



SWOG Procedures for Submission and Review of Data Requests, External Translational Medicine Proposals, and Biospecimen Availability Requests

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Outline

- SWOG Data Request Process
- NCTN/NCORP Data Archive
- Biospecimen Requests for Translational Medicine (TM) Studies
- Clinical Trials Search Tool (SWOG.org or CTSU.org)
- Clinical Trial Listing
- Master Form Set



SWOG Data Request Process

- SWOG makes research data available to:
 - Investigators – both SWOG members and external investigators.
 - Pharmaceutical companies.
- Data requests that include study endpoints will only be considered after the primary study analyses have been published.
- An investigator who wishes to use a SWOG dataset must make a formal request which is evaluated by the SWOG Executive Committee (EC). Upon approval, investigators will receive a SWOG EC letter of support.
- In addition to SWOG EC review and approval, the requesting investigator must also sign a Data Use Agreement (DUA) between the Investigator's Institution and SWOG.



SWOG Data Request Process

SWOG Data Sharing Request Template

- Accessible on the SWOG website, or via request to the Disease Committee Statistician or the SWOG Network Operations Center at protocols@swog.org.
- Key Items to Focus On:
 1. Thoughtful specification of objectives
 2. Assess lack of overlap with prior and ongoing work through literature review, discussions with study chair(s) and the disease committee.
 3. Confirm data elements are available
(This will be covered at the end of the presentation.)
 4. Review by the Disease Committee Chair

Title of Data Project:

Name of Requestor:

Requestor's Email Address & Telephone Number:

Name of Requestor's Institution:

Address of Requestor's Institution:

Requestor understands requested Data will be provided to Requestor at Requestor's Institution:

Yes No

SWOG Clinical trial(s) from which Data is requested:

Has primary manuscript(s) of the SWOG Clinical trial(s) from which Data is requested been published:

Yes No

Data Project objective(s):

Primary objective:

Secondary objective(s):

Brief Justification:

Rationale:

Background:

Significance:

Endpoints:

Primary endpoint:

Secondary endpoint(s):

Approach / Methods:

Statistical Plan:

Is this Data Sharing Request a collaborative effort involving additional Investigator(s) and / or Institutions(s):

Yes No

If Yes, name participating Investigator(s) and Institution(s):

Investigator and Institution:



Publications using SWOG Data

- Prior to submission, all abstracts and manuscripts must be forwarded to the SWOG Publications Office (pubs@swog.org) to ensure compliance with Group policy.
- Abstracts prepared for submission to any society meetings or seminars must be submitted to the Publications Office **no later than two weeks prior to submission**, or as determined by contractually bound timelines, to allow for authorship review and circulation to appropriate reviewers.



SWOG Data Request Process

- See [SWOG Policy No. 43](#) for more information.
- SWOG Policies are publicly available on [SWOG.org](#).

SWOG CANCER RESEARCH NETWORK
<http://swog.org>

<p>Policy Memorandum No. 43 Subject: Requests for Participant Data Departments Affected: All</p>	<p>Page 1 of 5 pages Original Release Date: April 2006 Revision Date: October 2019</p>
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**REQUESTS FOR PATIENT DATA
FROM SWOG STUDIES**

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NCTN/NCORP Data Archive

- NCTN/NCORP Data Archive is another resource for research proposals.
- Includes SWOG and **non-SWOG** coordinated trials.
- The archive contains clinical data from Phase II/III, Phase III, and select Phase II studies from:
 - Primary publications published after January 2015.
 - Non-primary publications presenting updated survival data published after April 2018.
- Search for and request NCI-sponsored clinical data here:
<https://nctn-data-archive.nci.nih.gov/>
- A signed DUA with the NCI is required to access the data. A SWOG agreement is not needed.



Biospecimen Requests for Translational Medicine (TM) Studies

- In addition to clinical data, specimens are available from the SWOG Biospecimen Bank for correlative studies.
- These banked specimens are available for secondary TM studies after the associated primary clinical trial outcomes have been presented / published and reported in ClinicalTrials.gov (i.e. more than 12 months after the CT.gov-defined Primary Completion date), via one of two pathways:
 - Pathway 1: NCTN-CCSC Proposals via NCTN Navigator System.
 - Pathway 2: SWOG TM Proposal



Biospecimen Requests for Translational Medicine (TM) Studies

- The application and review processes differ depending on the proposal pathway.
- So first, determine whether the trial and associated collected specimens appear in the NCTN Navigator System. If so, follow Pathway 1 for application via NCTN Navigator.
- [NCTN Navigator](#) inventory is currently limited to select treatment trials:
 - Trials conducted by NCTN clinical trials groups that were activated in 1995 or later,
 - Phase III or large biospecimen collection protocols with clinical data, and
 - Completed, with the primary outcome reported.



