SWOG | CANCER RESEARCH NETWORK

Oncology Research Professionals (ORP)
Site Operations Fall Meeting 2025

Doing the work that matters

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

Announcement and Updates Oncology Research Professionals (ORP) Committee

Presented by:

Connie Szczepanek, RN, BSN, CCRP

Spring Site Operations

September 18th, 1:00 PM - 2:30 PM CT

Open, Welcome, and Announcements		Site Operations Committee
SWOG Updates		
SWOG Network Operations Center	Administration & Study Funding	Pat Mize
	Quality Assurance (QA)	Laura Gonzales
	Information Systems	Cara Laubach
Statistics & Data Management Center (SDMC)		Kari Chansky
General Updates		
NCI Community Oncology Research Program (NCORP)		Brandy Heckman-Stoddard
CTEP		Andrea Denicoff
Pharmaceutical Management Branch (PMB)		Matt Boron
Closing Remarks		Site Operations Committee

CE Credits

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

Thursday, September 18, 2025 • 1:00 PM – 2:30 PM CT

Open, Welcome, and Announcements		Site Operations Committee
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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

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

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.

For quick reference…

See the SWOG Website:

Member Resources / Oncology Research Professionals

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

Quick Links to:

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

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

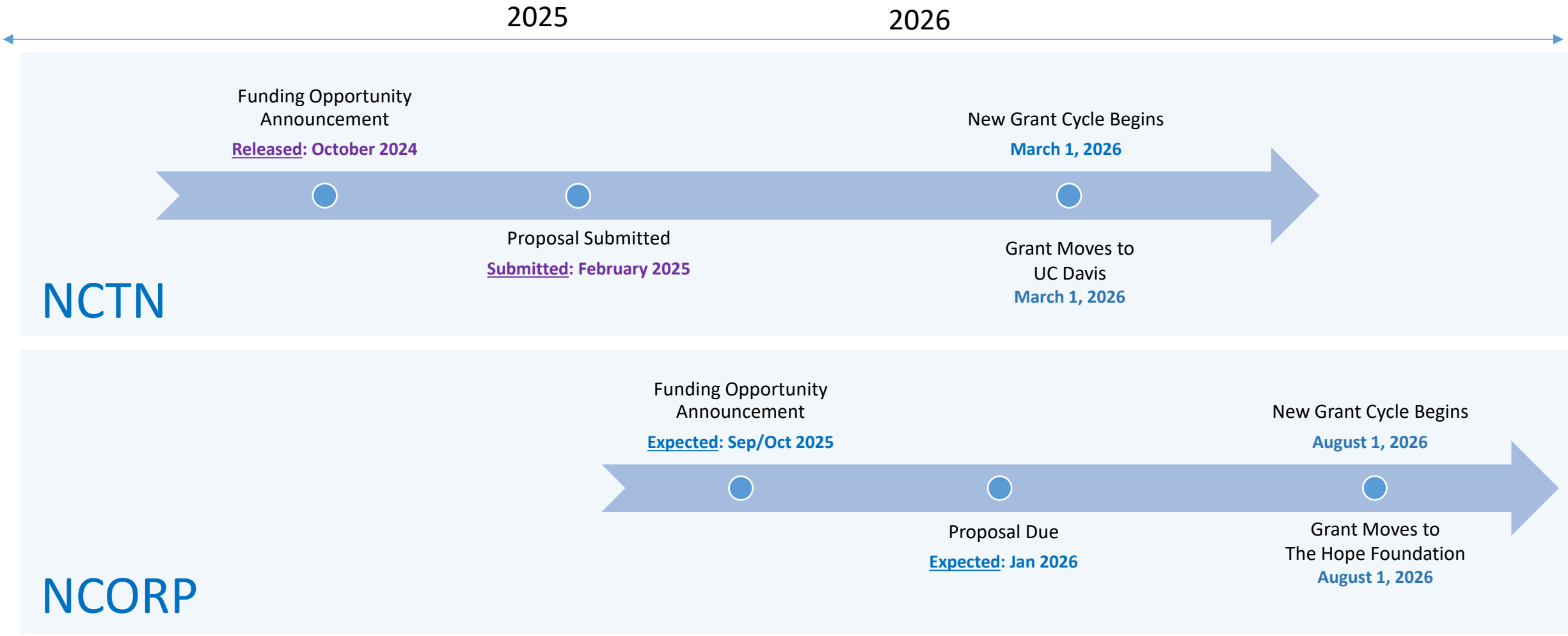
SWOG Network Group Operations Center
Administration & Funding Updates

Presenter:

Casey Dawson, SWOG Assistant Director of Administration

Pat Mize, SWOG Grants & Contracts Manager

SWOG NCTN/NCORP Renewal Timeline



NCORP Competitive Renewal

Member Site Requirements

- ✓ Letter of Intent (LOI)
  - FDP LOI Template
  - Signed by institutional signing official (OS)
- ✓ Letter of Support from Member Site PI
  - Optional, but appreciated!
  - Template provided

Please send any questions to FedGrants@swog.org

NCTN/NCORP Grant Extensions

- SWOG NCTN grant was extended to end of Feb 2026
  - ➢ Fixed rate subaward amendments have been issued

- SWOG NCORP grant was extended to the end of Jul 2026
  - ➢ Fixed rate subaward amendments are in the process of being issued in batches

Please send any questions to FedGrants@swog.org

Site Funding Contacts

Federal Funding	Payments: FedSitePayments@swog.org Awards: FedGrants@swog.org
Non-Federal Payments/Awards	Finance@thehopefoundation.org
National Coverage Analysis (NCA) or General Funding Questions	Funding@swog.org
SWOG Clinical Trials Partnerships (CTP) - non-federal studies	General: ctp@swog.org Funding: funding@swogctp.org

SWOG Clinical Trials Partnerships (CTP)

September 2025 Site Operations Update

21CTP.LEUK01 – ACTIVE

21CTP.LEUK01:

“A Phase II Trial of Asciminib, Dasatinib, Prednisone, and Blinatumomab for Participants with Newly Diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia”

ACTIVELY SELECTING SITES!

Learn more at
https://www.swogctp.org/trials/21ctpleuk01/

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.HN01 - ACTIVE

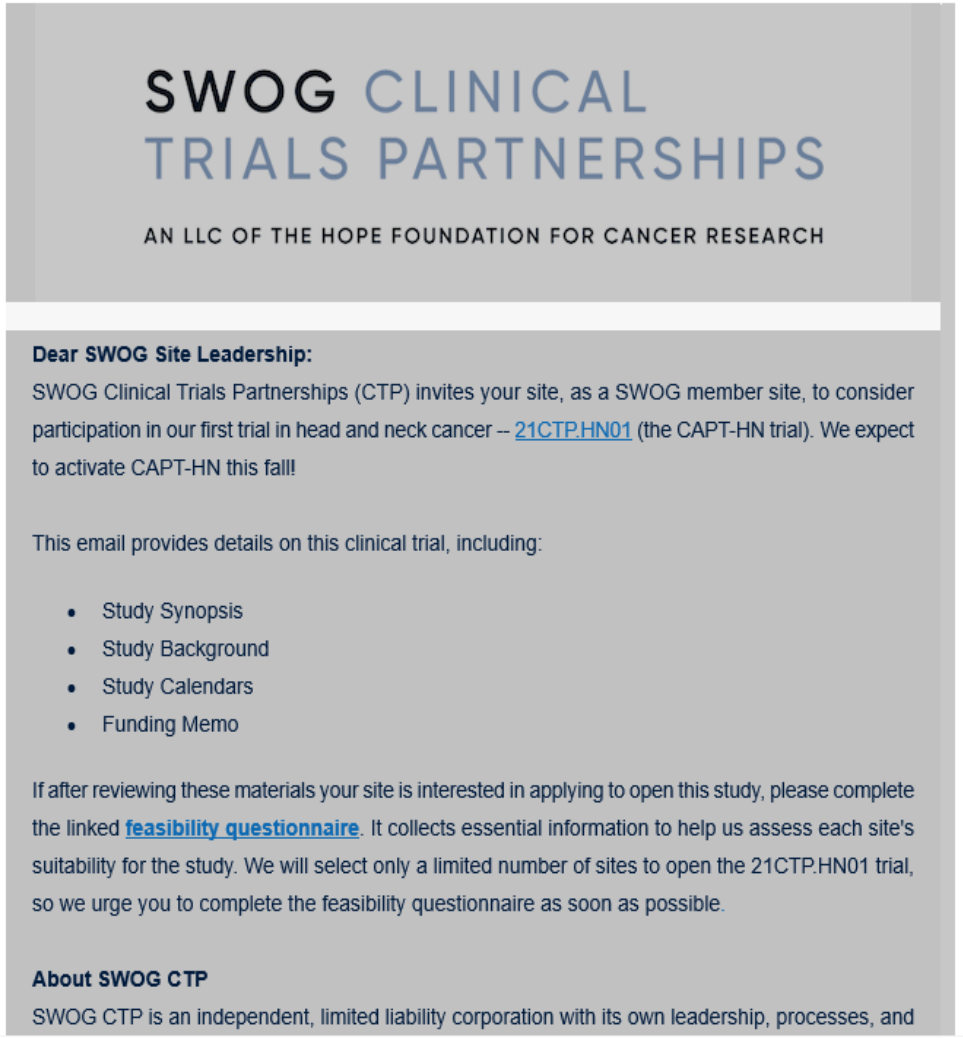
21CTP.HN01:

CAPT-HN "A Phase II Study of Combined Amivantamab, Carboplatin and Paclitaxel in Unresectable Locally Recurrent or Metastatic Head and Neck Cancer

Activated 09/15/2025!

ACTIVELY SELECTING SITES!

Learn more at
https://www.swogctp.org/trials/21ctphn01/



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 head and neck cancer -- 21CTP.HN01 (the CAPT-HN trial). We expect to activate CAPT-HN this fall!

This email provides details on this clinical trial, including:

- Study Synopsis
- Study Background
- Study Calendars
- Funding Memo

If after reviewing these materials your site is interested in applying to open this study, please complete the linked **feasibility questionnaire**. It collects essential information to help us assess each site's suitability for the study. We will select only a limited number of sites to open the 21CTP.HN01 trial, so we urge you to complete the feasibility questionnaire as soon as possible.

About SWOG CTP

SWOG CTP is an independent, limited liability corporation with its own leadership, processes, and

Upcoming Studies

21CTP.BREAST01:

MONITOR, "A Phase II Platform Trial Using Circulating Tumor DNA to Monitor Treatment Response in HR+, HER2-Metastatic Breast Cancer"

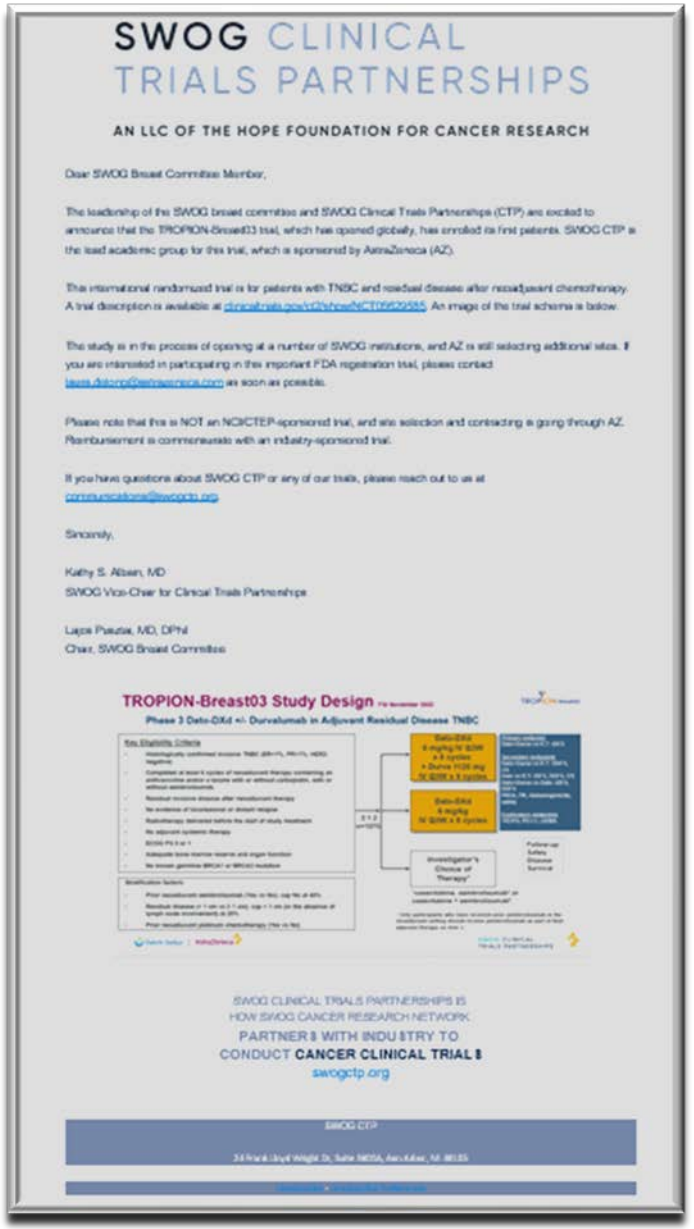
25CTP.Breast02

26CTP.Leuk02

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

Learn more at https://www.swogctp.org


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/NCT05629585. 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 laura.dobrenz@swogcancer.org 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 communications@swogctp.org.

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

Questions or Suggestions?

Please reach out!

