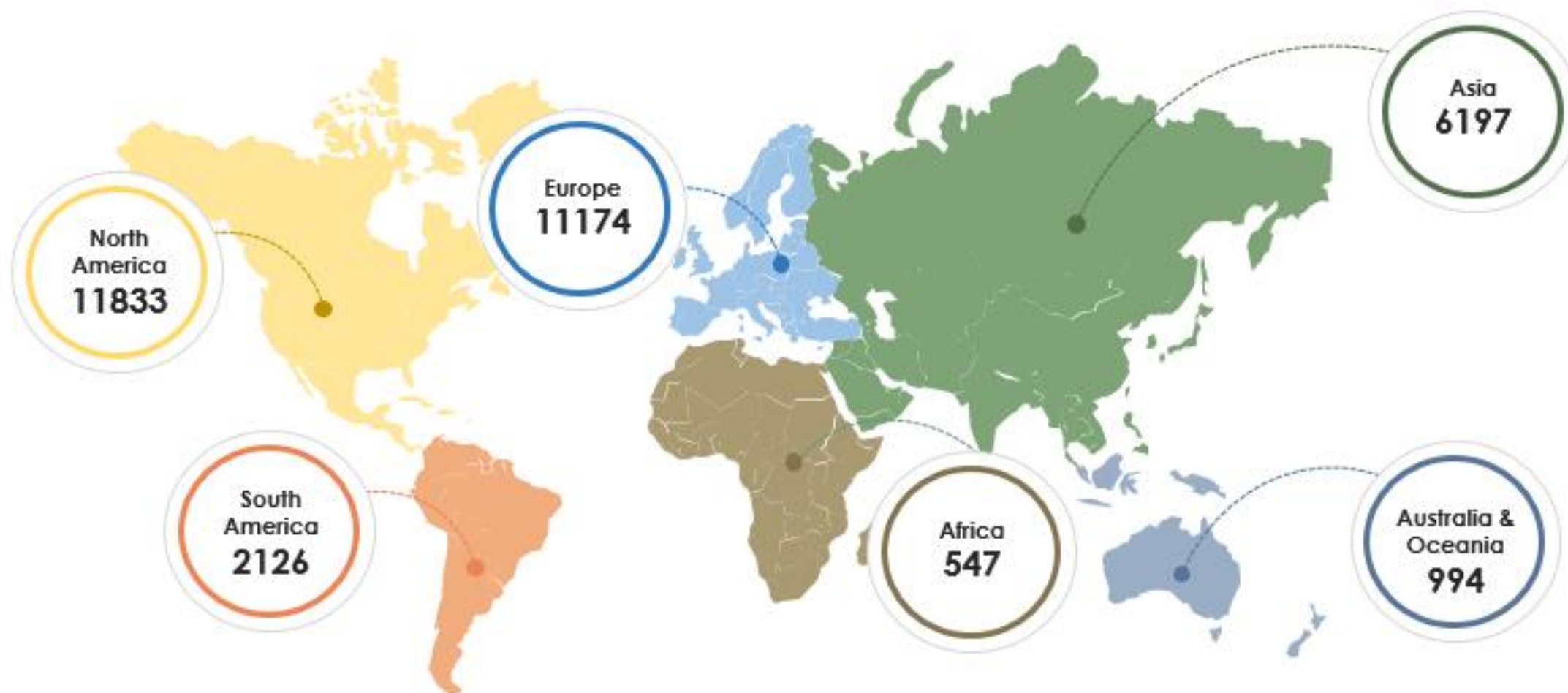
Sponsor can accept MRT request



Site User may receive GCP Training Credit without having to repeat training



# User Registration - Site Users Worldwide Distribution

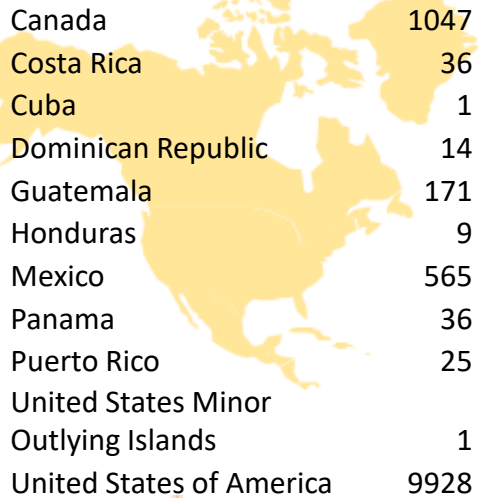


\* 32871 Registered site users \* 81 countries \* 9229 facilities \* 299 Studies



# User Registration - Site Users per Country

## North America 11833



Canada	1047
Costa Rica	36
Cuba	1
Dominican Republic	14
Guatemala	171
Honduras	9
Mexico	565
Panama	36
Puerto Rico	25
United States Minor Outlying Islands	1
United States of America	9928

