Oncology Research Professionals (ORP) Site Operations Meeting

SWOG Fall Meeting 2024

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

Announcement and Updates Oncology Research Professionals (ORP) Committee

Connie Szczepanek, RN, BSN, CCRP
Chair, SWOG ORP Committee

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.

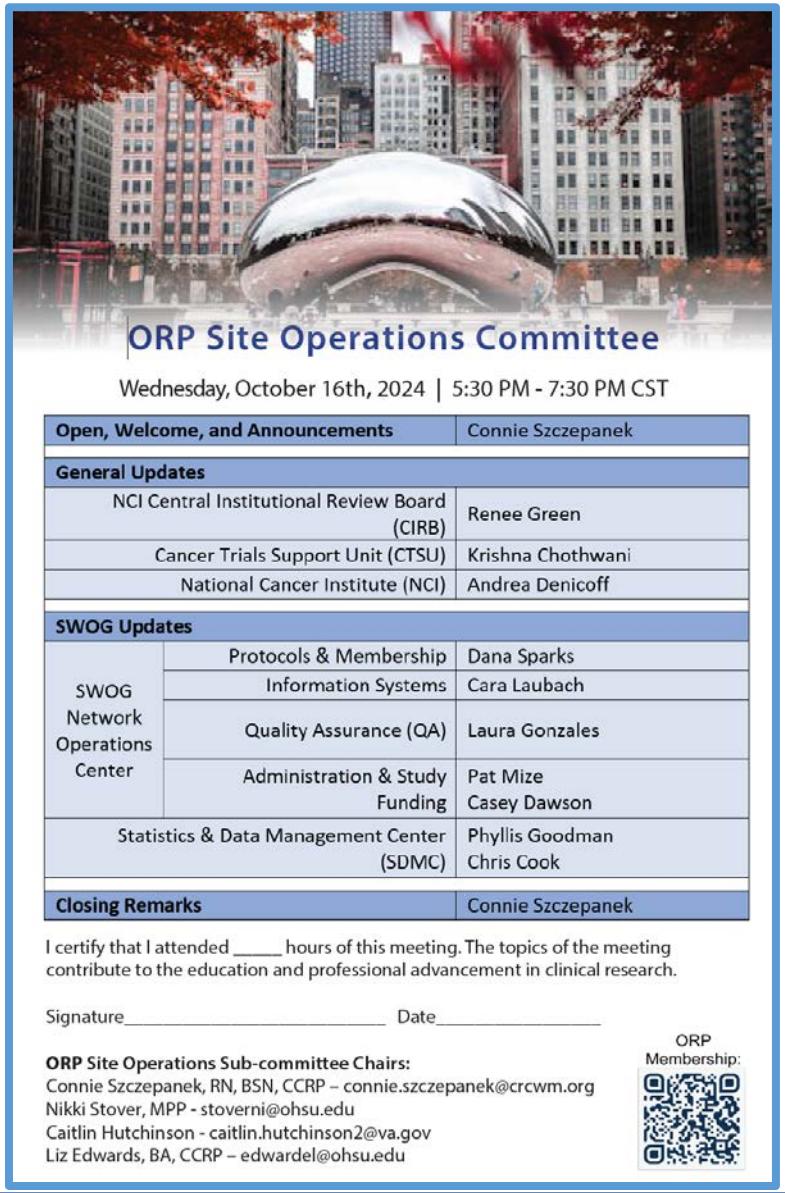
Fall Site Operations

October 16th 5:30p-7:30p CST

Open, Welcome, and Announcements		Connie Szczepanek
General Updates		
NCI Central Institutional Review Board (CIRB)		Renee Green
Cancer Trials Support Unit (CTSU)		Krishna Chothwani
National Cancer Institute (NCI)		Andrea Denicoff
SWOG Updates		
SWOG Network Operations Center	Protocols & Membership	Dana Sparks
	Information Systems	Cara Laubach
	Quality Assurance (QA)	Laura Gonzales
	Administration & Study Funding	Pat Mize Casey Dawson
Statistics & Data Management Center (SDMC)		Phyllis Goodman Chris Cook
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 16th, 2024 | 5:30 PM - 7:30 PM CST

Open, Welcome, and Announcements		Connie Szczepanek
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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_____

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

ORP Membership:

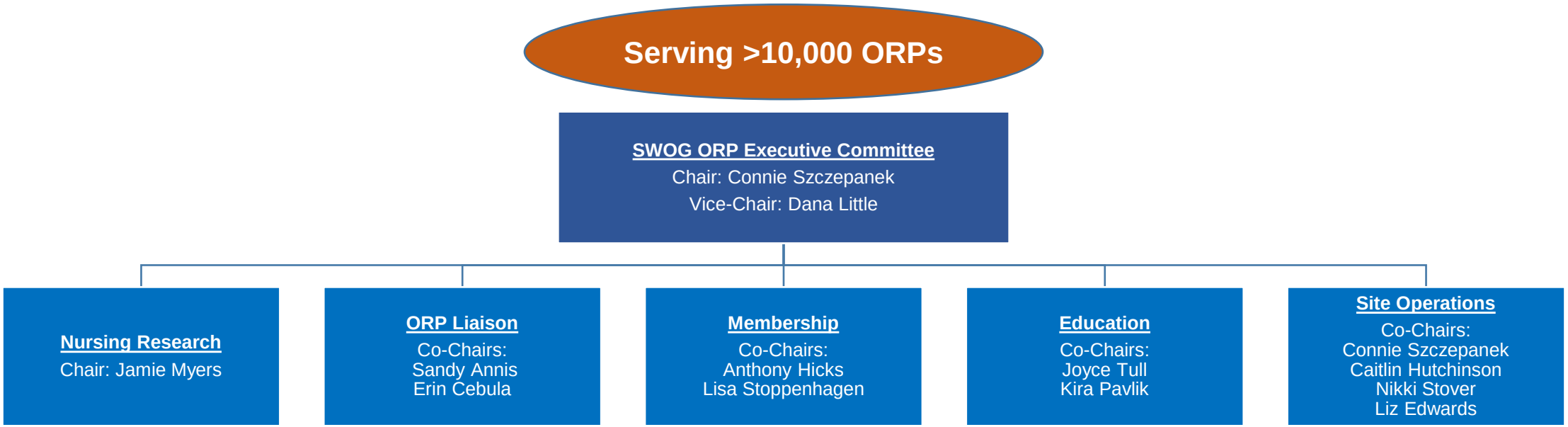
YOU are The ORP Committee!

"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."

ORP Executive Committee Members

Deb Bergevin	Erin Cebula	Joyce Nancarrow-Tull
Lisa Stoppenhagen	Sandy Annis	Dana Little
Connie Szczepanek	Liz Edwards	Anthony Hicks
Annette Betley	Caitlin Hutchinson	Jamie Myers
	Kira Pavlik	

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.

Quick Reference

See the ORP page on the SWOG Website:

Member Resources > Oncology Research Professionals

Quick Access to:

- Contact info of Committee Leaders
- Lead ORP (Head CRA) Training Modules
- APP Workshop

Get Involved with ORP

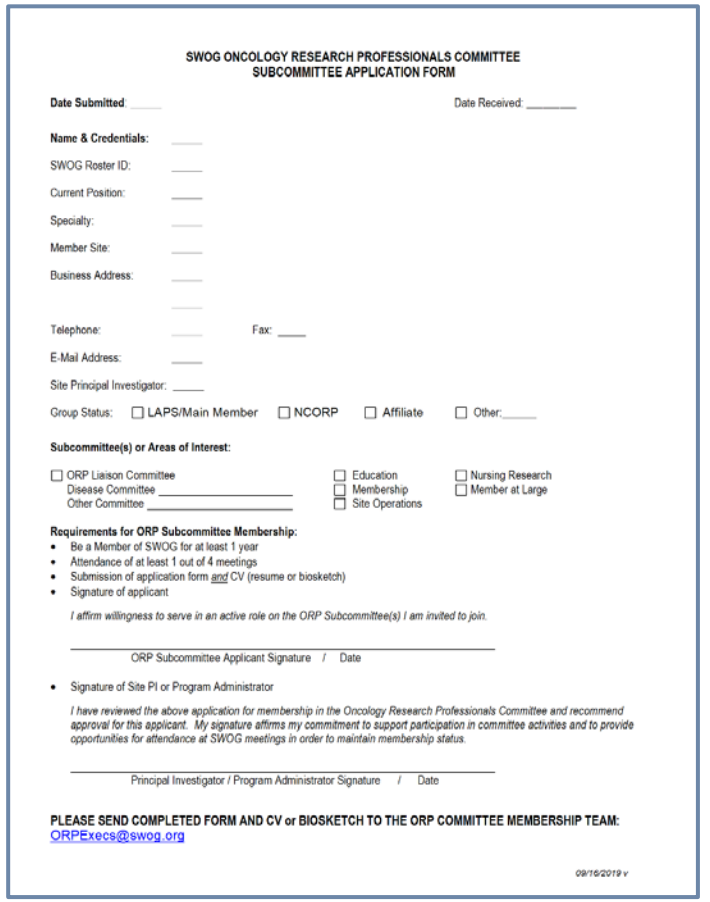
Follow the link to the ORP Membership Application on the ORP Member Resources page:

To get more involved please complete the ORP Membership Application.

Key Involvement Opportunities

- Disease Specific Liaisons
- Liaisons at Large
- Education Team

It only takes 5 minutes to apply!



SWOG ONCOLOGY RESEARCH PROFESSIONALS COMMITTEE
SUBCOMMITTEE APPLICATION FORM

Date Submitted: _____ Date Received: _____

Name & Credentials: _____
SWOG Roster ID: _____
Current Position: _____
Specialty: _____
Member Site: _____
Business Address: _____
_____
Telephone: _____ Fax: _____
E-Mail Address: _____
Site Principal Investigator: _____
Group Status: ☐ LAPS/Main Member ☐ NCORP ☐ Affiliate ☐ Other:_____

Subcommittee(s) or Areas of Interest:

☐ ORP Liaison Committee
Disease Committee _____
Other Committee _____
☐ Education
☐ Membership
☐ Site Operations
☐ Nursing Research
☐ Member at Large

Requirements for ORP Subcommittee Membership:
- Be a Member of SWOG for at least 1 year
- Attendance of at least 1 out of 4 meetings
- Submission of application form *and* CV (resume or biosketch)
- Signature of applicant

I affirm willingness to serve in an active role on the ORP Subcommittee(s) I am invited to join.

_____
ORP Subcommittee Applicant Signature / Date

- Signature of Site PI or Program Administrator

I have reviewed the above application for membership in the Oncology Research Professionals Committee and recommend approval for this applicant. My signature affirms my commitment to support participation in committee activities and to provide opportunities for attendance at SWOG meetings in order to maintain membership status.

_____
Principal Investigator / Program Administrator Signature / Date

PLEASE SEND COMPLETED FORM AND CV or BIOSKETCH TO THE ORP COMMITTEE MEMBERSHIP TEAM:
ORPExecs@swog.org

09/16/2019 v

Upcoming Funding Opportunities

All program information available at thehopefoundation.org/funding-opportunities

Apply or nominate by the noted deadlines below.

APP Mentorship Program November 1

Meyskens Lectureship November 1

SEED Fund Grants December 1

Impact Award January 15

CRA/Nurse Travel Support January 15

Vogelzang Scholars January 15

Career Engagement Award March 15

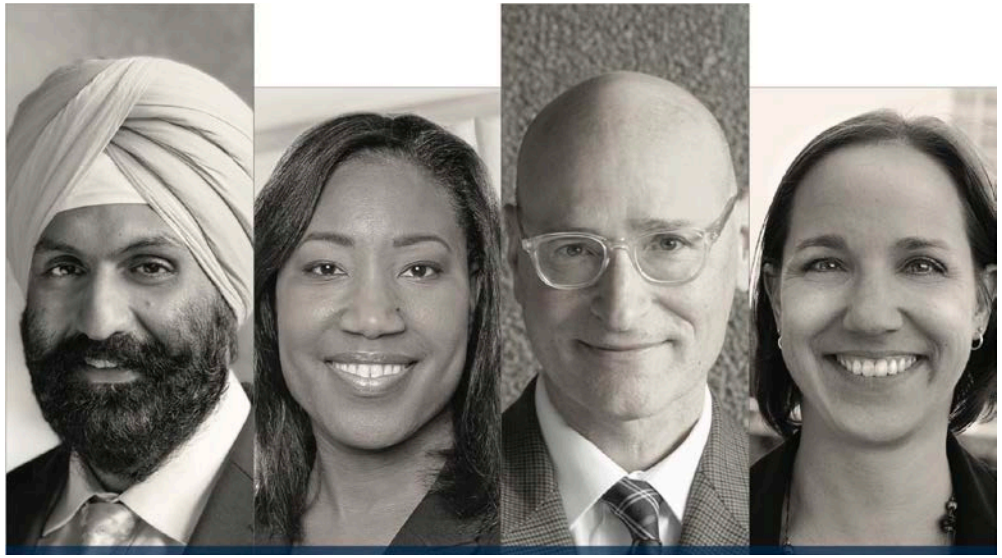
Coltman Fellowship Award March 15

THE HOPE FOUNDATION
FOR CANCER RESEARCH

Complete Your SWOG Member Profile

Help your committee, win a prize! Visit **swogdei.crab.org**

Engage in a bit of friendly competition to help us paint a richer picture of our membership. Check the leaderboard to see how your committee compares!



