



SWOG

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Oncology Research Professionals (ORP) Site Operations Spring Meeting 2025

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



Photo credit: https://media.wnyc.org/i/800/0/c/85/1/shutterstock_344201303.jpg



Announcement and Updates Oncology Research Professionals (ORP) Committee

**Presented by:
Connie Szczepanek, RN, BSN, CCRP & Caitlin Hutchinson, MS**



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.

Spring Site Operations

May 1st, 12:30p - 2:00p PST

Open, Welcome, and Announcements		Connie Szczepanek & Caitlin Hutchinson
General Updates		
Special Guest Speaker		Charles Blanke
Special Guest Speaker		Brandy Heckman-Stoddard
SWOG Updates		
SWOG Network Operations Center	Protocols & Membership	Dana Sparks
	Administration & Study Funding	Pat Mize & Casey Dawson
	Quality Assurance (QA)	Laura Gonzales
Statistics & Data Management Center (SDMC)		Rodney Sutter
Closing Remarks		Caitlin Hutchinson & Nikki Stover

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, May 1st, 2025 | 12:30 PM – 2:00 PM PT

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Picture Credit: <https://cdn.fodors.com/wp-content/uploads/2018/11/HERO-Alamo-Square-Hero.jpg>



YOU are The ORP Committee!



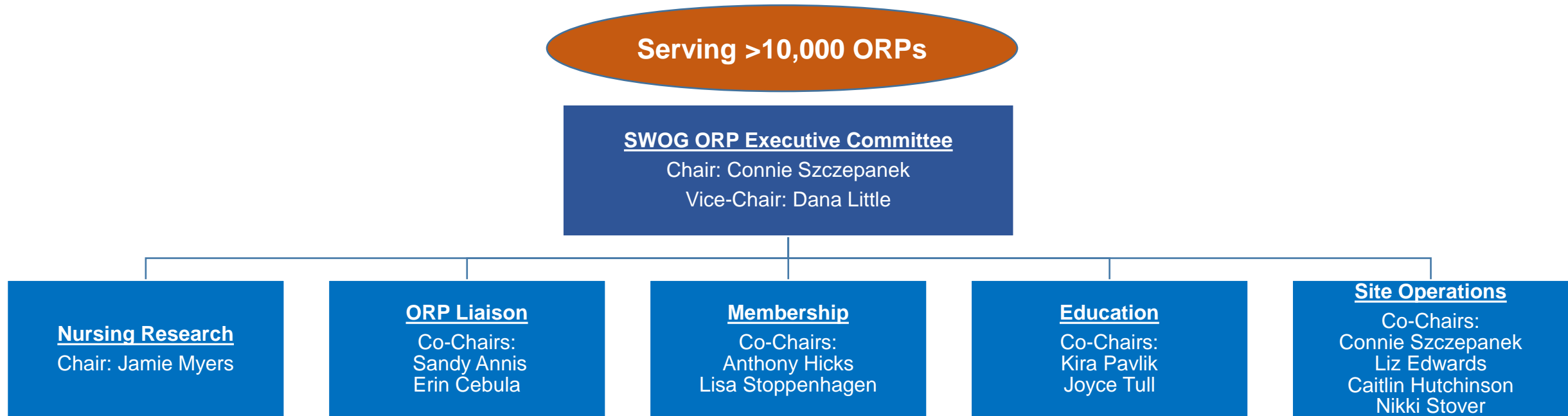
“SWOG holds a fundamental conviction that the Oncology Research Professionals (ORP) play a crucial role in the successful development, implementation, and analysis of any SWOG clinical trial.”