CTP@swog.org

Quality Assurance Updates

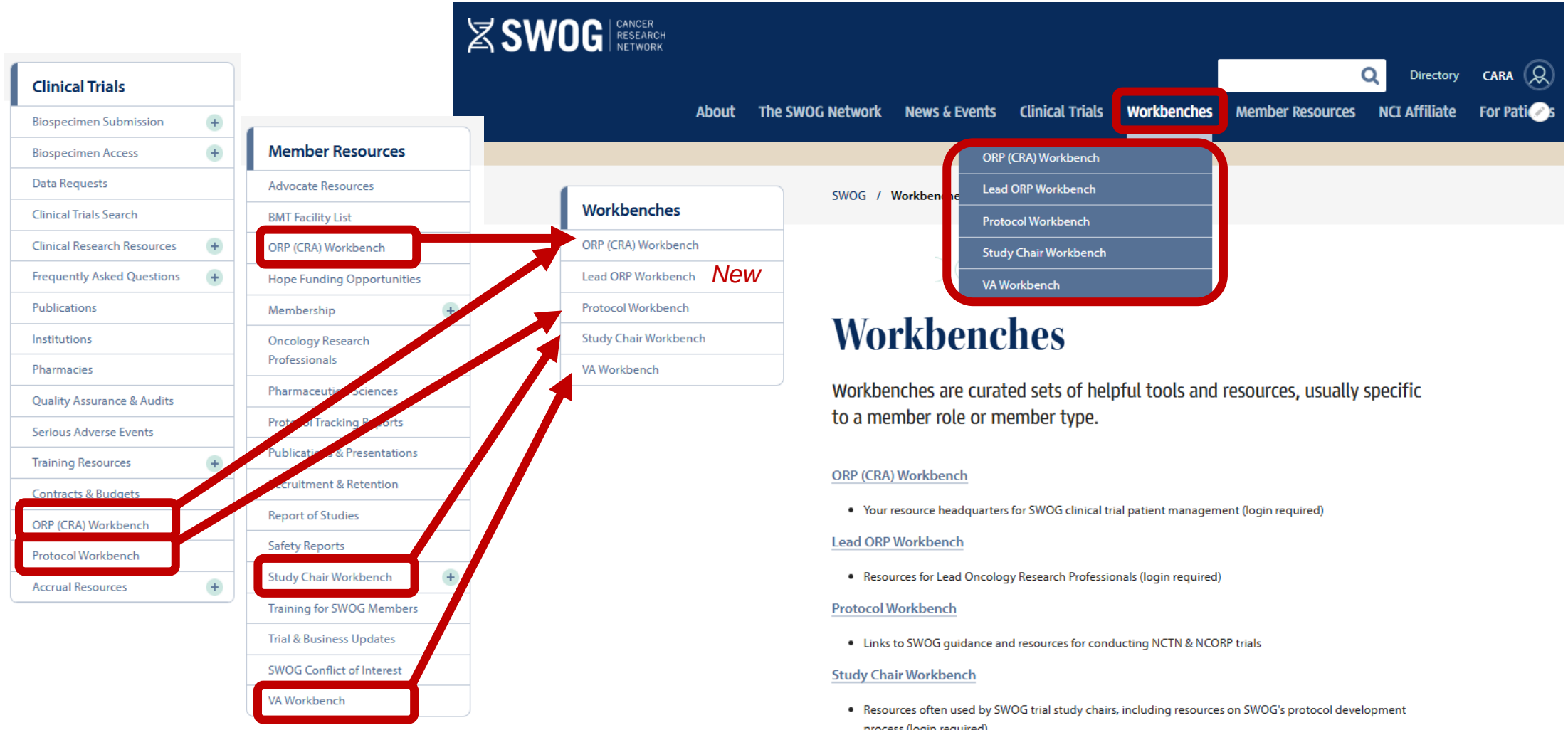
Presenter: Laura Gonzales, BSN, MA RN, OCN
Quality Assurance Manager
SWOG Operations Office
San Antonio, TX

SWOG Operations Center
Information Systems

Presented by:
Cara Laubach
Training Manager, SWOG Cancer Research Network

Oncology Research Professionals Educational Resources & Updates

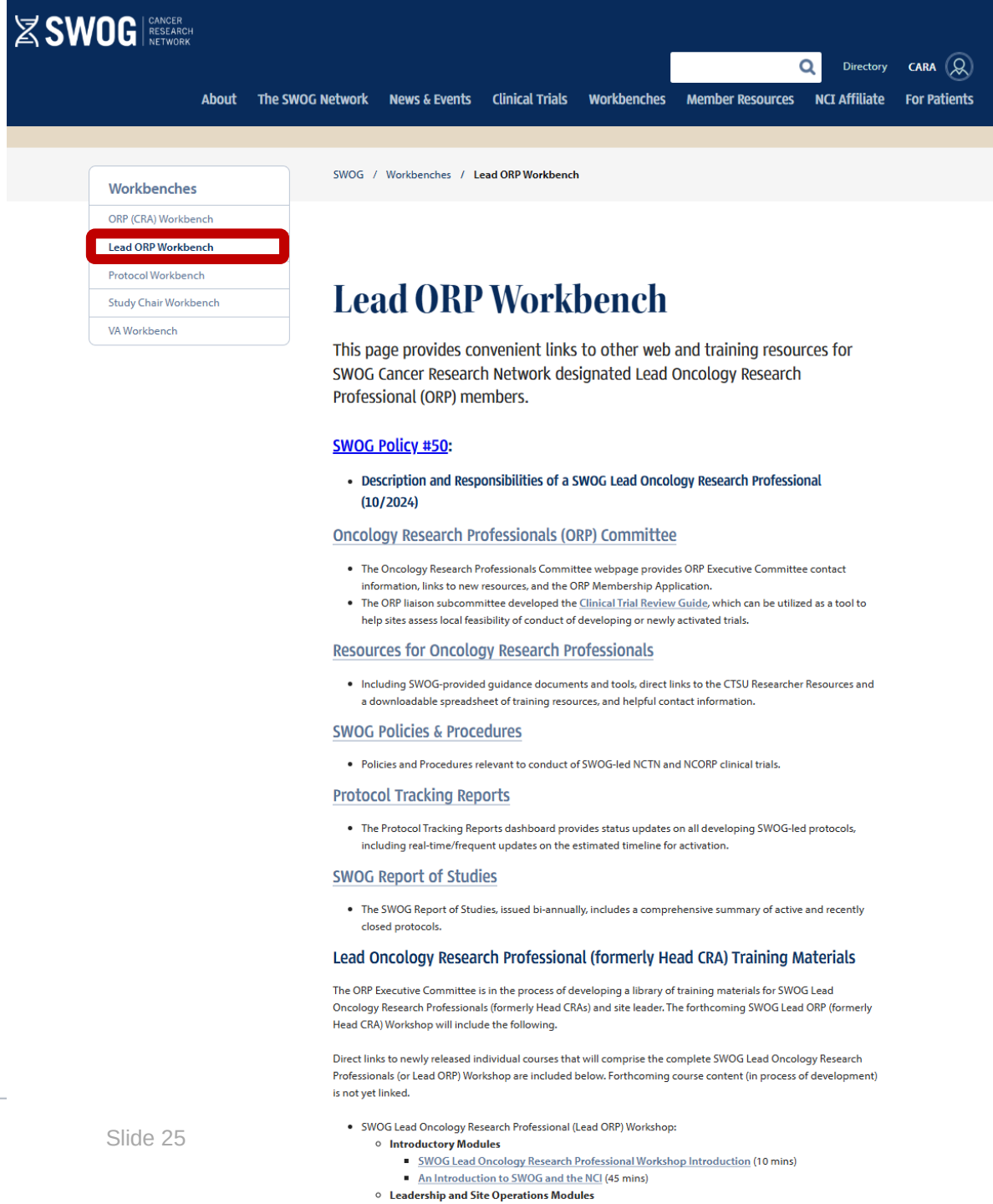
SWOG.org "Workbenches" Navigation menu



- All Clinical Trials and Member Workbenches are being migrated to a new location on SWOG.org

New Lead ORP Workbench

- Landing page for resources dedicated to SWOG Lead ORP members.
- Feedback: training@swog.org



Lead ORP Workshop

- **Introductory Modules**
  - SWOG Lead ORP Workshop Introduction (10 mins)
  - An Introduction to SWOG and the NCI (45 mins)
- **Leadership and Site Operations Modules**
  - Leadership Perspective (17 mins)
  - NCI Trials - Site Operations Perspective
- **SWOG and NCI Systems Module**
  - SWOG and NCI Systems Overview Training (14 mins)
- **Data Management and Resource Access Modules**
  - Data Management and Access Module Introduction for Lead ORPs (1 min)
  - CTSU Website Overview (9 mins)
  - SWOG Website Overview (4 mins)
  - SWOG CRA Workbench Overview (4 mins)
  - iMedidata RAVE Access for Lead ORPs (6 mins)
  - SWOG Specimen Tracking System (8 mins)
  - Central Monitoring (5 mins)
- **Funding and Site Payments Modules**
  - NCTN/NCORP Funding & Payment Dist. (20 mins)
  - Open Funding (10 mins)
  - National Coverage Analysis Overview (4 mins)
- **Study Activation and Management Modules**
  - Delegation of Tasks Log (2 mins)
  - Adverse Events Training for Lead ORPs (8 mins)
  - Dose Modifications Training for Lead ORPs (1 min)
  - Serious Adverse Event Reporting Training (30 mins)
  - SAE Reporting - Specific Exceptions to Expedited Reporting for Lead ORPs (4 mins)
  - Data Entry in Difficult Situations Training (2 mins)
  - Record Retention Training for Lead ORPs (3 mins)
- **Reports and Tools for Data Quality Modules**
  - Expectations and Expectation Reports (10 mins)
  - Vital Status Expectations Training (5 mins)
  - Specimen Expectations for Lead ORPs (8 mins)
  - Institution Performance Review (IPR) (10 mins)
  - Query Reports Training for Lead ORPs (4 mins)
  - CTSU reports - Data Quality Portal (DQP) (7 mins)
- **Regulatory Module**
  - Regulatory Expectations - QA Perspective (13 mins)
- **Quality Assurance Modules**
  - Audits and Quality Assurance Program (20 mins)
  - Protocol Deviations vs. Deficiencies Training (4 mins)
  - When is my Institution's next Audit Due? (2 mins)

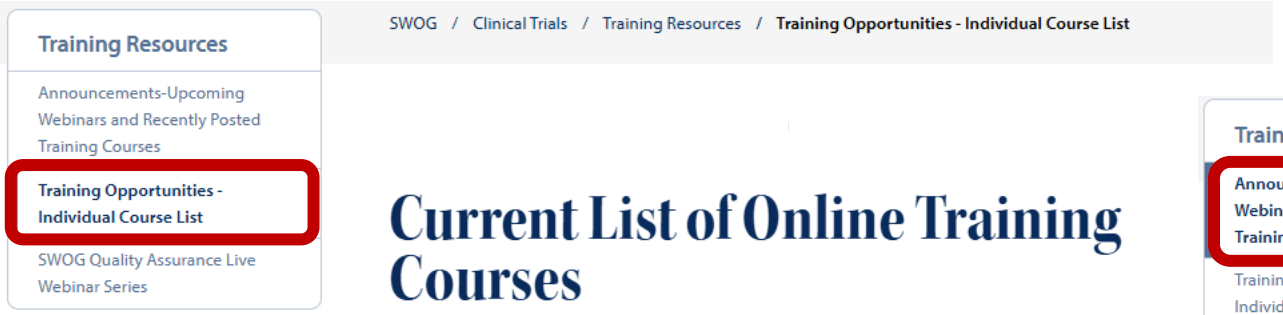
SWOG CANCER RESEARCH NETWORK

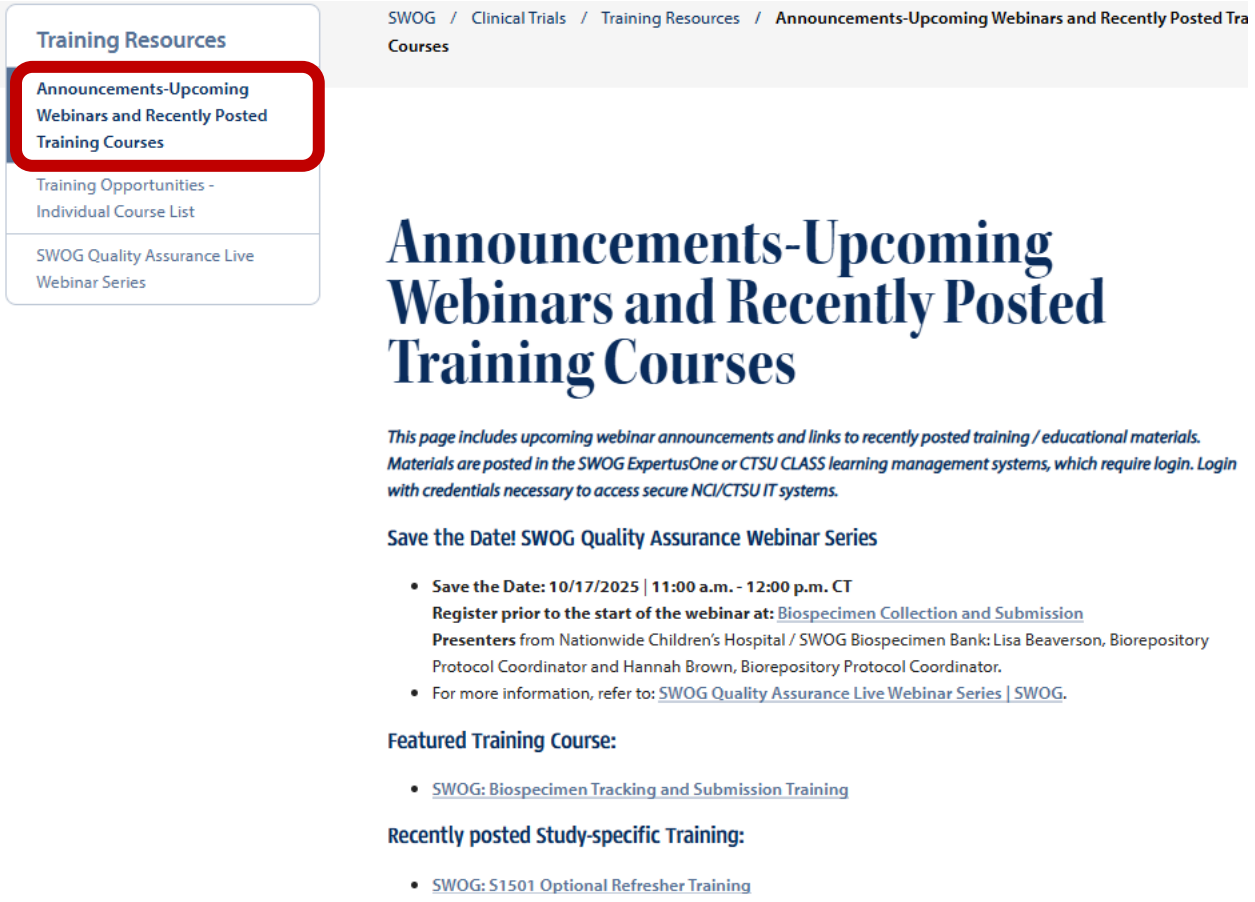
Refer to: Lead ORP Workshop to access the entire Workshop or Lead ORP Workbench | SWOG for individual course links