THE HOPE FOUNDATION
FOR CANCER RESEARCH

Apply by November 1

THE NCTN MAPP PROGRAM

A year-long mentoring program for Advanced Practice Providers including:

- Online APP training workshop
- Focused mentoring sessions
- Travel to professional meetings

APPLY NOW >

GILEAD

This program is made possible with generous support from Gilead

CIRB Updates and Worksheet Submission

SWOG Fall Meeting
October 16, 2024

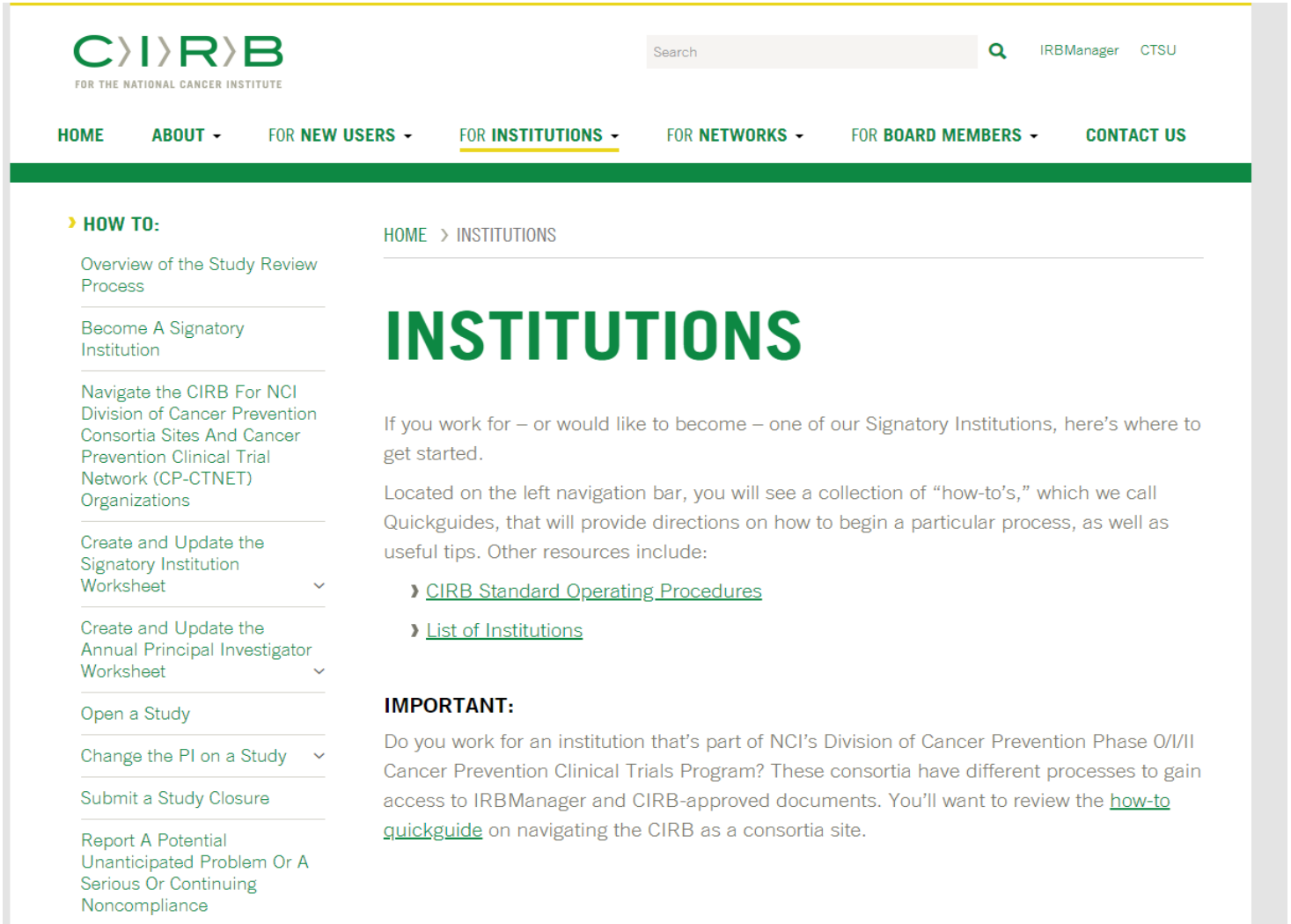
Renee Green, BA, RN
Local Context Administrator, NCI CIRB

C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

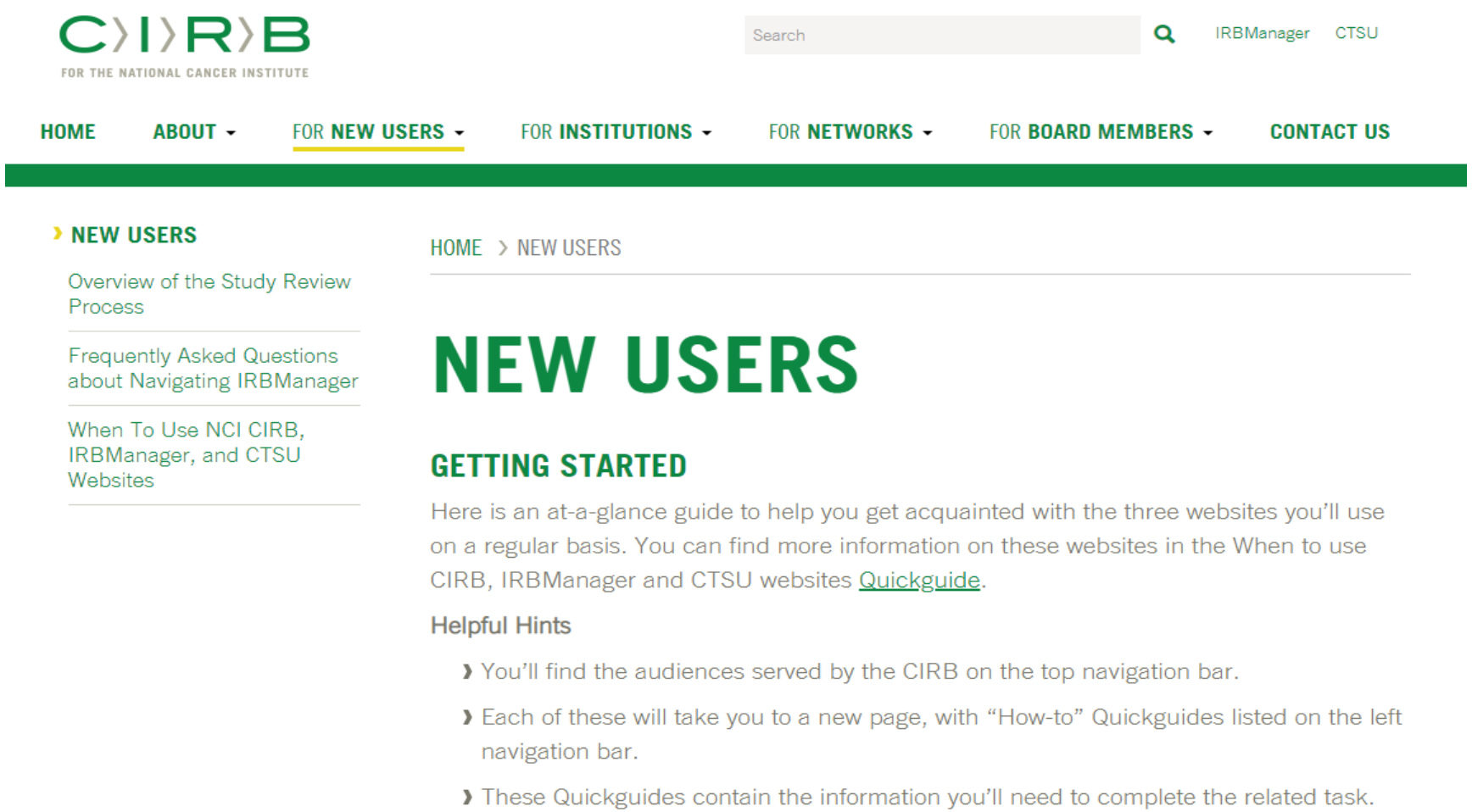
INFORMATION ABOUT THE CIRB

C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

CIRB WEBSITE



CIRB WEBSITE



CIRB WEBSITE

CIRB WEBSITE	CTSU WEBSITE	IRBMANAGER

What You'll Find Here

CIRB WEBSITE

- General information about the CIRB
- How to use the CTSU and IRBManager websites
- "How-to" guides (called Quickguides) on filling out worksheets in IRBManager

CTSU WEBSITE

- Study-related and enrollment information
- CIRB-related study documents
- Roster Update Management System (RUMS)
  - Make changes to your Signatory Institution's CIRB roster

IRBMANAGER

- Worksheets required by the CIRB
- User Dashboard
  - Studies open at your institution
  - PI responsible for each open study at your institution
  - Worksheets submitted by you, or by anyone at your institution

UPDATES:

- PRINCIPAL INVESTIGATOR WORKSHEET
- SIGNATORY INSTITUTION WORKSHEET
- STUDY CLOSURE OR TRANSFER OF STUDY WORKSHEET

PRINCIPAL INVESTIGATOR WORKSHEET REVISIONS

The Annual Principal Investigator Worksheet has been revised to clarify questions 15a, 15b, and 20c:

<u>June 2024 - Revisions</u>

- **Questions 15a and 15b – Reordered and provided choices for assessing potential study participant's mental capacity and understanding of the consent document and how the study is assessed.**
- **Question 20c – Removed. This information will now be captured in the revised question 8e on the Annual Signatory Institution Worksheet.**

<u>Completion of Principal Investigator Worksheet</u>:

- **Information for fields that stayed the same will be copied over. Those fields that changed from text to a list of options will need to be completed.**
- **If you select 'Copy to Amend' when making a copy of the Principal Investigator Worksheet, the changes will be highlighted.**

SIGNATORY INSTITUTION WORKSHEET REVISIONS

The Annual Signatory Institution Worksheet has been revised as follows (*These changes may require additional information to supplement what was provided in the previously approved submission):

<u>October 2023 - Revisions</u>

- Questions 4 and 5 – Clarified text regarding State and Local Laws
- Questions 7, 8, and 9 - Adding a field for Person Title
- Questions 8a – 8e – Clarified questions regarding Local Oversight
- Question 9 – Added and revised questions regarding notification, investigation, and reporting of potential unanticipated problems and/or serious or continuing noncompliance
- Question 10 – Clarified text regarding Financial Conflict of Interest
- Questions 11, 11a, 12, and 12a – Updated question text regarding institutional policies and guidelines that govern the informed consent document
- Question 14 and 14a – Updated question text regarding how assent and age of majority are documented (formerly Question 20)

<u>June 2024 - Revisions</u>

- Question 8e - Modified text to include receiving and resolving complaints or concerns regarding the investigators and/or research study team.

STUDY CLOSURE AND TRANSFER OF STUDY WORKSHEET

Study Closure Submission (Complete in IRBManager. Up to 10 studies can be entered for the same PI.)

All Requirements must be met prior to closure with the CIRB:

- The study is closed to accrual at the Signatory Institution and all Component and/or Affiliate Institutions relying on the Signatory Institution for this study.
- All study participants have completed study intervention(s) and follow-up activities OR no study participants were enrolled.
- There will be no further research activity for this study (this includes recruitment, enrollment, data collection, data analysis, data submission, etc.).

Each study closure requires an Early Study Closure Confirmation form (ECF). Criteria for ECF completion:

- Required for all studies, even those where no participants have been enrolled.
- Signature from Lead Protocol Organization's (LPO) required for documenting review and approval of early study closure regardless of the accrual status of the site. Approval is not guaranteed (e.g., registration trials).

**Exception for unsigned ECF: Memo from LPO also attached with the status of 'participant follow-up is complete' OR 'study is complete'.

COMMON SUBMISSION MISUNDERSTANDINGS

C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

TRANSLATED DOCUMENTS

- Spanish short forms cannot be used when a Spanish version of the consent form is approved and posted on CTSU. Additionally, the Signatory Institution is required to insert CIRB-approved translated boilerplate language into the Spanish version of the consent form. (Updated March 2022)
- Approval of documents translated by the institution need the following:
    1) An approved English version (can be submitted with translation),
    2) A translated version of the English document, and
    3) Certificate of accuracy that the translation reflects the English version. A three-way match is needed. This means the English version, the Translation, and the Certificate of Accuracy are all connected by “SOMETHING THAT MATCHES” which is a version number, local version date or protocol version date (for CIRB-approved English documents).
- Quality of Life (QOL) and Patient Reported Outcomes (PRO) are validated instruments which cannot be translated by the institutions. PROs are any documents being used to collect data for the protocol/study.

WORKSHEET SUBMISSIONS

PI Worksheets

- Use the selection provided for the questions. The selection of “Other” should not repeat the selections provided.
- The addition of the use of remote consent informs use of how the consent discussion will occur. The remote consent policy is not approved on this worksheet. This policy should be attached to Q11a of the Institution Worksheet.
- For Q16, the selection of “Translators or translation services are available for use during the consent process and throughout the study” cannot be entered as a single selection. It needs to be accompanied by either the short form or fully translated consent form selection as well.

Institution Worksheets

- For Q7, the responsible person to be entered should not be the IRB Chair. The responsible person should supervise or manage the entire IRB which includes the IRB chair.
- For Q8, all five parts have been revised to get more clarity for the oversight structure. Each part needs to be addressed to include this updated information being requested. The institution might need to revise their previously approved responses accordingly.
- For Q12, boilerplate language cannot contain and HIPAA language. HIPAA language needs to be in a separate standalone document, but it is not reviewed or approved by the CIRB.

WORKSHEET SUBMISSIONS

Study-Specific Worksheets

- Changes to the CIRB-approved consent document should be tracked to show the changes to be reviewed. Boilerplate language should not be tracked.
- Documents to be reviewed for approval need to be attached to the appropriate question: Q13 – Recruitment materials, Q14 – Assent forms and/or Age of Majority Consent, Q15 – translated documents.
- Documents which do not apply Q13 – Q15 should be attached to Q12.

Assent Waiver Worksheets

- Confirm the ages of assent before submitting the worksheet.
- Minors who reach the age of majority but are considered an impaired adult (i.e. has an ailment which impairs mental capacity) does not need an assent waiver. The institution's local policy for using a legally authorized representative would apply in this situation.

