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

Presented by: Shay Bellasea

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

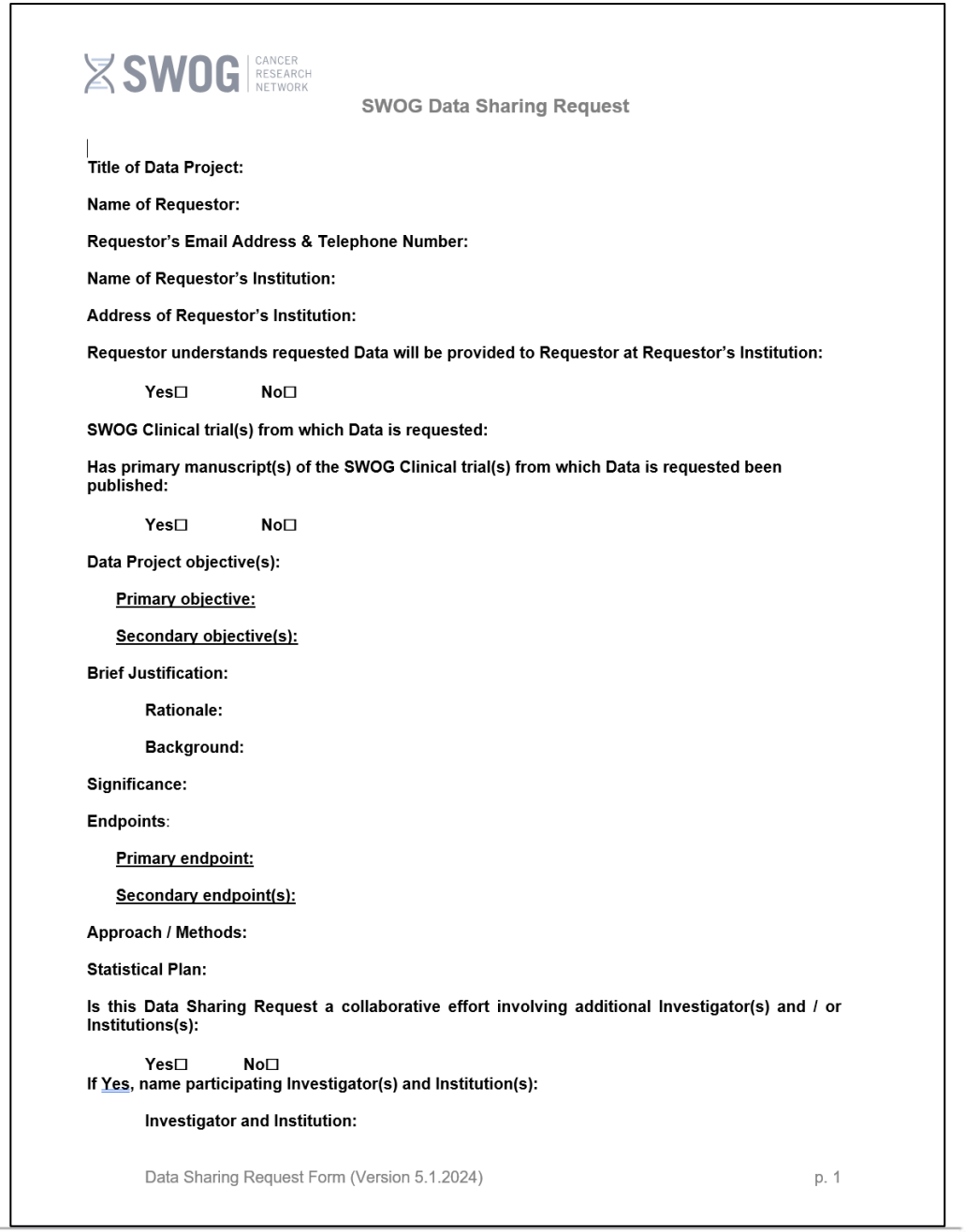
SWOG Data Request Process

- 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



SWOG CANCER RESEARCH NETWORK

SWOG Data Sharing Request

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:

Data Sharing Request Form (Version 5.1.2024) p. 1

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

Policy Memorandum No. 43
Subject: Requests for Participant Data
Departments Affected: All

Page 1 of 5 pages
Original Release Date: April 2006
Revision Date: October 2019

REQUESTS FOR PATIENT DATA FROM SWOG STUDIES

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.

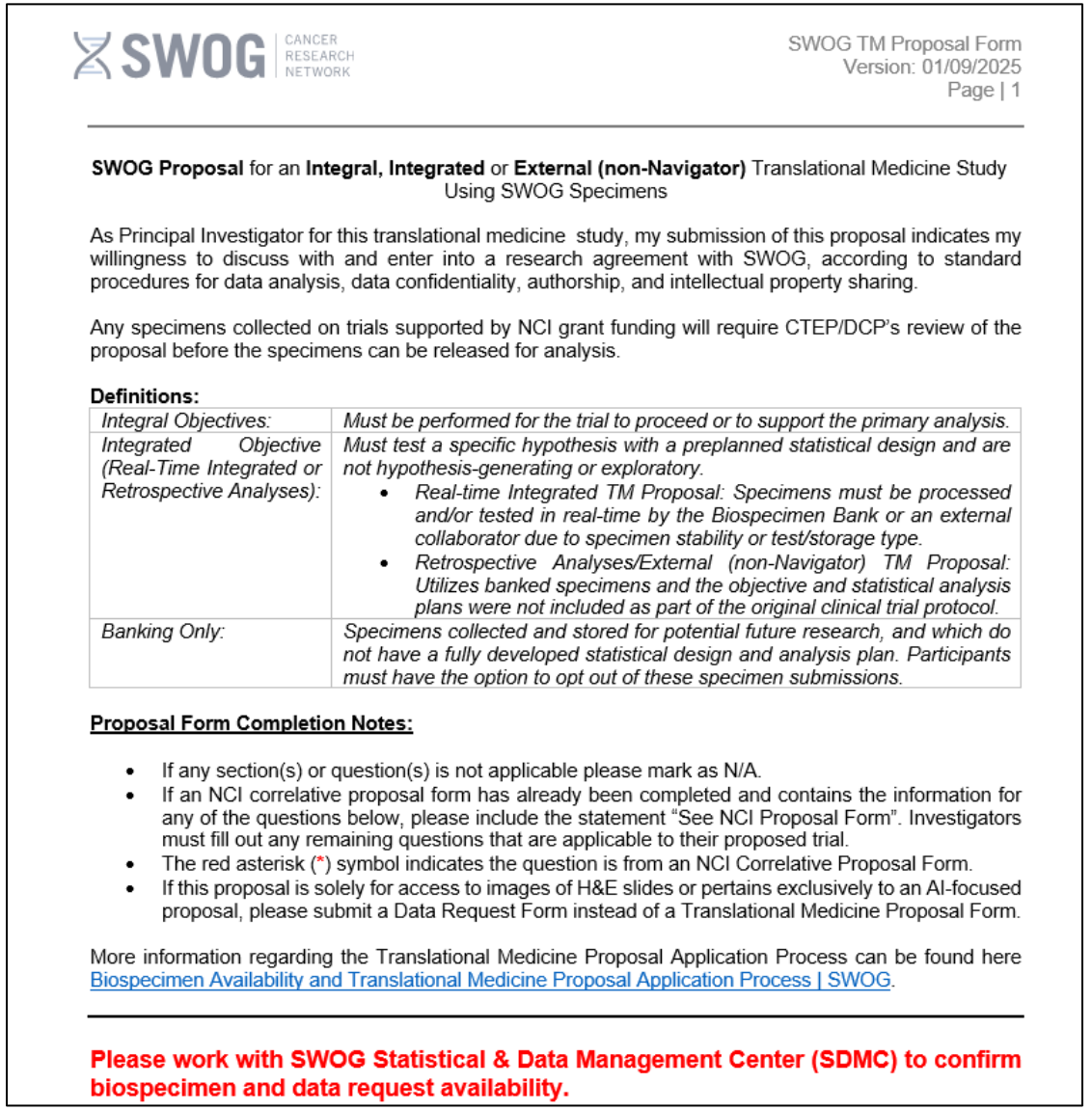
- When submitting the request, specify:
  1. Parent trial(s) from which specimens are being requested
  2. Type of specimen(s) being requested (e.g.: FFPE block, slides (thickness), Serum, Plasma, DNA, Frozen cells, etc.)
  3. Quantity per timepoint: Number of slides, vials, aliquots, etc.
  4. Requested/Required 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 CANCER RESEARCH NETWORK

