SWOG Fall Meeting 2025
Oishi Symposium

Chicago, IL
Welcome!

In honor of and with gratefulness for

Noboru Oishi MD

(1928 – 2020)

and

Jeri Oishi, RN

NCI National Clinical Trials Network

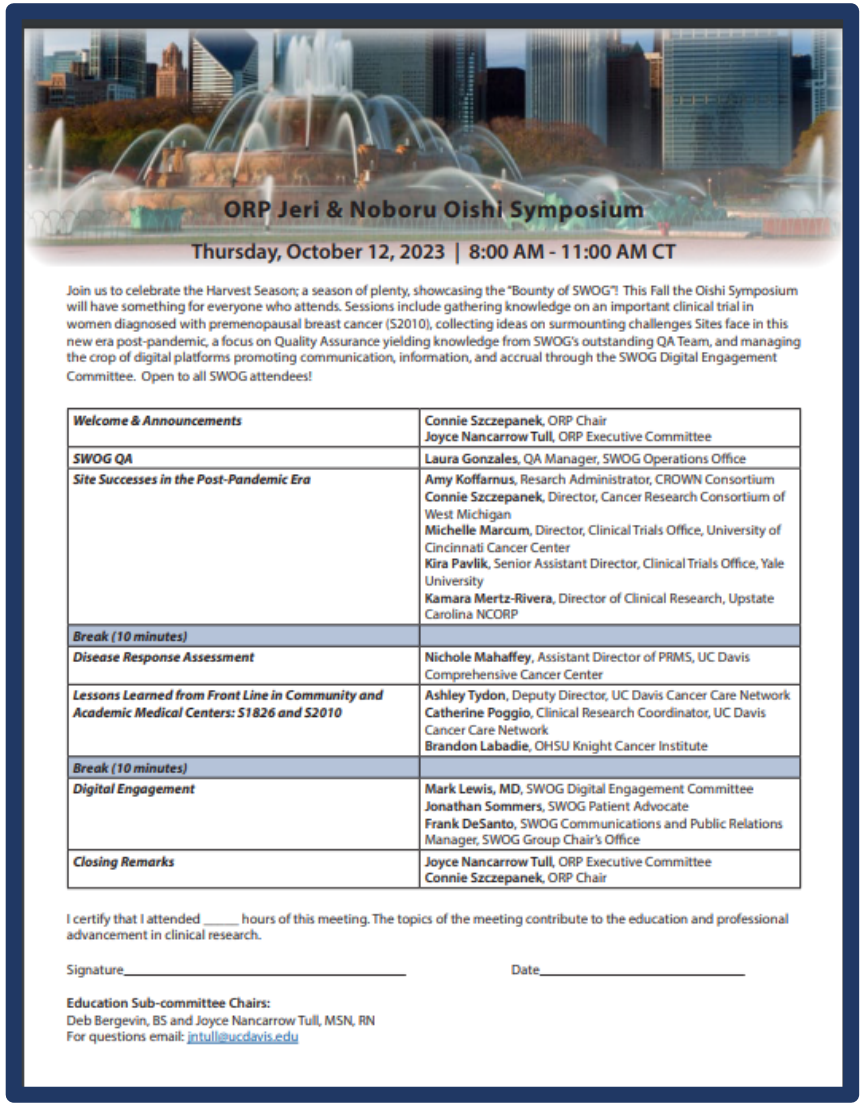
NCI Community Oncology Research Program

Although there are no formal CE credits for this meeting,

PLEASE KEEP YOUR COPY

of the agenda to reflect your attendance

(For use with certification)



ORP Jeri & Noboru Oishi Symposium

Thursday, October 12, 2023 | 8:00 AM - 11:00 AM CT

Join us to celebrate the Harvest Season; a season of plenty, showcasing the "Bounty of SWOG"! This Fall the Oishi Symposium will have something for everyone who attends. Sessions include gathering knowledge on an important clinical trial in women diagnosed with premenopausal breast cancer (S2010), collecting ideas on surmounting challenges Sites face in this new era post-pandemic, a focus on Quality Assurance yielding knowledge from SWOG's outstanding QA Team, and managing the crop of digital platforms promoting communication, information, and accrual through the SWOG Digital Engagement Committee. Open to all SWOG attendees!

Welcome & Announcements	**Connie Szczepanek**, ORP Chair **Joyce Nancarrow Tull**, ORP Executive Committee
SWOG QA	**Laura Gonzales**, QA Manager, SWOG Operations Office
Site Successes in the Post-Pandemic Era	**Amy Koffarnus**, Resarch Administrator, CROWN Consortium **Connie Szczepanek**, Director, Cancer Research Consortium of West Michigan **Michelle Marcum**, Director, Clinical Trials Office, University of Cincinnati Cancer Center **Kira Pavlik**, Senior Assistant Director, Clinical Trials Office, Yale University **Kamara Mertz-Rivera**, Director of Clinical Research, Upstate Carolina NCORP
Break (10 minutes)	
Disease Response Assessment	**Nichole Mahaffey**, Assistant Director of PRMS, UC Davis Comprehensive Cancer Center
Lessons Learned from Front Line in Community and Academic Medical Centers: S1826 and S2010	**Ashley Tydon**, Deputy Director, UC Davis Cancer Care Network **Catherine Poggio**, Clinical Research Coordinator, UC Davis Cancer Care Network **Brandon Labadie**, OHSU Knight Cancer Institute
Break (10 minutes)	
Digital Engagement	**Mark Lewis, MD**, SWOG Digital Engagement Committee **Jonathan Sommers**, SWOG Patient Advocate **Frank DeSanto**, SWOG Communications and Public Relations Manager, SWOG Group Chair's Office
Closing Remarks	**Joyce Nancarrow Tull**, ORP Executive Committee **Connie Szczepanek**, ORP Chair

I certify that I attended _____ hours of this meeting. The topics of the meeting contribute to the education and professional advancement in clinical research.

