SWOG NCORP Research Base Clinical Trials Active and Upcoming Studies

Study #	Study Title	Activation / Status	Accrual	Follow-up (from Reg Date)	Participating Sites
Cancer Ca	re Delivery Research Committee				
S1703	Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Negative Breast Cancer	July 2018	625 of 739 85%	6 years from Step 2 randomization date	NCTN and NCORP
S2417CD	A Pragmatic Randomized Controlled Trial to Evaluate the Effectiveness of an Intervention to Promote Guideline-Concordant Colorectal Cancer Surveillance	August 2025	0 of 654 0 %	1.5 years	NCORP Only
S2424CD	A Randomized Controlled Trial of an Intervention Called "Algorithm-Enabled Patients Activated in Cancer Care Through Teams" (A-PACT) to Improve Goals of Care Communication for People with Cancer	Activating Soon: Recruiting for NCORP Sites	Goal: 1000	1 year	NCORP Only
Palliative	Care Committee		'		
\$1501	Prospective Evaluation of Carvedilol vs No treatment in Prevention of Cardiac Dysfunction in Patients with Metastatic HER-2+ Breast Cancer	September 2017	373 of 491 76 %	2 years from Step 2 randomization date	NCTN and NCORP
S2408	A Randomized Phase III Blinded Trial of Lanreotide for The Prevention of Postoperative Pancreatic Fistula	February 2025	13 of 274 5%	1 year from surgery date	NCTN and NCORP
Preventio	on, Screening, and Surveillance Committee				
	Accrual completed on trials. New concepts are under development.				
Symptom	Management and Survivorship Committee				
S2013	Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study	August 2021	2278 of 3609 63 %	1 year	NCORP Only
S2205	Ice Compress: Randomized Trial of Limb Cryocompression Versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy	March 2023	444 of 777 57 %	1 year	NCTN and NCORP Limited institution

SWOG NCORP Research Base Clinical Trials Completed Accrual with Participants in Active Follow-up

Study #	Study Title	Activation/ Accrual Closure	Accrual	Follow-up Length from Reg Date	Participating Sites
Cancer Ca	re Delivery Research Committee	Tionau Ciocai C		nomineg Date	
		July 2021			
S1912CD	A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)	Accrual Complete December 2024	331 of 326	1 year	NCORP Only
S2108CD	A Cluster Randomized Trial Comparing An Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy	August 2022 Accrual Complete November 2024	1284 of 1282	2 years	NCORP Only Limited Institution
Preventio	n, Screening and Surveillance Committee				
S0820	A Double-Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High-Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III - Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)	March 2013 Accrual Complete June 2023	354 of 389	8 years	NCTN and NCORP
S1823	A Prospective Observational Cohort Study to Assess miRNA371 for Outcome Prediction in Patients with Early-Stage Germ Cell Tumors	June 2020 Accrual Complete May 2024	964 of 956	3 years	NCTN and NCORP
S1904	Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma In Situ - Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)	September 2020 Accrual Complete June 2024	412 of 415	5 years	Limited institution
Symptom	Management and Survivorship Committee				
S1600	A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes	February 2019 Accrual Complete October 2023	203 of 200	3 years (post- cystectomy date)	NCTN and NCORP
S2010	A Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Versus Patient Education Alone To Improve Persistence With Endocrine Therapy In Young Women With Stage I-III Breast Cancer (ASPEN)	January 2023 Accrual Complete January 2024	565 of 540	1.5 years	NCTN and NCORP



Trial Activation and Facilitation Resources

Fall 2025 Group Meeting Handout — Page 1 of 2 Online resources are accessible via hyperlinks below. (Where indicated, login is required; Recommend login prior to clicking on the link.)

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Identifying Upcoming Studies:

SWOG Protocol Development Tracking Reports and Dashboards (login at SWOG.org)

 These webpages provide real-time status updates on SWOG-led studies in the development pipeline, including targeted activation dates.

Feasibility Assessment Tool: Clinical Trial Review Guide (login at SWOG.org)

Getting Started with CTSU and NCI Applications:

- CTSU Operations Training Modules, accessible via CTSU.org >> Resources >> CTSU Operations Information >> General Procedures & Training (login at https://ctsu.cancer.gov/)
- SWOG and NCI Systems Overview Training (login at https://swog.exphosted.com/)

Site Rostering:

- CTSU RUMS User Guide (login at https://ctsu.cancer.gov/) and
- SWOG FAQs: Systems Access and Rostering Maintenance

Site Initiation: Refer to Section 13 of the SWOG-led protocol.

