

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

IMPACT

AACI Sites	Status
28	SIP Structure Complete
16	SIP Set-up Ongoing
12	Beginning Stages
42	Have Not Started
98	

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



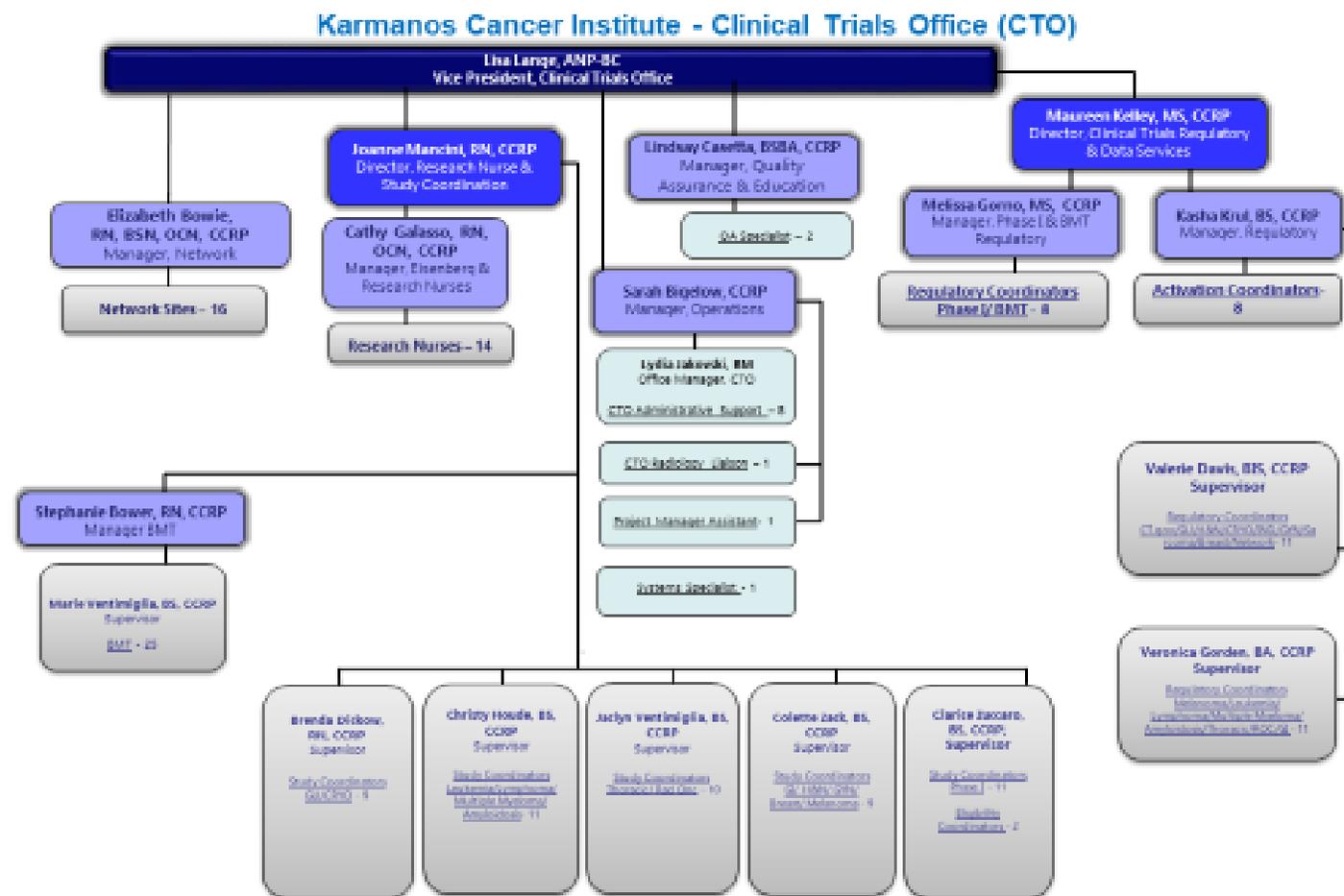
AACI Shared Investigator Platform

Lindsay Casetta, BSBA, CCRP
Manager, Quality Assurance & Education
Karmanos Cancer Institute
Detroit, Michigan



KCI CTO

- 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

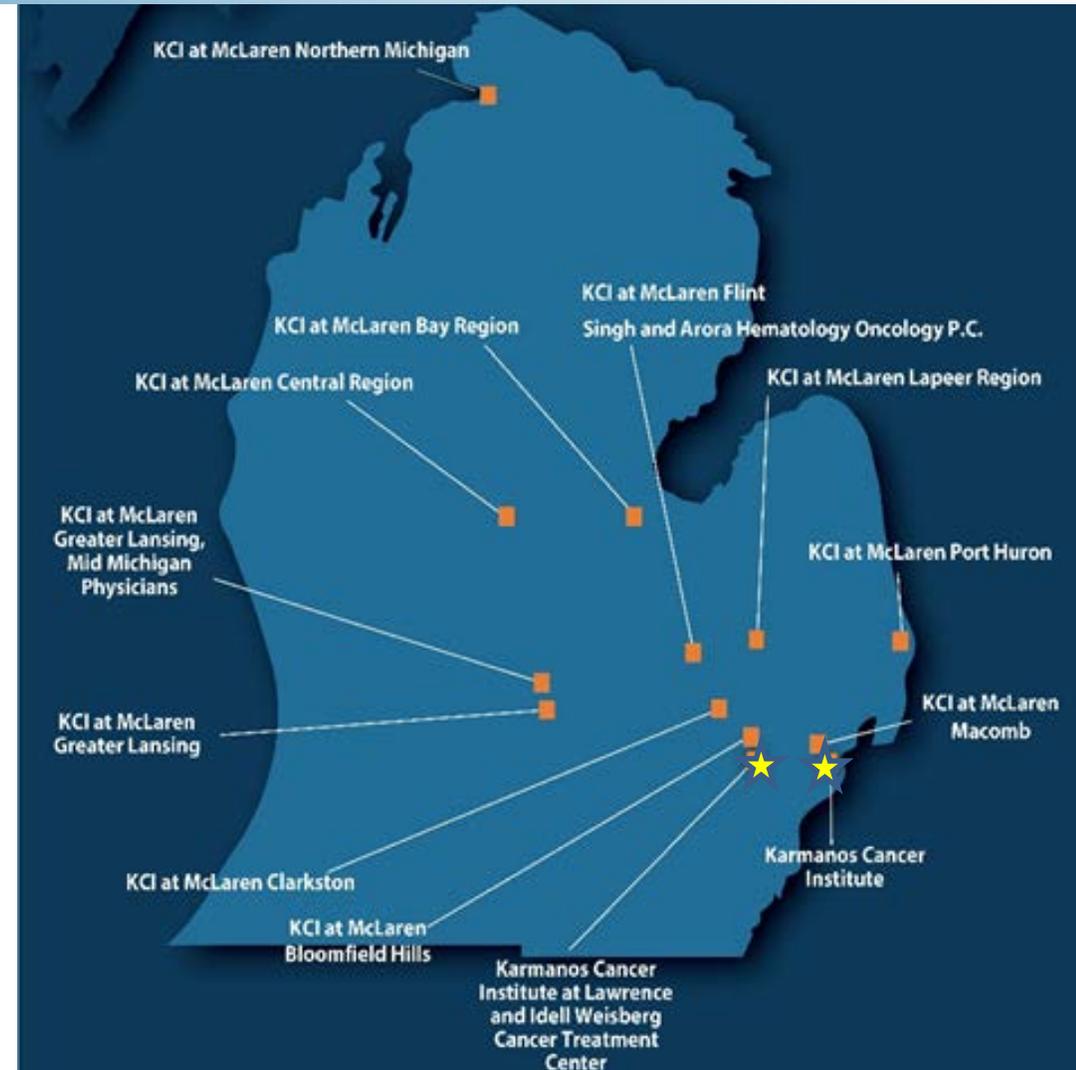
- Main Research location

★ Farmington Hills

- Satellite location

■ Karmanos Network

- Historically our Network locations have not been approved to conduct Industry sponsored research