Signature_____ Date_____

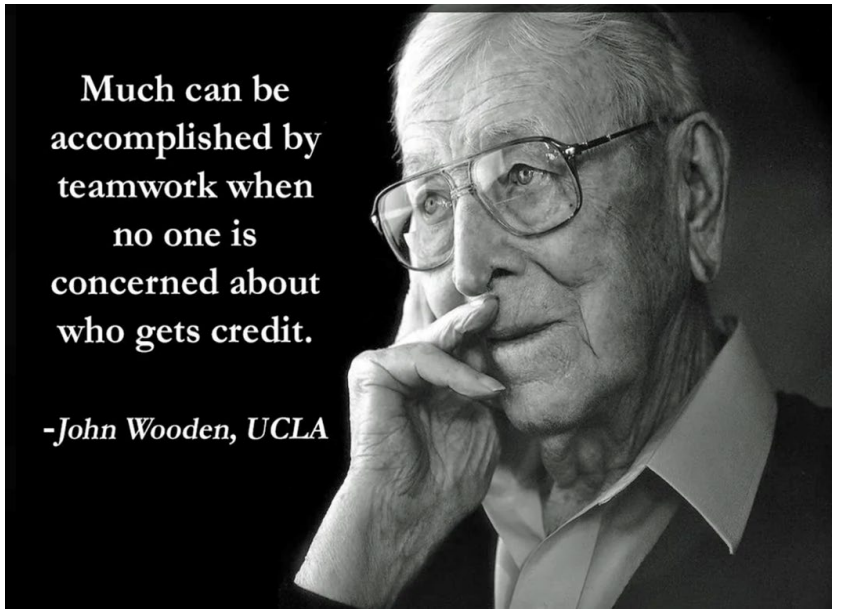
Education Sub-committee Chairs:
Deb Bergevin, BS and Joyce Nancarrow Tull, MSN, RN
For questions email: jntull@ucdavis.edu

YOU are The ORP Committee!

"SWOG holds a fundamental conviction that the **O**ncology **R**esearch **P**rofessionals (ORP) play a crucial role in the successful development, implementation, and analysis of any SWOG clinical trial."

Agenda

- Welcome, Opening Remarks, and Announcements
- CTSU Updates
- SWOG Quality Assurance
- SWOG Communications: Plain Language and Patient Summaries
- Cancer Research in the Communities We Serve: "Life, liberty and the pursuit of happiness": Implementing Equitable Access to Clinical Trials
- Panel Presentation: Community Engagement With Our Sites



Originally: Harry S. Truman 33rd President of The United States of America

Cancer Trials Support Unit
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Linking practice to progress

Cancer Trials Support Unit (CTSU) Updates

Krishna Chothwani, BS, ACRP-CP

CTSU Protocol Team Manager

Agenda

CTSU Public Website – Overview and New Staff Resources

Data Quality Portal (DQP) – Overview, Tips, Reminders, Frequently Asked Questions (FAQs), and Resources

Oncology Patient Enrollment Network (OPEN) - Slot Reservation for MYELOMATCH: Introduction, Process, and Resources