CIRB HELPDESK CONTACT

PHONE: 888.657.3711

SUPPORT@NCICIRBCONTACT.ZENDESK.COM

Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Linking practice to progress

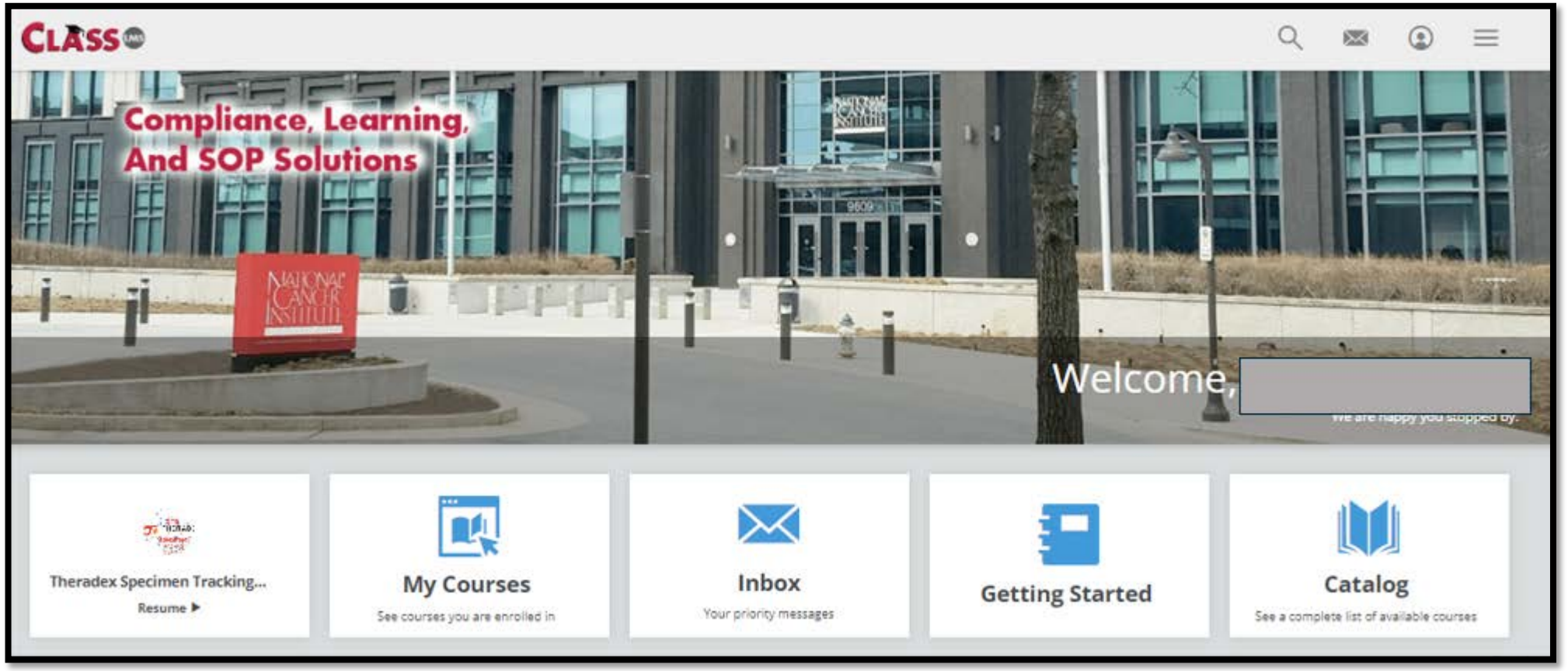
Cancer Trials Support Unit (CTSU) Compliance, Learning, and SOP Solutions (CLASS) Updates

Krishna Chothwani

CTSU Protocol Team Manager

CLASS-related Updates

- Expanded course options
- New training report on CTSU website



Courses Available in CLASS

- Longstanding CLASS trainings:
  - Clinical Trials Monitoring Branch (CTMB) auditor training
  - Theradex Specimen Tracking System (STS) training for ETCTN, NCICOVID, and Moonshot studies
  - Protocol-specific trainings

- More recent expansion to include more general research training
  - Separate folder in the CLASS catalog

General Site Training

- Wide range of topics
- Generally provided by an NCTN Group (e.g., Alliance, SWOG)
- Most are open to everybody via self-enrollment, although a few are limited to roster members*

NRG: An Overview of NRG*

Alliance: RECIST Basics

Alliance: Data Management Tips & Tricks

Alliance: Regulatory 101 and 102

SWOG Audits: Serious Adverse Event Reporting Training

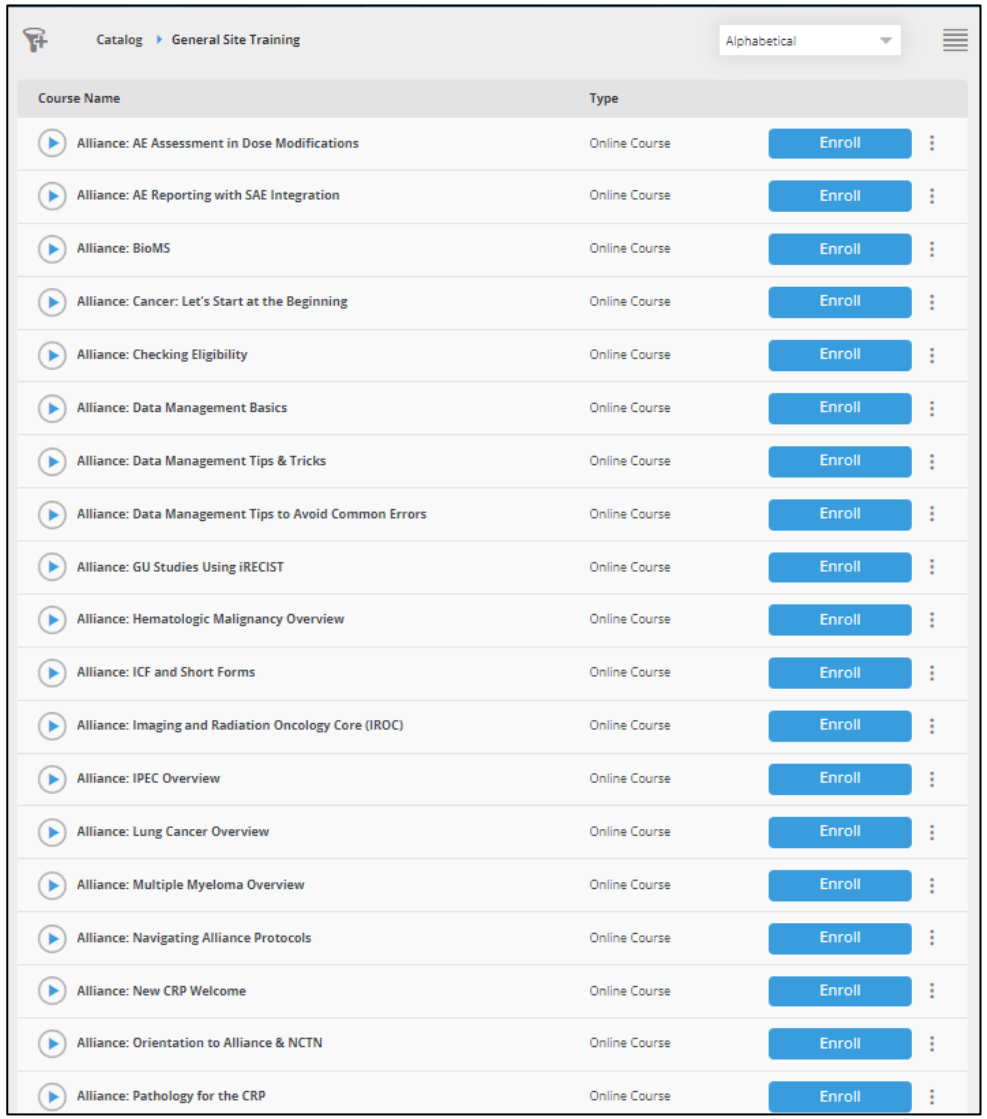
SWOG: Clinical Trials Training Course (CTTC)

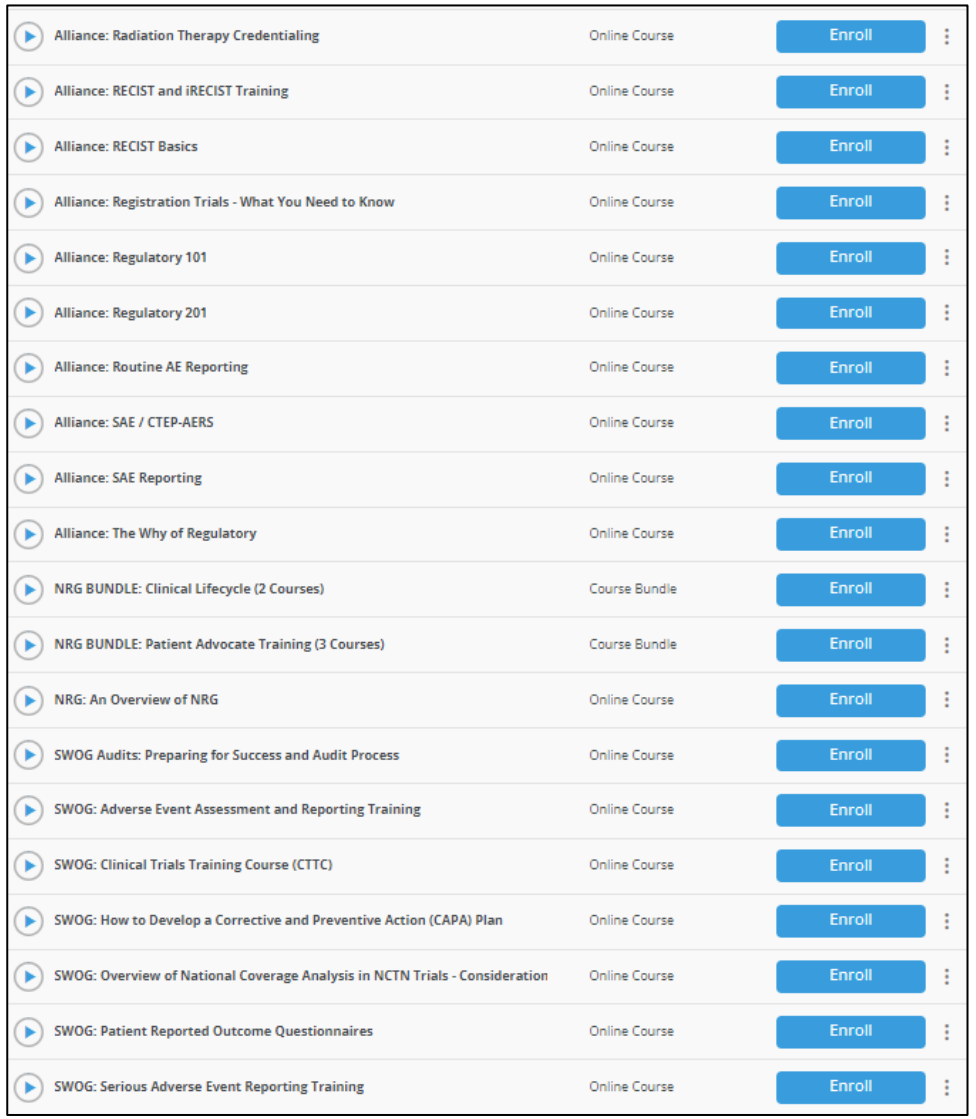
NRG Bundle: Clinical Lifecycle*

Alliance: Hematologic Malignancy Overview

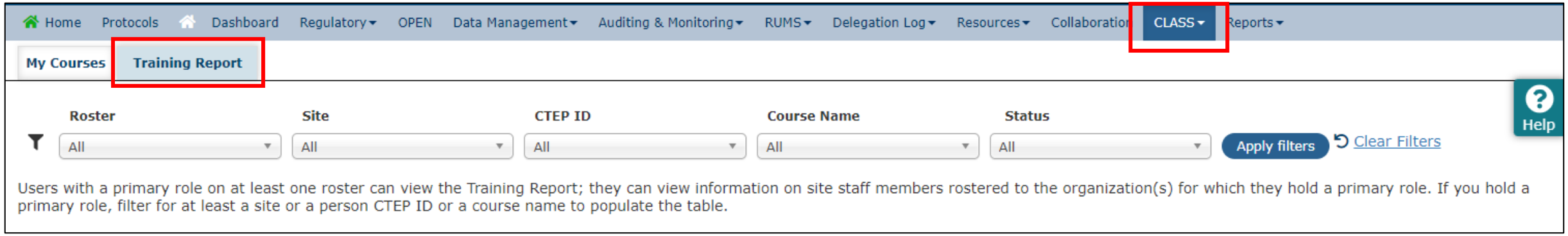
SWOG Audits: Preparing for Success and Audit Process

General Site Training (cont.)



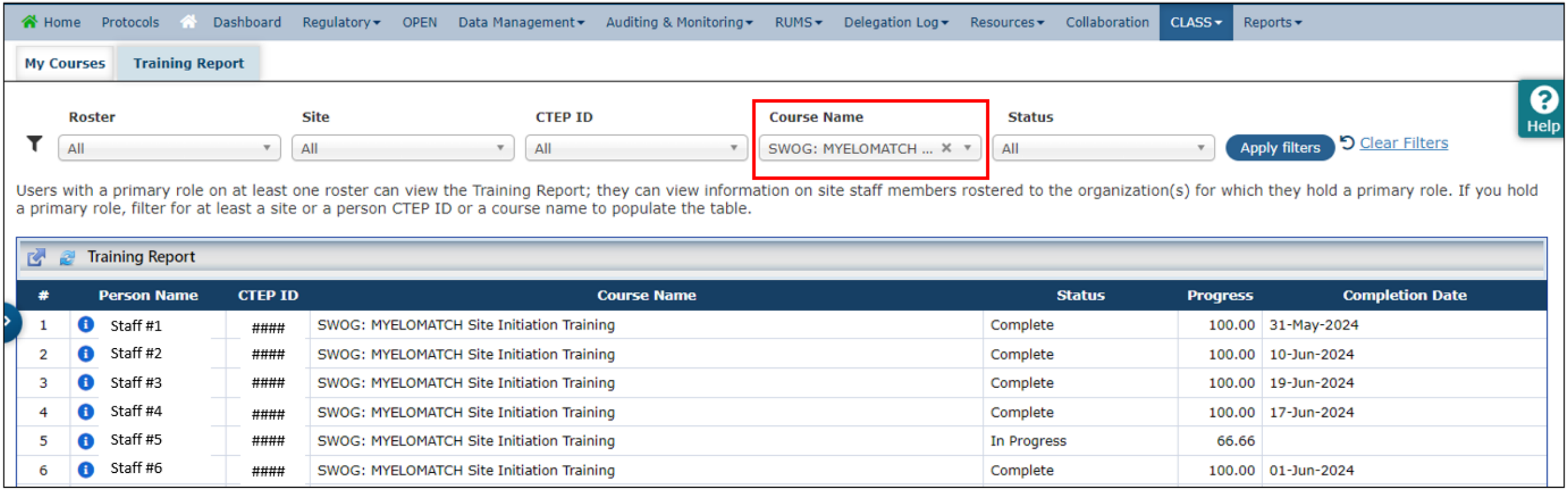


New CLASS Training Report



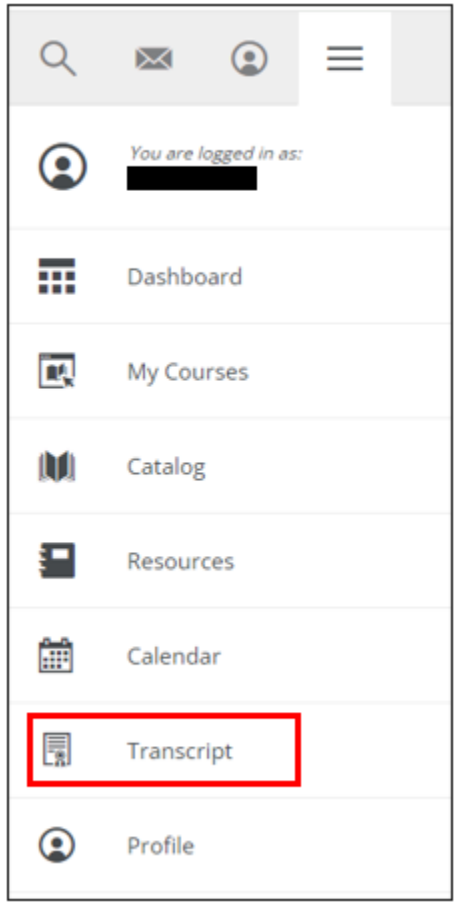
- Requires primary role on at least one roster/site
- Must set *at least one* of the following filters:
  - Site
  - CTEP ID
  - Course Name
- Export to Excel
- Help Topics available