Org Chart of SIP profile



- 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

Thank You



Karmanos Cancer Institute Clinical Trials Office

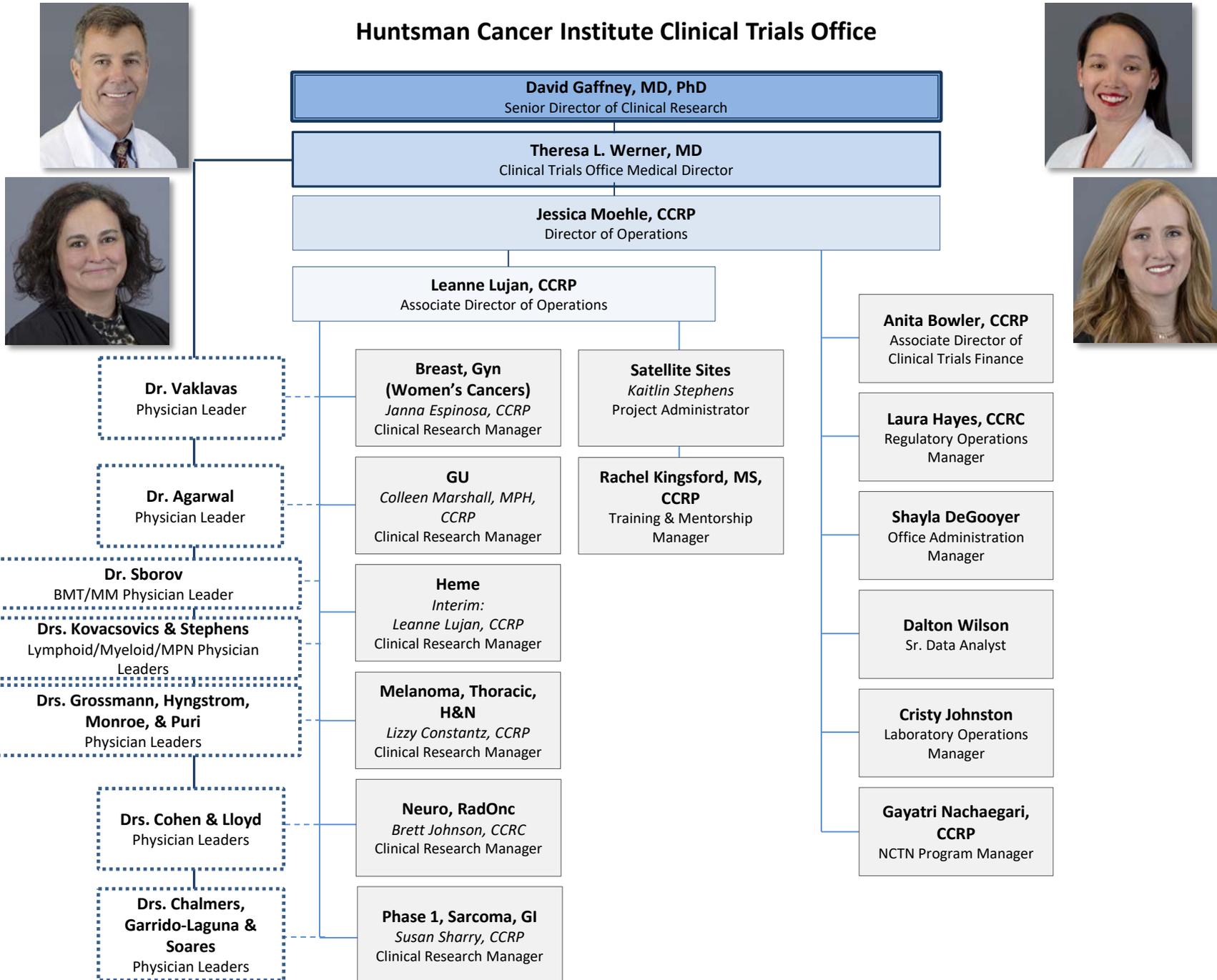
AACI CRI

Shared Investigator Platform

Huntsman Cancer Institute
University of Utah

Jessica Moehle
Director of Operations
Clinical Trials Office

Huntsman Cancer Institute Clinical Trials Office



Dr. Vakilav
Physician Leader

Dr. Agarwal
Physician Leader

Dr. Sborov
BMT/MM Physician Leader

Drs. Kovacovics & Stephens
Lymphoid/Myeloid/MPN Physician Leaders

Drs. Grossmann, Hyngstrom, Monroe, & Puri
Physician Leaders

Drs. Cohen & Lloyd
Physician Leaders

Drs. Chalmers, Garrido-Laguna & Soares
Physician Leaders

**Breast, Gyn
(Women's Cancers)**
Janna Espinosa, CCRP
Clinical Research Manager

GU
Colleen Marshall, MPH, CCRP
Clinical Research Manager

Heme
Interim:
Leanne Lujan, CCRP
Clinical Research Manager

Melanoma, Thoracic, H&N
Lizzy Constantz, CCRP
Clinical Research Manager

Neuro, RadOnc
Brett Johnson, CCRC
Clinical Research Manager

Phase 1, Sarcoma, GI
Susan Sharry, CCRP
Clinical Research Manager

Satellite Sites
Kaitlin Stephens
Project Administrator

Rachel Kingsford, MS, CCRP
Training & Mentorship Manager

Anita Bowler, CCRP
Associate Director of Clinical Trials Finance

Laura Hayes, CCRC
Regulatory Operations Manager

Shayla DeGooyer
Office Administration Manager

Dalton Wilson
Sr. Data Analyst

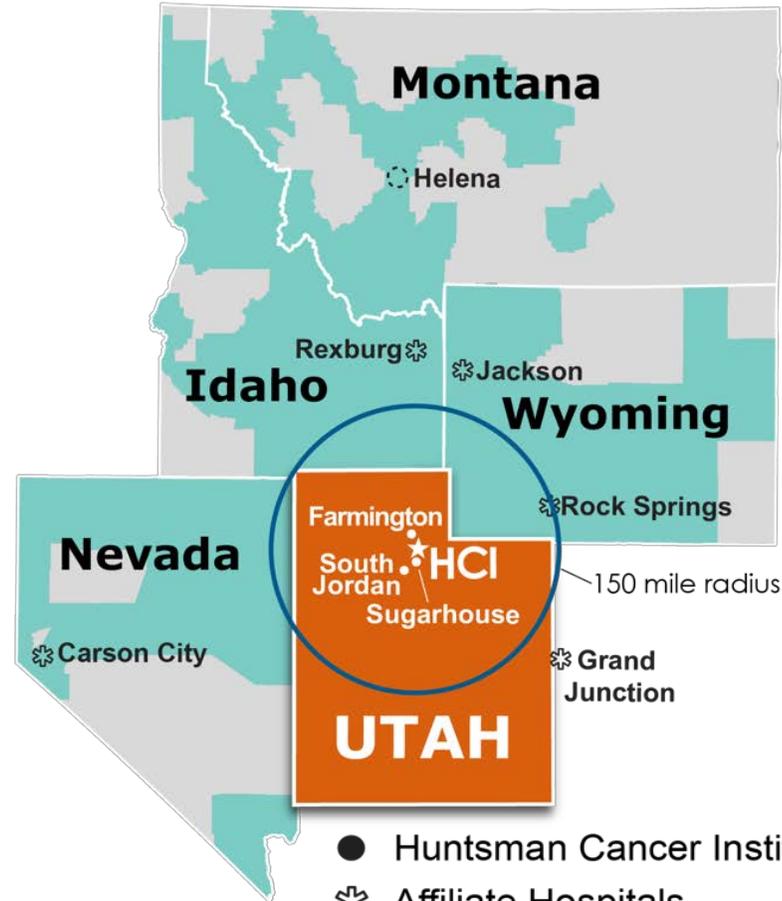
Cristy Johnston
Laboratory Operations Manager

