



Cognizant
Shared Investigator Platform

SIP Webinar - AACI

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Cognizant, Customer Engagement Team
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SIP is now the industry's preferred Site Collaboration Platform

SITE ADOPTION

2020 YTD

- 73,000+ Clinical research Site users across
- 84 countries
- 18,000+ Clinical research locations
- 800+ studies

SPONSOR ADOPTION

- **LIVE** across 7 of the **Top 10 Bio-pharmaceutical** companies
- 3 leading sponsor moving large portions of portfolio to SIP in 2020
- Several sponsors putting all new trials on SIP
- 3,220 Surveys conducted

INDUSTRY ADOPTION

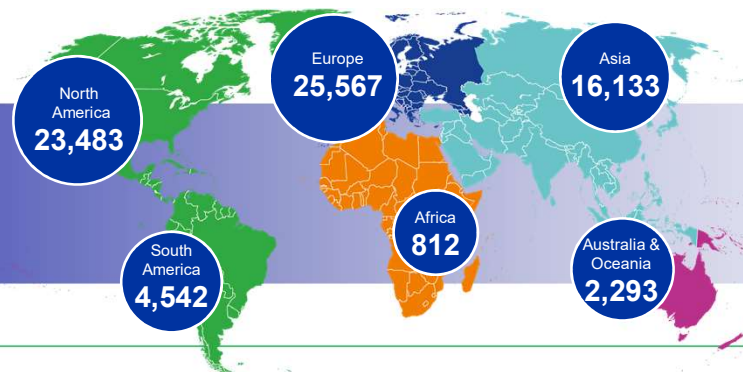
Alliances with Sites facing Organizations AACI, SCRS

Unified SIP Ecosystem :

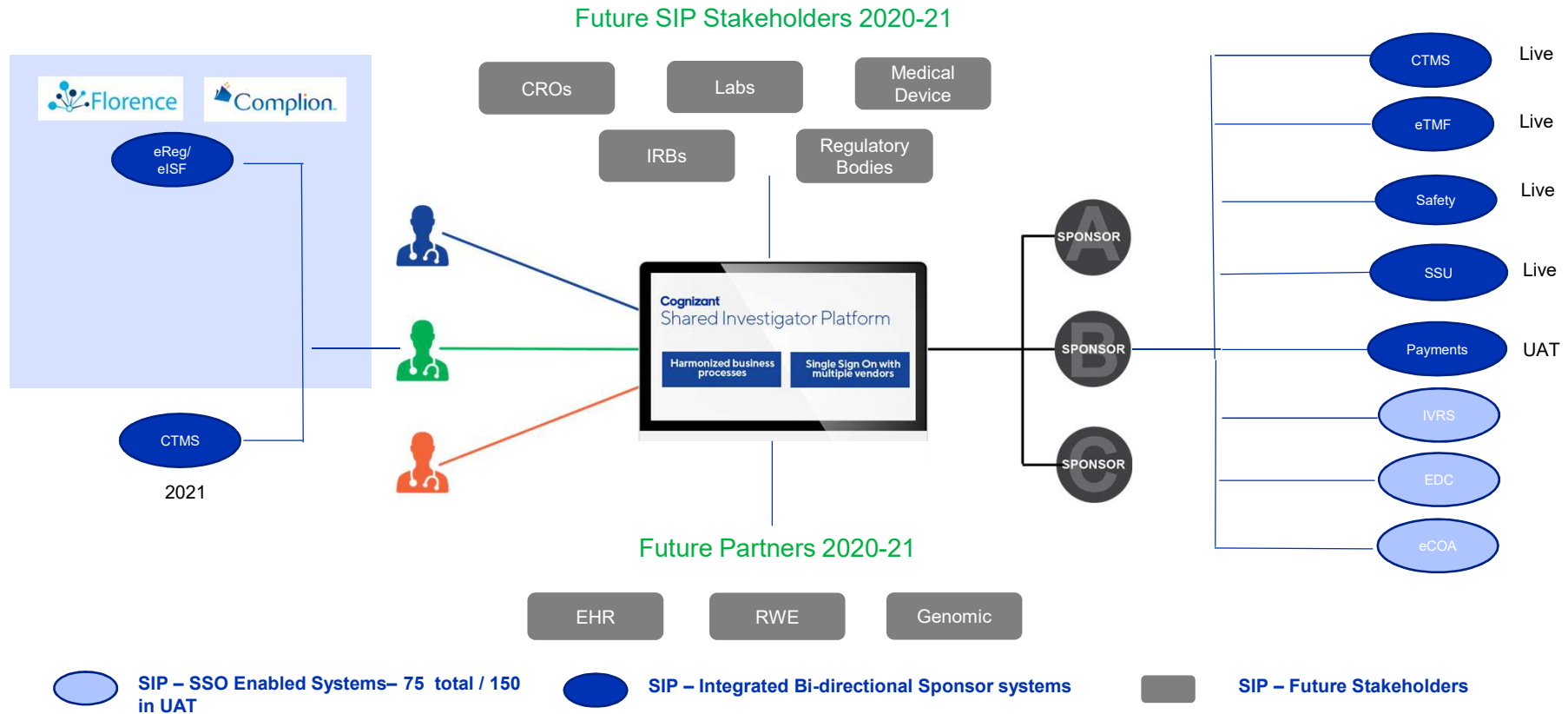
SIP Integrated with sponsor clinical operations systems including: eTMF, CTMS, Safety, SSU, Payments