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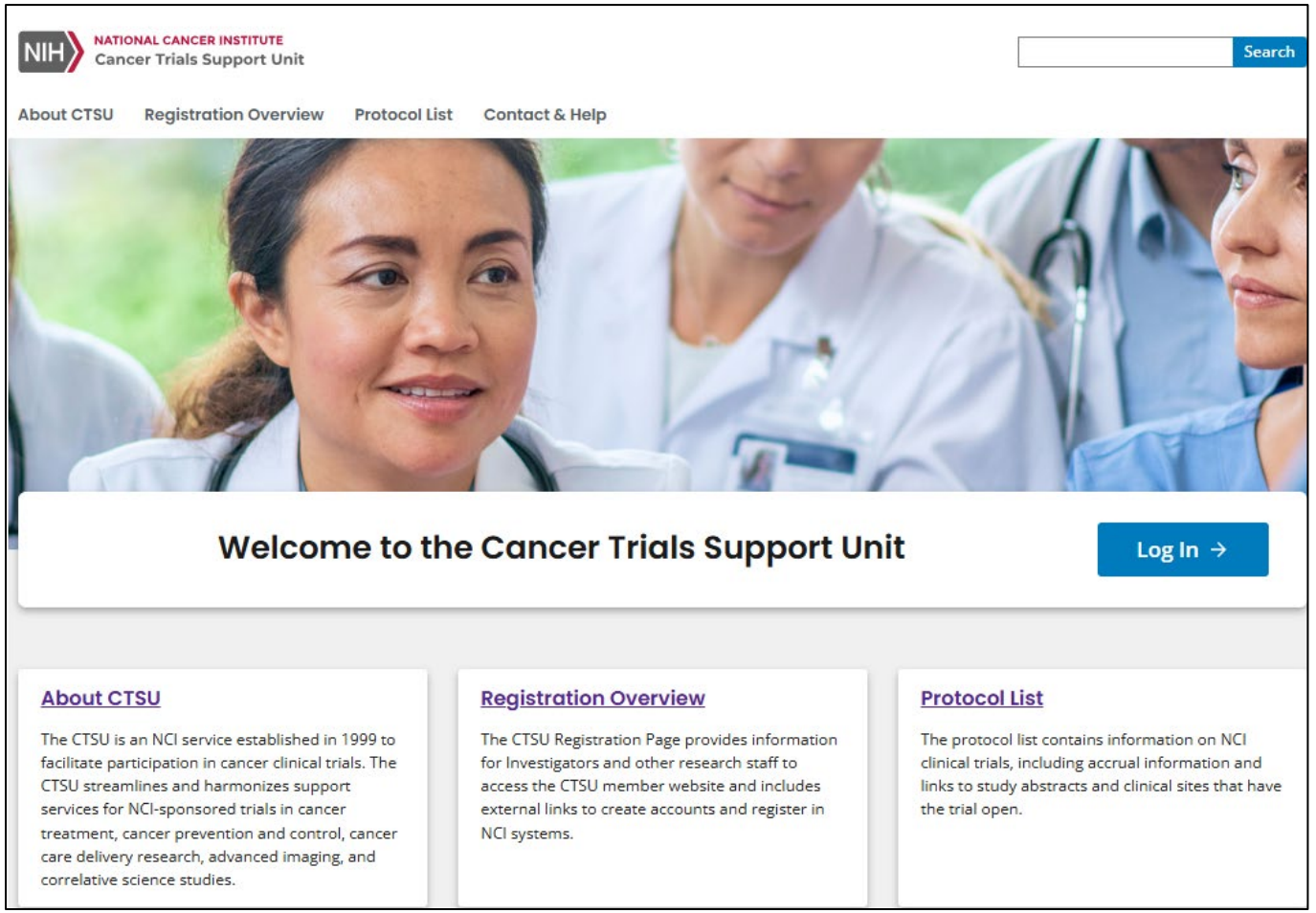
CTSU Public Website

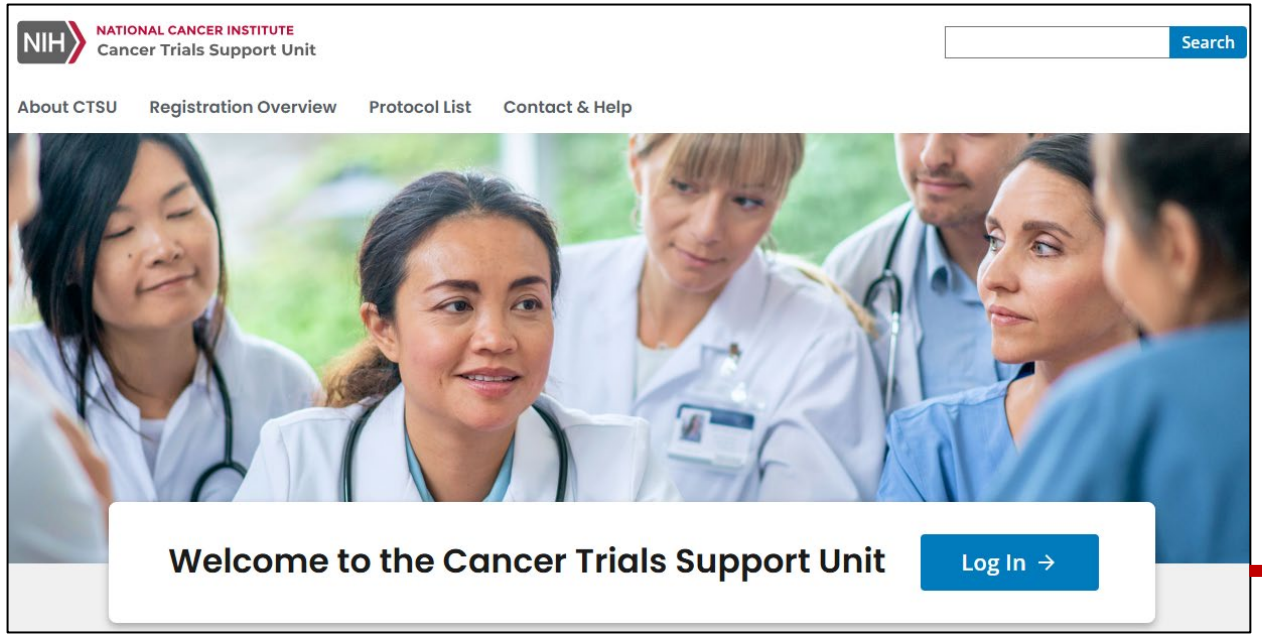
New Public Website: ctsu.cancer.gov

- ✓ **Moved to a .gov domain**
- ✓ **Streamlined content, modern aesthetic**
- ✓ **Complies with government standards**