NCI National Clinical Trials Network | NCI Community Oncology Research Program


About
The SWOG Network
News & Events
Clinical Trials
Workbenches
Member Resources
SWOG / Workbenches / ORP (CRA) Workbench
Find ORP Resources on the
ORP (CRA) Workbench
Your resource headquarters for SWOG clinical trial patient management.
Latest CRA Newsletter
Join the CRA Mailing list
Announcements
Oishi Symposium and Site Operations Presentations
Recordings from the Spring, 2025 Site Operations and Oishi Symposium presentations (among many others) have
Tools
BSA Calculator
Clinical Trial Review Guide
COVID Protocol Deviation Guidance
Creatinine Clearance Calculator
Date Counter
Ideal Body Weight Calculator
QT Interval (QTc)
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 Us
Contact the Statistics and Data Management Center (SDMC)
Helpful Contact Information Documents
ORP (CRA) Workbench
Popular Resources
OPEN Patient Registration
Rave Data Submission
Specimen Tracking
CTP Registration and Data Submission
SWOG QA / Audits / Monitoring
SWOG Best Practices
Tools
Resources
CRA Manual (for Oncology Research Professionals)
Patient Reports / Data Quality
Study Reports
Patient Management (Non-Rave Studies)
Training
Contact Us
Training
SWOG Clinical Trials Training Course (CTTC)
Your First Group Meeting
Every CRA Should Know...
Announcements/Current Training Opportunities
Training Resources
Study Reports
Studies with no required follow-up
Studies in Long Term Follow-up
SAEs for a Study
Study-wide Unblinding
Accrual by Site
Accrual by Race and Sex
Accrual by Disease Committee
BMT Facilities
RT Facilities
• "Studies with no required follow-up" is a report of studies that can be terminated with the IRB of record.
SWOG CRA Workbench
• Login with credentials required to access NCI/CTSU systems
• ORP (CRA) Manual
• Expectation, IPR and Query Reports
• Recent updates: "Announcements" and the Quarterly "CRA Newsletter"
• Helpful SWOG and CTSU Contact Information

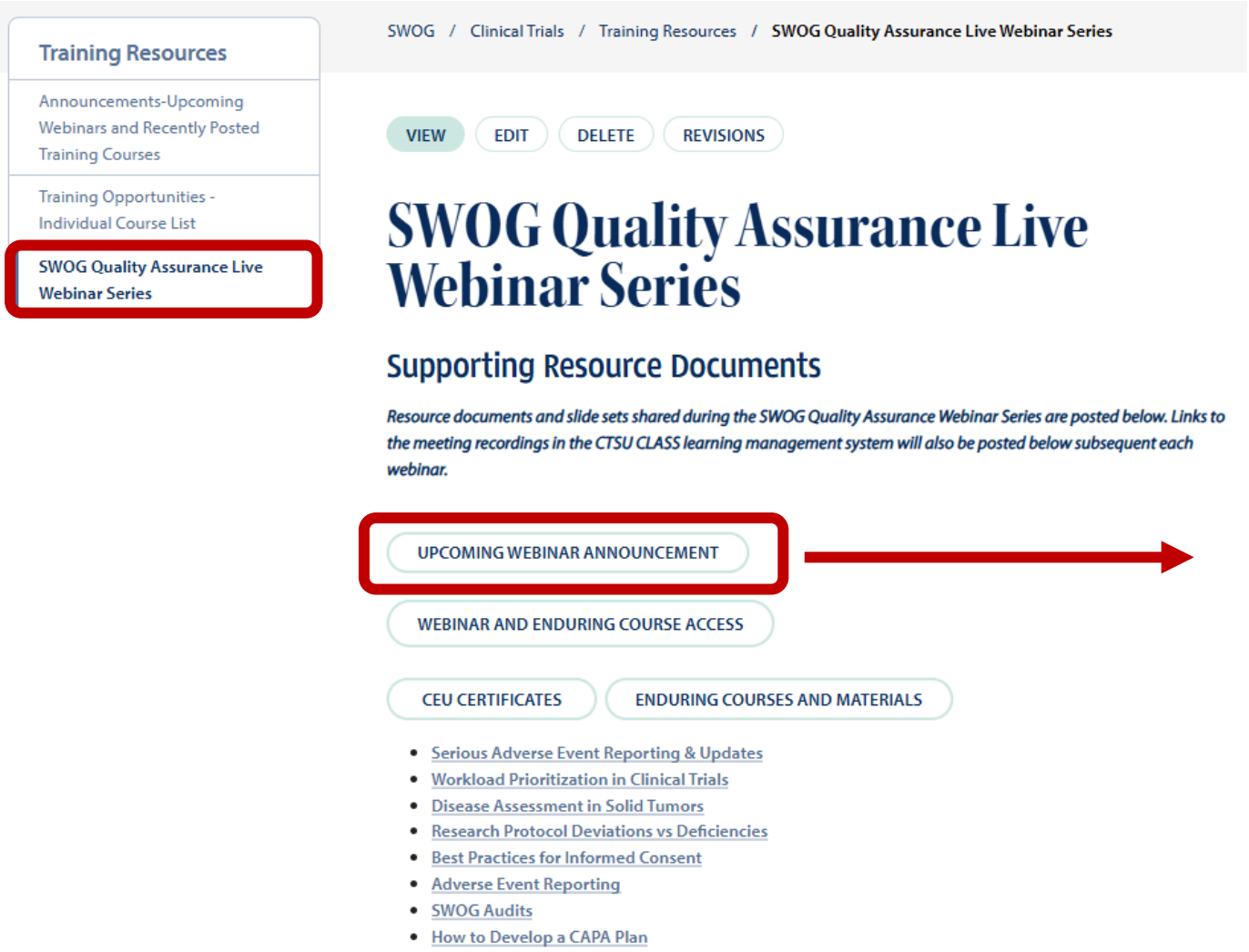
Training Announcements and List of SWOG-provided online training courses





Refer to: Current List of Online Training Courses

SWOG Quality Assurance Webinars

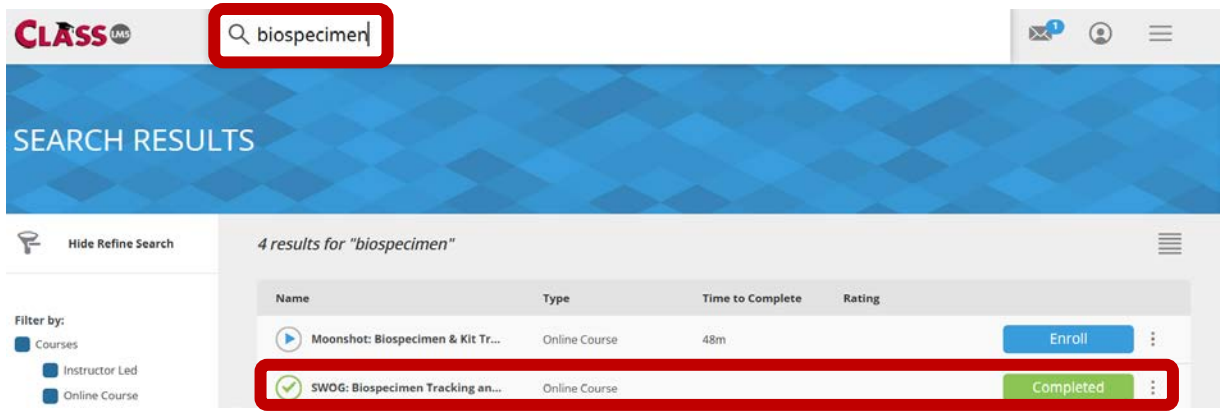


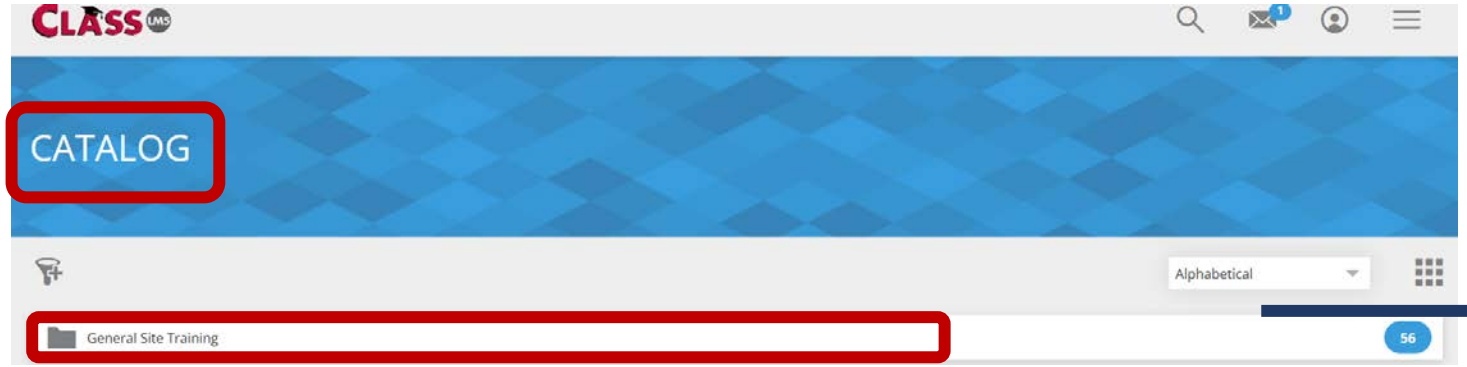
Biospecimen Collection and Submission
Friday, 10/17/2025 | 11:00 a.m. - 12:00 p.m. CT
Presenters: Lisa Beaverson and Hannah Brown
SWOG Biospecimen Bank

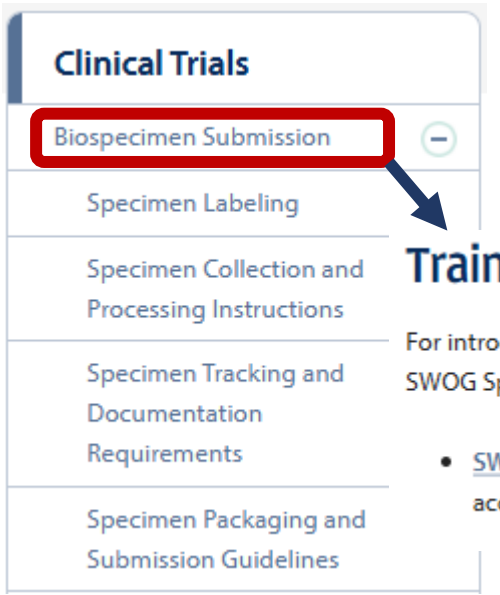
New SWOG Biospecimen Tracking and Submission Training

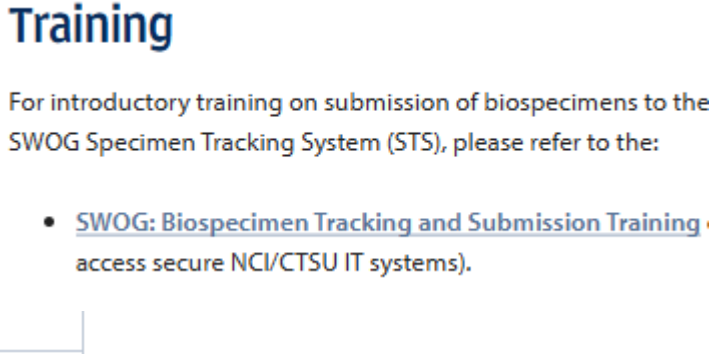
Accessible:

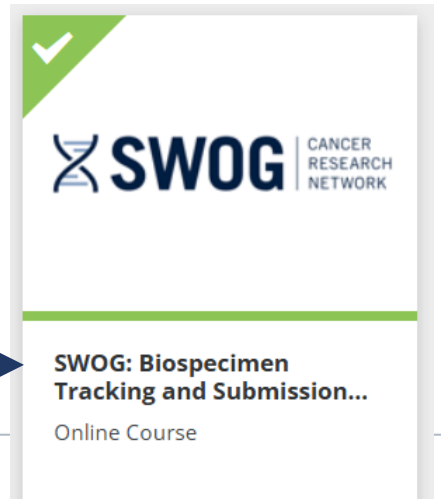
- Via CLASS search tool: Keyword “Biospecimen”
- Via the CLASS catalog: General Site Training folder.
- Via the SWOG Biospecimen Submission Webpage