## South America 2126



Argentina	521
Brazil	635
Chile	139
Colombia	556
Ecuador	2
Peru	273

## Africa 547



Algeria	5
Egypt	2
Mauritius	2
Morocco	5
South Africa	533

## Europe 11174



Austria	213
Belgium	525
Bosnia and Herzegovina	12
Bulgaria	172
Croatia	11
Czech Republic	571
Denmark	153
Estonia	23
Finland	117
France	917
Germany	948
Greece	186
Hungary	666
Ireland	87
Italy	1156
Latvia	25
Lithuania	40
Macedonia (the former Yugoslav Republic of)	2
Moldova (the Republic of)	3
Netherlands	250
Norway	58
Poland	1059
Portugal	136
Romania	135
Russian Federation	753
Serbia	43
Slovakia	45
Slovenia	3
Spain	1491
Sweden	49
Switzerland	122
Ukraine	368
United Kingdom of Great Britain and Northern Ireland	835

## Asia 6197



Afghanistan	1
China	2151
Georgia	35
Hong Kong	41
India	173
Israel	771
Japan	886
Jordan	2
Macedonia (the former Yugoslav Republic of)	2
Moldova (the Republic of)	3
Netherlands	250
Norway	58
Sri Lanka	2
Taiwan	403
Thailand	159
Turkey	736
United Arab Emirates	5
Viet Nam	14

## Oceania 994

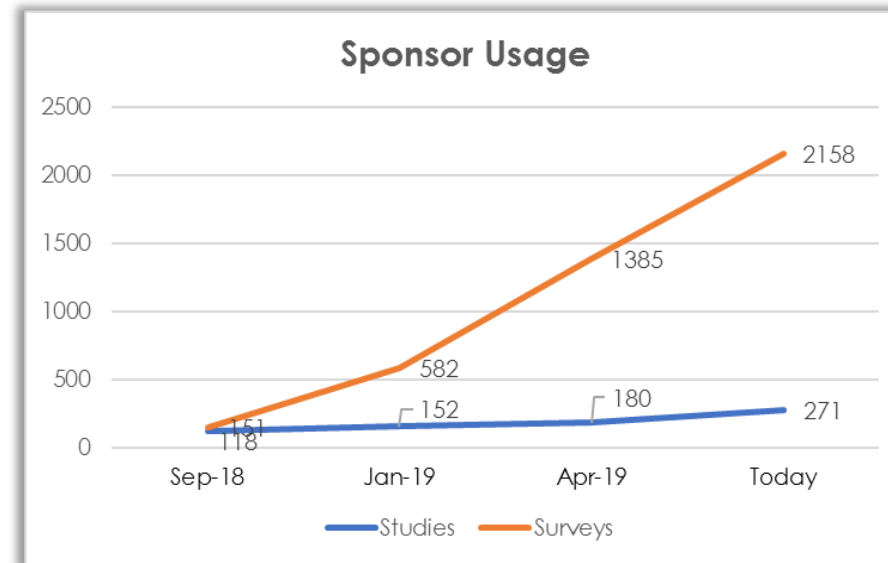
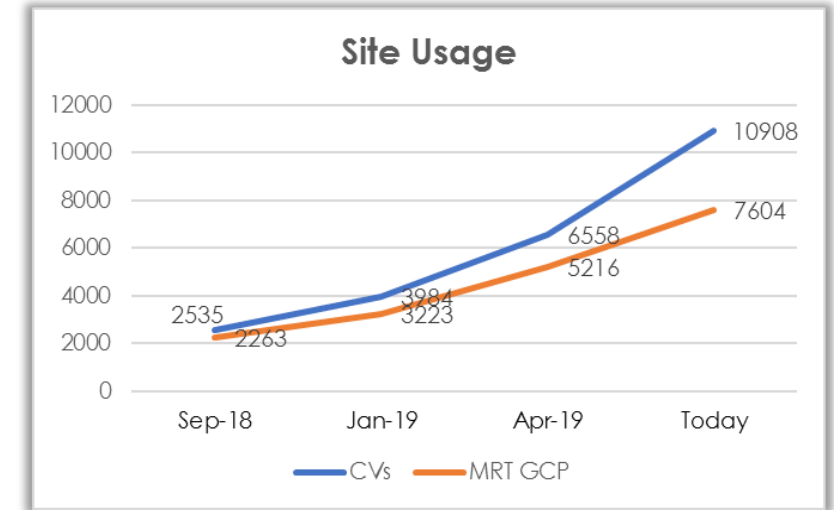
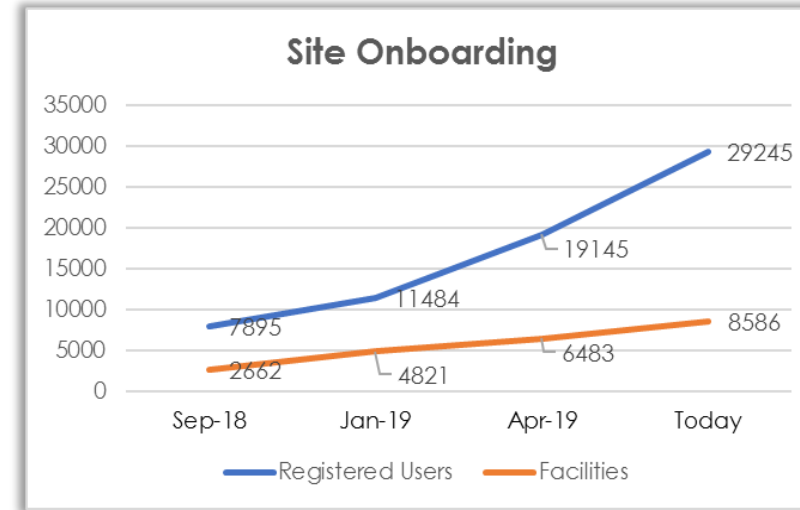


