Oncology Research Professionals (ORP) Site Operations Meeting

SWOG Fall Meeting 2022

Connie Szczepanek, RN, BSN, CCRP
Liz Edwards, BA, CCRP
Caitlin Hutchinson, MS

SWOG CANCER RESEARCH NETWORK
NCI National Clinical Trials Network
a National Cancer Institute program
NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

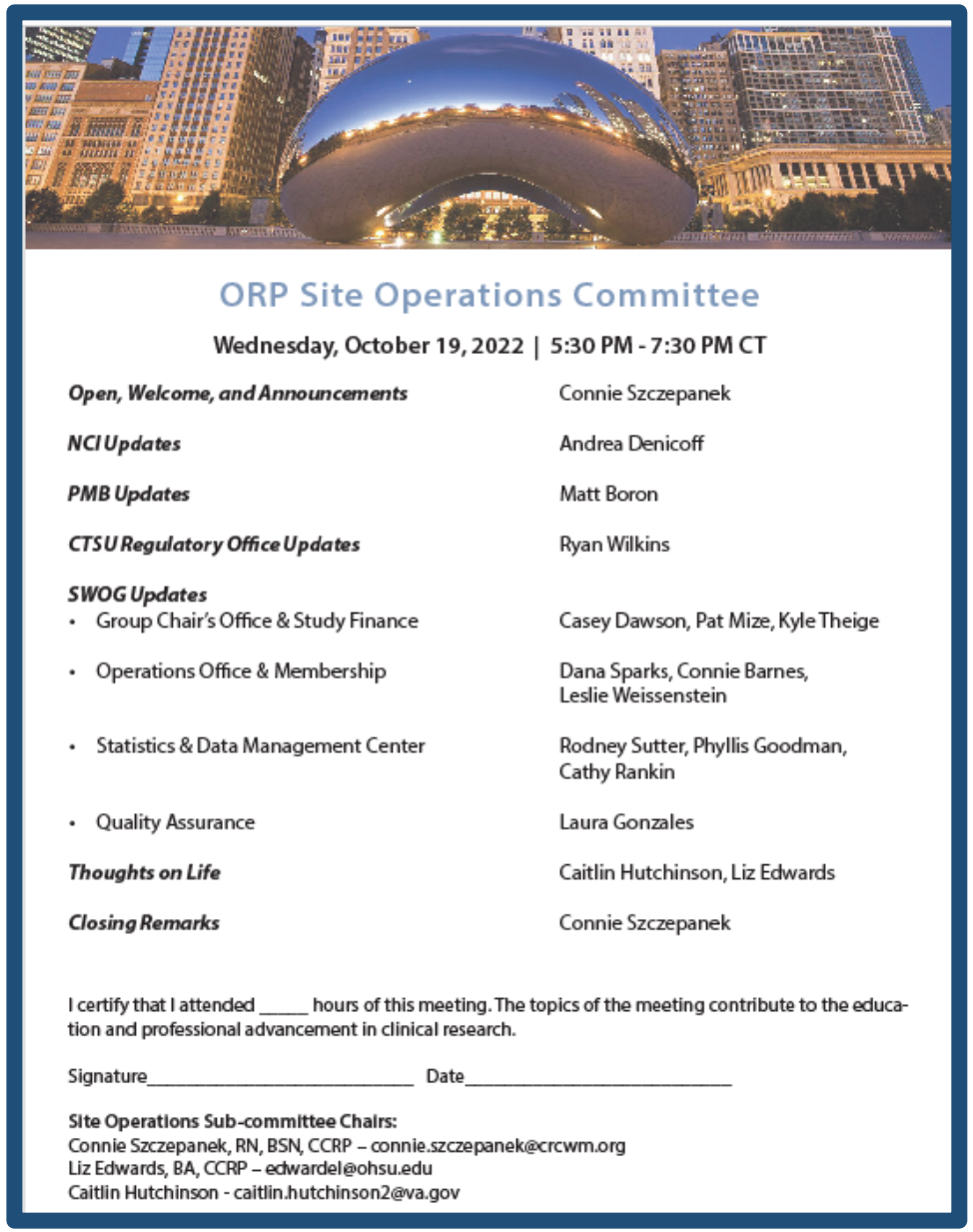
Logistics Details

- Please keep your phone on mute to help with sound quality.
- Questions can be submitted all throughout the meeting via the CHAT icon. We will present them to the speakers during the meeting.
- The presentations will be posted on the SWOG website within a few weeks.

FALL 2022 Site Operations Meeting Agenda
October 19, 5:30 – 7:30 PM CT

Open, Welcome, and Announcements	Connie Szczepanek
NCI Updates	Andrea Denicoff
PMB Updates	Matt Boron
CTSU Regulatory Office Updates	Ryan Wilkins
SWOG Updates	
*Group Chair's Office & Study Finance	Casey Dawson Pat Mize Kyle Theige
*Operations & Membership	Dana Sparks Connie Barnes
*Statistics & Data Management Center	Cathy Rankin
*Quality Assurance	Laura Gonzales
Thoughts on Life	Caitlin Hutchinson, Liz Edwards
Closing Remarks	Connie Szczepanek

- Although there are no formal CE credits for this meeting, you may print a copy of the agenda to reflect your attendance (e.g.: for use with SOCRA or ACRP).



ORP Site Operations Committee

Wednesday, October 19, 2022 | 5:30 PM - 7:30 PM CT

Open, Welcome, and Announcements	Connie Szczepanek
NCI Updates	Andrea Denicoff
PMB Updates	Matt Boron
CTSU Regulatory Office Updates	Ryan Wilkins
SWOG Updates	
• Group Chair's Office & Study Finance	Casey Dawson, Pat Mize, Kyle Theige
• Operations Office & Membership	Dana Sparks, Connie Barnes, Leslie Weissenstein
• Statistics & Data Management Center	Rodney Sutter, Phyllis Goodman, Cathy Rankin
• Quality Assurance	Laura Gonzales
Thoughts on Life	Caitlin Hutchinson, Liz Edwards
Closing Remarks	Connie Szczepanek

I certify that I attended _____ hours of this meeting. The topics of the meeting contribute to the education and professional advancement in clinical research.

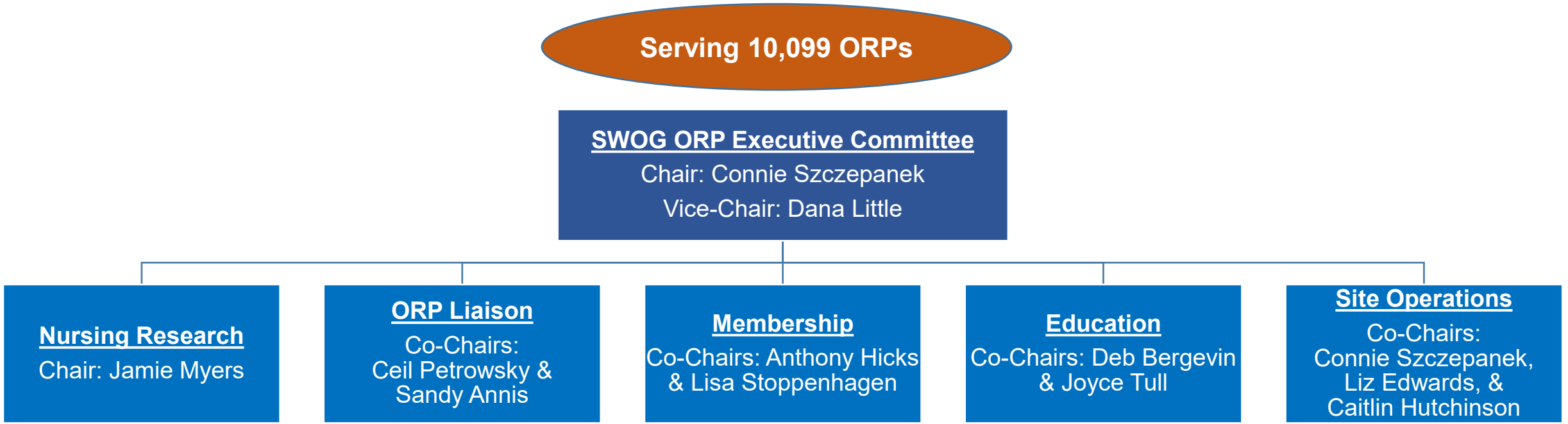
Signature_____ Date_____

Site Operations Sub-committee Chairs:
Connie Szczepanek, RN, BSN, CCRP – connie.szczepanek@crcwm.org
Liz Edwards, BA, CCRP – edwardel@ohsu.edu
Caitlin Hutchinson - caitlin.hutchinson2@va.gov

YOU are The ORP Committee!

"SWOG holds a fundamental conviction that the **O**ncology **R**esearch **P**rofessionals (ORP) play a crucial role in the successful development, implementation, and analysis of any SWOG clinical trial."

The SWOG Oncology Research Professionals (ORP) Committee & Sub-Committees



SWOG Cancer Research Network's Mission

- To significantly improve lives through cancer clinical trials and translational research.

ORP Committee Mission

- To support SWOG activities through promotion of integrity and excellence in clinical research through education, guidance, & collaborative contributions.

Acknowledgements

ORP Executive Committee Members	
Sandy Annis	Jamie Myers
Deb Bergevin	Joyce Nancarrow-Tull
Annette Betley	Ceil Petrowsky
Anthony Hicks	Lisa Stoppenhagen
Caitlin Hutchinson	Connie Szczepanek
Dana Little	

YOU are The ORP Committee!

To get more deeply involved, see the SWOG Website:

Member Resources / Membership / Committee Membership

https://www.swog.org/member-resources/membership/committee-membership

Key Involvement Opportunities

- Disease Specific Liaisons
- Liaisons at Large
- Education Team

The Role of an ORP Liaison

An ORP Liaison is a member of both the ORP Liaison Committee and a specific SWOG committee.

- **Reviews protocols in development** and provides feedback from a site and role perspective.
- Provides feedback to the SWOG Disease Committee after the study is activated addressing any **site implementation concerns**.
- Participates in **the development of tools** to assist research sites with study selection, implementation and compliance.
- Maintains **active lines of communication** with SWOG Protocol coordinators and committees.
- Reviews of **ORP Manual chapters**.
- **Mentors and supports** development of new liaison

Open Liaison Positions

Disease Committee	Position
Breast	Research Nurse
Symptom Control	Research Nurse
Early Therapeutics	Research Nurse and CRA
Gastrointestinal	Research Nurse
Leukemia	Research Nurse
Lymphoma	Research Nurse
Myeloma	CRA

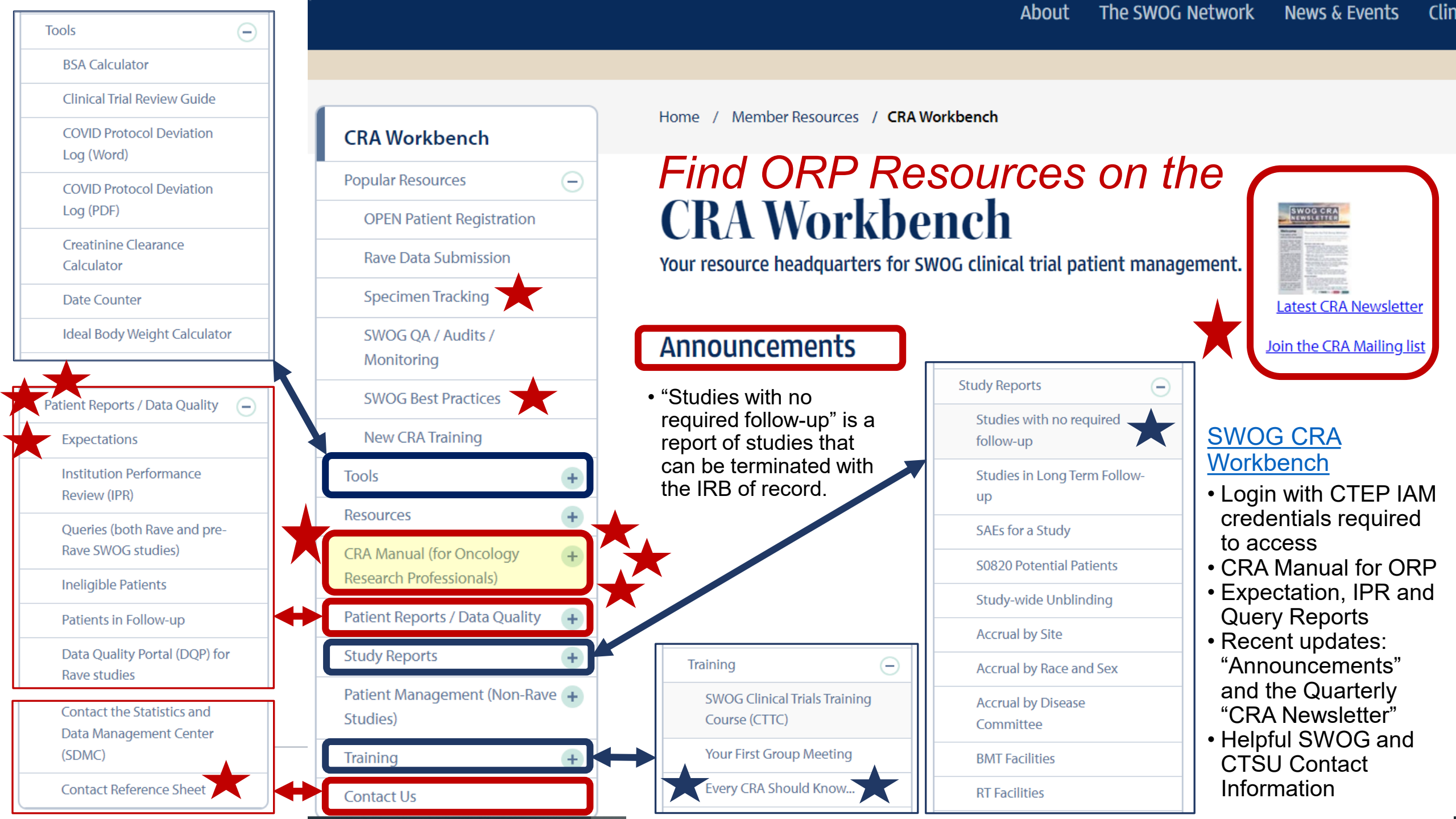
An *At Large Liaison Member* is:

- A CRA or RN that is a member of the ORP Liaison Committee and not a specific SWOG committee.
- A member of the ORP Liaison Committee may attend ORP Liaison Committee conference calls, participate in committee projects and receive mentoring from an experienced Liaison while awaiting an opening on a disease committee.

Co- Chair ORP Liaison Committee Ceil Petrowsky RN MSN OCN CCRC cpetrow@luc.edu

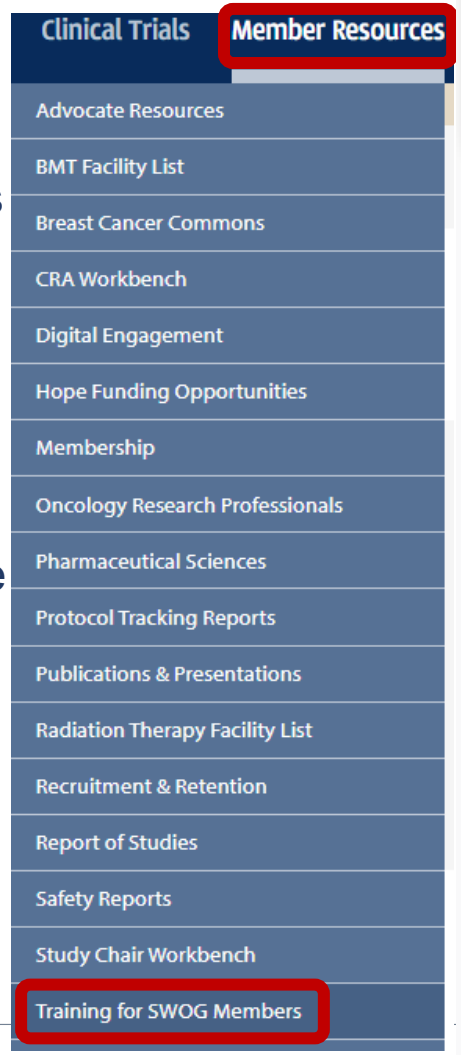
Co- Chair ORP Liaison Committee Alexandra Annis CRA aannis2@kumc.edu

SWOG ORP Resources


About
The SWOG Network
News & Events
Tools
BSA Calculator
Clinical Trial Review Guide
COVID Protocol Deviation Log (Word)
COVID Protocol Deviation Log (PDF)
Creatinine Clearance Calculator
Date Counter
Ideal Body Weight Calculator
Patient Reports / Data Quality
Expectations
Institution Performance Review (IPR)
Queries (both Rave and pre-Rave SWOG studies)
Ineligible Patients
Patients in Follow-up
Data Quality Portal (DQP) for Rave studies
Contact the Statistics and Data Management Center (SDMC)
Contact Reference Sheet
CRA Workbench
Popular Resources
OPEN Patient Registration
Rave Data Submission
Specimen Tracking
SWOG QA / Audits / Monitoring
SWOG Best Practices
New CRA Training
Tools
Resources
CRA Manual (for Oncology Research Professionals)
Patient Reports / Data Quality
Study Reports
Patient Management (Non-Rave Studies)
Training
Contact Us
Home / Member Resources / CRA Workbench
Find ORP Resources on the
CRA Workbench
Your resource headquarters for SWOG clinical trial patient management.
Latest CRA Newsletter
Join the CRA Mailing list
Announcements
• "Studies with no required follow-up" is a report of studies that can be terminated with the IRB of record.
Training
SWOG Clinical Trials Training Course (CTTC)
Your First Group Meeting
Every CRA Should Know...
Study Reports
Studies with no required follow-up
Studies in Long Term Follow-up
SAEs for a Study
S0820 Potential Patients
Study-wide Unblinding
Accrual by Site
Accrual by Race and Sex
Accrual by Disease Committee
BMT Facilities
RT Facilities
SWOG CRA Workbench
• Login with CTEP IAM credentials required to access
• CRA Manual for ORP
• Expectation, IPR and Query Reports
• Recent updates: "Announcements" and the Quarterly "CRA Newsletter"
• Helpful SWOG and CTSU Contact Information

New SWOG Learning Management System (LMS)

- Direct link to the LMS is located on the SWOG Member-side of the website under the “Member Resources” menu,
  - Also accessible to SWOG Members via direct url: https://swog.exposted.com.
  - Login with CTEP IAM credentials required to access.
- Online Clinical Trials Training Course, plus
  - Brief (5-15 minutes) modular course additions ongoing.
- All new SWOG study-specific training is maintained in the CTSU Compliance, Learning, and SOP Solutions (CLASS) Learning Management System [CTSU CLASS LMS]; Accessible NCTN-wide to staff with CTEP IAM login.



