Shared Investigator Platform

DCRF Jaarcongres 2019

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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

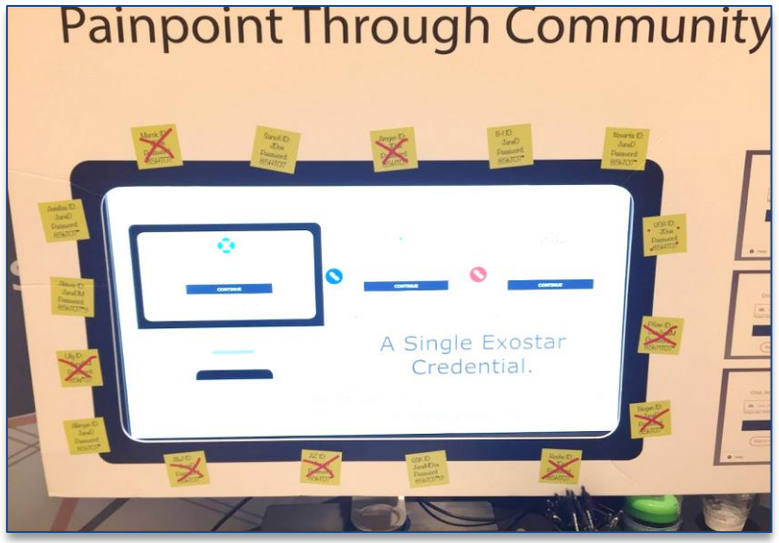

Photo courtesy of Exostar

- 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?

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.

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.

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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	**Single point of access** 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, **information is reused** across platform; **allow more time for trial execution & patient care**
Multiple competing priorities	Consolidated view of study tasks & surveys by due date; **prioritize and manage workload across studies**
Redundant training	**Centralized history** of GCP training; training **recognized by multiple Sponsors**
Provide the same information and documents repeatedly	Generate an e-Signed CV; upload common documents; **profile data accessible by all SIP Sponsors**; can be exported to use outside of SIP
Visibility for potential trial opportunities	Sponsors search **Facility & User Profile data for trial opportunities**
Regulatory documents are hard to track and send securely	Document exchange allows for **easy access, secure exchange & tracking** of regulatory documents
Sponsors do not consider Site input when developing new systems	TransCelerate **consulted with a Global Site Advocacy Group** to develop functionality
Every Sponsor "does it differently"	**Harmonization of delivery of content**; 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?

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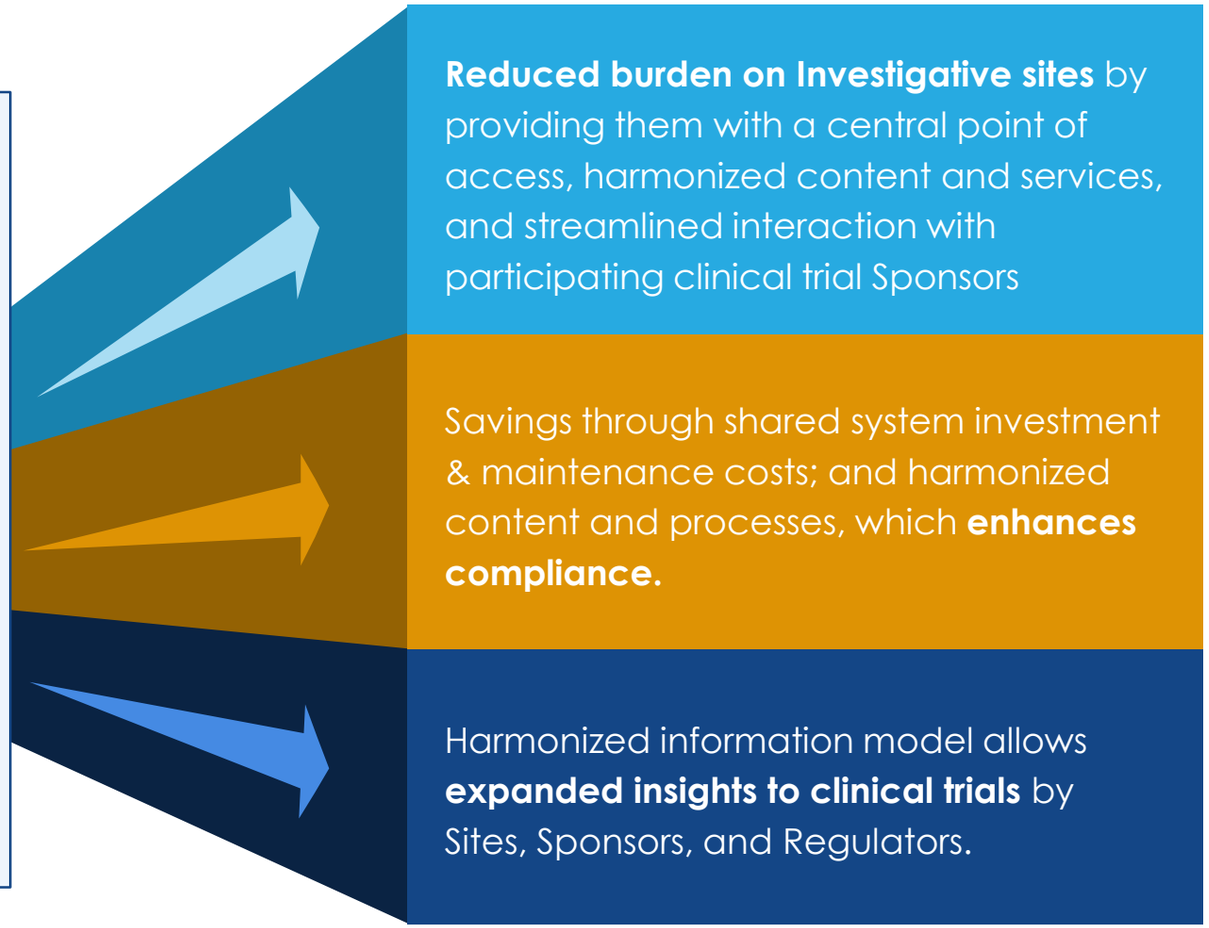
SIP Value Proposition

ISSUES

- **Different platforms and processes** across sponsors complicates day-to-day activities and for Investigators, increasing Site burden and risk of errors
- **Significant inefficiencies** for 1) Sponsors to develop and maintain individual portals and, 2) Investigators to train and keep current on and using different portals across numerous sponsors

SIP IMPACT



Reduced 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

Savings through shared system investment & maintenance costs; and harmonized content and processes, which **enhances compliance.**

Harmonized information model allows **expanded insights to clinical trials** by Sites, Sponsors, and Regulators.

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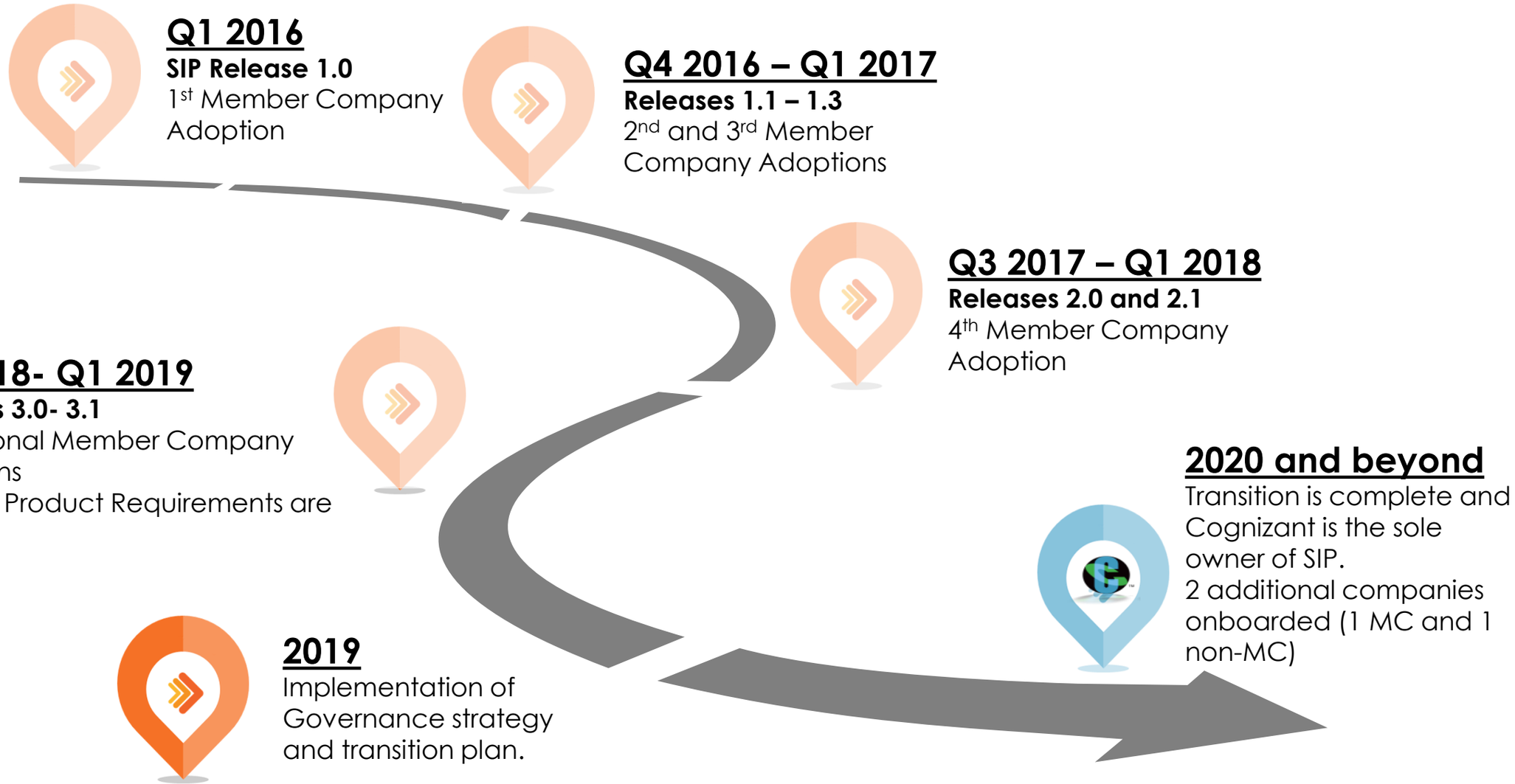
SIP Concept to Reality

SIP Journey



Q1 2016
SIP Release 1.0
1st Member Company Adoption

Q4 2016 – Q1 2017
Releases 1.1 – 1.3
2nd and 3rd Member Company Adoptions

Q3 2017 – Q1 2018
Releases 2.0 and 2.1
4th Member Company Adoption

Q3 2018- Q1 2019
Releases 3.0- 3.1
2 Additional Member Company Adoptions
SIP Core Product Requirements are fulfilled.