CLASS Training Report - Example



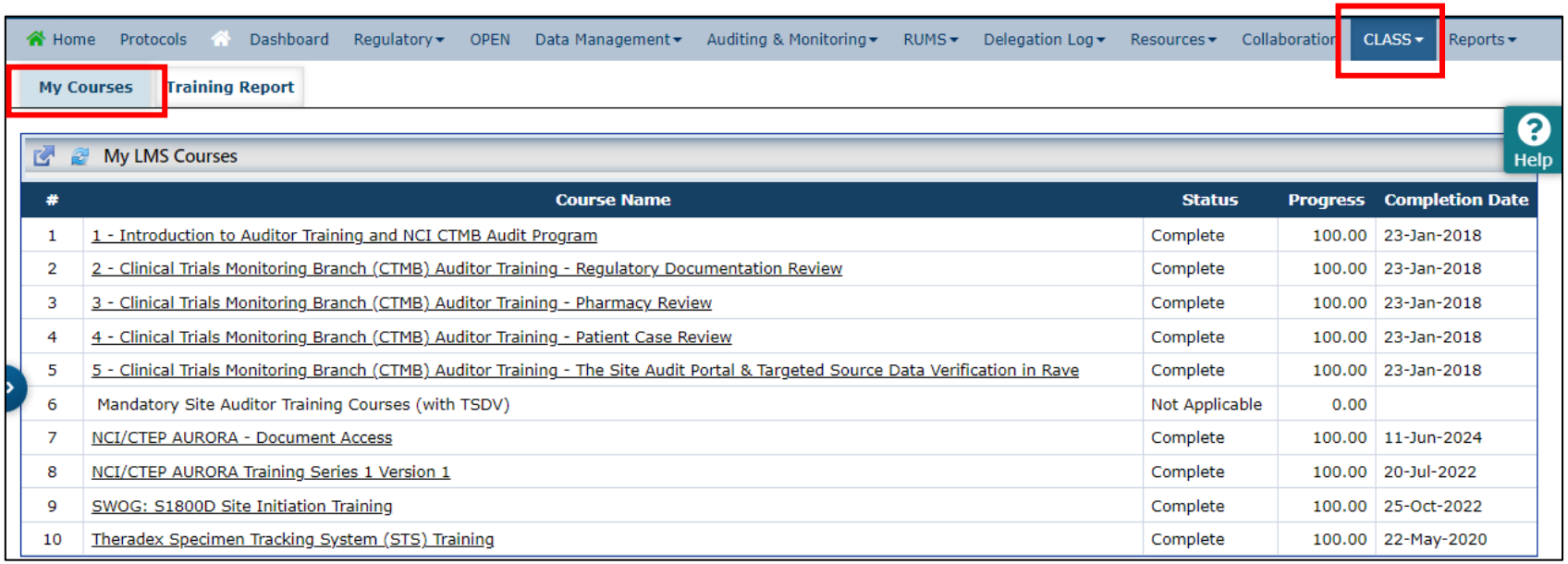
#	Person Name	CTEP ID	Course Name	Status	Progress	Completion Date
1	Staff #1	####	SWOG: MYELOMATCH Site Initiation Training	Complete	100.00	31-May-2024
2	Staff #2	####	SWOG: MYELOMATCH Site Initiation Training	Complete	100.00	10-Jun-2024
3	Staff #3	####	SWOG: MYELOMATCH Site Initiation Training	Complete	100.00	19-Jun-2024
4	Staff #4	####	SWOG: MYELOMATCH Site Initiation Training	Complete	100.00	17-Jun-2024
5	Staff #5	####	SWOG: MYELOMATCH Site Initiation Training	In Progress	66.66	
6	Staff #6	####	SWOG: MYELOMATCH Site Initiation Training	Complete	100.00	01-Jun-2024

Reminder: Checking Your Own Training Status



You can check your training status in CLASS…

…or on the CTSU website.



#	Course Name	Status	Progress	Completion Date
1	1 - Introduction to Auditor Training and NCI CTMB Audit Program	Complete	100.00	23-Jan-2018
2	2 - Clinical Trials Monitoring Branch (CTMB) Auditor Training - Regulatory Documentation Review	Complete	100.00	23-Jan-2018
3	3 - Clinical Trials Monitoring Branch (CTMB) Auditor Training - Pharmacy Review	Complete	100.00	23-Jan-2018
4	4 - Clinical Trials Monitoring Branch (CTMB) Auditor Training - Patient Case Review	Complete	100.00	23-Jan-2018
5	5 - Clinical Trials Monitoring Branch (CTMB) Auditor Training - The Site Audit Portal & Targeted Source Data Verification in Rave	Complete	100.00	23-Jan-2018
6	Mandatory Site Auditor Training Courses (with TSDV)	Not Applicable	0.00	
7	NCI/CTEP AURORA - Document Access	Complete	100.00	11-Jun-2024
8	NCI/CTEP AURORA Training Series 1 Version 1	Complete	100.00	20-Jul-2022
9	SWOG: S1800D Site Initiation Training	Complete	100.00	25-Oct-2022
10	Theradex Specimen Tracking System (STS) Training	Complete	100.00	22-May-2020

Thank You!

Questions? Contact: krishnachothwani@westat.com

Please note that this information will be re-presented as part of the CTSU updates during the Oishi Symposium session. CTSU also has a table at the ORP Open Forum session. Stop by with questions about these or other CTSU-related topics!

CTSU Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
Linking practice to progress

NCI Updates
SWOG Fall Meeting

Andrea Denicoff, MS, RN
Head, NCTN Clinical Trials Operations
Cancer Therapy Evaluation Program, NCI

NIH NATIONAL CANCER INSTITUTE

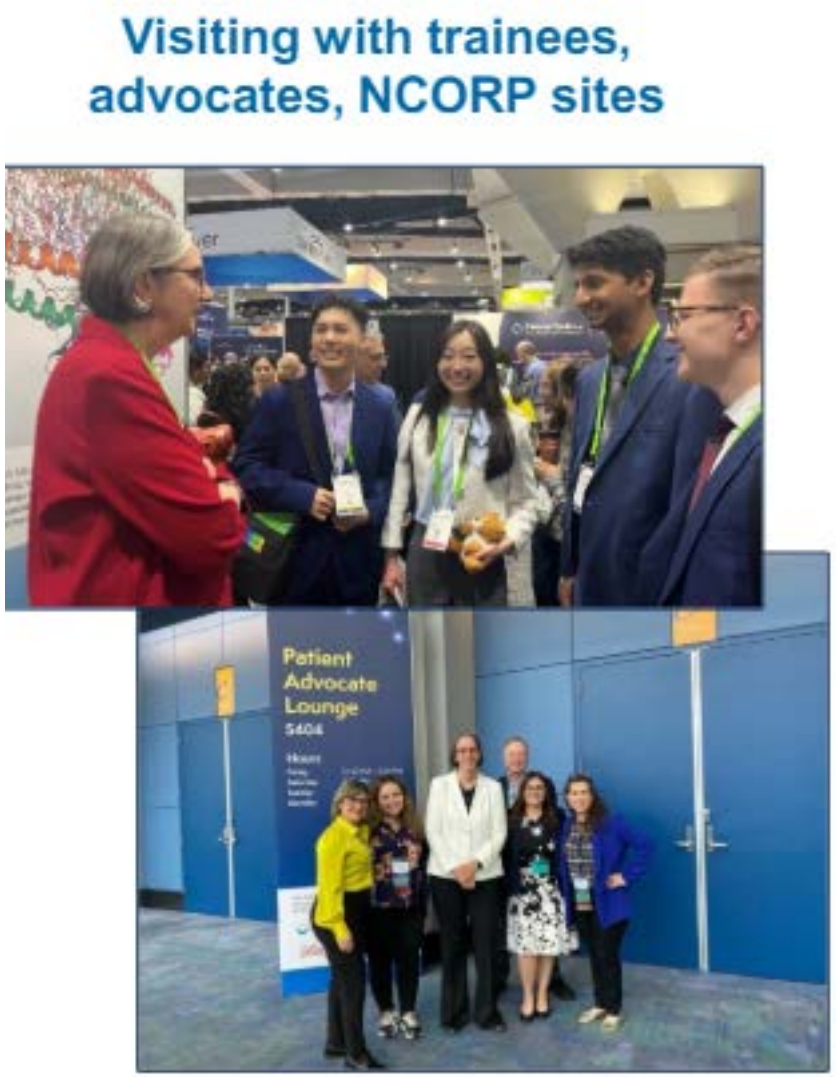
October 16, 2024

1. *Brief Updates*
2. *Streamlining Clinical Trials*
3. *Decentralized Clinical Trials Activities*

Brief Updates

NCI Director: Committed to Hearing from the Community

Dr. Kimryn Rathmell



National Cancer Plan

Everyone has a role.

8 goals:

- *Prevent Cancer*
- *Detect Cancers Early*
- *Develop Effective Treatments*
- *Deliver Optimal Care*
- *Maximize Data Utility*
- *Eliminate Inequities*
- *Optimize the Workforce*
- *Engage Every Person*

nationalcancerplan.cancer.gov

NCI Strategic Vision for Clinical Trials: 2030 and Beyond

Develop **flexible**, **faster**, **simpler**, **less expensive**, **high-impact** clinical trials that seamlessly integrate with clinical practice

- Streamline processes for trial design and execution
- Focus on essential endpoints
- Decrease regulatory hurdles and broaden trial access
- Increase efficiency of data collection

New NCI Virtual Clinical Trials Office pilot program

NCI Media Advisory

NIH to address dwindling clinical trial patient enrollment with centralized staffing support

February 29, 2024

Image: iStock

What:

- Centralized, remote staff support for NCI-supported clinical trials activities

Aims:

- **Improve accrual and retention rate** to trials – by addressing staffing challenges and burdens of clinical research

Status:

- 6 sites selected for initial pilot phase

Contributes to National Cancer Plan goals:

Update from the Streamlining Clinical Trials Implementation Committee (SCTIC)

SCTIC Members from the NCTN Groups

Co-Chairs: Sumithra Mandrekar and Andrea Denicoff

ALLIANCE:	Olwen Hahn	ECOG-ACRIN:	Erica Casella
	Colleen Watt		Sarah Zinn
	John Taylor		Yu-Hui Chen
	Shauna Hillman		Kerry Higgins
	Kristina Laumann	NRG:	Carol Aghajanian
CCTG:	Jessica Sleeth		Sara McCartney
	Dora Nomikos		Elaina Harper
	Roger Leung		Mei Polley
COG:	Thalia Beeles	SWOG:	Primo Lara
	Mary Beth Sullivan		Dana Sparks
	Todd Alonzo		Cathy Rankin
	Lindsay Renfro		Melissa Plets
IROC:	Michael Knopp		
	Stephen Kry		

Update from Streamlining Clinical Trials Implementation Committee (SCTIC)

- March 13, 2024: CTAC Acceptance of Standard Practices for Reduced Data Collection in NCTN IND-exempt protocols
  - https://deainfo.nci.nih.gov/advisory/ctac/0324/Mandrekar2.pdf

- Target Effective Date: Protocols activating after January 1, 2025

- SCTIC developed implementation plans for integrating streamlined data collection into NCTN Group and CTEP processes

https://ctep.cancer.gov/protocolDevelopment/docs/NCTN_Streamlined_Data_Standard_Practices.docx

Data Categories for Streamlined Data Standard Practices

- Routine adverse events (grade 3 or higher, no start/stop dates or attribution)
- Medical history
- Concomitant medications
- Physical exam
- Laboratory tests
- Imaging and other assessment procedures
- Patient-reported data

Focused on data needed for protocol specified endpoints, eligibility, stratification, treatment assignment and describing key patient characteristics in IND-exempt treatment trials

Scope: NCTN IND-Exempt Trials

Current (April 2024) NCTN TX Trial Portfolio Studies with a status of Approved, Active, Closed to Accrual		
IND Status/Holder	**Count**	**% of Total**
IND Exempt Study	**123**	**36%**
IND Study	**214**	**64%**
CTEP IND	152	45%
Group/Site IND	64	18%
Grand Total	**337**	**100%**

NCTN TX Trial IND Exempt Study Activations by Year							
Activation Year	**ALLIANCE**	**CCTG**	**COG**	**ECOG-ACRIN**	**NRG**	**SWOG**	**Grand Total**
2024	0	2	2	2	1	0	**7**
2023	5	0	0	5	4	3	**17**
2022	3	1	4	2	3	1	**14**
2021	0	0	2	0	4	1	**7**
2020	2	0	2	9	3	3	**19**
2019	1	0	1	3	5	1	**11**
2018	1	2	2	5	0	2	**12**
2017	1	0	3	4	7	0	**15**
2016	4	0	0	2	1	0	**7**
2015	2	0	2	3	2	1	**10**
2014	3	0	2	1	9	1	**16**
Grand Total	**22**	**5**	**20**	**36**	**39**	**13**	**135**
Average	**2**	**0**	**2**	**3**	**4**	**1**	**13**

Implementation of Streamlined Data in NCTN Trials

- NCTN Groups will hold informational sessions at meetings and communicate the new streamlined data standard practices for IND-exempt cancer treatment trials.
- CTEP will comment on concepts and protocols that IND-exempt trials will be expected to follow streamlined data standard practices.
- Investigators who identify a scientific or medical rationale in an IND-exempt trial to request more data to be collected must request an exception to the data standards from within their Group leadership.
- If Group leadership allows an exception, the investigator must then request exception to CTEP PRC with sufficient scientific rationale, which may or may not be approved.