Gayatri Nachaegari, CCRP
NCTN Program Manager

Clinical Trial Impact on Our Catchment Area (Utah) and the Broader Mountain West

Coming from >150 miles

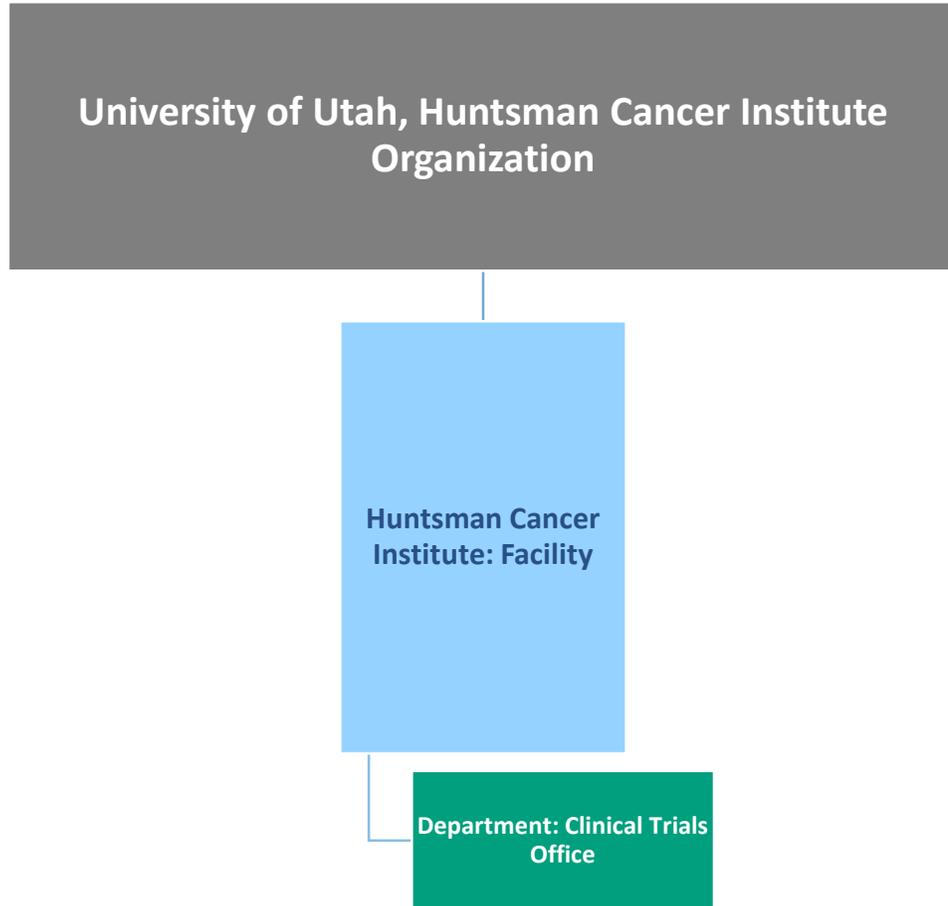
- 31% of HCI patients
- 29% of HCI treatment accruals



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

100 Miles

SIP Set Up



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

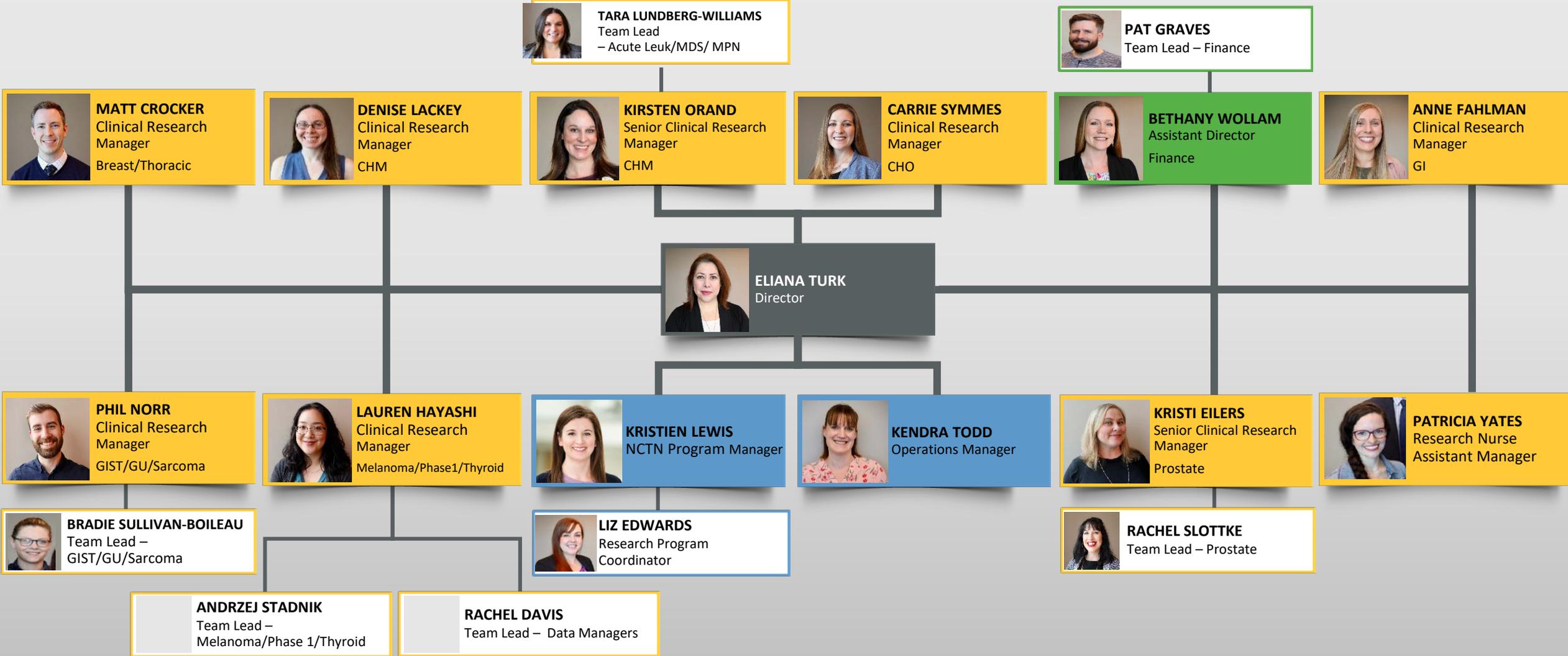
DATE: 18 June 2020 PRESENTED BY: Kendra Todd, Operations Manager



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)