Biospecimen Requests for Translational Medicine (TM) Studies

Pathway 1: NCTN-CCSC Proposal via Navigator

- For TM proposals using specimens in the Navigator System, investigators will submit a Letter of Intent (LOI) and subsequent application via NCTN Navigator for review and approval by the NCTN Core Correlative Sciences Committee (CCSC).
- Things to consider when submitting a Navigator proposal:
 1. Focus on validation and not exploratory aims.
 - Hypothesis-generating secondary objectives are allowed.
 2. Work with a local statistician on the application.
Clearly specified objectives with effect sizes and power calculations are critical.



Biospecimen Requests for Translational Medicine (TM) Studies

Pathway 2: SWOG TM Proposal

Important steps prior to submitting requests:

1. Review the protocol of interest:
 - Sections 1 and/or 18 contain integrated and integral TM objectives
 - Sections 12 and/or 15 to confirm specimens collected and corresponding timepoints.
2. Review the “Master Forms Set” for clinical data that was collected in association with the trial.
3. Reach out to the TM chair(s) for the protocol(s), or respective disease committee(s), to assess:
 - General scientific goals, including validating vs exploratory objectives.
 - Timing relative to when trial is reporting primary results.
 - Whether the concept overlaps with ongoing approved work.
4. Reach out to the disease committee statistician to:
 - Assess feasibility.
 - Inquire as to the availability of the requested type of specimens and associated data elements.



Biospecimen Requests for Secondary Translational Medicine (TM) Studies

Pathway 2: SWOG TM Proposal

Step 1: Confirm existence and availability of biospecimens

- E-mail the **primary statistician for the applicable research committee** to confirm biospecimen availability.
 - If you need assistance in determining whom to contact, E-mail: biospecimens@swog.org to be directed to the appropriate statistician.
- When submitting the request, specify:
 1. Parent trial(s) from which specimens are being requested
 2. Type of specimen(s) being requested (e.g.: FFPE block, slides (thickness), Serum, Plasma, DNA, Frozen cells, etc.)
 3. Quantity per timepoint: Number of slides, vials, aliquots, etc.
 4. Requested/Required timepoints
 5. Any limitations on patient population (subsets)
 6. Total estimated # of specimens required for proposed endpoints



Biospecimen Requests for Secondary Translational Medicine (TM) Studies

Pathway 2: SWOG TM Proposal

Step 2: Complete the [SWOG Proposal for an Integral, Integrated or External \(non-Navigator\) Translational Medicine Study Using SWOG Specimens Form](#) *in consultation with the relevant disease committee.*

- TM Proposals are reviewed by the SWOG Executive Review Committee (EC).
- After SWOG EC approval, the proposal must be reviewed and approved by the NCTN CCSC.
- If approved, authorization for use of specimens requires a Material Use Agreement between the requesting Investigator’s Institution and SWOG.

SWOG Proposal for an Integral, Integrated or External (non-Navigator) Translational Medicine Study Using SWOG Specimens

As Principal Investigator for this translational medicine study, my submission of this proposal indicates my willingness to discuss with and enter into a research agreement with SWOG, according to standard procedures for data analysis, data confidentiality, authorship, and intellectual property sharing.

Any specimens collected on trials supported by NCI grant funding will require CTEP/DCP’s review of the proposal before the specimens can be released for analysis.

Definitions:

<i>Integral Objectives:</i>	<i>Must be performed for the trial to proceed or to support the primary analysis.</i>
<i>Integrated Objective (Real-Time Integrated or Retrospective Analyses):</i>	<p><i>Must test a specific hypothesis with a preplanned statistical design and are not hypothesis-generating or exploratory.</i></p> <ul style="list-style-type: none"> • <i>Real-time Integrated TM Proposal: Specimens must be processed and/or tested in real-time by the Biospecimen Bank or an external collaborator due to specimen stability or test/storage type.</i> • <i>Retrospective Analyses/External (non-Navigator) TM Proposal: Utilizes banked specimens and the objective and statistical analysis plans were not included as part of the original clinical trial protocol.</i>
<i>Banking Only:</i>	<i>Specimens collected and stored for potential future research, and which do not have a fully developed statistical design and analysis plan. Participants must have the option to opt out of these specimen submissions.</i>

Proposal Form Completion Notes:

- If any section(s) or question(s) is not applicable please mark as N/A.
- If an NCI correlative proposal form has already been completed and contains the information for any of the questions below, please include the statement "See NCI Proposal Form". Investigators must fill out any remaining questions that are applicable to their proposed trial.
- The red asterisk (*) symbol indicates the question is from an NCI Correlative Proposal Form.
- If this proposal is solely for access to images of H&E slides or pertains exclusively to an AI-focused proposal, please submit a Data Request Form instead of a Translational Medicine Proposal Form.