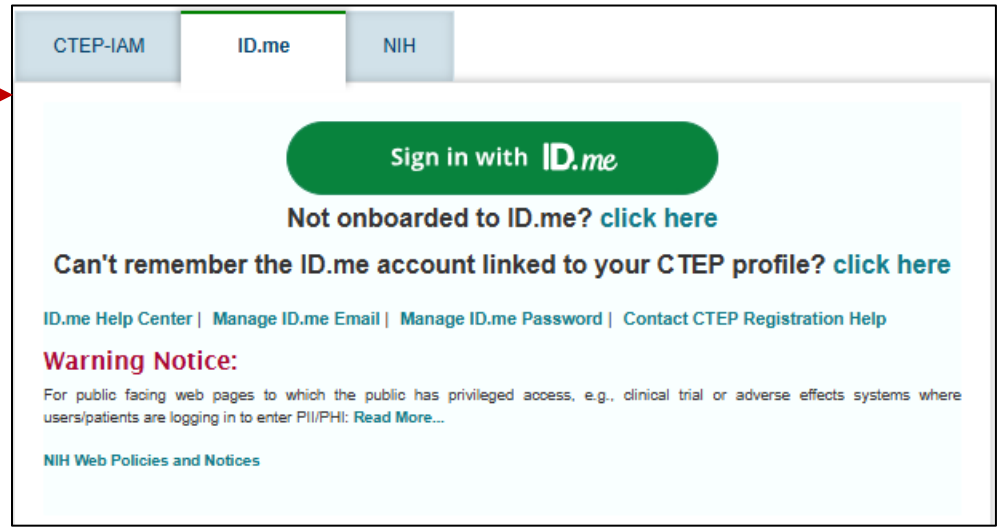


https://ctsu.cancer.gov/

Log In Point for Member Side

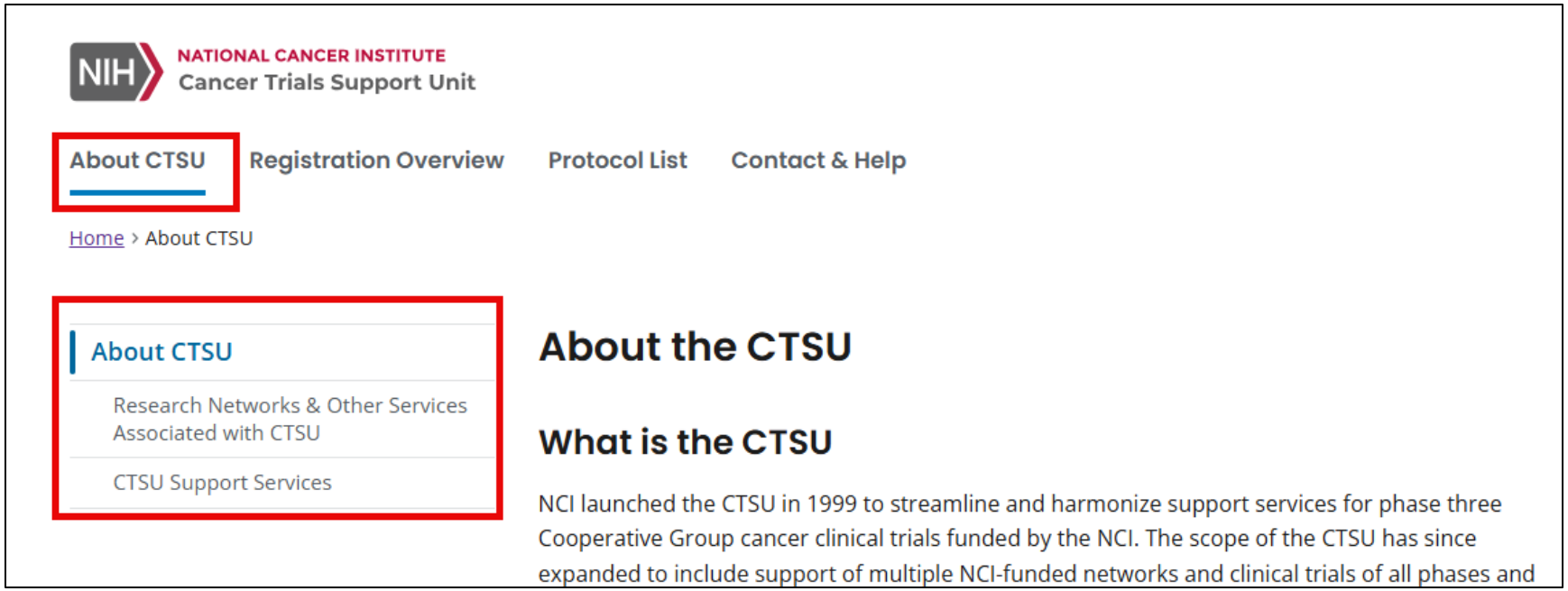


Use your ID.me credentials to log in



About CTSU

- Serves as an introduction to CTSU
- Starting point for new staff/onboarding
  - Not meant to be comprehensive for new member education
  - More in-depth information is on the member side in Resources



https://ctsu.cancer.gov/

Registration Overview

- Who can register
  - Explains the five registration types in Cancer Therapy Evaluation Program (CTEP) Registration and Credential Repository (RCR) system that can access CTSU
  - Describes rosters
  - Shows roles needed for access to some CTSU applications and systems

