Workload Prioritization in Clinical Trials

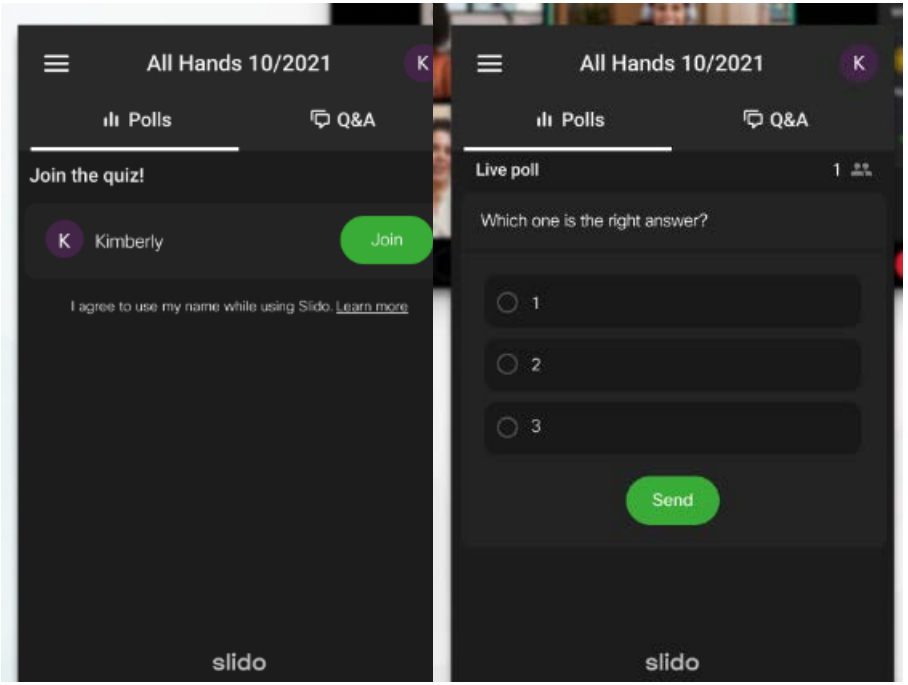
Disclosures:

SWOG plans to offer CEU credit for participation

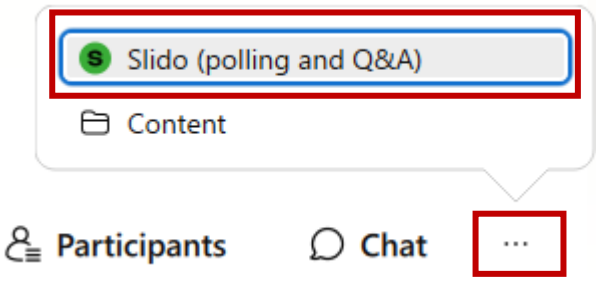
- This activity will be submitted to the Maryland Nurses Association for approval to award contact hours. Maryland Nurses Association is accredited as an approver of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation.
- To receive 1.5 CEU contact hours via webinar attendance, participants must:
  - Login with CTEP credentials and "Enroll" to the SWOG ExpertusOne Course via the following link: QA webinar-Workload Prioritization in Clinical Trials *prior to* the start of the webinar. We recommend enrolling by September 5, 2024. After enrolling, participants will receive a system-generated calendar invite with a link to the course.
    - On 9/6/24: Individually log in to the webinar *via the join link* in the SWOG ExpertusOne Course. Verify that your name is appearing correctly in the WebEx.
  - Attend the entire educational activity and then complete and submit the self-evaluation form via Survey Monkey, identifying two strategies to assist in managing their workload.
    - The link to the post-activity evaluation will be provided via WebEx chat message at the conclusion of the webinar.
- CEU certificates will be batch-issued to all attendees who completed the post-activity evaluation within approximately one week after the webinar.
- Note: Participants who are not able to participate in the entire webinar due to any reason will be able to subsequently review the content and meeting recording online via a separate course link (to be published after the webinar) and complete the post-activity evaluation to obtain 1.5 CEU contact hours via completion of the online course.
- No one with the ability to control content of this activity has a relevant financial relationship with an ineligible company.
- For questions about SWOG ExpertusOne Course access, contact training@swog.org.

Polling questions through Slido

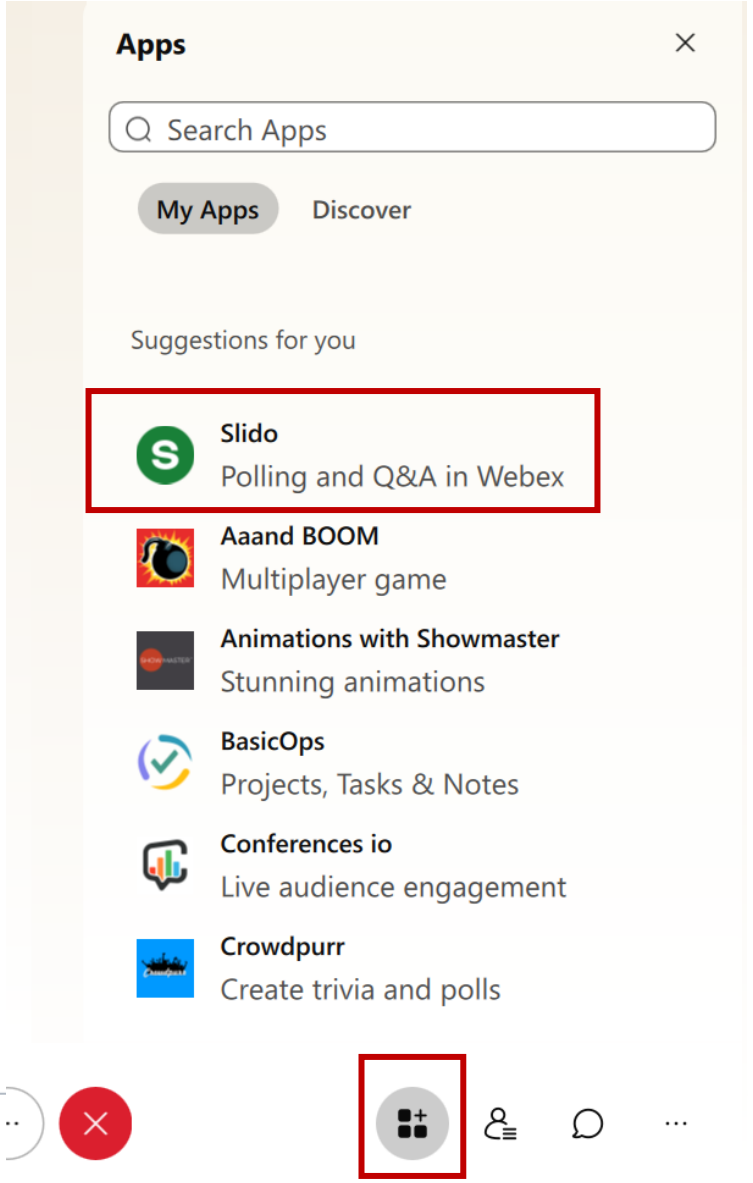
- Slido Panel should pop-up when the poll is launched, where you can join the poll and “send” your response.



- If the panel does not pop-up: Go to the “3 dots” menu and then select “Slido (polling and Q&A)”



- OR, if Slido does not appear under the 3 dots menu, Go to: **Apps >> Slido >> Active session**



What type of institution do you work at?

Vecteezy.com

A. Lead Academic Participating Site (LAPs)

B. Member Institution

C. Affiliate Site

D. NCI Community Oncology Research Program (NCORP)

E. Component of NCORP

F. Other

What research task is the most difficult to keep up with?

https://theresiliencysolution.com/how-to-reduce-stress-at-work/

A. Regulatory (study start up, amendments, etc.)
B. Reporting requirements to the IRB
C. Reconsenting
D. Data Entry
E. Specimen submission
F. Subject coordination
G. Drug accountability
H. 2 or more of the above and more

Are you currently or have you previously been involved in conducting workload assessments at your site?