2020 and beyond
Transition is complete and Cognizant is the sole owner of SIP.
2 additional companies onboarded (1 MC and 1 non-MC)

2019
Implementation of Governance strategy and transition plan.

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What is the Shared Investigator Platform?

Cognizant

SIP Product Owner/ Systems Integrator

LIFERAY.

Platform software

EXOSTAR

Identity/credential Provider

Innovative, cloud-based solution which aims to **revolutionize the Site-Sponsor relationship**

ca

Vendor supporting Security

DrugDev do more trials

Investigator Registry Vendor

sumtotal

Vendor providing Study Training functionality

SHARED INVESTIGATOR PLATFORM

Single sign-on (SSO) for seamless investigator experience

* SafeDx

Document Management /Safety Vendor

* goBalto™

Study Activation Vendor

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

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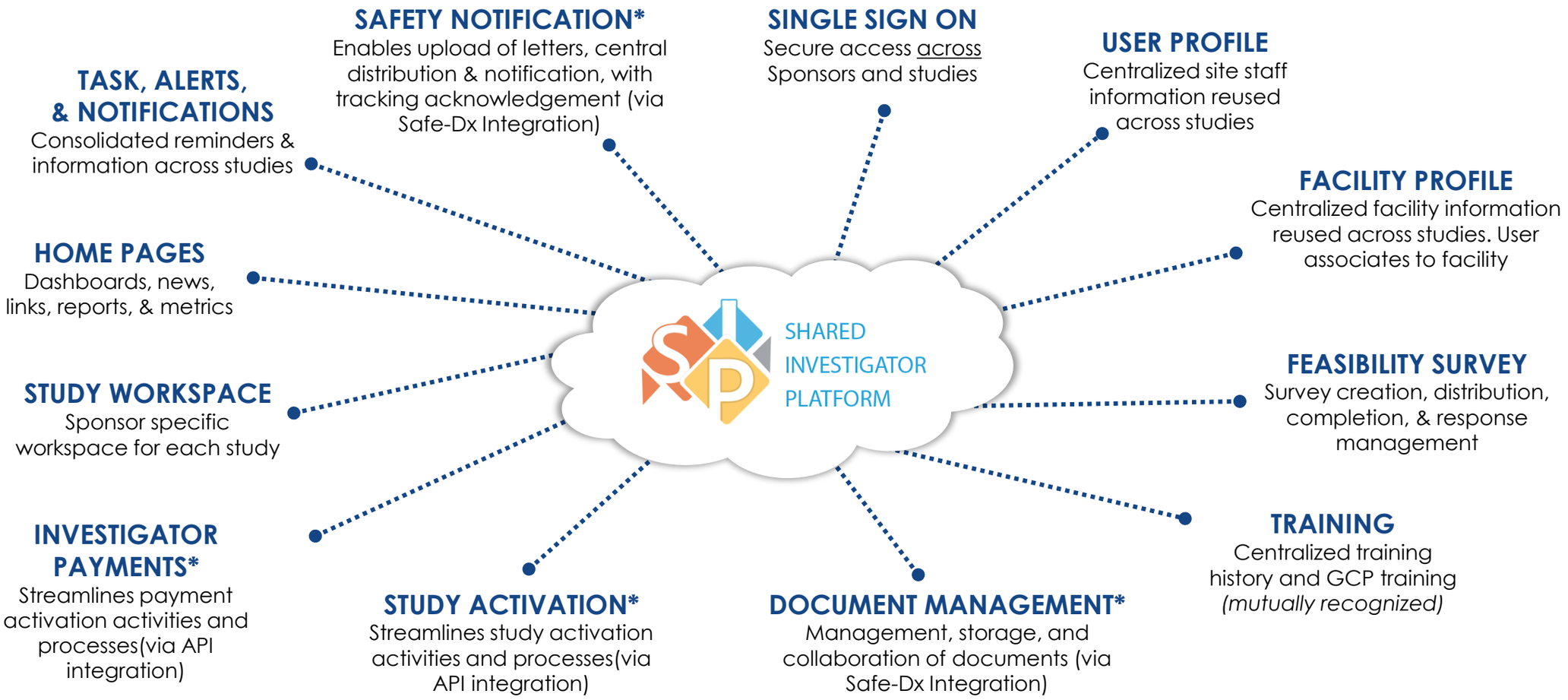
SIP Functionality



BULK INVITES
Ability to invite multiple personnel simultaneously to enhance onboarding

SMO/ ARO/ Site Network
Centralized workflows to align with SMOs', AROs', and Site Networks' operating models

ONGOING STUDIES
Enable migration of ongoing studies and relevant information

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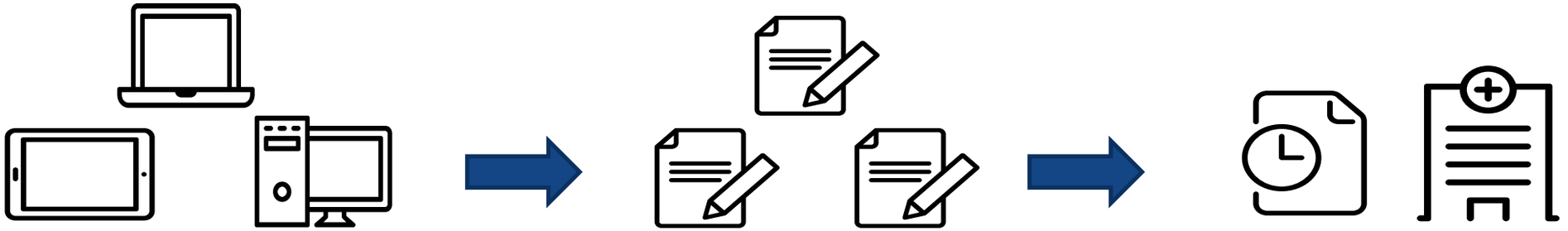
*Non-core modules provided via optional, open, public API

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

Process without SIP

Several hours to provide redundant profile information for each study



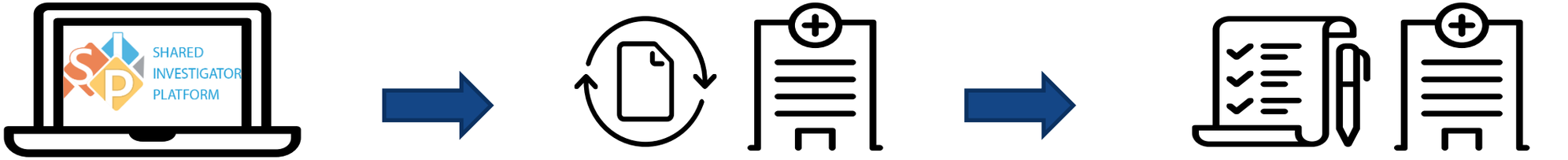
Log onto multiple portals with varying processes for different Sponsors

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

Process with SIP

~1-2 hours to complete the Profile across studies



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

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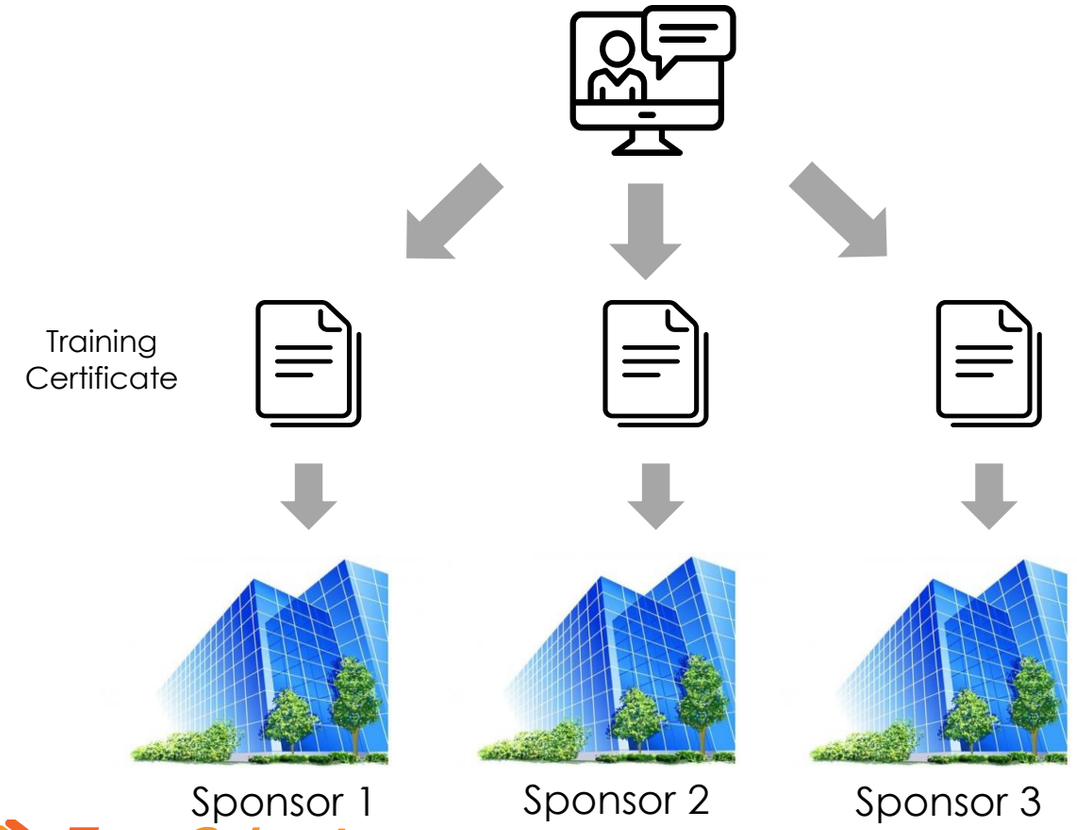
Key Benefit- Mutual Recognition Training (MRT) Program