SWOG has launched a new Learning Management System (LMS)!

THE EXPERTUSONE LMS WILL BE HOME TO ALL TRAINING THAT IS SPECIFIC TO SWOG MEMBERS.

Training certificates are viewable and printable for one year after completing a course.

Courses are available in brief 5- to 15-minute modules.

Content is regularly added and updated. See the “Announcements” window for new content.

In a user-friendly interface, you can view trainings, take surveys, and complete assessments all from one LMS content player – also available for mobile devices.

Allows us to host virtual classes integrated with WebEx or Zoom.

NCTN-wide training — such as for protocol-specific requirements and PRO training — will remain in the CTSU CLASS system. But SWOG internal training for members and staff will be in ExpertusOne.

Some of the training content now within ExpertusOne:

- Study Chair Workshop
- Young Investigator Workshop Online
- Investigational Agent Handling
- Clinical Trials Training Course
- Team Science

Access SWOG’s new LMS at swog.exphosted.com, or link from the “Training for SWOG Members” item on the “Member Resources” menu. Use your CTEP IAM credentials to log in.

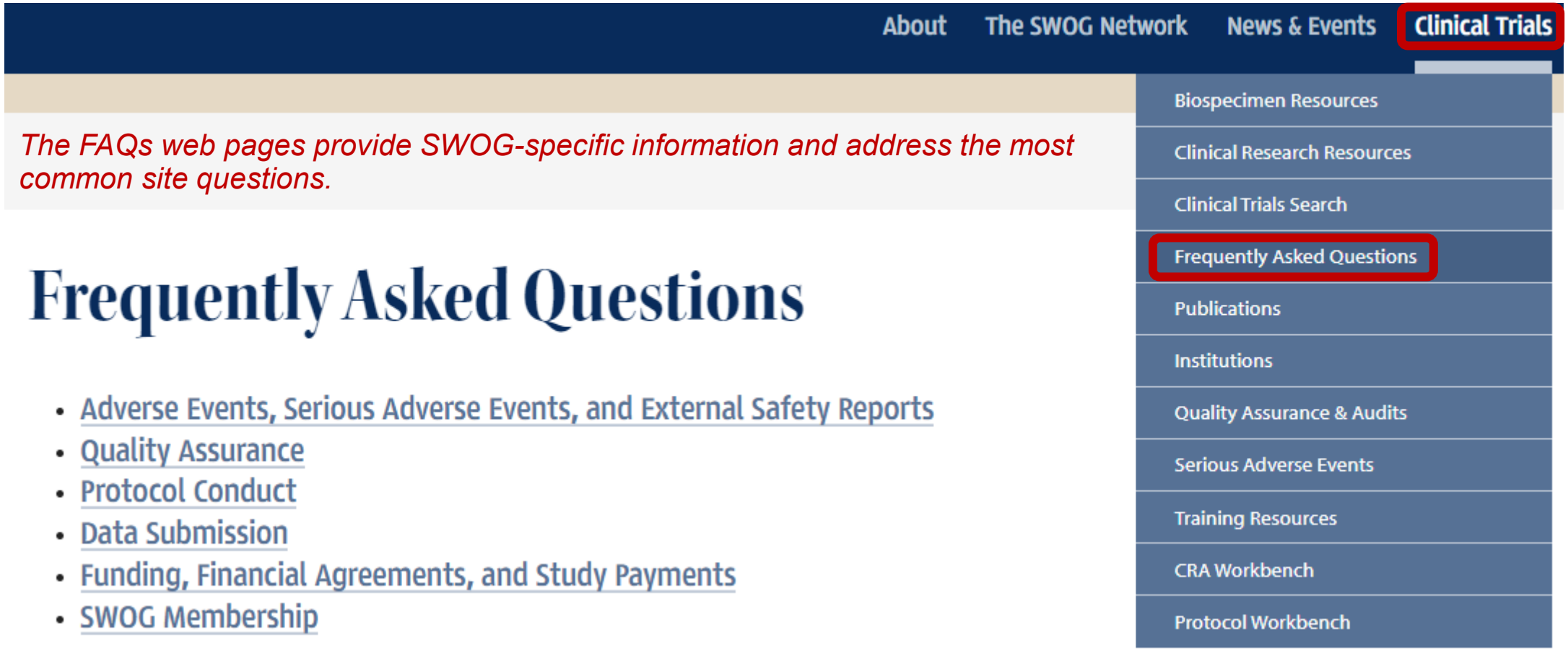
swog.exphosted.com

expertusone
www.expertusone.com

SWOG CANCER RESEARCH NETWORK

Frequently Asked Questions webpages

(launched Spring 2022)



Clinical Research Resources webpages *(launched Fall 2021)*

- Resources for Oncology Research Professionals
  - ❖ SWOG Data Submission Guidance, Tips, and Tricks
- Regulatory and Ethical Research Conduct References, such as the NIH Department of Bioethics Videocasts of Past Lectures
- Human Subjects Research Protection Training
- Continuing Education and Training Programs

Patient-Friendly Summaries and Social Media Toolkits

- Linked from SWOG.org/clinical-trials and CTSU.org pages for newly activated trials.
- Summary questions selected by a team of patient advocates & health education experts to give patients key info to help them decide whether they want to learn more about a study.

S1914

Clinical trial summary (S1914)

Comparing Treatments for High Risk, Early Stage Non-Small Cell Lung Cancer

What is the purpose of this clinical trial?

Surgery is the standard treatment for early stage non-small cell lung cancer. However, some people can't get surgery to remove their lung cancer. Other people don't want to have surgery. In these cases, the standard treatment is radiation, using a procedure called stereotactic body radiotherapy, or SBRT. This clinical trial is testing whether SBRT can be improved when used with a new cancer immunotherapy drug called a checkpoint inhibitor. Other clinical trials have found this immunotherapy can be effective in treating non-small cell lung cancer, and that it may work well if used with radiation. This study aims to find out whether SBRT plus a checkpoint inhibitor is a better treatment.

This trial is set up to find out:

- How long participants survive in each group at the end of the five-year study period
- How long people remain cancer free in the two treatment groups, and if participants have any side effects from taking the study medicine

Why is this trial important?

This trial is important because even after SBRT, non-small cell lung cancer may return. Doctors want to find a better way to treat people so that they live longer, healthier lives. Other trials have shown that this new type of immunotherapy, called a checkpoint inhibitor, can benefit people with non-small cell lung cancer. There is also some evidence that checkpoint inhibitors work well, and are safe, when given along with radiation treatments. This is one of the largest studies so far to test this idea in people with high risk, early stage non-small cell lung cancer.

Who can be in this trial?

This trial is for men and women over the age of 18, with stage 1 or 2 non-small cell lung cancer. The cancer cannot have spread to lymph nodes or any other part of the body.

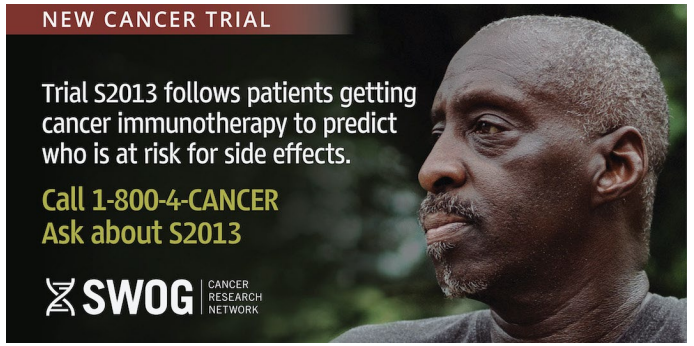
This trial may be for people who:

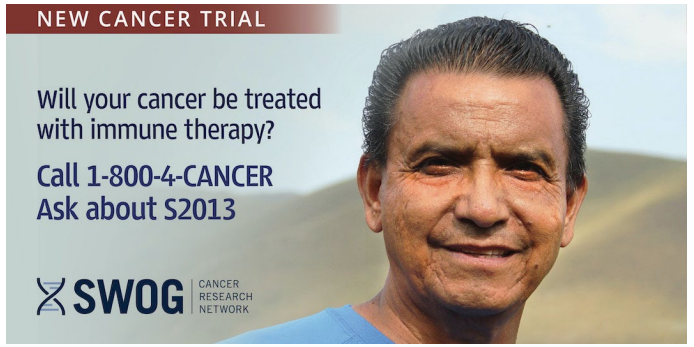
- Have proven stage 1 or 2 non-small lung cancer
- Are at higher risk for their cancer growing and spreading based on the size of their tumor, or other tumor features
- Have no evidence of their cancer spreading to another part of their body
- Cannot or will not have lung cancer surgery

This trial is not for people who:

- Have a major infection, an autoimmune disease, or a current or past case of hepatitis B, hepatitis C, or HIV
- Are pregnant
- Have a history of certain types of serious lung disease

S2013





Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

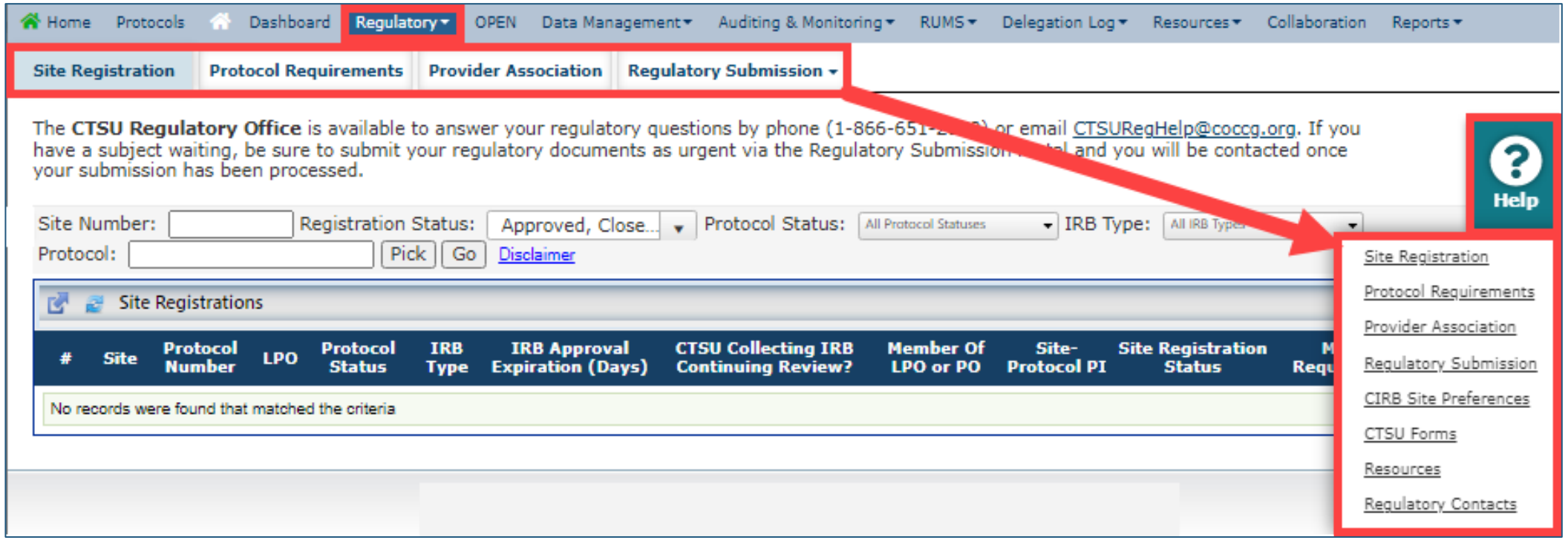
Linking practice to progress

CTSU Resources

For New Site Staff

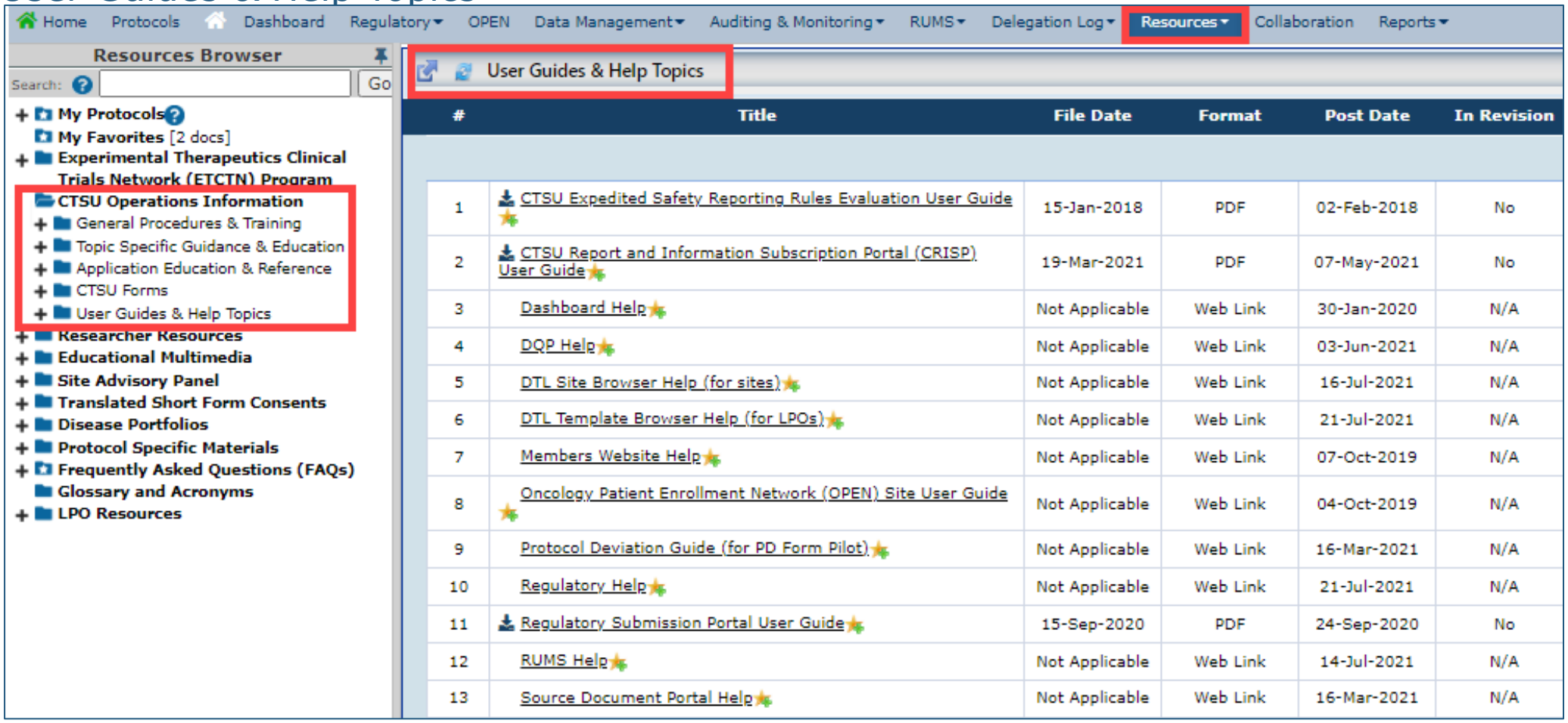
Help Topics

- Help topics appear on most CTSU screens, and have replaced user guides
- They are unique to the screen being viewed
- Clicking the icon shows the drop-down, a link opens the page, which has navigation
- Home help topics give an overview of the entire website