- Yes
- No

Assessing Clinical Trial Workload

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Nurse Consultant

Division of Cancer Prevention, NCI

Objectives

- Background
- Why assess workload?
- Literature review
    - Pilot Project
    - Take aways
- CT sponsor effort

Background

- Trials are becoming more complex:
  - Over last 10 years average complexity scores increased > 10% *(Markey, et.al)*
  - Between 1999 – 2005:
    - Number of procedures increased 6.5% annually
    - Frequency of procedures increased 8.7% annually
    - Median number of CRF pages increased from 55 to 180 *(Getz, et.al.)*
- Consequences of increased complexity results in:
  - longer timelines to get treatments to patients,
  - higher likelihood of protocol changes,
  - higher patient and investigator *(AND Staff)* burden,
  - increase chances of errors and biases,
  - and challenges to replicate in the future. *(Markey, et.al.)*

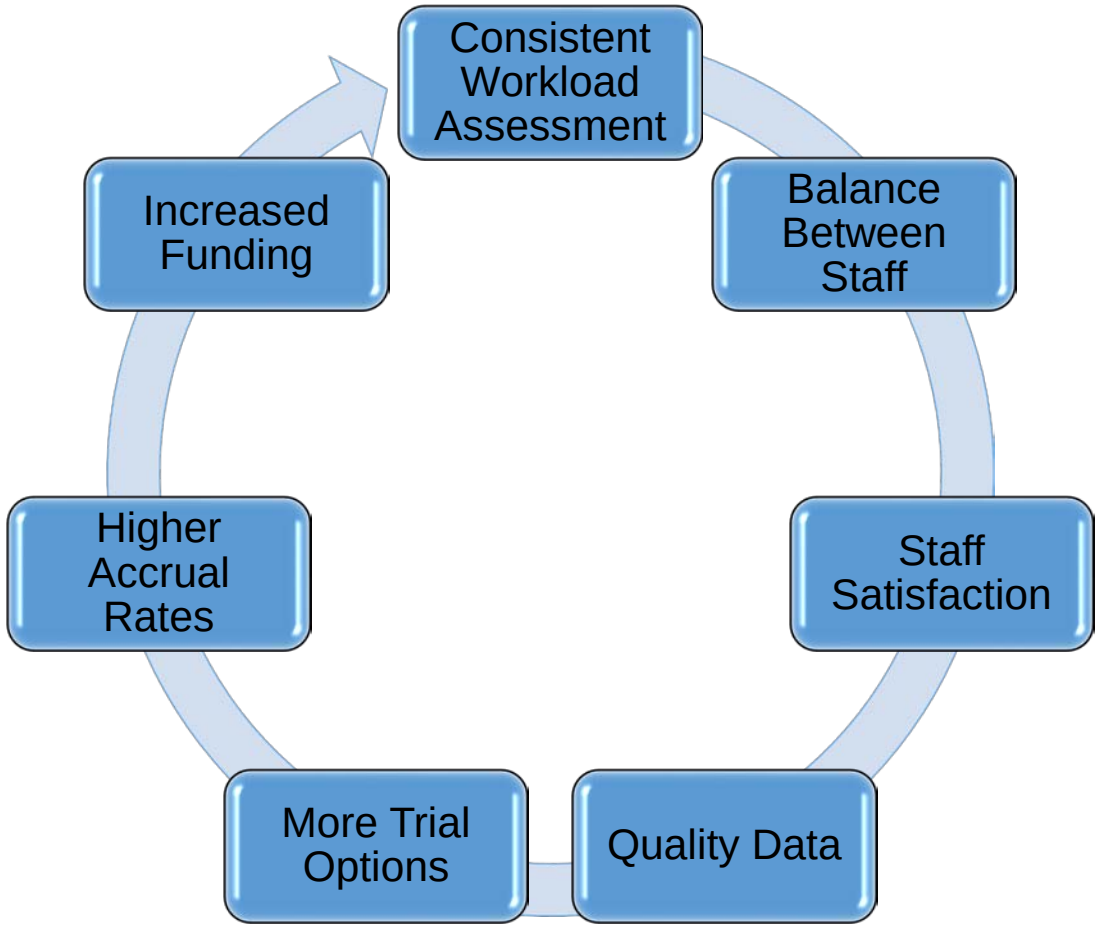
Research Staff Impact

- Many challenges associated with managing trials:
  - Institutional/investigator push to activate trials to meet patient populations
  - Insufficient staff/continual staff turnover
  - Lack of available qualified professionals
  - Competition with local CROs/research entities
- Research programs:
  - Need to work efficiently & effectively
  - Prevent burnout & turnover
  - Maintain data quality

Why Assess Clinical Trial Workload?

- Have actual metrics of research staff effort (not just statements “I’m overwhelmed”)
  - Provide validation of need for more staff
  - Budget justification (institution, grant applications, etc.)
- Tool for staff management
  - Assess and ensure equal distribution of work
  - Change in metrics over time / Signals indicating reaching maximum effort
  - Staff-specific issues (accruing patients, knowledge gaps, etc.)
  - Monitor data submission delinquency
  - Interim and annual performance reviews

Implications for Assessing Clinical Trial-Associated Workload



Literature Review Summary

Name	Pub Year	Model/Focus/Metric	Findings
Fowler & Thomas Acuity Rating Tool (Research Practitioner 4(2):64-71. 2003)	2003	Points assigned to protocol tasks. Time in hrs/protocol task X # points = score	500 – 750 points/coordinator 3 – 7 trials per coordinator
NCI Trial Complexity Elements & Scoring Model(http://ctep.cancer.gov/protocolDevelopment/docs/trial_complexity_elements_scoring.doc)	2009	Points assigned for each of 10 elements Standard complexity = 0 pts Mod complexity = 1 pt High complexity = 2 pts	None reported
US Oncology Research Study Clinical Coordination Grading (Unpublished. Personal communication)	2009	Points assigned to each of 21 grading criteria. Complexity based on number of points (↑ points = ↑ score)	None reported
Ontario Protocol Assessment Level (OPAL) (Smuck, et al: JOP 7(2):80-84. 2011)	2011	Score of 1-8 assigned based on # of contact events, type of trial	None reported
University of Michigan – Research Effort Tracking Application (RETA) (James, et al: J of NCCN 9(11):1228-1233. 2011)	2011	Staff logged daily time spent per protocol tasks	70-75% staff time = trial-related tasks 25-30% = non-trial (vacation, mtgs, etc) 72% of DM effort ->opening studies 25% effort ->not yet open/closed
Wichita CCOP Protocol Acuity Tool (WPAT) (Good, et al: JOP 9(4):211-215. 2013)	2013	Trials ranked 1-4 based on 6 complexity elements	Data collected over 10 years * Yrly average Acuity Score per nurse: Tx=30.6; CC=37.8;Off S=15.9 * Yrly average Pts per nurse: New enrollments=69;On S=103;Off S=97
Assessing Clinical Trial-Associated Workload in Community-Based Research Programs Using the ASCO Clinical Trial Workload Assessment Tool (Good, et al: JOP 12(5):e536-e547. 2016)	2016	Trials ranked 1-4 based on 6 complexity elements	Reported acuity scores among 5 groups: CCOP/MB-CCOP with ≤ 7 FTE; CCOP/MB-CCOP > 7 FTE; Community-based hospitals; Private practice, not hospital-based; Private practice, hospital-based

Literature Review Summary

Name	Pub Year	Model/Focus/Metric	Findings
Richie, et al. (Mayo) Trial complexity & Coordinator Capacity https://acrpnet.org/2020/02/11/establishing-the-link-between-trial-complexity-and-coordinator-capacity	2019 & 2020	11 study elements and 3 levels of effort; minimal (1 pt), moderate (2 pts) & maximum (3 pts). Scores for each element also weighted to account for those elements having a stronger impact on complexity.	Ideal workload for CRC = Score 375 – 400 points. Now have a foundation to base budget upon to address trial feasibility and discussions with study PIs to request additional funding support.
Markum Jones, et al. (England/Scotland) Evaluating follow-up and complexity in cancer CT (EFACCT) https://pubmed.ncbi.nlm.nih.gov/32075839/	2020	Effort to define complexity/workload to inform development of a workload assessment tool (TRACAT). 14 trial rating indicators reported	Enhanced communication, interoperability, funding and capacity emerged as key priorities.
Fabbri, et al. (Italian) How many trials can a CRC manage? The Clinical Research Coordinator Workload Assessment Tool (IWAT) https://pubmed.ncbi.nlm.nih.gov/32936710/	2021	3 sections: Protocol, On-Treatment, Follow up. Protocol: Promoter, frequency of visits On treatment: # of centralized procedures, setting, frequency of on-site patient access. Follow up: # of centralized procedures	IWAT score for each study range 20 – 930. Score of 500 – 600 considered an appropriate value for full time CRC.
Sadiq, et al. (Canadian) Development of Enhanced CT Workload Assessment Tool: The BC CT Complexity Tool.(BC-CT2) https://www.aaci-cancer.org/Files/Admin/CRI/2023/37-Development-of-Enhanced-Clinical-Trial-Workload-Assessment-Tool-BC-Clinical-Trial-Complexity-Tool.pdf	2023	3 sections: Protocol, Screening/On study, Follow up. Each subcategory has range of scores. Protocol: Phase, type of intervention, # of arms, degree of coordination, complexity of treatment, frequency of monitoring visits, patient enrollment feasibility. Screening/On study: ICF process, randomization steps, length of treatment, frequency of pt visits, extra trial procedures (outside of SOC). Follow up: Frequency, # of FU activities	Tool found to be simple and easy to use. Actual data not provided. Next steps will be to validate the tool.
Chehal, et al. (Miami) Assessing CT Complexity & Clinical Research Team Capacity by Sylvester Workload Assessment Tool (SWAT) https://www.aaci-cancer.org/Files/Admin/CRI/2024/63---Assessing-Clinical-Trial-Complexity-and-Clinical-Research-Study-Team-Capacity-by-Sylvester-Workload-Assessment-Tool.pdf	2024	10 elements each divided into 3 sub-levels 0, 1, 2, or 3. 0 = no effort.	Scores: 1 – 10 = minimal effort suited for CRC 1 11 – 20 = moderate effort suited for CRC 2 ≥ 21 = maximum effort suited for CRC 3
Gasperoni, et al. (Switzerland) **Pharmacy** Workload in CT Management: A Preliminary Complexity Assessment Tool for Sponsored Oncology and Haematology Trials. (Pharm-CAT) https://pubmed.ncbi.nlm.nih.gov/38785499/	2024	15 items divided into 3 sections: Study design, drug management and drug preparation	Low complexity scores = 0 – 19 Medium complexity = 20 – 25 High complexity = > 26