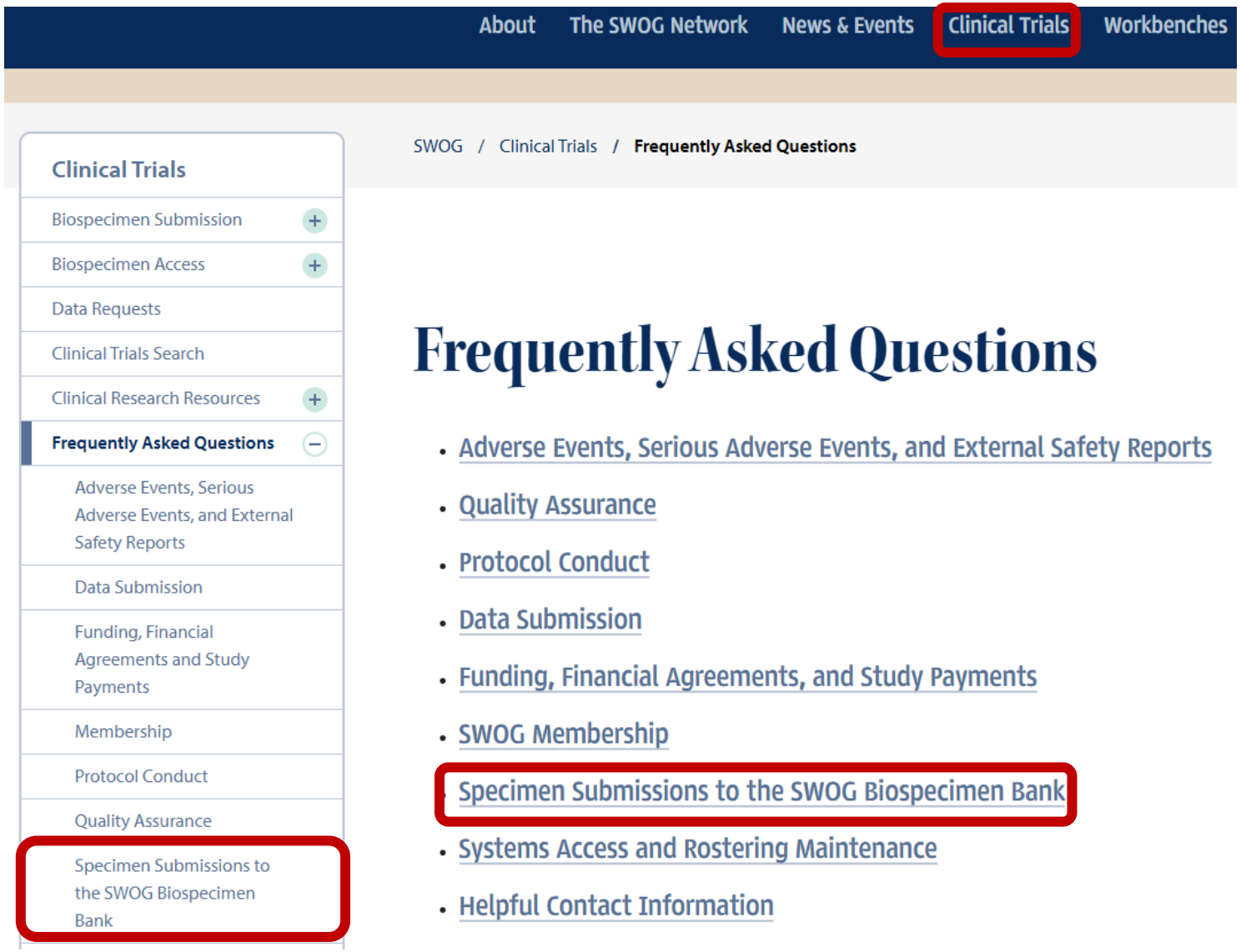








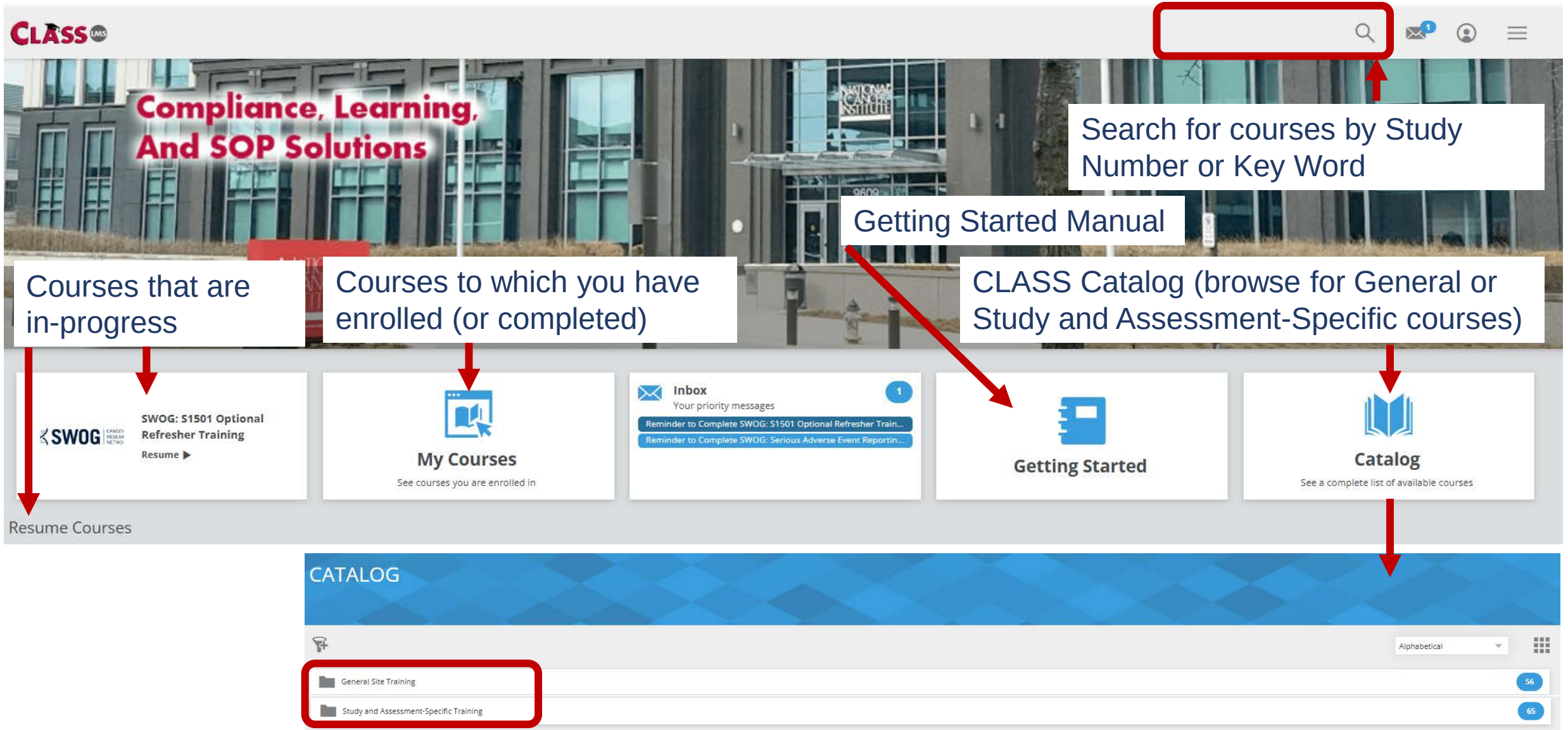
Frequently Asked Questions webpages



Clinical Research Resources webpages

- 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

CTSU CLASS Learning Management System



SWOG ExpertusOne Learning Management System:
Forthcoming Updates (Q1 2026)

- Additional administrative functionality
- New content launcher
  - Course components more visible
- New course / completion status export functionality
- Direct course links will change
  - Announcement will be distributed in Q1 2026

Who is the best first point of contact for help with reporting an SAE?

A. adr@swog.org

B. protocols@swog.org

C. ChatGPT

D. The Data Coordinator (or data coordinators' distribution list) for the study.

Where can Study-Specific Training be found for SWOG-led studies? (Select the best answer)

A. In the CTSU CLASS LMS (via the search tool or catalog).
B. Links to the training are posted on the CTSU protocol abstract page under Documents >> Education and Promotion.
C. Via links in SWOG and CTSU Broadcast announcements.
D. Via links in Protocol Sections 13 and 15 for protocol-required training or Protocol Section 15 for optional training.
E. All of the above.

All of the following can be found under “Resources” on the SWOG ORP (CRA) Workbench:

- Clinical Trial Review Guide
- Creatinine Clearance Calculator
- Ideal Body Weight Calculator
- Date Counter

A. True.

B. False.

Where can helpful information for submission of specimens to the SWOG Biospecimen Bank be found? (Select the best answer)

A. Always check the Protocol. In SWOG-led protocols: Refer to Protocol Section 15.

B. The Specimen Submission FAQs on SWOG.org.

C. The Biospecimen Collection and Submission Procedures webpage on SWOG.org.

D. The SWOG Biospecimen Tracking and Submission Training Course in CLASS.

E. All of the above.

What does the SPEER acronym stand for? (Select the best answer)

A. SPEER Is an acronym? It is a verb meaning to ask or to inquire.

B. Small Portions of Enticing Eggplant Ravioli

C. Special Elves in Enchanting Rituals

D. Sparing Potential Embarrassment in Egg Rolling

E. Specific Exceptions to Expedited Reporting

Where can a list of all specimens (required and optional) that need to be submitted for a SWOG-led study be found? (Select the best answer)

A. In Protocol Section 15. For recently activated protocols: A helpful specimen table is included in Protocol Section 15.

B. This list can be requested by emailing either protocols@swog.org or the study's data coordinators (distribution list).

C. In the SWOG Specimen Tracking System (STS) under the Specimen Requirements Summary link.

D. All of the above.

E. A and C.

The SWOG ORP (CRA) Manual – posted on the SWOG ORP (CRA) Workbench contains.... (Select the best answer)

A. Standard data submission timeframes for the Initial Forms Set (IFS), On-Treatment Forms, Off-Treatment Notice, Follow-up Forms, Notice of Death.

B. Instructions for how to access SWOG Expectation Reports and Example Expectation Reports.

C. Instructions for how/when studies can be closed out for follow-up and an explanation of the SWOG “List of Studies with No Required Follow-up” report.

D. An explanation of the timeframes in which a revision must be locally activated.

E. General rules and guidelines for data submission.

F. All of the above.

Special Thanks

SWOG CANCER RESEARCH NETWORK

Thanks for all that you do in support of SWOG clinical trials!!

NCI National Clinical Trials Network

NCI Community Oncology Research Program

SDMC Updates

Kari Chansky, MS

Coordinating Statistician
SWOG Statistics and Data Management Center
Seattle, WA

SWOG Activations

S1800E: Randomized Phase II/III Study of Docetaxel and Ramucirumab with or Without Cemiplimab (REGN2810) for Participants Previously Treated with Platinum-Based Chemotherapy and Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study)
Activated 04/28/2025

S2417CD: A Pragmatic Randomized Controlled Trial To Evaluate The Effectiveness of an Intervention called Current Together After Cancer (CTAC) to Promote Guideline-Concordant Colorectal Cancer Surveillance
Activated 08/04/2025

SWOG Activations

SN2426: A Randomized Phase II Study of Subcutaneous Amivantamab Versus Cetuximab in Immunocompromised Participants with Recurrent Inoperable or Metastatic Cutaneous Squamous Cell Carcinoma
Planned Activation: 09/01/2025

S2427: Single Arm Phase 2 Study of Bladder Preservation with Immunoradiotherapy After a Clinically Meaningful Response to Neoadjuvant Therapy in Patients with Muscle Invasive Bladder Cancer (BRIGHT)
Planned Activation 09/01/2025

SWOG Activations - CTP

21CTP.LEUK01: A Phase II Trial of Asciminib, Dasatinib, Prednisone, and Blinatumomab for Participants with Newly Diagnosed Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia *aged 60 or older who are not candidates for standard intensive chemotherapy*.
Activated: 05/15/2025

https://swogctp.org/trials/21ctpleuk01

All SWOG sites are invited to consider and apply

Questions? Reach out to protocols@swogctp.org

SWOG Activations - CTP

21CTP.HN01: CAPT-HN: A Phase II Study of Combined Amivantamab, Carboplatin and Paclitaxel in Unresectable Locally Recurrent or Metastatic Head and Neck Cancer.

Planned Activation: 09/15/2025

https://swogctp.org/trials/21ctphn01/

All SWOG sites are invited to consider and apply

Questions? Reach out to protocols@swogctp.org

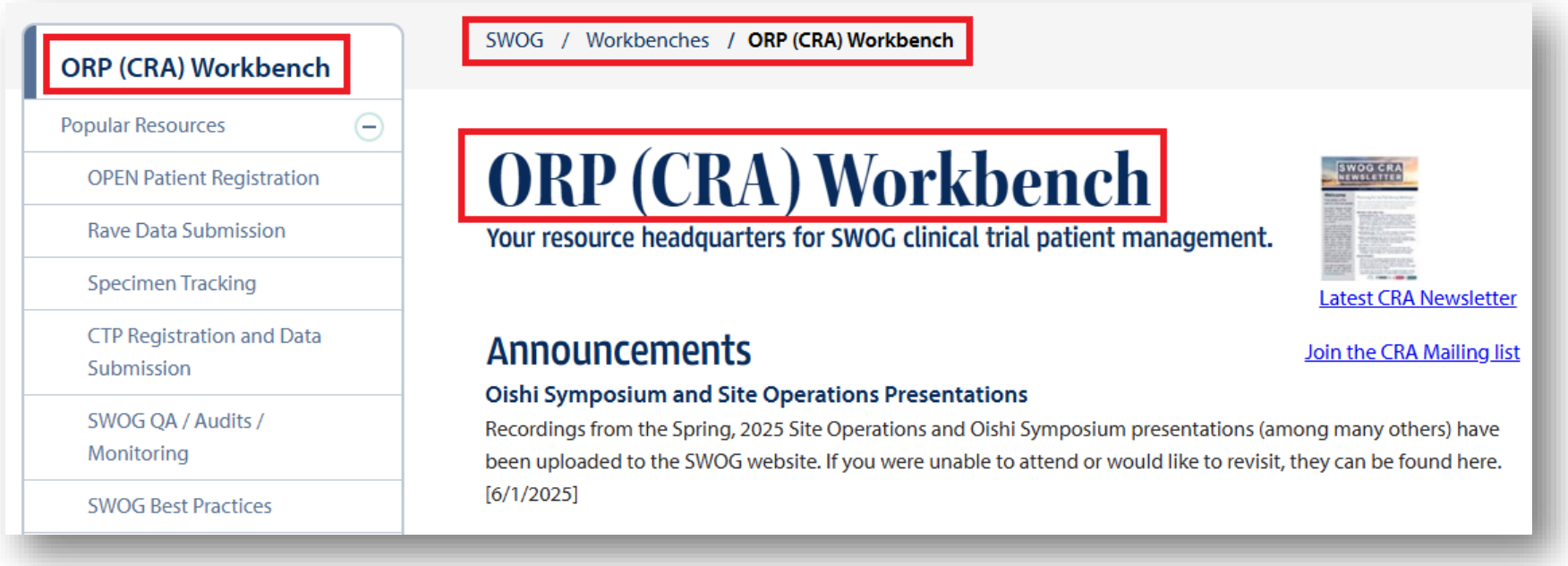
MyeloMATCH – Specimen Tracking

- MyeloMATCH transitioning to full utilization of SWOG Specimen Tracking System
- Pilot phase has launched: *Screening trial and MM1YA-S01*
- All groups, including labs, have received demos
- Non-SWOG groups are translating specimen requirements to SWOG specimen metadata template
- All treatment trials to be added at the end of the pilot
- *Questions? Contact: myelo-match-support@nih.gov*

ORP (CRA) Workbench (Renamed)