ORP Executive Committee Members

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

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



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Special Guest Speaker

Charles Blanke, MD

SWOG Group Chair





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Special Guest Speaker

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)





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SWOG Operations Center Protocols & Membership

Presented by:
Dana Sparks, MAT
Director of Operations & Protocols



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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



2025

2026

Funding Opportunity
Announcement

October 10, 2024

4.5 months

Proposal Submitted

End of February 2025

New Grant Cycle Begins

March 1, 2026

Grant Moves to
UC Davis

March 1, 2026

NCTN

Funding Opportunity
Announcement

Mid-2025

90+ Days

Proposal Due

Mid to Late 2025

New Grant Cycle Begins

Jun - Aug 2026

Grant Moves to
The Hope Foundation

Jun - Aug 2026

NCORP

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
- SWOG NCORP grant **expected to be extended** to between Jun – Aug 2026

Please send any questions to FedGrants@swog.org

Funding Team at ORP Open Forum



Friday, May 2nd at 11:00am – 12:30pm
Pacific L-O, Pacific Concourse Level
In Person Only

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

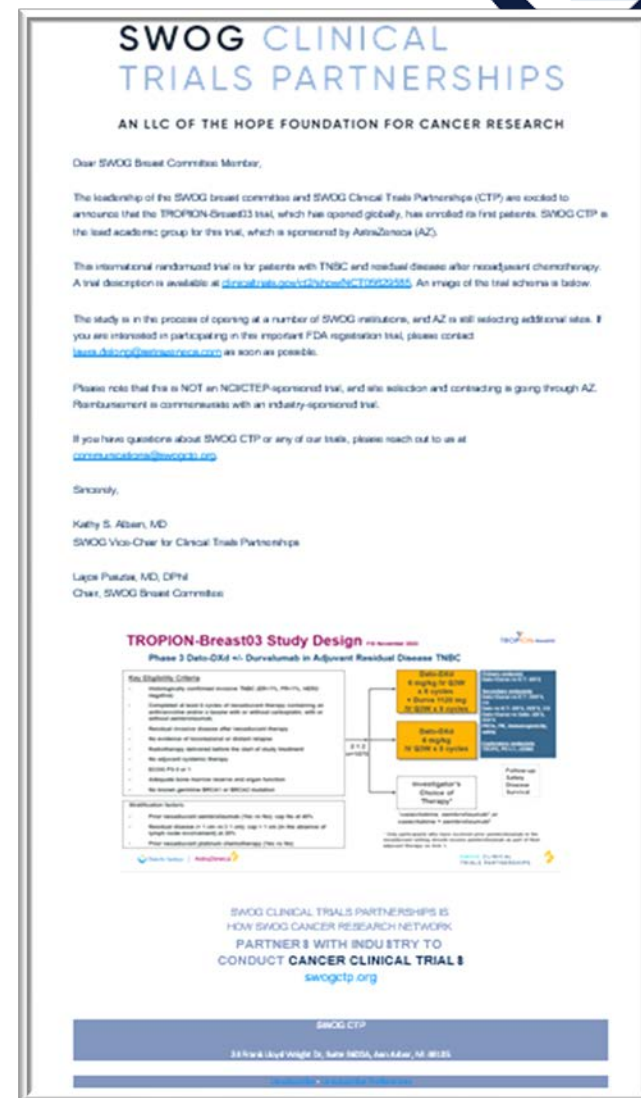


SWOG Clinical Trials Partnerships (CTP)

May 2025 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



21CTP.LEUK01 – ONGOING SITE SELECTION



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

ACTIVELY SELECTING SITES!

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

Upcoming SWOG CTP trial in leukemia

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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

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!



Friday, May 2 at 11-12:30pm

Pacific L-O (Pacific Concourse Level)

In Person Only



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Quality Assurance Updates

Presenter: Laura Gonzales, BSN, MA RN, OCN

Quality Assurance Manager

SWOG Operations Office

San Antonio, TX

When reporting SAEs in CTEP-AERS, please add the date of discovery into CTEP-AERS Section 3: Describe Event.