Resources: Central Location for Help Topics

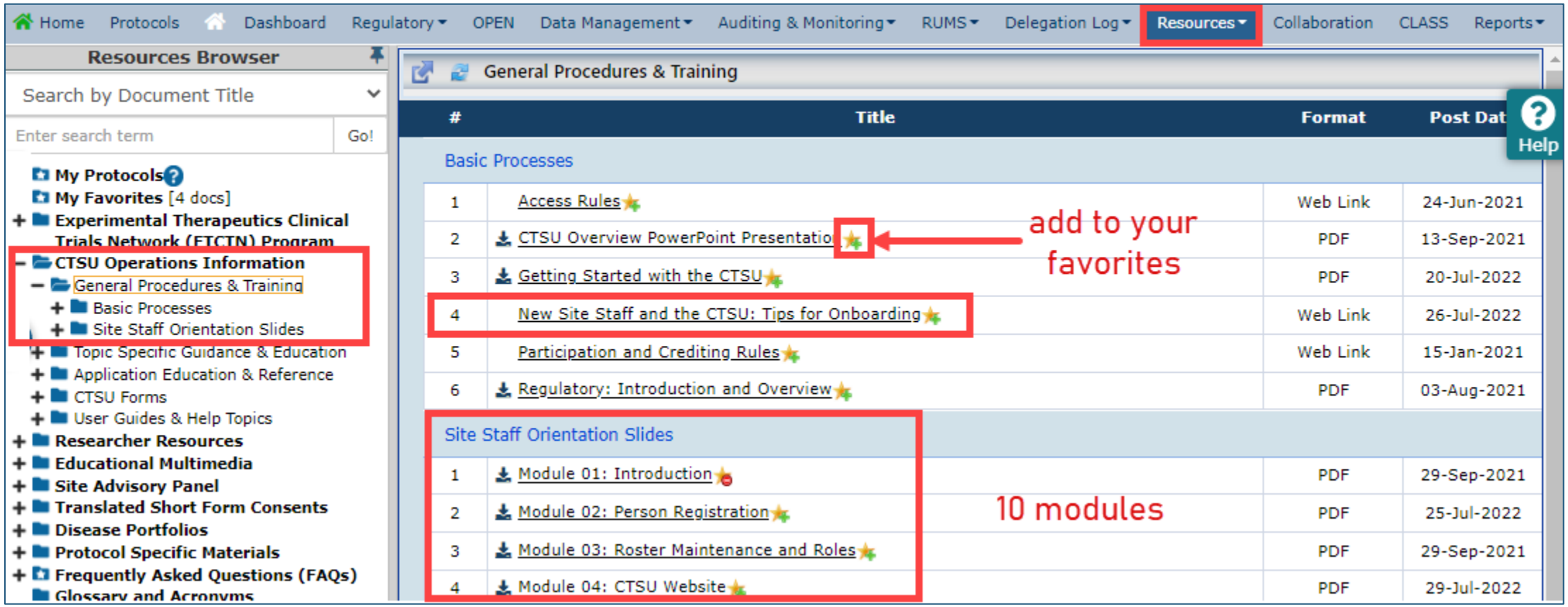
- **All** help topics appear in the Resources section → CTSU Operations Information → User Guides & Help Topics



#	Title	File Date	Format	Post Date	In Revision
1	CTSU Expedited Safety Reporting Rules Evaluation User Guide	15-Jan-2018	PDF	02-Feb-2018	No
2	CTSU Report and Information Subscription Portal (CRISP) User Guide	19-Mar-2021	PDF	07-May-2021	No
3	Dashboard Help	Not Applicable	Web Link	30-Jan-2020	N/A
4	DQP Help	Not Applicable	Web Link	03-Jun-2021	N/A
5	DTL Site Browser Help (for sites)	Not Applicable	Web Link	16-Jul-2021	N/A
6	DTL Template Browser Help (for LPOs)	Not Applicable	Web Link	21-Jul-2021	N/A
7	Members Website Help	Not Applicable	Web Link	07-Oct-2019	N/A
8	Oncology Patient Enrollment Network (OPEN) Site User Guide	Not Applicable	Web Link	04-Oct-2019	N/A
9	Protocol Deviation Guide (for PD Form Pilot)	Not Applicable	Web Link	16-Mar-2021	N/A
10	Regulatory Help	Not Applicable	Web Link	21-Jul-2021	N/A
11	Regulatory Submission Portal User Guide	15-Sep-2020	PDF	24-Sep-2020	No
12	RUMS Help	Not Applicable	Web Link	14-Jul-2021	N/A
13	Source Document Portal Help	Not Applicable	Web Link	16-Mar-2021	N/A

New Site Staff Resources

- Resources > CTSU Operations Information > General Procedures and Training, contains introductory materials
- Tips for Onboarding and Site Staff Orientation Slides are geared for new site staff



Funding Opportunities

CRA and Nurse Travel Support Program

- Provides traveler funding for group meeting attendance
- Offered through SWOG's public charity, **The Hope Foundation for Cancer Research**
- Watch for notices regarding Applications for the SWOG Spring Meeting Visit **tinyurl.com/CRA-NURSE**

Reminders

- **Spring 2023 SWOG Group Meeting**
  - May 10-13, 2023
  - Hyatt Regency San Francisco
  - San Francisco, California

Additional ORP Sessions Thursday

- Jeri & Noboru Oishi Symposium
- ORP Open Forum

NCTN Performance Survey Results

Andrea Denicoff, MS, RN
Grace Mishkin, PhD, MPH

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SWOG Site Operations Mtg
Oct. 19th, 2022

Survey Context and Goals

Background: Brief survey developed to gather feedback from external NCTN stakeholders after 3 years of NCTN operations under the current grant (3/1/2019 – 2/28/2025) in advance of the NCTN recompetition

Goals: Gather feedback about the NCTN structure, processes, and achievement of program goals and identify areas for improvement

Survey Development, Participants, and Distribution

- Development
  - Questions based on previous survey conducted in 2016-2017, which was developed and edited by NCI staff and NCTN group leadership
  - Approved under OMB Clearance No. 0766

- Participants
  - Email lists requested from each Group for key personnel and leadership
  - Emails added for all LAPS and NCORP Contact PIs and admins
  - 1,505 unique LAPS and Group participants emailed, in addition to email to the NCORP PI and admin listservs (some overlap expected)

- Distribution
  - Programmed and distributed in SurveyMonkey
    - 1 initial and 2 follow-up emails sent to each email on the list
  - Open 32 days: July 25 to August 26, 2022

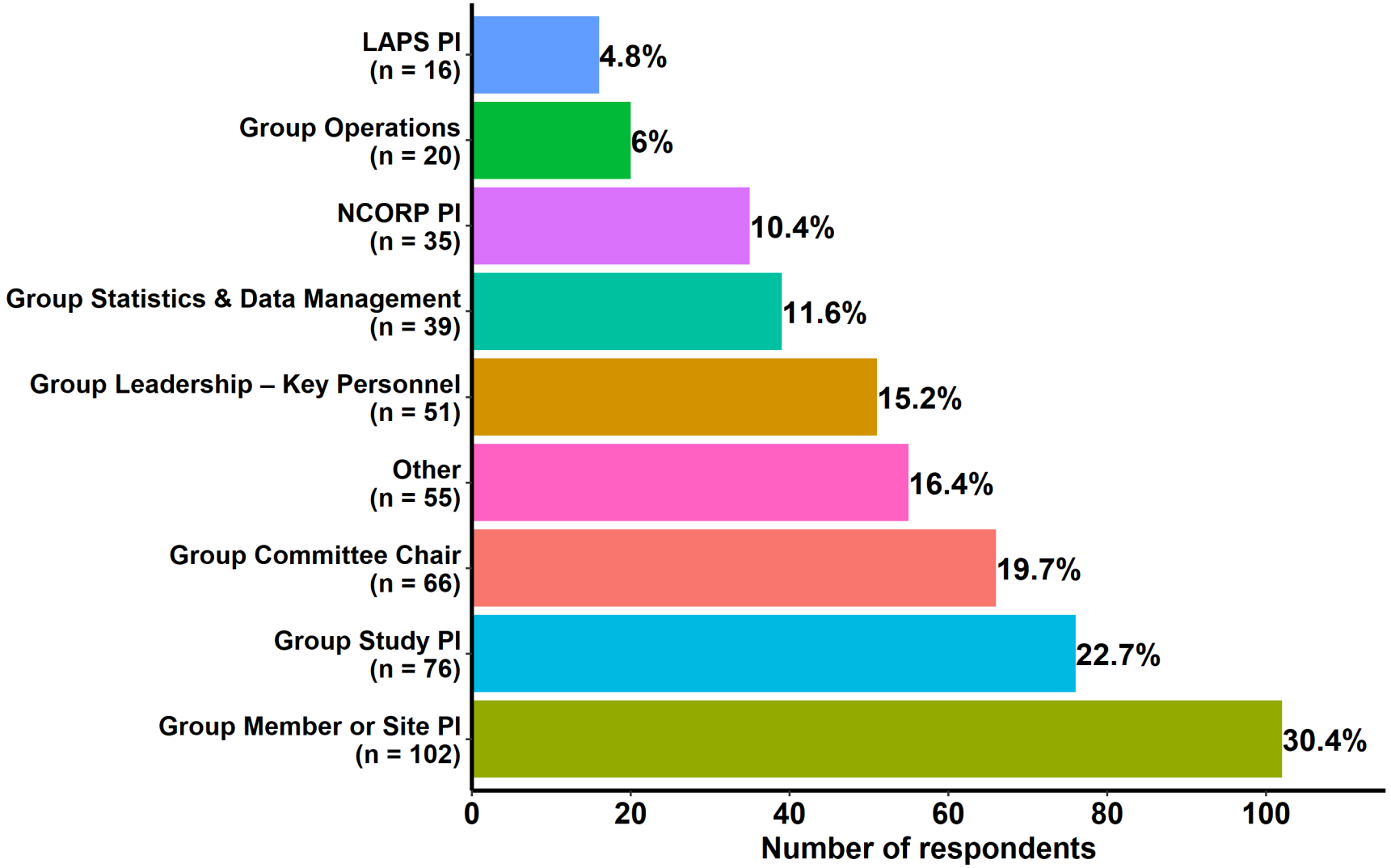
Survey Response Rate

- Number who started the survey out of the 1505 who were sent the survey: **335 (22.3%)**
- Number who completed the “overall satisfaction” question out of the 1505 who were sent the survey: **272 (18.1%)**
- Drop-off from first to last survey question: **254 (16.9%)**

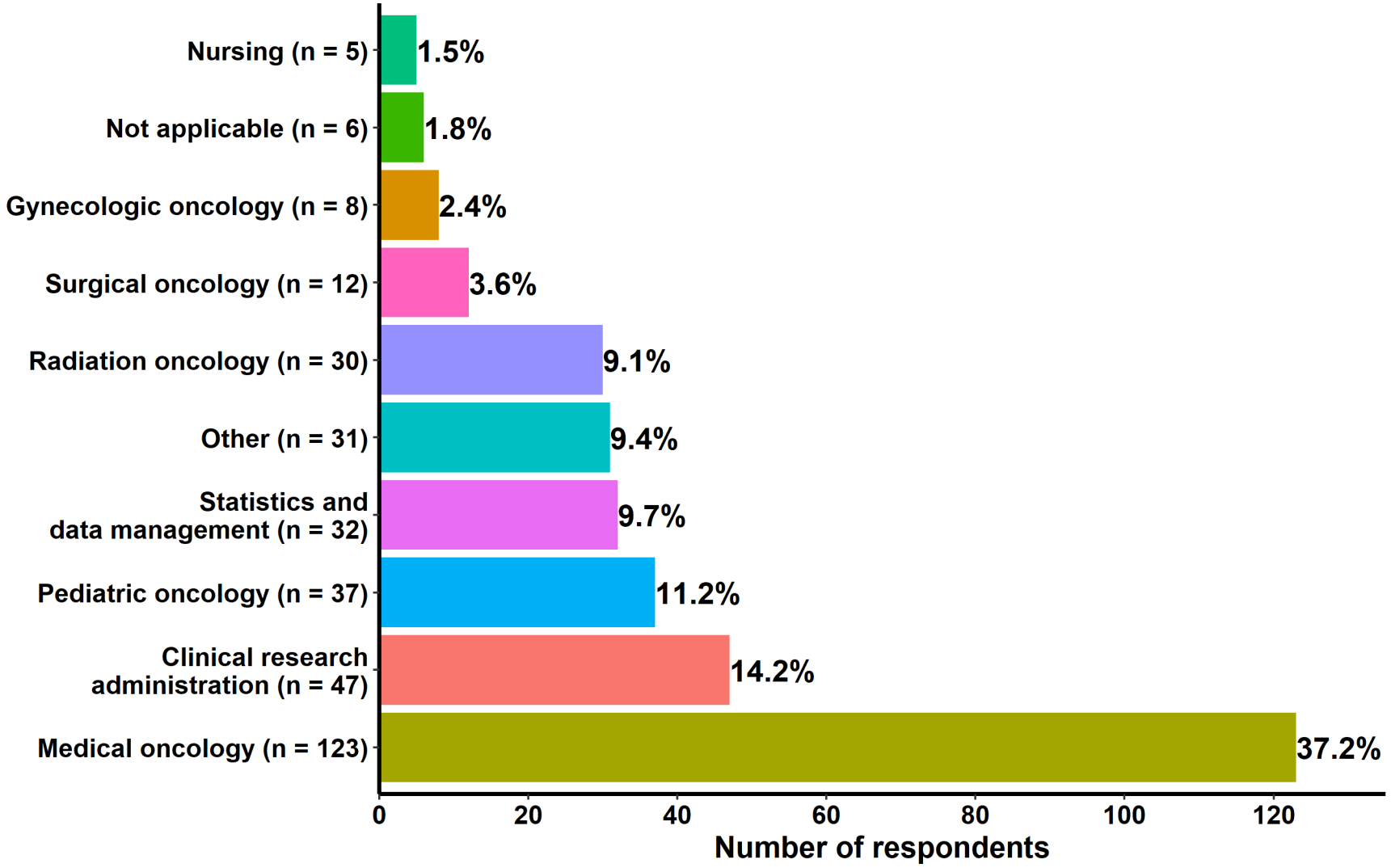
Respondents by Group Affiliation (n=335)

Which NCTN Group(s) are you affiliated with?	Number of Respondents who Selected Group (could select multiple)	% of Total Respondents (% of n=335)
Alliance	161	48.1
COG	82	24.5
ECOG-ACRIN	137	40.9
NRG	167	49.8
SWOG	134	40.0
CCTG	38	11.3

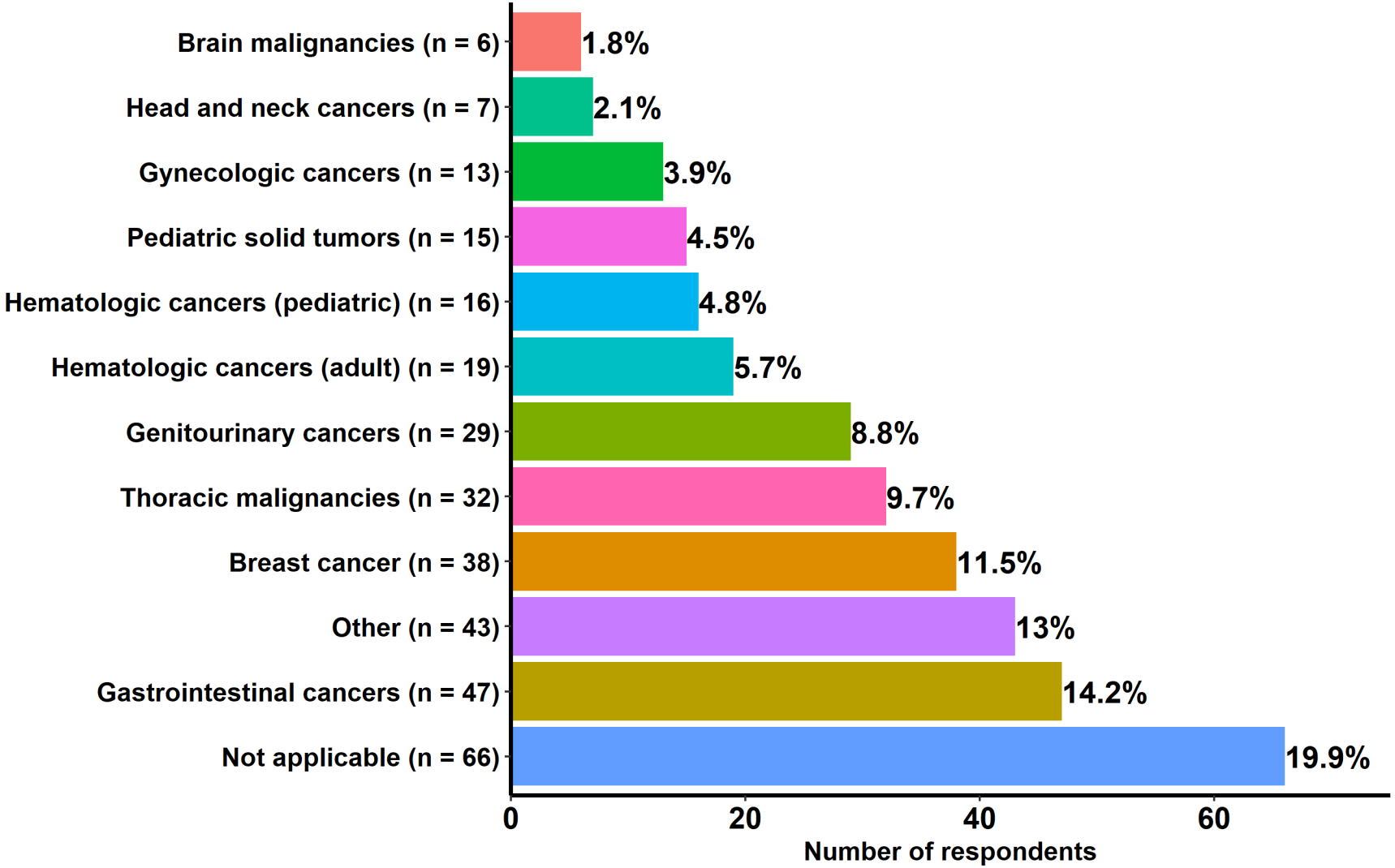
Respondents by Role(s)
Number of respondents = 335



