IMPLEMENTING THE SHARED INVESTIGATOR PLATFORM

MODERATOR: HOBS APELL

SENIOR EXECUTIVE DIRECTOR, CLINICAL TRIALS

THE UNIVERSITY OF KANSAS CANCER CENTER
Implementing the Shared Investigator Platform

2020 AACI SIP TASK FORCE

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AACI SIP TASK FORCE PROGRESS

- February 2019 – AACI SIP Task Force Formed
- May 2019 – Conducted a SIP User Feedback Experience Survey to identify the challenges of SIP implementation. Received 28 AACI cancer centers responses
- Engaged Cognizant and industry partners in several meetings in 2019 to address SIP implementation challenges, understand sponsor timelines and expectations (April, July, September, December).
- August 2019 – authored an AACI Commentary: Simplifying Clinical Trials: Using Technology to Improve Operations
- January 2020 – attended SIP Summit in Bridgewater, NJ hosted by Cognizant
  - Discussed common roadblocks across institutions
  - Readdressed industry sponsor timelines and expectations
  - Requested site administrator access to facilitate SIP set up
- March – May 2020 - Conducted a phase II SIP Feedback Experience Survey completed by 28 AACI cancer centers working with SIP implementation
- May 2020 – Requested Cognizant Webinar for members not familiar with the SIP
- June 2020 – Hosting SIP Implementation best practices Webinar
Implementing the Shared Investigator Platform

**IMPACT**

### AACI Sites Status

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<thead>
<tr>
<th>AACI Sites</th>
<th>Status</th>
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<tr>
<td>28</td>
<td>SIP Structure Complete</td>
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<tr>
<td>16</td>
<td>SIP Set-up Ongoing</td>
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<tr>
<td>12</td>
<td>Beginning Stages</td>
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<tr>
<td>42</td>
<td>Have Not Started</td>
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**SIP MEMBERS: Pharma/Biotech**

- Amgen
- Bayer
- BMS
- Lilly
- Merck
- Pfizer
- Roche/Genentech
PRESENTERS

Lindsay Casetta, CCRP
Manager, Quality Assurance & Education Clinical Trials Office
Barbara Ann Karmanos Cancer Institute: 11 Years

Jessica Moehle, BS, CCRP
Director of Operations, Clinical Trials Office
Huntsman Cancer Institute at the University of Utah: 14 Years

Kendra Todd, MBA
Operations Manager
Knight Clinical Research Management
OHSU Knight Cancer Institute: 15 Years

Lestter Cruz Serrano, M.D.
Medical Affairs Advisor
Shared Investigator Platform
Cognizant Life Sciences
AACI Shared Investigator Platform

Lindsay Casetta, BSBA, CCRP
Manager, Quality Assurance & Education
Karmanos Cancer Institute
Detroit, Michigan
• 154 FTE who support research operations across the KCI Network
• Approximately 300 studies open
• 1310 interventional accruals in 2019
  – 611 were to treatment trials
Karmanos Network

★ Detroit
  – Main Research location

★ Farmington Hills
  – Satellite location

Karmanos Network
  – Historically our Network locations have not been approved to conduct Industry sponsored research
We have not yet added our Network locations into SIP. If and when they are approved to conduct research we will then add.
Current Status

- All Organizational & Facility data has been added into SIP
- Overwhelming majority of users have registered
  - Physicians, Study Coordinators, & Regulatory Coordinators
- We have hired a Systems Specialist to assist the CTO with NCI RCR, Forte eReg, and SIP users and facility updates
- We are working with the SIP pharmaceutical representative to assist with delegating users and associating with a role within SIP from the backend
- Starting to use the feasibility function
Lessons Learned

• Ensure that ALL users have delegated their profile to the Facility Profile Manager

• Instruct users to not create any additional departments
  – This defaults that user as the Department Profile Manager
AACI CRI
Shared Investigator Platform

Huntsman Cancer Institute
University of Utah

Jessica Moehle
Director of Operations
Clinical Trials Office
Clinical Trial Impact on Our Catchment Area (Utah) and the Broader Mountain West

Coming from >150 miles
• 31% of HCI patients
• 29% of HCI treatment accruals

- Huntsman Cancer Institute Locations
- Affiliate Hospitals
- Developing Affiliate Hospital
- Counties with Treatment Accruals

100 Miles
Cognizant Recommendation: University of Utah, Huntsman Cancer Institute

- 1 Organization Profile
  - For centralized delegation of user profiles, feasibility, and study-site profiles
- 1 Facility was created in SIP (vs. the 4 that we started with) because it can conduct trials independently of all other locations and is the only primary location
  - 3 other locations listed under “Additional Locations” section of Facility/Department profiles
- Huntsman is part of the University of Utah, however were setup as an independent facility because they wanted to have their center further broken down into departments
SIP Status for Implementation

- Institution and Facility details complete
- 5 PIs successfully registered and delegated...with help
- 1 feasibility assessment successfully completed leading to site selection
- ~20 staff registered (Regulatory & CTO Program Managers)
- Have ~110 investigators to register (MDs, PAs, NP, etc.)
- Using White Glove Service offered by sponsor which gives dedicated support from Cognizant
Lessons Learned

• Communicate to Investigators and CTO staff regularly; do not attempt to register or set up your profile on your own.