[My Submissions](#) [Report Adverse Events](#) [Manage Reports](#)

✓ 1. Reporter

 >

✓ 2. Adverse Events

 >

✓ 3. Describe Event

 >

✓ 4. Course/Cycle

 >

✓ 5. Study Interventions

 >

✓ 6. Subject Details

 > 7. Other Causes > 8. Labs >

✓ 9. Attribution

 >

10. Review & Submit

Describe Event

Instructions This is one of the most critical sections of the report. Provide detailed information within the Description & treatment of event(s) field, including the presentation of the event, the treatment of the event, clinical findings, and the timing of the event in relation to study interventions. Be as complete as possible. **DO NOT INCLUDE Personally identifiable information (PII).** PII includes information that directly identifies an individual (e.g., name, address, social security number, or other identifying number such as medical record number or hospital ID.)

* Description & treatment of event(s) Date of discovery was MM/DD/YYYY.

Without this date, SWOG may assume the SAE was reported late, and this can lead to major deficiencies during audits.

Questions: ADR@swog.org



Upcoming QA Live Webinar

Cytogenetics Discussion

Presented by

Kathleen Calzone, PhD, RN, AGN-BC, FAAN

Friday, June 20th, 2025

11:00am Central

Registration information will be upcoming
in SWOG Broadcast Emails, CTSU
Broadcast Emails, and SWOG's QA Live
Webinar Series webpage.



SWOG Quality Assurance Live Webinar Series



- **Serious Adverse Event Reporting Updates (March 21, 2025)**
- **Disease Assessment in solid Tumors (December 6, 2024)**
- **Workload Prioritization in Clinical Trials (September 6, 2024)**
- **Research Protocol Deviations vs. Deficiencies (June 11, 2024)**

Links to the webinar recordings, resource documents, and slide sets shared during each webinar are posted at the link below:

<https://www.swog.org/swog-quality-assurance-live-webinar-series>

Questions?



QAmail@swog.org

SDMC Updates



Rodney Sutter, CCRP
Program Director, Therapeutic Studies
SWOG Statistics and Data Management Center
Seattle, WA



SWOG Activations



PROSPECT-LUNG (CTIU2317-A082304-S2402): A randomized phase III study of adjuvant versus perioperative Chemoimmunotherapy for Patients with Resectable Stage IIA-IIIA NSCLC

Activated 12/11/2024

S2408: A Randomized Phase III Blinded Trial of lanreotide for the Prevention of Postoperative Pancreatic Fistula

Activated 02/14/2025

S2414: Incorporating pathologic reSponse in patients with early staGe lung cancer to optimize immunotHerapy in the adjuvanT setting (INSIGHT)

Activated 03/14/2025



SWOG Activations

MyeloMATCH MM10A-S03: A randomized phase 2 trial of C-DEC, venetoclax, and enasidenib compared with azacitidine and venetoclax for newly diagnosed older adults with IDH2 mutant AML: A myeloMATCH treatment trial

Activated 04/01/2025

S1800E: A Randomized phase II/III study of Docetaxel and Ramucirumab with or without Cemiplimab in patients with stage IV or recurrent NSCLC previously treated with chemotherapy and anti-PD-(L)1 therapy

Should activate 05/01/2025



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.*

Planned Activation: 05/15/2025

- A number of sites have already been selected to participate
- Study team is looking for an additional 30 participants
- All SWOG sites are invited to consider and apply
- Further information available at: swogctp.org/trials/21ctpleuk01
- If after reviewing your site is interested to apply, complete the feasibility questionnaire **no later than 05/16/2025**
- Questions? Reach out to protocols@swogctp.org



MyeloMATCH – Screening



- MyeloMATCH team working to reduce the number of screening registrations where there is not trials open for substudy enrollment → using slot reservations
- Memorandum sent on 03/14/2025:
 - *The purpose of this memorandum is to notify sites that as of March 17, 2025, slot reservation is required for participant registration to MYELOMATCH. This will be included in an upcoming protocol revision. Slot reservation is being implemented to align participant registrations with current resources. Up to 3 slots will be open each day at 11:00am Eastern time, with an initial total of 12 slots per week. The number of available slots at any given time can be seen in OPEN by navigating to the Slot Reservation → Report tab. Please note: Sites should not enroll participants unless a relevant substudy is open at the site. For example, if the site has no substudies from the younger AML basket open, then participants younger than age 60 should not be enrolled on MYELOMATCH.*
- Questions? Contact: myelo-match-support@nih.gov