SWOG TM Proposal Form
Version: 01/09/2025
Page | 1

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:

Integral Objectives:	*Must be performed for the trial to proceed or to support the primary analysis.*
Integrated Objective (Real-Time Integrated or Retrospective Analyses):	*Must test a specific hypothesis with a preplanned statistical design and are not hypothesis-generating or exploratory.* • *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.* • *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.*
Banking Only:	*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.*

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

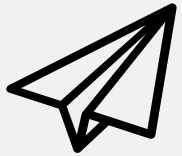
Forms: SWOG TM Proposal Form, TM Triage slides, NCI CCSC Form

01| SWOG TM Proposal Form completed

- 👩‍⚕️ Fill out SWOG TM Proposal Form
- 👩‍⚕️ Complete Triage Slides
- 📊 Confirm specimen availability with the Bank
- 📊 Stats PRC Review
- 🗂️ Circulate SWOG TM Proposal Form for Committee approvals
- 🗂️ **Submit SWOG TM Proposal Form and slides for SWOG Executive Comm (Triage) Review**

02| SWOG Executive "Triage" Review & Approval

- 👩‍⚕️ Confirm funding source
- 👩‍⚕️ Present proposal to Triage.
- 👩‍⚕️ Address comments if required
- 📊 Address comments if required
- ⚖️ Confirm contractual obligations
- ⭐ **Receive SWOG Approval**



03| NCI submission

- 🏛️ Review SWOG TM Proposal Form, if necessary
- 🗂️ **Submit NCI CCSC Form to PIO**

04| NCI / CCSC review & Approval

- 👩‍⚕️ Address comments if required
- 📊 Address comments if required
- ⭐ **Receive NCI Approval**
- 🗂️ Circulate approval to stakeholders.

05| Regulatory Approval, Funding & Specimen Release

- 👩‍⚕️ **Send local IRB approval and confirmation of funding to the Bank**
- ⚖️ **Finalize MUA/MDUA & secure signatures**
- ⚖️ **Send executed document to the Bank**
- 📊 Send pull list to specimen Bank.
- 🏛️ Ship specimens to designated lab

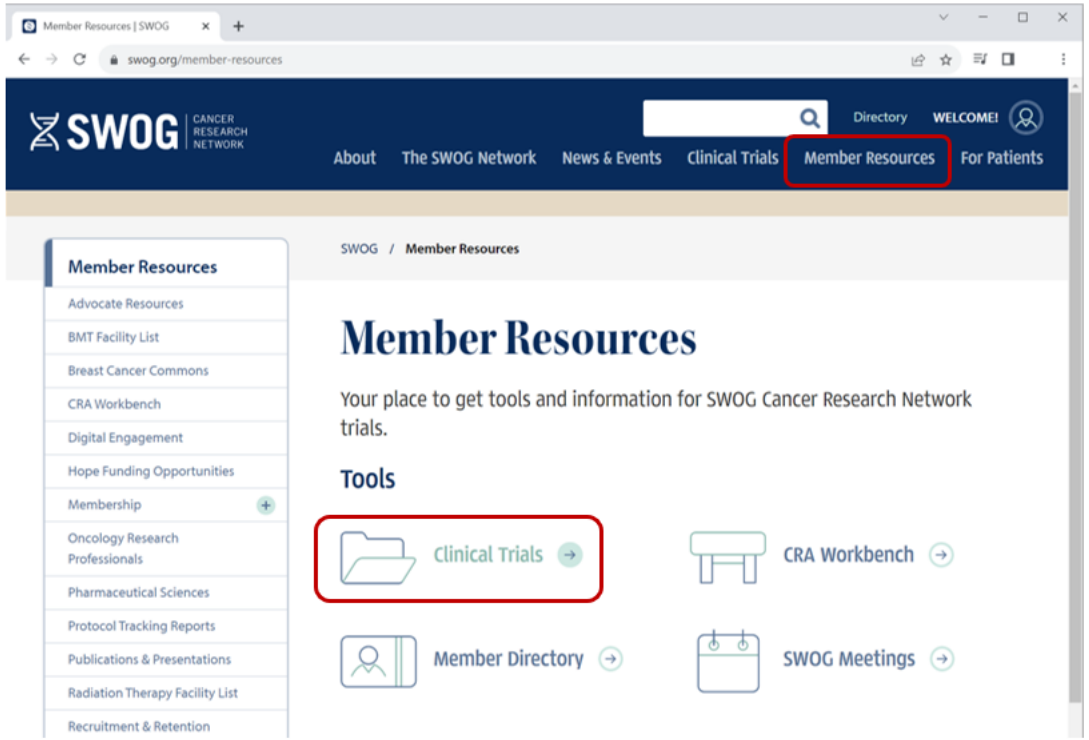
Key (Responsible Parties):

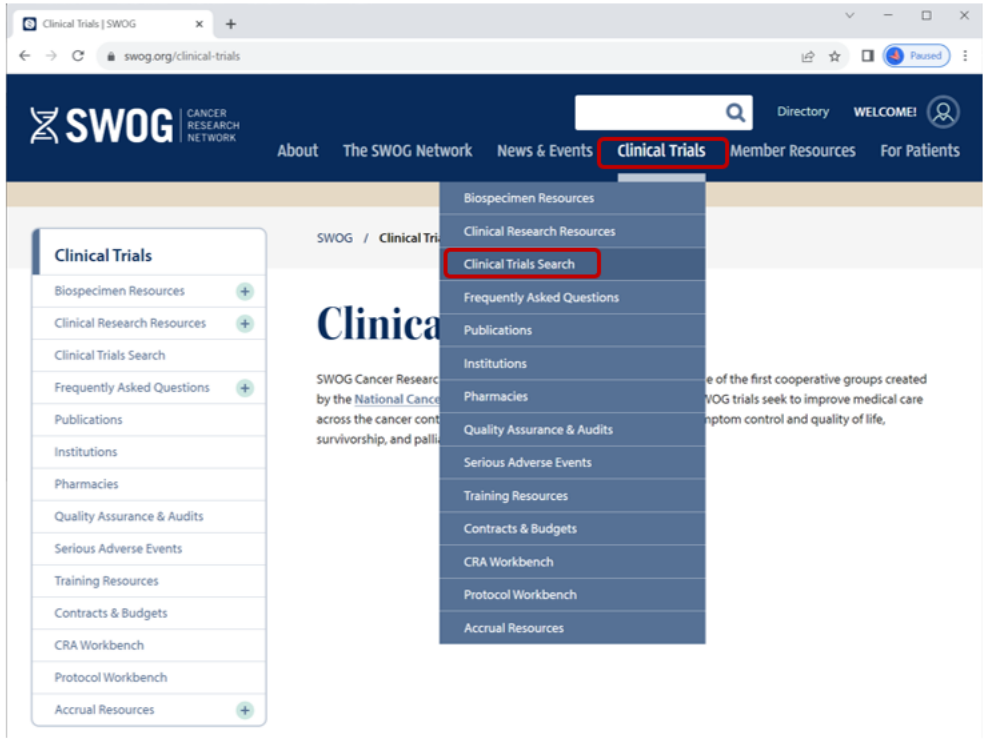
- 👩‍⚕️ **Principal Investigator**
- 📊 **SWOG Statistical and Data Management Center (SDMC)**
- 🗂️ **Protocol Project Manager (PPM) – SWOG Network Operations Center – San Antonio**
- ⚖️ **Contract Attorney – SWOG Network Operations Center – Portland**
- 🏛️ **The Bank – Nationwide Children's Hospital**

Click here to download this flowchart from SWOG.org.