American Samoa	1
Australia	788
New Zealand	205

Macedonia (the former Yugoslav Republic of)	2
Moldova (the Republic of)	3
Netherlands	250
Norway	58

# SIP Implementation and Scale

- ❖ 6 Sponsor Companies are live on the Platform
- ❖ 2 others to join in 2020
- ❖ Avg ~2500 users registered per month in 2019
- ❖ 1037 Site Personnel >1 Study
- ❖ 90 Investigators > 1 Sponsor



# What's In It For Me?

## Site & Site Personnel

<b>Single Sign On</b>	<ul style="list-style-type: none"><li>➤ Single Sign On cross multiple Industry Systems and reduced account management activities</li></ul>
<b>Site Data Owned by Site</b>	<ul style="list-style-type: none"><li>➤ Site own user and facility profiles - SQ&amp;T's CV and SPF.</li><li>➤ Enter data once and maintain it.</li></ul>
<b>One for all</b>	<ul style="list-style-type: none"><li>➤ Reduce answers to repeated questions by multiple studies/sponsors.</li><li>➤ Streamlined GCP waiver process for Mutually Recognized Training</li><li>➤ Integration with Trifecta's Investigator Space Learning Management System</li><li>➤ Common experience across SIP-participating sponsors</li></ul>
<b>Consolidated Overview</b>	<ul style="list-style-type: none"><li>➤ Increased visibility into start up activities including training and document status</li><li>➤ Consolidated task list across studies and sponsors</li><li>➤ Insight into all outstanding feasibility surveys</li><li>➤ One stop-shop for study links</li></ul>
<b>Documentation</b>	<ul style="list-style-type: none"><li>➤ Secure document exchange and reduce paper work</li><li>➤ Access to a temporary document warehouse for study documents</li></ul>