Early Study Closure Requests

SWOG requires studies to remain open until the study has been published and added to SWOG's 'Studies with no Required F/U' report on the CRA Workbench:



CRA Workbench

Popular Resources

OPEN Patient Registration

Rave Data Submission

Specimen Tracking

SWOG QA / Audits / Monitoring

SWOG Best Practices

Tools

Resources

CRA Manual (for Oncology Research Professionals)

Patient Reports / Data Quality

Study Reports

Studies with no required follow-up

Studies in Long Term Follow-up

SAEs for a Study


Study-wide Unblinding

Accrual by Site

Home / Member Resources / CRA Workbench

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 Fall, 2024 Site Operations and Oishi Symposium presentations (among many others) have been uploaded to the SWOG website. If you were unable to attend or would like to revisit, they can be found here. [11/12/2024]


[Fall 2024 Group Meeting Recordings | SWOG](#)


Early Closure Requests for SWOG-Coordinated Trials


Please note when a SWOG trial closes to accrual or if you have met the follow-up requirements for patients enrolled to a trial, it does not necessarily mean you can submit a request to close the study early with the CIRB. SWOG requires studies to remain open until the study has been published and added to SWOG's 'Studies with no Required F/U' report on the CRA Workbench. If the study has been added to that report, there is no need to submit an official form to us requesting to close. Just provide that list to the CIRB along with your part of the form filled out and they should go ahead and approve. [11/12/2024]

Institutional Performance Review (IPR) – Query Metrics

For a while, SWOG has been providing information around a proposed plan to incorporate outstanding queries into monthly IPR metrics. The changes (outlined below) were approved by the Board of Governors at the Spring, 2024 Group Meeting were implemented over the summer. Please review your reports regularly on the CRA Workbench and make note if your site is out of compliance. [11/12/2024]

 SWOG | CANCER RESEARCH NETWORK

 National Clinical Trials Network
a National Cancer Institute program

 Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health



Early Study Closure Requests

- No Enrollments? Complete and submit the form ✓
 - *Be sure to verify this for all sites listed*
- Studies with FDA Registration Intent? These will not be approved unless they are listed on the No Required F/U report or had no enrollments
- Very few exceptions
- Questions? SWOGStudyClosureRequest@crab.org



Site Scores



- SWOG Policy #33 was updated and approved by the Board of Governors at the Spring, 2024 Group Meeting to include the introduction of a new Site Score
- The Site Score is a weighted measure of IPR metrics that serves as a tool for SWOG and site leadership to evaluate a site's overall performance compared to other sites
- DM institutions with more than 5 SWOG-credited accruals in the prior 13 months are scored
- These are calculated every 6 months in January and July
- Excellent ratings will be recognized at each Group Meeting

➤ *Starting in March, 2025 the Site Score now includes queries from IPR metrics*



IPR – Query Metrics

- Manual Queries Posted by:
 - SDMC
 - Biorepository
 - SWOG Auditors
- Responsiveness to Queries: Any query that is unresolved and is more than 30 days overdue is delinquent. A site is non-compliant if > 5% of the queries posted in the last 13 months are delinquent or any query > 13 months ago is still unresolved.
- When out of compliance 3+ months in a row, warning letter sent

➤ *Sites are doing well!*



SDMC Leadership Change



Phyllis Goodman, MS
Managing Statistician



Cathryn Rankin, MS
Coordinating Statistician



Kari Chansky, MS
Coordinating Statistician



CRA Workbench Resources



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

Internal Users Only

Home / Member Resources / CRA Workbench

CRA Workbench

Your resource headquarters for SWOG clinical trial patient management.