74 Single Sign On Technology Partners, eReg Binder, SSU, EDC, CTMS, RWE

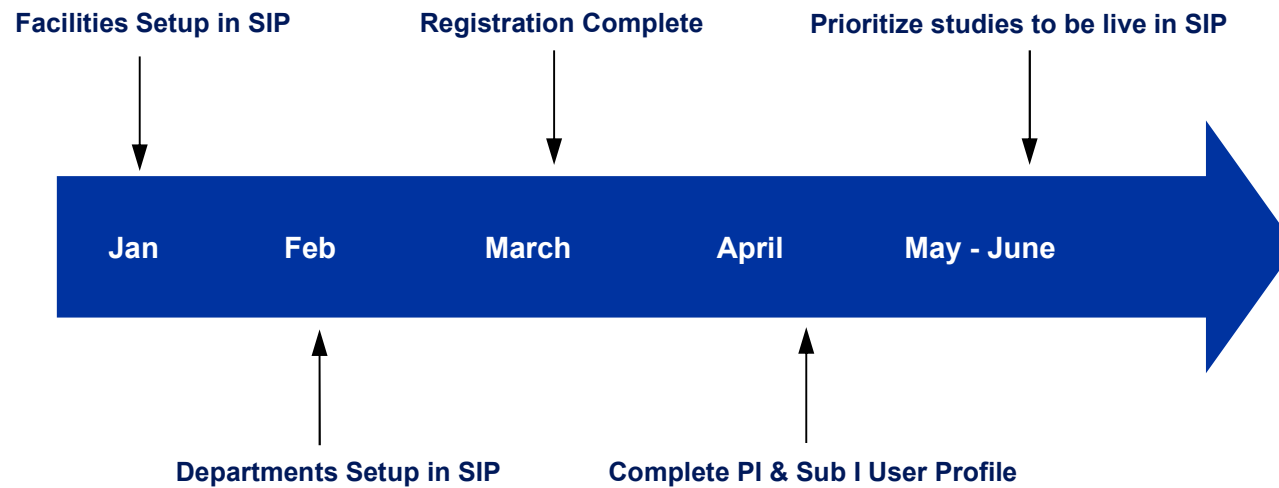
User Registration – Site Users Worldwide Distribution