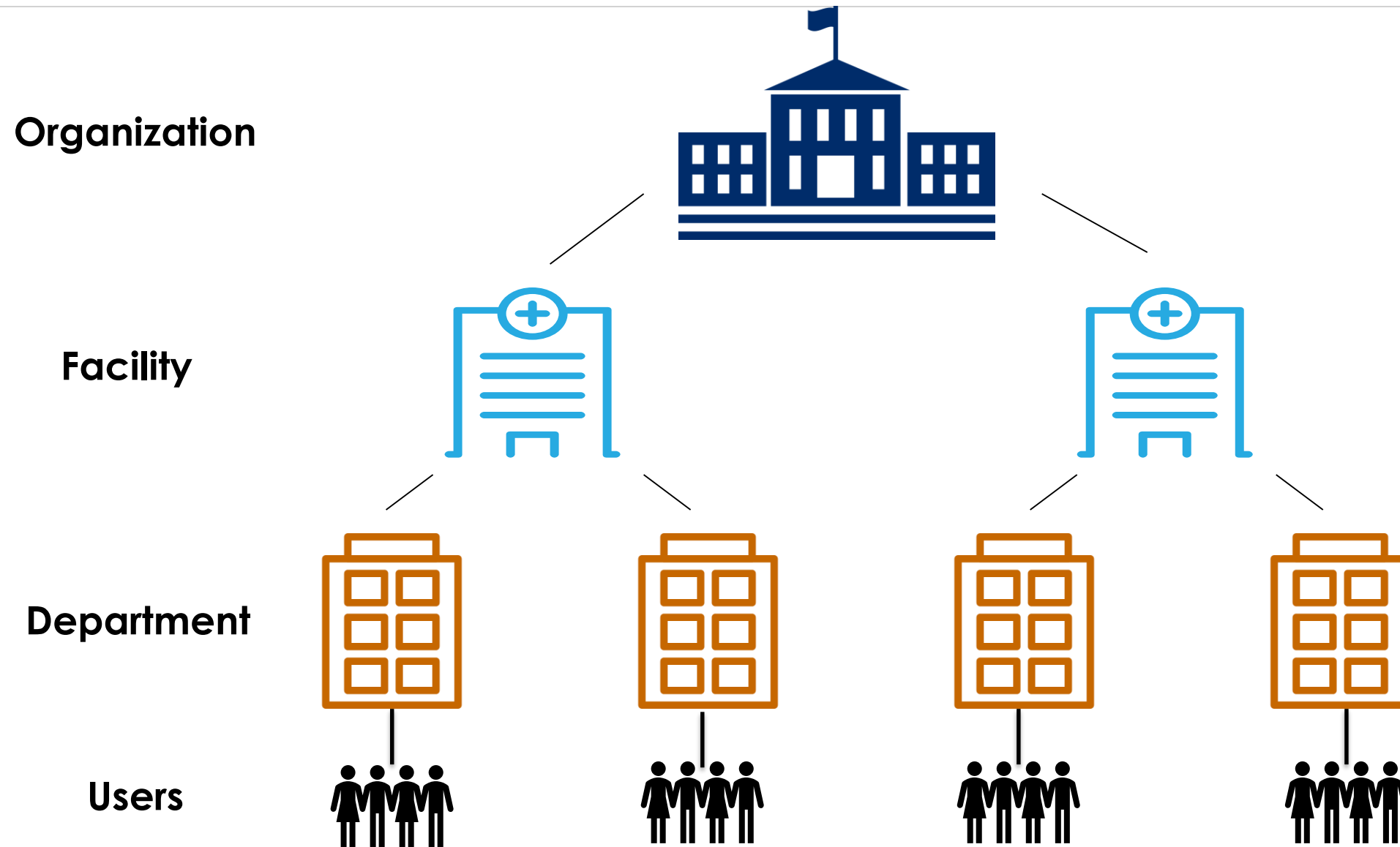
**Reduce administrative work**

**&**

**focus on what matters most**



# Organization, Facility, and Department Relationship



# What does it look like?

The screenshot displays the TransCelerate BioPharma user interface. At the top is a dark navigation bar with icons and labels for Home, User Profile, Facility, Sponsor, Documents, Survey, Training, and Reports. Below this is a light blue announcement banner featuring a calendar icon with '5 Overdue', '0 Due Today', and '0 Due Later' tasks, a date '15 Mar 2017', and a headline 'TCB Reports Impact in the Way Clinical Trial Information Was Shared' with a link to 'View All System Announcements'. The main content area is titled 'Tasks' and shows a list of tasks under the 'My Tasks(5)' filter. The tasks include 'Generate CV' (due Oct 25, 2017), a task with a 'null' title (due Nov 3, 2017) marked as 'Task Completed', and another 'null' task (due May 8, 2018). To the right, there are sections for 'Favorites' (listing A1A-MC-AMBR-Lilly, A1001001-Pfizer, and BO29999-Roche) and 'Recent Studies'. A 'Links' section at the bottom right contains links to 'Clinical Trials' and 'TCB Home'. The TransCelerate BioPharma logo is in the bottom left corner.

Home User Profile Facility Sponsor Documents Survey Training Reports

5 Overdue 0 Due Today 0 Due Later

15 Mar 2017

**TCB Reports Impact in the Way Clinical Trial Information Was Shared**  
Read this release about TransCelerate BioPharma Inc.'s measurable pro [View All System Announcements](#)

Tasks

My Tasks(5) My Tasks

**Generate CV** Due On 25 Oct 2017  
Please generate your CV as your profile was updated by you or your delegate or you have received credit for GCP training.

**null** Due On 03 Nov 2017  
Please remember to Submit existing Financial Discloses for PI's and SubI's that will appear on 1572  
Task Completed

**null** Due On 08 May 2018  
Suzy Sunshine with email address as suzysunshine2018@gmail.com has added Madison Community Hospital and Clinic to their User Profile.  
You may now add them as a member of the Site Staff for Site 100 belonging to Lilly Study A1A-MC-AMBR-Lilly for the SIP Ambassadors to use for demoing the SIP

**Favorites** Recent Studies

A1A-MC-AMBR-Lilly  
A1001001-Pfizer  
BO29999-Roche  
[Set Favorites >>](#)

**Links**

Clinical Trials  
TCB Home

TransCelerate BioPharma

# What does it look like?

The screenshot displays a web application interface for clinical trial management. At the top is a dark navigation bar with icons and labels for Home, User Profile, Facility, Sponsor, Documents, Survey, Training, and Reports. Below this, a section shows task counts: 5 Overdue, 0 Due Today, and 0 Due Later. A 'Tasks' section contains three items, each with a red 'null' status and a description related to generating a CV, submitting financial disclosures, and adding site members. A 'Sponsor' dropdown menu is open, listing various pharmaceutical companies including Lilly, Pfizer, Roche, AbbVie, Allergan, Amgen, AstraZeneca, BMS, Curie, Franklin, Higgs, Livingstone, and MSD. To the right, there's a 'My Tasks' button and a 'Favorites' section listing specific trial identifiers like 'A1A-MC-AMBR-Lilly'. Below that is a 'Links' section with 'Clinical Trials' and 'TCB Home'. The bottom of the page features the TransCelerate Biopharma logo and a URL.

Home User Profile Facility Sponsor Documents Survey Training Reports

5 Overdue 0 Due Today 0 Due Later

Tasks

**Generate CV**  
Please generate your CV as your profile was updated for credit for GCP training.

**null**  
Please remember to Submit existing Financial Disclosures will appear on 1572

**null**  
Suzy Sunshine with email address as suzysunshine Hospital and Clinic to their User Profile. You may now add them as a member of the Site Sponsor/AMBR-A Study for the SIP Ambassadors to use for

View All Workspaces

Lilly Pfizer Roche AbbVie Allergan Amgen AstraZeneca BMS Curie Franklin Higgs Livingstone MSD