Process without SIP

Investigator must complete GCP Training for each Sponsor



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

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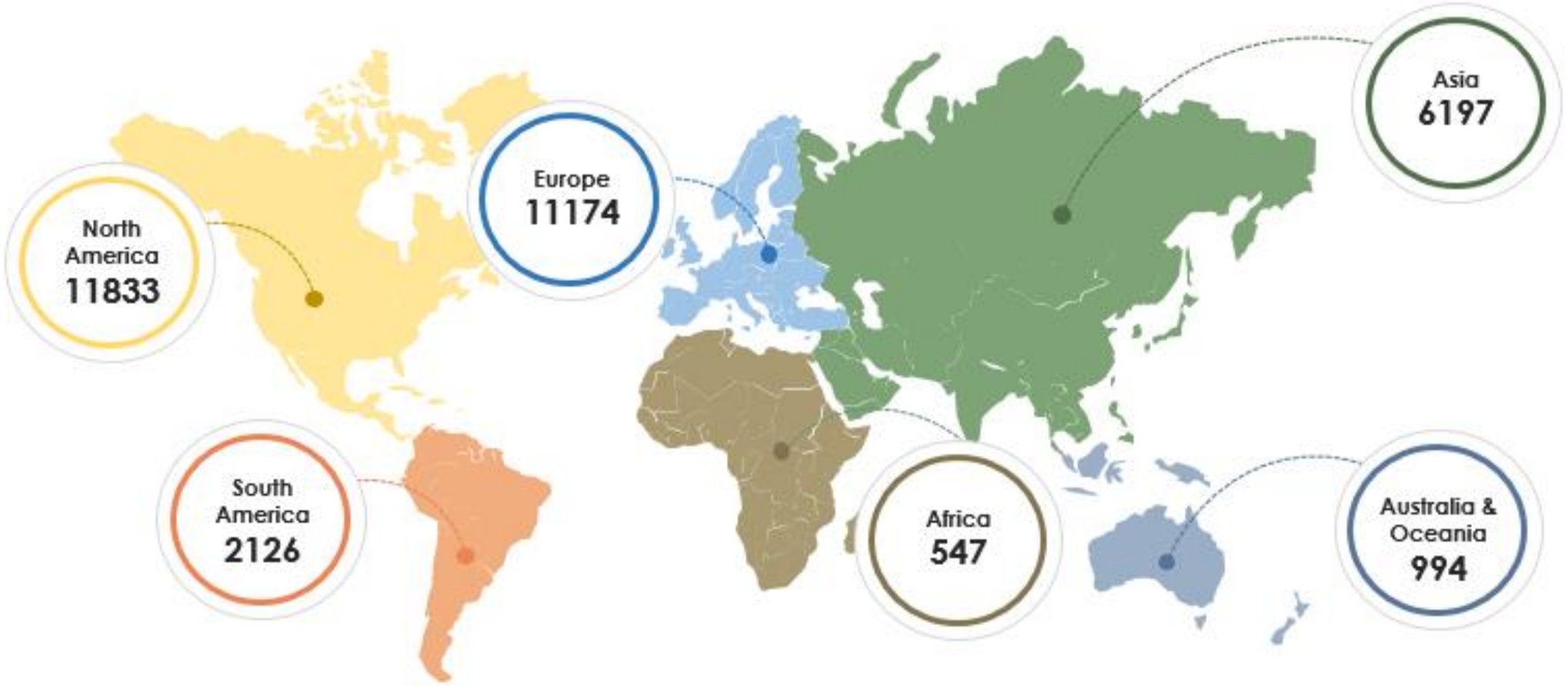
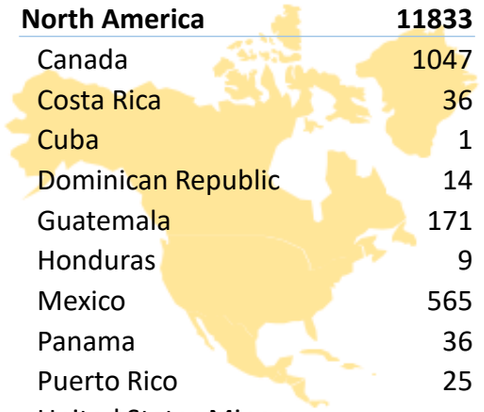
User Registration - Site Users Worldwide Distribution



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

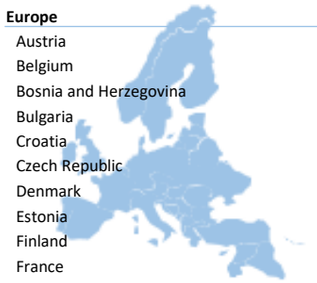
User Registration - Site Users per Country



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

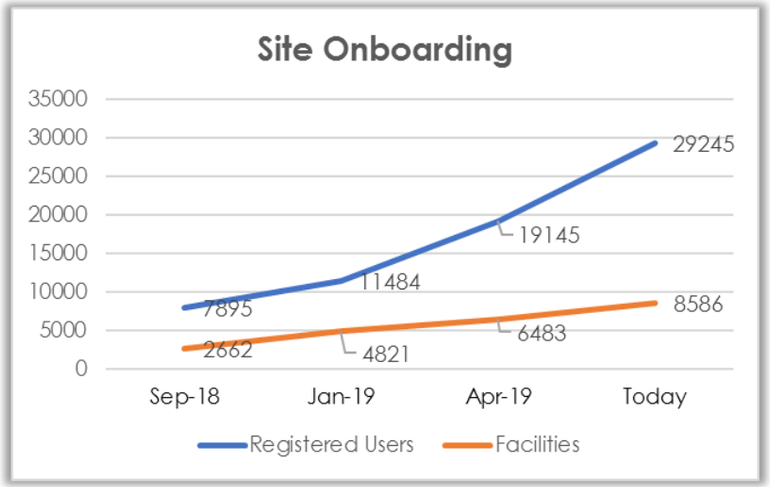
Asia	6197
Afghanistan	1
China	2151
Georgia	35
Hong Kong	41
India	173
Israel	771
Japan	886
Jordan	2
Sri Lanka	2
Taiwan	403
Thailand	159
Turkey	736
United Arab Emirates	5
Viet Nam	14

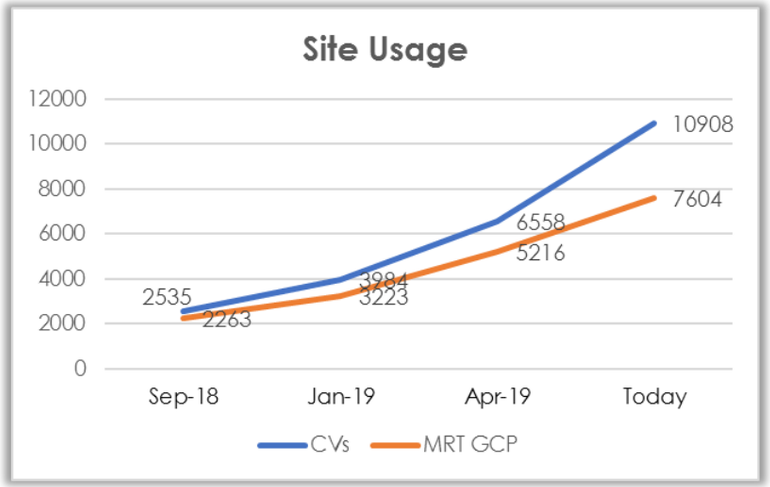
Oceania	994
American Samoa	1
Australia	788
New Zealand	205

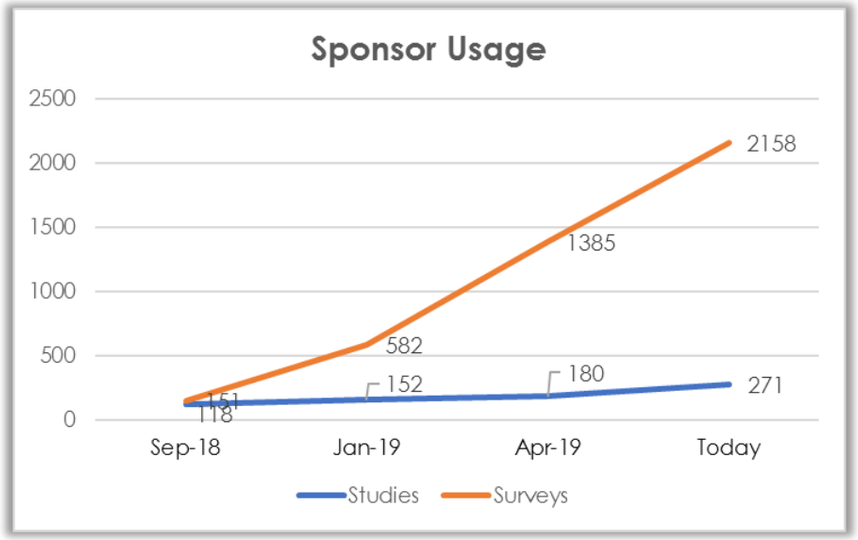
Macedonia (the former Yugoslav Republic of)	2
Moldova (the Republic of)	3
Netherlands	250
Norway	58

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







as of 5 August 2019

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What's In It For Me?
Site & Site Personnel