Knight Cancer Institute Clinical Research Management Org Chart



TARA LUNDBERG-WILLIAMS
Team Lead
- Acute Leuk/MDS/ MPN

PAT GRAVES
Team Lead - Finance

MATT CROCKER
Clinical Research Manager
Breast/Thoracic

DENISE LACKEY
Clinical Research Manager
CHM

KIRSTEN ORAND
Senior Clinical Research Manager
CHM

CARRIE SYMMES
Clinical Research Manager
CHO

BETHANY WOLLAM
Assistant Director
Finance

ANNE FAHLMAN
Clinical Research Manager
GI

ELIANA TURK
Director

PHIL NORR
Clinical Research Manager
GIST/GU/Sarcoma

LAUREN HAYASHI
Clinical Research Manager
Melanoma/Phase1/Thyroid

KRISTIEN LEWIS
NCTN Program Manager

KENDRA TODD
Operations Manager

KRISTI EILERS
Senior Clinical Research Manager
Prostate

PATRICIA YATES
Research Nurse Assistant Manager

BRADIE SULLIVAN-BOILEAU
Team Lead -
GIST/GU/Sarcoma

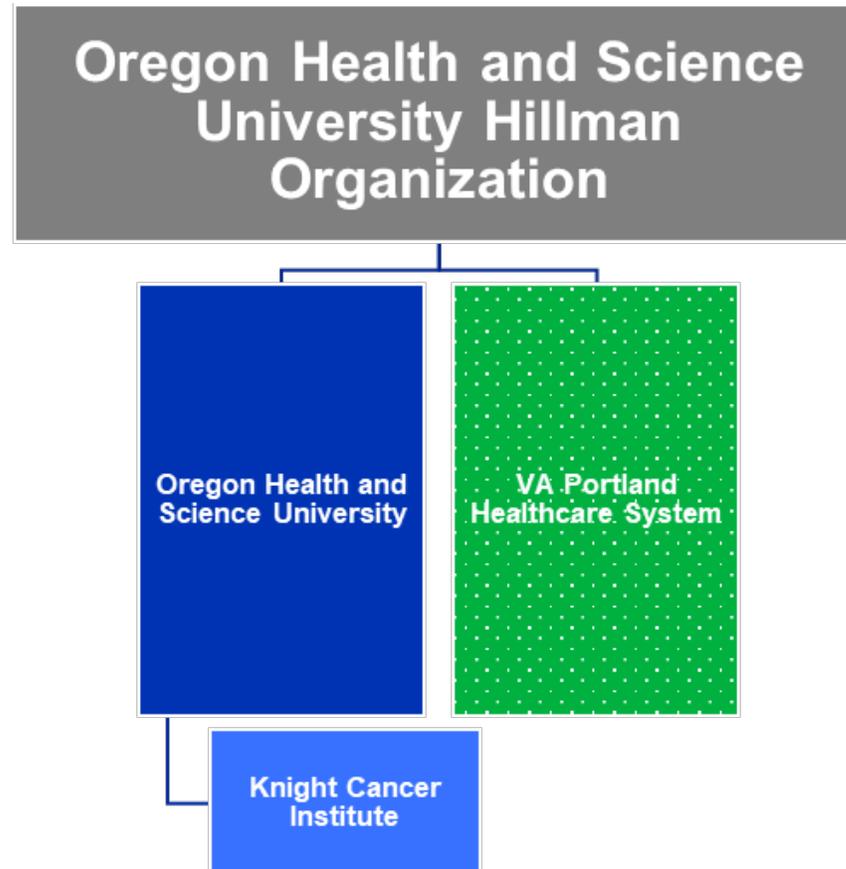
LIZ EDWARDS
Research Program Coordinator