Improve Clinical Trial  
A1A-MC-AMBR

My Tasks

**Favorites** Recent Studies

A1A-MC-AMBR-Lilly  
A1001001-Pfizer  
BO29999-Roche  
Set Favorites >>

**Links**

Clinical Trials  
TCB Home

TransCelerate BIOPHARMA

sponsor/member/studysitehome?sid=MVZiK0tITGVFMHRkQUt0bFo2aEVVQT09&

# What does it look like?

The screenshot displays the A1A-MC-AMBR study portal. At the top is a red navigation bar with icons and labels for Home, User Profile, Facility, Sponsor, Documents, Survey, Training, and Reports. Below this is a breadcrumb trail: Sponsor > Lilly > A1A-MC-AMBR > Study Home. The main content area is titled 'A1A-MC-AMBR' and features a tabbed interface with 'STUDY HOME' selected. The 'Tasks' section shows 1 overdue task, 0 due today, and 0 due later. The 'Study News' section, marked with '2 New', contains two announcements: 'Database Lock Approaching' (04 Apr 2018) and 'Lab closed for the Holiday' (04 Apr 2018). The 'Study Links' section provides links to eDC, IWRS, and the Safety Mailing System. A 'Site Tasks' box at the bottom left indicates 1 task for 1 October 2019. The TransCelerate Biopharma logo is in the bottom left corner.

Home User Profile Facility Sponsor Documents Survey Training Reports

Sponsor > Lilly > A1A-MC-AMBR > Study Home

## A1A-MC-AMBR

STUDY HOME STUDY SUMMARY STUDY SITE PROFILE STUDY DOCUMENTS STUDY TRAINING STUDY CONTACTS

### Tasks

1 Overdue

0 Due Today

0 Due Later

Site Tasks  
1 October 2019

### Study News 2 New

**04 Apr 2018 Database Lock Approaching**  
Please remember to complete all queries by Wednesday for lock on Friday. Thank you!

**04 Apr 2018 Lab closed for the Holiday**  
The lab will be closed on Monday to the upcoming holiday. Please send all samples to arrive by Saturday. Thank you!

[View All Study News>>](#)

### Study Links

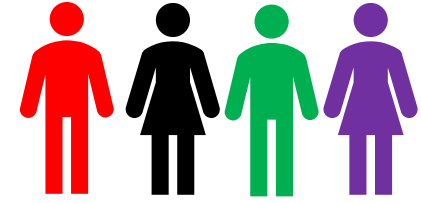
[eDC](#)

[IWRS](#)

[Safety Mailing System](#)

**TransCelerate**  
BIOPHARMA

# Steps for site user



- Register (create Exostar account if not already done)
- Complete user profile or delegate to other user for completion (e.g. PI => SC, administrative support)

Important: delegee needs to be registered to SIP too.

- Link user profile to the Facility
  - ➔ First user profile linked is the FPM, but this can be delegated
- Generate CV
- Submit GCP Training Credit Request



# User profile

**SHARED INVESTIGATOR PLATFORM**

Anna Doe  
Site User  
User ID: doea\_5737

Home User Profile Facility Sponsor Documents Survey Training Reports Admin

User Profile > My Profile

### My Profile

Last Modified Date 10-Apr-2019

Anna Doe  
Rahway, New Jersey  
999-999-9999  
sipfive@aol.com

SIP User Profile Form Ask PI to add me to a Study **Delegate**

USER PROFILE ABBREVIATED CV HISTORY EXPORTED USER PROFILE

Basic Details Facilities Education Professional Experience Research Experience GCP Training License Details

Profile Attachments Publications & Presentations

Preview Abbreviated CV Generate & eSign Abbreviated CV Export User Profile PI Study History

#### Basic Details

##### NAME & CRITICAL CONTACT DETAILS

Title		Edit
First Name	Anna	
Middle Name		
Last Name	Doe	
Suffix		
Initials		
Mobile/Cell Phone	999-999-9999	
Email Address	sipfive@aol.com	


##### JOB TITLE & ROLE




Job Title/Profession	
Role	Investigator

##### PRIMARY BUSINESS ADDRESS

Enter your primary business address. For Investigators, this should be the address you would include on the Form 1572 or equivalent.

# Facility Profile





Anna Doe  
Site User  
User ID: doea\_5737

Home

User Profile

Facility

Sponsor

Documents

Survey

Training

Reports

Admin

Facility > Duke University Medical Center

Duke University Medical Center

✓ Facility Name & Address

✓ Facility Contacts

○ Therapeutic Areas & Patient Population

○ IRB/ERB/Ethics Committee

○ Local Lab

○ Consent & Training

○ Facility & Equipment

○ Investigational Product (IP) & Controlled Substances

○ Source Documentation

Additional Information & Attachments

Organization Affiliations

Facility Contacts

The following Facility Contact roles can be assigned at the Facility level.

1. Facility Profile Managers (FPM)



- FPM have the ability to set-up, edit and maintain the Facility Profile.
- Only one individual can be selected as "Primary" FPM. The Primary FPM receives all of the Facility Profile related messages.
- FPMs can create Departments under their Facility and assign applicable Department Profile Managers (DPM) to manage the Department Profile.

2. Facility Clinical Trial Contact (FCTC)

- FCTC is copied on all Survey and Study Invitation notifications sent to Investigators associated to Facility.

3. Head of Facility (HoF)


- HoF is copied on all Survey and Study Invitation notifications sent to Investigators associated to Facility.
- HoF is added as the study site staff for the study sites associated to this Facility and its Departments and is given read-only access to view those study site profiles.
- You need to add Head of Facility as a FPM / DPM in the Facility and Department(s) profile, if you wish to provide him or her with the access to edit the Facility/Department Profile.
- The Head of Facility Delegate has the same rights as the Head of Facility.