Next Steps

- SCTIC planning to meet next with plans to:
  - Form a small group of SCTIC members to monitor progress on implementation and provide updates to larger group
  - Form a small group to develop metrics for evaluating the impact of the implementation of streamlined data collection standard practices.
    - Engage the trans-NCTN Clinical Research Professionals (CRP) Working Group to gather their input on metrics and avoid creating burden.

Clinical Trials With Decentralized Elements

Clinical Trials with Decentralized Elements

- FDA Guidance Sept. 2024: The FDA[1] defines decentralized elements as trial-related activities that occur remotely at locations convenient for participants, such as telehealth or visits with a local HCP.
- Background: Many flexibilities used during the COVID-19 pandemic were found to be extremely beneficial to patients and NCTN/NCORP sites asked to have these continue beyond the pandemic.
- NCTN Groups and NCORP Research Bases worked collaboratively with CTEP and DCP to develop a checklist and protocol language, where needed, to use in future trials.

1 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements

Checklist and Sample Protocol Language for Decentralized Clinical Trial (DCT) Activities

- **Checklist** – helps NCTN/NCORP protocol authors and study teams think through what DCT activities to include in a study

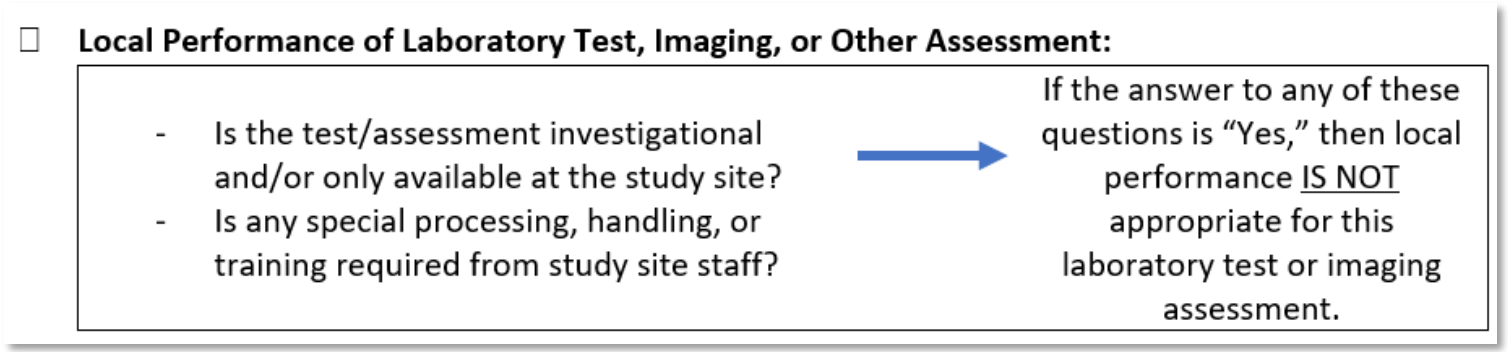
- **Sample Protocol Language** – encouraged to use so that DCT activities are implemented consistently across studies

- **Additional Resources** – links to other relevant resources and guidance

Checklist Topics – Considerations for DCT Activities in NCTN Protocols

- Remote Consent
- Care by a Local Health Care Provider (HCP) for a Study Visit
- Telehealth Visits with Study Team
- Local Performance of Laboratory Test, Imaging, or Other Assessment
- Administration of Injectable/IV SOC agents by a Local HCP
- Administration of Radiation Therapy by a Local HCP
- Shipment of Oral CTEP-IND Agent Directly to Participants

Example



☐ **Local Performance of Laboratory Test, Imaging, or Other Assessment:**

- Is the test/assessment investigational and/or only available at the study site?
- Is any special processing, handling, or training required from study site staff?

→ If the answer to any of these questions is "Yes," then local performance IS NOT appropriate for this laboratory test or imaging assessment.

Thank you!

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SWOG | CANCER RESEARCH NETWORK

SWOG Operations Center
Protocols & Membership

Presented by:
Dana Sparks, MAT

CTEP and SWOG Decentralized Trial Implementation Plans

- Decentralized Clinical Trial (DCT) activities in the United States are allowed per FDA guidance and are encouraged in NCTN trials.
- The FDA defines DCTs as a clinical trial where all or some of the trial-related activities occur at locations other than traditional clinical trials sites, and has established guidance to support these trials.
- Trials without an Investigational New Drug application (IND) or Investigational Device Exemption (IDE) may be more amenable to DCT activities.
- Institutional policy or local/state laws may apply to certain DCT activities, such as remote consent and telehealth.
- For non-US sites participating in NCTN trials, the Lead and Crediting Groups must establish a policy for international NCTN sites.

- NCI CTEP created a working group on decentralized trials in the NCTN setting comprised of representatives from each NCTN group and from a variety of practice settings including NCORP representation.
- The stated intent of this working group and these activities was to allow sites as much flexibility as possible relating to site implementation of decentralized trial activities as well as tailoring appropriate decentralized trial activities to the specific trial and including specific language in protocols to provide guidance and also to provide sites with support for local implementation.
- The product of this working group was a trial checklist to allow protocol staff to assess the appropriateness of specific decentralization elements on a protocol specific basis and to provide a basis for protocol specific language.

Elements of the checklist:

- Remote consent

Does the study require: - **A mandatory research-related, in-person assessment for eligibility check prior to registration?**		**If the answer to this question is "Yes," then remote consent MAY NOT be appropriate for this study.**

- Care by a Local Health Care Provider (HCP) for a Study Visit
  - A Local HCP is not registered as an investigator for a clinical trial. When using a local HCP, the FDA recommends that quality control measures should be put in place to help reduce variability and assess consistency and completeness of required procedures. The activities provided by the Local HCP must be conducted under the oversight of the Responsible Investigator (RI), who is the investigator responsible for the patient's care at the clinical trial site.
- Telehealth Visits

Does the visit require: - **Specimen collections requiring specialized processing to be done at a registered clinical trials site?** - **Performance of an in-person physical exam or assessment requiring detailed knowledge of the investigational product/therapy or assessing a protocol objective, such as neurocognitive tests?**		**If the answer to any of these questions is "Yes," then this visit IS NOT appropriate to be conducted by telehealth.**

Elements of the checklist:

- Local Performance of Laboratory Test, Imaging, or Other Assessment

- Is the test/assessment investigational and/or only available at the study site? - Is any processing, handling, or training outside the scope of regular practice required from site staff?		If the answer to any of these questions is "Yes," then local performance IS NOT appropriate for this laboratory test or imaging assessment.

- Administration of Injectable/IV Investigational Products by a Local HCP

Is the injectable/IV agent under an IND? Note: IND oral agents are self-administered under the direction of the Responsible Investigator.		If the answer is "Yes," then this visit IS NOT appropriate to be conducted by local health care provider (HCP).

- Administration of Radiation Therapy by a Local HCP

Is the radiation therapy considered investigational and/or must adhere to the protocol-specified radiation therapy treatment administration?		If the answer is "Yes," then this visit IS NOT appropriate to be conducted by local health care provider (HCP).

- Shipment of Oral CTEP-IND Agent Directly to Participants by the Site

- NCI-CTEP has provided suggested approved protocol language and potential placement of this information in protocols for each of these elements
- The NCORP program staff have reviewed these elements and the suggested language and have signed on to the use of the checklist and language for NCORP studies.
- SWOG has implemented the decentralized checklist and elements in one activated study and is actively deploying the use of the checklist for developing protocols.

S2312 Appendix 18.3
Guidance for Decentralized Clinical Trial Activities and Streamlining Data Collection

NOTE: These standard practices for submission of data to Medidata Rave do not override or otherwise affect clinical practice standards for data collected in the local medical record. Participating investigators and clinical staff at trial sites should adhere to all applicable standards for recording clinical information in the local medical record.

Some of the following clinical trial activities refer to care provided by Local Health Care Professionals (HCPs) (Non-Research Staff). Local HCPs are defined as HCPs who are not registered as an investigator for this clinical trial. Local HCPs must perform trial activities under the oversight of the Responsible Investigator (RI), who is the investigator responsible for the participant's care at the clinical trial site.

The RI must ensure that the data is entered into Medidata Rave and is responsible for making any decisions regarding study objectives.

a. Remote Consent

Remote consent, eSignature, and eConsent are permitted for this study as per the NCI's CIRB Remote Consenting Procedures found in NCI Central Institutional Review Board Standard Operating Procedures (https://www.ncicirb.org/about-cirb/sops).

b. Telehealth Visits with Study Team

The off treatment post progression study visits may be conducted by phone or videoconferencing technology (i.e., "virtual visits"), including adverse event assessments, in accordance with local laws and regulations. This only applies to participants who have not consented to optional blood for banking.

c. Local Performance of Laboratory Tests

Laboratory tests outlined in Section 9.0 Study Calendar may be performed by a local laboratory. The RI should submit laboratory test results to Medidata Rave.

d. Local Performance of Imaging Tests

Not allowable for this study.

Scans outlined in Section 9.0 Study Calendar must be performed at the registered clinical trial site.

Scans may be performed at a sub-affiliate site as long as the images and reports are available within the EMR system to the registering investigator for review within protocol-defined timelines/windows.

e. Administration of Commercial Agents by a Local HCP

The standard of care protocol-specified therapy may be administered by a local healthcare professional (HCP) with appropriate reporting of therapy administration data and adverse event information to the Responsible Investigator (RI).

All decisions on care within the clinical trial are made by the RI.

The RI is still required to report any protocol deviations and unanticipated problems that occur (e.g., non-compliance with protocol therapy) per standard procedures.

All requirements necessary to document agreement for provision of data from a local HCP to the RI are left to the discretion of the registered clinical trial site.

f. Streamlining Data Collection - Adverse Event Reporting

Because this study is IND exempt, the principles of the Streamlining Clinical Trials Working Group are being followed as outlined in the report located at https://deainfo.nci.nih.gov/advisory/ctac/0324/Mandrekar2.pdf. Consequently, sites are requested to submit only AEs of Grade 3 through Grade 5 to Medidata Rave as outlined in Section 8.7 and 8.8.

Resources:

1. NCI Central Institutional Review Board Standard Operating Procedures: https://www.ncicirb.org/about-cirb/sops
2. NCI CTEP Pharmaceutical Management Branch: https://ctep.cancer.gov/branches/pmb/agent_management.htm
3. A Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, DCTD, NCI: https://ctep.cancer.gov/investigatorresources/investigators_handbook.htm
4. NCI Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN) Program Including NCI Community Oncology Research Program (NCORP) and NCORP Research Bases [April 2023]: https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring.htm
5. Office of Human Research Protections, Guidance on Engagement of Institutions- Institutions Not Engaged in Human Subjects Research: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html
6. SACHRP Recommendations on “Decentralized Clinical Trials for Drugs, Biological Products, and Devices - Guidance for Industry, Investigators, and Other Stakeholders” [July 20, 2023]: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations-decentralized-clinical-trials-drugs-biological-products-devices-guidance-industry-investigators-stakeholders.html
7. FDA Draft Guidance Document: Decentralized Clinical Trials for Drugs, Biological Products, and Devices: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices

SWOG Streamlining Clinical Trials Implementation Plan for IND-Exempt Trials

SWOG has already streamlined much of our data collection for IND exempt studies, so we do not require significant changes in our processes.

- For the remaining updates, ideally, CTEP has posted information about implementation of SCTIC principles and will update their review forms (as many of our procedures are designed to piggyback from and reference CTEP/grant documentation). https://ctep.cancer.gov/protocolDevelopment/docs/NCTN_Streamlined_Data_Standard_Practices.docx
- We believe that CTEP requirements for Serious Adverse Event reporting and for Data Mapping Utility (DMU) reporting may first need to be aligned with SCTIC principles prior to the individual groups having the latitude to make changes related to those elements.

- Operations SOPs and Protocol Templates - Dana Sparks and Crystal Miwa

  SWOG Operations procedures build from CTEP/grant instructions and (in relation to data collection language) from SDMC SOPs.

  SOPs are also imbedded in our protocol template document instructions, so are not a separate process for updating.

  Protocol template updates are always ongoing. There are very few (or possibly no) specific protocol template updates that will need to be made based on SCTIC principles.

  The majority of the changes we will need to make are related to data collection SOPs (addressed on the next slide), but we are continuing to discuss whether templated language for eligibility criteria for HIV/HBV/HCV will require alteration in the template for eligibility criteria.

  Data collection language will be driven from SDMC SOPs, but will include collection of fewer baseline source documents (pathology/operative/radiology). We do not expect any obstacles in implementation.

- SDMC SOPs and CRF Templates (to include processes for review and approval of protocols and CRFs) – Cathy Rankin and Melissa Plets

  We will update Study Build Guidance documents to include a section on IND-exempt streamlining data collection.

  This will involve input and review from SDMC leaders and study reviewers.

  Updates to the guidance documents will be accompanied by creation of CRF template versions that align with SCTIC recommendations.

  We are able to implement this as soon as the recommendations are finalized and do not expect any obstacles in implementation.

- Data Systems

We do not anticipate any systemic changes at our level will be necessary as the data collection processes and content are individualized by protocol. However, centralized system changes may be needed at CTEP.

- Training materials

SOP updates in Operations and SDMC will be accompanied by training of current and future staff members – this process is routine. Our leadership has been participating in this effort and we will provide a summary of all activities to a wider leadership audience when the discussions have been completed. We do not expect any obstacles in implementation.

We would appreciate centralized reference documents (URL posting or similar) from CTEP to address investigator information/training.