RACHEL SLOTTKE
Team Lead - Prostate

ANDRZEJ STADNIK
Team Lead -
Melanoma/Phase 1/Thyroid

RACHEL DAVIS
Team Lead - Data Managers

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



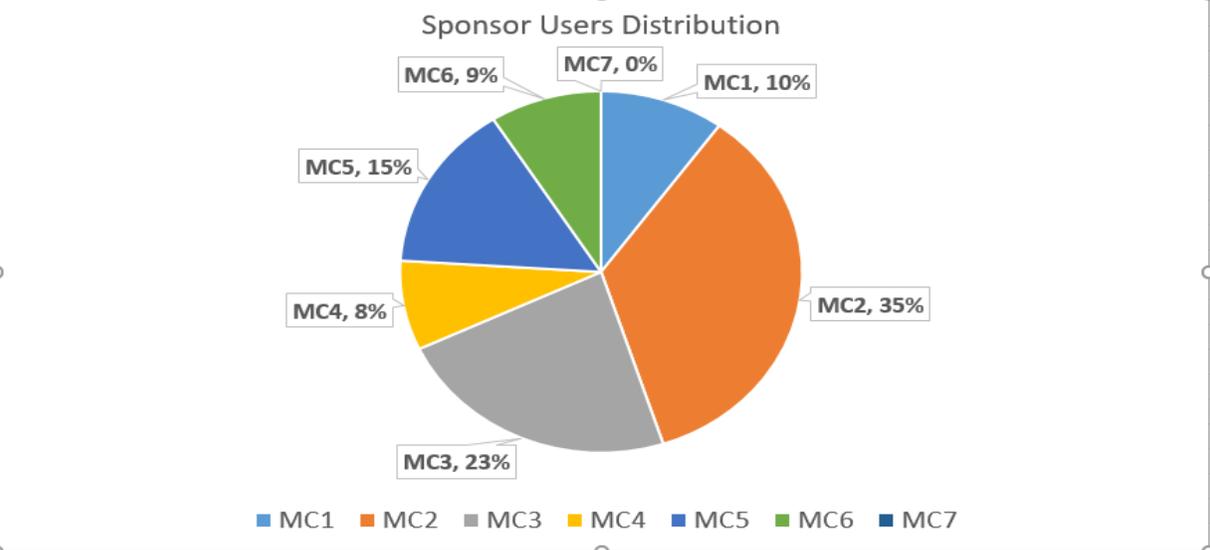
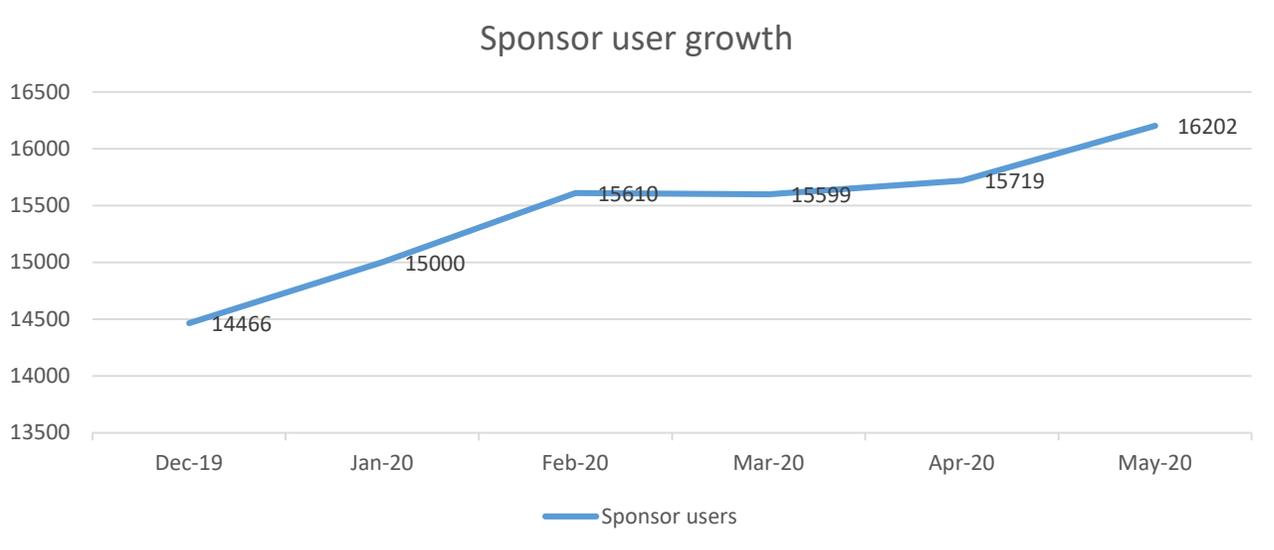
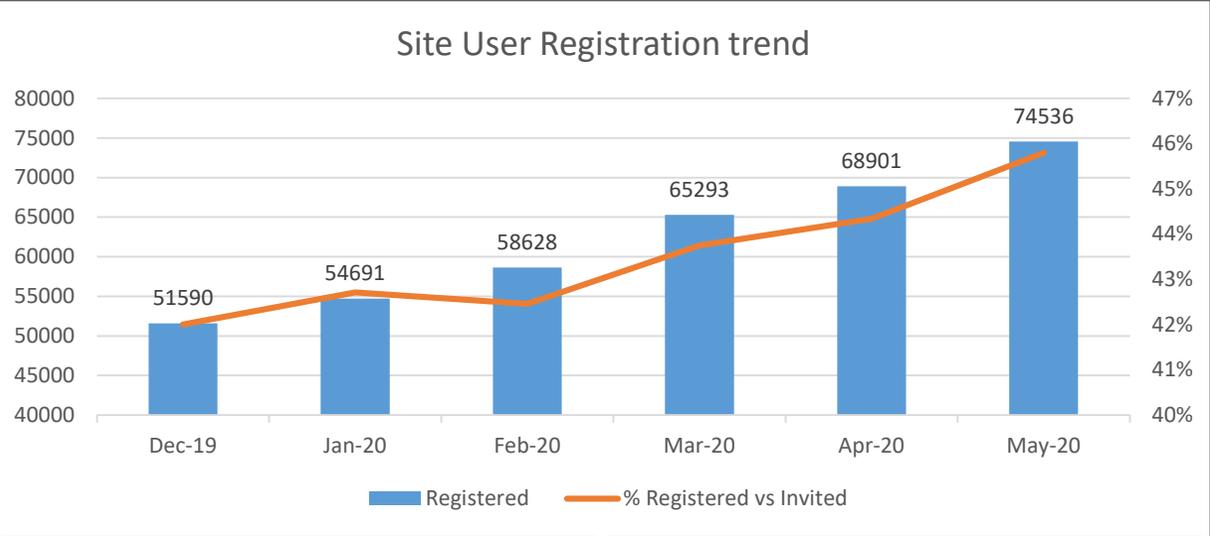
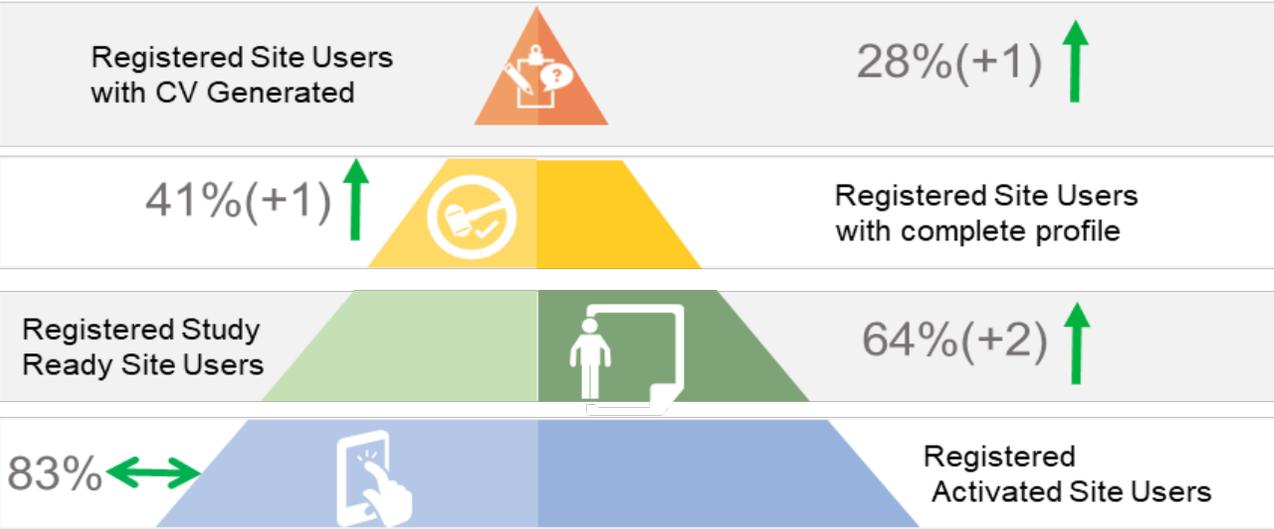
AACI SHARED INVESTIGATOR PLATFORM

Lestter Cruz Serrano, M.D.