ASCO Workload Assessment Tool (2015)

1. **Evaluate protocol for workload-related elements:**
   - Complexity of treatment,
   - Trial specific laboratory and/or testing requirements,
   - Treatment toxicity potential,
   - Data forms required (consider complexity and number of forms),
   - Degree of coordination required (involvement of ancillary departments, outside offices/sites and/or disciplines)
   - Number of randomizations/steps.
2. **Assign a score utilizing a range of 1 – 4 as follows:**

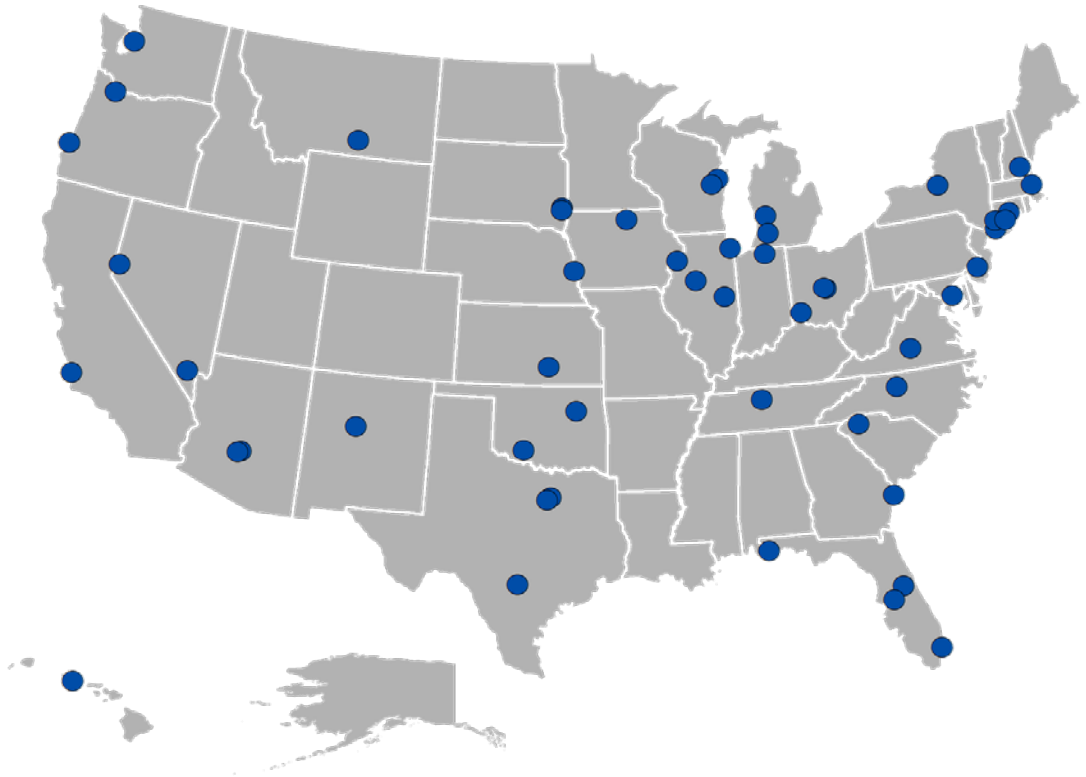
Score	Scoring Criteria
1	• Observational/Registry trial
2	• Testing oral agents with minimal toxicity • Tests/procedures considered standard of care • Data forms require basic information easily captured from medical record • Requires minimal coordination with outside and/or ancillary staff • Non-randomized or single randomization (May include standalone laboratory/correlative science studies, cancer control symptom management trials and hormone therapy trials)
3	• Testing chemotherapy and/or radiation therapy regimen (may include high toxicity potential oral agents) • Increased toxicity potential when compared to a score of “2” • Involves non-standard of care "research" tests/procedures • Data forms more complex and higher in number • Requires coordination with 1 - 2 other disciplines/ancillary departments • Single time point, randomized Phase II or III (Includes most randomized Phase II & III treatment trials)
4	• Very complex • Multiple drug regimens • High degree of toxicity potential • Involves multiple non-standard of care "research" tests/procedures • Data forms more complex, daily to weekly data collection required and higher in number • Requires coordination with $\geq$ 2 disciplines/ancillary departments • Multiple randomizations and/or steps (i.e., bone marrow transplant, leukemia, lymphoblastic lymphoma, myeloma trials)

ASCO Workload Assessment Tool: Two Acuity Metrics

- **Protocol Acuity Score**
  - Scored 1 to 4 (Per Protocol Acuity Scoring Worksheet)
    - On Study/On active treatment
    - Follow-up (assumed 1)
      - On Study/Off active treatment
      - Off Study
- **Nurse/CRA Acuity Score (Patient Centered Effort)**
  - Calculation
    - protocol acuity score x number of patients
      - Individual Nurse/CRA FTE

ASCO Workload Assessment Project Participating Sites

- 51 completed 6 months of data collection
  - May through November 2013



5 Groups based on type and size

1. Group 1: CCOPs/MBCCOPs ≤ 7 FTEs (13)
2. Group 2: CCOPs/MBCCOPs > 7 FTEs (10)
3. Group 3: Community hospitals/NCCCPs (8)
4. Group 4: Non-hospital-based private practice/private research networks (12)
5. Group 5: hospital-based private practice (7)

Results

- Acuity scores for staff with patients on study receiving treatment higher than FU
- Treatment trials higher acuity than cancer control, observational/registry & prevention
- Industry trials higher acuity than NIH/NCI, academic and other
- Evidence suggests trial acuity better measure of workload than number of patients

Good, et al. Journal of Oncology Practice, 2016. 12(5):e536-e547

ASCO Workload Assessment Tool Status

- Total Registrants (8/15/19): 403 unique sites
  - United States: 371
  - International: 32
    - Australia, Brazil, Canada, Chile, China, India, Ireland, Italy, South Korea, Spain, Saudi Arabia, Thailand, United Kingdom, Switzerland
  - Community-based: 253
  - Academic: 116
  - Other (e.g., government, etc.): 34
- No longer available
  - Required updating to be more reflective of current trials, other aspects of CT work
    - Budget would not support
  - Usage reduced/limited
    - Too many steps? Limited time to complete?
  - Participating sites were able to export data to continue locally
- Ways to assess staff CT-associated workload still requested
  - How to monitor easily and consistently while providing useable information?

Fabbri, et. al. (2021>Italian – “IWAT”)

Category	Sub-Classification	Score
# Centralized Procedures*	0	0
	1	1
	2	3
	≥ 3 or Phase I	5
Setting	Adjuvant – only hormone	0.5
	Prospective observational	1
	Adjuvant with CHT	3
	Advanced	5
Frequency of on-site pt access	Every 9 weeks or more	1
	Every 2 – 8 weeks	3
	Every 13 days or less	5

* Requires collection & shipment of tumor tissue or central laboratory sample, ECG traces and/or imaging reports, etc.

Sadiq, et. al. (2023 > Canadian - BC-CT2)

Category	Sub-Classification	Score
Type of Intervention	Pragmatic Trial Design	0.5
	Non-therapeutic Intervention	1
	Therapeutic treatment	5
Length of Treatment	N/A (non-therapeutic)	0
	Single occurrence	1
	Set number of treatment cycles or SOC therapy	3
	Treatment until progression/prolonged tx reg	5
Frequency of visits	Daily to weekly	5
	Q2 – 3 weeks	3
	Q4 – 7 weeks	1
	Q 8+ weeks	0.5
Frequency of FU	Monthly	3
	Q 3 months	1
	Q 6 months or more	0.5

Richie, et al. (2020 > Mayo Clinic Florida)

Category	Sub-Classification	Score	Weighted Score
Informed Consent Process (# of pages)	1 – 10	1	1.3
	11 – 19	2	
	> 20	3	
Eligibility Criteria	1 – 10 criteria	1	1.6
	11 – 20 criteria	2	
	> 21 criteria	3	
Screening procedures for eligibility*	1 – 5	1	1.3
	6 – 10	2	
	> 10	3	
Procedures after baseline/randomization**	1 – 10	1	1.6
	11 – 20	2	
	> 20	3	

* Done after ICF signed and before start of treatment. Example: 1) One lab draw with 5 studies would count as 2 procedure. 2) If needs to go to separate labs, would be counted separately.
** Each set of labs, EKGs, etc. all count separately.
Weighted Score = Based on category's impact on complexity of effort. Ranged from 1.2 – 1.7. Less complex/less time consuming multiplied by 1.2 (e.g., type of study recruitment). Most complex/time consuming multiplied by 1.7 (e.g., AE reporting)

Gasperoni, et al. (2024 > Pharmacy Workload - Pharm-CAT)

Category	Sub-Classification	Score
Type of Drug	Oral	2
	Injectable	3
Number of Drugs	1 drug	1
	2 drugs	2
	≥ 3 drugs	3
Storage Conditions	Controlled room temp or under refrigeration	1
	Controlled room temp and under refrigeration	2
	Deep Freeze	3
Drug resupply	Automatic	1
	Manual	3
Dose Preparation	Ready-to-use	1
	Personalized dose	2
	Reconstitution of drug + personalized dose	3

Sponsor Level Assessment

NCI Effort to Assess NCI Clinical Trial Workload to Inform Funding Decisions

Why is NCI Division of Cancer Prevention (DCP) Assessing CT Workload?