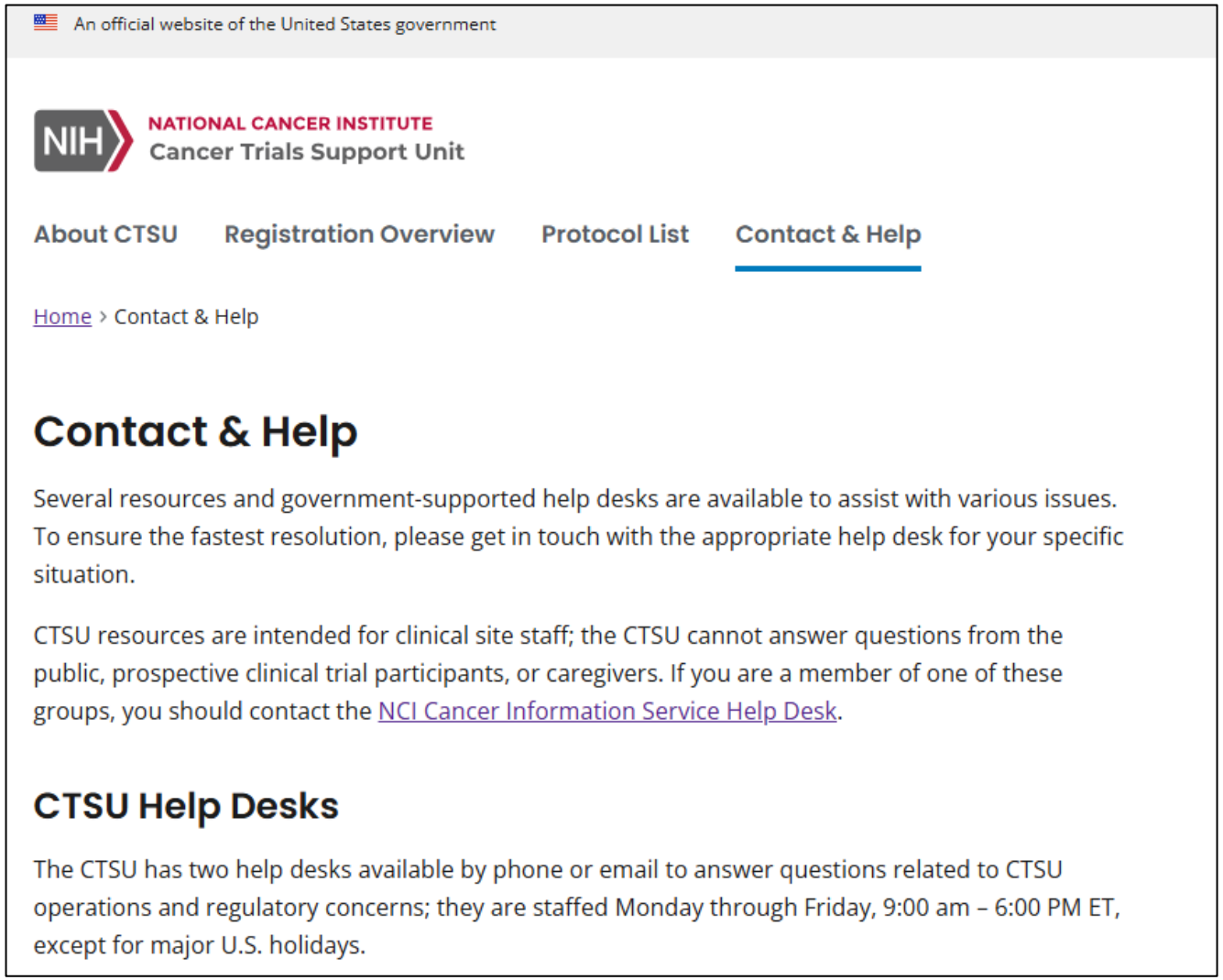
- How to register
  - Explains registration *is not through CTSU*
  - Links to the new **CTEP User Registration Page** with all instructions and resources in one place

Public Protocol List

- Lists studies open for cross-network participation
- Links to ClinicalTrials.gov when available
- Current accrual
- Contains search filters