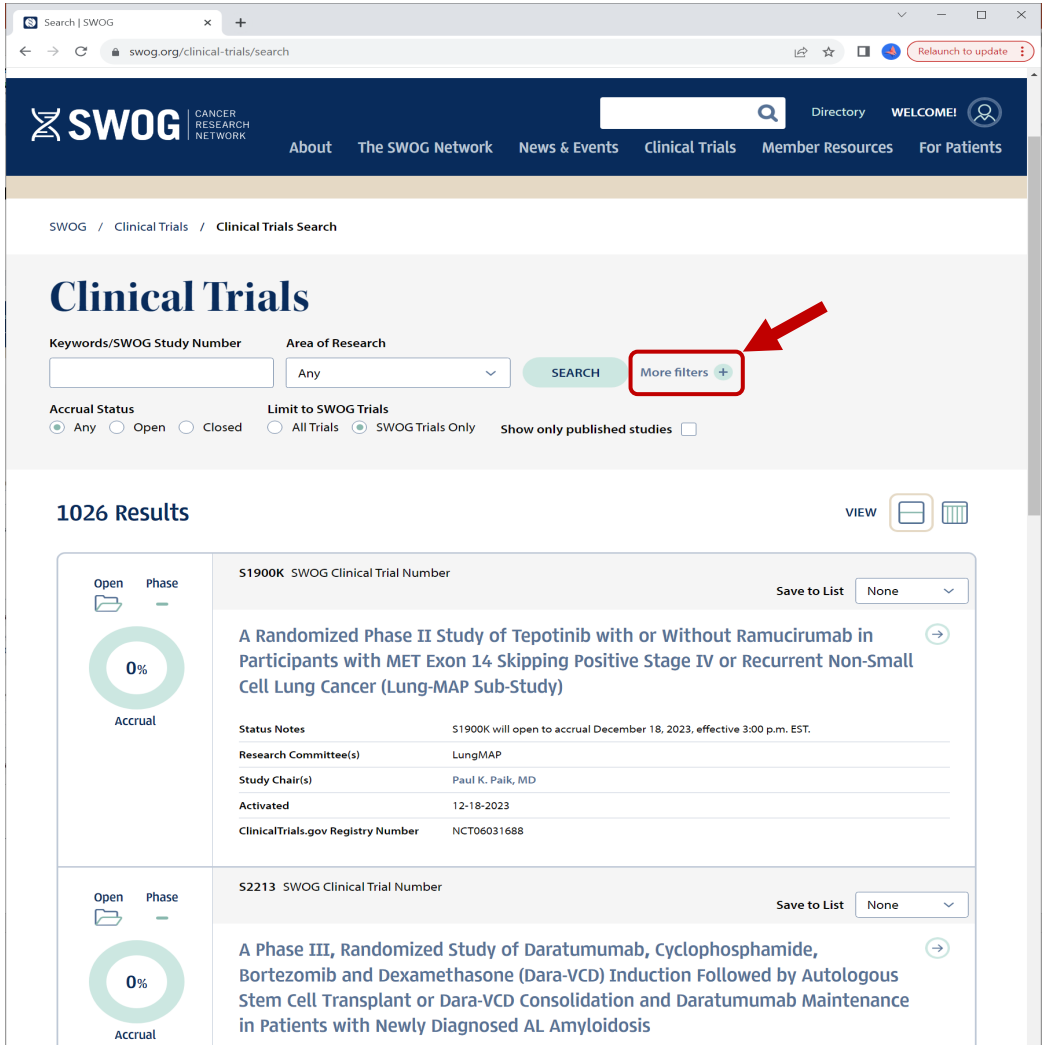
SWOG.org Clinical Trials Search Tool

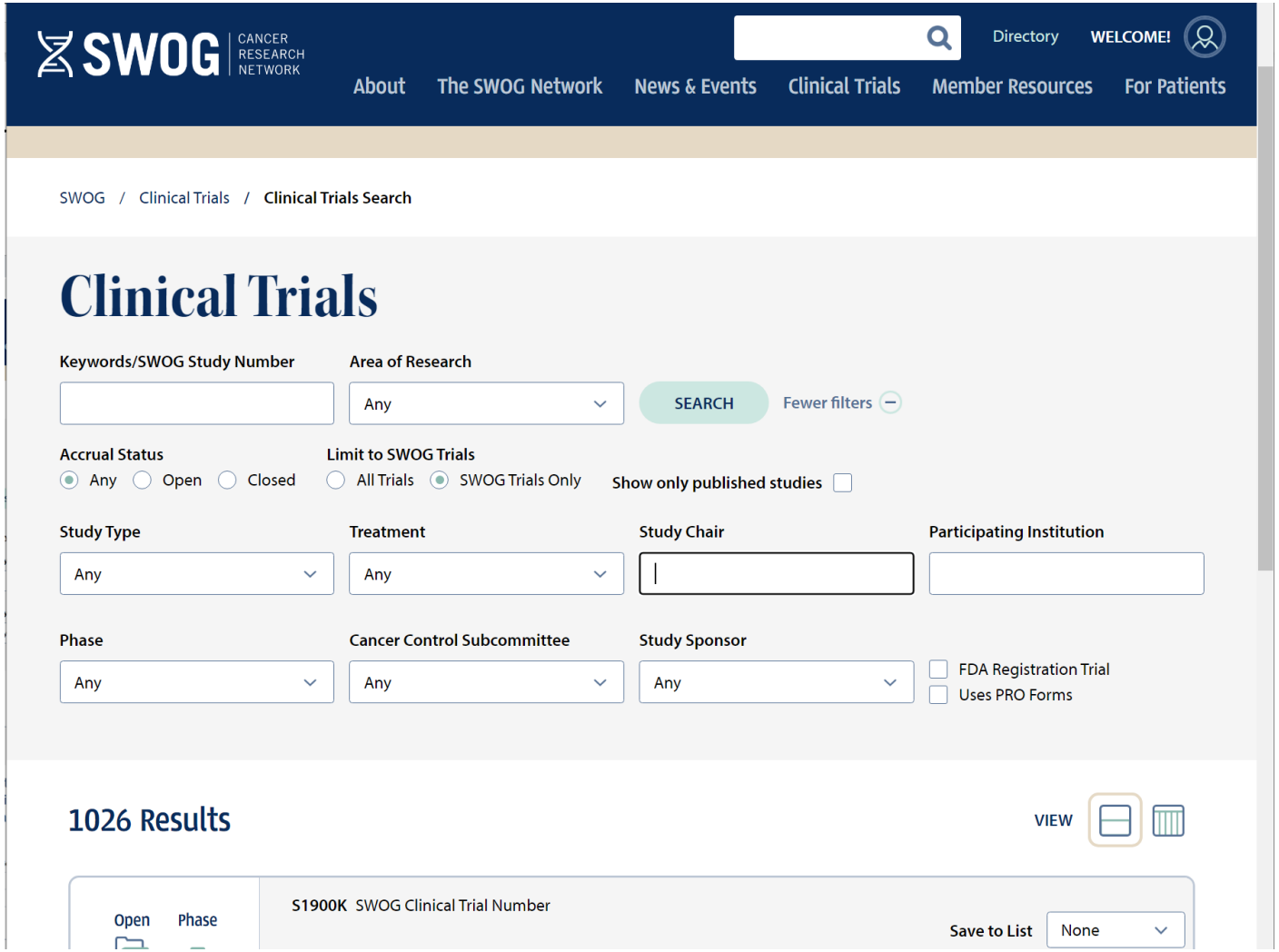
- How do you find trials that match your research goals?
- What data are available for those trials?