- NCI DCP Purpose:
  - Compare funding across NCORP DCP Cancer Control trials
    - Assess for consistency
    - Does effort/workload match funding?
  - Standardize a method for scoring workload
    - Use scores to inform funding decisions for NCORP DCP trials

2021 NCI Workload Assessment Tool Criteria*

- Onboarding/start up effort
- Collaboration/Coordination required
- Credentialing/training
- Number of study arms
- Number of randomizations
- Complexity of intervention
- Frequency & length of intervention/treatment
- Type of agent/device
- Blinding
- Protocol-required visits/assessments
- Acuity of patient population
- Availability of study population
- Participant reported data
- Provider specific forms
- Data collection complexity
- Study design
- Participation in regular calls/webinars
- Requires access to atypical systems
- Length of follow up
- Central review required
- Non-standard of care study treatment/procedures
- Biospecimens (#, frozen/dry ice, batching, kits provided)
- QoL/PRO documents

*Derived from NCI Complexity Tool and Wichita/ASCO Workload Assessment Tools

NCI Workload Assessment Tool

Criteria	Criteria Description	Workload-Associated Activity	Potential Points
Onboarding/Start up effort	Effort associated with local site implementation process	Requires changes in standardized systems/processes (e.g., non-standard administration timing/ancillary therapy, specific EHR/EMR requirements, etc)	3
		Requires engagement of dept/staff unfamiliar with clinical trials	3
Collaboration/Coordination required	Non-oncology modalities/specialties will be required to implement trial and/or to have access to study population	1 modality/specialty	1
		2 modalities/specialties	2
		3 modalities/specialties	3
		≥ 4 modalities/specialties	4
Credentialing/training required	Additional training required such as neurocognitive testing, surgical procedure, radiology/radiation therapy procedures	1 type of training/credentialing	3
		≥ 2 types of training/credentialing (e.g., RT & Neurocog assessment)	4
Number of study arms		1	0
		2	2
		≥ 3	3
Number of randomizations/steps		One registration or randomization step	0
		Registration (Step 0) & randomization (Step 1) occurs in two separate steps	2
		Multiple randomizations/steps (> 2 steps, Step 0, 1, 2, etc)	3

Applying Workload Assessment: Did it Make a Difference?

- Pre-Implementation
  - 51 trials activated between 2014 – 2021
  - Average workload score ~ 25
    - Decision = trials ≥ 25 would receive full funding (exceptions applied to large sample size trials)
  - 38 funded at full funding score range = 9 – 37
  - 13 funded at lower funding levels
    - Scores ranged 12 - 34
    - 6 with scores 24 - 34 had large sample sizes
    - 7 with scores 12 - 29

- Post-Implementation
  - 20 trials activated between 2022 - 2024
  - Applied rule: trials ≥ 25 would receive full funding (exceptions applied to large sample size trials)
  - 11 funded at full funding with score range = 16 – 36
    - 1 trial with score = 16 activated in early 2022 prior to full implementation. Next highest score = 23.
  - 9 funded at lower funding levels
    - Scores ranged 13 - 37
    - 3 with scores ≥ 25 had large sample sizes
    - 6 with scores ≤ 18

NCI Workload Assessment Status

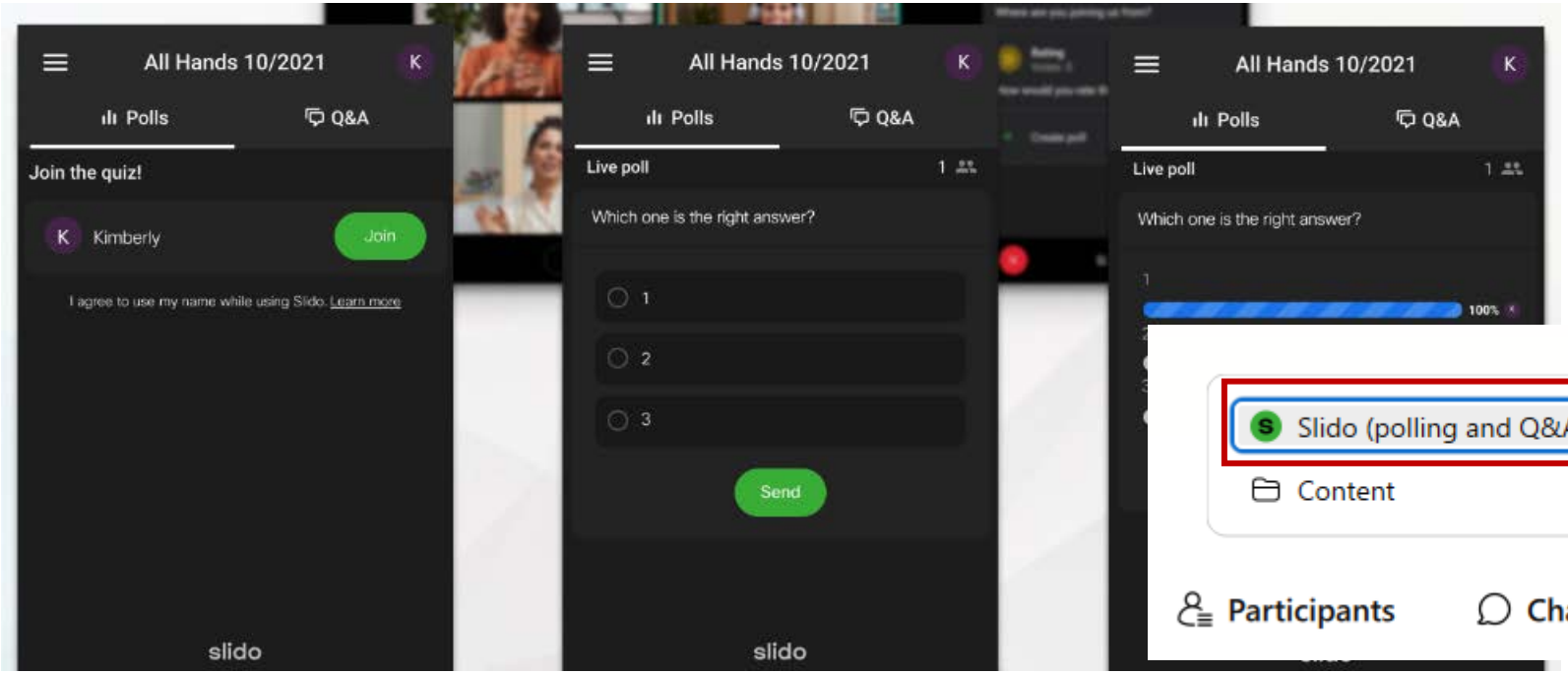
- In process of revising tool
- Why revise?
  - Literature review supports areas for improvement
  - Many criteria may be too subjective
  - Being done by single person; needs to be conducive to multiple users
  - Community & RB input not obtained with current version
    - Uncertain if capturing appropriate and sufficient criteria to reflect community-based workload
    - Research base insight needs to be applied