Broadening Eligibility Criteria

- https://ctep.cancer.gov/protocolDevelopment/docs/CTEP_Broadened_Eligibility_Criteria_Guidance.pdf

  Based on 2017/2021 Joint Recommendations from the American Society of Clinical Oncology (ASCO) and Friends of Cancer Research (Friends)ASCO/Friends published recommendations in October 2017 to broaden clinical trial eligibility relating to brain metastases, minimum age, HIV infection, organ dysfunction, and prior and concurrent malignancies (Kim, ES, et al. J Clin Oncol 2017, PMID: 28968170), CTEP developed protocol template language for eligibility and announced to all CTEP-funded lead protocol organizations and investigators that future protocols submitted to CTEP as of September 2018 include the protocol inclusion criteria text found in this guidance document to broaden eligibility criteria, unless clinical or scientific rationale supported some type of modification.

  In May 2021, ASCO/Friends published additional recommendations to broaden eligibility criteria relevant to washout periods, concomitant medications, prior therapies, laboratory reference ranges and test intervals, and performance status (Kim, ES, et al. Clin Cancer Res. 2021, PMID:33563632), and this additional guidance from 2021 is included as a part of the CTEP template and guidance.

  NCI has proposed to remove the exclusion criteria seen in some protocols relating to psychiatric illness.

  NCI's National Clinical Trials Network (NCTN) will utilize these modernized eligibility criteria in clinical trials going forward. These guidelines may be modified based on protocol-specific or drug development-specific needs under the condition that a scientific or clinically based rationale is provided specifically.

  Since eligibility criteria must be as broad as safely possible to achieve diverse and representative populations in future clinical trials, CTEP will continue to collaborate with investigators and industry partners in a shared responsibility to expand eligibility and access to trials.

SWOG | CANCER RESEARCH NETWORK

SWOG Operations Center
Information Systems

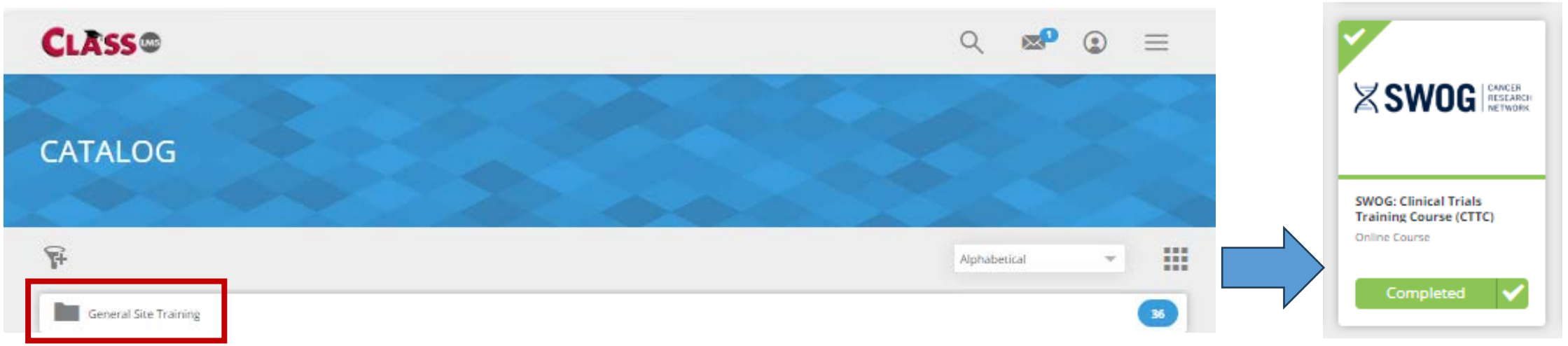
Presented by:
Cara Laubach

SWOG Protocol template update – Biospecimen submissions

- SWOG has updated the SWOG protocol template (Section 15) to more clearly communicate biospecimen submission requirements.
- Going forward all newly developed SWOG protocols with biospecimen submission requirements will include a simple summary table at the beginning of the biospecimen submission section of the protocol (Section 15).
    - The table will include the following information: Specimen Type/Amount, Timepoint, whether it is a required submission, and whether a collection kit is being provided.
    - For additional views, sites can refer to sortable tables that will soon be accessible via the SWOG specimen tracking system.

SWOG Clinical Trials Training Course (CTTC) – Now Posted in CTSU (CLASS)

- The online version of the CTTC has been transitioned to the CTSU CLASS learning management system.
  - Anyone with credentials to access NCI systems can access the course in the CLASS Catalog under the "General Site Training" folder or via the direct link to the course: https://www.ctsu.org/Public/class.aspx?courseid=0b0190ea-b489-4505-b4a3-b8c7a368c0bd



  - Please update any local site onboarding materials to reflect the new CTTC link.
  - Effective 10/21/24: Learners will no longer be able to enroll to the CTTC in the SWOG ExpertusOne Learning Management System.
  - Learners who previously enrolled in, but have not yet completed, the CTTC in ExpertusOne will have until April 2025 (at time of next online CTTC course updates) to complete the course in ExpertusOne.

Prior SWOG Quality Assurance Webinars Posted as Enduring Courses

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

CEU Courses in ExpertusOne:

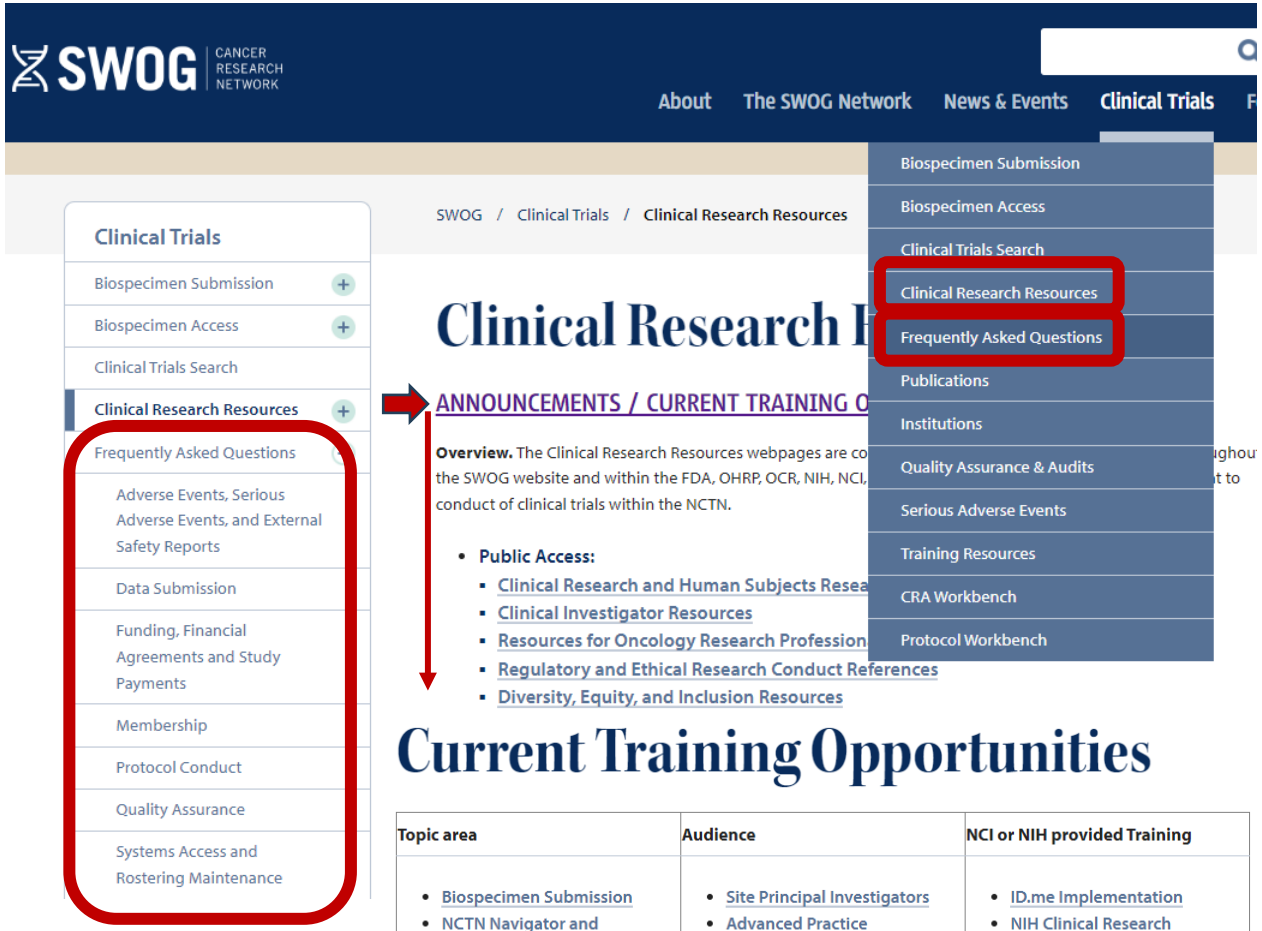
- **Workload Prioritization in Clinical Trials** (1.5 contact hours)
- **Research Protocol Deviations vs Deficiencies** (1 contact hour)
- **Best Practices for Informed Consent** (1 contact hour)

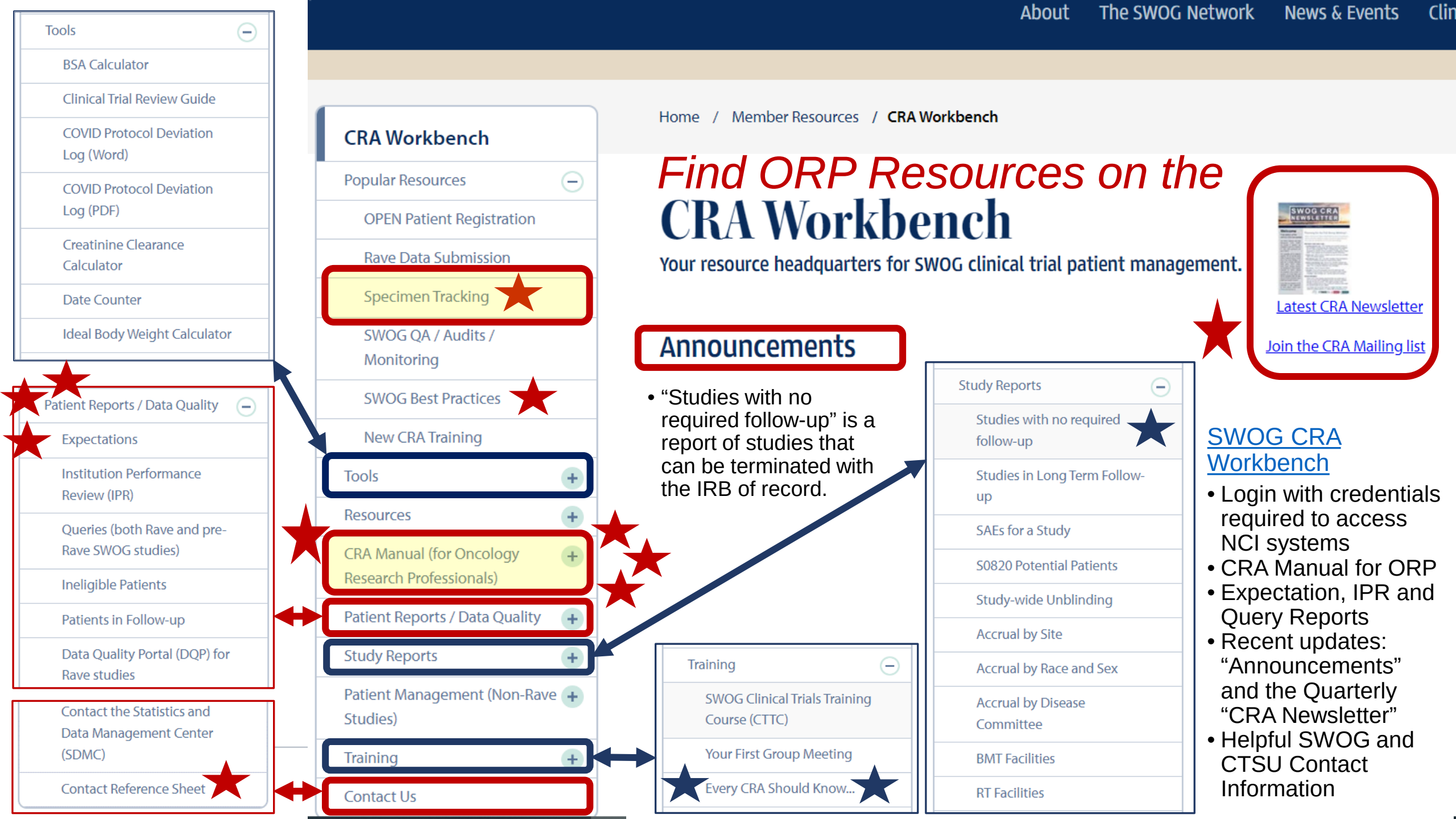
Non-CEU Courses now in CLASS:

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

Website Resources – SWOG.org

- Frequently Asked Questions | SWOG Webpages
- Training Resources | SWOG includes direct links to SWOG training workshops.
- The Announcements / Current Training Opportunities | SWOG section of the webpages announces newly published individual training courses that are not part of a complete SWOG training workshop.
  - Includes links to prior Group Meeting presentations (such as SWOG QA Audits - Top 10 Deficiencies, Improving Specimen Submissions to the SWOG Biospecimen Bank, or Biospecimen Quality, Compliance, Tips and Tricks), links to training for SWOG ORPs, such as: the SWOG and NCI Systems Overview Training or NCTN and NCORP Study Funding and Payment Distribution, and links to training materials in Spanish.