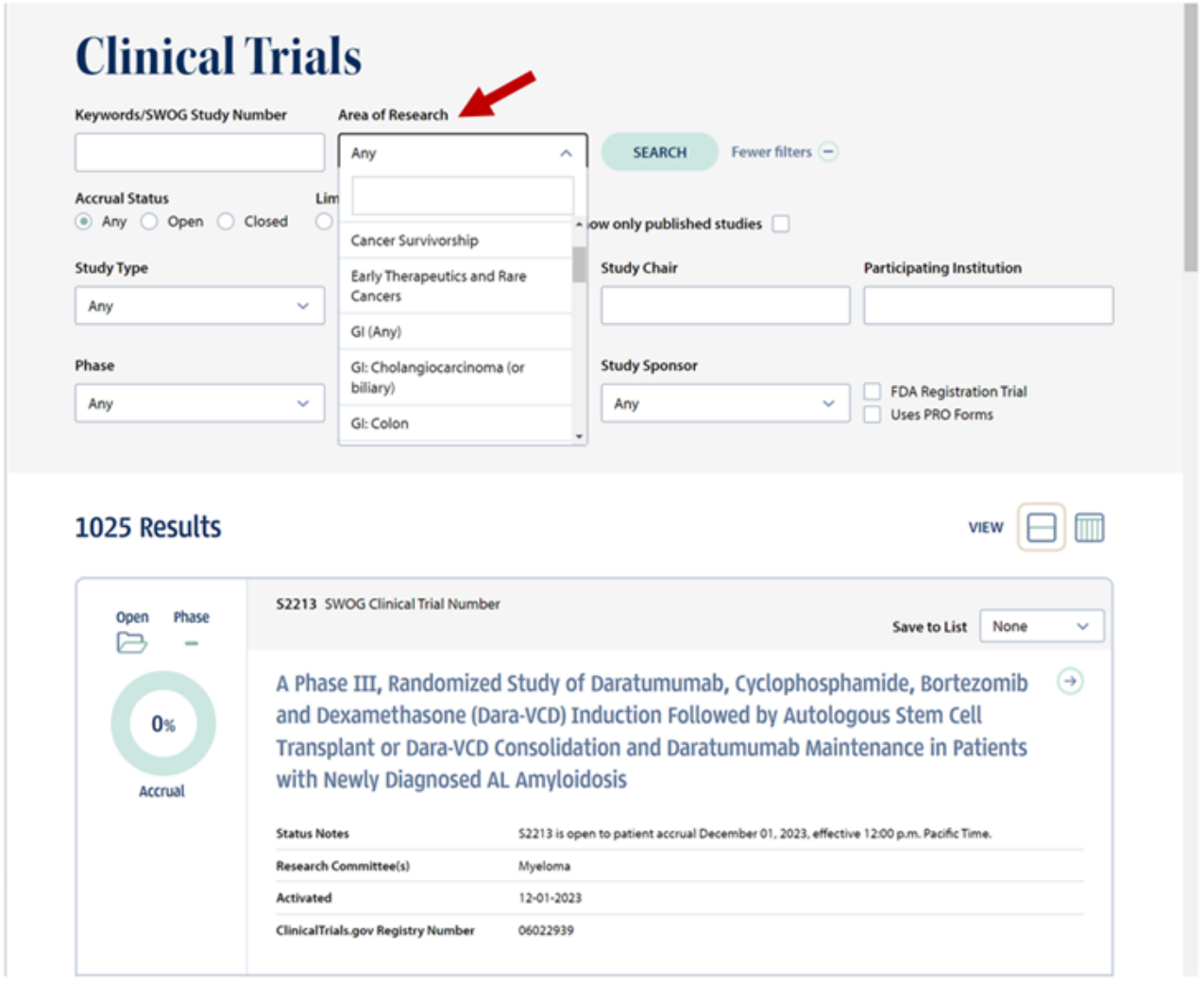


SWOG.org - Searching for Clinical Trials: Filters

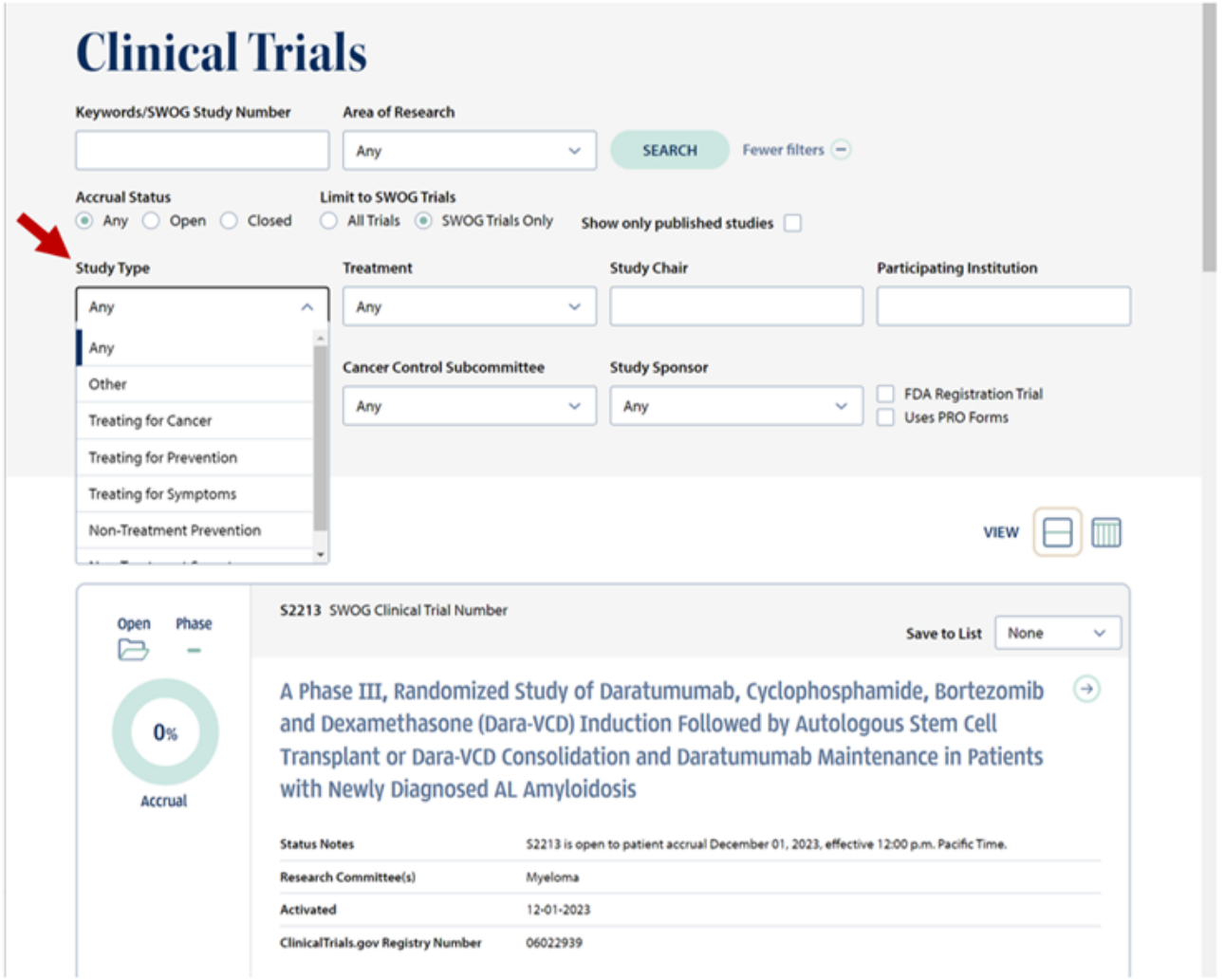




SWOG.org - Searching for Clinical Trials: Filters