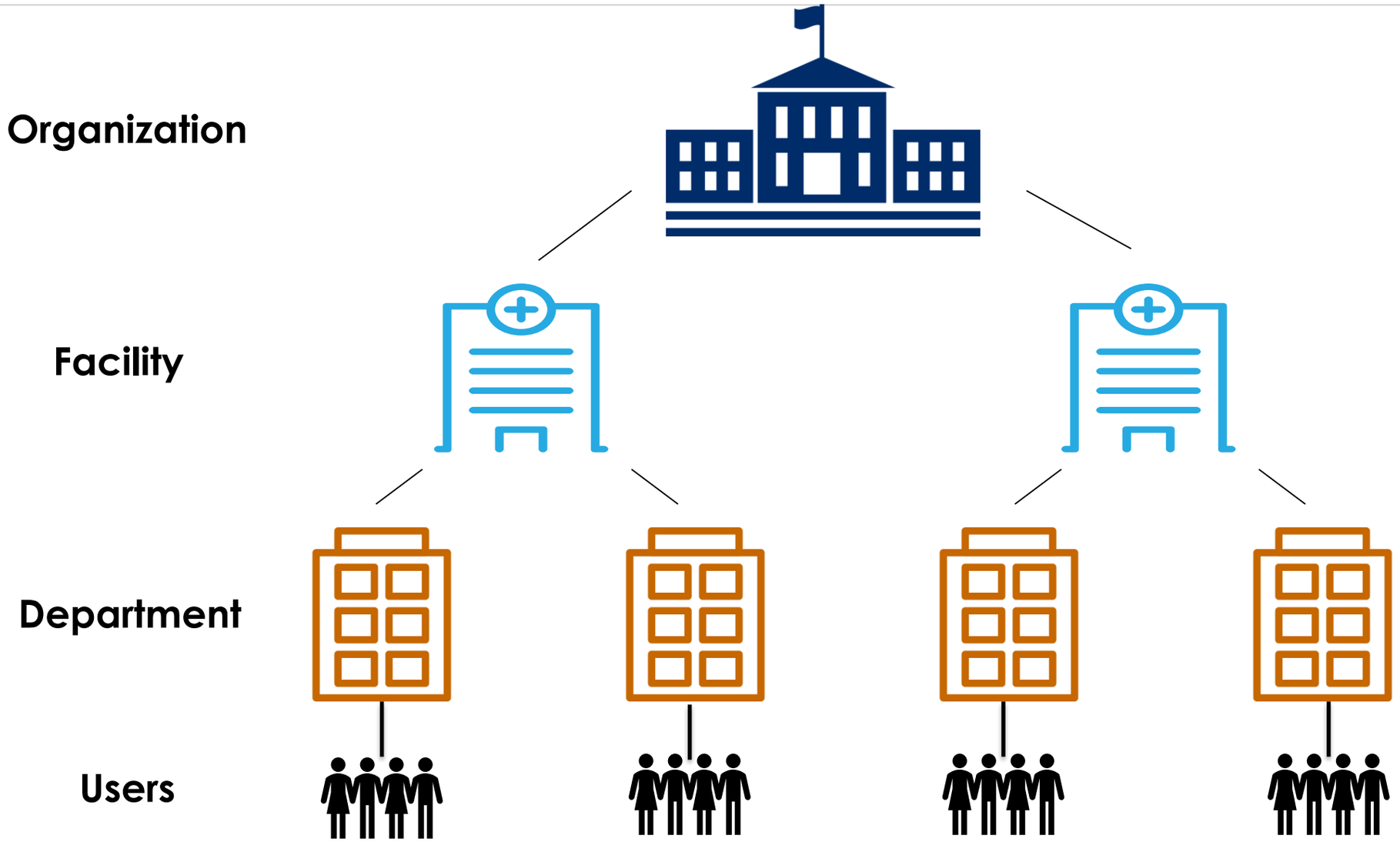
Single Sign On	➢ Single Sign On cross multiple Industry Systems and reduced account management activities
Site Data Owned by Site	➢ Site own user and facility profiles - SQ&T's CV and SPF. ➢ Enter data once and maintain it.
One for all	➢ Reduce answers to repeated questions by multiple studies/sponsors. ➢ Streamlined GCP waiver process for Mutually Recognized Training ➢ Integration with Trifecta's Investigator Space Learning Management System ➢ Common experience across SIP-participating sponsors
Consolidated Overview	➢ Increased visibility into start up activities including training and document status ➢ Consolidated task list across studies and sponsors ➢ Insight into all outstanding feasibility surveys ➢ One stop-shop for study links
Documentation	➢ Secure document exchange and reduce paper work ➢ Access to a temporary document warehouse for study documents