The End State: A SIP-Unified Clinical Ecosystem



AACI Member Institution Milestones



Sample of AACI sites that have completed SIP structure setup

- UCLA Jonsson Comprehensive Cancer Center
- UC San Diego Moores Cancer Center
- University of Colorado Cancer Center
- Yale Cancer Center Phase 1 Pilot Team
- Georgetown Lombardi Comprehensive Cancer Center
- Moffitt Cancer Center
- University of Florida Health Cancer Center
- Winship Cancer Institute of Emory University
- The University of Chicago Medicine Comprehensive Cancer Center
- The University of Kansas Cancer Center
- Sidney Kimmel Comprehensive Cancer Center Johns Hopkins University
- Siteman Cancer Center
- Rutgers Cancer Institute of New Jersey
- Memorial Sloan Kettering Cancer Center
- Laura and Isaac Perlmutter Cancer Center NYU Langone
- The Ohio State University Comprehensive Cancer Center James Cancer Hospital & Solove Research Institute
- Princess Margaret Cancer Centre University Health Network
- OHSU Knight Cancer Institute
- UPMC Hillman Cancer Center
- Fox Chase Cancer Center Temple Health
- Vanderbilt-Ingram Cancer Center
- Huntsman Cancer Institute; University of Utah
- Barbara Ann Karmanos Cancer Institute Wayne State University

AACI sites who have started the facility set-up process

- O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham
- University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center
- Wilmot Cancer Institute University of Rochester Medical Center
- Indiana University Melvin & Bren Simon Cancer Center
- Stephenson Cancer Center University of Oklahoma
- The University of Arizona Cancer Center
- UCSF Helen Diller Family Comprehensive Cancer Center
- USC Norris Comprehensive Cancer Center
- City of Hope Comprehensive Cancer Center
- Duke Cancer Institute Duke University Medical Center
- The Cleveland Clinic Cancer Center
- University of Cincinnati Cancer Institute
- University of Wisconsin Carbone Cancer Center
- VCU Massey Cancer Center
- Simmons Comprehensive Cancer Center UT Southwestern Medical Center



Shared Investigator Platform (SIP) Overview

Adrian Kizewski

Cognizant, Customer Engagement Team

Shared Investigator Platform

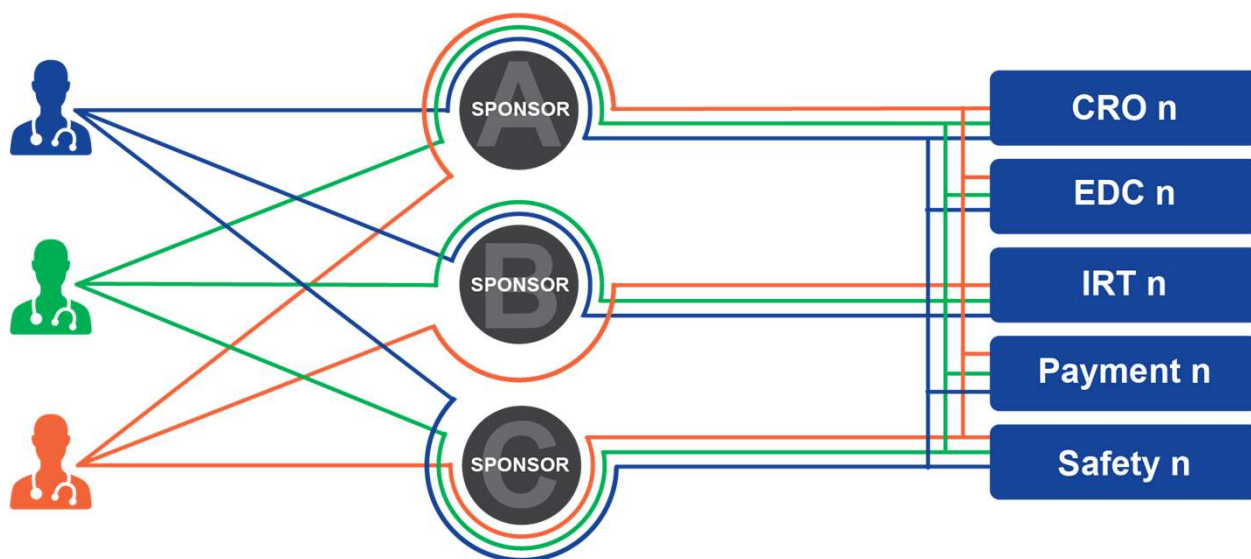
A world map with a dark blue background. The map is overlaid with a network of glowing white nodes and curved white lines, representing global connectivity. The nodes are distributed across all major continents, with a higher density in North America and Europe. The lines connect these nodes, forming a complex web that spans the globe.