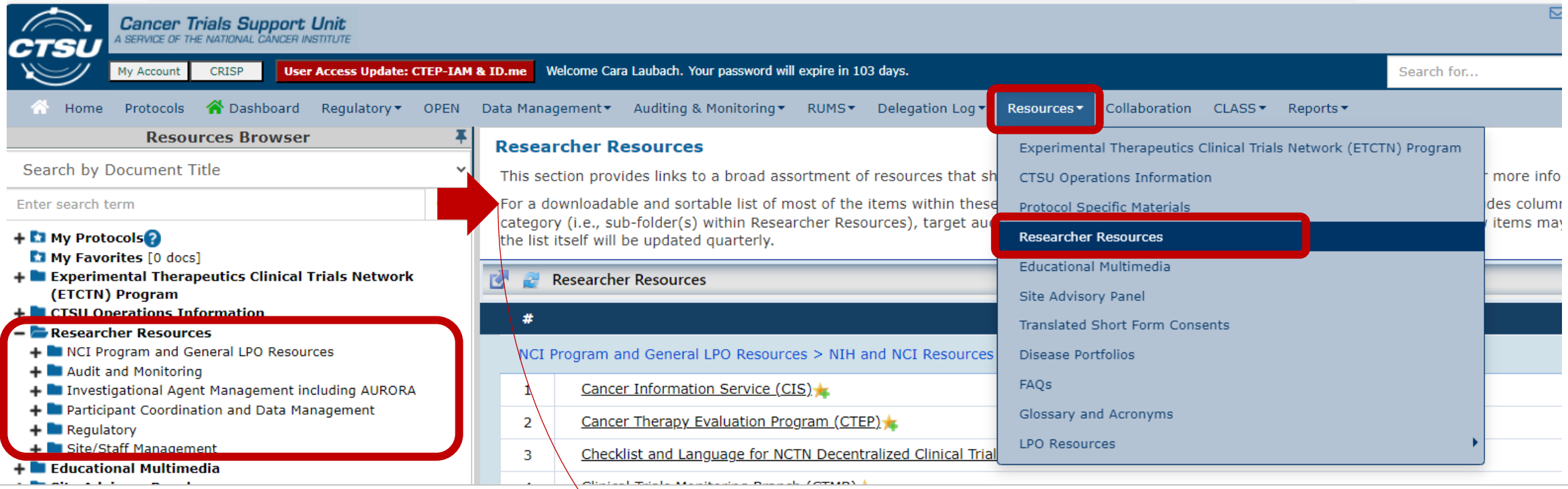

About
The SWOG Network
News & Events
Tools
BSA Calculator
Clinical Trial Review Guide
COVID Protocol Deviation Log (Word)
COVID Protocol Deviation Log (PDF)
Creatinine Clearance Calculator
Date Counter
Ideal Body Weight Calculator
Patient Reports / Data Quality
Expectations
Institution Performance Review (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 credentials required to access NCI systems
• CRA Manual for ORP
• Expectation, IPR and Query Reports
• Recent updates: "Announcements" and the Quarterly "CRA Newsletter"
• Helpful SWOG and CTSU Contact Information

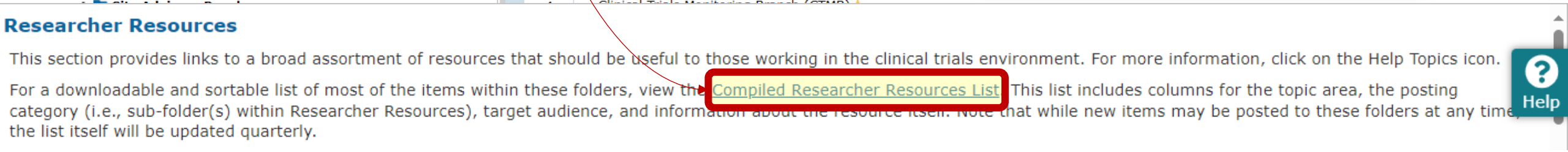
SWOG Training Resources List for Oncology Research Professionals – Transitioned to CTSU.org

- ORP onboarding and training resource list (previously under the Clinical Research Resources section of the SWOG website at: SWOG Training Resources List for Oncology Research Professionals).
    - Includes links to federal and Lead Group training and clinical research resources for oncology research professionals.
- These resources have been transitioned to CTSU.org: Resources >> Researcher Resources.
- Thank you to NCI, CTSU!
  and Lead Group WG members.
    - Please update any local site bookmarks / documents to reflect the NEW compiled researcher resources (downloadable) spreadsheet link (below):
        - https://www.ctsu.org/readfile.aspx?EDocId=1937857&CTSUCreated=Y

CTSU Researcher Resources

- Additional resource links are now accessible on CTSU.org under Resources >> Researcher Resources.





Reminder: SAE Reporting Requirements updates

- Effective August 30, 2024 NCI implemented a global safety update to the notification procedures for serious adverse events (expedited reporting requirements).
- The primary change is to require 24-hour notification to IND/IDE sponsors for ALL SAEs, irrespective of grade/severity, if the AEs meet any of the SAE criterion defined in FDA regulations, followed by a completed expedited report in 5 or 10 calendar days.
- Affected trials include: All CTEP-supported Clinical Trials Networks and Consortia IND/IDE trials (and any trials supported by another organization under CTEP IND) that:
    1. Use the current CTEP expedited reporting tables (effective date of May 5, 2011) and
    2. Still have patients on treatment as of August 30, 2024 (i.e., trials that have a status of “Active”, “Closed to Accrual”, or “Temporarily Closed to Accrual” as of that date).
- For more information, refer to the Memorandum and list of Protocols with Updated Adverse Event (AE) Tables posted on CTSU.org.
- For questions on reporting requirements for SWOG-led studies: Email adr@swog.org.

Quality Assurance Updates

Laura Gonzales, BSN, MA, RN, OCN

QA Manager

Network Operations Office – San Antonio

- Quarterly Quality Assurance Live Webinar Series (registration information and links to post-meeting recordings)

SWOG Quality Assurance Live Webinar Series

Disease Assessment in Solid Tumors (December 6, 2024)

We hope you can join us for the Disease Assessment in Solid Tumors Webinar.

Save the Date: 12/6/2024 from 11:00 a.m. - 12:00 p.m. CT.
Presenter: Rose Ermete RN, BSN, OCN, CRN-BC, CCRP.

Registration Required: *Prior to the start of the webinar:* Enroll to the SWOG ExpertusOne Course via the following link: Disease Assessment in Solid Tumors Webinar. (Login with NCI credentials).
We recommend enrolling by December 5, 2024. After enrolling, participants will receive a system-generated calendar invite with a link to the course.

This activity will be submitted to the Maryland Nurses Association for approval to award 1.0 CEU contact hour. Maryland Nurses Association is accredited as an approver of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation. To obtain 1 CEU contact hour participants must attend the entire webinar (via the above SWOG ExpertusOne course link) and complete the post-course evaluation in Survey Monkey. No one with the ability to control content of this activity has a relevant financial relationship with an ineligible company.

Previous QA Webinars

- ADVERSE AND SERIOUS ADVERSE EVENT REPORTING
- SWOG AUDITS
- HOW TO DEVELOP A CAPA PLAN
- BEST PRACTICES FOR INFORMED CONSENT
- RESEARCH PROTOCOL DEVIATIONS VS DEFICIENCIES
- WORKLOAD PRIORITIZATION IN CLINICAL TRIALS

On 8/30/24, NCI implemented some changes to SAE reporting for all protocols using an IND. This was in response to a finding that NCI was not in compliance with the FDA. The FDA stated that all SAEs (on IND trials) must be reported within 24 hours, regardless of grade/severity. A global change to CTEP-AERS was made to implement the new reporting timeframes.

Questions?

adr@swog.org

LUNGMAP Audit Changes

The following changes to auditing will occur when Revision #9 is approved:

1. LungMAP substudies that do not have potential FDA registration intent will be audited on a regular audit schedule (every three years).
2. SWOG will no longer audit all LungMAP registrations. LungMAP substudies that do not have potential FDA registration intent will be audited by the group to whom the registration is credited.

SWOG Network Group Operations Center
Administration & Funding Updates

Presenter:
Casey Dawson, SWOG Assistant Director of Administration
Pat Mize, SWOG Grants & Contracts Manager

New Staff

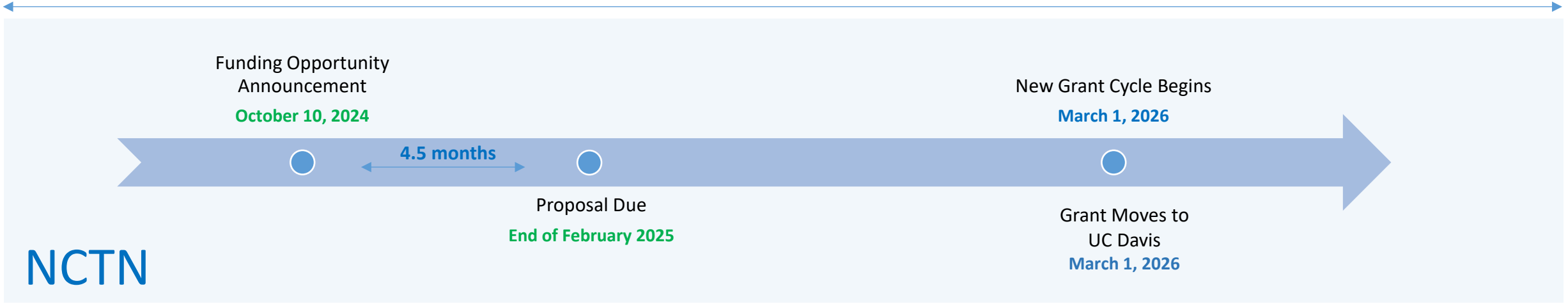
Welcome Denise!

SWOG Grants & Contracts Coordinator

NCTN Competitive Renewal

NCTN Competitive Renewal RFAs have arrived!

SWOG NCTN/NCORP Renewal Timeline



NCTN Competitive Renewal

Member Site Requirements

Member Site Emails sent!

Membership Categories:

- Main Member
- Affiliate of Main Member
- VA Storefront Sites

NCTN Competitive Renewal

Member Site Requirements

- ✓Letter of Intent/Support
  - Signed by institutional signing official (OS)
  - Include required language
- ✓Performance Site Form, including UEI number
- ✓Key Personnel Form for Member Site PI
  - Biosketch
  - eRA Commons ID ***new requirement***
- ✓Letter of Support from Member Site PI (Optional)

Please send any questions to FedGrants@swog.org

NCTN/NCORP Grant Extensions

- SWOG NCTN/NCORP grants end in 2025 (technically)
- SWOG will receive 1-year extensions for NCTN/NCORP

SWOG will be issuing amendments to Fixed Rate Subawards in early to mid-2025 to extend term

Please send any questions to FedGrants@swog.org

Funding Team at ORP Open Forum

Thursday, October 17th at 12:30pm – 2:00pm

Crystal B, Lobby Level, West Tower

In Person Only

Site Funding Contacts

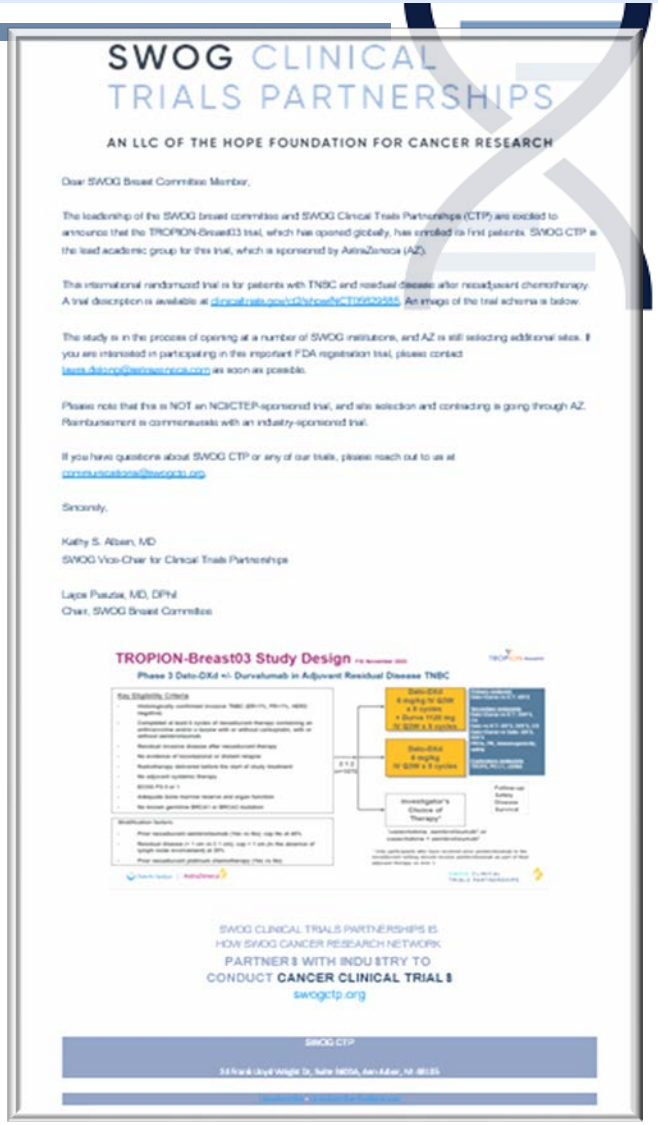
Federal Funding	FedSitePayments@swog.org
Non-federal Funding	Finance@thehopefoundation.org
National Coverage Analysis (NCA) or General Funding Questions	Funding@swog.org

SWOG Clinical Trials Partnerships (CTP)

OCT 2024 Site Operations Update

Getting Started with SWOG CTP…

- SWOG Member sites will be notified about CTP studies via email
  - Study Synopsis
  - Study Feasibility Questionnaire
  - Study Calendar and Specimen Collection
  - Study Funding
- Interested sites will complete a short study feasibility questionnaire
- Once selected, sites will complete contract for the study


SWOG CLINICAL TRIALS PARTNERSHIPS

AN LLC OF THE HOPE FOUNDATION FOR CANCER RESEARCH

Dear SWOG Breast Committee Member,

The leadership of the SWOG breast committee and SWOG Clinical Trials Partnerships (CTP) are excited to announce that the TROPION-Breast03 trial, which has opened globally, has enrolled its first patients. SWOG CTP is the lead academic group for this trial, which is sponsored by AstraZeneca (AZ).

This international randomized trial is for patients with TNBC and residual disease after neoadjuvant chemotherapy. A trial description is available at clinicaltrials.gov/ct2/show/NCT04595565. An image of the trial schema is below.

The study is in the process of opening at a number of SWOG institutions, and AZ is still selecting additional sites. If you are interested in participating in this important FDA registration trial, please contact [redacted] as soon as possible.

Please note that this is NOT an NCI/CTEP-sponsored trial, and site selection and contracting is going through AZ. Reimbursement is commensurate with an industry-sponsored trial.

If you have questions about SWOG CTP or any of our trials, please reach out to us at [redacted]

Sincerely,

Kathy S. Albain, MD
SWOG Vice-Chair for Clinical Trials Partnerships

Lajos Pusztai, MD, DPhil
Chair, SWOG Breast Committee

TROPION-Breast03 Study Design

Phase 3 Dato-DXd +/- Durvalumab in Adjuvant Residual Disease TNBC

SWOG CLINICAL TRIALS PARTNERSHIPS IS HOW SWOG CANCER RESEARCH NETWORK PARTNERS WITH INDUSTRY TO CONDUCT CANCER CLINICAL TRIALS
swogctp.org

SWOG CTP

[redacted]

21CTP.LEUK01 – ONGOING SITE SELECTION

Study info and feasibility survey will be sent to SWOG Site PI's and Head CRA's

Estimated activation Q4 2024!