Select	Name	Email Address	Roles	Actions
Primary FPM				
★	Doe, Anna	sipfive@aol.com	Facility Profile Manager	 

Add Facility Contact

< Facility Name & Address


Therapeutic Areas & Patient Population >

 **TransCel**  
BIOPHARMA

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# Create Department (1)



Anna Doe  
Rahway, New Jersey  
999-999-9999  
sipfive@aol.com

SIP User Profile Form

Ask PI to add me to a Study

Delegate

USER PROFILE

ABBREVIATED CV HISTORY

EXPORTED USER PROFILE

Basic Details

Facilities

Education

Professional Experience

Research Experience

GCP Training

License Details

Profile Attachments

Publications & Presentations

Preview Abbreviated CV

Generate & eSign Abbreviated CV

Export User Profile

PI Study History

### Facilities

Add any Facilities and affiliated Departments where you conduct Clinical Research. These Facilities will be listed on your Curriculum Vitae. The CV is limited to 10 combined Facilities/Departments. The Facility you identify as primary will be listed first. Click on 'Actions' to Add Department, Export or Remove the Facility/Department from your user profile

Primary Facility	Facility Name and Address ^	Department Name and Address ^	Actions
☆	<b>Brigham and Women's Faulkner Hospital</b> 1153 Centre Street, Boston, Massachusetts, United States of America, 02130		⚙️
★	<b>Duke University Medical Center</b> 2301 Erwin Road, Durham, North Carolina, United States of America, 27710	<div>Add Department</div> <div>Export Facility Profile</div> <div>Remove Facility</div>	⚙️
☆	<b>Hospital X</b> Rua Padre João Manuel, São paulo, São Paulo, Brazil		⚙️
☆	<b>Instituto de Diabetes y Riesgo Cardiovascular SA de CV</b> Avenida Francisco Villa 1308, Puerto Vallarta, Jalisco, Mexico, 48328		⚙️
☆	<b>Instituto de Informacion de Investigacion en Salud Mental</b> Calle Dr. Enrigue Pena 122, Monterrey, Nuevo León, Mexico, 64710		⚙️
☆	<b>Kasia Hospital</b> 18, wirki i Wigury, Wochy, Warszawa, Warszawa, Mazowieckie, Poland, 02-143		⚙️

Add Facility

Show Rows 10 Page 1 of 1

Basic Details

SAVE

Education

# Create department (2)

SHARED INVESTIGATOR PLATFORM

Anna Doe  
Site User  
User ID: doea\_5737

Home User Profile Facility Sponsor Documents Survey Training Reports Admin

Facility > Duke University Medical Center > Add Department(s)

### Add Department(s)

Select and add one or more Departments to your profile


<input type="checkbox"/>	Department Name ^	Address	City	State/Province/Region	Contact DPM
No Records					




Showing 0 to 0 of 0 entries Show 10 entries

ADD DEPARTMENTS TO YOUR USER PROFILE CREATE NEW DEPARTMENT NO DEPARTMENT CANCEL

For e.g. private practices

# Create Department (3)





Anna Doe ▾  
Site User  
User ID: doea\_5737

HomeUser ProfileFacilitySponsorDocumentsSurveyTrainingReportsAdmin

Facility > Duke University Medical Center > Create New Department

## Create New Department

1 Department Name & Address

Department Name & Address

Enter the Department Name and type. The Facility address is populated for your convenience, and can be updated as needed. Once a Department Profile is created, 'Department Type' cannot be edited, please review the 'Department Type' before you save the Department Profile.

Facility Name	Duke University Medical Center
Facility Type	Select Facility Type ▾
Department Name	Department Name
Department Type	Select Department Type ▾
Street Name and Number	2301 Erwin Road
Building/Floor/Room/Suite	
Additional Address Info	
Country	United States of America
State/Province/Region	North Carolina
City	Durham
Zip/Postal Code	27710

SAVE

CANCEL



# Create Department (4)

SHARED INVESTIGATOR PLATFORM

Anna Doe  
Site User  
User ID: doea\_5737

Home User Profile Facility Sponsor Documents Survey Training Reports Admin

Facility > Duke University Medical Center > Create New Department

## Create New Department

**Department Name & Address**

Enter the Department Name and type. The Facility address is populated for your convenience, and can be updated as needed. Once a Department Profile is created, 'Department Type' cannot be edited, please review the 'Department Type' before you save the Department Profile.

Facility Name: Duke University Medical Center

City: Durham

Zip/Postal Code: 27710

**New Department Created/ Identify Contact**


You have successfully created the Cardiology in Duke University Medical Center.




One or more Department Contacts need to be assigned to create and maintain the Department Profile. Who would you like to assign as Department Profile Manager?