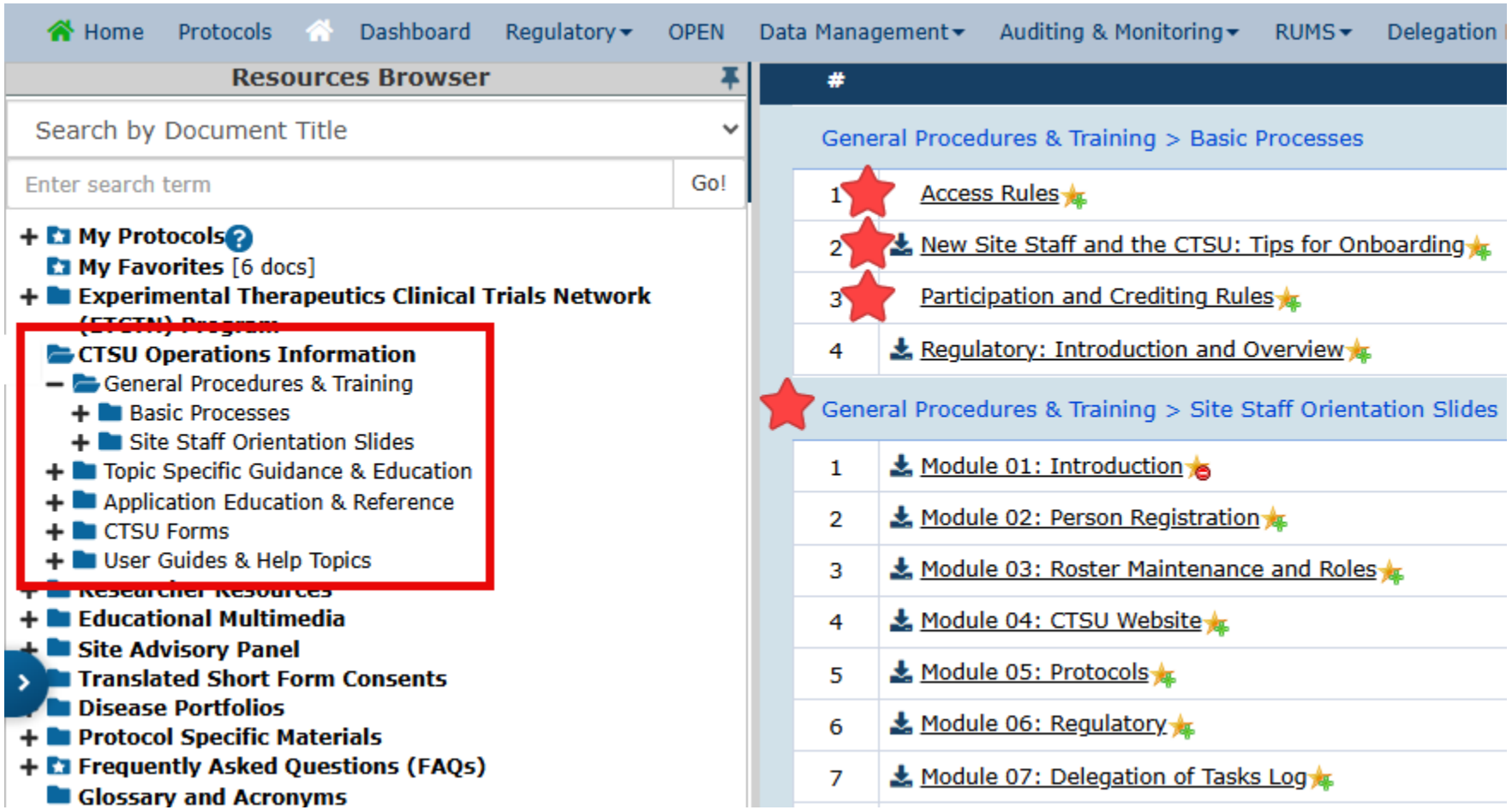
Contact & Help Page

- Contains CTSU Help Desk information
- Also includes other Help Desks frequently contacted
- Explains where to go for specific issues