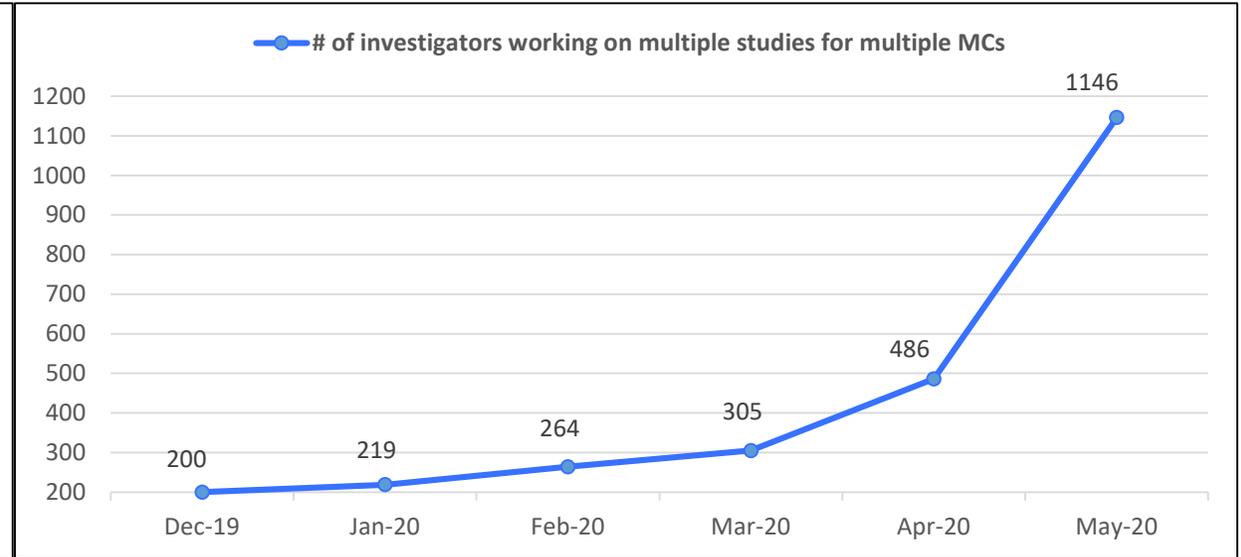
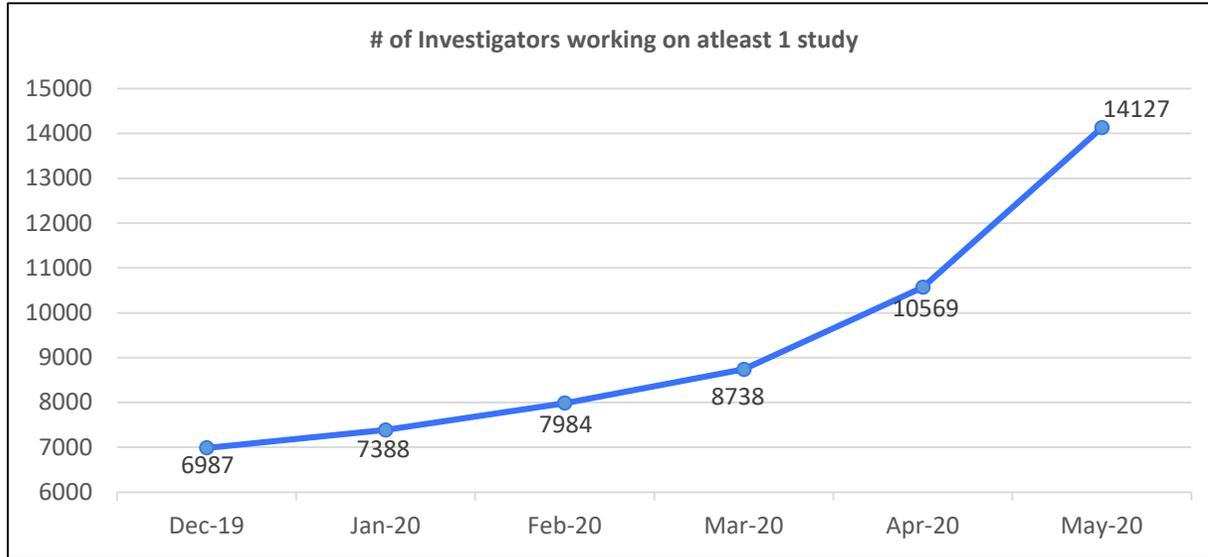
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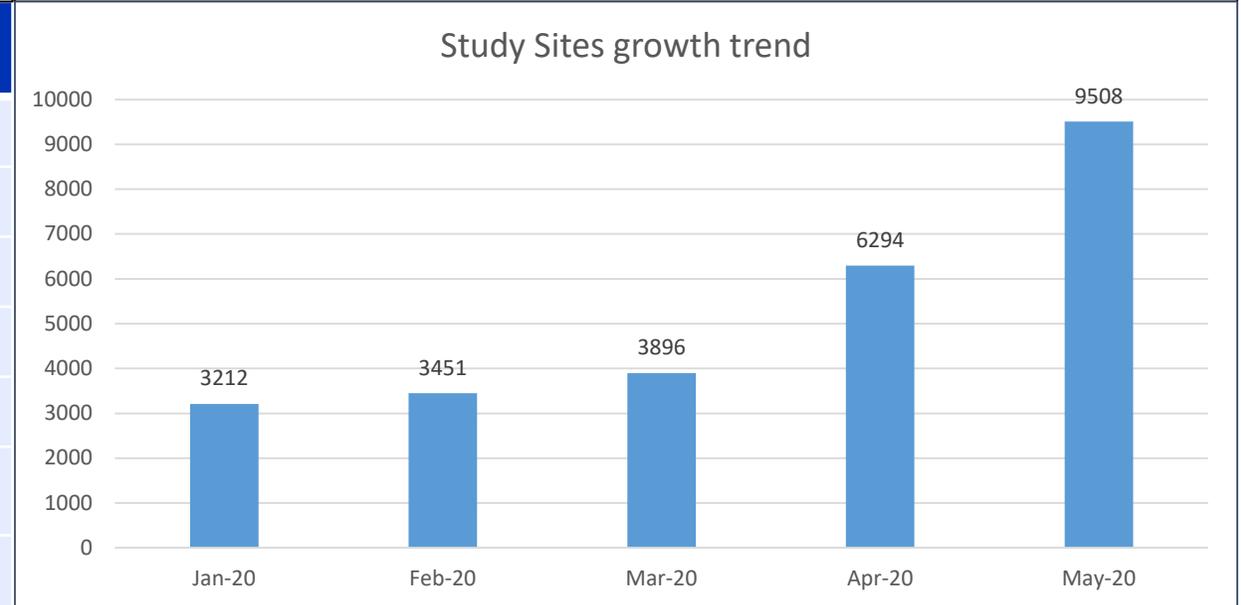
User Registration – Site & Sponsor user trends



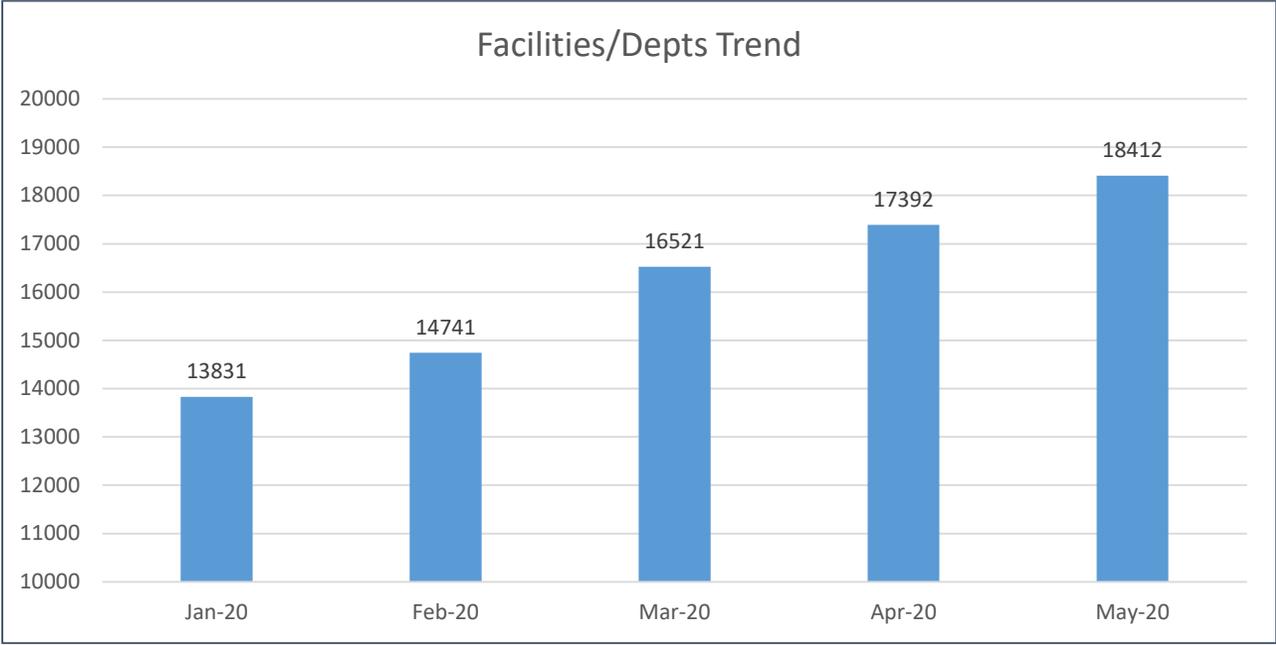
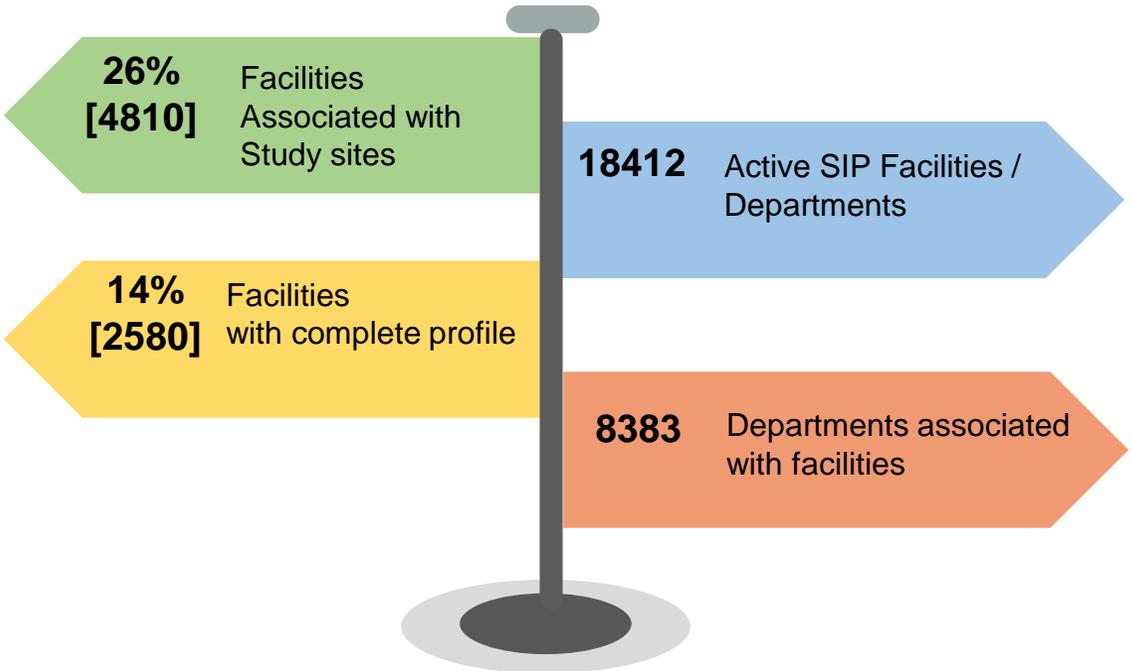
Study Activity Trends