- SWOG FAQs: Funding, Financials, and Study Payments
- The CTSU Site Registration Help Topics (login at https://ctsu.cancer.gov/)
- NCI CIRB Standard Operating Procedures and Start Guide (login at https://ctsu.cancer.gov/)
- NCI CIRB How to Open a Study Guide (login at https://ctsu.cancer.gov/)
- The CTSU Regulatory Submission Portal User Guide (login at https://ctsu.cancer.gov/)

Informed Consent Process: (For all of the following login at https://swog.exphosted.com/)

- Plain Talk: Communicating with Participants About Clinical Trials
- QA Perspective on Informed Consent: A Process, Not a Document
- SWOG Plain Language Tools: Patient-friendly Trial Summaries
- Tips for the Real World
- So Much Consenting, So Little Time

Participant Enrollment: Refer to Section 13 of the SWOG-led protocol.

- Oncology Patient Enrollment System (OPEN) user guide (login at https://ctsu.cancer.gov/)
- Open Funding (login at https://swog.exphosted.com/)

Data Submission and Management:

CTSU Rave Roles, Training, and Resources (login at https://ctsu.cancer.gov/)

Key SWOG Policies and Procedures for Study Management:

Policy 12	SWOG Registration and Treatment Policies
Policy 15	Applicability of IND Applications and Investigator Brochures/Support From Pharmaceutical Companies
Policy 18	Data Evaluation Policy and Procedure
Policy 19	Quality Assurance Program
Policy 20	New Agent Studies and Safety Monitoring
Policy 21	Data and Safety Monitoring
Policy 22	Ethical and Regulatory Considerations
Policy 23	Serious Adverse Events
Policy 25	Drug Ordering
Policy 29	Roster of Investigators Maintenance Policies and Procedures
Policy 30	Responsibility for Patient Follow-Up
Policy 33	Institutional Performance Review
Policy 36	Affirmation of Integrity
Policy 38	Research Calculations for Clinical Trials
Policy 39	Acquisition, Maintenance and Use in Research of Tissue and Other Biologic Patient Specimens



General Training and Informational Resources

Fall 2025 Group Meeting Handout — Page 2 of 2 (Where indicated, login is required; Recommend login prior to clicking on the link.)

9/1/2025

Getting Started with SWOG:

- Vital Information and Contacts
- SWOG CRA Manual for Oncology Research Professionals (login at https://swog.exphosted.com/)
- CTSU Website Overview (9 mins) (login at https://swog.exphosted.com/)
- SWOG Website Overview (4 mins) (login at https://swog.exphosted.com/)
- SWOG ORP (CRA) Workbench Overview (4 mins) (login at https://swog.exphosted.com/)
- iMedidata RAVE Access for Lead ORPs (6 mins) (login at https://swog.exphosted.com/)
- SWOG Specimen Tracking System for Lead ORPs (8 mins) (login at https://swog.exphosted.com/)

NCORP-provided materials (accessible via the NCORP-Portal):

- NCORP Resources, includes NCORP Guidelines walkthrough, Site Orientation, and funding overview information. (login required)
- NCORP Meeting/WebEx Materials, includes helpful resource materials from monthly administrator meetings, study-specific webinars, and prior NCORP annual meeting materials. (login required)

SWOG-led Study Accrual Tracking: Reports & Dashboards (login ORP Workbench & SWOG.org)

Tools for Clinical Trial Conduct: <u>SWOG ORP (CRA) Workbench Tools</u> (login at <u>ORP Workbench</u>)

Tools for a Successful Audit: SWOG Quality Assurance & Audits

SWOG Training for Oncology Research Professionals:

Clinical Trials Training Course (login required)

Specimen Submission Training:

- SWOG: Biospecimen Tracking and Submission Training (login at https://classlms.org/)
- Improving SWOG Biospecimen Bank Submissions (login at https://swog.exphosted.com/)
- Biospecimen Quality, Compliance, Tips and Tricks (login at https://swog.exphosted.com/)
- Complete Guidelines for Specimen Submission

SWOG Regulatory Workshop

SWOG Quality Assurance Webinar Series, including:

(Login at https://classlms.org/ required to access the following QA Webinar Series enduring courses)

- Cytogenetics (1 CEU contact hour)
- Serious Adverse Event Reporting & Updates (1 CEU contact hour)
- <u>Disease Assessment in Solid Tumors</u> (1 CEU contact hour)
- Workload Prioritization in Clinical Trials (1.5 CEU contact hours)
- Best Practices for Informed Consent (1 CEU contact hour)
- Research Protocol Deviations vs Deficiencies (1 CEU contact hour)
- Adverse Event Reporting
- SWOG Audits: Preparing for Success and Audit Process
- How to Develop a CAPA Plan

Additional SWOG-provided Training:

- For more training resources refer to:
 - SWOG Training Resources
 - Announcements
 - List of online training courses
 - SWOG ORP (CRA) Workbench (login at ORP Workbench)
 - SWOG Oncology Research Professionals (login at SWOG.org)

Onboarding and Refresher Training:

Compiled Researcher Resources List, now accessible via CTSU.org >> Resources >> Researcher Resources.