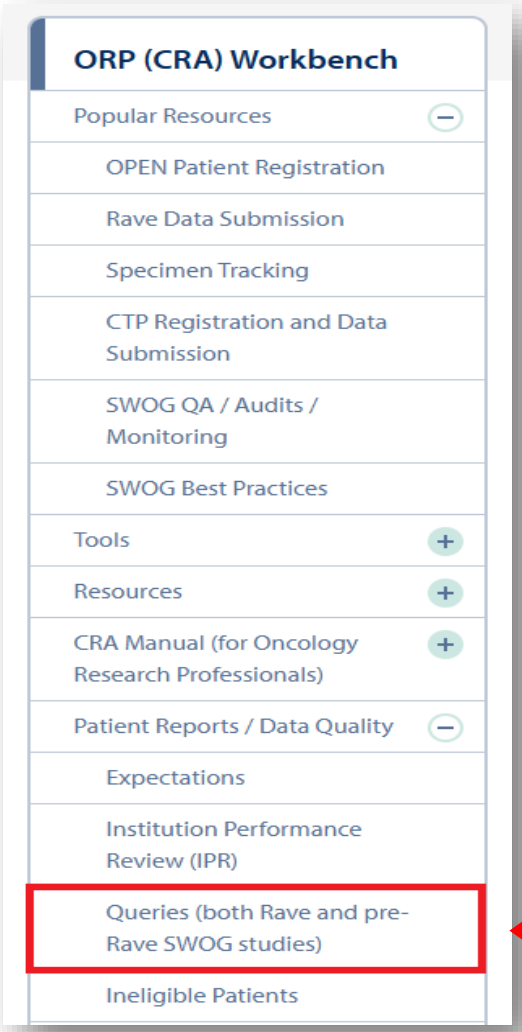
ORP (CRA) Workbench (Renamed)

- **Updated landing page**



- ***ORP Manual – NEW!! Ch. 17 (CTP)***

Query Reports



- Site Score has included queries from IPR metrics starting in March 2025
- Query reports for your site can be accessed via the ORP (CRA) Workbench

Query Reports

CRA Newsletter – Summer and Fall

- NCORP Clinical Trials Workshop
- Who's Who at SDMC and NOC
- SAE Reporting Resources
- Spring 2025 Clinical Trials Training Course
- Vital Status Forms

Send your ideas!
CRANewsletter@crab.org

SAE Discover Date

- Spring 2025 – Requests to add SAE discover date to comments section of CTEP AERS report
- Knowledge of discover date (versus only the SAE date) often allows the SAE Coordinator to understand whether an SAE was reported on time
- Improvement since April!
  - Discover date reporting - ↑
  - Proportion of SAEs flagged as “LATE” - ↓

THANK YOU!!

SDMC Staffing Updates

Gabby Lopez, MS
Statistical Research Associate

Welcome back, Gabby!

Contact Us

breastquestion@crab.org
cancercontrolquestion@crab.org
giquestion@crab.org
guquestion@crab.org
leukemiaquestion@crab.org
lungquestion@crab.org
lymphomaquestion@crab.org
melanomaquestion@crab.org
myelomaquestion@crab.org
raretumors@crab.org
LungMAPquestion@crab.org

SWOGComboMATCHquestion@crab.org
SWOGiMATCHquestion@crab.org
SWOGMyeloMATCHquestion@crab.org

NCI CTEP Updates

Presented by:

Andrea Denicoff, MS, RN

SWOG Fall Meeting
NCI/CTEP Update

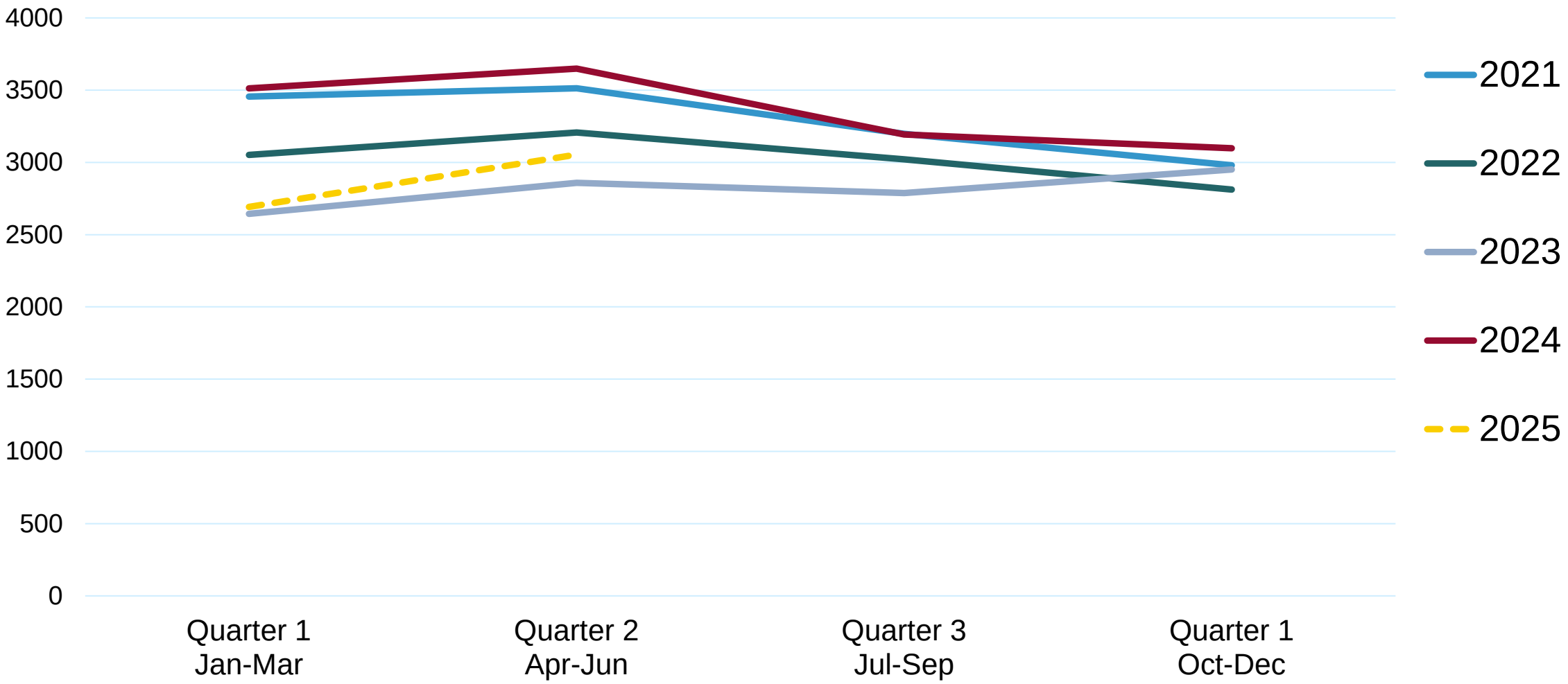
Andrea Denicoff, MS, RN
Grace Mishkin, PhD, MPH
September 18, 2025

NIH NATIONAL CANCER INSTITUTE

Agenda

1. *NCTN Accrual Updates*
2. *Streamlining Clinical Trials*
3. *Streamline SOC Risk Lists*
4. *Informed Consent Template Revision*
5. *NCTN Trial Lists by Cancer Type – Location on updated CTEP Website*

NCTN Quarterly Intervention Accrual January 2021 – June 2025



NCTN Intervention Accrual by Enrolling Site Types

	Percent of NCTN Intervention Accruals by Full Member Site Type		
Enrolling Site Type (with integral subsites)	**Mar 2023-Feb 2024**	**Mar 2024-Feb 2025**	**Mar 2025-Jul 2025**
LAPS	29.6%	28.9%	29.6%
NCORP	25.4%	26.3%	25.8%
Rostered	45.0%	44.8%	44.6%

Streamlining Clinical Trials Update

Streamlining Clinical Trials Data Collection

- CTAC Streamlining Clinical Trials Working Group 2024 report outlined Data Collection Standard Practices for NCI NCTN trials
- Standard Practices focus on limiting data collection to elements essential for safety and study's primary and secondary objectives
- Anticipated to reduce the operational burden of NCI NCTN trials
- Initial scope of trials covered by standard practices begun 1/2025:
  - NCI CTEP-managed NCTN phase III and phase II/III
  - IND-exempt, i.e., trials that can be conducted without an Investigational New Drug Application (~ 35% of NCI NCTN trials)

Prindiville SA et al. Streamlining cancer clinical trials: new standard data practices. *J Natl Cancer Inst.* 2025;117(3):396–401. doi:10.1093/jnci/djae239. https://pubmed.ncbi.nlm.nih.gov/39325869/

Data Categories for Streamlined Data Standard Practices

- Routine adverse events (only 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

Implementation Progress: Streamlined Treatment Trials since January 1, 2025

	Alliance	CCTG	COG	ECOG-ACRIN	NRG	SWOG	Totals
IND-Exempt: Activated	2	2	0	3	4	1	12
IND-Exempt: Under Development	2	0	1	0	1	1	5
IND: Activated	2	0	0	0	0	1	3
IND: Under Development	0	0	0	0	0	0	0
							26

- No NCTN Group has requested exemptions from the streamlined data collection practices specified for IND-exempt trials.

Data as of 9/3/25

Currently Active IND-exempt NCTN Streamlined Clinical Trials (1)

A032303	GAIN-BCG: Gemcitabine Alternating with INtravesical BCG Randomized Against BCG Alone for Patients with Recurrent High Grade Non-Muscle Invasive Bladder Cancer
CCTG-PR26	A Randomized Phase III Clinical Trial for the Addition of Docetaxel to Androgen Receptor Pathway Inhibitors in Patients with Metastatic Castration Sensitive Prostate Cancer and Suboptimal PSA response: TRIPLE-SWITCH
CCTG-BR38	Consolidative Use of Radiotherapy to Block (CURB2) Oligoprogression in Patients with Metastatic Non-Small-Cell Lung Cancer - A Randomized Phase 3 Trial
CTIU2317-A082304-S2402	Perioperative versus Adjuvant Systemic Therapy in Patients with Resectable Non-Small Cell Lung Cancer – PROSPECT LUNG
EAA241	A Randomized Phase II Trial Comparing Daratumumab-Bortezomib-Dexamethasone versus Cyclophosphamide-Bortezomib-Dexamethasone in Newly Diagnosed Multiple Myeloma with Light Chain Cast Nephropathy (LCCN)
EA2234	A Randomized Phase II/III Trial of Intraperitoneal Paclitaxel Plus Systemic Treatment vs Systemic Treatment Alone in Gastric Carcinomatosis – STOPGAP II

Active NCTN IND-exempt Streamlined Clinical Trials (2)

EA4232	A Randomized Phase III Study To Evaluate Benefits of ASCT in Patients with PTCL That Achieved a First CR (CR1) Following Induction Therapy - PTCL-STAT
NRG-BN014	A Phase III Randomized Clinical Trial of Proton Craniospinal Irradiation Versus Involved-Field Radiotherapy for Patients with Breast Cancer or Non-Small Cell Lung Cancer Leptomeningeal Metastasis (Radiate-LM)
NRG-GI011	A Phase III Randomized Trial of Dose Escalated Radiation in Locally Advanced Pancreas Cancer (LAPC) Patients (LAP100)
NRG-GU015	The Phase III Adaptive Radiation and Chemotherapy for Muscle Invasive Bladder Cancer Trial (ARCHER)
NRG-GY036	A Phase III Trial of One vs. Two Years of Maintenance Olaparib, with or Without Bevacizumab, in Patients with BRCA1/2 Mutated or Homologous Recombination Deficient (HRD+) Ovarian Cancer Following Response to First Line Platinum Based Chemotherapy
S2312*	A Phase III Study of Cabazitaxel with or Without Carboplatin in Patients with Metastatic Castrate-Resistant Prostate Cancer (mCRPC), Stratified by Aggressive Variant Signature ***Appendix 18.3: Guidance for Decentralized Clinical Trial Activities and Streamlining Data Collection***

Streamlined Clinical Trial Identified on Protocol Face Sheet

NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG Oncology
Four Penn Center
1600 JFK BLVD Suite 1020
Philadelphia, PA 19103
Nrgoncology.org

NRG-GI011: A PHASE III RANDOMIZED TRIAL OF DOSE ESCALATED RADIATION IN LOCALLY ADVANCED PANCREAS CANCER (LAPC) PATIENTS (LAP100)

ClinicalTrials.gov Identifier NCT06958328

This trial utilizes the NCI Streamlined Clinical Trial Data Submission Standards

Next Steps Streamlining Data Collection & Acknowledgements

- **Other areas for further Expansion:**
  - Explore standards for non-treatment studies (e.g., NCORP trials)
  - Explore practices for data submitted to document administration of pharmacologic therapies
  - Explore potential options for IND trials (CTAC WG)

- **Streamlining Trials Implementation Committee**
  - **ALLIANCE:** Sumithra Mandrekar, Olwen Hahn, Colleen Watt, John Taylor, Shauna Hillman, Kristina Laumann
  - **CCTG:** Jessica Sleeth, Dora Nomikos, Roger Leung
  - **COG:** Thalia Beeles, Mary Beth Sullivan, Todd Alonzo, Lindsay Renfro
  - **ECOG-ACRIN:** Erica Casella, Sarah Zinn, Yu-Hui Chen, Kerry Higgins
  - **NRG:** Carol Aghajanian, Sara McCartney, Elaina Harper, Mei Polley
  - **SWOG:** Primo Lara, Dana Sparks, Cathy Rankin, Melissa Plets
  - **IROC:** Michael Knopp, Stephen Kry
  - **NCI WG:** Andrea Denicoff, Shanda Finnigan, Mike Montello, Bhanu Ramineni, Gary Smith, Jennifer Ptak, Sheila Prindiville, Iris Castro, Sharon Williams, Judith Hautala, Oren Grad, Tawny Clark

Streamlining Standard of Care (SOC) Risk Lists

Streamlining Standard of Care (SOC) Risk Lists

- In protocol documents, we will no longer include the Comprehensive Adverse Events and Potential Risk Lists (CAEPR) for SOC agents or regimens being used per FDA label in IND studies simply because the agent still remains in the CTEP IND portfolio for investigational use.
  - **Will reduce the burden of amending protocols due to CAEPR updates and ICD revisions via CTEP Rapid Requests for Amendments (RRA) process**
- In consent documents, we will no longer use the long CAEPR lists, instead, CTEP is developing abbreviated SOC risk lists to maintain consistency across all CTEP-supported trials and NCI CIRB – coming soon!
  - **Will reduce lengthy consent forms**