**I WILL CREATE/MAINTAIN THE DEPARTMENT PROFILE** **I WILL ASSIGN SOMEONE ELSE**

**SAVE** **CANCEL**

# Department Profile





Anna Doe ▾  
Site User  
User ID: doea\_5737

Home

User Profile ▾

Facility ▾

Sponsor ▾

Documents ▾

Survey ▾

Training ▾

Reports

Admin ▾

Facility > Duke University Medical Center > Cardiology

Cardiology

☒ Department Name & Address

☒ Department Contacts

☐ Therapeutic Areas & Patient Population

☐ IRB/ERB/Ethics Committee

☐ Local Lab

☐ Consent & Training

☐ Department & Equipment

☐ Investigational Product (IP) & Controlled Substances

☐ Source Documentation

Additional Information & Attachments

Organization Affiliations

Department Contacts



The following Department Contact roles can be assigned at the Department level.

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- DPM has the ability to set-up, edit and maintain the Department Profile.
- One individual can be selected as "Primary" DPM. The Primary DPM receives all of the Department Profile related messages.

2. Department Clinical Trial Contact (DCTC)

- DCTC is copied on all Survey and Study Invitation notifications sent to Investigators associated to Department.

Select	Name	Email Address	Roles	Actions
Primary DPM				
<input checked="" type="checkbox"/>	Doe, Anna	sipfive@aol.com	Department Profile Manager	 

Add Department Contact

< Department Name & Address

Therapeutic Areas & Patient Population >

# SIP Foundational Training and Resources

## Email introduction to Sites

[To: Investigator and Site Staff  
Subject: Register for the Shared Investigator Platform  
Attach: SITES: Introducing SIP

Dear Investigator and Site Staff,

We're delighted to announce that **(insert Member Company)** is using the Shared Investigator Platform (SIP). If you haven't heard of it, SIP, a TransCelerate initiative, is a common platform that will allow you to enter critical information like training, research and professional experiences, and site capabilities only one time for all studies sponsored by participating SIP companies. As more studies begin using SIP, your administrative burden and the number of log-ins you're required to use will decrease -- allowing you more time for working with patients. Once your profile is in SIP, you'll also be able to generate your CV and be visible to all member companies for future study opportunities.

Please see the attached PDF to learn more about SIP, understand the registration process for your site, and find out where you can get support.

Short 2-3 minute videos are also available for introducing SIP to sites:

About TransCelerate  
Site Capabilities Made Simple with SIP  
SIP Fast Facts

Study Management Made Simple with SIP Video new!

Shared Investigator Platform: From Concept to Reality  
Video new!

## Sites Guide to Getting Started in SIP

**Getting started with SIP: Easy as 1-2-3!**

**Key Benefits for Sites**

- Built for Sites, with Sites
- SIP is a cross-industry solution designed by TransCelerate Members to make Sites' lives easier.
- SIP is complimentary to Sites.
- Study Management Made Simple
- Where Sponsors Meet New Sites
- User and Facility Profiles saved in SIP share your research experience and site capabilities with participating Sponsors
- The antidote for redundancy
- Data and documents you maintain in SIP can automatically be reused and leveraged from study to study, Sponsor to Sponsor

**The Steps to Getting Started**

- STEP 1** Register for SIP
- STEP 2** Activate Your Account
- STEP 3** Review SIP Orientation
- Ready, Go!** Complete User Profile

**STEP 1 REGISTER FOR SIP**

- Participating Sponsors will initiate SIP invitations.
- Add [do-not-reply@sharedinvestigator.com](mailto:do-not-reply@sharedinvestigator.com) as a trusted email sender so you don't miss your SIP invitation.
- Click the registration link within invitation email and follow prompts to enter User Information

**STEP 2 ACTIVATE YOUR ACCOUNT**

- Within minutes of registration, you will receive a second email to activate account.
- Click the activation link and follow prompts to create password, set up security questions.
- In the First Logon popup message, click link to navigate now to SIP for Step 3

**STEP 3 SIP 2-PAGE ORIENTATION**

- Click the link to view the 2-page Site User Orientation Guide (1-2 minutes)
- Click Read and Acknowledged button to proceed to your personal SIP dashboard.
- Congratulations, you are ready to use SIP!
- Go to [www.sharedinvestigator.com](http://www.sharedinvestigator.com) at any time to access the platform.

**Ready, Go! TIPS FOR INVESTIGATORS after Steps 1-2-3:**

- Don't delay completion of your User Profile. You can assign a Delegate to complete this task.
- If sent a survey: Complete or delegate your survey.
- If invited to a study: Accept the Study Participation Invitation in SIP & complete or delegate your study site profile.

**Help Sponsors to get to know you...**

- Complete Your User Profile (all users)**  
Enter data directly in SIP, OR  
Click Delegate and enter an email address to allow someone else to complete your profile on your behalf, OR  
Associate to a SIP Facility or Department. If not found, create a new one. Facility/ Dept. Profiles are created once for multiple SIP users. Avoid creating duplicates!
- Complete your Facility Profile (FPM)**  
Facility Profile Manager "FPM" is a SIP role typically assigned to a site/center manager during facility creation.  
Enter data directly in SIP, OR  
Import the Facility Form completed offline ([www.transceleratebiopharmainc.com/wp-content/uploads/2018/03/Facility-Profile-Form.pdf](http://www.transceleratebiopharmainc.com/wp-content/uploads/2018/03/Facility-Profile-Form.pdf)). If the Facility you associated with already has a Facility Profile Manager, your work is done!
- Generate your CV (PI & Sub-Investigators)**  
Click Generate CV button in your completed User Profile to generate a 2-page TransCelerate abbreviated CV.  
New CVs are automatically shared with SIP Sponsors.
- Invite others from your Facility to join SIP**  
Invite others from your Facility using the Bulk Invitation feature, OR  
Contact Sponsor to request SIP invitations.
- View SIP Videos** OR find out more about the TransCelerate SIP Initiative ([www.transceleratebiopharmainc.com](http://www.transceleratebiopharmainc.com))