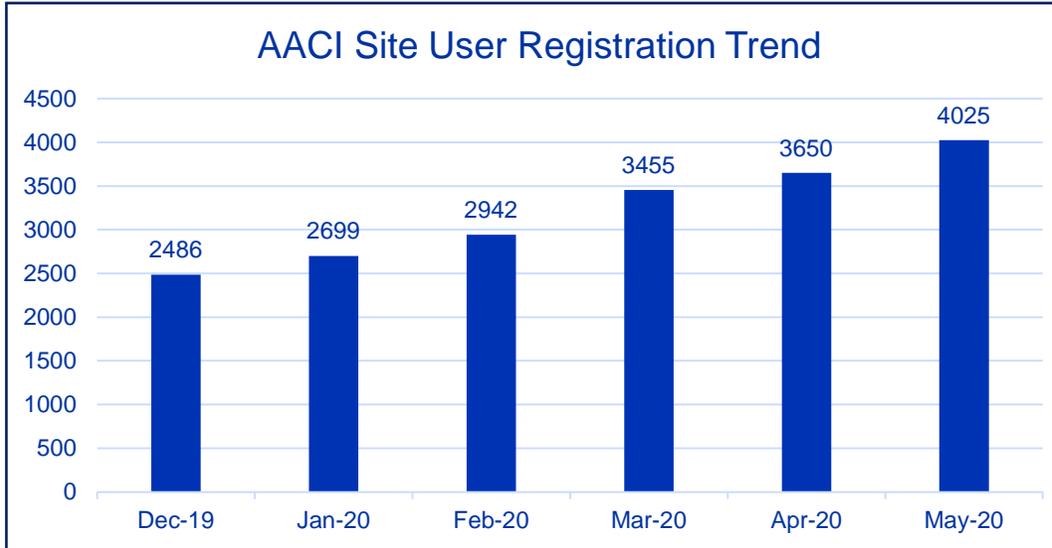
MC	# of Studies	# of investigators shared across MCs
MC1	180	369
MC2	231	831
MC3	100	778
MC4	338	142
MC5	6	165
MC6	10	99
MC7	2	0



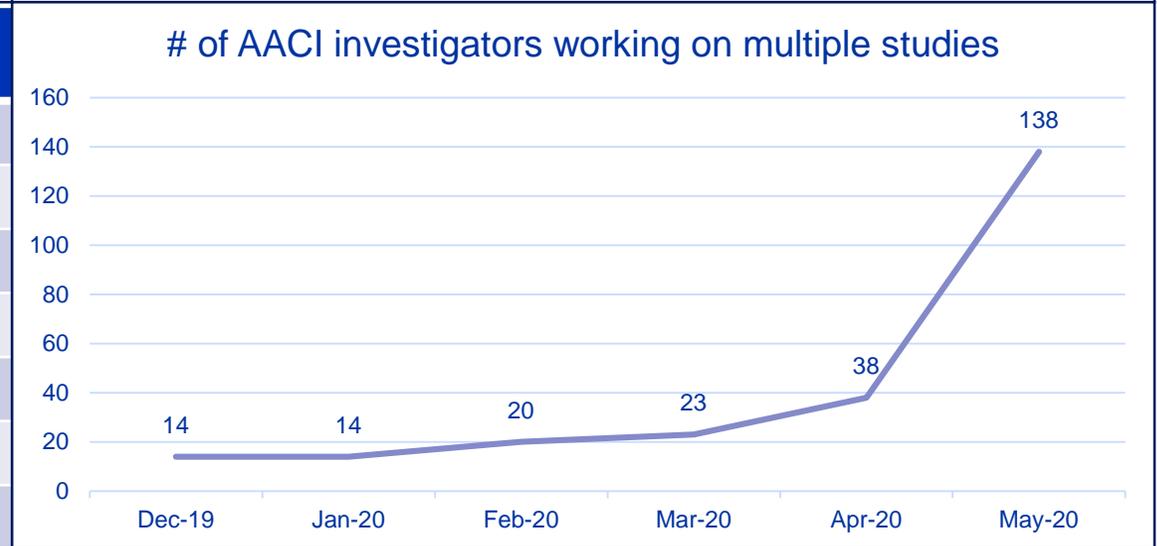
Facilities & Departments Creation trends



AACI Site Trends



Sponsor	# of Studies
MC1	3
MC2	3
MC3	11
MC4	149
MC5	11
MC6	23
MC7	0



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



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.