SWOG.org - Searching for Clinical Trials: Filters



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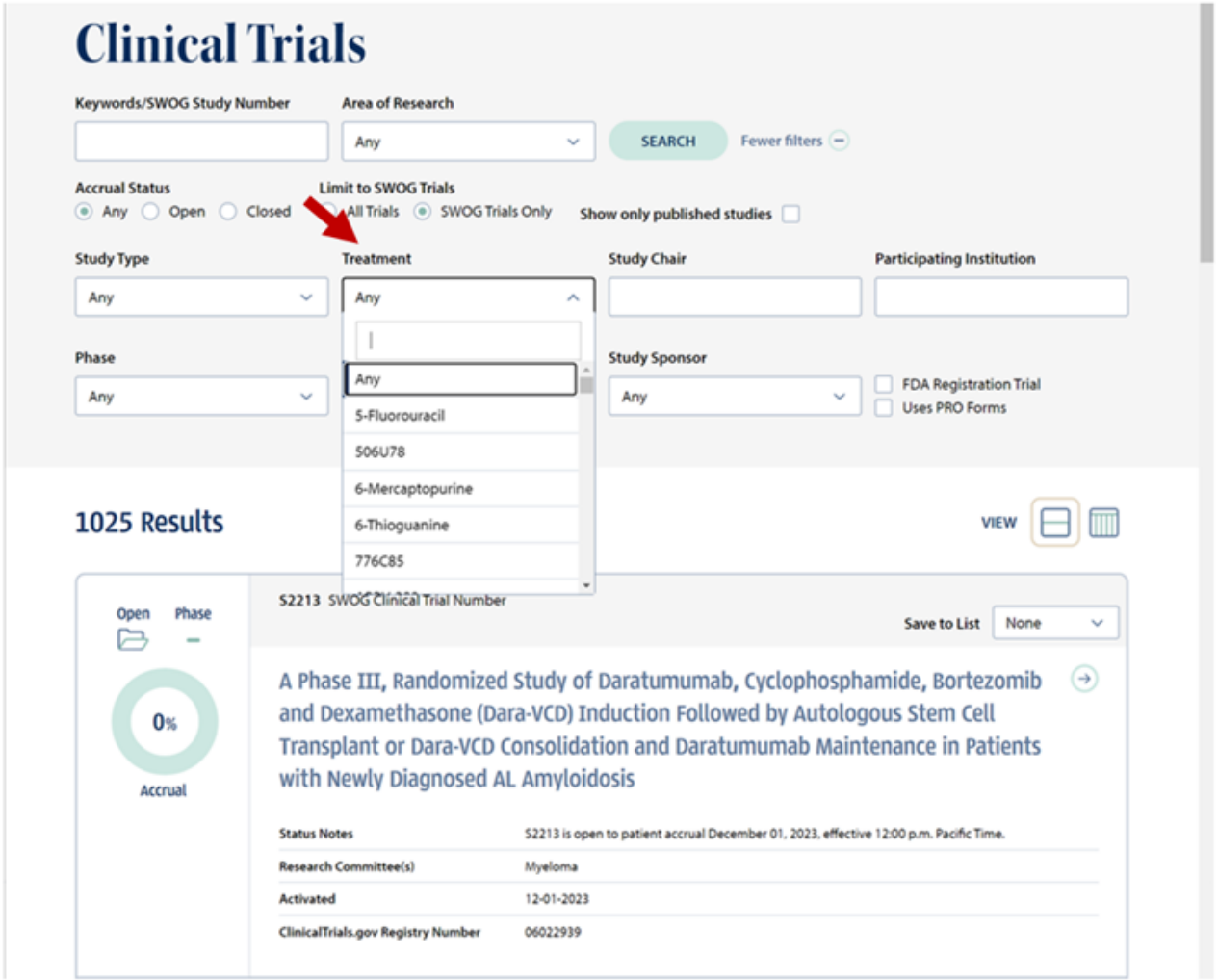

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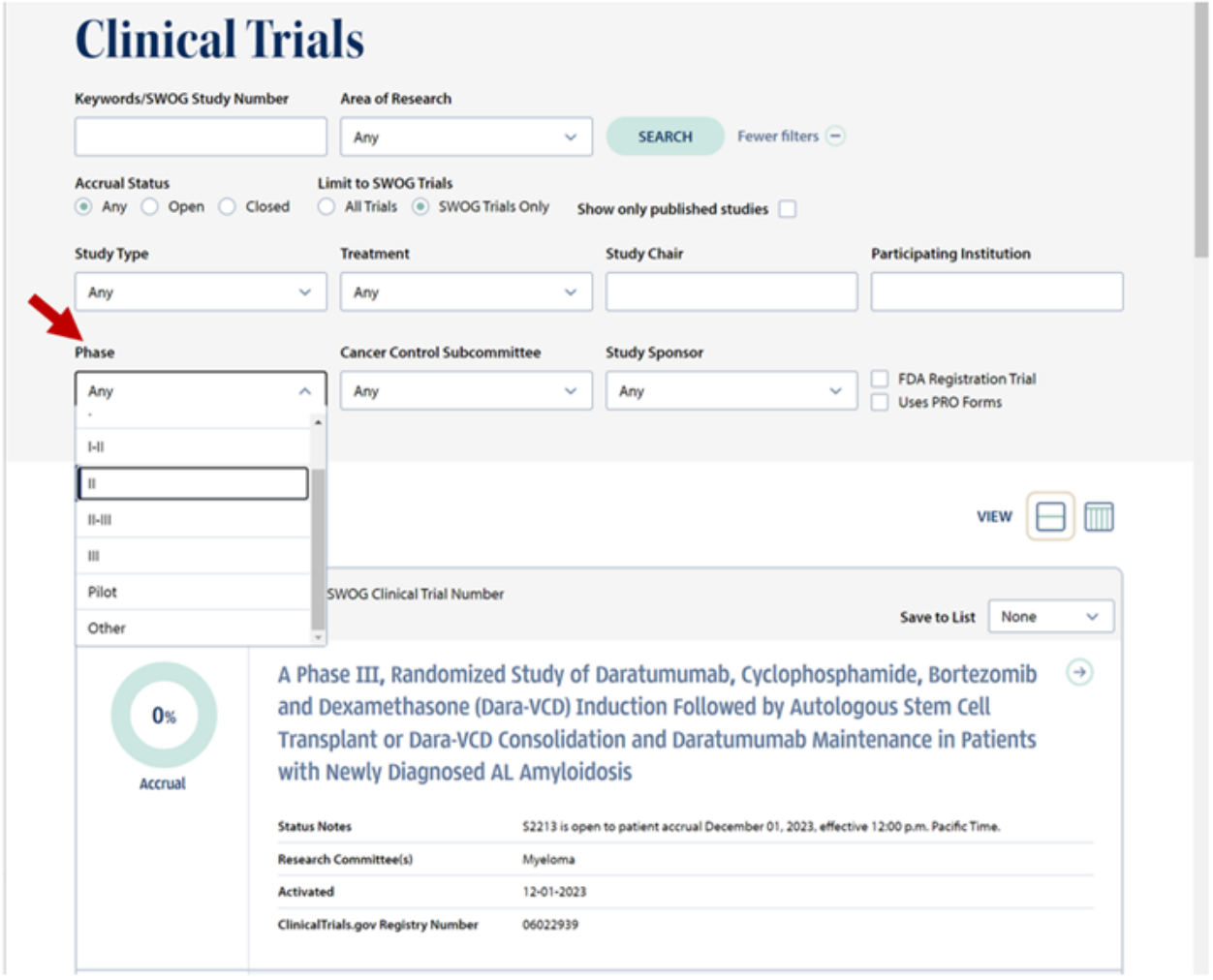