Reduce administrative work

&

focus on what matters most

Organization, Facility, and Department Relationship



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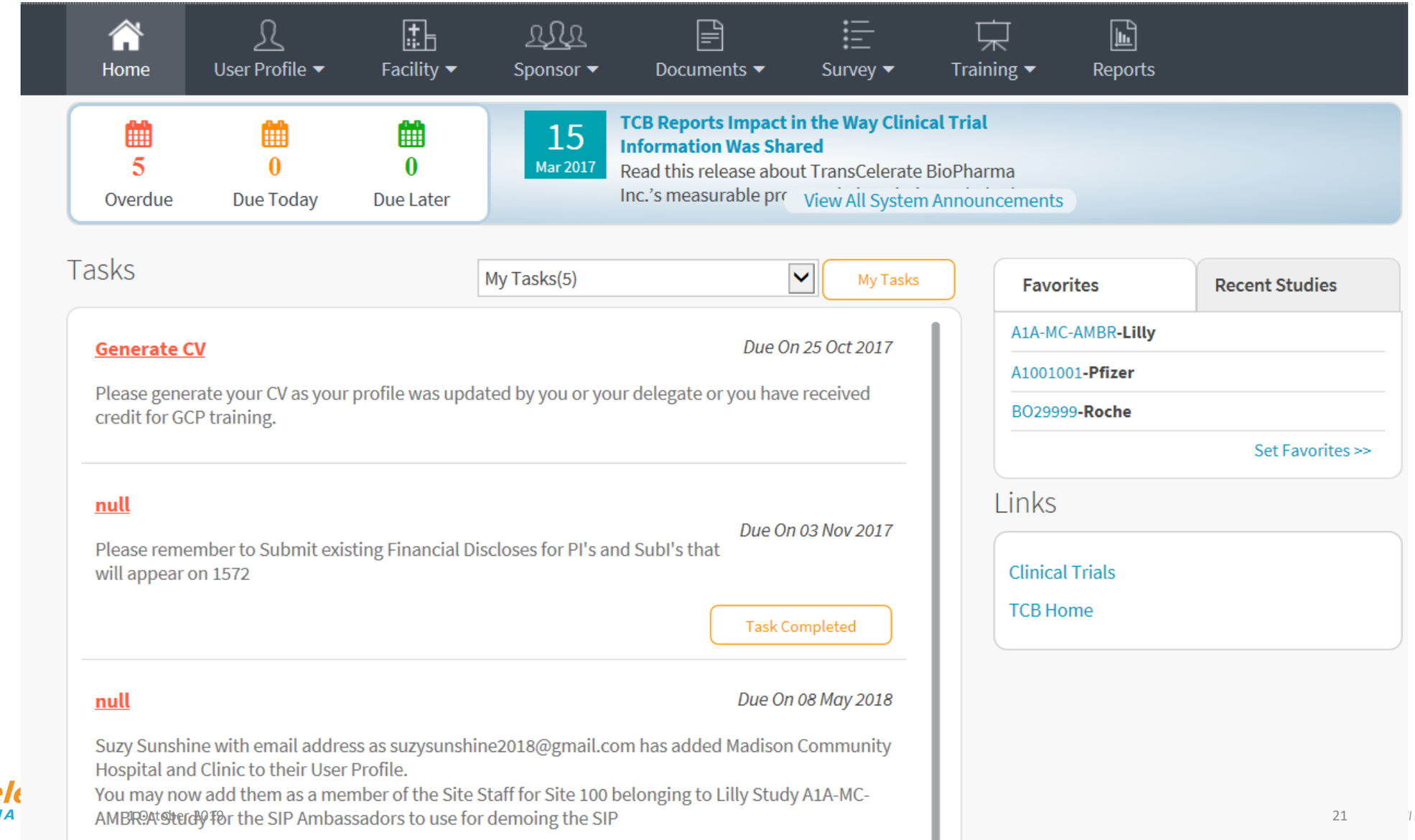
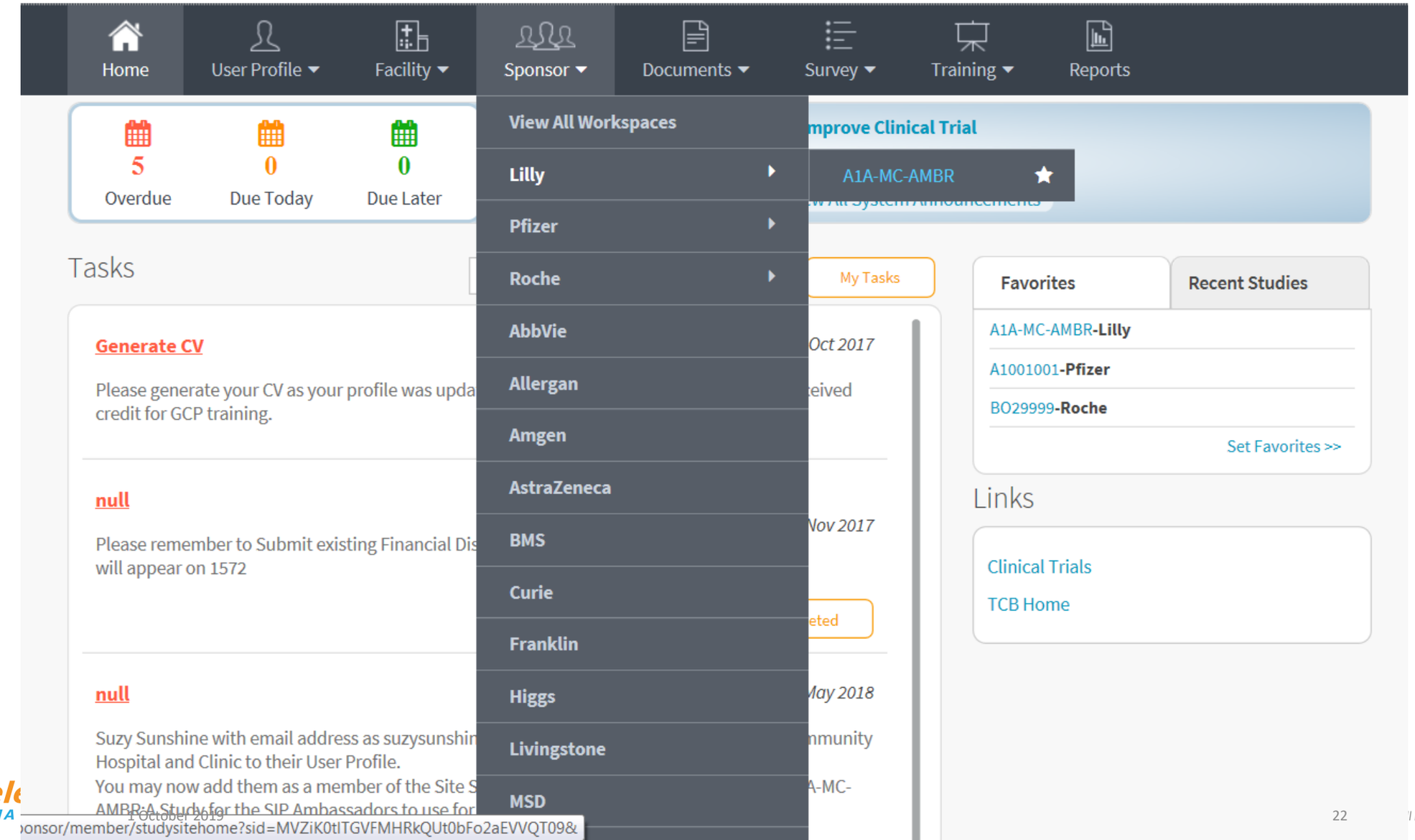
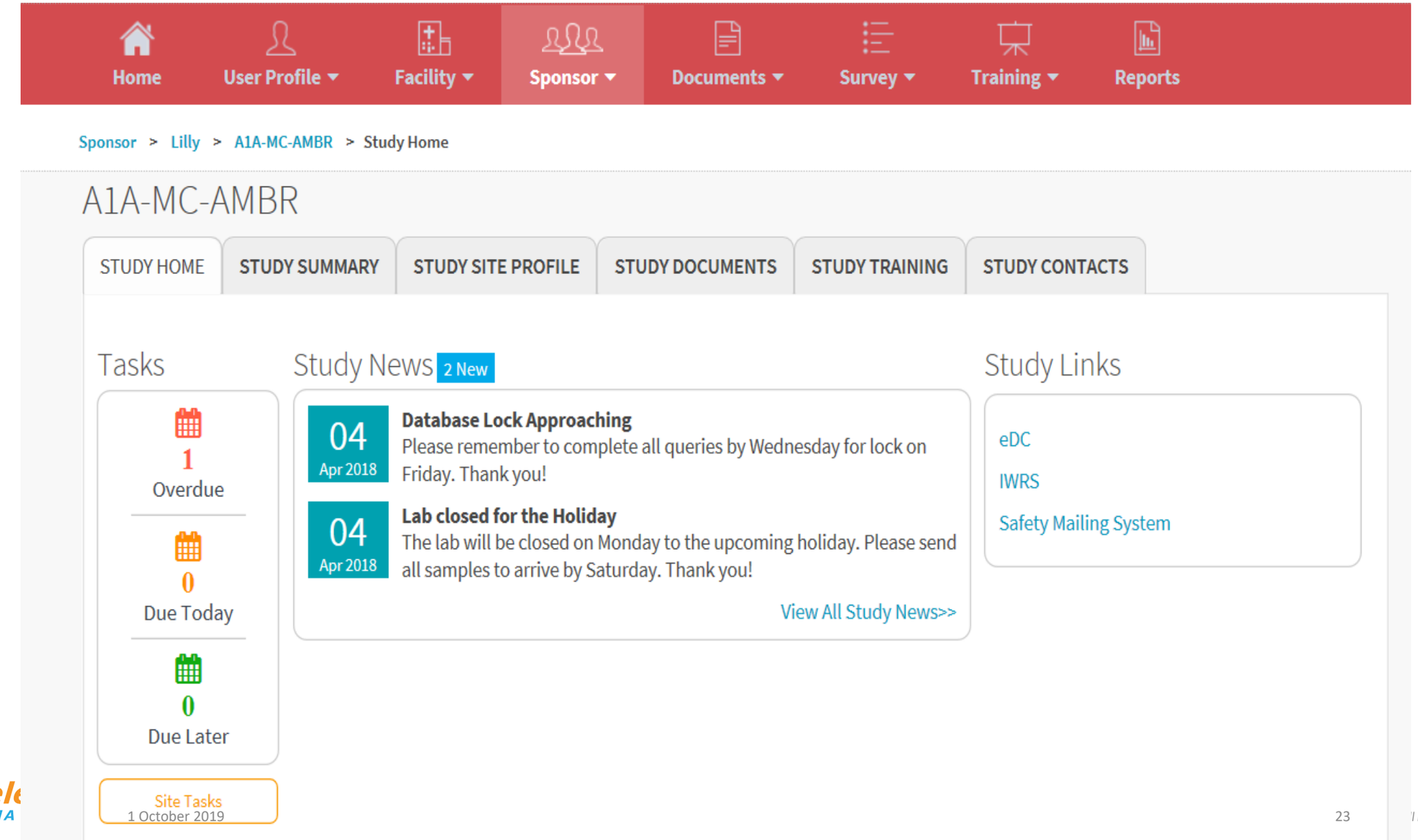
What does it look like?



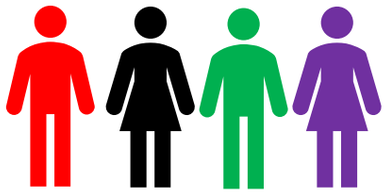
What does it look like?



What does it look like?