More information regarding the Translational Medicine Proposal Application Process can be found here [Biospecimen Availability and Translational Medicine Proposal Application Process | SWOG](#).

Please work with SWOG Statistical & Data Management Center (SDMC) to confirm biospecimen and data request availability.



5. Research Design and Methods: Tissue/Biospecimen Type, Processing & Shipping Information

Note: Access the [SWOG Biospecimens Resources website](#) for additional information regarding standard collection, processing, packing and shipping instructions. Note in this proposal whether standard instructions apply or provide additional information.

a. Required Information for all TM Proposals

- i. ***What tissue/biospecimen types are you requesting? (e.g., FFPE malignant primary tumor tissue):**
Click or tap here to enter text.
- ii. **Which timepoints are being requested? (e.g., Baseline, C1D3, Progression)**
Click or tap here to enter text.
- iii. ***Required number of biospecimens per specimen type (e.g. 5 FFPE slides) and include allowable alternatives:**
Click or tap here to enter text.
- iv. ***Required number and thickness of sections from each biospecimen (if solid tissue is requested):**
Click or tap here to enter text.
- v. ***Required amount of the other type of biospecimen (if biospecimens other than solid tissue are requested) and include allowable alternatives:**
Click or tap here to enter text.
- vi. ***How many cases will have material left for future studies if the requested biospecimens are provided for this study?**
Click or tap here to enter text.
- vii. **Will residual specimens be returned to the SWOG Bank? If not what is the plan for these residual specimens?**
Note: only specimens handled within a laboratory with CLIA, ISO/IEC, CAP, or similar certification may be returned to the SWOG Bank.
Click or tap here to enter text.

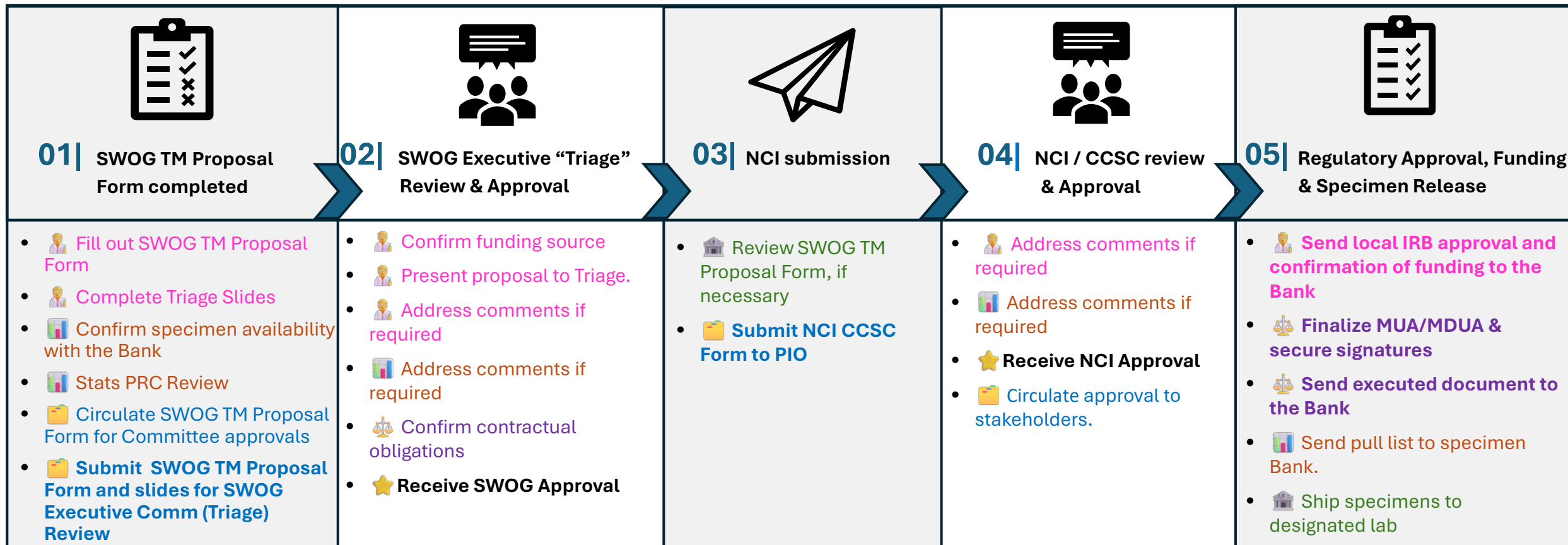
c. Retrospective Analysis of Banked Specimens (External non-Navigator)