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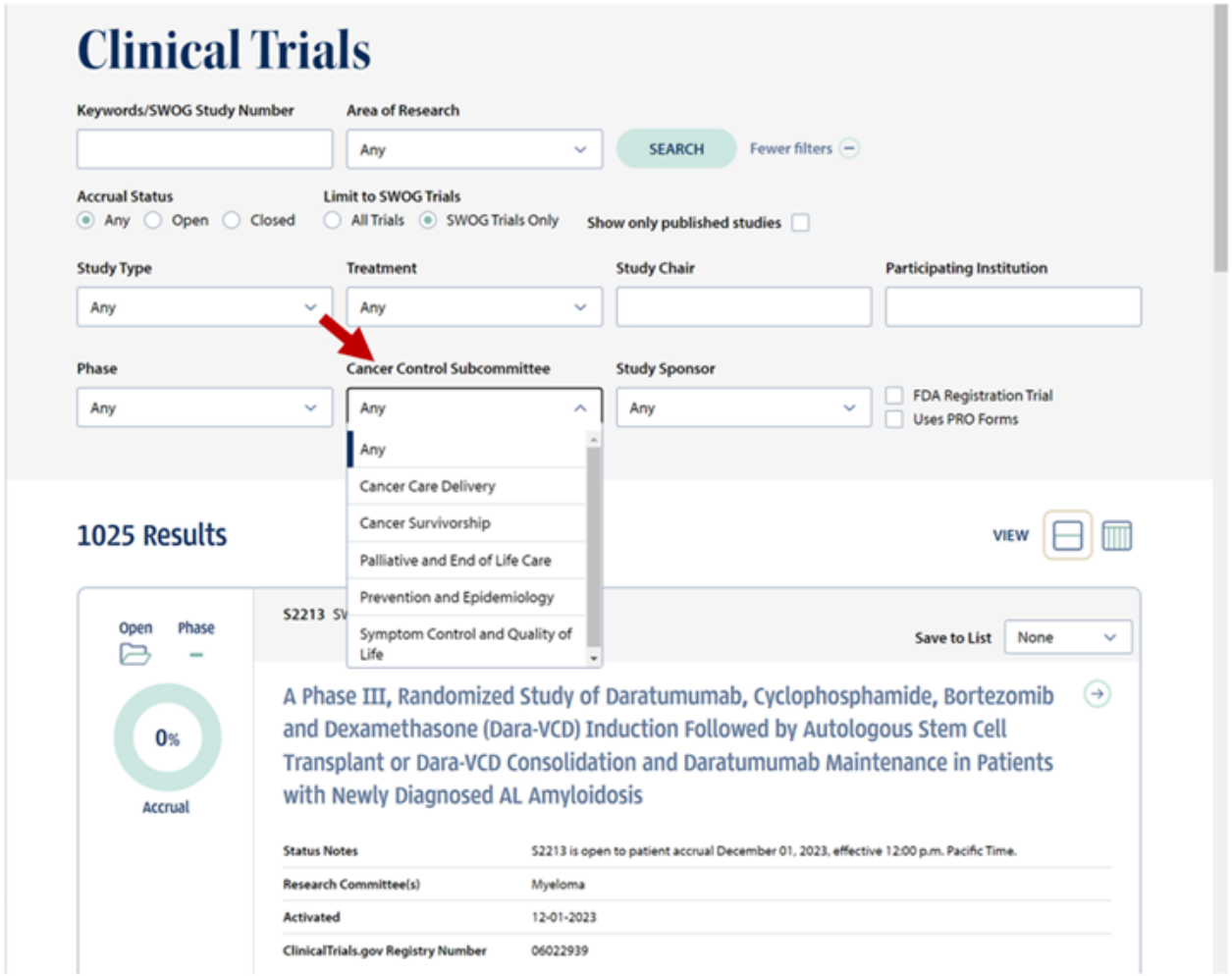

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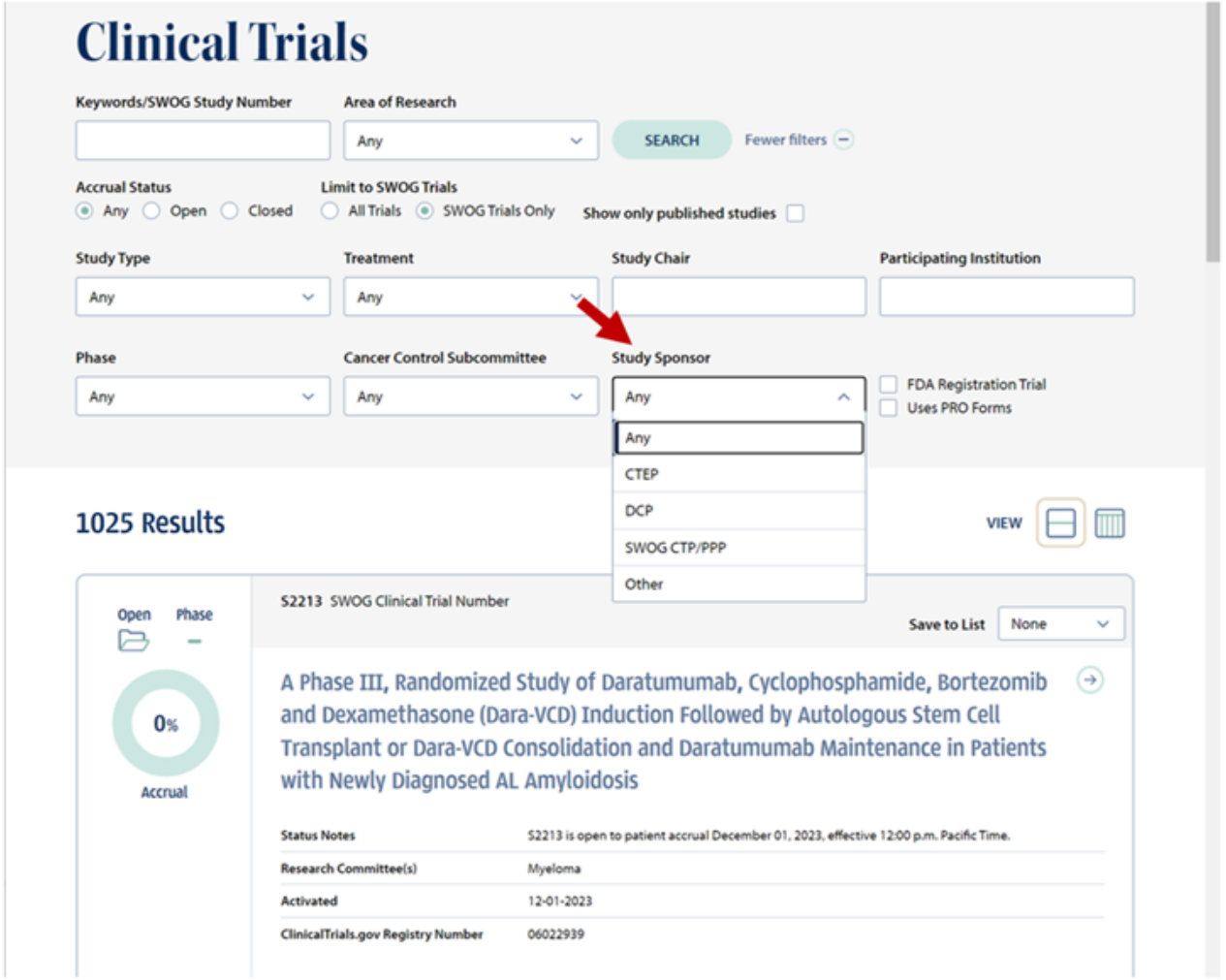
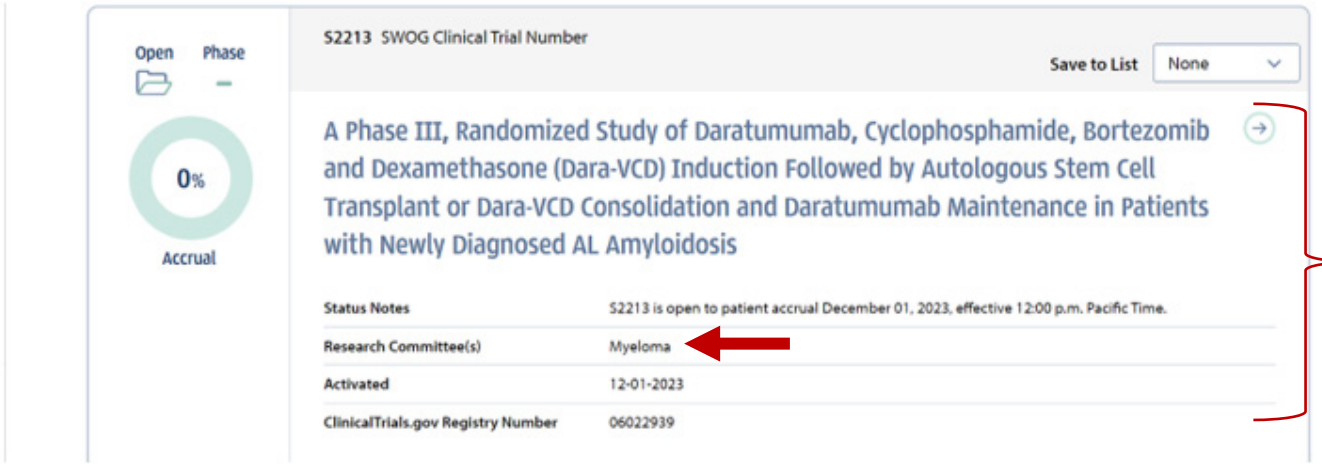