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

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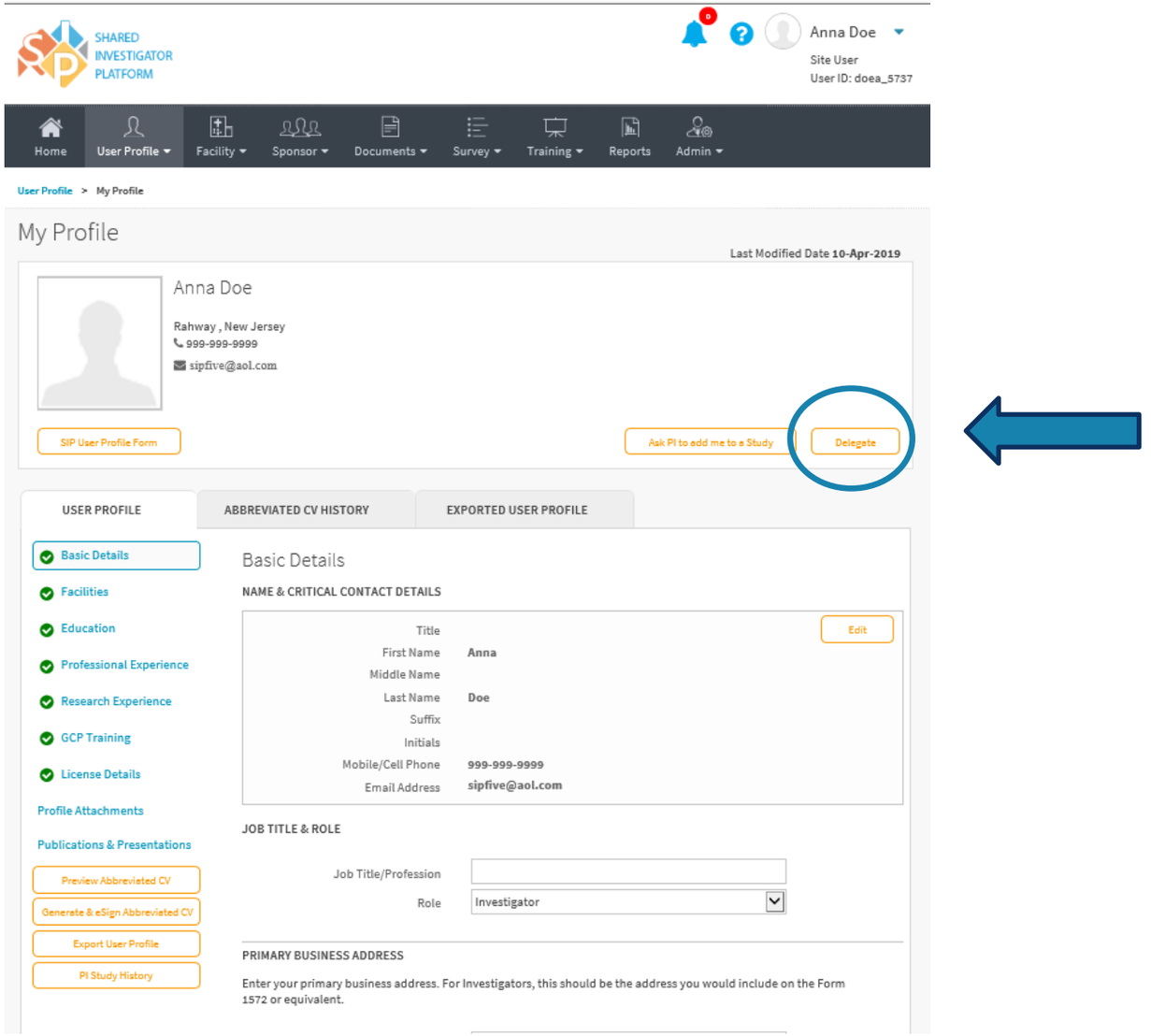
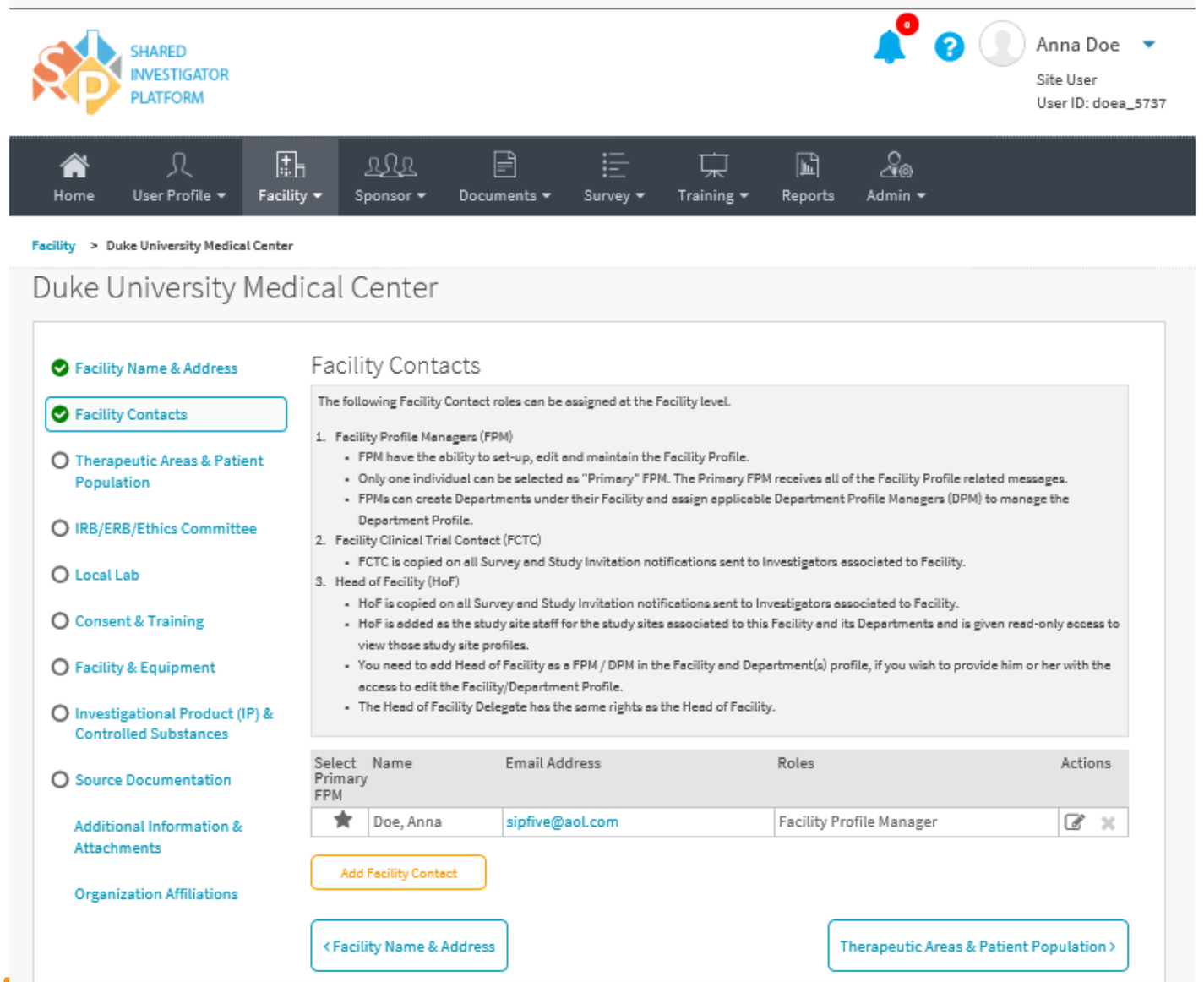
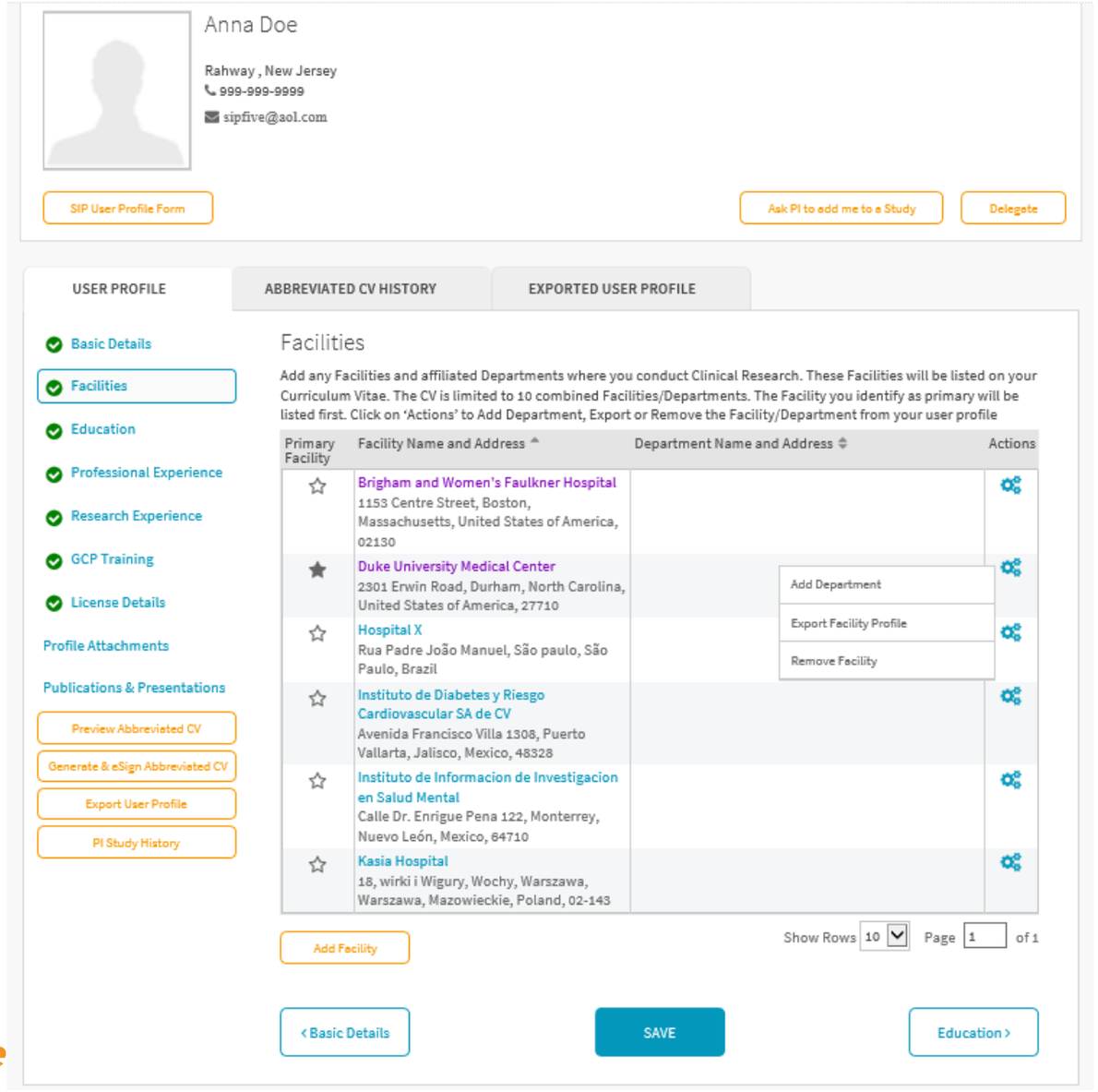
User profile



Facility Profile



Create Department (1)