The Shared Investigator Platform is an open industry collaboration platform that **streamlines trial activities and data sharing** for and between sites, sponsors and related stakeholders, resulting in:

**“Improved
operational
efficiencies”**

**“Accelerated
timelines”**

Investigators believe the Sponsor-centric clinical research eco-system is inefficient



75% sites report
too many user IDs &
passwords¹

15% of start-up time spent on
redundant non-specific
trainings/doc¹

Lack of central location
for study documents¹
(distribution mainly done by emails)

44% “One and done PI”
could not find trial
opportunities²

These pain points needed the industry to come together to find an “industrial solution”
in the form of the Shared Investigator Platform (SIP).

¹Data per Center Watch Survey 2017

²One and done: Reasons principal investigators conduct only one FDA-regulated drug trial', Published in Contemporary Clinical Trials Communications, Jun 2017

SIP – an open industry collaboration platform for all stakeholders – provides a more efficient approach – reduces site burden and increases efficiency



One User Name & Password across multiple Sponsors and their tools

Mutually Recognized Training across multiple Sponsors

Central location for study documents & harmonized business processes across Sponsors

Trial Demand meets Supply

SIP Capabilities





Cognizant
Shared Investigator Platform

SIP Demo

Utsav Kumar

Cognizant, Customer Engagement Team

Definitions of Facility & Department in SIP

FACILITY

- A geographical clinical research location
- A collection of associated locations within close proximity to each other where a clinical study can be conducted
- Examples of Facilities are included but not limited to:
 - Hospital
 - Medical Center
 - Institutes
 - Private Practice Physicians or any Facility that does not require separate departments