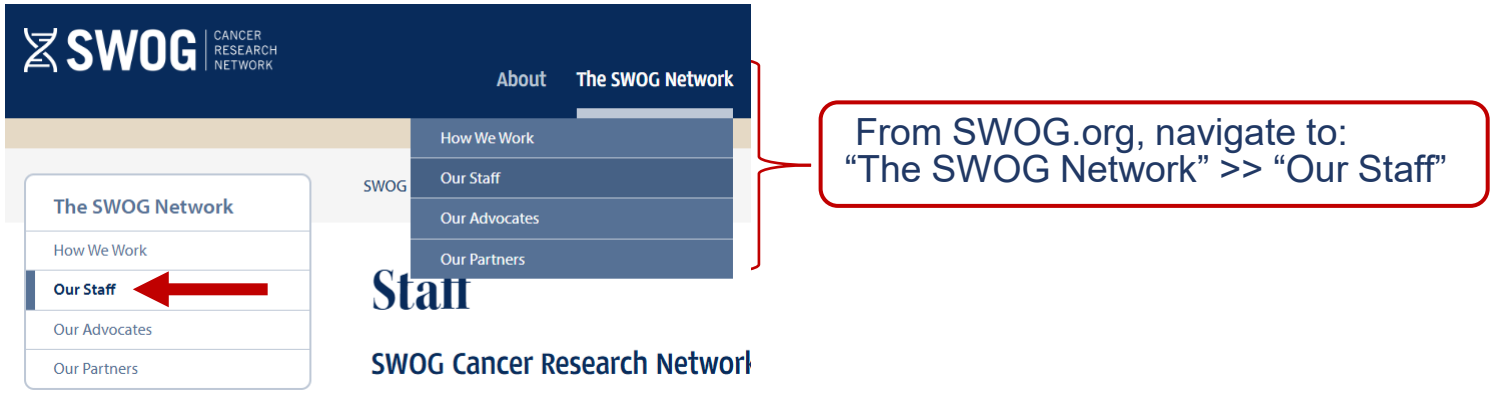
SWOG.org – Identifying the Primary Statistician for a SWOG-led study



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

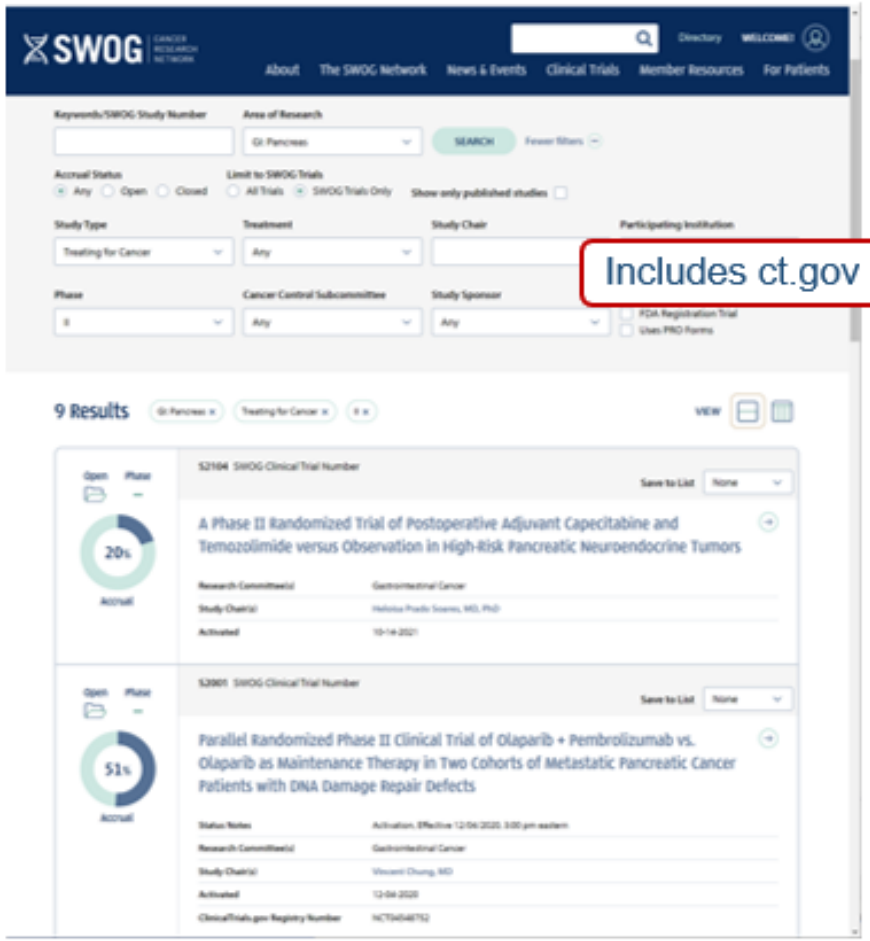
Statistics and Data Management Center -

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

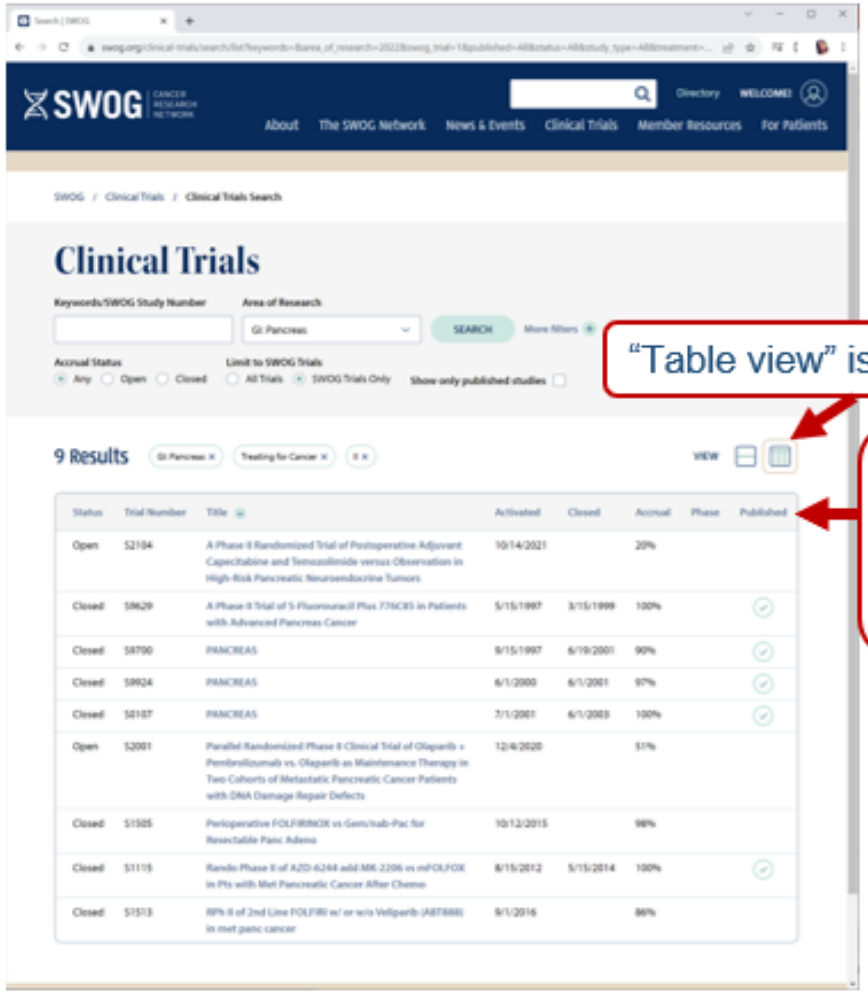
Cancer Research And Biostatistics
1505 Westlake Ave N, Ste 750
Seattle, WA 98109
Phone: 206-652-9711

- 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



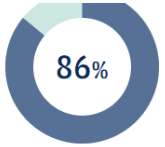
Includes ct.gov registry number.