[Latest CRA Newsletter](#)

[Join the CRA Mailing list](#)

Announcements

Updates to Specimen Tracking

A couple of updates have been made to the Specimen Tracking interface. In Step 2 of Logging a Specimen, the "Filter" at the top has been updated so that now at least one key filter is required before a list of samples is displayed. We have moved the "Test" button to the banner and put a watermark on the [11/7/2022]

SWOG

Introductory information regarding the project being developed by the SWOGC using the nCartes platform can be viewed [here](#). See the May 27, 2022 [The Front Line](#) post for more information. [11/7/2022]

SWOG Biospecimen Bank Kit Management URL

The Kit Management URL has changed. Please make certain to update your bookmarks with the new URL: <https://kits.bpc-apps.ncchri.org/>. If you try to access the old URL, there is no redirect as the server supporting the old URL is end of life and users will receive an error message. [8/25/2021]



CRA Workbench Resources



- ◆ Best Practices for SWOG Studies
- ◆ CRA Newsletter Archive
- ◆ CTCAE
- ◆ Data Submission Guidance, Tips
- ◆ SWOG FAQ's
- ◆ SWOG Glossary
- ◆ SWOG ORP Committee
- ◆ SWOG Policies



CRA Workbench Reports



CRA Workbench

Popular Resources

OPEN Patient Registration

Rave Data Submission

Specimen Tracking

SWOG QA / Audits / Monitoring

SWOG Best Practices

New CRA Training

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[Join the CRA Mailing list](#)

Announcements

Updates to Specimen Tracking

A couple of updates have been made to the Specimen Tracking interface. In Step 2 of Logging a Specimen, the "Filter" at the top has been updated so that now at least one key filter is required before a list of samples is displayed. We are hopeful that this will make it easier to identify and select the correct specimen. Also, to avert potential problems for when the Test environment is chosen inadvertently, we have moved the "Test" button to the right side of the page and within the Test environment we have updated the banner and put a watermark on the packing list. The upcoming Winter CRA Newsletter will have more details. [12/1/2022]

SWOG EMP

Using the nCartes platform can be [7/2022]

SWOG Bios

The Kit Manag... marks with the new URL: <https://kits.bpc-apps.nchri.org/>. If you try to access the old URL, there is no redirect as the server supporting the old URL is end of life and users will receive an error message. [8/25/2021]

Patient Reports, Data Quality



CRA Workbench Reports



- ◆ Expectation Reports
- ◆ IPR Reports
- ◆ Query Reports
- ◆ Patients in Follow Up
- ◆ Ineligible Patients Report
- ◆ Data Quality Portal for Rave Studies

SPRING 2025
CRA NEWSLETTER
ISSUE No. 23



CRA Newsletter: Spring Edition



- Issue #23 Published on March 25
- Send your ideas! CRANewsletter@crab.org
 - Clinical Trials Training Course (CTTC)
 - SWOG NCORP Clinical Trials
 - Who's Who at SDMC and NOC
 - Date of Discovery in CTEP-AERS
 - Legacy SWOG Trials
 - Vital Status Forms



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



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Closing Remarks

Presented by:

Caitlin Hutchinson, MS & Nikki Stover, MPP

Special Thanks



- Each of our speakers
- Courtney Wille
- Hyatt staff



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



Reminders

Tomorrow, Friday, May 2nd

- **Jeri & Noboru Oishi Symposium** 8:00 AM – 10:30 AM PT (Hybrid)
- **ORP Open Forum** 11:00 AM – 12:30 PM PT (In-person)

Fall 2025 SWOG Group Meeting

September 18 - 20, 2025
Hyatt Regency Chicago
Chicago, Illinois



Photo credit: https://media.wnyc.org/i/800/0/c/85/1/shutterstock_344201303.jpg

Ever Forward