Example of Consent Risk List Based on CAEPR

Possible Side Effects of Nivolumab (Table Version Date: April 22, 2025)

Common side effects (some may be serious) In 100 people receiving Nivolumab, more than 20 and up to 100 may have:
• Cough, shortness of breath
• Anemia which may cause tiredness, or may require blood transfusions
• Infection, possibly in the blood, especially when white blood cell count is low
• Diarrhea, nausea, vomiting, constipation, belly pain, loss of appetite
• Headache
• Back pain, pain in muscles or joints
• Cold symptoms such as stuffy nose, sneezing, sore throat
• Fever
• Tiredness
• Rash, itching, blistering, peeling of skin

Occasional side effects (some may be serious) In 100 people receiving Nivolumab, from 4 to 20 may have:
• Reaction during or following infusion of the drug which may cause fever, chills, rash, low blood pressure
• High blood pressure which may cause headaches, dizziness, blurred vision
• Abnormal heartbeat which may cause fainting
• Lung problems including fluid around the lung leading to shortness of breath, cough, chest pain
• Swelling of the body, arms, legs
• Damage to the liver which may cause yellow eyes and skin, tiredness

Occasional side effects (some may be serious) In 100 people receiving Nivolumab, from 4 to 20 may have:
• Kidney damage which may cause swelling, may require dialysis
• A tear, hole, or blockage in the throat or bowels which may cause pain, vomiting, or may require surgery
• Heartburn
• Sores on lips and in mouth, difficulty swallowing
• Swelling and redness of the eye, visual loss
• Dry eyes, dry mouth
• Muscle weakness, cramps, or stiffness
• Burning, numbness, tingling, or painful sensations
• Dizziness, difficulty sleeping
• Weight loss or weight gain
• Red, dry skin and hair, loss of skin color

Rare side effects that are serious In 100 people receiving Nivolumab, 3 or fewer may have:
• Makes the immune system too active so it attacks the cells or organs of the body, which may cause fever, rash, yellow eyes and skin, shortness of breath, headache, weakness, swollen lymph nodes
• Heart attack
• Heart failure which may cause shortness of breath, swelling of ankles, and tiredness
• Blood clot in lung which may cause swelling, pain, shortness of breath
• Internal bleeding which may cause belly pain, black tarry stool, blood in vomit
• Swelling of the brain which may cause headache, blurred vision, stiff neck, and/or confusion

Continues on an additional page

Example of Streamlined SOC Risk List based on FDA Label

Usual Treatment Risks

The usual treatment for your cancer has side effects. This study consent form does not talk about all the risk of your usual treatment. Some of the more frequent side effects of Nivolumab are:

- Makes the immune system too active so it attacks the cells or organs of the body, which may cause fever, rash, yellow eyes and skin, shortness of breath, headache, weakness, swollen lymph nodes
- Cough, shortness of breath
- Diarrhea, nausea, vomiting, constipation, belly pain, loss of appetite
- Headache
- Back pain, pain in muscles or joints
- Tiredness

Other side effects are less likely but may be serious. Your doctor and your care team will talk to you in more detail about all the side effects, how common and serious they are, and how to manage them.

Update on Informed Consent Template Revision

NCI Informed Consent Document (ICD) Template V3

- NCI boilerplate consent language developed in the 1990s
- **V1:** NCI ICD template released 2/15/2013
- **V2:** Major revisions to meet new Final Rule requirements launched released 10/10/2017
  - **V2.1** Minor revisions to data and specimen sharing and banking released 11/27/2018
- **V3:** Major revisions to streamline and modernize content
  - Distributed for final feedback September-October 2025
  - Expected to be released Q4 2025

Major Changes Proposed in NCI ICD Template V3

- **Template Structure**
  - Removing example text from the main Template document and creating a separate Examples document. This improves the **navigability** of the Template document, significantly **shortens** the Template document, and will allow us to **update** the Examples document more frequently.
  - Removing special formatting for template author instructions and insertions to improve usability.
- **ICD Structure and Content**
  - Streamlining, reducing duplication, and focusing more on the information potential participants need to know.
  - Reorganizing and renaming certain sections to improve the flow.
  - Creating a new section to describe additional mandatory and optional research being done as part of the study.
  - Instructions on use of streamlined risk lists for Commercial/SOC agents.

Updated CTEP Website: New Link for NCTN Trial Listing by Cancer Type

NCTN Trials by Cancer Type

View PDFs showing the latest portfolio of CTEP-supported cancer clinical trials open to enrollment in the NCTN (updated monthly).

Download a single PDF with all NCTN trials by disease.

Adult Trials

- Brain Cancer Trials
- Breast Cancer Trials
- Endocrine/Neuroendocrine Cancer Trials
- Gastrointestinal (GI) Cancer Trials
- Genitourinary (GU) Cancer Trials
- Gynecologic Cancer Trials
- Head and Neck Cancer Trials
- Leukemia Trials
- Lymphoma Trials
- Myeloma Trials
- Sarcoma Trials
- Skin Cancer Trials
- Thoracic Cancer Trials

Pediatric and AYA Trials

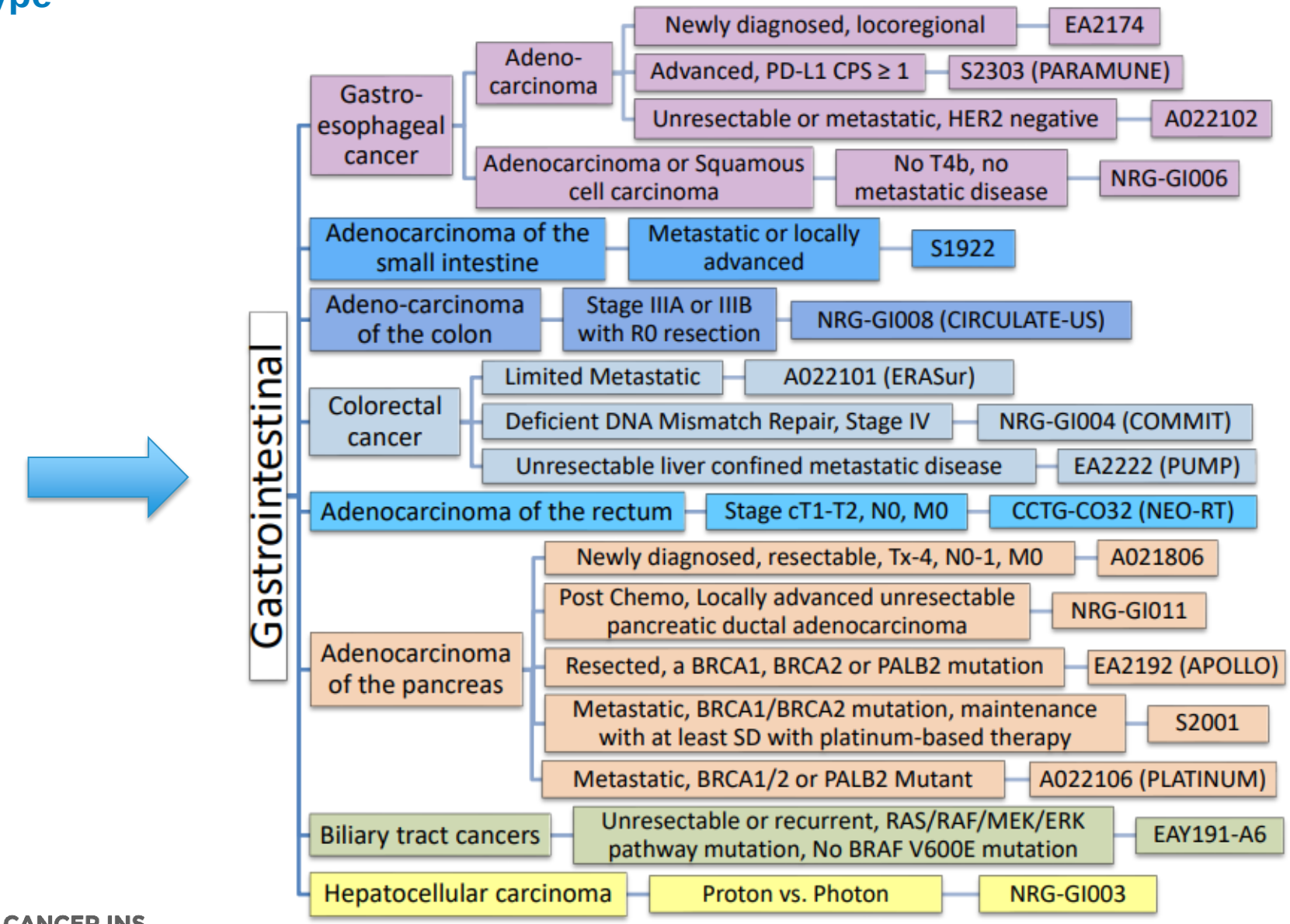
- Pediatric Brain Cancer Trials
- Pediatric Hematologic Trials
- Pediatric Solid Tumor Trials
- Adolescent and Young Adult (AYA) Trials

https://dctd.cancer.gov/research/networks/nctn#nctn-trials-by-cancer-type

Example of NCTN Cancer Type Portfolio

NCTN Gastrointestinal Cancer Trials Portfolio (Open as of 8/15/2025)

Each far right box includes the NCTN protocol number with a hyperlink to the associated ClinicalTrials.gov webpage. Click on it to view the protocol title and study information.



Thank you!

NCTNProgram@mail.nih.gov

SWOG | CANCER RESEARCH NETWORK

Pharmaceutical Management Branch (PMB)

Presented by:
Matt Boron, RPh
PMB / CTEP / NCI

Agenda

2025 updates to audit guidelines

- introduction of AURORA
- definition of NCI DARF
- Participant return clarification
- clarification on non-compliance issues

AURORA eDARF

- release to all NCI sites
- integration
- mandatory?

Types of DARFs

- **Site may choose which DARF type to use:**
  - **NCI DARF**: Paper or non-NCI eDARF that prints to match NCI DARF
  - **NCI Oral DARF**: Paper or non-NCI eDARF that prints to match NCI Oral DARF
  - **eDARF**: AURORA accountability log

CTEP IND study - NCI supplied study agent	NCI DARF - *Required* (see above)
CTEP IND study – Study agent not directly supplied by NCI repository (including radiopharmaceuticals)	
Study utilizing non-CTEP IND agent and study agent not supplied by NCI	*NCI paper DARF (AURORA eDARF not available)
Study utilizing non-CTEP IND agent and study agent is supplied by NCI	

* The NCI DARF is not required to be the form used for drug accountability. Refer to protocol for specific drug accountability instructions.

Revisions by Category under Pharmacy Component

- NCI DARFs Completely and Correctly Filled Out ✓
- DARFs are Protocol and Study Agent Specific
- Satellite Records of Dispensing Area
- Agent Inventory and Accountability Documentation ✓
- Return of Study Agent [NCI-sponsored studies] ✓
- Study Agent Storage
- Adequate Security
- Authorized Prescription(s)

Dispensed study agent

Old Wording in Guidelines

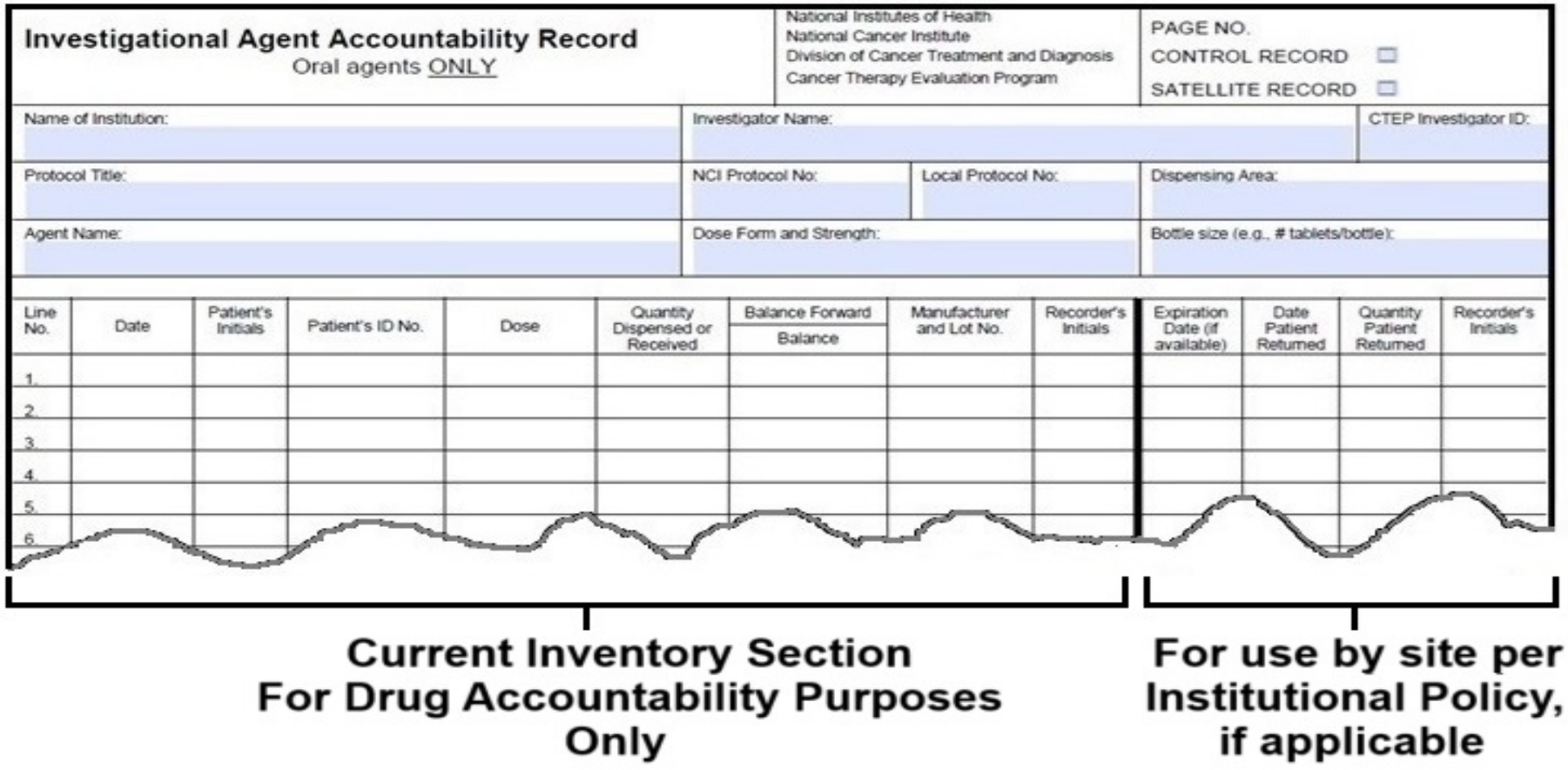
Non-Compliance - NCI DARFs Completely and Correctly Filled Out

- Patient/study participant returns of oral study supplied agents not documented on the Oral DARF
- Patient/study participant returns of non-oral, non-patient-specific agent supplies are documented on the DARF
- Patient/study participant returns of non-oral, patient-specific agent supplies are not documented on the DARF

Revised wording

Non-Compliance - NCI DARFs Completely and Correctly Filled Out

- Study participant return of **oral** agents are documented as part of 'current inventory' section on DARF
- Study participant returns of **non-oral** study agent are documented on the DARF



Investigational Agent Accountability Record
Oral agents ONLY

National Institutes of Health
National Cancer Institute
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:	CTEP Investigator ID:
Protocol Title:	NCI Protocol No: / Local Protocol No:	Dispensing Area:
Agent Name:	Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.												
2.												
3.												
4.												
5.												
6.												