• Dedicate 1-2 key internal SIP points of contact/administrators who can absorb the work upfront

• Use a White Glove Service from a sponsor/Cognizant to help with the investigator & staff profile set up

• Have SIP as a standing agenda item at each CTO Operations Leadership meeting for status updates and to increase familiarity

• Be patient with the process and communicate to each different CRO & Sponsor your site status
OHSU Knight Cancer Institute

DATE: 18 June 2020  PRESENTED BY: Kendra Todd, Operations Manager
Overview

• Primary location is in Portland Oregon with satellites throughout Oregon.
• Catchment area: Oregon, SW Washington and Northern California
• Currently 569 subjects on active treatment and 859 in follow up
• 150+ enrolling providers
• 459 trials (368 interventional (of these, 324 were treatment) and 91 non-interventional)
Structure for OHSU, **Knight Cancer Institute** in SIP
Current Status

• Facility profile completed.

• Currently 75% of physicians and clinical research staff are registered and have profiles set up.

• Just starting to use the feasibility functionality.

• .5 FTE dedicated over last 8-9 months to help set up
Lessons learned/challenges

• Ask for help in setting up the facility profile. Don’t guess.

• If issues arise or something should be adjusted, reach out to your sponsor contact or Cognizant, they are willing to listen and help get the issue fixed.

• Be patient

• Communicate with staff and SIP staff timelines and issues
AACI SHARED INVESTIGATOR PLATFORM

Lestter Cruz Serrano, M.D.
Medical Affairs Advisor
Shared Investigator Platform
Cognizant Life Sciences
User Registration – Site & Sponsor user trends

Registered Site Users with CV Generated: 28% (+1)

Registered Site Users with complete profile: 41% (+1)

Registered Study Ready Site Users: 64% (+2)

Registered Activated Site Users: 83%

Site User Registration trend

Dec-19 Jan-20 Feb-20 Mar-20 Apr-20 May-20

Registered

% Registered vs Invited

Sponsor user growth

MC1, 10%
MC2, 35%
MC3, 23%
MC4, 8%
MC5, 15%
MC6, 9%
MC7, 0%

Sponsor Users Distribution
Study Activity Trends

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<tr>
<th>MC</th>
<th># of Studies</th>
<th># of investigators shared across MCs</th>
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<td>180</td>
<td>369</td>
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<tr>
<td>MC2</td>
<td>231</td>
<td>831</td>
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<td>MC3</td>
<td>100</td>
<td>778</td>
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<td>MC4</td>
<td>338</td>
<td>142</td>
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<td>MC5</td>
<td>6</td>
<td>165</td>
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<td>MC6</td>
<td>10</td>
<td>99</td>
</tr>
<tr>
<td>MC7</td>
<td>2</td>
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# of Investigators working on atleast 1 study

- Dec-19: 6987
- Jan-20: 7388
- Feb-20: 7984
- Mar-20: 8738
- Apr-20: 10569
- May-20: 14127

# of investigators working on multiple studies for multiple MCs

- Dec-19: 200
- Jan-20: 219
- Feb-20: 264
- Mar-20: 305
- Apr-20: 486
- May-20: 1146

Study Sites growth trend

- Jan-20: 3212
- Feb-20: 3451
- Mar-20: 3896
- Apr-20: 6294
- May-20: 9508
Facilities & Departments Creation trends

- **26%** [4810] Facilities Associated with Study sites
- **14%** [2580] Facilities with complete profile

### Active SIP Facilities / Departments
- **18412**

### Departments associated with facilities
- **8383**

**Facilities/Depts Trend**

- Jan-20: 13831
- Feb-20: 14741
- Mar-20: 16521
- Apr-20: 17392
- May-20: 18412
AACI Site Trends

**AACI Site User Registration Trend**

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<th>Value</th>
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<td>Apr-20</td>
<td>3650</td>
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<td>May-20</td>
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**# of AACI Investigators working on at least 1 study**

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**Sponsor**

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<td>MC1</td>
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**# of AACI investigators working on multiple studies**

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<td>Mar-20</td>
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<td>Apr-20</td>
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<tr>
<td>May-20</td>
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Impact of Site’s Utilization of SIP

The Objective
Provide data that supports the hypothesis that site staff and sponsors experience efficiencies through continued use of SIP.