- N/A: This section is not applicable.
- i. **Clarify if all specimens as defined below are being requested or if there are specific criteria or patient subsets:**
Click or tap here to enter text.
 - ii. ***How many cases in the trial currently have biospecimens?**
Click or tap here to enter text.
 - iii. ***Will this study exhaust any existing biospecimen resources? (e.g., tissue blocks, archived unstained slides, blood/products?)**
Click or tap here to enter text.
 - iv. **Will the SWOG Bank be required to do any processing of specimens prior to shipping?**
Click or tap here to enter text.
 - v. **Specify the shipping instructions (including shipping temperature, wet/dry ice, timing of shipment, return labels, etc.):**
Click or tap here to enter text.

External (non-Navigator) Translational Medicine Study

After the trial results are presented/published and reported in ClinicalTrials.gov

Forms: SWOG TM Proposal Form, TM Triage slides, NCI CCSC Form



Key (Responsible Parties):

- **Principal Investigator**
- **SWOG Statistical and Data Management Center (SDMC)**
- **Protocol Project Manager (PPM) – SWOG Network Operations Center – San Antonio**
- **Contract Attorney – SWOG Network Operations Center – Portland**
- **The Bank – Nationwide Children’s Hospital**

[Click here to download](#) this flowchart from SWOG.org.



SWOG.org Clinical Trials Search Tool

- How do you find trials that match your research goals?
- What data are available for those trials?

Member Resources | SWOG

swog.org/member-resources

SWOG CANCER RESEARCH NETWORK

Directory WELCOME!

About The SWOG Network News & Events Clinical Trials **Member Resources** For Patients

Member Resources

- Advocate Resources
- BMT Facility List
- Breast Cancer Commons
- CRA Workbench
- Digital Engagement
- Hope Funding Opportunities
- Membership
- Oncology Research Professionals
- Pharmaceutical Sciences
- Protocol Tracking Reports
- Publications & Presentations
- Radiation Therapy Facility List
- Recruitment & Retention

SWOG / Member Resources

Member Resources

Your place to get tools and information for SWOG Cancer Research Network trials.

Tools

- Clinical Trials**
- CRA Workbench
- Member Directory
- SWOG Meetings

Clinical Trials | SWOG

swog.org/clinical-trials

SWOG CANCER RESEARCH NETWORK

Directory WELCOME!

About The SWOG Network News & Events **Clinical Trials** Member Resources For Patients

Clinical Trials

- Biospecimen Resources
- Clinical Research Resources
- Clinical Trials Search**
- Frequently Asked Questions
- Publications
- Institutions
- Pharmacies
- Quality Assurance & Audits
- Serious Adverse Events
- Training Resources
- Contracts & Budgets
- CRA Workbench
- Protocol Workbench
- Accrual Resources

SWOG / Clinical Trials

Clinical Trials

SWOG Cancer Research Network is one of the first cooperative groups created by the National Cancer Institute. SWOG trials seek to improve medical care through symptom control and quality of life.

SWOG.org - Searching for Clinical Trials: Filters

The screenshot shows the SWOG.org Clinical Trials search interface. At the top, there is a search bar and navigation links: About, The SWOG Network, News & Events, Clinical Trials, Member Resources, and For Patients. Below the navigation, the page title is "Clinical Trials Search". The main search area includes a "Keywords/SWOG Study Number" input field, an "Area of Research" dropdown menu set to "Any", a "SEARCH" button, and a "More filters +" button highlighted with a red box and a red arrow. Below the search area, there are options for "Accrual Status" (Any, Open, Closed) and "Limit to SWOG Trials" (All Trials, SWOG Trials Only). A "Show only published studies" checkbox is also present. The results section shows "1026 Results" and a "VIEW" button. Two trial results are displayed:

Open	Phase	Accrual	Study Title	SWOG Clinical Trial Number	Save to List
<input type="checkbox"/>	-	0%	A Randomized Phase II Study of Tepotinib with or Without Ramucirumab in Participants with MET Exon 14 Skipping Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)	S1900K	None
<small>Status Notes: S1900K will open to accrual December 18, 2023, effective 3:00 p.m. EST.</small>					
<small>Research Committee(s): LungMAP</small>					
<small>Study Chair(s): Paul K. Paik, MD</small>					
<small>Activated: 12-18-2023</small>					
<small>ClinicalTrials.gov Registry Number: NCT06031688</small>					

Open	Phase	Accrual	Study Title	SWOG Clinical Trial Number	Save to List
<input type="checkbox"/>	-	0%	A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis	S2213	None

