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

North America 23,483
Europe 25,567
Asia 16,133
South America 4,542
Africa 812
Australia & Oceania 2,293

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The End State: A SIP-Unified Clinical Ecosystem

Future SIP Stakeholders 2020-21
- CROs
- Labs
- Medical Device
- IRBs
- Regulatory Bodies
- CTMS
- eTMF
- Safety
- SSU
- Payments
- UAT
- Cognizant
- Shared Investigator Platform
- eReg/eISF
- Future Partners 2020-21
- CTMS
- Live
- eTMF
- Live
- Safety
- Live
- SSU
- Payments
- UAT
- IVRS
- EDC
- eCOA
- EHR
- RWE
- Genomic
- SIP – SSO Enabled Systems – 75 total / 150 in UAT
- SIP – Integrated Bi-directional Sponsor systems
- SIP – Future Stakeholders

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AACI Member Institution Milestones

- Facilities Setup in SIP
- Registration Complete
- Prioritize studies to be live in SIP
- Departments Setup in SIP
- Complete PI & Sub I User Profile
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
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

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

1 Data per Center Watch Survey 2017
2 One 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.
SIP Capabilities
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

- **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 Consortiums
  - Academic Research Organizations (ARO)
  - Universities
Profile Data is reused across Sponsors/Studies
Delegating SIP Maintenance

**Investigator**

### Delegation to a User
- ✔ User Profile - 1 Delegate
- ✔ Survey – 1 Delegate
- ✔ Study Site Profile Maintenance – 1 per Facility/Department (Prior to Site Selection)
- ✔ Document Contact/Safety Contact – Multiple users per Facility/Department

### Delegation to an Organization
- ✔ User Profile Delegate– OPM can assign multiple
- ✔ Survey Delegate – OPM can assign multiple
- ✔ Study Site Profile Maintenance Delegate – OPM can assign multiple
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)
Next Steps

Adrian Kizewski
Cognizant, Customer Engagement Team Lead
SIP Onboarding – Next Steps

1. SET UP ORG/FACILITY/DEPARTMENTS
   - Cognizant and Sponsors (SIPOnboarding@cognizat.com) sets up AACI Organization/Facilities & Contacts
   - Set Up Departments
   - Set Up Org. Profile
   - Create Affiliate Org/Facilities

2. PREPARE & COMMUNICATE
   - Eliminate IT Roadblocks
   - Communicate SIP Benefits
   - SIP Job Aids/Training

3. ONBOARD YOUR FACILITIES/STAFF
   - Send Bulk Invitations
   - Staff Completes Registration
   - Staff Support PI Onboarding

4. COMPLETE USER & FACILITY PROFILES
   - Multiple Options Available
     - Staff Data Entry
     - File Upload from Existing Site System
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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