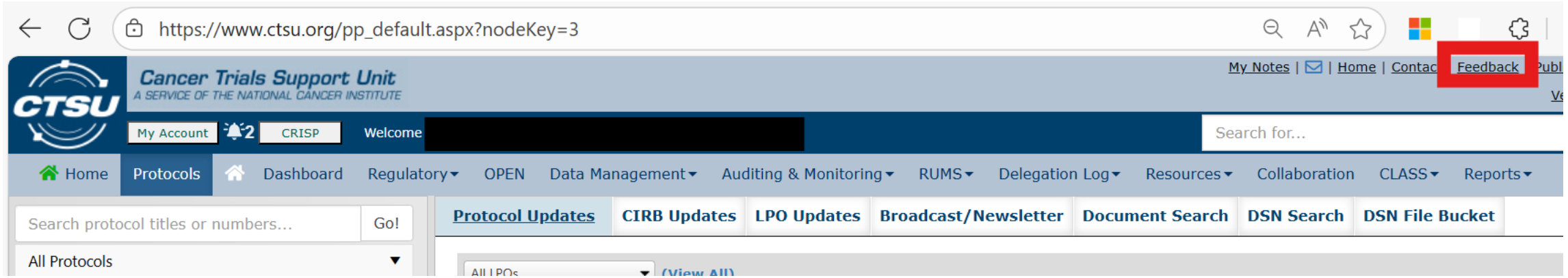
New Staff Education

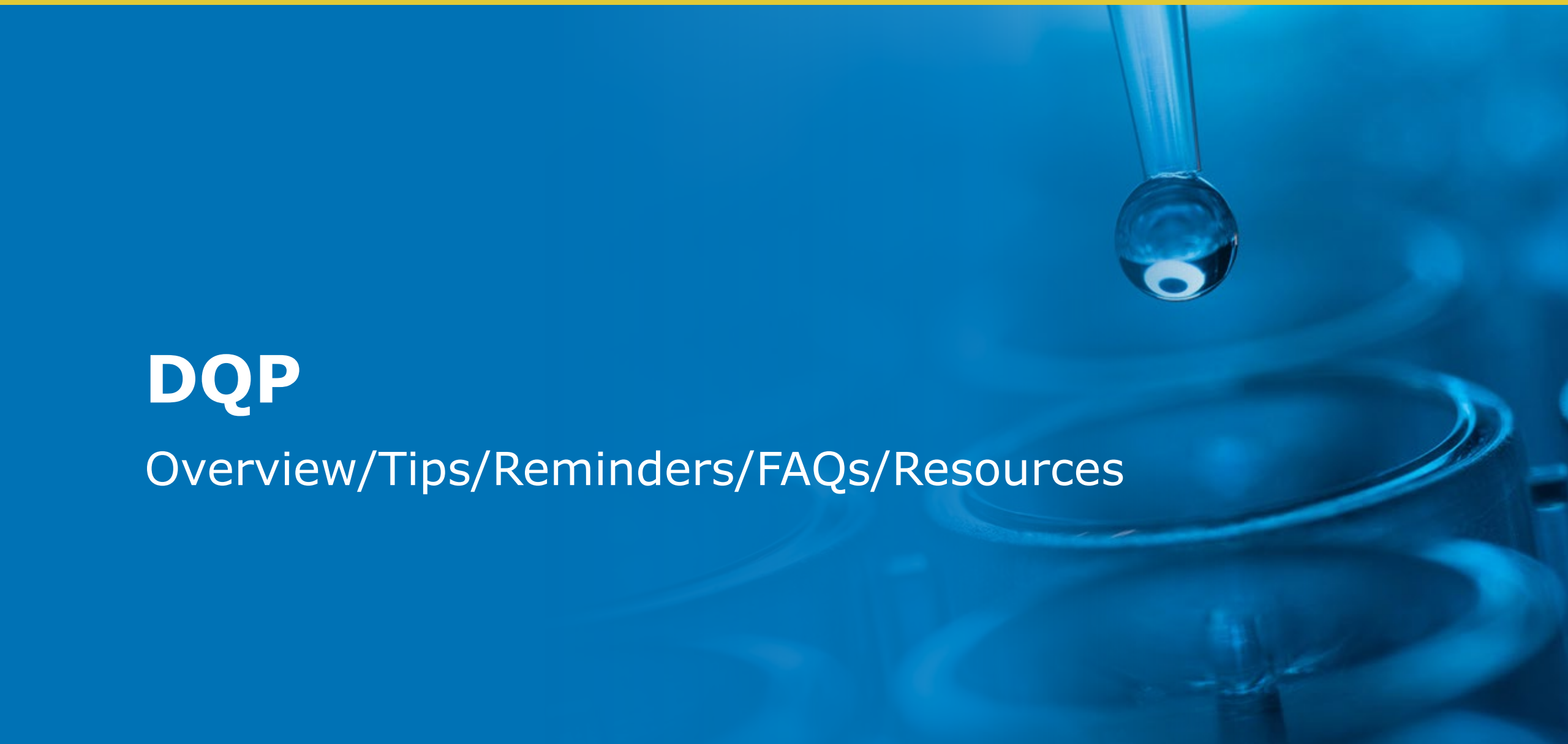
- Recommend the *About CTSU* and *Registration* sections for new staff education
  - Comprised of information that was previously in posted PDFs
- Additional materials are in Resources > CTSU Operations



Feedback

- Email **ctsucontact@westat.com** or via the Feedback link on the member site





DQP

Overview/Tips/Reminders/FAQs/Resources

DQP Benefits

One Stop Shopping

- Access all Rave studies
- Direct-link into Rave URLs and directly manage queries/delinquencies
- Monitor data quality and timeliness
- Review metrics and performance