Respondents by Area of Expertise
Number of respondents = 331



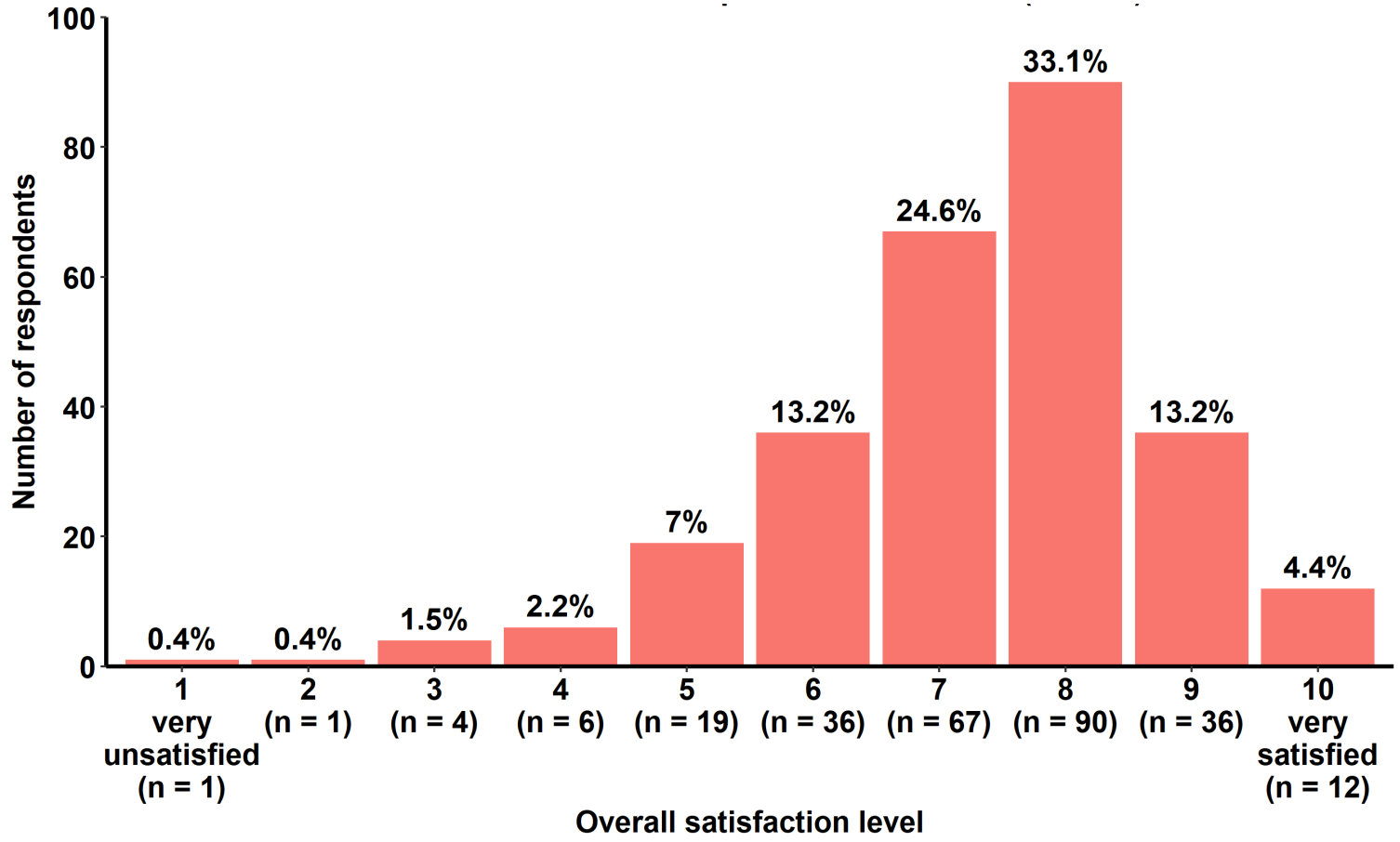
Respondents by Area of Disease
Number of respondents = 331



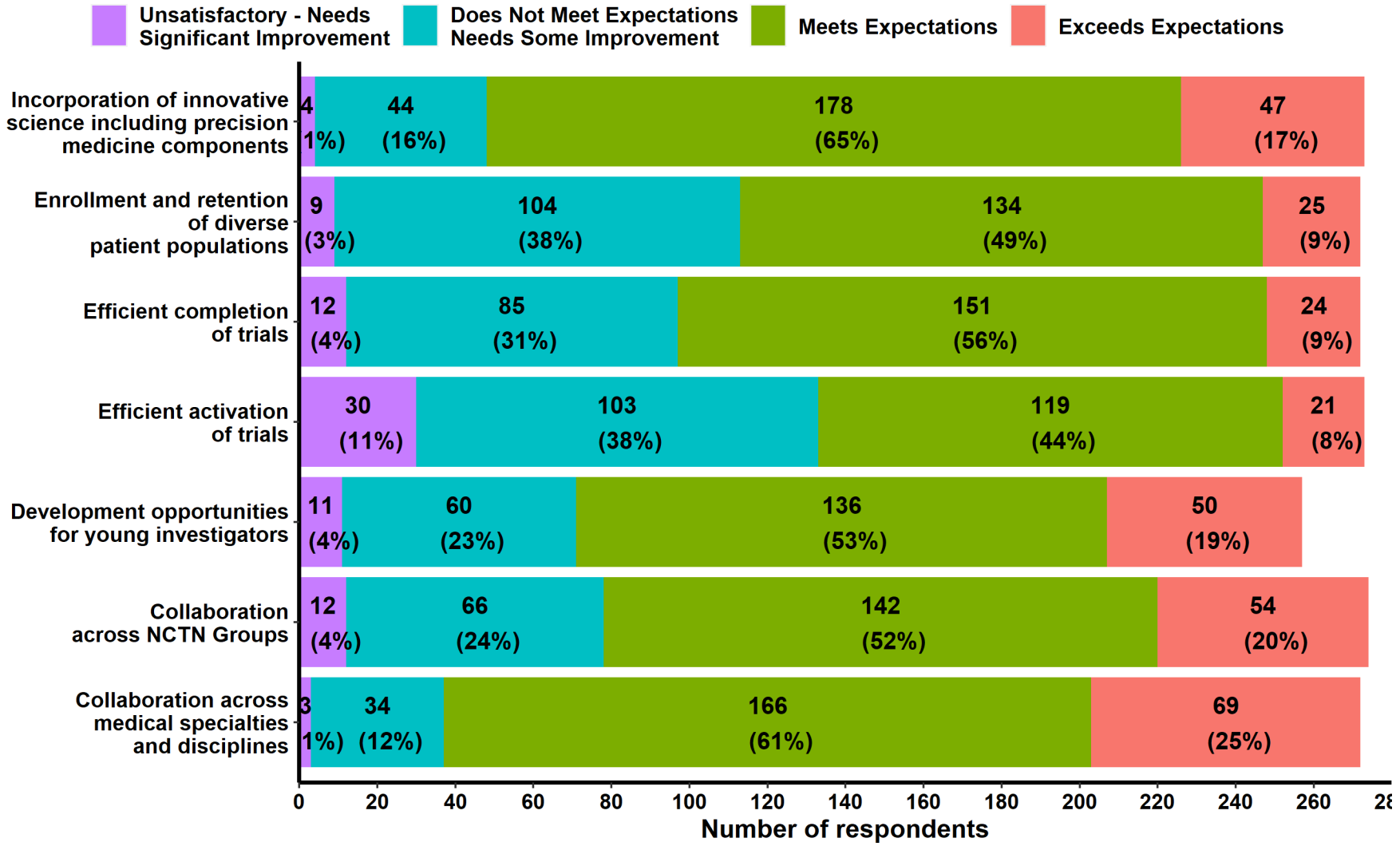
Overall Satisfaction with the NCTN
Number of respondents = 272 (18.1% of total asked)

88.5% gave an answer in “satisfied” range (6 to 10) ***[2017 – 65%]***

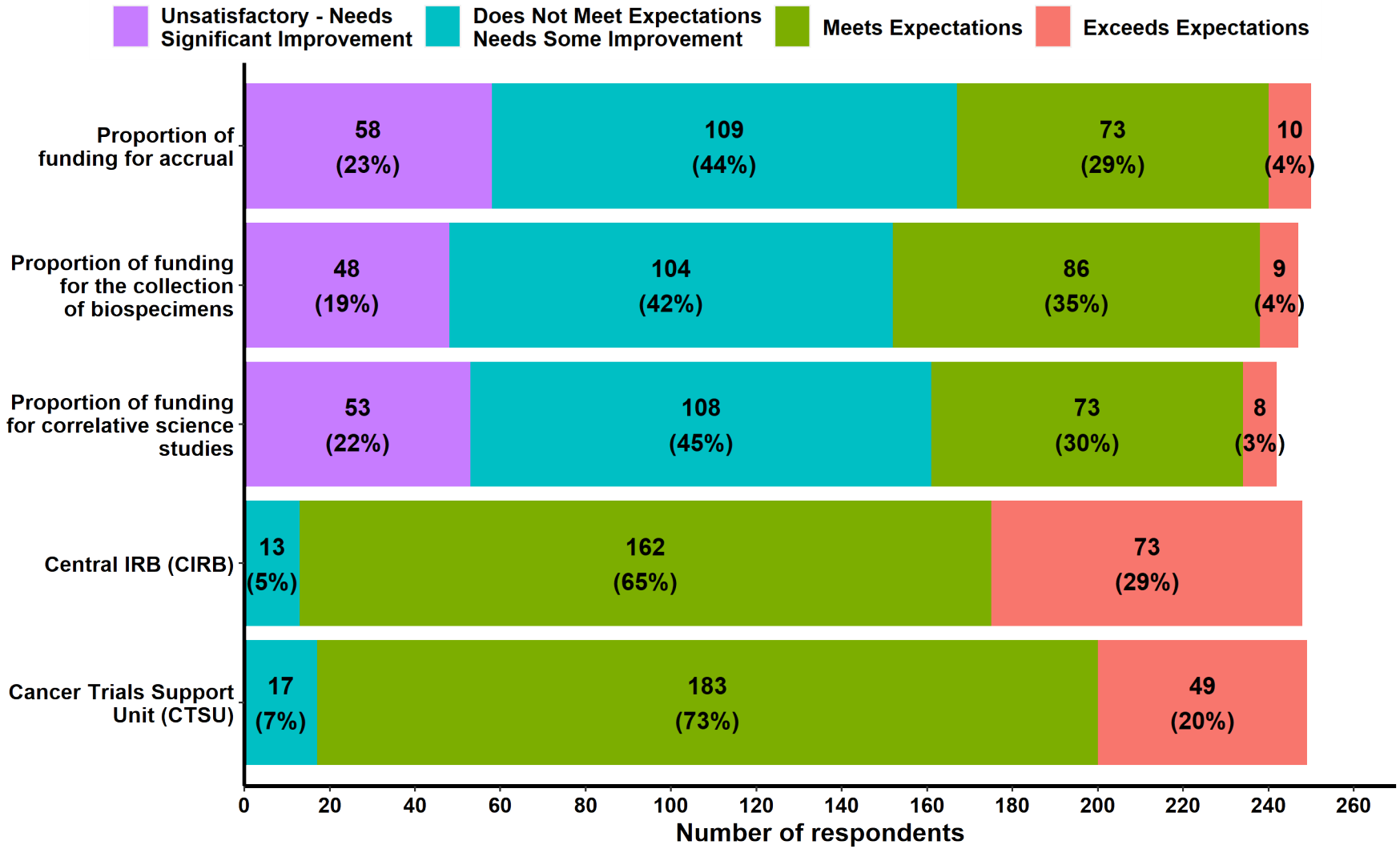
50.7% gave an answer in “very satisfied” range (8 to 10) ***[2017- 24%]***



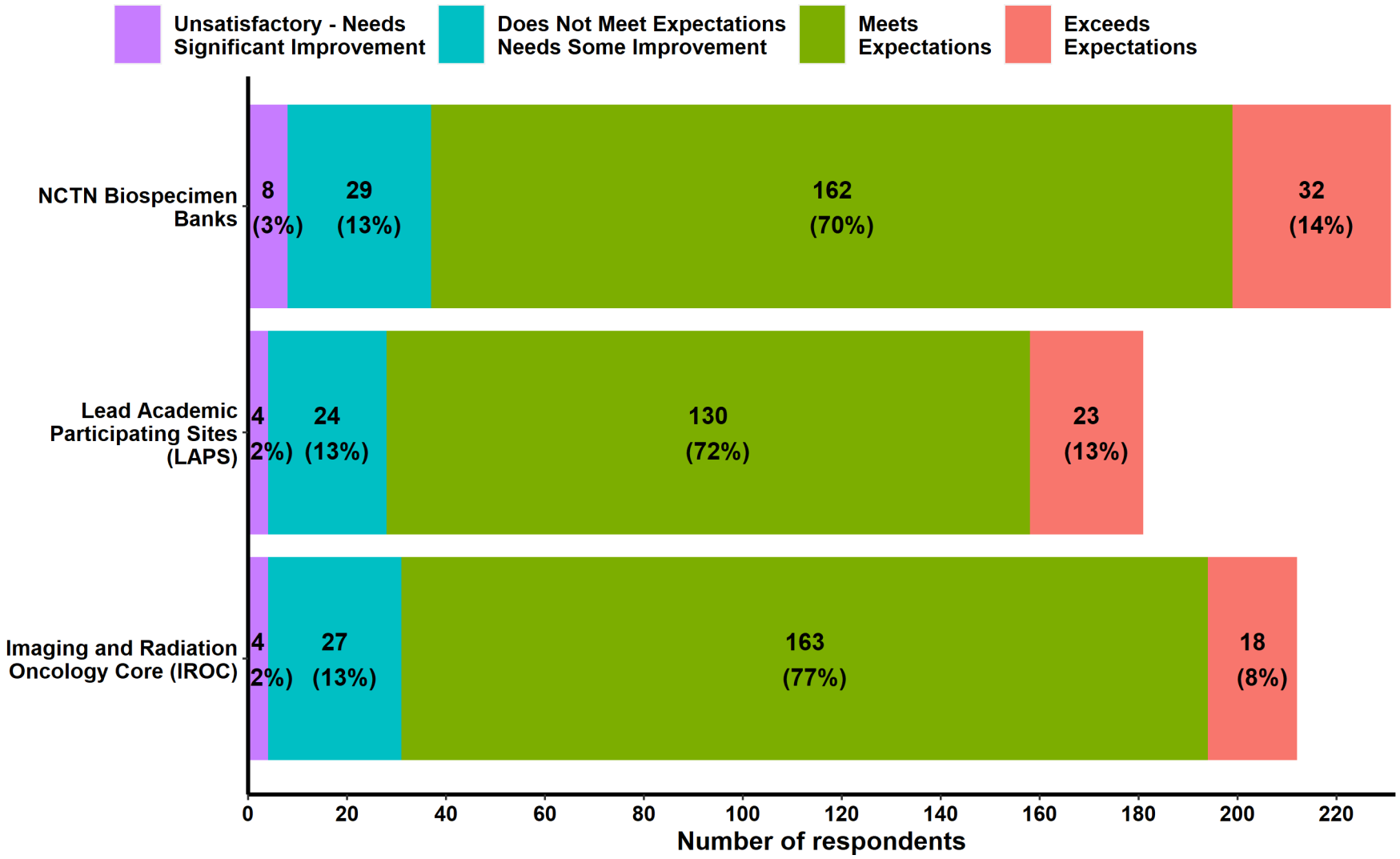
Overall, how satisfied are you with the degree to which the NCTN is achieving the following goals? (n~270)