Lilly Results
Lilly assessed the experience of PIs that have participated in multiple Lilly studies to date, comparing their first SIP study experience with their subsequent SIP study experience.

- 29% reduction of average time from sponsor sending study invite to PI accepting invitation
- 3 hours of PI training savings due to mutually recognized training in SIP
- Sponsors receive site study data (study staff, shipping info, etc.) 36% faster
- CV generation & distribution activities time savings of 1 hour/site/study

Cognizant Results
Cognizant assessed PIs that have participated in multiple studies across all sponsors, comparing PIs who have worked on one SIP study to those that have worked on multiple SIP studies.

- 5.6 days faster for survey completion
- 7.5 days faster for study acceptance

Key Take Aways
- Time savings allow sites to concentrate on other patient related activities
- Efficiencies can be found with more exposure and routine use
- The results demonstrated quantitative and qualitative examples of efficiency gained by sites/study teams over time
- Across sponsors, sites are gaining experience and can navigate SIP quicker
- Site Staff time savings realized through multiple study experiences on SIP with sponsor companies

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Steps for SIP onboarding

1. Reaching out and contacting our SIP onboarding team (SIPOnboarding@cognizant.com) or the sponsor registration partner
2. Attending the overview and demo calls that are conducted
3. Working with our consulting team and sponsor registration partner to get facility structure enabled
4. Attend working session during which our Cognizant consulting team and the sponsor registration partner will provide further training
5. Working with the sponsor registration partner to complete profiles and onboard site staff
6. Onboarding the PI's
We will now take questions for our presenters. Please use the question box on the lower right to submit a question. Questions will be answered as time permits.

Thank you for joining today’s Association of American Cancer Institutes Clinical Research Innovation webinar. Information about this and other webinars can be found on our website at www.aaci-cancer.org.
University of Kansas Cancer Center

• 1 Organization Profile for the Cancer Center
  – To serve as the umbrella for all University of Kansas Cancer Center facilities in SIP and show the type of affiliation

• 7 Facilities were created in SIP for just the cancer center locations and 1 location was created as a department underneath the Clinical Research Center facility

• University of Kansas Cancer Center delegations for each of their PI’s:
  – Each PI will delegate their user profile, feasibility, and study-site profile to the Organization profile for central delegation
Detailed Structure for KUMC, University of Kansas Cancer Center in SIP

The University of Kansas Cancer Center Organization

The University of Kansas - Clinical Research Center
The University of Kansas Cancer Center – Overland Park
The University of Kansas Cancer Center – Hospital
The University of Kansas Cancer Center – Lee’s Summit
The University of Kansas Cancer Center – North Kansas City Hospital
The University of Kansas Cancer Center – North
The University of Kansas Cancer Center – Westwood
The University of Kansas Cancer Center – Indian Creek

The University of Kansas Cancer Center- Clinical Research Center

NCI Designated Cancer Center

The University of Kansas Cancer Center

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<th>Institution</th>
<th>Status</th>
<th>Institution</th>
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<td>BC Cancer</td>
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# SIP Set-Up: Beginning Stages

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<tr>
<td>Robert H. Lurie Comprehensive Cancer Center of Northwestern University</td>
<td>BMS submitted helpdesk ticket to correct structure/organization details</td>
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<tr>
<td>Abramson Cancer Center of the University of Pennsylvania</td>
<td>Dr. Cruz reached out to Maria Hendricks; meeting June 8</td>
</tr>
<tr>
<td>The University of Texas MD Anderson Cancer Center</td>
<td>Dr. Cruz to meet with Dina Aziz June 18</td>
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<tr>
<td>Sylvester Comprehensive Cancer Center University of Miami Health System</td>
<td>Merck scheduled a meeting on June 19</td>
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<tr>
<td>Mayo Clinic Cancer Center</td>
<td>Merck scheduling a meeting</td>
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<tr>
<td>Stanford Cancer Institute</td>
<td>Merck scheduling a meeting</td>
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<tr>
<td>UNC Lineberger Comprehensive Cancer Center University of North Carolina at Chapel Hill</td>
<td>Meeting March 6; working to schedule follow up meeting</td>
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<td>Herbert Irving Comprehensive Cancer Center Columbia University Medical Center</td>
<td>Roche/Genentech working to schedule a meeting</td>
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<td>UC Davis Comprehensive Cancer Center</td>
<td>Cognizant reached out to Dr. Ahmed Bayoumi</td>
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<td>Samuel Oschin Comprehensive Cancer Institute Cedars-Sinai Medical Center</td>
<td>Cognizant reached out to Marie Malikowski</td>
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<td>UAMS Winthrop P. Rockefeller Cancer Institute</td>
<td>Eli Lilly reached out to site</td>
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<td>Dana-Farber Cancer Institute Harvard Medical School</td>
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