"Table view" is condensed

Indicates whether the study has been published.

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

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

Research committees

Gastrointestinal Cancer

Treatment

5-Fluorouracil Irinotecan Leucovorin Calcium ABT-888

Eligibility Criteria

Publication Information

Publications link to papers

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 Noel;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

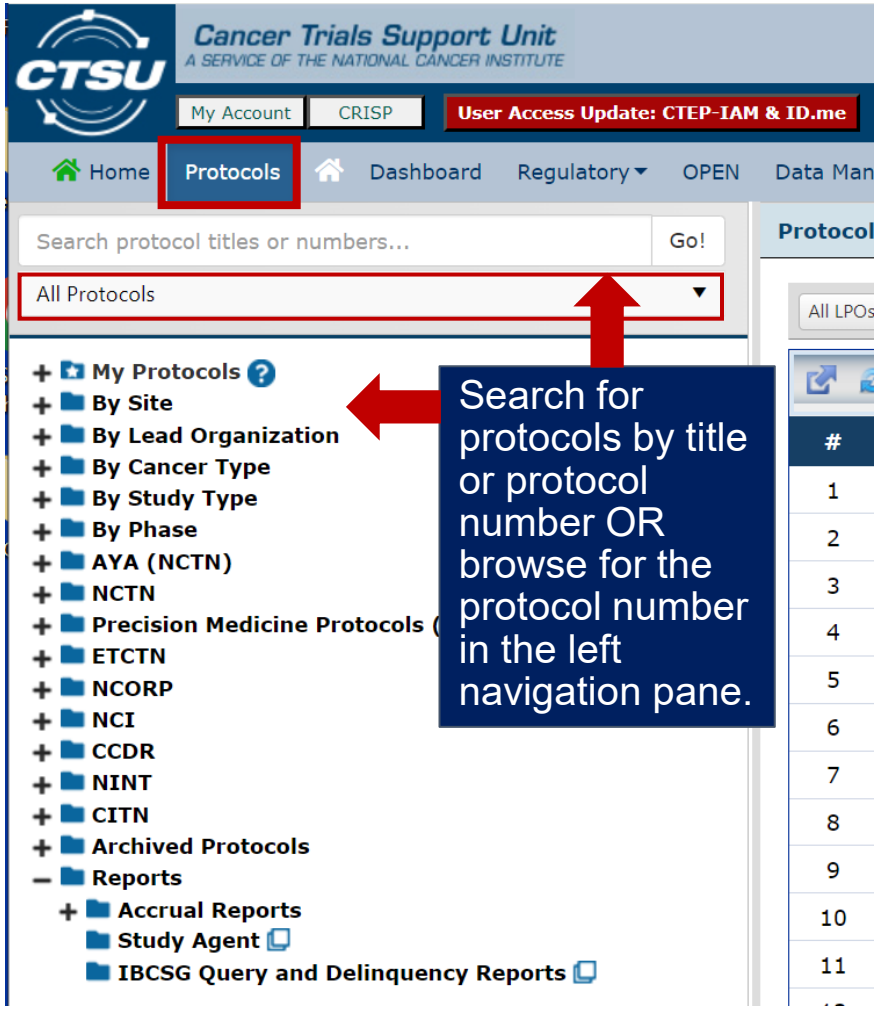
Influence of Modeling Choices on Value of Information Analysis: An Empirical Analysis from a Real-world Experiment

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]

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

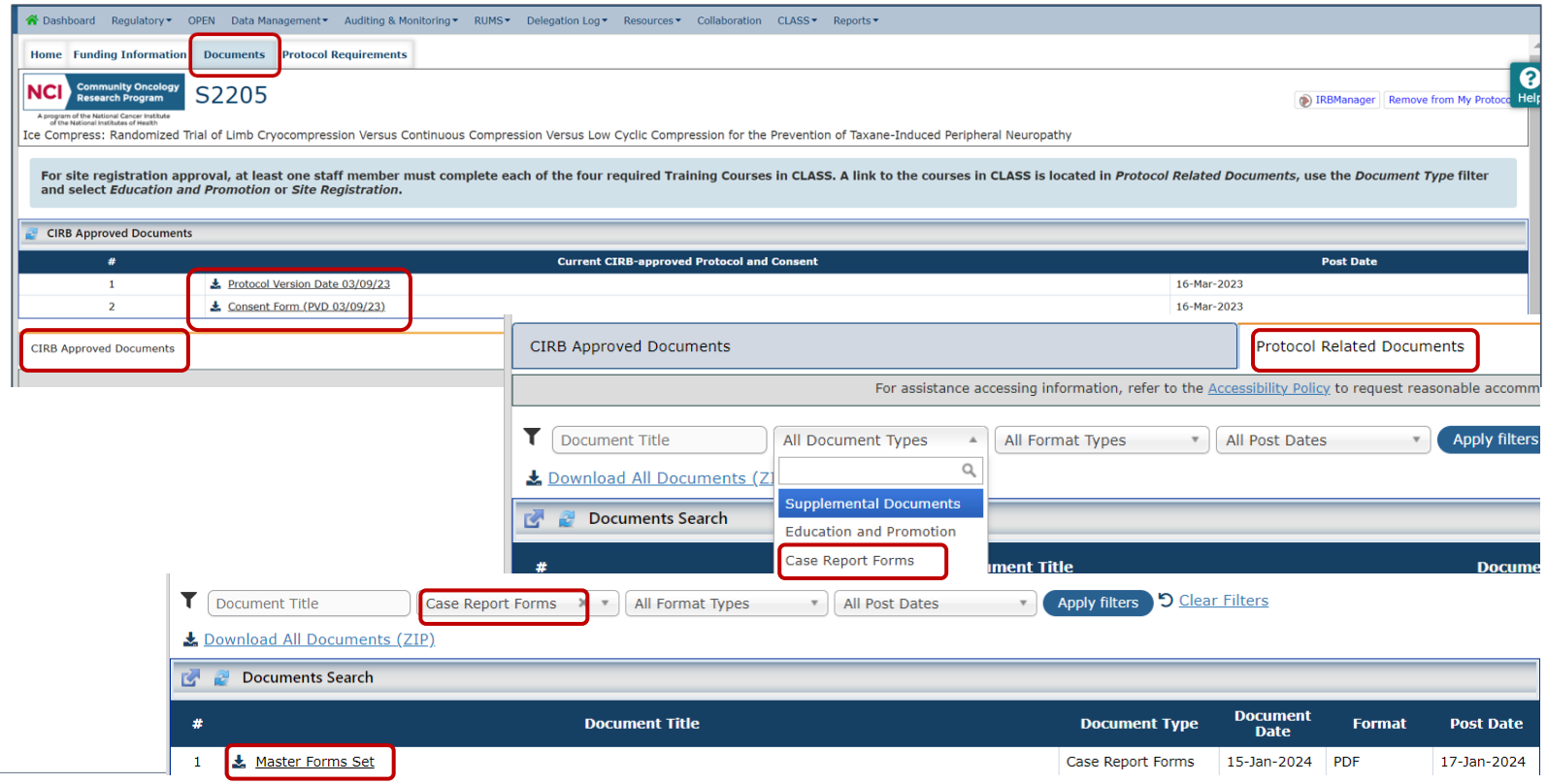
Accessing Protocol-Specific information on CTSU.org



Search for protocols by title or protocol number OR browse for the protocol number in the left navigation pane.

Documents>>CIRB-approved Documents tab includes: Protocol and Consent

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



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	☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐☐☐ mg/m²	☐☐☐.☐ mg	☐☐☐.☐ mg
Carboplatin	☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐☐☐.☐ mg	☐☐☐.☐ mg	☐☐☐.☐ mg
Docetaxel	☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐☐ mg/m²	☐☐☐.☐ mg	☐☐☐.☐ mg
Nab-Paclitaxel	☐☐ ☐☐☐ ☐☐☐☐	☐☐ ☐☐☐ ☐☐☐☐	☐☐☐ mg/m²	☐☐☐.☐ mg	☐☐☐.☐ 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.