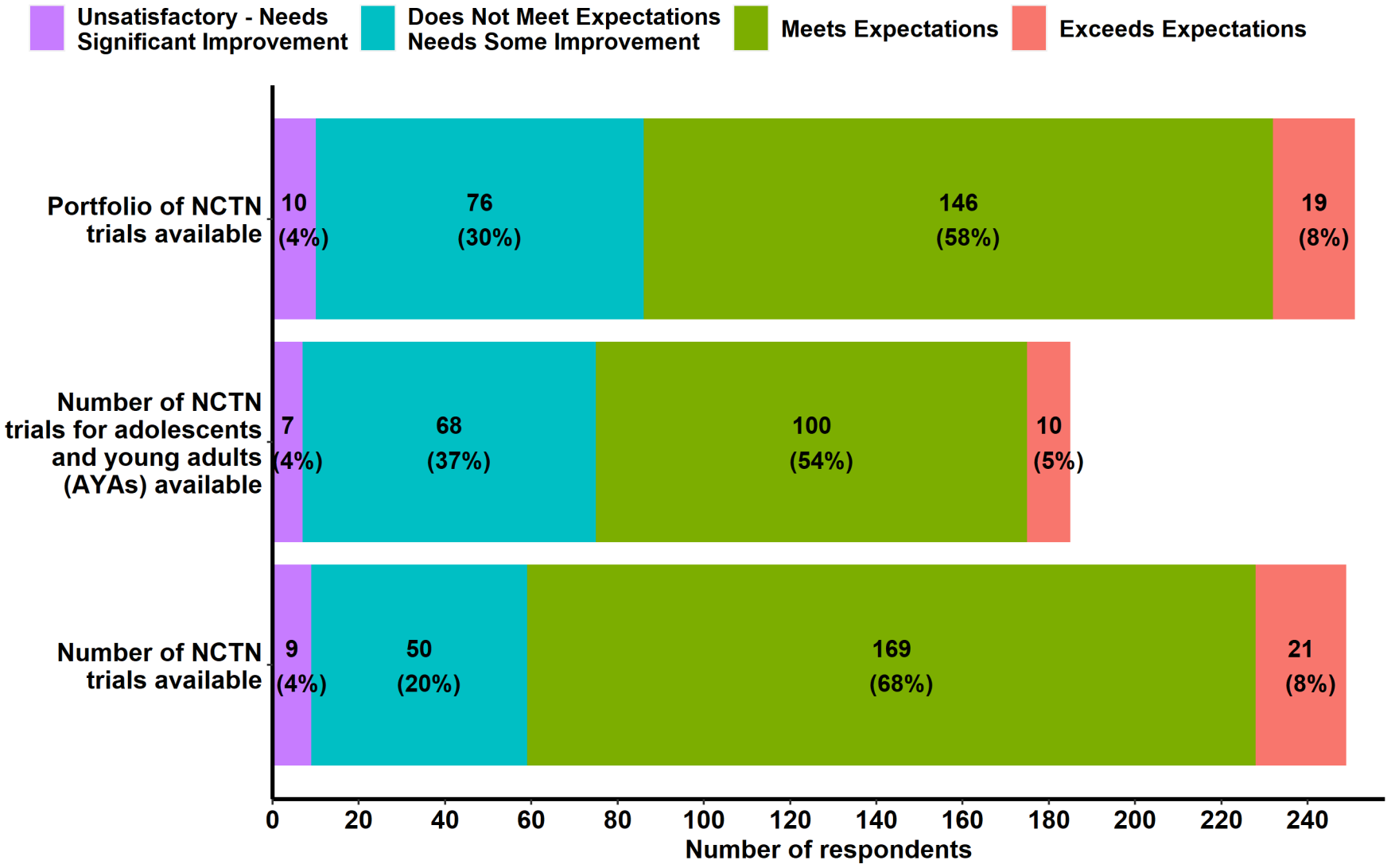
Overall, how satisfied are you with the following centralized services and administrative aspects of the NCTN? (n~250)



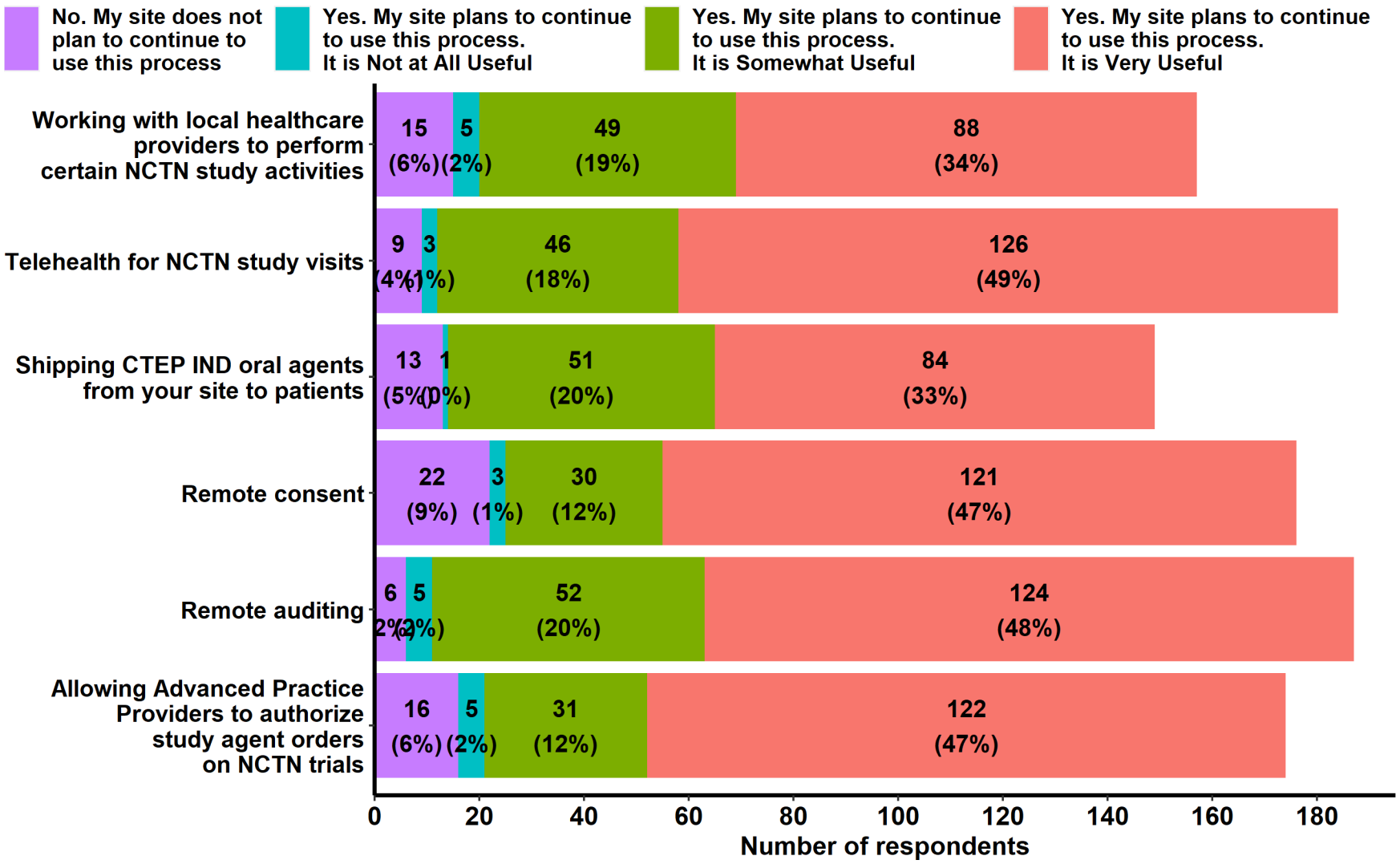
Overall, how satisfied are you with the following programs within the NCTN?



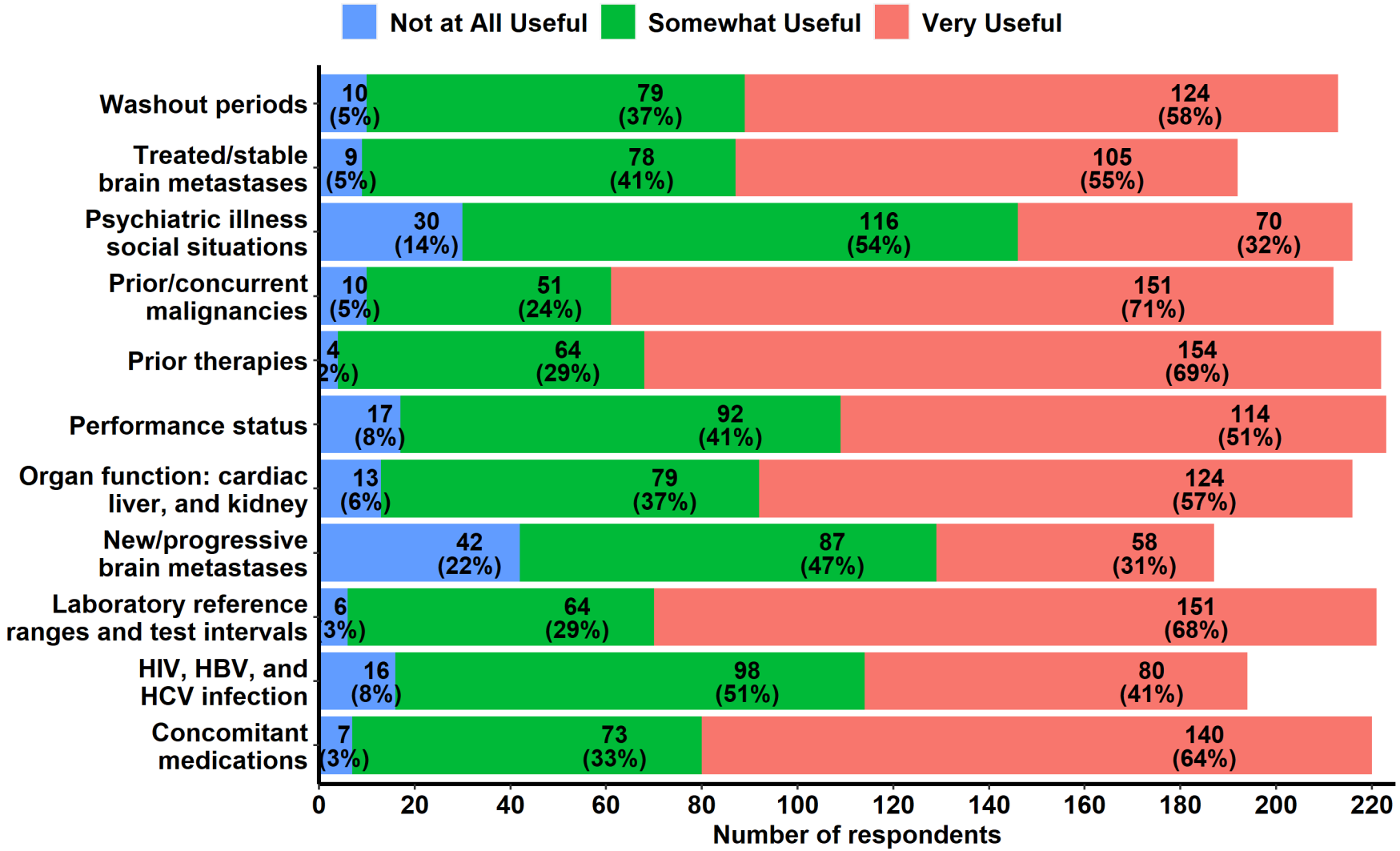
Overall, how satisfied are you with the following aspects of the NCTN menu of trials ?



For each of the following new processes, does your site plan to continue to use the new process?



Which of the following categories of broadened eligibility criteria do you think will have the greatest impact?



Qualitative Questions – Preview of Part 2

What improvements or changes would you like to see in the NCTN?

- **More standardization/consistency/same expectations/common guidelines – protocol writing, forms in RAVE, data reporting, auditing, and policies and procedures. (“simplify trials”)**
- **More intergroup/trans-NCTN meetings**
- **Increase funding: support increased workload of complex trials (staffing needs) and support enrollment and retention of underserved populations**
- **Foster collaboration**
- **Enhance recognition: authorship/Joint leadership/Junior PIs**
- **Activation of trials: need to be more timely and more efficient**
- **Continue changes implemented during pandemic, allow more flexible and decentralized trial activities**

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www.cancer.gov

www.cancer.gov/espanol

Pharmaceutical Management Branch (PMB) Updates

Matt Boron, RPh

PMB, CTEP, DCTD

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Site Operations Meeting
October 19, 2022

AGENDA

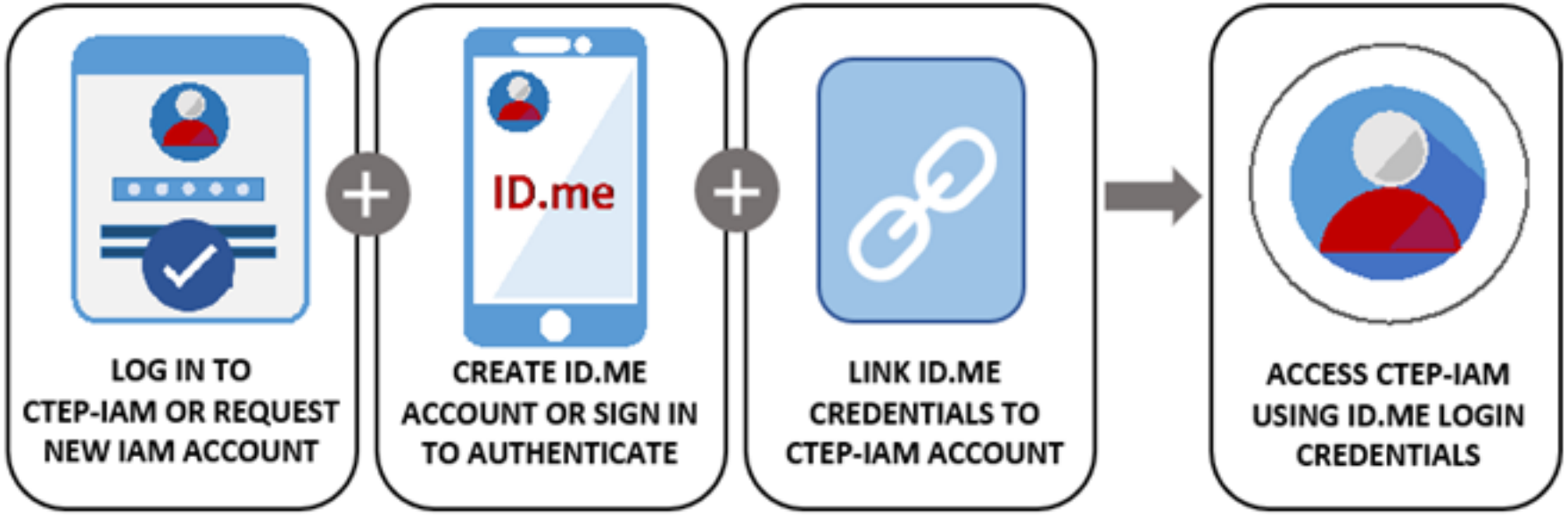
- ID.me
- Agent Shipping
- AURORA

Enhanced IT Security required for all Federal Systems

- Identity verification and MFA is required for all federal systems and meets NIST SP 800-63-3 Digital Identity Guidelines
- Began July 8, 2022, CTEP-IAM integrated with ID.me to meet this requirement
- ***All users must complete ID verification and MFA with ID.me by July 1, 2023***

Making sure all users are who they say they are.

ID.me to IAM Workflow



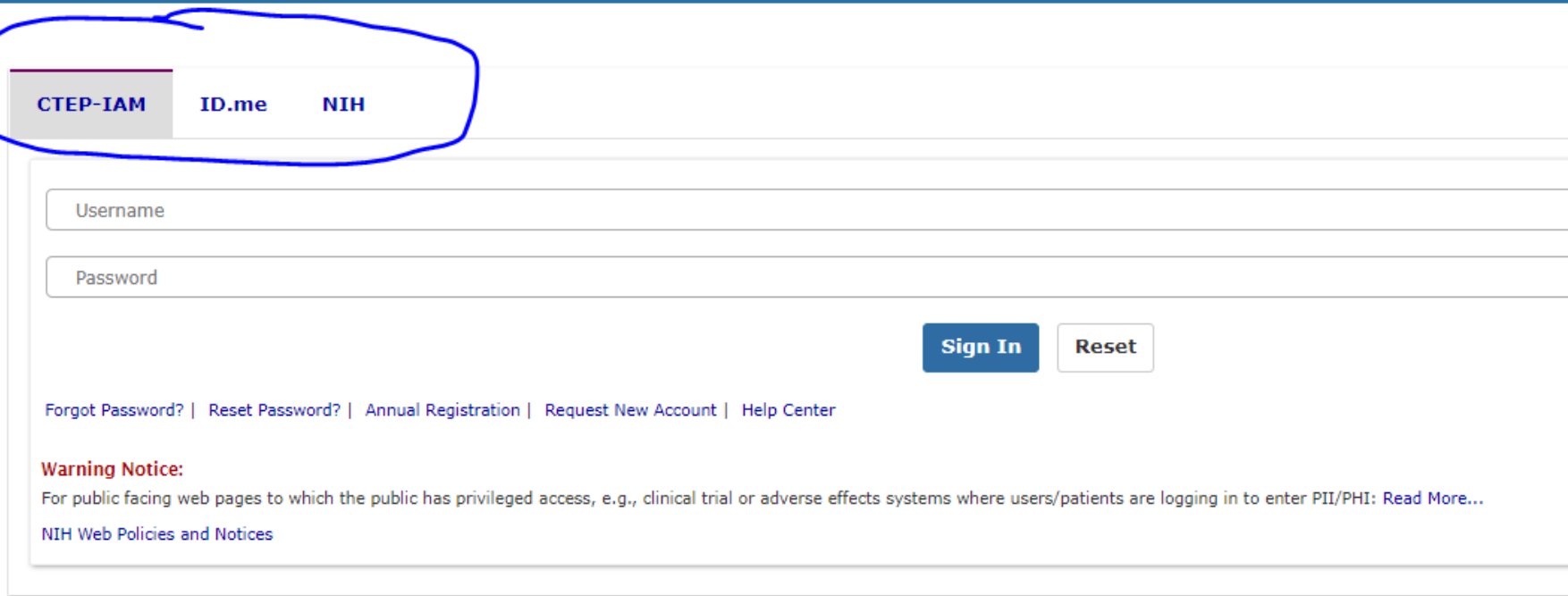
For more information:
https://ctep.cancer.gov/investigatorResources/NCI_CTEP_IAM_User_Access_Update.htm

Registration and Credential Repository (RCR)

Welcome to the National Cancer Institute's **Registration and Credential Repository** (RCR) system. The RCR is available for the electronic submission of NCI registration documents by clinical research personnel participating on NCI-sponsored clinical trials. The system, in combination with other NCI Clinical Oncology Research Enterprise (CORE) applications, ensures real-time updates to control trial activities and system access. The RCR meets FDA regulatory requirements while maintaining an annual registration submission lifecycle to allow investigators to quickly participate on research trials, increase efficiency and lower the cost of conducting clinical trials.

An IAM account is required to access the RCR system. Click **Request New Account** to obtain this account or click here to check on your IAM account status.

We've made updates to RCR - take a look at What's New!