DEPARTMENT

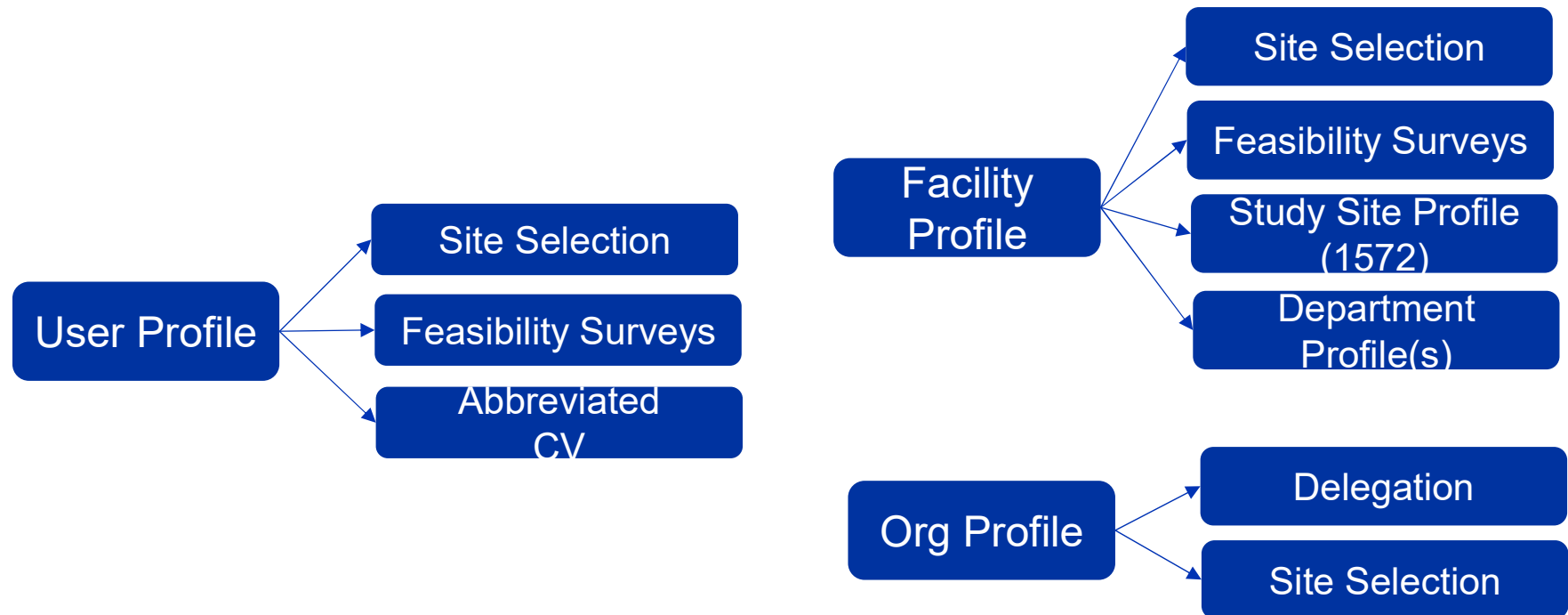
- A group within a Facility where a clinical study can be conducted
- May include: Therapeutically Aligned Departments -.
- Examples of Departments are included but not limited to:
 - Emergency Services
 - Family Medicine
 - Hematology Department
 - Rehabilitation Services
 - Urgent Care
 - Women's Services