Current Inventory Section For Drug Accountability Purposes Only

For use by site per Institutional Policy, if applicable

DARF is an inventory accountability log, not a participant compliance document.

Undispensed Study Agent

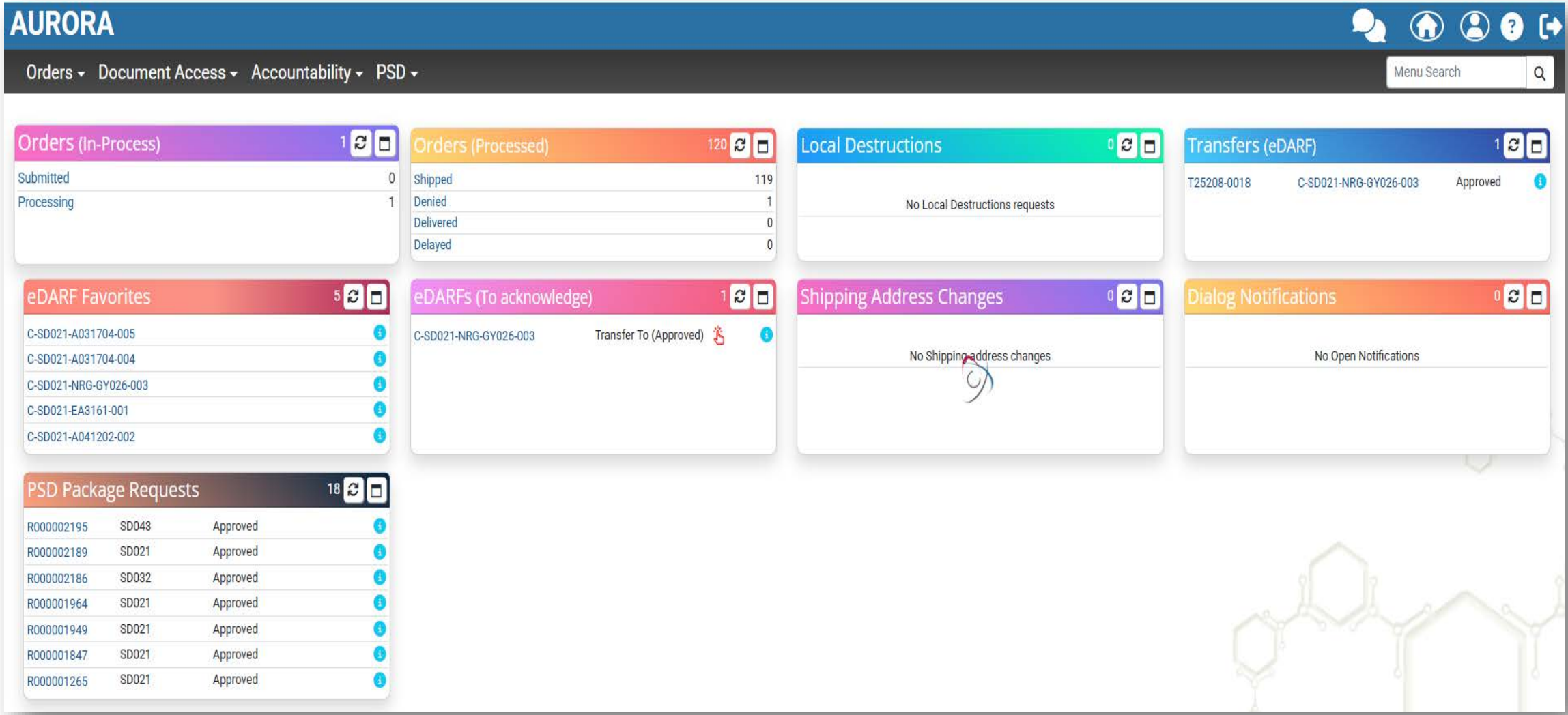
[includes *return / transfer of study agent from Satellite to Control pharmacy]*

Non-compliance - Return of Study Agent [NCI-sponsored studies]

- Study agent is transferred to investigator or protocol without NCI written approval
- Study agent returned to PMB that should have been destroyed on-site or study agent returned to PMB that was not supplied by PMB
- Return Form or documentation of local destruction not maintained
- Unused/un-dispensed NCI-supplied study agents not returned, transferred or locally destroyed within 90 calendar days when requested by the NCI, or when patients/study participants are in follow-up, study is closed to enrollment and no NCI-supplied study agent is being administered

Non-compliance - Return of Study Agent [NCI-sponsored studies]

- Study agent is transferred to another site, investigator or protocol without NCI written approval
- Undispensed study-provided agent returned to NCI when supplied by another source
- Return Form or documentation of local destruction for undispensed inventory is not maintained
- Undispensed NCI-supplied study agent not returned, transferred or locally destroyed within 90 calendar days when requested by the NCI
- Undispensed NCI-supplied study agent remains on inventory greater than 90 days after all study participants are in follow-up, or study is closed to enrollment and no NCI-supplied study agent is being administered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Orders
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Accountability
PSD
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Orders (In-Process) 1
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Processing 1
Orders (Processed) 120
Shipped 119
Denied 1
Delivered 0
Delayed 0
Local Destructions 0
No Local Destructions requests
Transfers (eDARF) 1
T25208-0018 C-SD021-NRG-GY026-003 Approved
eDARF Favorites 5
C-SD021-A031704-005
C-SD021-A031704-004
C-SD021-NRG-GY026-003
C-SD021-EA3161-001
C-SD021-A041202-002
eDARFs (To acknowledge) 1
C-SD021-NRG-GY026-003 Transfer To (Approved)
Shipping Address Changes 0
No Shipping address changes
Dialog Notifications 0
No Open Notifications
PSD Package Requests 18
R000002195 SD043 Approved
R000002189 SD021 Approved
R000002186 SD032 Approved
R000001964 SD021 Approved
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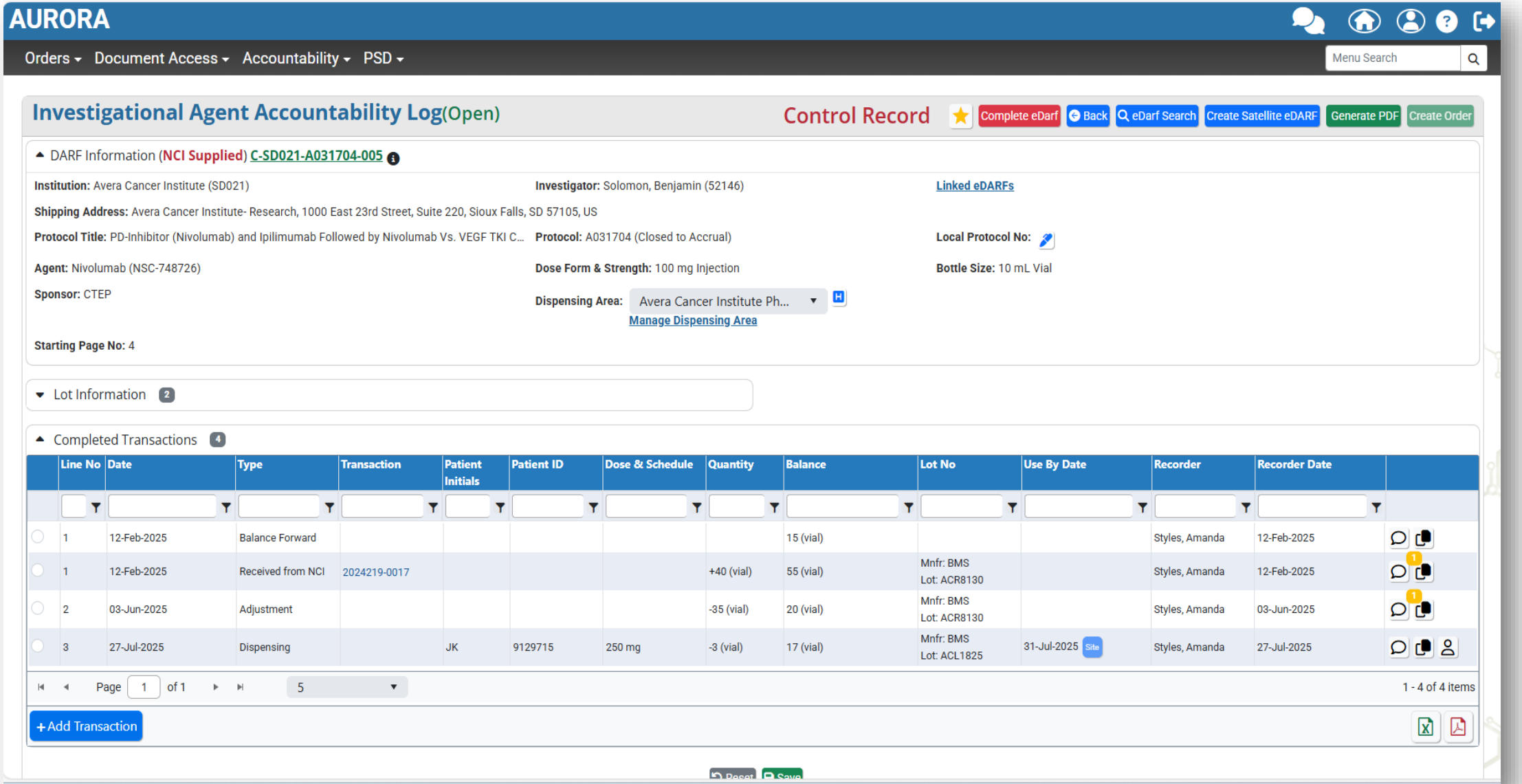
R000001265 SD021 Approved


AURORA
Orders
Document Access
Accountability
PSD
Menu Search
Investigational Agent Accountability Log(Open)
Control Record
Complete eDarf
Back
eDarf Search
Create Satellite eDARF
Generate PDF
Create Order
DARF Information (NCI Supplied) C-SD021-A031704-005
Institution: Avera Cancer Institute (SD021)
Investigator: Solomon, Benjamin (52146)
Linked eDARFs
Shipping Address: Avera Cancer Institute- Research, 1000 East 23rd Street, Suite 220, Sioux Falls, SD 57105, US
Protocol Title: PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab Vs. VEGF TKI C...
Protocol: A031704 (Closed to Accrual)
Local Protocol No:
Agent: Nivolumab (NSC-748726)
Dose Form & Strength: 100 mg Injection
Bottle Size: 10 mL Vial
Sponsor: CTEP
Dispensing Area: Avera Cancer Institute Ph...
Manage Dispensing Area
Starting Page No: 4
Lot Information 2
Completed Transactions 4
Line No
Date
Type
Transaction
Patient Initials
Patient ID
Dose & Schedule
Quantity
Balance
Lot No
Use By Date
Recorder
Recorder Date
1 12-Feb-2025 Balance Forward 15 (vial) Styles, Amanda 12-Feb-2025
1 12-Feb-2025 Received from NCI 2024219-0017 +40 (vial) 55 (vial) Mnfr: BMS Lot: ACR8130 Styles, Amanda 12-Feb-2025
2 03-Jun-2025 Adjustment -35 (vial) 20 (vial) Mnfr: BMS Lot: ACR8130 Styles, Amanda 03-Jun-2025
3 27-Jul-2025 Dispensing JK 9129715 250 mg -3 (vial) 17 (vial) Mnfr: BMS Lot: ACL1825 31-Jul-2025 Site Styles, Amanda 27-Jul-2025
Page 1 of 1
5
1 - 4 of 4 items
+Add Transaction
Reset
Save

Investigational Agent Accountability Record

National Institutes of Health
National Cancer Institute
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