ID.me resources

- CTEP ID.me info page and FAQ: https://ctep.cancer.gov/investigatorResources/NCI_CTEP_IAM_User_Access_Update.htm
  - ID.me CTEP FAQ: https://ctep.cancer.gov/investigatorResources/docs/FAQs-IAM-IDme-Integration_with_hyperlinked_sections.pdf
- NIST SP 800-63-3 – Digital Identity Guidelines: https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-3.pdf
- NCI ID.me help center: https://help.id.me/hc/en-us/articles/4711388572695-NCI-ID-me

Investigational Agent Shipping

- CTEP IND oral agents for shipment to patient only
  - Check with sponsor if not CTEP IND
- Must have a site-level SOP
  - Available for audit
- Not for every occasion
  - Should not be the base treatment plan
- Exceptions
  - Dangerous Goods / REMS

https://ctep.cancer.gov/content/docs/CTEP_Oral_IND_Agent_Shipment_Guideline.pdf

AURORA Updates

- AURORA is PMB's centralized agent inventory management system.
- AURORA consists of several modules, including:
  1. Agent Ordering and review of order status (replaces OAOP)
  2. Access to PMB provided documents (stock recovery notices, IB, and MSDS)
  3. Creation and Maintenance of the PSD (Primary Shipping Designee) shipping addresses and Primary Ordering Designees
  4. Enhanced communication tools to connect with PMB
  5. Creation and maintenance of electronic NCI Investigational Agent (Drug) Accountability Records (eDARF) and associated inventory management practices

When we talk about AURORA, it is not just eDARFs.

High Level Benefits of AURORA

- Elimination of all paper records = no lost documents
- Improved sponsor and site compliance with regulatory requirements = system validation throughout trial conduct reduces audit and inspection findings
- Prevention of medication dispensing errors and common accountability errors = improved patient care
- PMB-determined agent expiration dates are populated on the eDARF = no missing stock notifications

High Level Benefits of AURORA, continued

- AURORA's record retention supports straight-forward pharmacy monitoring and auditing = reduced # pharmacy findings on audit
- Electronic access for pharmacy monitoring and auditing = improves compliance by allowing central and remote auditing
- Efficient inventory management and accountability record storage and retention = push button reports on demand
- Streamlined communication between trial sites and PMB = reduced email volume

AURORA Updates

- The AURORA Training and Resources website is now available on the PMB website: https://ctep.cancer.gov/branches/pmb/aurora.htm
  - Table added summarizing AURORA function accessibility by site user access roles
  - NCI/CTEP AURORA Training course is available through the CLASS Learning Management System website (https://classlms.org) and a few additional videos will be added soon. Users may self-enroll in the ***NCI/CTEP Aurora Training*** course in the catalog
  - AURORA Overview presentation and slides from July 2022
  - AURORA FAQs
  - Help button within AURORA

AURORA Updates

- The AURORA implementation plan and frequently asked questions (FAQs) are available on the FAQ website:
  - https://ctep.cancer.gov/branches/pmb/faq.htm
  - Phase 1 release: AURORA will include agent ordering, document access (including stock recovery letters, IB, and MSDS), and PSD worksheet modules. OAOP will be shutdown and users re-directed to AURORA
  - Phase 2 release: eDARF module (final timeline TBD)
  - Check back for updates to the FAQs and timing of AURORA releases and/or sign up for the PMB Listserv (https://list.nih.gov/cgi-bin/wa.exe?SUBED1=NCI-DCTD-CTEP-PMB&A=1)

AURORA Function	Primary Shipping Designees	Primary Ordering Designees	Control site-assigned Satellite Designees	Investigators	All Other Users
Agent Ordering	✓	✓		✓	
Document Access - IB	✓	✓	✓	✓	✓
Document Access - MSDS, stock recovery	✓	✓		✓	
View PSD worksheet	✓	✓		✓	
Create and Edit PSD worksheet	✓			✓*	
Agent Accountability	✓ Control Dispensing Area and Satellite Dispensing Area records	✓ Control Dispensing Area and Satellite Dispensing Area records	✓ Satellite Dispensing Area records only	✓	

***Only investigators serving as a primary shipping designee have the ability to create new PSD records and submit updates to current PSD records.**

AURORA Updates

- Questions/comments contact PMB:
  - By email (preferred): pmbafterhours@mail.nih.gov
  - By phone M-F 8:30am – 4:30pm ET: 240-276-6575

NATIONAL CANCER INSTITUTE

www.cancer.gov

www.cancer.gov/espanol

Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Linking practice to progress

CTSU

Common Regulatory Challenges and Best Regulatory Practices

Agenda

Local IRB Approvals

NCI CIRB Approvals

PI Validations

CTSU Website – Site Registration

Local IRB Approvals

Local IRB Approvals

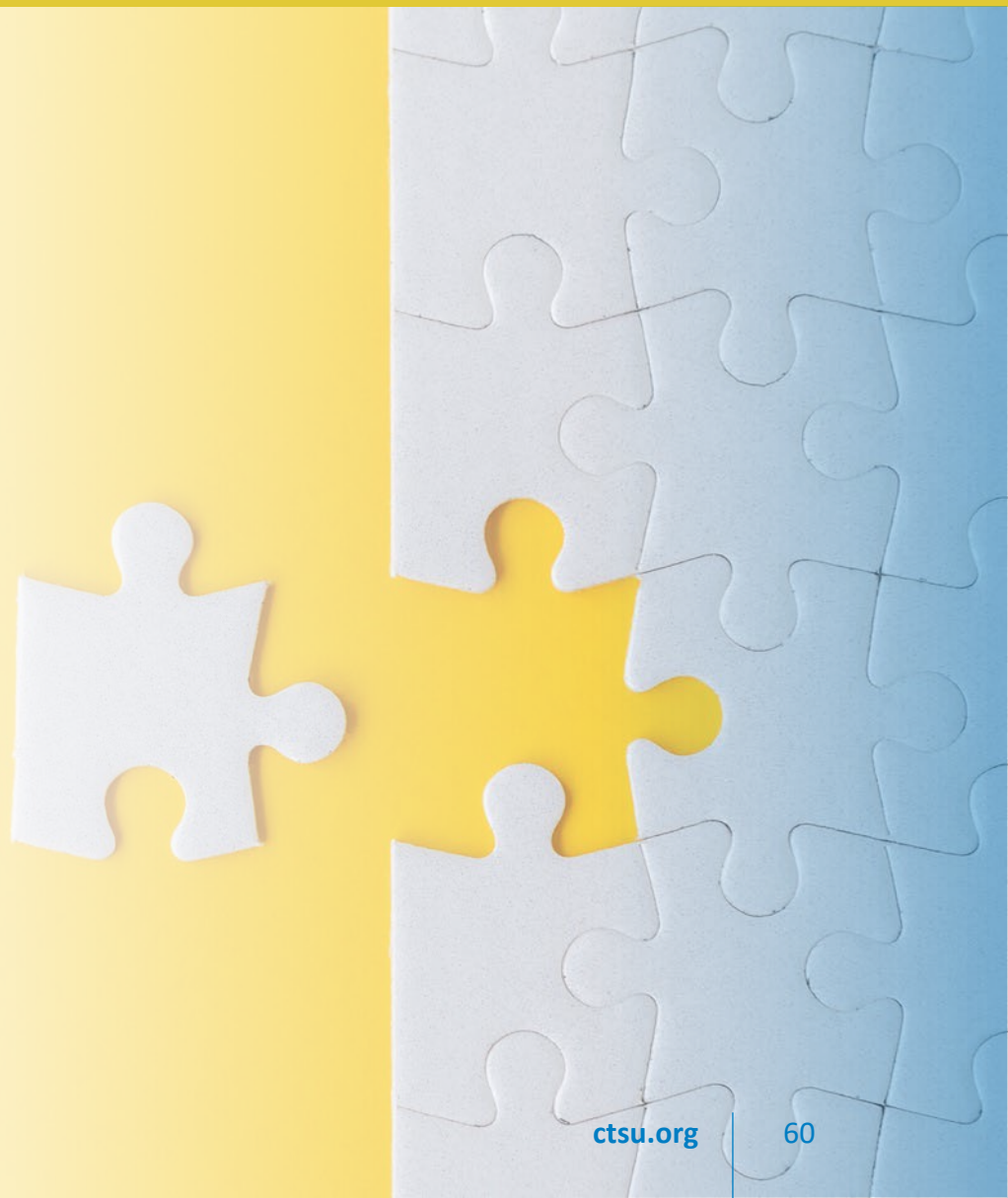
- Nearly 15,000 local IRB Approvals processed last year
- Required data points:

Site Name/Site CTEP ID	**Meeting Date**
PI	Approval Date
Approval Type	Expiration Date
Level of Review	***IRB Number***
Protocol Version	

- Protocol Version and IRB Number are the most common data points that are not included in a submission of a local IRB Approval

Protocol Version

- The version of the protocol reviewed by the IRB must be provided with the submission of all local IRB Approvals
  - **Initial IRB approvals** – Protocol version must be provided on the valid IRB approval documentation
  - **IRB amendment approvals** – Protocol version must be provided on the valid IRB approval documentation
  - **IRB continuing review approvals** – Protocol version can be provided on supporting documentation, including in the comments of the Regulatory Submission Portal cover page

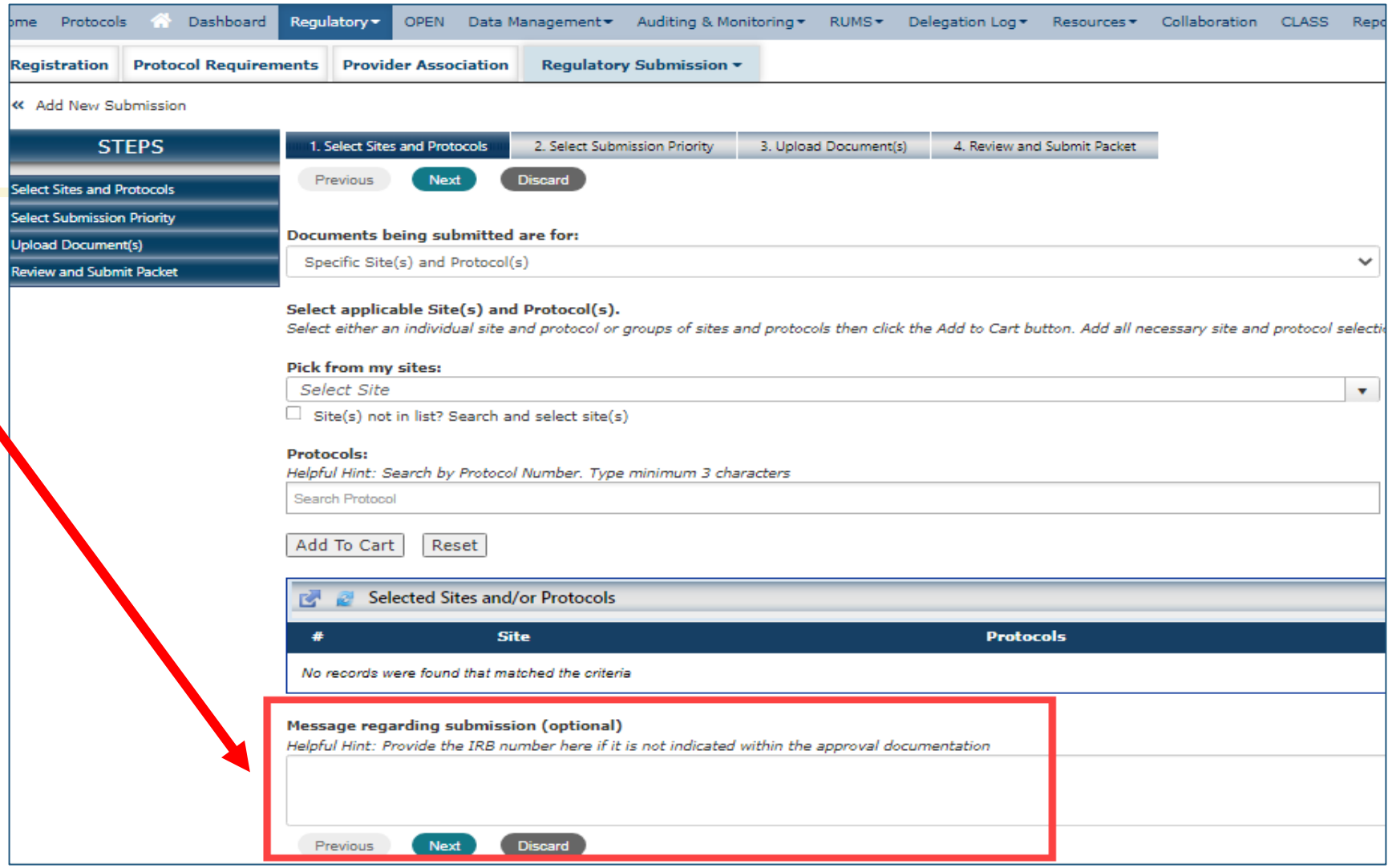


IRB Number

- The IRB Number of the board that performed the review must be provided for all local IRB approval submissions
- Can be provided on supporting documentation, such as the CTSU IRB Certification Form, or in the comments of the RSP cover page
- Must be the IRB's OHRP Registration Number
  - Must be in the format of IRB########
- Expedited Approvals?
  - IRB Number of reviewer's board
  - IRB Number of the board reported to
  - IRB Number of the primary board

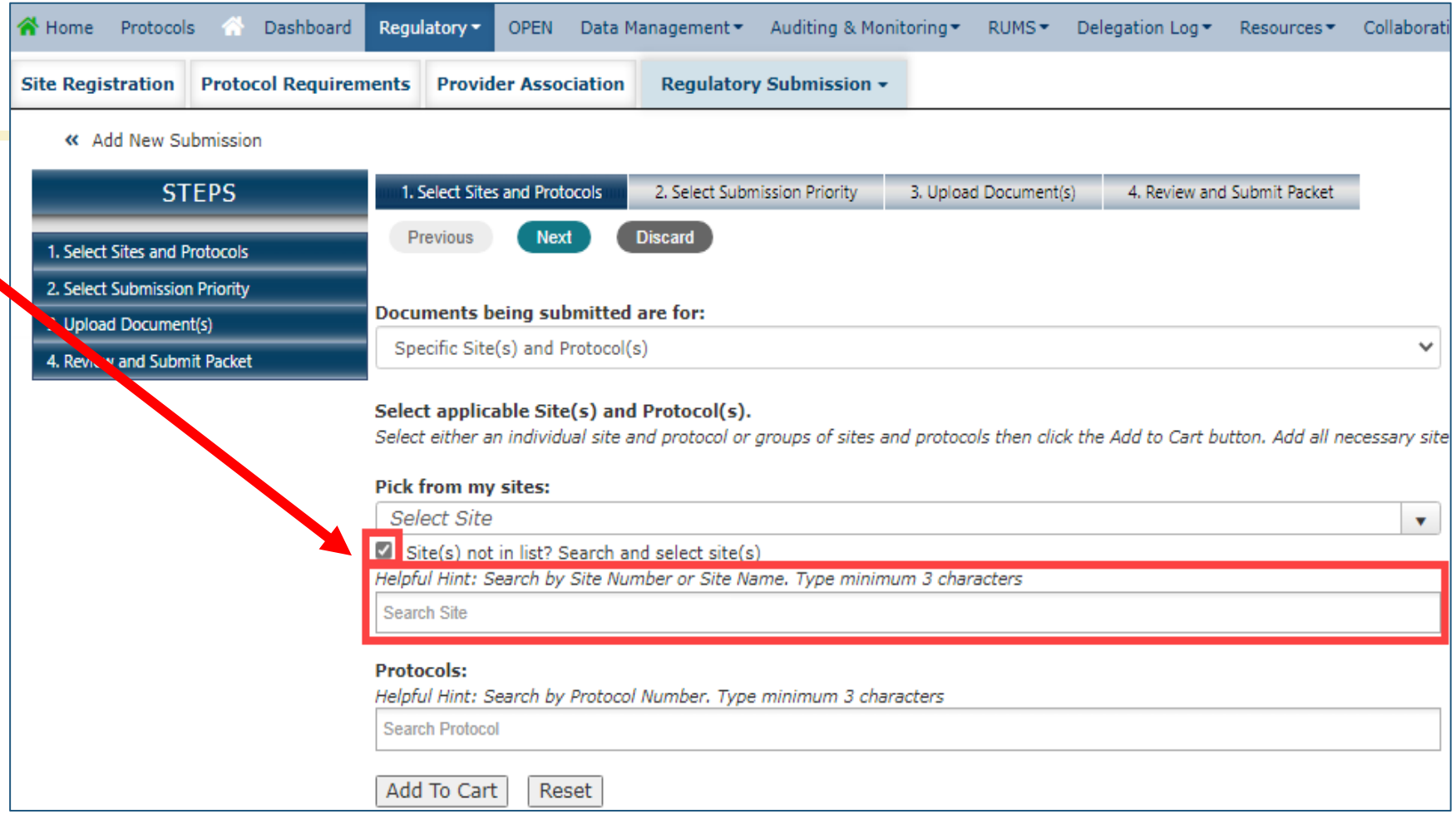
Regulatory Submission Portal (1)

Comment Section



Regulatory Submission Portal (2)