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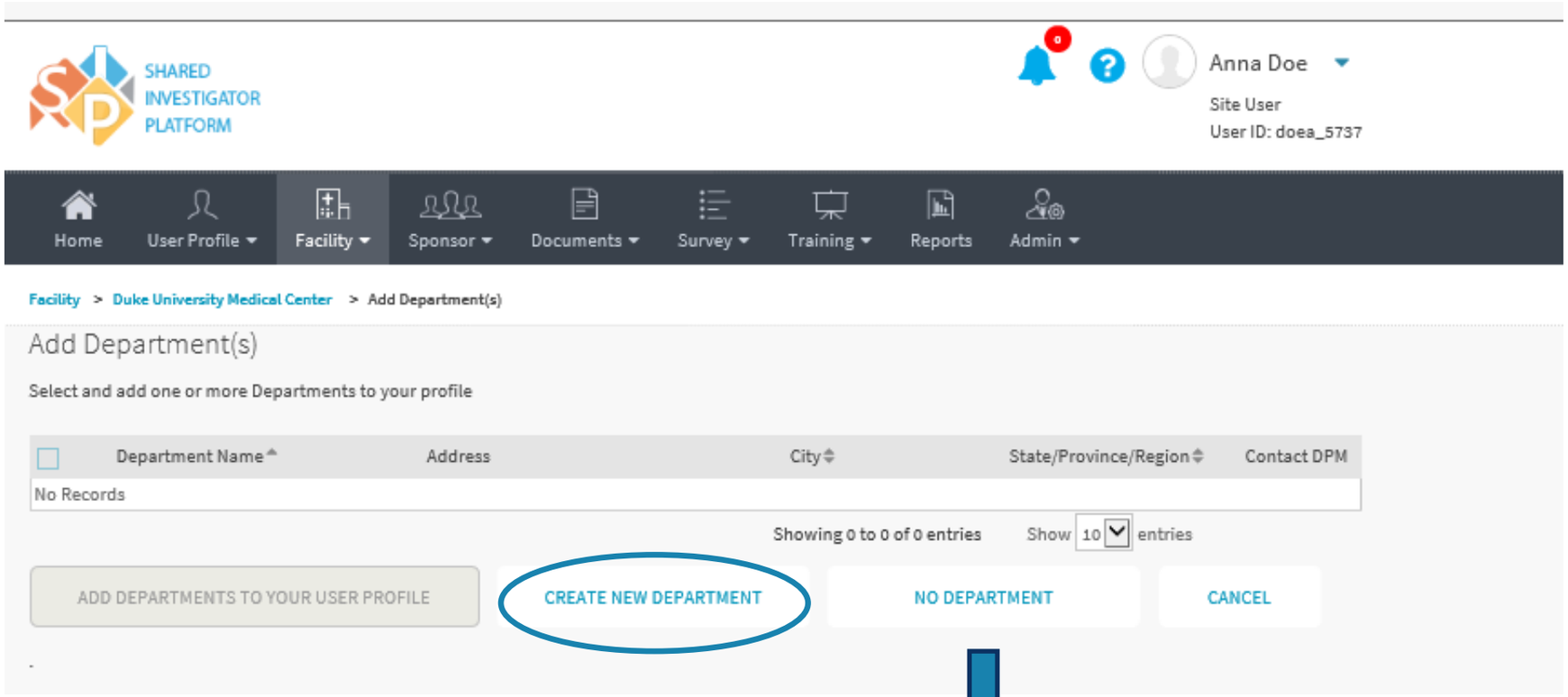
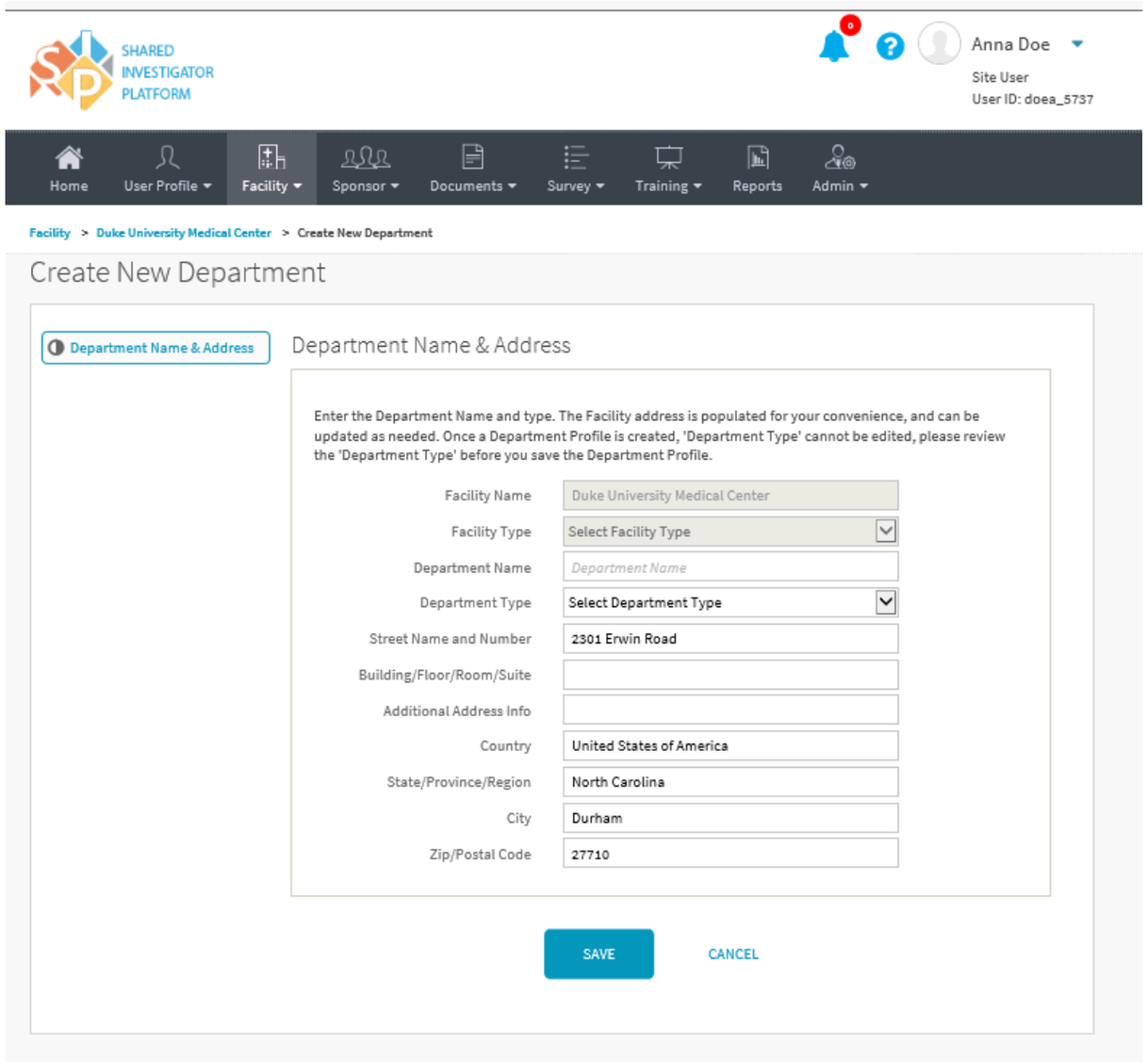
Create department (2)



For e.g. private practices

Create Department (3)



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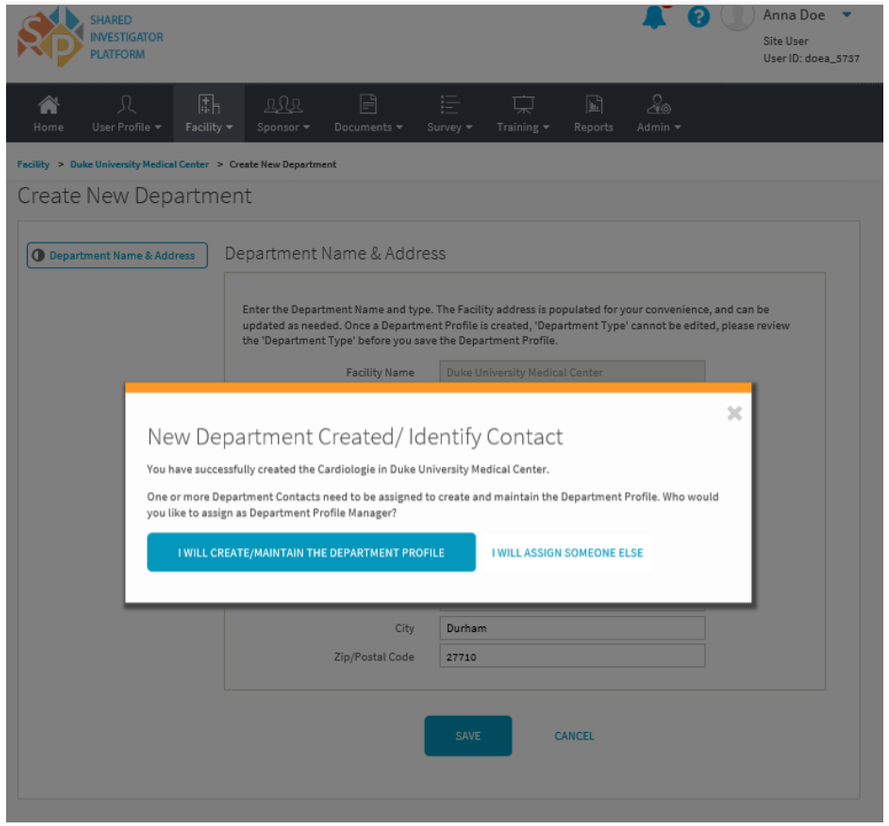
Create Department (4)



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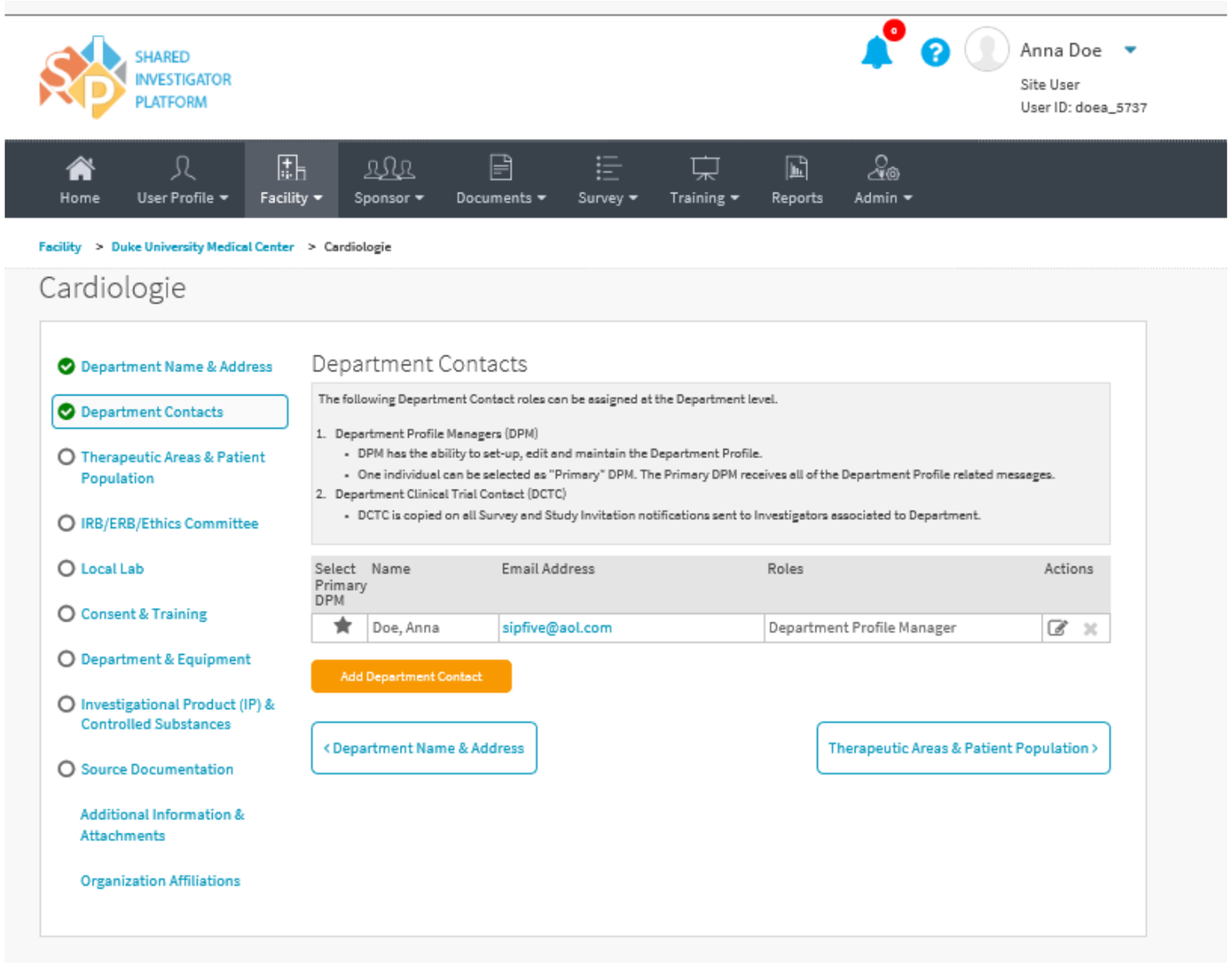
Department Profile