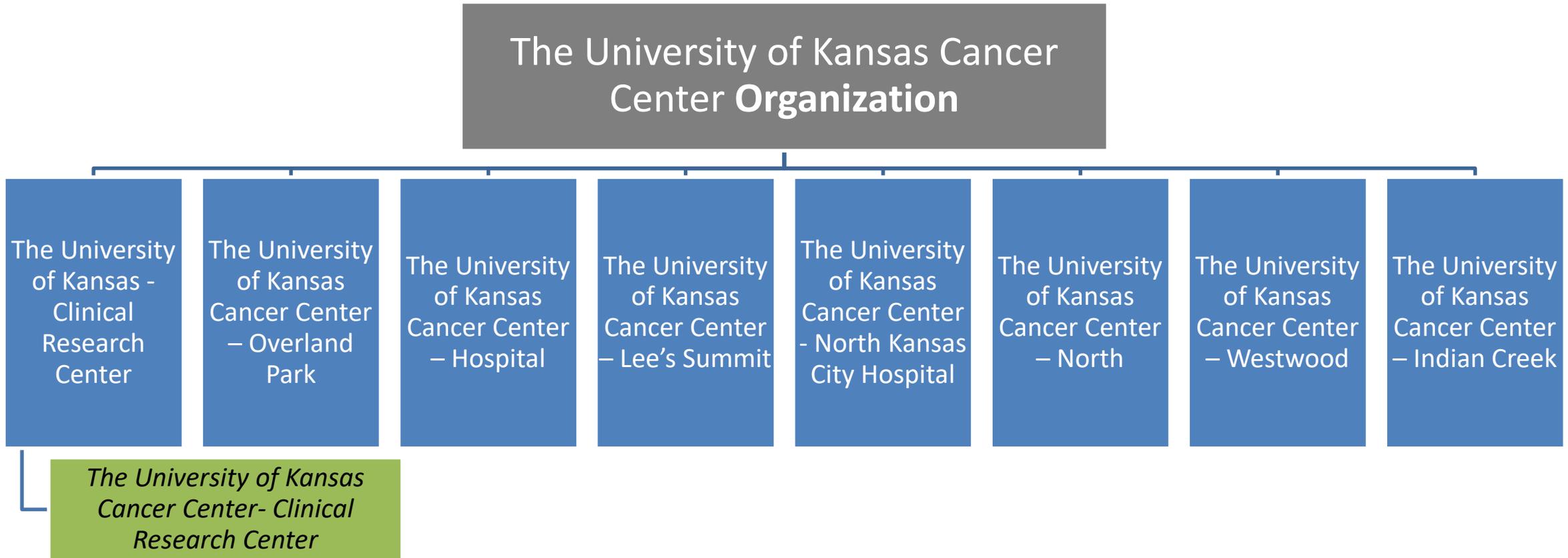
Thank you for joining today's Association of American Cancer Institutes Clinical Research Innovation webinar. Information about this and other webinars can be found on our website at www.aaci-cancer.org.

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



SIP Structure Complete

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

SIP Set-Up Ongoing

Institution	Status	Site response awaited	Initial meeting scheduled	Structure recommendation in progress	Structure recommendation finalized
City of Hope Comprehensive Cancer Center	Set-up ongoing				•
University of Illinois Cancer Center	Set-up ongoing				•
University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center	Set-up ongoing				•
VCU Massey Cancer Center	Set-up ongoing			•	
The Cleveland Clinic Cancer Center	Set-up ongoing			•	
University of Cincinnati Cancer Institute	Set-up ongoing			•	
Sidney Kimmel Cancer Center at Jefferson Health	Set-up ongoing			•	
University of Wisconsin Carbone Cancer Center	Set-up ongoing			•	
O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham	Set-up ongoing			•	
USC Norris Comprehensive Cancer Center	Set-up ongoing			•	
Simmons Comprehensive Cancer Center UT Southwestern Medical Center	Set-up ongoing			•	
Tulane Cancer Center	Set-up ongoing		•		
Penn State Cancer Institute	Set-up ongoing	•			
Indiana University Melvin & Bren Simon Cancer Center	Set-up ongoing	•			
Stephenson Cancer Center University of Oklahoma	Set-up ongoing	•			
The University of Arizona Cancer Center	Set-up ongoing	•			

SIP Set-Up: Beginning Stages

Institution	Status
Robert H. Lurie Comprehensive Cancer Center of Northwestern University	BMS submitted helpdesk ticket to correct structure/organization details
Abramson Cancer Center of the University of Pennsylvania	Dr. Cruz reached out to Maria Hendricks; meeting June 8
The University of Texas MD Anderson Cancer Center	Dr. Cruz to meet with Dina Aziz June 18
Sylvester Comprehensive Cancer Center University of Miami Health System	Merck scheduled a meeting on June 19
Mayo Clinic Cancer Center	Merck scheduling a meeting
Stanford Cancer Institute	Merck scheduling a meeting
UNC Lineberger Comprehensive Cancer Center University of North Carolina at Chapel Hill	Meeting March 6; working to schedule follow up meeting
Herbert Irving Comprehensive Cancer Center Columbia University Medical Center	Roche/Genentech working to schedule a meeting
UC Davis Comprehensive Cancer Center	Cognizant reached out to Dr. Ahmed Bayoumi
Samuel Oschin Comprehensive Cancer Institute Cedars-Sinai Medical Center	Cognizant reached out to Marie Malikowski
UAMS Winthrop P. Rockefeller Cancer Institute	Eli Lilly reached out to site
Dana-Farber Cancer Institute Harvard Medical School	Site awaiting security checkpoint enhancement (R6.0)

SIP Set-up Has Not Started

Institution	Status	Institution	Status
Loma Linda University Cancer Center	Received contact from AACI	Wake Forest Baptist Comprehensive Cancer Center	Received contact from webinar
Salk Institute Cancer Center	no contact	Fred and Pamela Buffett Cancer Center	Received contact from AACI
Sanford Burnham Prebys Medical Discovery Institute	no contact	Dartmouth-Hitchcock Norris Cotton Cancer Center	Received contact from webinar
UCI Chao Family Comprehensive Cancer Center	Received contact from webinar	University of New Mexico Comprehensive Cancer Center	Received contact from AACI
GW Cancer Center	Received contact from AACI	Albert Einstein Cancer Center Albert Einstein College of Medicine	no contact
Georgia Cancer Center, Augusta University	no contact	Roswell Park Comprehensive Cancer Center	Received contact from AACI
University of Hawai'i Cancer Center University of Hawai'i at Mānoa	Received contact from AACI	Stony Brook University Cancer Center	Received contact from webinar
Holden Comprehensive Cancer Center University of Iowa	Received contact from webinar	The Tisch Cancer Institute at the Mount Sinai Health System	no contact
Cancer Center at Illinois	no contact	Upstate Cancer Center SUNY Upstate Medical University	Received contact from AACI
Cardinal Bernardin Cancer Center Loyola University Medical Center	Received contact from AACI	Case Comprehensive Cancer Center	Received contact from AACI
Purdue University Center for Cancer Research	no contact	The Wistar Institute	no contact
UK Markey Cancer Center	Received contact from webinar	Hollings Cancer Center Medical University of South Carolina	Received contact from webinar
UofL James Graham Brown Cancer Center	no contact	Comprehensive Cancer Center St. Jude Children's Research Hospital	Received contact from AACI
Feist-Weiller Cancer Center LSU Health Shreveport	Received contact from AACI	LIVESTRONG Cancer Institutes The University of Texas at Austin Dell Medical School	no contact
Stanley S. Scott Cancer Center	no contact	Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine	Received contact from AACI
Boston University Cancer Center	Received contact from AACI	Mays Cancer Center UT Health San Antonio	Received contact from AACI
Murtha Cancer Center at Walter Reed Bethesda	Received contact from AACI	University of Texas Medical Branch Cancer Center	Received contact from AACI
The Jackson Laboratory Cancer Center	no contact	University of Virginia Cancer Center	Received contact from AACI
University of Michigan Rogel Cancer Center	Received contact from webinar	The University of Vermont Cancer Center	Received contact from webinar
Masonic Cancer Center University of Minnesota	Received contact from AACI	Fred Hutchinson Cancer Research Center	Received contact from webinar
UMMC Cancer Center and Research	Received contact from AACI	WVU Cancer Institute	Received contact from webinar