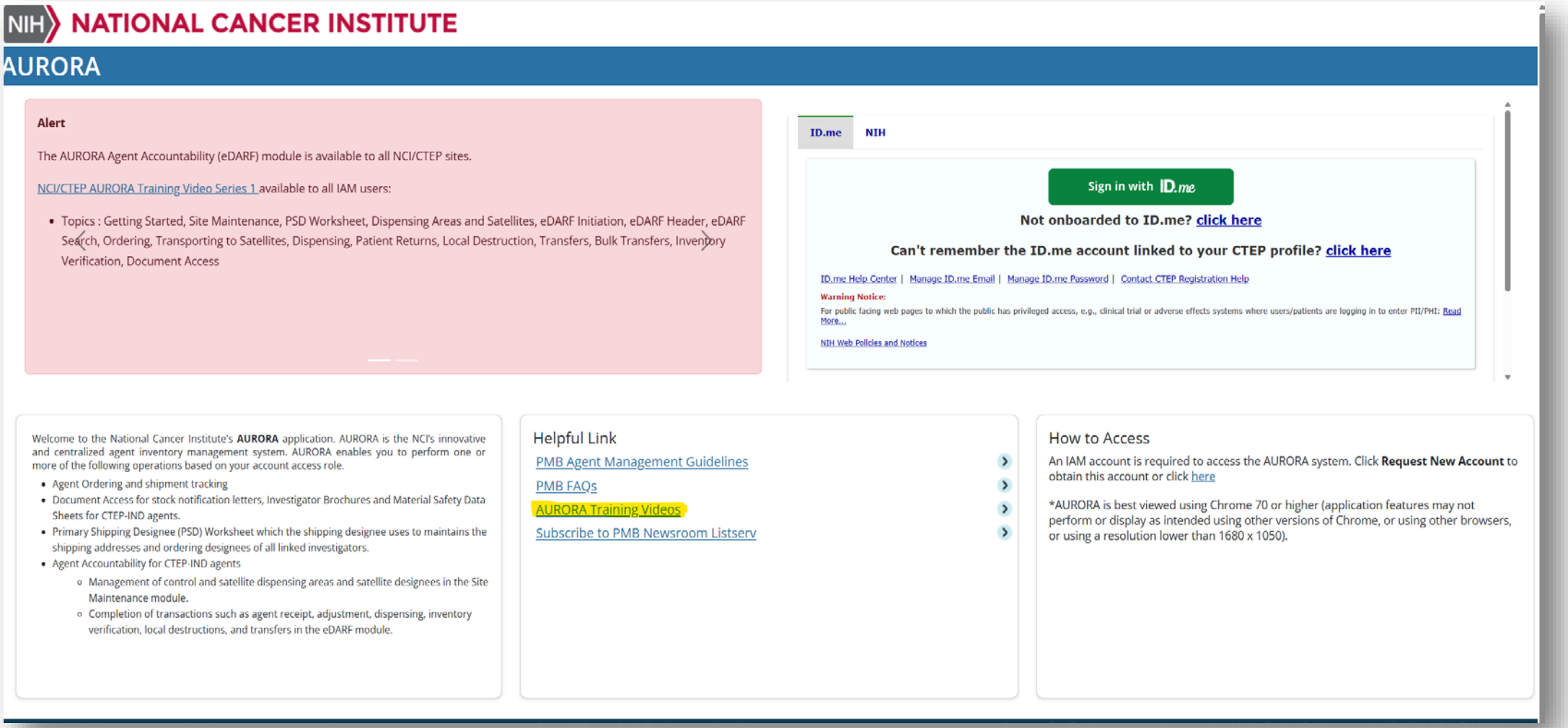
CONTROL C-SD021-A031704-005

Name of Institution:	Avera Cancer Institute (SD021)	**Investigator Name:**	Dr. Benjamin M. Solomon (52146)
Shipping Address:	Avera Cancer Institute- Research, 1000 East 23rd Street, Suite 220, Sioux Falls, SD 57105, US	**Protocol Title:**	PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab Vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated REnal Cell CancEr [PDIGREE]

NCI Protocol No:	A031704	**Sponsor:**	CTEP	**Local Protocol No:**	
Dispensing Area:	Avera Cancer Institute Pharmacy				
Agent:	Nivolumab (NSC-748726)	**Dose Form ; Strength:**	100 mg Injection	**Bottle Size (e.g. # tablet/bottle)**	10 mL Vial

Line No.	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Manufacturer/ Lot No	Use By Date	Recorder	Recorded Date
2	03-Jun-2025	Adjustment					-35 (vial)	20 (vial)	ACR8130 (BMS)		Styles, Amanda	03-Jun-2025
	Comments:	discrepancy on audit									Styles, Amanda	03-Jun-2025
3	27-Jul-2025	Dispensing		JK	9129715	250 mg	-3 (vial)	17 (vial)	ACL1825 (BMS)	31-JUL-2025 (STYLESA)	Styles, Amanda	27-Jul-2025

Generated By: *Amanda Styles, PharmD, BS* *Date:* *Aug 25, 2025 06:33:53 am* *File Name:* *C-SD021-A031704-005-STYLESA-08252025-06-33.pdf*



https://ctepcore.nci.nih.gov/aurora/login

References:

- Reengineered website -- https://dctd.cancer.gov/programs/ctep
- PMB Agent Management -- https://dctd.cancer.gov/research/ctep-trials/for-sites/agent-management
- AURORA Best Practices -- https://dctd.cancer.gov/research/ctep-trials/for-sites/agent-management/aurora-best-practices.pdf
- AURORA CLASS training -- https://www.ctsu.org/Public/class.aspx?courseid=778fd651-c326-4591-b8ab-7c02c2c57054
- PMB email – PMBAfterHours@mail.nih.gov

Questions?

SWOG | CANCER RESEARCH NETWORK

NCORP Updates

Presented by:

Brandy Heckman-Stoddard, PhD, MPH

Division of Cancer Prevention Chief, Breast and Gynecologic Cancer Research Group

Acting Chief, Community Oncology and Prevention Trials Research Group

Acting Director, NCI Community Oncology Research Program (NCORP)

NCI Community Oncology Research Program

A program of the National Cancer Institute of the National Institutes of Health

NCI NCORP Update

Brandy Heckman-Stoddard, PhD, MPH
Director, NCORP

NIH NATIONAL CANCER INSTITUTE

SWOG Operations Committee
September 18, 2025

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Program Official

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NRG, Alliance, CCDRSC liaison

Ashley Buscetta, MSN, FNP-BC
CCDR Project Scientist
COG

Michelle Doose, PhD, MPH
CCDR Project Scientist
Wake Forest, CCDRSC liaison

Monica Epstein, BSN, RN, OCN
COG, URCC

Beverly Lee, MS
Project Scientist

Cecilia Lee, DrPH, RN
ECOG-ACRIN, Treatment QOL
SxQoLSC liaison

Bernard Parker, MD, FACP
SWOG, Alliance Control

Wendy Rubinstein, MD, PhD
Alliance Prevention
CPSC liaison

Brennan Streck, RN, PhD, MPH
Wake Forest, Treatment QOL

Alyssa Voss, MPH
Project Scientist

Changes to NCI NCORP Site Support

- Each NCORP Site will have a single NCORP Project Scientist
  - Work with your Site on all areas of science (prevention, control & CCDR)
  - Increase continuity and engagement with Site staff

- The Project Scientist will meet with you regularly and be responsible for approving changes in NCORP-SYS

- Each NCORP Site has a Program Officer who is responsible for administrative oversight of the award and work with OGA

NCORP Recompetition

- Forecasts have been published
  - NOT-CA-25-042 - Notice of Funding Opportunity (NOFO) for NCI Community Oncology Research Program (NCORP) Research Bases (UG1 Clinical Trial Required)
  - NOT-CA-25-043 - Notice of Funding Opportunity (NOFO) for NCI Community Oncology Research Program (NCORP) Community Sites (UG1 Clinical Trial Not Allowed)
  - NOT-CA-25-044 - Notice of Funding Opportunity (NOFO) for NCI Community Oncology Research Program (NCORP) Academic Community Sites (UG1 Clinical Trials Not Allowed)
- RFAs are still working their way through the approval process
- **Estimated Post Date:** Aug 29, 2025

  Estimated Application Due Date: Nov 14, 2025

  Estimated Award Date: Aug 01, 2026

Protocols Closed to Accrual

- A191901, Optimizing Endocrine Therapy Through Motivational Interviewing and Text Interventions, closed 8/31/25
- WF-1805CD, Implementation and Effectiveness Trial of HN-STAR, Step 1: Enrollment closed as of 2/13/2025. Fully Closed 6/26/25

NCORP Trials Pending Activation

Trial Number	Title	Status	Sample Size
A212101	Evaluation of Provider vs. Patient Mediated Cascade Genetic Testing of First-Degree Relatives of Patients With Newly Diagnosed Colorectal Cancer	Pending	182
A221801	The Revitalized Trial: Reducing Vaginal Atrophy with Fractional CO2 Laser for Breast Cancer	Pending	250
A222302	Distance-Based Exercise to Preserve Function and Prevent Disability (DEFEND)	Pending	80 Limited Site Enrollment
A232301CD	AYA Access Study: An Enhanced eHealth and Chat-Bot Enabled Delivery Model for Clinical Genetic Services in Community AYA Cancer Patients	Pending	465
EA6232	Phase II Double-Blind Trial of Sulforaphane for Therapeutic Prevention of Melanoma in Patients with Multiple Atypical Nevi and a Prior History of Melanoma	Pending	378

NCORP Trials Recently Activated

Trial Number	Title	Activation Date	Sample Size
A222301	High-Dose Prophylactic Gabapentin (HOPE) to Prevent Opioid Use for Oral Mucositis Pain During Head and Neck Chemoradiotherapy: A Phase III Clinical Trial	6/4/2025	1/228
NRG-CC013	A Randomized, Masked, Placebo Controlled, Phase II Trial Of Concurrent Chemoradiation With BMX-001 In Patients With Head And Neck Squamous Cell Carcinoma Receiving Concurrent Chemoradiation	6/2/2025	7/98
NRG-CC015	Harnessing E-Mindfulness Approaches for Living After Breast Cancer HEAL-ABC: Harnessing E-Mindfulness Approaches for Living-After Breast Cancer	6/15/25	0/402
WF-2403	Building Capacity within the NCORP Network through an Education and Mentorship Intervention for Advanced Practice Providers (COACH-APP)	4/21/2025	Mentors: 7/7 APPs: 0/97
S2417CD	A Pragmatic Randomized Controlled Trial To Evaluate The Effectiveness of an Intervention called Current Together After Cancer (CTAC) to Promote Guideline-Concordant Colorectal Cancer Surveillance	8/4/25	Pt- 654 Non-pt- 393

Recently Activated NCTN Studies

June 29, 2025 to August 24, 2025 - Sorted by Phase & Study

Study #	Phase	Study Title	Activation Date	Planned Accrual
EAA241	2	A Randomized Phase II Trial Comparing Daratumumab-Bortezomib-Dexamethasone Versus Cyclophosphamide-Bortezomib-Dexamethasone in Newly Diagnosed Multiple Myeloma with Light Chain Cast Nephropathy (LCCN)	8/11/2025	74
EA2234	2/3	A Randomized Phase II/III Trial of Intraperitoneal Paclitaxel Plus Systemic Treatment vs Systemic Treatment Alone in Gastric Carcinomatosis - STOPGAP II	8/19/2025	78
A012303	3	ShortStop-HER2: Shortened Duration of Adjuvant Therapy in Patients with Early-Stage HER2+ Breast Cancer Who Achieve pCR After Neoadjuvant Chemotherapy with HER2 Blockade	7/25/2025	1,524
NRG-GU015	3	The Phase III Adaptive Radiation and Chemotherapy for Muscle Invasive Bladder Cancer Trial (ARCHER)	8/14/2025	486

Non-Investigational New Drug/Non-Treatment (NINT) Registration Type

NCI Registration and Credential Repository (RCR) utilizes 6 person registration types

- Investigator (IVR) — MD, DO, or international equivalent;
- Non-Physician Investigator (NPIVR) — advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD);
- Non-Investigational New Drug (IND)/Non-Treatment (NINT) - (e.g., MD, DO, NP, PA, PharmD, PhD, EdD) investigators who wish to exclusively participate in non-IND/non-treatment studies flagged for NINT participation;
- Associate Plus (AP) — clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications such as the Roster Update Management System [RUMS], OPEN, Rave, acting as a primary site contact, or with consenting privileges;
- Associate (A) — other clinical site staff involved in the conduct of NCI-sponsored trials; and
- Associate Basic (AB) — individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems.

Rationale for NINT Registration Type

- Simplify the registration process for individuals who wish to exclusively participate in non-IND/non-treatment studies in an investigator role
- Encourage participation in screening, surveillance, and Cancer Care Delivery Research (CCDR) studies
- Ensure regulatory requirements are met by vetting participating staff and not using workarounds (e.g., enrolling under NCORP PI)

Registration Types – Documentation Requirements

Documentation Required	IVR	NPIVR	NINT	AP	A	AB
CTEP-IAM Account with ID.me credentials	✓	✓	✓	✓	✓	✓
FDA Form 1572 • Practice sites, IRBs, and labs	✓	✓				
Financial Disclosure Form	✓	✓		✓		
NCI Biosketch (education, training, employment, certification, licensure, ABMS certification, GCP Training, personal statement, memberships, honors, publications, research support)	✓	✓		✓		
NINT Investigator Acceptance Form • Practice sites, IRBs, and labs • NINT Biosketch (education, licensure, ABMS certification, GCP Training)			✓			
GCP Training Certificated (mandatory file upload)	✓	✓	✓	✓		
Agent Shipment Form (if applicable)	✓					
CV (optional file upload)	✓	✓		✓		
Annual Re-registration	✓	✓	✓	✓	✓	✓

Checking in a Year Later

- To date - no NINT's have been rostered to an NCORP site
- Have you attempted to register an NINT?
- What are the barriers to registering NINT's at your NCORP's?

PAR-24-274: NCI Research Specialist (Clinician Scientist) Award (R50 Clinical Trial Not Allowed)

The Research Specialist Award is designed to encourage the development of stable research career opportunities for exceptional clinician scientists who want to continue to participate in the NCI clinical trials networks through leadership in the:

1) development of national clinical trials

2) implementation of NCI clinical trials in their institutions

3) national service to the NCI clinical trials networks through participation in the scientific review committees, monitoring committees and other activities

Budget:

1. salary support for the Research Specialist commensurate with their level of effort on NCI funded clinical trials with a minimum of 2.4 and a maximum of 4.8 person-months funded by this award;
2. travel costs to attend research meetings/conferences: not to exceed $2,500 per year; and
3. $2,000 per year for travel costs for the Principal Investigator to attend an annual meeting for Research Specialist (Clinician Scientist) Award recipients

- **Application due dates:** November 4, 2025
- **Pre-Application Webinar:** Access the pre-application webinar recording.

2025 NCORP Annual Meeting


Thank you!
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www.cancer.gov/espanol

SWOG | CANCER RESEARCH NETWORK

Closing Remarks

Presented by:

Nikki Stover, MPP

SWOG | CANCER RESEARCH NETWORK

Hot Off the Press Announcements

Photo credit: https://son-of-encouragement.blogspot.com/2012/01/extra-extra-extra-dave-macpherson.html

Special Thanks

- Each of our speakers
- Courtney Wille
- Hyatt staff

Photo credit: https://cdn.wallpapersafari.com/93/2/yn19CR.jpg

Reminder

Spring 2026 SWOG Group Meeting

April 30 – May 2, 2026
Hyatt Regency San Francisco
San Francisco, California

Doing the work that matters