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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 capabiltiies 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 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.

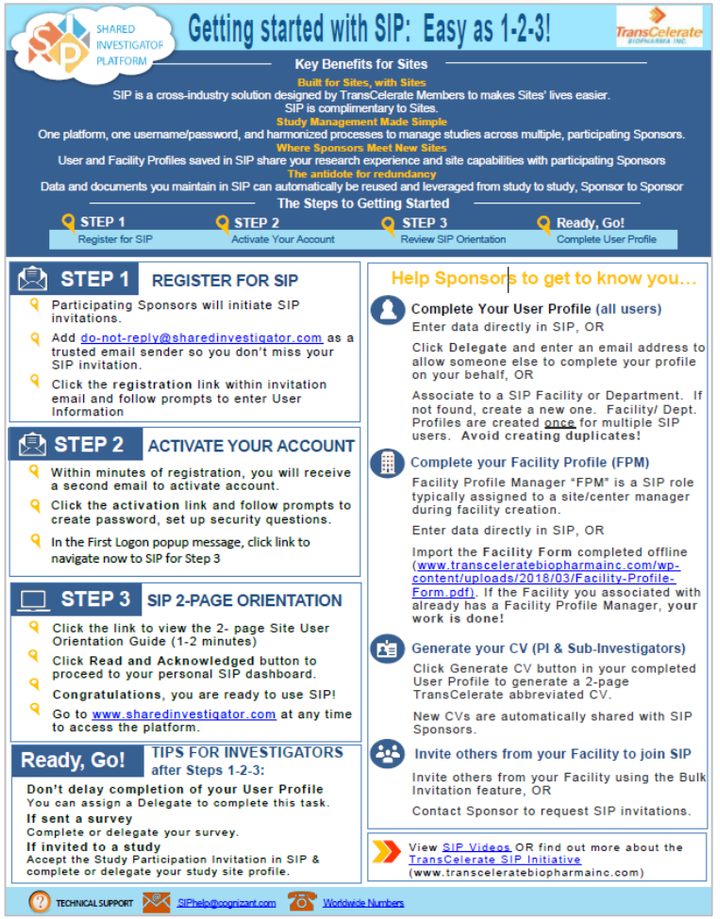
Short 2-3 minute videos are also available for introducing SIP to sites:

About TransCelerate
Site Capabilities Made Simple with SIP
SIP Fast Facts

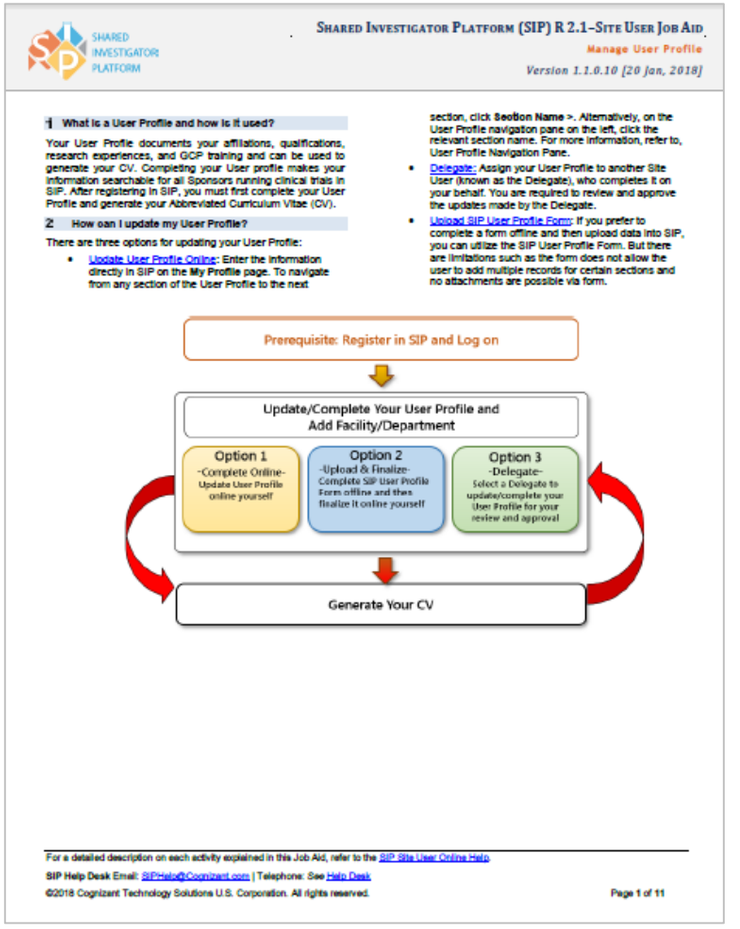
Study Management Made Simple with SIP Video new!

Shared Investigator Platform: From Concept to Reality Video new!

Sites Guide to Getting Started in SIP



Cognizant SIP Job Aids



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

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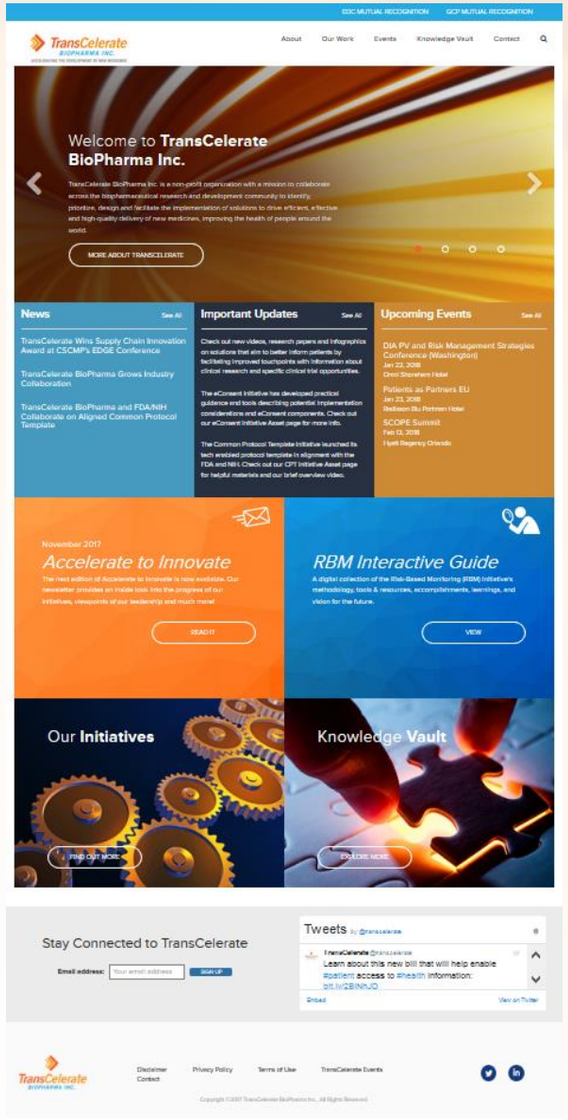
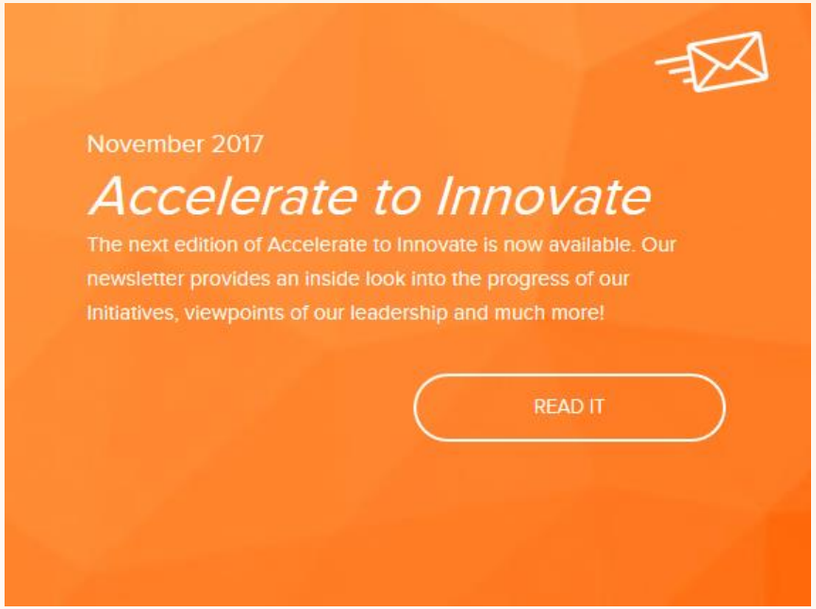
Questions?





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