The screenshot shows the SWOG.org Clinical Trials search interface with the filters expanded. The search area includes a "Keywords/SWOG Study Number" input field, an "Area of Research" dropdown menu set to "Any", a "SEARCH" button, and a "Fewer filters -" button. Below the search area, there are options for "Accrual Status" (Any, Open, Closed) and "Limit to SWOG Trials" (All Trials, SWOG Trials Only). A "Show only published studies" checkbox is also present. The filters section includes:

- Study Type: Any
- Treatment: Any
- Study Chair: [Empty Input Field]
- Participating Institution: [Empty Input Field]
- Phase: Any
- Cancer Control Subcommittee: Any
- Study Sponsor: Any
- FDA Registration Trial:
- Uses PRO Forms:

The results section shows "1026 Results" and a "VIEW" button. One trial result is displayed:


Open	Phase	Accrual	Study Title	SWOG Clinical Trial Number	Save to List
<input type="checkbox"/>	-	0%	A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis	S1900K	None




SWOG.org - Searching for Clinical Trials: Filters

Clinical Trials

Keywords/SWOG Study Number

Area of Research 

SEARCH Fewer filters 

Accrual Status Any Open Closed Limited

Study Type



Phase

Study Chair


Participating Institution


Study Sponsor FDA Registration Trial Uses PRO Forms

Show only published studies

1025 Results VIEW  

S2213 SWOG Clinical Trial Number Save to List

A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis 

Accrual  0%

Status Notes S2213 is open to patient accrual December 01, 2023, effective 12:00 p.m. Pacific Time.

Research Committee(s) Myeloma

Activated 12-01-2023

ClinicalTrials.gov Registry Number 06022939



SWOG.org - Searching for Clinical Trials: Filters

Clinical Trials

Keywords/SWOG Study Number: Area of Research: **SEARCH** Fewer filters

Accrual Status: Any Open Closed Limit to SWOG Trials: All Trials SWOG Trials Only Show only published studies

Study Type: **Treatment:** **Study Chair:** **Participating Institution:**

Cancer Control Subcommittee: **Study Sponsor:** FDA Registration Trial Uses PRO Forms

VIEW

S2213 SWOG Clinical Trial Number Save to List:

Open Phase **0%** **Accrual**

A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis

Status Notes	S2213 is open to patient accrual December 01, 2023, effective 12:00 p.m. Pacific Time.
Research Committee(s)	Myeloma
Activated	12-01-2023
ClinicalTrials.gov Registry Number	06022939

SWOG.org - Searching for Clinical Trials: Filters

The screenshot displays the SWOG.org Clinical Trials search interface. At the top, there are input fields for 'Keywords/SWOG Study Number' and 'Area of Research' (set to 'Any'), a 'SEARCH' button, and a 'Fewer filters' link. Below these are filter sections for 'Accrual Status' (Any, Open, Closed), 'Limit to SWOG Trials' (All Trials, SWOG Trials Only), and 'Show only published studies'. Further down are filters for 'Study Type', 'Phase', 'Treatment' (with a dropdown menu open showing options like 'Any', '5-Fluorouracil', '506U78', '6-Mercaptopurine', '6-Thioguanine', and '776C85'), 'Study Chair', 'Participating Institution', 'Study Sponsor', 'FDA Registration Trial', and 'Uses PRO Forms'. The search results show '1025 Results' and a 'VIEW' button. A detailed view of a trial is shown below, including an 'Accrual' progress indicator at 0%, the trial title 'A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis', and a table of metadata.

Field	Value
Status Notes	S2213 is open to patient accrual December 01, 2023, effective 12:00 p.m. Pacific Time.
Research Committee(s)	Myeloma
Activated	12-01-2023
ClinicalTrials.gov Registry Number	06022939



SWOG.org - Searching for Clinical Trials: Filters

Clinical Trials

Keywords/SWOG Study Number: Area of Research: **SEARCH** Fewer filters

Accrual Status: Any Open Closed Limit to SWOG Trials: All Trials SWOG Trials Only Show only published studies

Study Type: Treatment: Study Chair: Participating Institution:

Phase: Cancer Control Subcommittee: Study Sponsor: FDA Registration Trial Uses PRO Forms

VIEW

SWOG Clinical Trial Number: Save to List:

0%
Accrual

A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis

Status Notes: 52213 is open to patient accrual December 01, 2023, effective 12:00 p.m. Pacific Time.