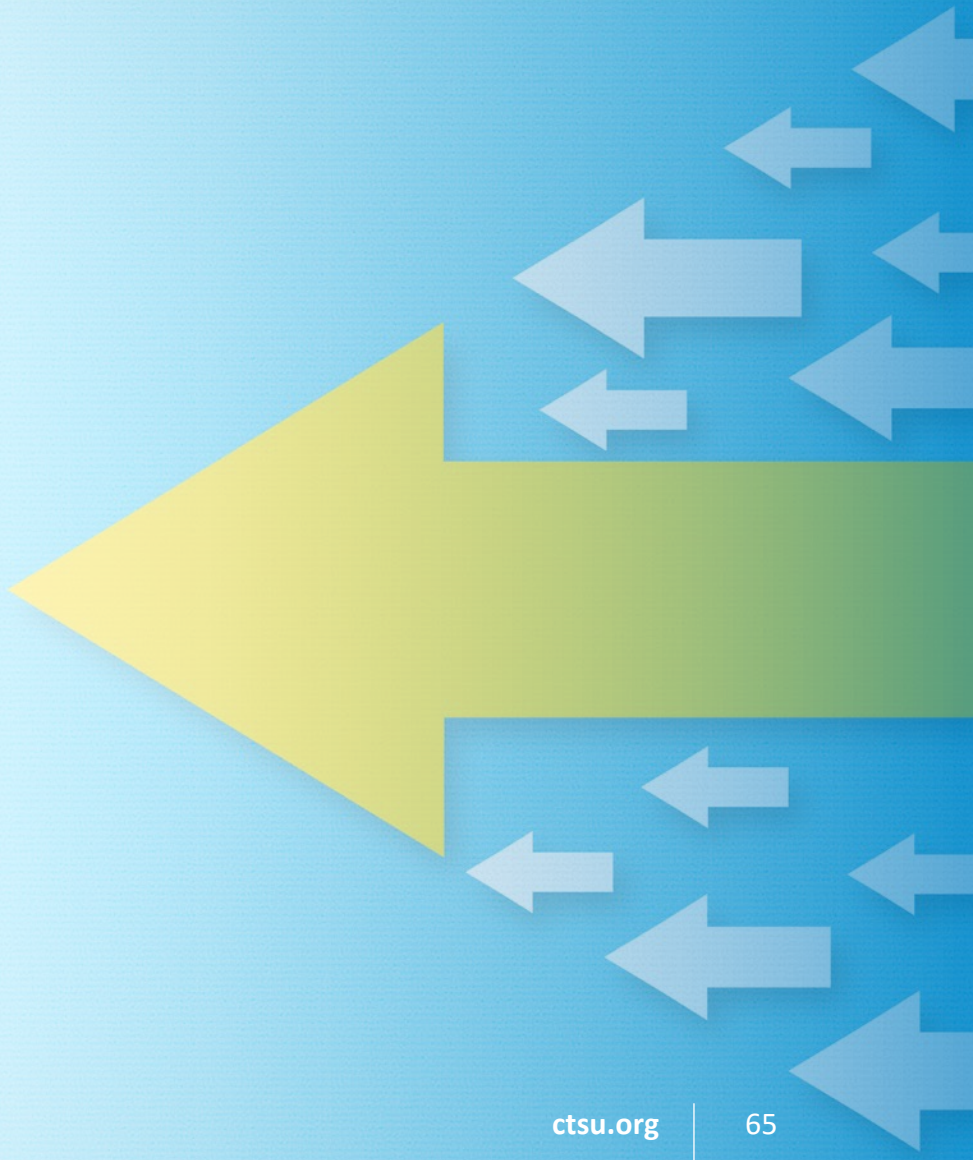
Site Selection



NCI CIRB Approvals

NCI CIRB Approvals

- CIRB and CTSU have established a web-service for the submission of all CIRB approvals to the CTSU
- Participating sites no longer have to submit documentation of CIRB IRB approvals to the CTSU
- CIRB Signatory Institution designates participating sites by establishing Site Preference settings via email correspondence with the CTSU (CTSURegPref@coccg.org)



Site Preference Settings

- Network Levels:
  - **ETCTN LAO** – Current ETCTN studies
  - **ETCTN P2C** – Legacy ETCTN studies
  - **NCTN Adult** – Alliance, AMC, ECOG-ACRIN, CCTG, NRG, and SWOG
  - **NCTN Pediatric** – COG, PBTC, and PEP-CTN
  - **Multi-Network** – comprising two or more of the Network Levels above

- Site Preference Settings:
  - **All** – approvals applied to all active participating sites on the Signatory Institution's roster
  - **Site Specific** – approvals applied to a specific set of active sites on the Signatory Institution's roster
  - **Protocol** – applied to the active sites on the Signatory Institution's roster as designated by the Signatory on a study-by-study basis
  - **None** – Signatory Institution not participating in studies in this Network Level

CIRB Roster Updates

- A few key points to keep in mind when adding a site or sites to a CIRB Signatory Institution's roster:
  - Is the site's Federalwide Assurance (FWA) up to date with OHRP and on file with CTSU?
  - Is the site Active on at least one NCTN or ETCTN roster?
  - Do the Site Preferences need to be updated with the addition of the new site?
    - Site Preference settings of *All* or *None* do not require action
    - Site Preference settings of *Site Specific* or *Protocol* will require a notification to the CTSU if approvals for the Network Level studies with these preferences should be applied to the newly added sites
  - Does the PI on the Signatory Institution's approval meet all of the PI Validations at the newly added site?

PI Validations

PI Validations

- RSS automatically makes the following validations for all PIs that are entered into the system for an IRB Approval
  - PI has an Active CTEP registration status
  - PI must have a Registration Type of IVR (investigator) or NPIVR (non-physician investigator), if allowed by the study sponsor
  - PI is Active at the site on a participating organization's roster
  - PI has the site listed as a Practice Site on their FDA 1572 in RCR
  - PI has the IRB Number of the board that issued the approval listed on their FDA 1572 in RCR
- If the PI fails any of the validations above the site's registration status will be set to "Pending" and new patient enrollments will not be able to be completed in OPEN

CTSU Website – Site Registration

CTSU Website – Site Registration

Home | Protocols | Dashboard | **Regulatory** | OPEN | Data Management | Auditing & Monitoring | RUMS | Delegation Log | Resources | Collaboration | CLASS | Reports

Site Registration | **Protocol Requirements** | **Provider Association** | **Regulatory Submission** | **CIRB Site Preferences**

The **CTSU Regulatory Office** is available to answer your regulatory questions by phone (1-866-651-2878) or email CTSURegHelp@coccg.org. If you have a subject waiting, be sure to submit your regulatory documents as urgent via the Regulatory Submission Portal and you will be contacted once your submission has been processed.

Help

Site Number: Registration Status: Approved, Close... Protocol Status: Temporarily Closed IRB Type: All IRB Types

Protocol: Pick Go Disclaimer

2 12

#	Site	Protocol Number	LPO	Protocol Status	IRB Type	IRB Approval Expiration (Days)	CTSU Collecting IRB Continuing Review?	Member Of LPO or PO	Site-Protocol PI	Site Registration Status	Missing Requirements	Status Reason
11		S1608	SWOG	Temporarily Closed to Accrual	CIRB	106	Yes	Y		Pending	N	Protocol is Temporarily Closed to Accrual
12		S1614	SWOG	Temporarily Closed to Accrual	CIRB	127	Yes	Y		Pending	N	Protocol is Temporarily Closed to Accrual

Page 2 of 2 End of Records Last update: 5:45:27 PM UTC

CTSU Website – Site Registration: Requirements List

Site's Protocol Specific Requirements

Site Number : **Site Registration Status :** Pending **Protocol :** S1608
Principal Investigator :
Print

							Site PSR Status		
#	Description	Submission Type	Source	Required for Enrollment?	Required by Date	LPO Review Required?	N/A	Received	Complied
1	IRB Approval	Specific Site(s) and Protocol(s)		✓	Prior to Enrollment			✓	✓
2	Lenalidomide Training 1	Specific Site(s) Only	SITE	✓	Prior to Enrollment			✓	✓
3	Lenalidomide Training 2	Specific Site(s) Only	SITE	✓	Prior to Enrollment			✓	✓

Child Sites Registration Status Report for Protocol S1608

#	Site	Site Name	Status	Comments	Missing Requirement (if applicable)

Regulatory Office Contact Information

- **Regulatory Helpdesk**
  - CTSURegHelp@coccg.org
  - 215-651-CTSU (2878)
- **CIRB Site Preferences**
  - CTSURegPref@coccg.org

Questions?

Ryan Wilkins

215-789-3651

rwilkin@coccg.org

SWOG Group Chairs Office

Casey Dawson, Assistant Director of Administration
Pat Mize, MBA, Grants and Contracts Manager
Kyle Theige, Senior Grants and Contracts Coordinator

National Coverage Analysis (NCA)

- What is a Clinical Trials Coverage Analysis?
  - A coverage analysis is a review of all tests, procedures, and interventions associated with a clinical trial (CT) to determine which ones are ‘billable’ and which are ‘not billable’ to a third party payer against the national guidelines and coverage rules
- Who performs the NCA’s?
  - The Clinical Trials Support Unit (CTSU) creates the NCAs for NCTN and NCORP trials
  - SWOG also does internal coverage analysis to aid in identifying study budget needs
- Why are NCA’s performed?
  - NCAs are intended to be a guide for the sites as they consider their participation in SWOG trials
- Where can you find NCA’s?
  - Once completed, official NCAs are posted on the CTSU dashboard

Financial Agreements

- Fixed-price subawards for federal member site payments are now required by the National Cancer Institute (NCI) for Cooperative Groups
- Current project period dates:
  - NCTN funding: **03/01/2019 – 02/28/2025**
  - NCORP funding: **08/01/2019 – 07/31/2025**
- Non-federal site payments are *not* affected
  - Non-federal site payments will continue to be distributed via current PSA w/ SWOG-CTP

Site Payments

- SWOG does *NOT* accept invoices for federal site payments
- Instead, payments are **triggered** as indicated on the study's funding memo:
  - Base Intervention (patient enrollment)
  - Biospecimen submission (entered into OPEN)
  - QOL/PRO Questionnaires (entered into OPEN)
- Federal Site Payments:
  - Processed via SWOG GCO (located at OHSU)
  - Typically run bi-monthly
- Non-Federal Site Payments:
  - Processed via SWOG-CTP (located at The Hope Foundation)
  - Typically run monthly

Funding Memos

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network
a National Cancer Institute program

PROTOCOL S2207

RANDOMIZED PHASE II STUDY OF THE ADDITION OF COO (CELL-OF-ORIGIN)-DIRECTED THERAPEUTIC AGENTS TO TAFASITAMAB-BASED THERAPY IN NON-TRANSPLANT-ELIGIBLE PATIENTS WITH RELAPSED/REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA

Study Activation Date: XX/XX/20XX

Trial Type: CTEP IND

Funding Source and Study Component		Collect Type	Study Specific Notes	Enter Date in Open? (c)	NCTN Funding per Patient (a) Std/HP LAPS	NCORP Funding per Patient (b) Std/HP
Federal	Step 1 Screening		1	No	$600	$600
Federal	Base Intervention – Standard / High Performance LAPS & NCORP	Mandatory		No	$3,000/$4,600	$3,000/$4,600
Federal	Biospecimen – Tissue Baseline and Relapse	Mandatory Request	2	Yes	$200	$200
Federal	Biospecimen – Blood Multiple Time Points	Mandatory Request	2	Yes	$300	$300
Federal (DCP)	Questionnaires – QOL/PRO	Mandatory	3	Yes	$1000	$1000
Total Potential Federal Funds					**$5,100/$6,700**	**$5,100/$6,700**
Total Potential Funds					**$5,100/$6,700**	**$5,100/$6,700**

Funding Memos

Activity	Does Cover	Does *NOT* Cover
Base Intervention (Treatment Intervention)	• Site effort for study • Enrollment efforts • Data collection, data management and data submission • Pharmacy set-up	• Standard or non-standard of care (SOC) procedures
Biospecimen Submission	• Site effort and supplies for submission of biospecimens • Institutional supplies, processing, packing effort/materials • Shipping to biobank/lab	• Cost of biopsies and/or blood draws
Quality of Life (QOL) *NCTN studies only*	• Site effort towards QOL correlatives	• Effort for QOL on NCORP studies is part of the capitation amount

Funding Memos

Study Specific Notes:

1. Screening payment will be triggered by registration onto Step 1 in OPEN. This payment represents a portion of the CTEP IND base intervention payment.

2. Sites are eligible to receive additional federal funds for biospecimen submissions. See information contained in section 15 of Protocol for detailed information on biospecimen collections. Payments will be triggered by submission of information for the first time point for each submission type into the OPEN system.

3. Sites are eligible to receive additional federal funds for Quality of Life/Patient Reported Outcomes (QOL/PRO). See information contained in section 15 of Protocol for detailed information. Payment will be triggered by submission of information for the first time point into the OPEN system.

Funding Questions?

- Contact Information
  - General funding/NCA questions
    - SWOG Funding (funding@swog.org)
  - Federal funding specific questions
    - Kyle Theige (theige@ohsu.edu)
  - Non-Federal funding specific questions
    - Debbie Allen (debbie@thehopefoundation.org)
    - Mariela Pucci (mariela@thehopefoundation.org)

SWOG Clinical Trials Partnerships

- Busy developing studies with several industry partners including Genentech, Novartis and AstraZeneca
- Active collaborations in the following spaces:
  - Leukemia; MDS, MPN/MDS, CMML
  - Breast cancer
  - Bladder cancer
  - Non-small cell lung cancer
  - Head and neck squamous cell cancer
  - Cutaneous squamous cell cancer

CTP Process Overview

- Sites will be contacted via email about CTP trial opportunities
- Interested sites will need to complete study feasibility assessment
- CTP will be utilizing WCG IRB as central IRB
- CTP will be posting NCA's for all CTP trials

- Velos Clinical Trial Management System and Florence Electronic Trial Master File will be used to streamline site communications and start-up efforts, house study documents, assist in management of Investigator Site Files (ISF), regulatory requirements, and monitoring/auditing efforts

CTP Updates and News

- CTP Update Forum recording will be posted to the meeting website
- You can also find news and contact info on the CTP website
  - https://www.swogctp.org/
  - ctp@swog.org

Operations

Dana Sparks, M.A.T., Director of Operations and Protocols

Connie Barnes, Membership

SDMC Updates

CATHY RANKIN, MS

COORDINATING STATISTICIAN

SWOG Statistics and Data Management Center
Seattle, WA

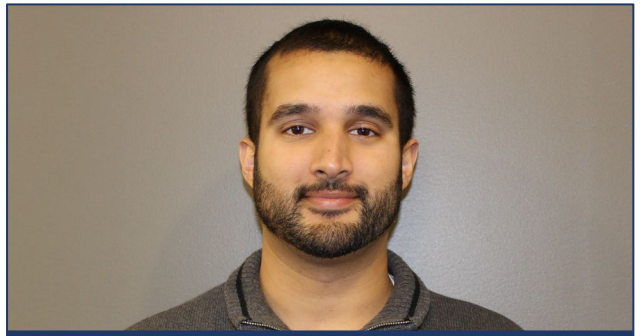
Data Management – *Retirement!*

Tracy Maher
Clinical Research Data Operations Supervisor
Disease Sites: Leukemia, Myeloma
Therapeutics DC since: 1997

Laura Kingsbury
Data Coordinator
Disease Sites: GU, Lung
Therapeutics DC since: 1984

Dona Marrah
Project Manager, Clinical Monitor
SWOG since: 1993

Data Management – New Staff



Manny Kharbanda
Data Coordinator
Cancer Control &
Prevention DC since: 2022

Aubrey Gilmore
Data Coordinator
Disease Sites: Breast, GI
Therapeutics DC since: 2022

Daria Chugina
Data Coordinator
Disease Sites:
Lymphoma, Myeloma
Therapeutics DC since: 2022

Data Management – New Staff

Kevin Moralda
Data Coordinator
Disease Sites: Lung
Therapeutics DC since: 2022

Matt Gospe
Data Coordinator
Disease Sites: Leukemia, Melanoma
Therapeutics DC since: 2022

New NCI Precision Medicine Initiatives

Existing NCI Precision Medicine Trials:

- LungMAP
- Adult MATCH
- ALCHEMIST
- Pediatric MATCH

New Initiatives:

- ComboMATCH – adding targeted agent to another anticancer therapy
- MyeloMATCH – long term treatment tracking using current and investigational agents for AML and MDS patient
- iMATCH – centralized profiling to calculate TMB and GEP

ComboMATCH (EAY191)

It is hypothesized that genomically-driven, evidence-based addition of a targeted agent to another anticancer therapy will produce greater clinical benefit than treatment without the added targeted agent.

ECOG-ACRIN to coordinate the master registration trial.

Any Network Group can coordinate targeted therapy treatment trials.