**TECHNICAL SUPPORT** [SIPhelp@cognizant.com](mailto:SIPhelp@cognizant.com) **Worldwide Numbers**

## Cognizant SIP Job Aids

**SHARED INVESTIGATOR PLATFORM (SIP) R 2.1-Site User Job Aid**  
Manage User Profile  
Version 1.1.0.10 [20 Jan, 2018]

**1 What is a User Profile and how is it used?**

Your User Profile documents your affiliations, qualifications, research experiences, and GCP training and can be used to generate your CV. Completing your User profile makes your information searchable for all Sponsors running clinical trials in SIP. After registering in SIP, you must first complete your User Profile and generate your Abbreviated Curriculum Vitae (CV).

**2 How can I update my User Profile?**

There are three options for updating your User Profile:

- Update User Profile Online:** Enter the information directly in SIP on the My Profile page. To navigate from any section of the User Profile to the next section, click Section Name >. Alternatively, on the User Profile navigation pane on the left, click the relevant section name. For more information, refer to, User Profile Navigation Pane.
- Delegate:** Assign your User Profile to another Site User (known as the Delegate), who completes it on your behalf. You are required to review and approve the updates made by the Delegate.
- Upload SIP User Profile Form:** If you prefer to complete a form offline and then upload data into SIP, you can utilize the SIP User Profile Form. But there are limitations such as the form does not allow the user to add multiple records for certain sections and no attachments are possible via form.

**Prerequisite: Register in SIP and Log on**

**Update/Complete Your User Profile and Add Facility/Department**

- Option 1 -Complete Online- Update User Profile online yourself**
- Option 2 -Upload & Finalize- Complete SIP User Profile form offline and then finalize it online yourself**
- Option 3 -Delegate- Select a Delegate to update/complete your User Profile for your review and approval**

**Generate Your CV**

For a detailed description on each activity explained in this Job Aid, refer to the [SIP Site User Online Help](#)  
SIP Help Desk Email: [SIPhelp@cognizant.com](mailto:SIPhelp@cognizant.com) | Telephone: See [Help Desk](#)  
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# Conclusion

- Developed in collaboration with sites, industry, organizations (networks, SMO's...) and CRO's
- Standard approach across the companies using the platform
- Will reduce the administrative burden through
  - re-use of information (enter it once – maintain it – it's your data)
  - single sign-on (reduction of n° of different portals/passwords)
  - streamlined document delivery (all documents in one place)
  - Streamlined training delivery (study and non-study specific training)
  - Streamlined feasibility process
- Give sites back time to spend on what matters most : patient care

# Questions?



**Welcome to TransCelerate BioPharma Inc.**

TransCelerate BioPharma Inc. is a non-profit organization with a mission to collaborate across the biopharmaceutical research and development community to identify, prioritize, design and facilitate the implementation of solutions to drive efficient, a flexible and high-quality delivery of new medicines, improving the health of people around the world.

**News**

- TransCelerate Wins Supply Chain Innovation Award at CSCMP's EDGE Conference
- TransCelerate BioPharma Grows Industry Collaboration
- TransCelerate BioPharma and FDA/NIH Collaborate on Aligned Common Protocol Template

**Important Updates**

- Check out new videos, research papers and infographics on solutions that aim to better inform patients by facilitating informed consent with information about clinical research and specific clinical trial opportunities.
- The eConsent Initiative has developed practical guidance and book describing potential implementation considerations and eConsent components. Check out our eConsent initiative Asset page for more info.
- The Common Protocol Template Initiative launched its two essential protocol templates in alignment with the FDA and NIH. Check out our CPT Initiative Asset page for helpful materials and our brief overview video.

**Upcoming Events**

- DSAPV and Risk Management Strategies Conference (Washington) Jan 22, 2018
- Gene Therapy 101: Patients as Partners EU Jan 23, 2018
- Reform the Common Data Model: SCOPE Summit Feb 13, 2018
- Hydrex Clinical Trials

**Accelerate to Innovate**

The next edition of Accelerate to Innovate is now available. Our newsletter provides an inside look into the progress of our initiatives, viewpoints of our leadership and much more!

**RBM Interactive Guide**

A digital collection of the Risk-based Monitoring (RBM) initiative's workshops, tools & resources, accomplishments, learnings, and vision for the future.

**Our Initiatives**

**Knowledge Vault**

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November 2017

**Accelerate to Innovate**

The next edition of Accelerate to Innovate is now available. Our newsletter provides an inside look into the progress of our Initiatives, viewpoints of our leadership and much more!

Thank You!

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[www.TransCelerateBioPharmaInc.com](http://www.TransCelerateBioPharmaInc.com)

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