Research Committee(s): Myeloma

Activated: 12-01-2023

ClinicalTrials.gov Registry Number: 06022939



SWOG.org - Searching for Clinical Trials: Filters

Clinical Trials

Keywords/SWOG Study Number: Area of Research: **SEARCH** Fewer filters ⊖

Accrual Status: Any Open Closed Limit to SWOG Trials: All Trials SWOG Trials Only Show only published studies

Study Type: Treatment: Study Chair: Participating Institution:

Phase: Cancer Control Subcommittee: Study Sponsor: FDA Registration Trial Uses PRO Forms

1025 Results VIEW

Open Phase Save to List

0% Accrual

A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis

Status Notes: S2213 is open to patient accrual December 01, 2023, effective 12:00 p.m. Pacific Time.

Research Committee(s): Myeloma

Activated: 12-01-2023

ClinicalTrials.gov Registry Number: 06022939



SWOG.org - Searching for Clinical Trials: Filters

Clinical Trials

Keywords/SWOG Study Number Area of Research Fewer filters

Accrual Status Any Open Closed Limit to SWOG Trials All Trials SWOG Trials Only Show only published studies

Study Type Treatment Study Chair Participating Institution

Phase Cancer Control Subcommittee Study Sponsor FDA Registration Trial Uses PRO Forms

1025 Results

0%
Accrual

S2213 SWOG Clinical Trial Number

A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis

Status Notes S2213 is open to patient accrual December 01, 2023, effective 12:00 p.m. Pacific Time.

Research Committee(s) Myeloma

Activated 12-01-2023

ClinicalTrials.gov Registry Number 06022939

SWOG.org – Identifying the Primary Statistician for a SWOG-led study

Open Phase
Save to List None

0%
Accrual

S2213 SWOG Clinical Trial Number

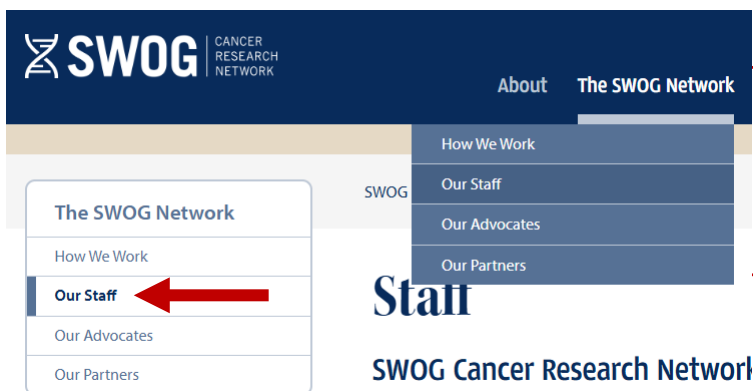
A Phase III, Randomized Study of Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone (Dara-VCD) Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis

Status Notes	S2213 is open to patient accrual December 01, 2023, effective 12:00 p.m. Pacific Time.
Research Committee(s)	Myeloma
Activated	12-01-2023
ClinicalTrials.gov Registry Number	06022939

The Research Committee under which the primary clinical trial was conducted will be identified on the protocol abstract page on SWOG.org, as shown here.

- First, identify the Research Committee that is associated with the conduct of the primary clinical trial via the protocol abstract page on SWOG.org.
- The contact information for the Primary Statistician that supports the associated Research Committee can be found via the [Staff webpage on SWOG.org](#).

SWOG.org – Identifying the Primary Statistician for a SWOG-led study



From SWOG.org, navigate to:
“The SWOG Network” >> “Our Staff”

SWOG Cancer Research Network Statistics and Data Management Center -

Fred Hutchinson Cancer Center
1100 Fairview Avenue North, M3-C102
Seattle, WA [98109-1024](tel:206-667-1024)
Phone: [206-667-4623](tel:206-667-4623)
Fax: [206-667-4408](tel:206-667-4408)

Cancer Research And Biostatistics
1505 Westlake Ave N, Ste 750
Seattle, WA 98109
Phone: [206-652-9711](tel:206-652-9711)

- After identifying the Research Committee associated with the primary clinical trial:
 - The name and contact email for the Primary Statistician that supports the associated Research Committee is available via the [Staff webpage on SWOG.org](#) under the *SWOG Statistics and Data Management Center* office locations.
 - Note: Primary Statisticians work out of both the Fred Hutchinson Cancer Center (under Biostatistics Faculty) and Cancer Research and Biostatistics (under Biostatistics) locations.



SWOG.org Search Results

Includes ct.gov registry number.