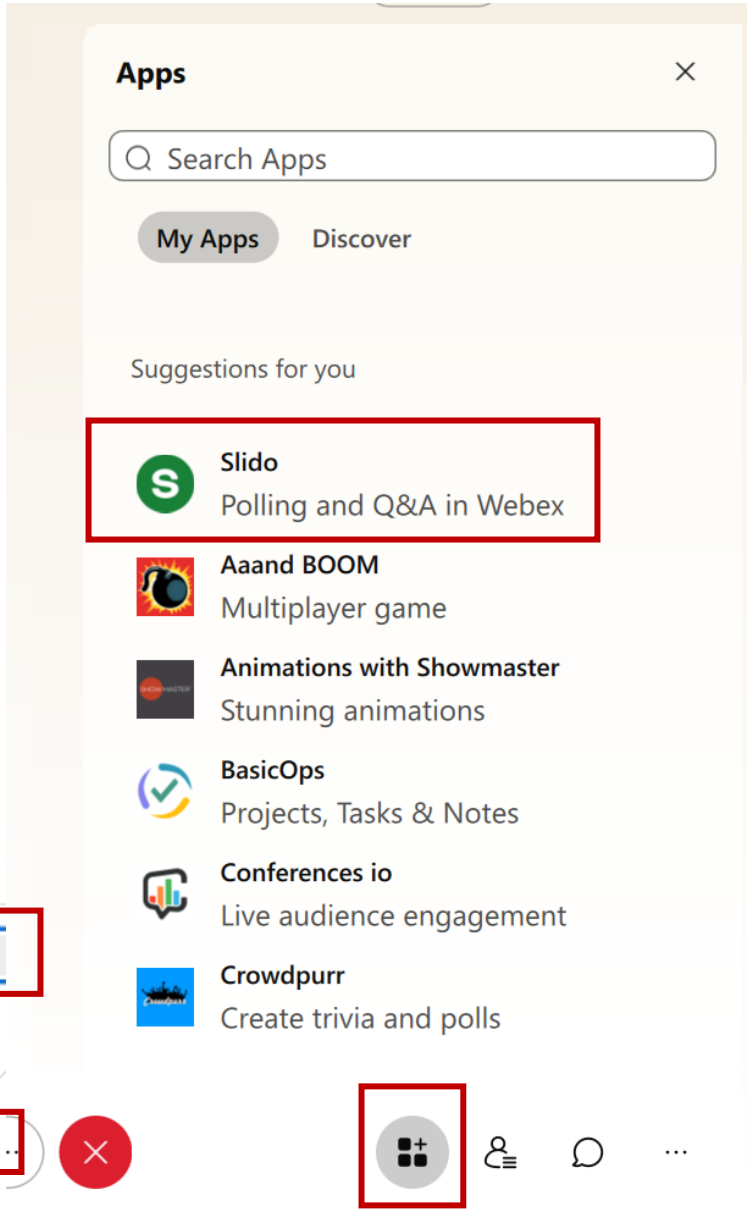

stay tuned...
More to Come!

Take aways:

- Each research site should be assessing staff workload on a consistent basis
- Need to “find the time” rather than not doing it because you are too busy
- Pick a tool or develop one that fits your situation
- Don’t just count patients. Protocol-specific complexity makes a difference.
- Use the data to inform/update leadership/administration
- Share it with your staff!
- Sponsors should also take trial complexity into consideration when designing & funding trials.

What tools have you implemented for workload assessments at your site that you have found useful?





Site Perspective

Gayatri Nachaegari, M.Pharm, CCRP

University of Utah Medical Center – LAPS

Tammie L. Mlodozyniec, BS, CCRP

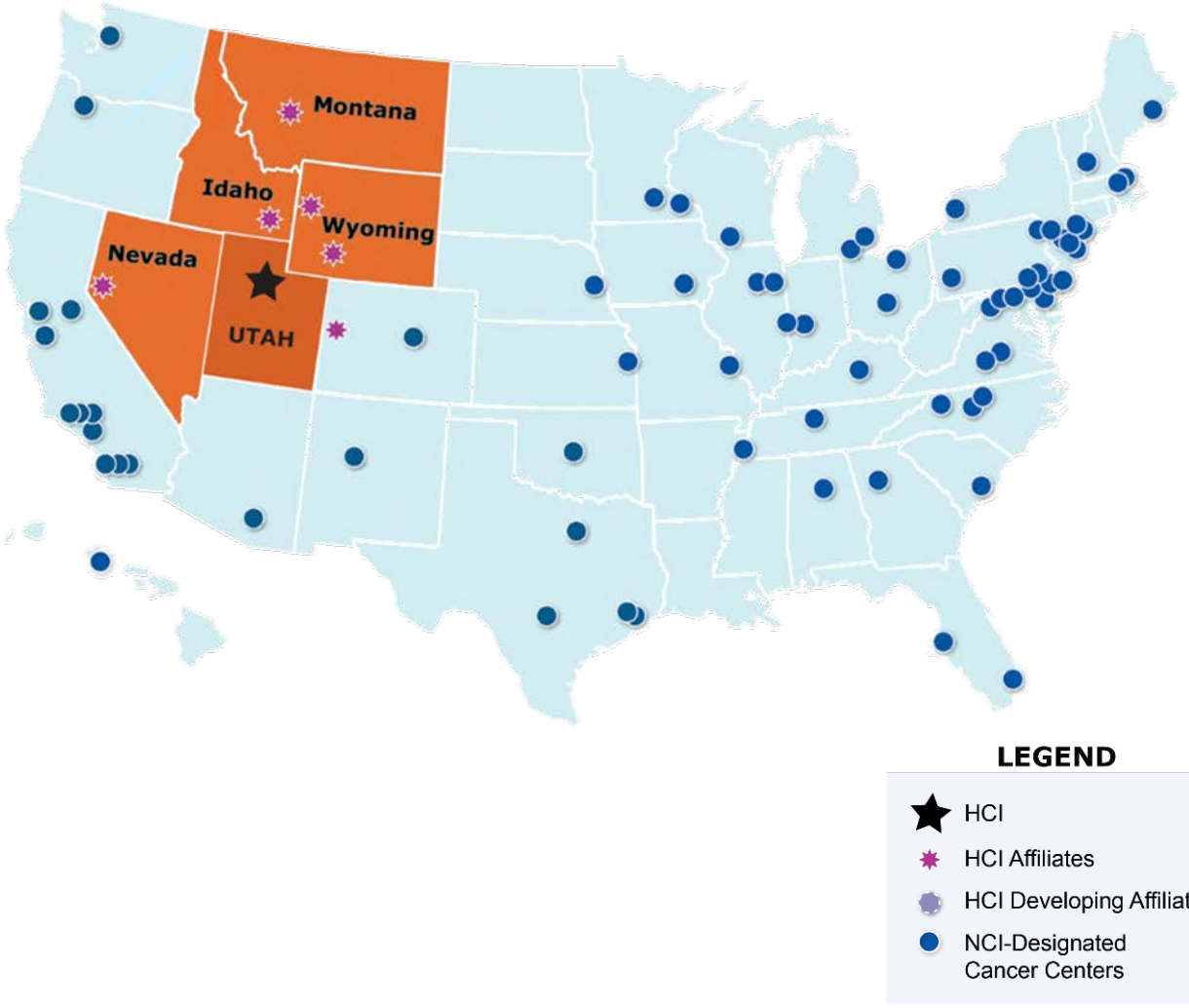
ESSENTIA Health NCORP


UNIVERSITY OF UTAH
HUNTSMAN
CANCER INSTITUTE
The National Cancer Institute-designated Comprehensive Cancer Center for Utah, Nevada, Montana, Wyoming, and Idaho.

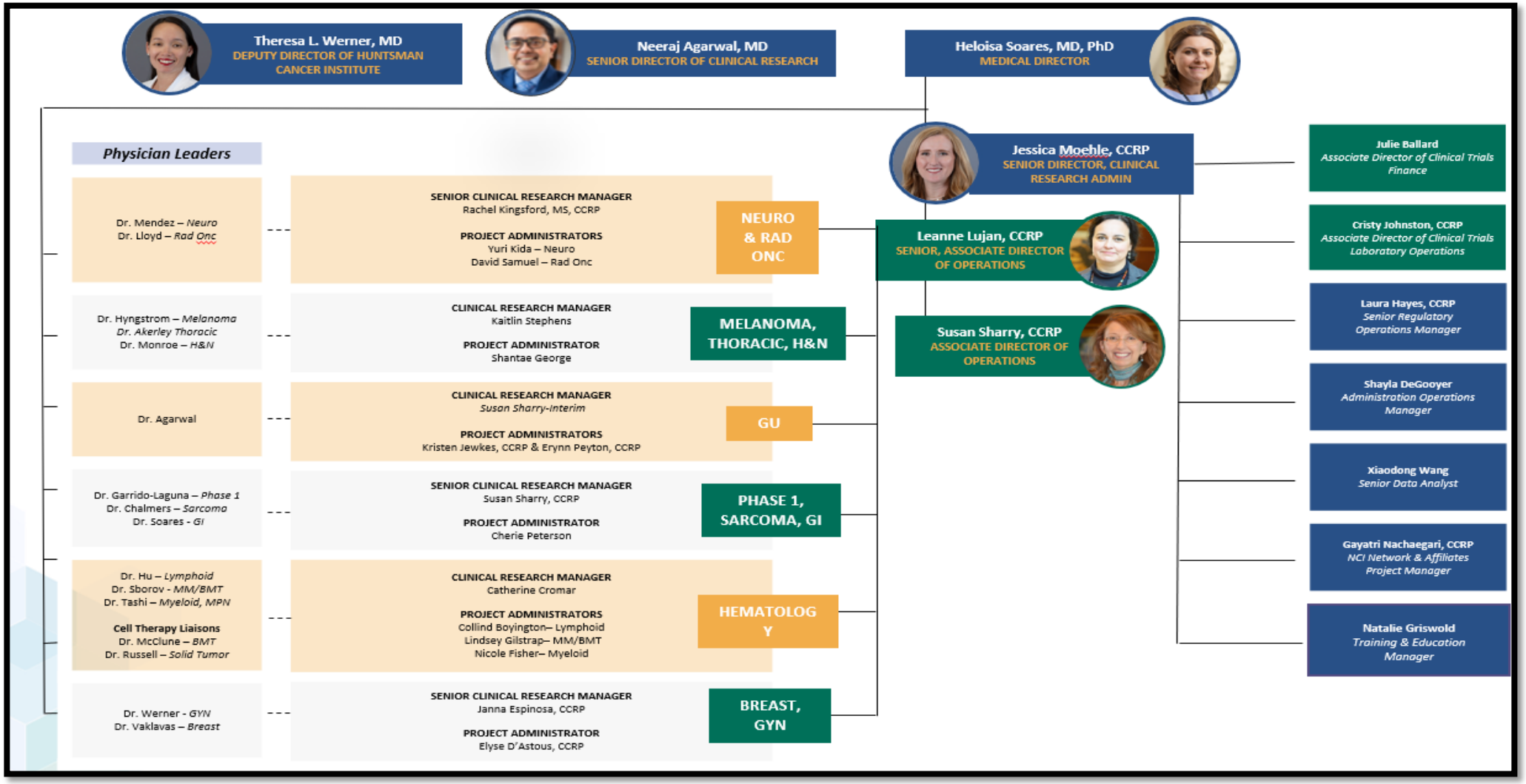
The Area We Serve

- HCI serves **17%** of the contiguous U.S. landmass (524,000 sq. miles)
  - Only NCI designated cancer center in the area
  - 10.3 million people
  - 43 American Indian nations
  - 35,000 annual cancer cases