Definition of Organization in SIP

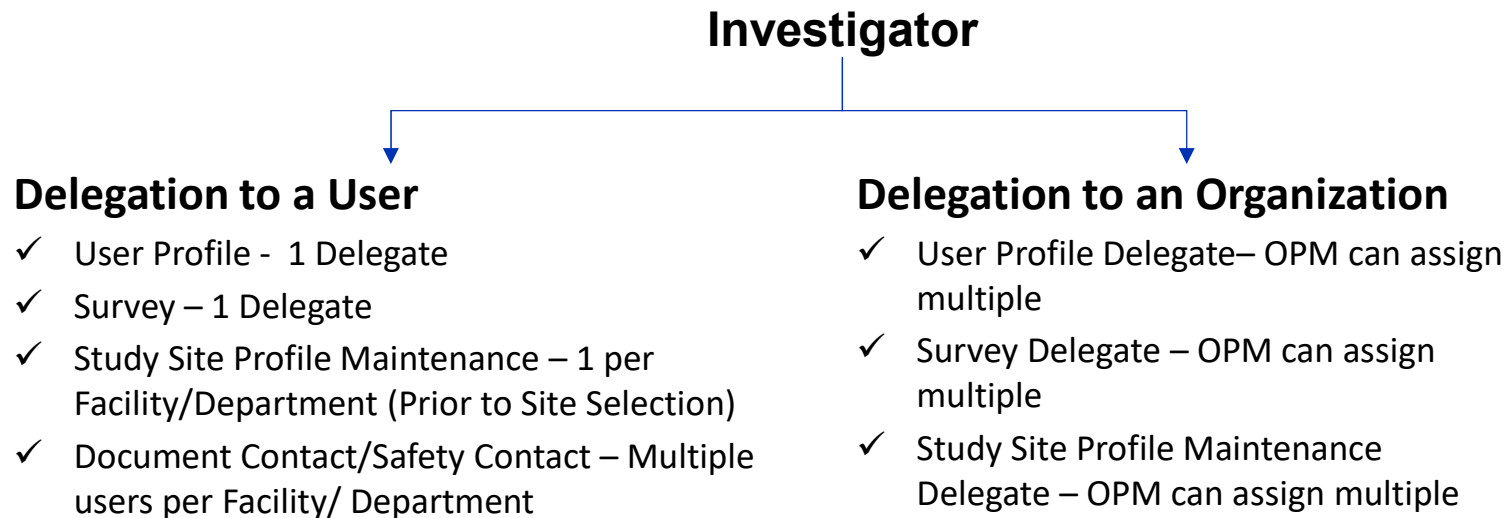
ORGANIZATION

- Internal Organization –
 - A Central Office that provides Administrative Support
 - You can set up an Organization if your leadership team requires oversight across all of your studies, for example
- External Organization -
 - A corporation, alliance, consortium or network that provides centralized business and/or operational services to multiple affiliated Facilities, Departments or Investigators
 - Affiliation may be exclusive (for all studies) or study-based (for select studies only).
- Note – when there are multiple central offices that operate regionally or are based on Therapeutic Area, you can set up **more than one** organization in SIP. This is common for AROs, Universities or large SMOs/Networks.
- Examples of organizations include but are not limited to:
 - Site Management Organizations (SMO)
 - Trial Management Organizations (TMO)
 - Investigator Site Networks (ISN)
 - Independent Practice Associations (IPA)
 - Site Alliances or Consortia
 - Academic Research Organizations (ARO)
 - Universities

Profile Data is reused across Sponsors/Studies



Delegating SIP Maintenance



Delegating SIP Maintenance – Other Delegations

- ✓ Profile Managers (FPM/DPM/OPM) - Sites can assign multiple
- ✓ Facility/ Department roles including contracting, regulatory, and others – Profile Managers can assign multiple
- ✓ Once a Site is selected, the Study Site Profile Maintenance Delegate can assign multiple delegates to:
 - Study Site Maintenance
 - Safety Contact
 - Regulatory Contact
- ✓ Site Administrator - optional entitlement at the Facility and Department level that gives FPMs/DPMs the ability to assign delegates for all Investigators in the Facility/Department (R6.0)



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Next Steps

Adrian Kizewski

Cognizant, Customer Engagement Team Lead

SIP Onboarding – Next Steps



Amgen “Registration Partner” Sites

- University of Florida Health Cancer Center
- UK Markey Cancer Center
- UofL James Graham Brown Cancer Center
- Dartmouth-Hitchcock Norris Cotton Cancer Center
- Rutgers Cancer Institute of New Jersey
- Stony Brook University Cancer Center
- Upstate Cancer Center SUNY Upstate Medical University
- University of Cincinnati Cancer Institute
- Penn State Cancer Institute
- Abramson Cancer Center of the University of Pennsylvania
- Sidney Kimmel Cancer Center at Jefferson Health
- The Wistar Institute
- The University of Vermont Cancer Center
- WVU Cancer Institute

Bristol Myers Squibb “Registration Partner” Sites (Jeanette.Teague@bms.com)

- The University of Arizona Cancer Center
- Loma Linda University Cancer Center
- USC Norris Comprehensive Cancer Center
- Holden Comprehensive Cancer Center University of Iowa
- Robert H. Lurie Comprehensive Cancer Center of Northwestern University
- The University of Kansas Cancer Center
- University of Michigan Rogel Cancer Center
- Duke Cancer Institute Duke University Medical Center
- University of New Mexico Comprehensive Cancer Center
- Albert Einstein Cancer Center Albert Einstein College of Medicine
- Roswell Park Comprehensive Cancer Center
- The Tisch Cancer Institute at the Mount Sinai Health System
- The Ohio State University Comprehensive Cancer Center James Cancer Hospital & Solove Research Institute
- UPMC Hillman Cancer Center
- Hollings Cancer Center Medical University of South Carolina
- Simmons Comprehensive Cancer Center UT Southwestern Medical Center