9 Results

VIEW [Table View Icon]

Open Phase 20% Accrual

S2104 SWOG Clinical Trial Number

A Phase II Randomized Trial of Postoperative Adjuvant Capecitabine and Temozolamide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors

Research Committee(s) Gastrointestinal Cancer

Study Chair(s) Melissa Pardo Seaman, MD, PhD

Activated 10-14-2021

Open Phase 51% Accrual

S2001 SWOG Clinical Trial Number

Parallel Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab vs. Olaparib as Maintenance Therapy in Two Cohorts of Metastatic Pancreatic Cancer Patients with DNA Damage Repair Defects

Status Notes Activation Effective 12-04-2020 3:00 pm eastern

Research Committee(s) Gastrointestinal Cancer

Study Chair(s) Vincent Chung, MD

Activated 12-04-2020

ClinicalTrials.gov Registry Number NCT04548752

"Table view" is condensed

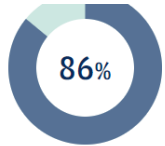
Indicates whether the study has been published.

9 Results

VIEW [Table View Icon]

Status	Trial Number	Title	Activated	Closed	Accrual	Phase	Published
Open	S2104	A Phase II Randomized Trial of Postoperative Adjuvant Capecitabine and Temozolamide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors	10/14/2021		20%		
Closed	19629	A Phase II Trial of S-Fluorouracil Plus T166CS in Patients with Advanced Pancreas Cancer	5/15/1997	3/15/1999	100%		✓
Closed	18700	PANCREAS	9/15/1997	6/10/2001	90%		✓
Closed	19624	PANCREAS	6/1/2000	6/1/2001	97%		✓
Closed	18187	PANCREAS	7/1/2001	6/1/2003	100%		✓
Open	S2001	Parallel Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab vs. Olaparib as Maintenance Therapy in Two Cohorts of Metastatic Pancreatic Cancer Patients with DNA Damage Repair Defects	12/4/2020		51%		
Closed	S1505	Peroperative FOLFIRINOX vs Gem/Tab-Pac for Resectable Panc Adeno	10/12/2015		96%		
Closed	S1115	Randomized Phase II of AZD-6244 add MK-2206 vs mFOLFIRINOX in Pts with Met Pancreatic Cancer After Chemo	8/15/2012	5/15/2014	100%		✓
Closed	S1513	8P in 2nd Line FOLFIRINOX or w/o Veliparib (ABT588) in met panc cancer	6/1/2016		86%		

Clinical Trial Listing



Accrual

discontinue the experimental treatment but may continue on FOLFIRI alone. Patients on both arms should continue study follow-up.

Activated	09/01/2016
Participants	ALL NATIONAL CLINICAL TRIALS NETWORK MEMBERS

Research committees

Gastrointestinal Cancer

Treatment

5-Fluorouracil Irinotecan Leucovorin Calcium ABT-888

Research committees

Gastrointestinal Cancer

Treatment

5-Fluorouracil Irinotecan Leucovorin Calcium ABT-888

Eligibility Criteria -

Histologically or cytologically documented pancreatic adenocarcinoma. Pancreatic neuroendocrine tumors, lymphoma of the pancreas, or ampullary cancer are not eligible; Must have metastatic disease that is measurable, CT scans or MRIs of the chest, abdomen, and pelvis used to assess measurable disease must have been completed within 28 days prior to reg. CT Scans or MRIs used to assess non-measurable disease must have been completed within 42 days prior to reg.

Must not have history of brain mets; must have had one and only one prior regimen of systemic therapy for metastatic disease unless the patient received systemic therapy with gemcitabine/nab-paclitaxel for resectable or borderline/locally advanced unresectable disease and progressed with metastatic disease within 3 months of the past dose of systemic therapy; systemic therapy and chemoradiotherapy for tx of resectable, borderline resectable or locally advanced unresectable disease is allowed and does not count toward prior therapy for metastatic disease; must have completed systemic therapy at least 14 days prior to reg, any surgical procedure must have been

Eligibility Criteria +

Publication Information -

2021

[Randomized Phase II Study of PARP Inhibitor ABT-888 \(Veliparib\) with Modified FOLFIRI versus FOLFIRI as Second Line Treatment of Metastatic Pancreatic Cancer: SWOG S1513](#)

EG Chiorean;K Guthrie;P Philip;E Swisher;F Jalikis;M Pishvaian;J Berlin;M Nos;J Suga;I Garrido-Laguna;D Cardin;M Radke;M Duong;A Lowy;H Hochster Clinical Cancer Research, Dec 1;27(23):6314-6322

PMid: PMID34580114 | PMC number: PMC8639715

2020

[Influence of Modeling Choices on Value of Information Analysis: An Empirical Analysis from a Real-world Experiment](#)

DD Kim;G Guzauskas;C Bennette;A Basu;D Veenstra;S Ramsey;JJ Carlson PharmacoEconomics Feb;38(2):171-179; 2019 Oct 21. doi: 10.1007/s40273-019-00848-8. [Epub ahead of print]