ComboMATCH (EAY191)

Genomic testing ordered by physician at a designated lab

↓

Register in OPEN to **EAY191** - ComboMATCH Registration Trial

↓

Treatment trial assignment based on genomic and clinical data

↓

Register to ComboMATCH treatment trial

↓

Upon progression, potential subsequent treatment trial assignment

EAY191-S3

Phase II Study of Paclitaxel + Ipatasertib in Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors

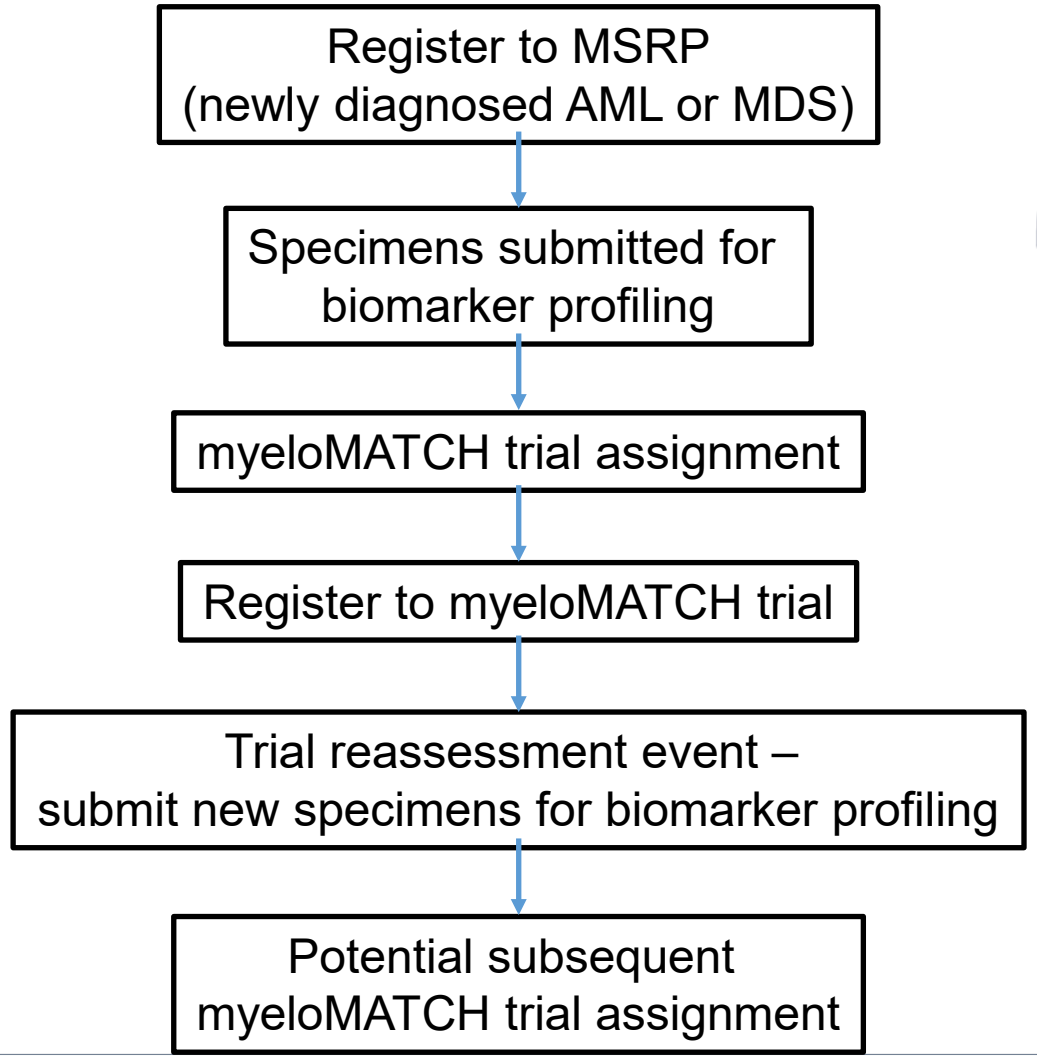
MyeloMATCH

Includes a master screening and reassessment protocol (MSRP) coordinated by SWOG

MSRP will assign participants to an appropriate myeloMATCH clinical trial if one is available

Eligible participants must be suspected to have untreated AML or MDS

At reassessment event, MSRP will determine eligibility for an additional myeloMATCH trial



MyeloMATCH trials in the pipeline

Untreated AML:

MM1YA-S01 – age ≤ 59 high risk AML

MM1OA-S02 – age ≥ 60 *TP53*-mutated AML

MM1OA-S03 – age ≥ 60 IDH2 mutant AML

MM1YA-CTG01 – age ≤ 59 intermediate risk AML

AML, received induction on myeloMATCH clinical trial:

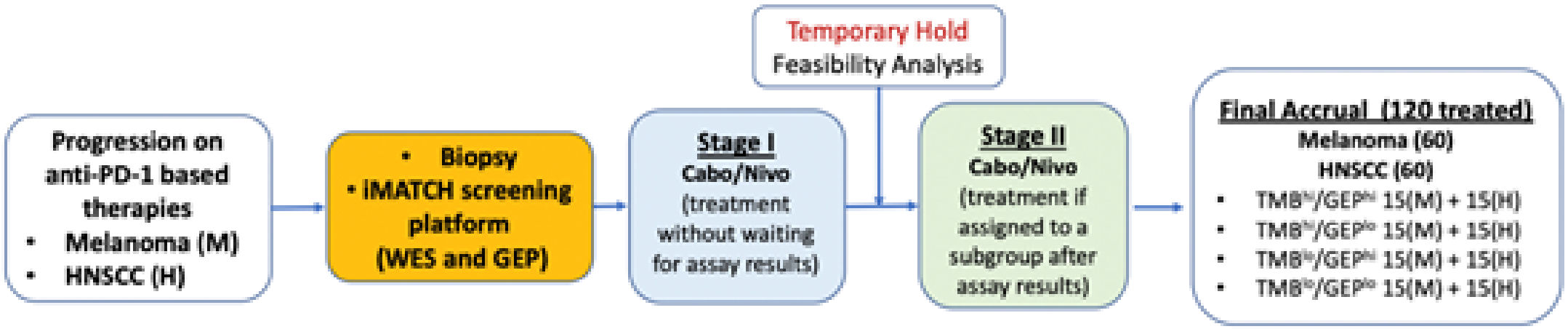
MM2YA-EA01 – age ≤ 59; achieved CR/CRi on induction; MRD+

iMATCH

Pilot Study

S2101 - A Phase II Study of Combining Cabozantinib and Nivolumab in Participants with Advanced Solid Tumors (IO refractory Melanoma or HNSCC) Stratified by Tumor Biomarkers – an immunoMATCH Pilot Study

iMATCH


Progression on anti-PD-1 based therapies
• Melanoma (M)
• HNSCC (H)
• Biopsy
• iMATCH screening platform (WES and GEP)
Stage I
Cabo/Nivo
(treatment without waiting for assay results)
Temporary Hold
Feasibility Analysis
Stage II
Cabo/Nivo
(treatment if assigned to a subgroup after assay results)
Final Accrual (120 treated)
Melanoma (60)
HNSCC (60)
• TMB^{hi}/GEP^{hi} 15(M) + 15(H)
• TMB^{hi}/GEP^{lo} 15(M) + 15(H)
• TMB^{lo}/GEP^{hi} 15(M) + 15(H)
• TMB^{lo}/GEP^{lo} 15(M) + 15(H)

Quality Assurance Updates

Laura Gonzales, BSN, MA RN, OCN

Quality Assurance Manager
SWOG Operations Office
San Antonio TX

Quality Assurance Department

- Laura Gonzales, BSN, MA, RN, OCN - QA Manager
- Maggie Spillers, BSN, RN QA - Assistant Manager
- Rose Ermete, BSN RN, OCN, RN-BC, CCRP - Senior QA Nurse Auditor
- Heather Hillman, BSN, RN, OCN - Senior QA Nurse Auditor
- Michelle Phillips, RN, OCN - Senior QA Nurse Auditor
- Alison Arellano, BS, CCRP - QA Auditor
- Sabrina Barrera, BA QA - Auditor

Quality Assurance Department

- Roxann Bates, BSN, RN - QA Nurse Auditor
- Rose Hardesty, BA, AS, RN, CCRP - QA Nurse Auditor
- Tina Rosas, BSN, RN - QA Nurse Auditor
- Misty Juarez SAE Coordinator
- Dominique McReynolds, BSN, RN - SAE Coordinator
- Katherine Farmer - QA Associate
- Landra Priestly - QA Associate
- Elaine Armstrong, MS - QA Consultant

Protocol Deviations

- SWOG now follows CIRB guidance
- Potential unanticipated problem
- Continuous or serious non-compliance

Local IRB may require additional reporting

SWOG COVID-19 Deviation and Diagnosis Guidance
SWOG memo dated 6/1/22

The NCI has removed the requirement to report COVID-19 minor protocol deviations to CIRB at time of Continuing Review as follows:

- This requirement started for all trials with CR date on or after July 1, 2020 and will end **for all trials on June 30, 2022.**
- **The requirement to collect date of initial Covid diagnoses will end for most trials* on June 30, 2022.**
- In response to this change in requirement, Rave will be modified to remove the Covid Diagnosis and Deviation Form, as is appropriate.

* **Exceptions**

- **The trials that must continue to report COVID-19 Diagnoses are: S1418, S1501, S1826, S1918, and S1925.**

Additions to the SWOG Glossary (Published on the CRA Workbench)

- ON-STUDY:
  - Time from Registration (in OPEN) through completion requirements (including follow-up).
- OFF-STUDY:
  - Participant is no longer receiving protocol-directed intervention per Section 7 (protocol-directed intervention can include surveillance or observational Arm A), the site has submitted an Off-Treatment Notice and all follow-up requirements have been met.
  - This includes the infrequent occasions where participants are no longer able to be contacted for further follow-up.
- ON-TREATMENT:
  - Duration of time when participant is receiving protocol-directed intervention per Section 7 (protocol-directed intervention can include surveillance or observational arms).
- OFF-TREATMENT:
  - Participant is no longer receiving protocol-directed intervention per Section 7 (protocol-directed intervention can include surveillance or observational arms), the site has submitted an Off-Treatment Notice but is still submitting follow-up requirements per protocol.

Back to (the new) Normal

QA Audits Remote vs Onsite

2021:

- 69 onsite audits — 306 remote audits

2022 (as of 8/31/22):

- 73 onsite audits — 141 remote audits

The QA audit team is ready and willing to come to your site for audits but has procedures to conduct remote audits if necessary.

Thoughts on Life

Caitlin Hutchinson

Liz Edwards


THIS IS FINE.

Poll Everywhere Instructions

Cell phone

1. Text **COURTNEYWILL940** to 22333
2. When you see the “Poll Everywhere” question screen, text the answer (i.e., A, B, C, D, E, or F) to 22333

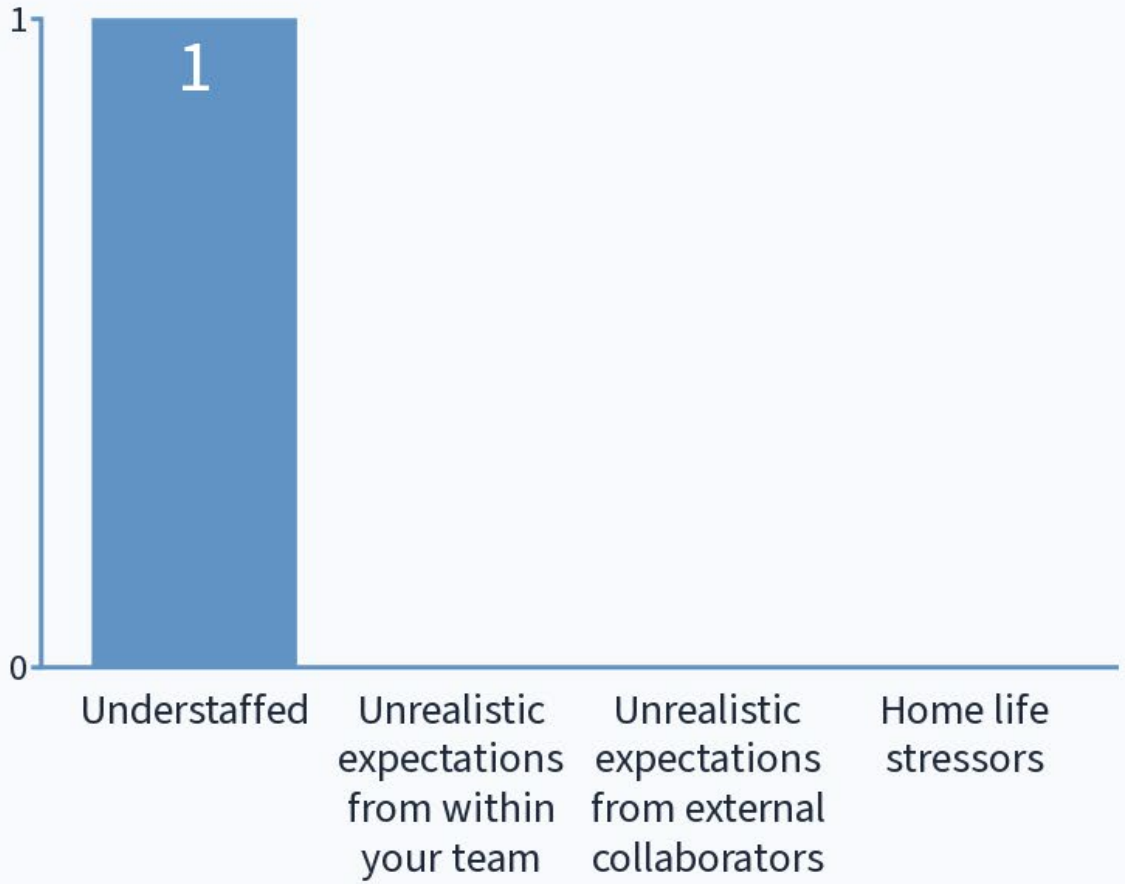
Computer

1. In your web browser go to: **PollEv.com/courtneywill940**
2. When you see the “Poll Everywhere” question screen, choose the answer (i.e., A, B, C, D, E, or F)

What contributes most to your sense of burnout?

- Understaffed
- Unrealistic expectations from within your team
- Unrealistic expectations from external collaborators
- Home life stressors

What contributes most to your sense of burnout?



What helps you manage the Sunday Scaries?

- Having protected time to prioritize tasks next week's tasks
- Supervisor steps in and shares the workload
- Feeling safe asking for help
- Collaboration between supervisors and staff to regularly assess, triage, and reassign work
- Self care fun (vacation, TV show, glass o' wine)

What helps you manage the Sunday Scaries?

What is your work love language?

- Coffee
- Ending meetings early/No Friday meetings
- Having protected time outside of meeting commitments
- Written SOPs/consistent training

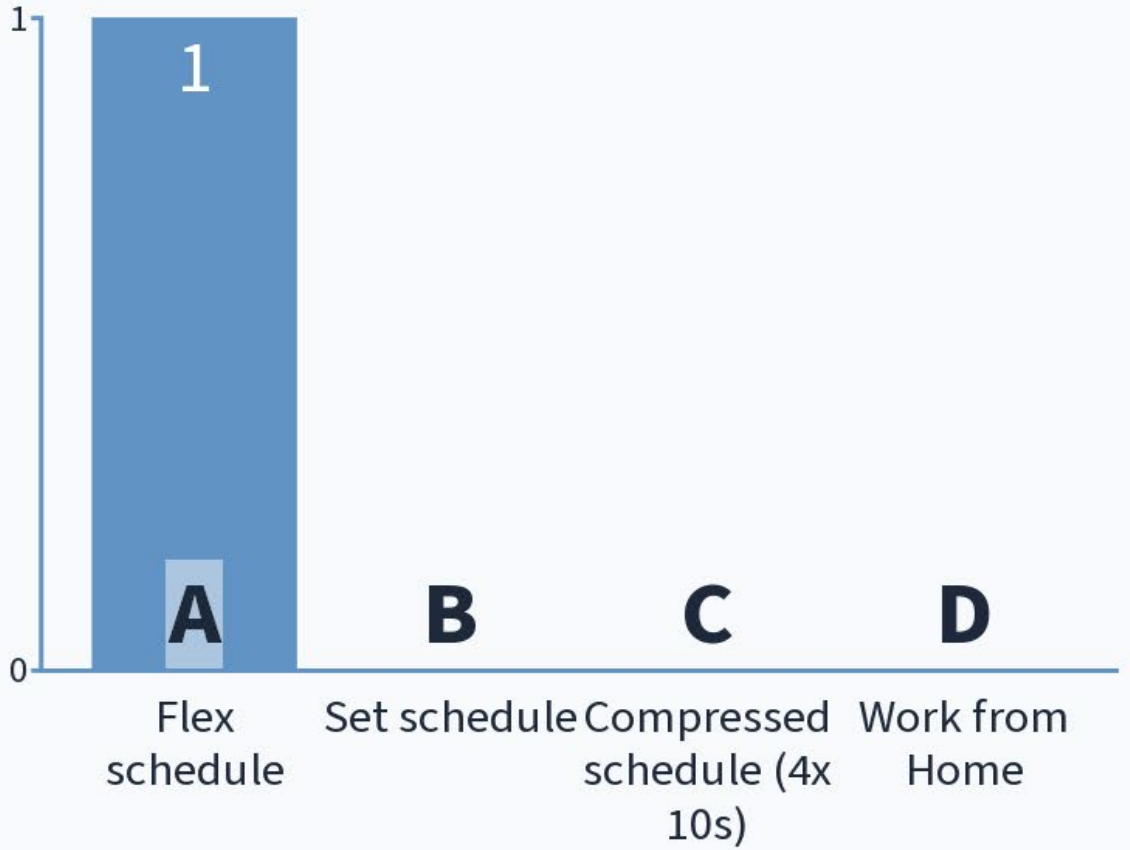
What is your work love language?

What helps you communicate your needs best?

What helps with work/life balance the most?

Flex schedule	**A**
Set schedule	**B**
Compressed schedule (4x 10s)	**C**
Work from Home	**D**

What helps with work/life balance the most?



What motivates you most at work?

Special Thanks

- All of our Speakers
- Courtney Wille
- Site Ops Workgroup Members
  - Liz Edwards
  - Caitlin Hutchinson

Closing Comments