Eli Lilly “Registration Partner” Sites (glee@lilly.com)

- O’Neal Comprehensive Cancer Center at the University of Alabama at Birmingham
- UAMS Winthrop P. Rockefeller Cancer Institute
- Salk Institute Cancer Center
- Sanford Burnham Prebys Medical Discovery Institute
- UC San Diego Moores Cancer Center
- Samuel Oschin Comprehensive Cancer Institute Cedars-Sinai Medical Center
- UCLA Jonsson Comprehensive Cancer Center
- UC Davis Comprehensive Cancer Center
- Indiana University Melvin & Bren Simon Cancer Center
- Purdue University Center for Cancer Research
- Boston University Cancer Center
- The Jackson Laboratory Cancer Center
- UMMC Cancer Center and Research
- Fred and Pamela Buffett Cancer Center
- Laura and Isaac Perlmutter Cancer Center NYU Langone
- University of Wisconsin Carbone Cancer Center
- Medical College of Wisconsin Cancer Center

Merck “Registration Partner” Sites (lisa_maynard@merck.com)

- BC Cancer
- Princess Margaret Cancer Centre University Health Network
- Mayo Clinic Cancer Center, Arizona
- Stanford Cancer Institute
- University of Colorado Cancer Center
- GW Cancer Center
- Mayo Clinic Cancer Center, Florida
- Sylvester Comprehensive Cancer Center University of Miami Health System
- Moffitt Cancer Center
- Winship Cancer Institute of Emory University
- Georgia Cancer Center, Augusta University
- University of Hawai'i Cancer Center University of Hawai'i at Mānoa
- The University of Chicago Medicine Comprehensive Cancer Center
- Sidney Kimmel Comprehensive Cancer Center Johns Hopkins University
- Murtha Cancer Center at Walter Reed Bethesda
- Mayo Clinic Cancer Center
- OHSU Knight Cancer Institute
- Fox Chase Cancer Center Temple Health
- Comprehensive Cancer Center St. Jude Children's Research Hospital
- Vanderbilt-Ingram Cancer Center
- The University of Texas MD Anderson Cancer Center
- Huntsman Cancer Institute University of Utah

Pfizer “Registration Partner” Sites (Regina.L.Calderon@Pfizer.com)

- UCI Chao Family Comprehensive Cancer Center
- Georgetown Lombardi Comprehensive Cancer Center"
- Stanley S. Scott Cancer Center
- Tulane Cancer Center
- Feist-Weiller Cancer Center LSU Health Shreveport"
- University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center"
- Barbara Ann Karmanos Cancer Institute Wayne State University"
- UNC Lineberger Comprehensive Cancer Center University of North Carolina at Chapel Hill"
- Wake Forest Baptist Comprehensive Cancer Center
- LIVESTRONG Cancer Institutes The University of Texas at Austin Dell Medical School"
- University of Texas Medical Branch Cancer Center
- Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine"
- Mays Cancer Center UT Health San Antonio"
- Fred Hutchinson Cancer Research Center

Roche/Genentech “Registration Partner” Sites (reddy.monica@gene.com)

- City of Hope Comprehensive Cancer Center
- UCSF Helen Diller Family Comprehensive Cancer Center
- Yale Cancer Center Yale School of Medicine
- University of Illinois Cancer Center
- Cardinal Bernardin Cancer Center Loyola University Medical Center
- Cancer Center at Illinois
- Dana-Farber Cancer Institute Harvard Medical School
- Masonic Cancer Center University of Minnesota
- Siteman Cancer Center
- Herbert Irving Comprehensive Cancer Center Columbia University Medical Center
- Memorial Sloan Kettering Cancer Center
- Wilmot Cancer Institute University of Rochester Medical Center
- Case Comprehensive Cancer Center
- The Cleveland Clinic Cancer Center
- Stephenson Cancer Center University of Oklahoma
- University of Virginia Cancer Center
- VCU Massey Cancer Center



Thank you Cognizant

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