- HCI has three satellite sites in Utah and six affiliate hospitals in the Mountain West to expand access to clinical services and clinical trials

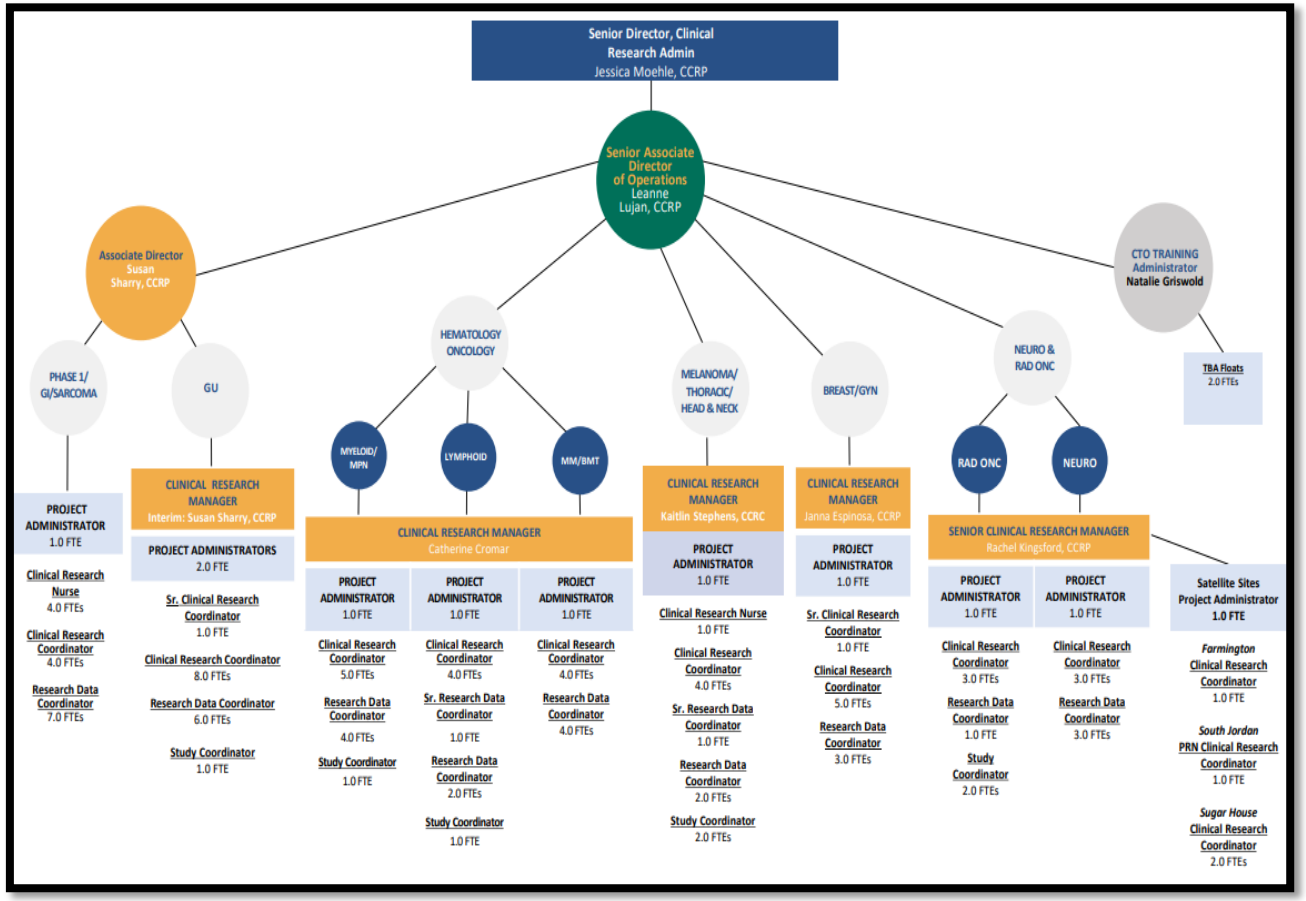


Our Leadership Team

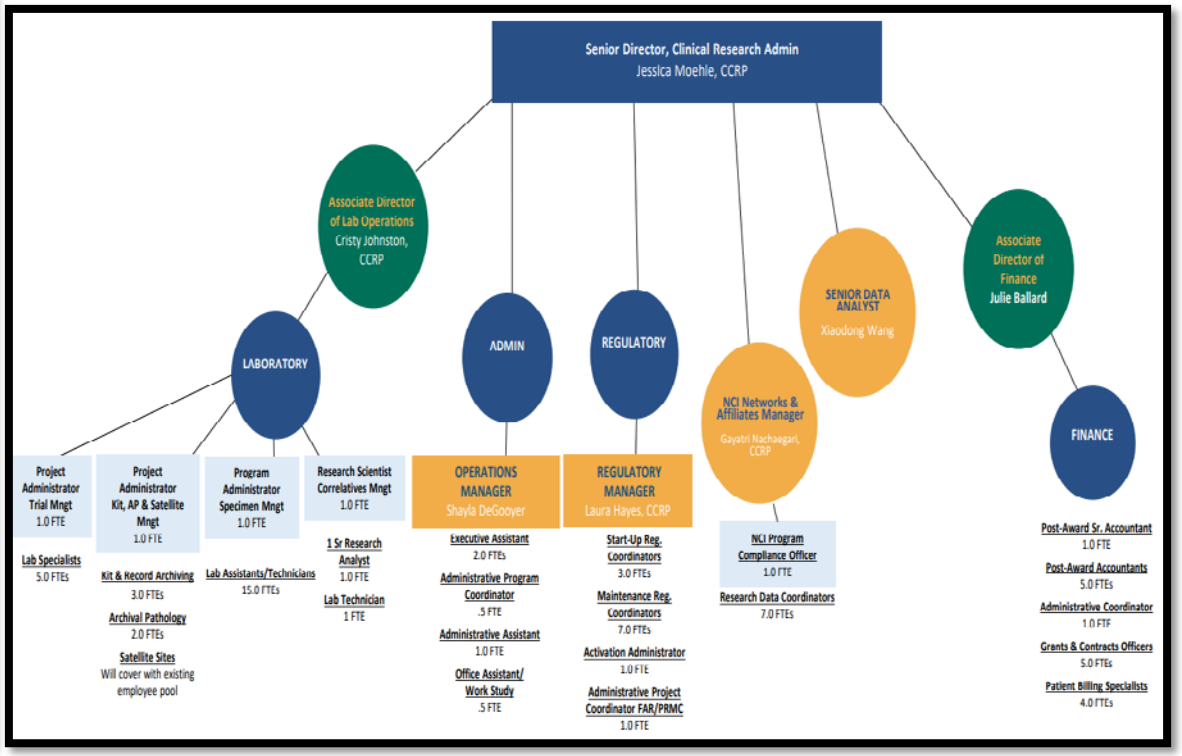


Our Clinical Trials Office of **174** staff

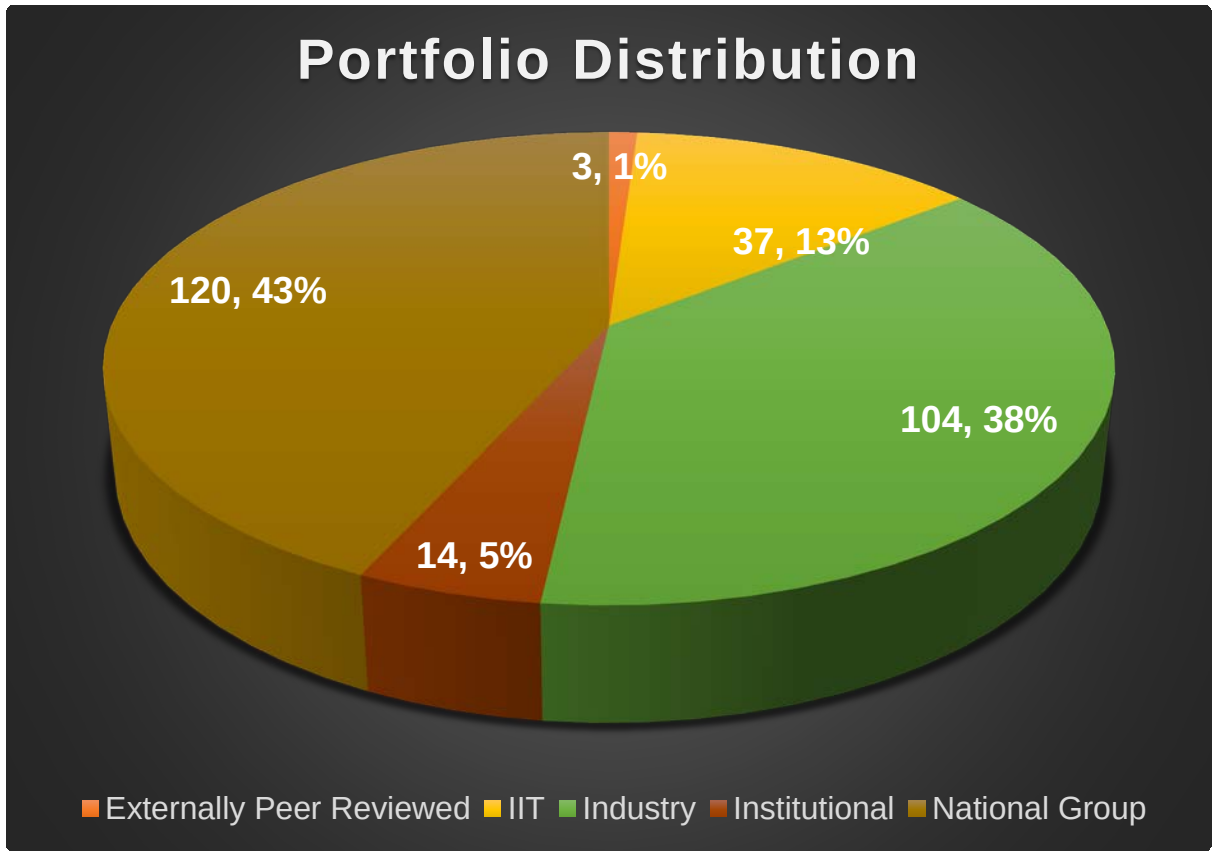
Coordination Org Chart

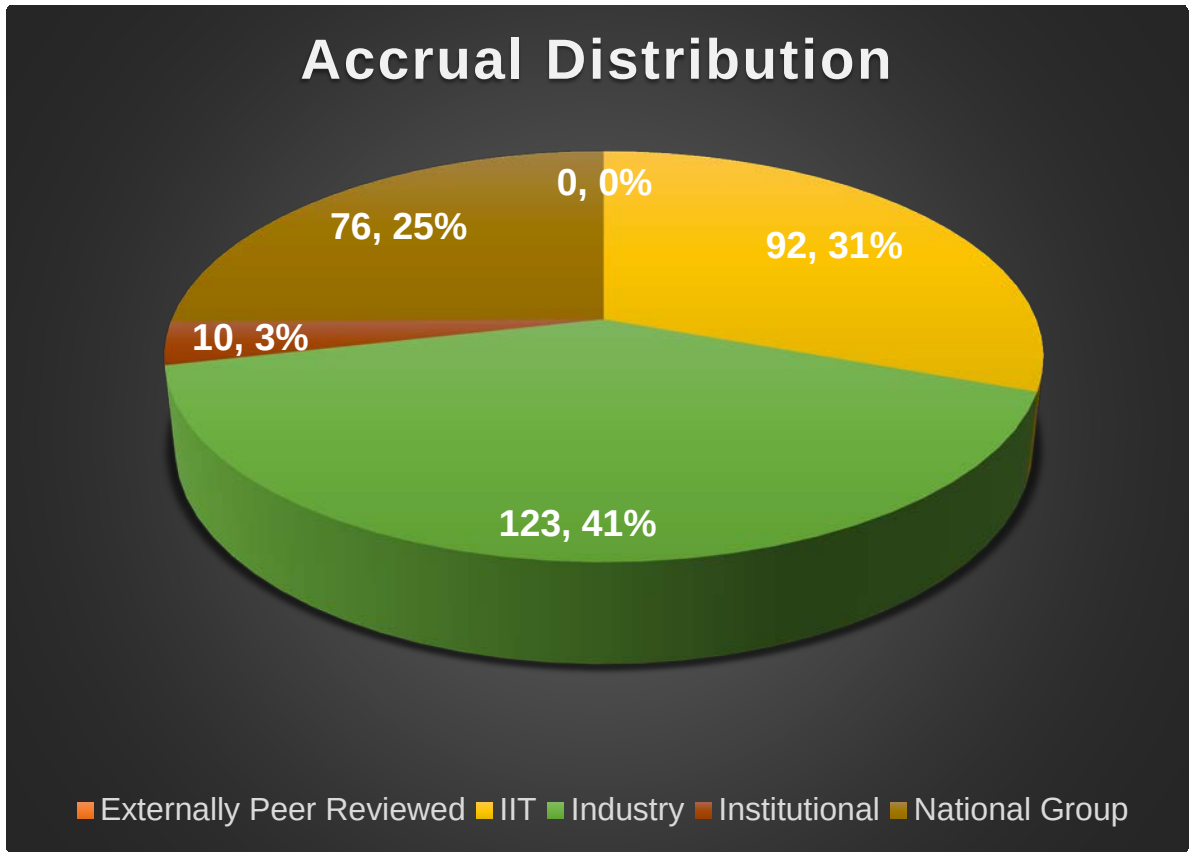


Operational Org Chart

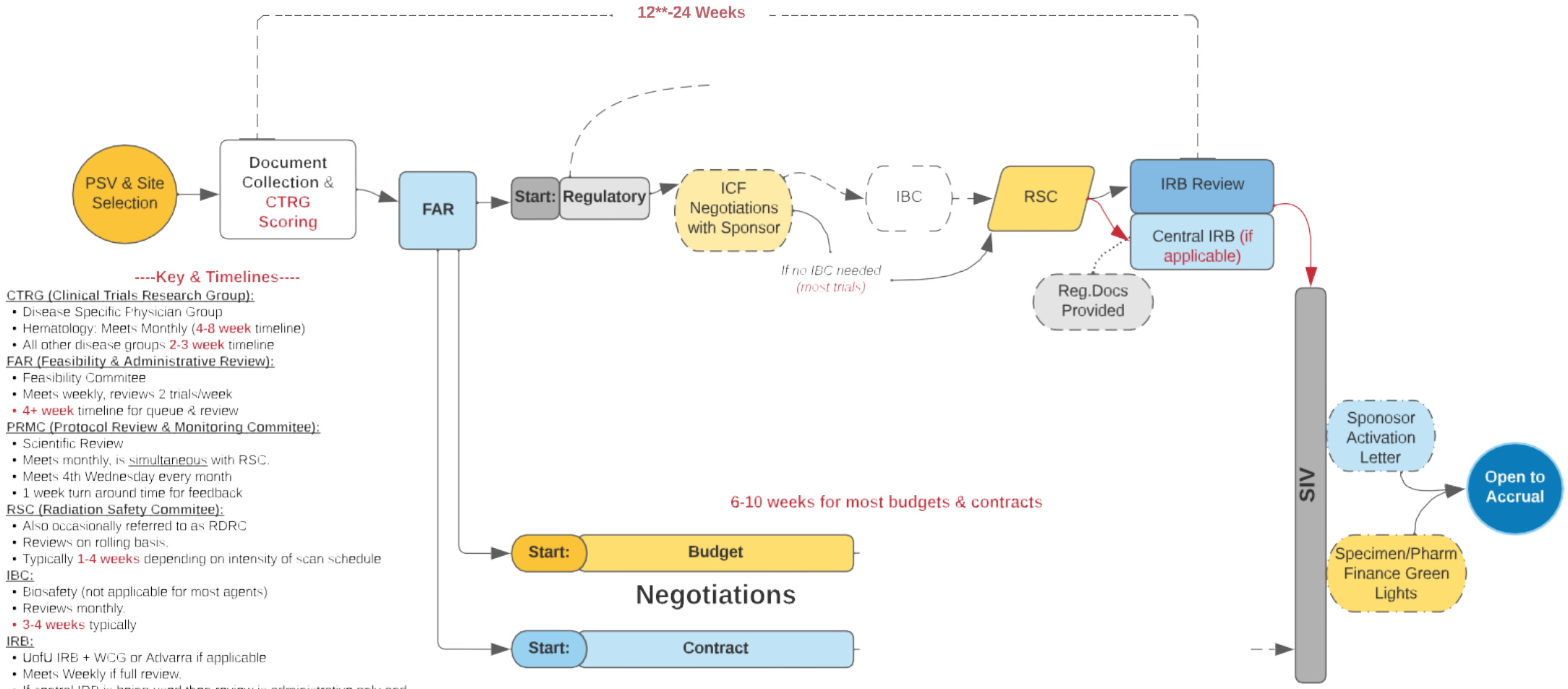


Trial Portfolio and Accrual

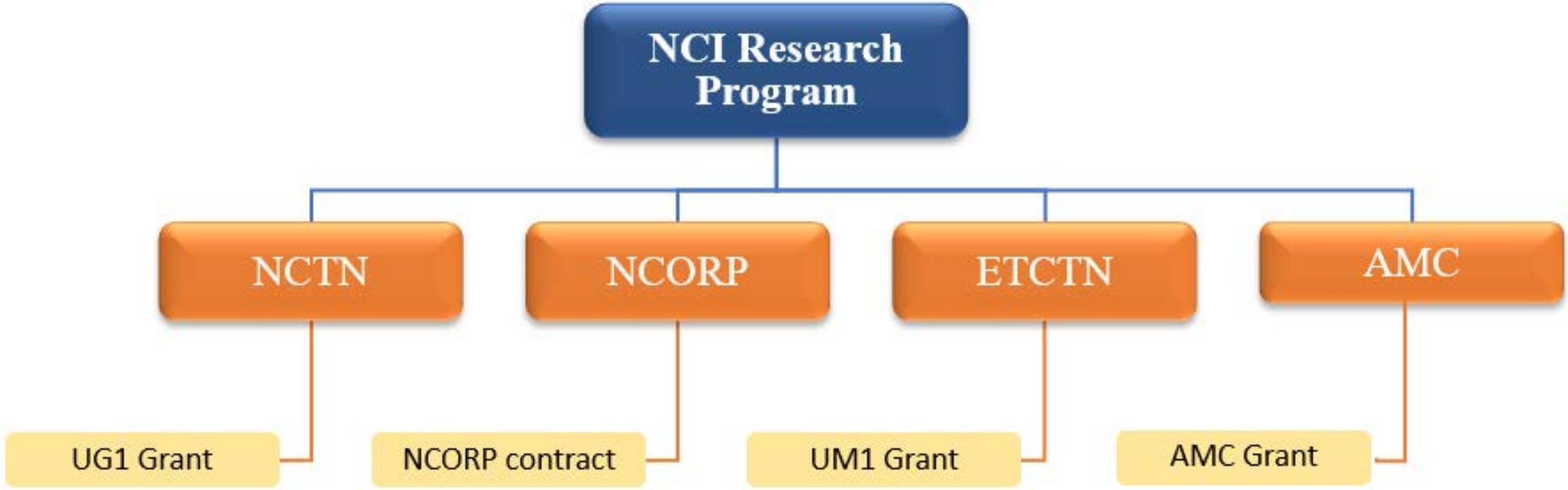




Overall Workflow



NCI's Programs & HCI Affiliation



National Cancer Institute (NCI)
National Clinical Trials Network (NCTN).
NCI Community Oncology Research Program (NCORP)
Experimental Therapeutics Clinical Trials Network (ETCTN)
Early Drug Development Opportunity Program (EDDOP)
The AIDS Malignancy Consortium (AMC)

NCI Program

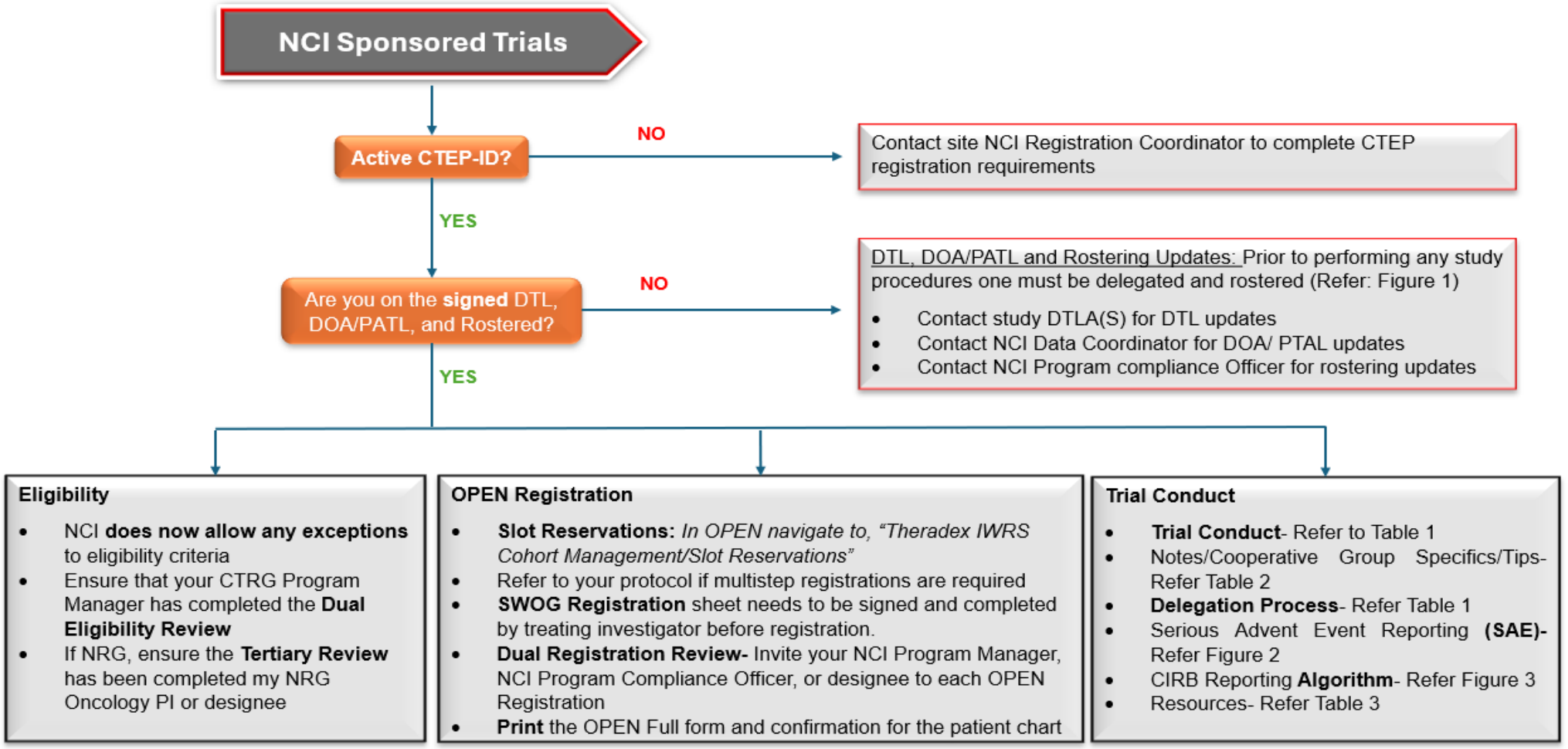
Includes:

- NCI Data Team: 7 Data coordinators
- NCI Compliance Office: 1 NCI Quality Assurance role
- NCI Networks & Affiliate sites Program Manager: 1 for oversight of team, grants and affiliate sites

Work On:

- Onboarding of new staff & Continuing education
- Weekly data expectation
- Quality reviews by Research Compliance Office
- Attending PI oversight meetings & disease group meetings
- NCTN & ETCTN Executive meeting

Workflow Tool



Thank you!

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Workload Prioritization in Clinical Trials

Tammie Mlodozyniec, BS, CCRP

Essentia Health NCORP

“Grace & Grit” Impact of COVID

- Forced us to look at current processes, streamline tasks, improve communication, embrace technology, be more efficient, have a back up plan, & “Grace & Grit”

Priorities

#1 Patient Safety

- Follow Protocol

#2 Team Members

- Keep learning
- Team Kudos
- Work Life Balance

#3 Program

- Commitment to Sponsors
- Commitment to Community
- Funding
- PI

Communication & Collaborating

- Prior to Opening Trial-Meet with Section Leaders
- Create a Recruitment Plan that Works for Everyone
- Create Study Specific Solicited AEs
- Lab Manager Create Lab Instructions
- Double Check Beacon Build Prior to Meeting with Committee
- Briefing Study with Team-Review Details
- Update Oncology Clinical Trials Booklet and Website

Onboarding New Team Members

- Onboarding Organizations Checklist
- Onboarding Research Checklist
- Training Manual
- Set up New Member with Mentor
- Have Mentor Double Check Work
- Follow SOPs for Training
- Remind them “When in Doubt, Give a Shout”

Data & Queries

- Check RAVE Weekly for Queries/Missing Data
- Forward Delinquent Data, Query, and Expected Data Reports Monthly
- Remind Team that Quality, Clean, On Time Data is Important
- Review ALL Deviations Weekly with Team

Resources Toolbox

- Research Base CRP Resources
- Dr. Okuno’s iRECIST
- Attend Trial Webinars
- SoCRA
- Attend Research Base Meetings

Prior QA Webinars Accessible for Review

Links to Previous Webinars and Upcoming Webinar Announcements are posted at: **SWOG Quality Assurance Live Webinar Series | SWOG**

CEU Courses in ExpertusOne:

- **Research Protocol Deviations vs Deficiencies** (1 contact hour)
- **Best Practices for Informed Consent** (1 contact hour)

Non-CEU Courses now in CLASS:

- **Adverse Event Reporting**
- **Serious Adverse Event Reporting**
- **SWOG Audits: Preparing for Success and Audit Process**
- **How to Develop a CAPA Plan**