Learn more at www.swogctp.org

Upcoming SWOG CTP trial in leukemia

SWOG CLINICAL TRIALS PARTNERSHIPS

AN LLC OF THE HOPE FOUNDATION FOR CANCER RESEARCH

Dear SWOG Site Leadership:

SWOG Clinical Trials Partnerships (CTP) invites your site, as a SWOG member site, to consider participation in our first trial in leukemia -- 21CTP.LEUK01.

This email provides details on this clinical trial, including:

- Study Synopsis
- Study Calendars
- Specimen Collection Details
- Funding Memo

If after reviewing these materials your site is interested in applying to open this study, please complete the linked **feasibility questionnaire** **no later than April 30th**. It collects essential information to help us assess each site's suitability for the study. We expect to select approximately 35 sites to open the 21CTP.LEUK01 trial.

About SWOG CTP

SWOG CTP is an independent, limited liability corporation with its own leadership, processes, and funding agreements. But the missions of SWOG and SWOG CTP are the same -- to significantly improve lives through cancer clinical trials and translational research.

If you have questions about SWOG CTP or any of our trials, which include no federal funding, please reach out to us at protocols@swogctp.org.

Sincerely,

Anjali S. Advani, MD

Michaela Liedtke, MD

21CTP.LEUK01 Study Chairs

21CTP.HN01 PROTOCOL IN DEVELOPMENT!

HN01: Phase I/II Study in Recurrent Metastatic Head and Neck Cancer

Anticipated Site Selection and Activation- Q3 2025

Learn more at www.swogctp.org

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Sincerely,

Anjali S. Advani, MD
Michaela Liedtke, MD

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

Active Industry Collaborations*

- Acute lymphocytic leukemia
- Breast cancer triple negative - adjuvant
- Breast cancer ER+ HER2 - metastatic
- Bladder cancer - neoadjuvant
- Head/neck squamous cell - advanced

**pipeline, platform, subtype*

Pending Collaborations

- CNS Working Group
- Digital Engagement
- Immunotherapeutics
- Colorectal – metastatic
- Anal – locally advanced
- Several company pipelines
- SWOG VA Committee

Learn more at the ORP Open Forum!

Thursday, October 17th at 12:30pm – 2:00pm

Crystal B, Lobby Level (West Tower)

In Person Only

SDMC Updates

Phyllis Goodman, M.S.

SWOG Statistics and Data Management Center
Seattle, WA

S1826 – Data to FDA

- Retrofitting the trial for post-marketing FDA submission
- Data Cleaning process is ongoing
  - Queries from BMS re: clinical, PRO-CTCAEs and imaging
  - Currently reports are sent twice a week but will be reduced to weekly
- **Avance** has been engaged to assist in:
  - Image submission (PET/CT scans) and query resolution
- BMS anticipates submitting data to FDA by the end of May 2025
- Remember - Patients are to be followed for 10 years so continue submitting follow-up and survival data
- Thank you for your efforts!

Institution Performance Review

- Change in source of information for PI and Lead ORP from SWOG roster to CTSU roster
  - There were some differences in (1) how affiliates were associated with Tier 1 sites, and (2) Registration status
  - Allows addition of Co-Lead ORP to the distribution list

Institution Performance Review

- Metric for Timeliness of Query Resolution
  - Policy #33 updated in April 2024 to include as a formal IPR measure.
  - Included for the first time in July 2024 report

- Overall “Site Score”
  - Weighted measure of IPR categories
    - IFS, Vital Status Updates, Forms and Specimen Submission
    - Query responsiveness will be added in 2025
  - Categories: Excellent, Very Good, Good, Adequate, Poor
  - Excellent sites with at least 10 registrations in the last 13 months will be recognized at Plenary Session and in Group Meeting agenda book

Tier 1 Site Score Distribution – Six Month Average (Oct 2024)

Category	Points	Number of Sites (n=99)
Excellent	10.0 – 12.0	19 (19.2%)
Very Good	8.0 – 9.9	43 (43.4%)
Good	6.0 – 7.9	14 (14.1%)
Adequate	3.0 – 5.9	20 (20.2%)
Poor	< 3.0	3 (3.0%)

- Must have registered > 5 patients in the last 13 months to have a Site Score calculated
- Must have registered >10 patients in the last 13 months to be acknowledged at Plenary

Site Score Report

- Aggregate at the Tier 1 level
- To calculate a meaningful score, site must have at least 5 registrations in previous 13 months
- Average Score at the top of the report
- Monthly metrics for each category and overall monthly score for prior 6 months (newest on the left, oldest on the right)
- Measures that are out of compliance are highlighted in red
- Scoring metric with point assignment and overall Site Score Categories provided at the bottom of the report

Site Score Report - Example

Tier1 Institution:

Six-Month Average Score: 10

	AUG2024		JUL2024		JUN2024		MAY2024		APR2024		MAR2024	
	11	Points	10	Points	10	Points	10	Points	10	Points	9	Points
Score (max.12)												
IFS	0/12 = 0.0%	3	0/13 = 0.0%	3	0/16 = 0.0%	3	0/18 = 0.0%	3	0/19 = 0.0%	3	0/21 = 0.0%	3
IFS13	0		0		0		0		0		0	
Forms	8/751 = 1.1%	2	17/761 = 2.2%	2	10/871 = 1.1%	2	9/869 = 1.0%	2	10/924 = 1.1%	2	26/933 = 2.8%	1
Vital Status	1/33 = 3.0%	3	2/34 = 5.9%	2	3/34 = 8.8%	2	3/37 = 8.1%	2	2/38 = 5.3%	2	4/42 = 9.5%	2
Specimens	0/19 = 0.0%	3	0/20 = 0.0%	3	0/25 = 0.0%	3	0/31 = 0.0%	3	0/43 = 0.0%	3	0/47 = 0.0%	3
Specimens 13	0		0		0		0		0		0	
Query	7/33 = 21.2%*	0	3/30 = 10.0%	1	5/35 = 14.3%*	0		2	<na>		<na>	
Query 13	0		0		0				<na>		<na>	

Point Assignment				
Measure	**3 Points**	**2 Points**	**1 Points**	**0 Points**
IFS	0%	> 0% - 5%	> 5% - 10%	> 10% or IFS13 > 0
Forms	< 1%	1% - 2.5%	> 2.5% - 5%	> 5%
Vital Status	< 5%	5% - 10%	> 10% - 15%	> 15%
Specimens	0%	> 0% - 5%	> 5% - 10%	> 10% or SPEC13 > 0

Site Score Categories	
Category	Point Total
Excellent	10.0 - 12.0 points
Very Good	8.0 - 9.9 points
Good	6.0 - 7.9 points
Adequate	3.0 - 5.9 points
Poor	< 3.0 points

What Does 15/30/60 Mean?

	Expectations			Rave/DQP	
	Due Date	**Grace Period (days)**	**Counts in IPR (days)**	**Target Date**	**Overdue in DQP**
Initial Forms Set (IFS)	Registration Date +15	30	> 30 past due date	Registration Date	> 15
On treatment	Date of per-protocol visit + 30	60	> 60 past due date	Date of per-protocol visit	> 30
Off treatment	Date of per-protocol visit + 60	60	> 60 past due date	Date of per-protocol visit	> 60

SWOG 2024 Trial Activations

Opened in Q2-Q3

S2303: Advanced **Gastric and Esophageal** adenocarcinoma

MYELOMATCH: Master Screening and Reassessment Protocol- **Leukemia/AML**

MM1YA-S01: **AML** High Risk, Age < 60

S2308: Low tumor burden follicular **Lymphoma**

S2312: Metastatic castrate-resistant **Prostate Cancer**

S1900J: MET Amplification-Positive Stage IV or Recurrent NSC **Lung** Cancer

"Expected" Q4

S2414: Early-Stage Non-Small Cell **Lung** Cancer

MM1OA-S03: Newly Diagnosed Older Adults with IDH2 Mutant **AML**

21CTP.LEUK01: Newly Diagnosed Philadelphia Chromosome Positive (Ph+) **ALL**

SWOG | CANCER RESEARCH NETWORK

nCartes

Presented by:
Chris Cook

SWOG-nCartes
EHR-to-EDC

Agenda

- Results
- Installation Considerations
- Updates

Results: Adoption

- SWOG sites live or going live: 11
- Additional SWOG sites in pre-onboarding: 3
- Patients supported/processed: 140+
- Studies in production: 7
- Case report forms processed: 3,000+

Results: Time Savings

- Varies by study, source data, and study personnel
- In general, substantial time savings; not just incremental

- Pilot test
  - 100 case report forms completed in an average of 2 minutes and 20 second per form by an experienced study coordinator
  - Site estimated time savings of 5 to 15 minutes per form, with the range depending on form size/complexity, for a typical coordinator
  - Similar results noted in production at multiple sites

Results: Time Savings (cont.)

- Medical Informatics Europe August 2024 peer-reviewed conference article: “Comparing the Accuracy of Traditional vs. FHIR®-Based Extraction of Electronic Health Record Data for Two Clinical Trials” – Maryam Garza, PhD, MPH, MMCi, et al.
  - Site staff noted “up to 50% time savings in MRA, data entry, and QC”
  - https://ebooks.iospress.nl/volumearticle/68949

Results: Time Savings (cont.)

"nCartes has been invaluable in streamlining our hematology trials, which often involve extensive structured data and complex lab results. **For most clinical research coordinators, data entry has become approximately 60%** faster thanks to nCartes. Even in trials with simpler data sets, we've seen improvements of 75-85% in efficiency, as nCartes seamlessly pulls in the majority of the data. This allows us to focus on reviewing unstructured data, such as treatment details and adverse events, all accessible within the platform. I'm excited about the prospect of launching more trials at UC Davis through nCartes."

Leslie Garcia

Senior Clinical Research Coordinator

UC Davis Comprehensive Cancer Center

Significant Error Rate Improvement

Site Error Rate Check – Traditional vs. nCartes Assisted

	Total Errors	Total Fields Checked	Total Error Rate	Format Errors	Data Entry Errors
Unassisted (Manual)	47	232	20%	20 (9%)	27 (12%)
Automated (nCartes)	0	232	0.0000		

- Format errors all due to decimal length
- Data entry errors included transposed data, unit conversions, incorrect and missed data
- SWOG article in peer review at the *Journal of the Society for Clinical Data Management (jscdm.org)*

Installation Considerations

- HL7 FHIR is the preferred interface standard although nCartes also supports HL7 V2
- One site reported additional Epic fees to support aspects of the interface --- check with your IT staff
- Data from Epic Care Everywhere is generally not available – legal issue among healthcare providers, not a technical issue
- Otherwise, installations are relatively straightforward and leverage out-of-the-box Epic and nCartes APIs

Updates

S1802 (prostate cancer)	S1925 (leukemia)
S1803 (myeloma)	S1931 (renal cancer)
S1826 (lymphoma)	S2013 I-CHECKIT
S1827 (lung cancer)	S2200 (renal cancer)
S1918 (lymphoma)	

- Adding S2207 (lymphoma), S2308 (lymphoma), 2206 (breast), 2212 (breast)

SWOG-nCartes 2024 Leap Day Webinar: SWOG Site Comments

- “it’s been a huge time saver for us”
- "it’s been very easy for us to quickly submit lab values and complete study data entry”
- “our data managers and staff are very excited to add more of our studies to the system”
- "very happy that SWOG was able to partner with this company to make this happen for us"
- “the error rate on data extraction was zero”

THANK YOU

To learn more, you can stop by the SWOG-nCartes booth or email SWOG at:

SWOG-EHR-EDC@CRAB.ORG

Retirement Addition

2014

SELECT

SDMC

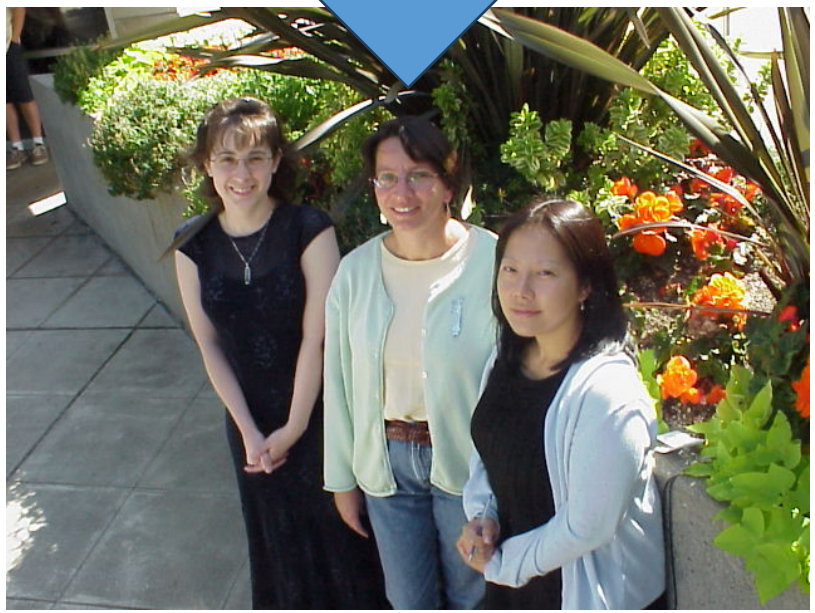
Group

EARLY 2000s


2009

SELECT Statisticians

2001



2002

2003


2009

2013

2014

2022

PHS Research Staff Appreciation Award

Phyllis Goodman, a 31-year veteran of Fred Hutch's Public Health Sciences Division, has won the 2022 PHS Research Staff Appreciation Award."

Phyllis Goodman (left)
Dr. Garnet Anderson (right)

Where will she be in 2025?

Only time will tell!

Special Thanks

- All of our Speakers
- Tech Support team
- Courtney Wille

Reminders

Tomorrow, Thursday, October 17th

- **Jeri & Noboru Oishi Symposium**, 8:00 AM – 11:00 AM CST
- **ORP Open Forum**, 12:30 PM – 2:00 PM CST

Spring 2025 SWOG Group Meeting

April 30 - May 3, 2025
Hyatt Regency San Francisco
San Francisco, California

https://www.pexels.com/search/fall%20activities%20in%20chicago/