Publications link to papers



CTSU.org Website Access

- Site staff set up their CTEP-IAM account, register with Registration and Credentialing Repository (RCR), and ID.me
- To obtain/update CTEP-IAM account: <https://ctepcore.nci.nih.gov/iam>
- To register in the RCR: <https://ctepcore.nci.nih.gov/rcr>
- To set up ID.me account:
https://ctep.cancer.gov/investigatorResources/NCI_CTEP_IAM_User_Access_Update.htm
- RCR Quick Reference Guide – Provides an overview of the CTEP-IAM and RCR registration process

Accessing Protocol-Specific information on CTSU.org

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Documents>>CIRB-approved Documents tab includes: Protocol and Consent Documents>>Protocol-Related Documents tab: includes: Case Report Forms and Memos

Documents

Protocol Requirements

NCI Community Oncology Research Program S2205

Ice Compress: Randomized Trial of Limb Cryocompression Versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy

For site registration approval, at least one staff member must complete each of the four required Training Courses in CLASS. A link to the courses in CLASS is located in Protocol Related Documents, use the Document Type filter and select Education and Promotion or Site Registration.

#	Document Title	Document Type	Document Date	Format	Post Date
1	Protocol Version Date 03/09/23		16-Mar-2023		
2	Consent Form (PVD 03/09/23)		16-Mar-2023		

CIRB Approved Documents

Protocol Related Documents

Document Title: Case Report Forms

#	Document Title	Document Type	Document Date	Format	Post Date
1	Master Forms Set	Case Report Forms	15-Jan-2024	PDF	17-Jan-2024



Master Forms Set from a SWOG Trial

SWOG S2205 ONSTUDY FORM

Patient Identifier Study Identifier S 2 2 0 5 Registration Step 1

Patient Initials _____ (L, F M)

Page: Onstudy: Participant and Disease Description

Instructions: Submit this form within 15 days of initial registration. Date is in DD MON YYYY format. Explain any blank fields or blank dates in the **Comments** section.

Performance Status 0 1 2 3 4

Height cm

Weight . kg

What was the date of the history and physical exam?

What was the date of the initial diagnosis of the solid tumor malignancy for which the participant is planning to receive taxane-based chemotherapy?

What is the type of tumor for which the participant is receiving taxane-based chemotherapy?

Breast
 Lung
 Endometrium
 Ovary
 Other, specify _____

Did the participant have a history of skin or limb metastases? Yes No

Did the participant previously receive neurotoxic chemotherapy? (e.g. taxanes, platinum agents, vinca alkaloids, or bortezomib) Yes No

Did the participant have pre-existing clinical peripheral neuropathy? Yes No

Did the participant have a history of Raynaud's phenomenon? Yes No

Did the participant have a history of cold agglutinin disease? Yes No

Did the participant have a history of cryoglobulinemia? Yes No

Did the participant have a history of cryofibrinogenemia? Yes No

Did the participant have a history of post-traumatic cold dystrophy? Yes No

Did the participant have a history of peripheral arterial ischemia? Yes No

Did the participant have any open skin wounds or ulcers of the limbs? Yes No

SWOG S2205 TREATMENT

Participant Identifier Study Identifier S 2 2 0 5 Registration Step 1

Participant Initials _____ (L, F M) Cycle Number

Page: Treatment

TREATMENT FOR THIS CYCLE

If any assigned agent was not administered during this cycle, then leave Start Date and End Date empty, enter "0" for the total dose administered and complete the Treatment Adjustments form. If any assigned agent was withdrawn in a previous cycle, enter "No" for dose modifications and enter "0" for the planned doses and the total dose administered.

Treatment Name	Start Date	End Date	Planned Dose Per Administration	Planned Total Dose	Total Dose Administered
Paclitaxel	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> mg/m ²	<input type="text"/> <input type="text"/> . <input type="text"/> mg	<input type="text"/> <input type="text"/> . <input type="text"/> mg
Carboplatin	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/> mg	<input type="text"/> <input type="text"/> . <input type="text"/> mg	<input type="text"/> <input type="text"/> . <input type="text"/> mg
Docetaxel	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> mg/m ²	<input type="text"/> <input type="text"/> . <input type="text"/> mg	<input type="text"/> <input type="text"/> . <input type="text"/> mg
Nab-Paclitaxel	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> mg/m ²	<input type="text"/> <input type="text"/> . <input type="text"/> mg	<input type="text"/> <input type="text"/> . <input type="text"/> mg

Will the participant continue to receive taxane therapy? Yes No



SWOG is committed to sharing data and samples.

To ensure a successful data or TM application, do your homework to make certain that the proposal is sound and feasible.