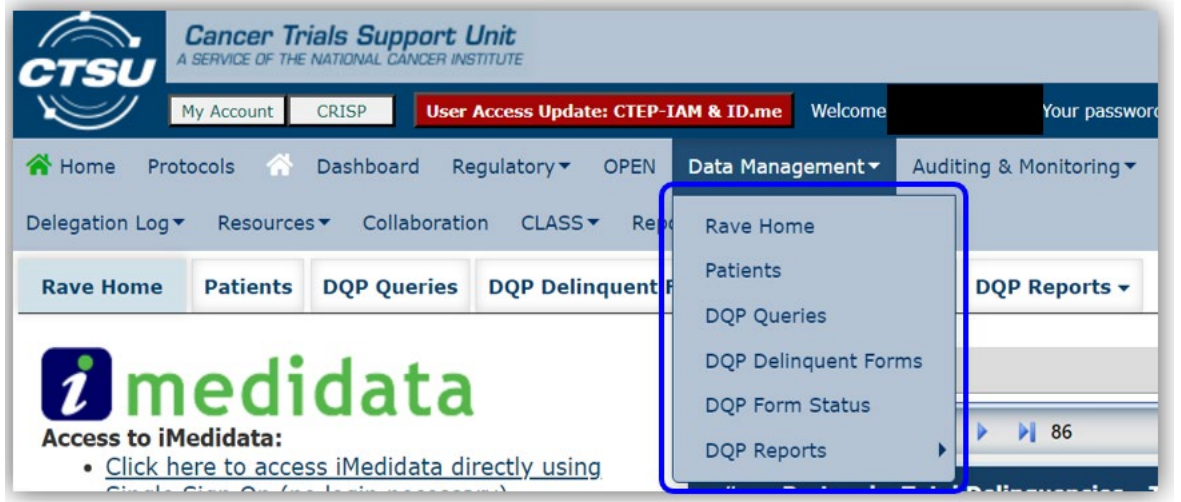
Standardized Experience

- Consistent experience across Lead Protocol Organizations (LPOs) and Rave studies

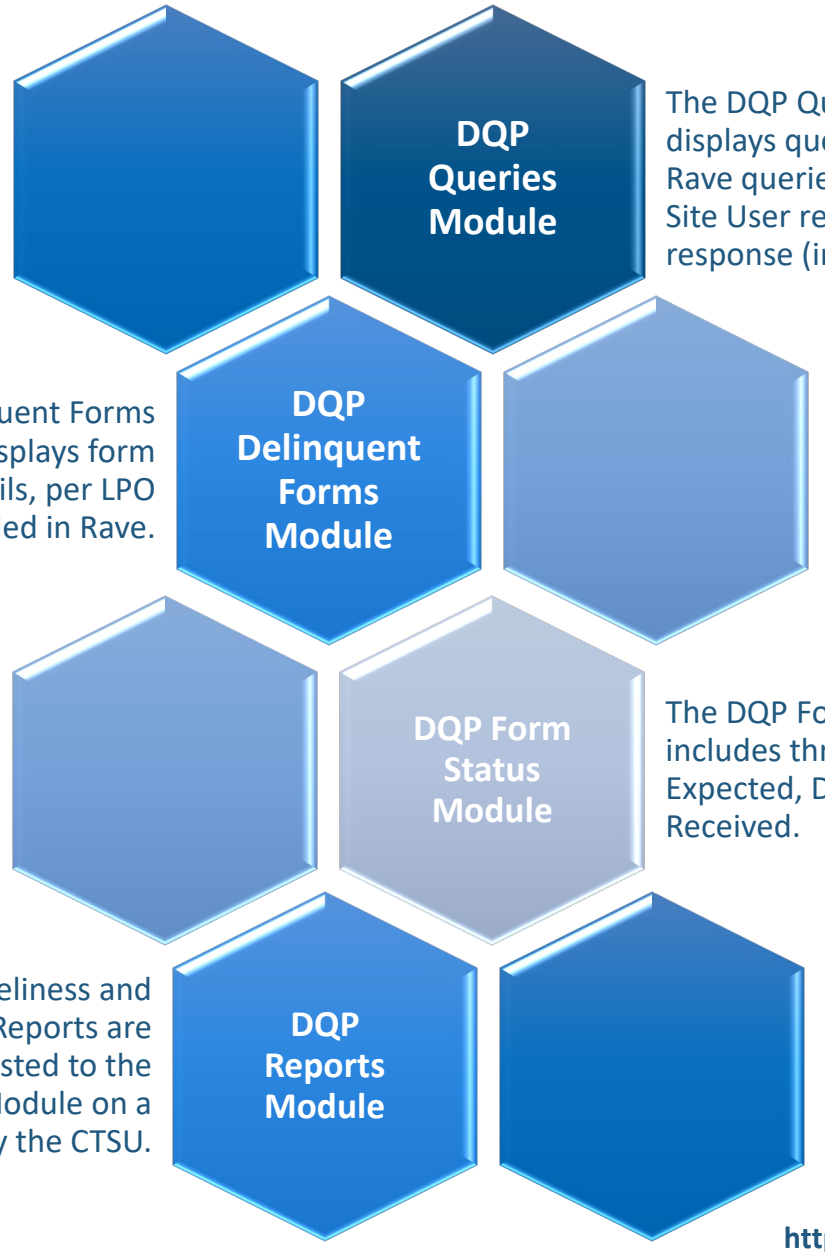
Reports and Other Tools

CTSU member website > Data Management

- Five Rave/DQP tab dropdown options
  - Four DQP subtabs plus a Rave Home subtab
- CTEP-IAM and ID.me accounts are required to access



DQP Modules



The DQP Queries Module displays query details for Rave queries that require Site User review and response (in Rave).

The DQP Delinquent Forms module displays form delinquency details, per LPO requirements specified in Rave.

The DQP Form Status Module includes three statuses: Expected, Delinquent, and Received.

The DQP Form Timeliness and Query Timeliness Reports are generated and posted to the DQP Reports Module on a quarterly basis by the CTSU.

CTSU Data Delinquency Notifications

- Bi-Monthly notifications sent via email to site staff assigned a Primary Contact role on one or more LPO rosters
  - Numeric A-M NCI site codes issued the 1st and 15th of each month
  - NCI site codes N-Z issued the 8th and 22nd of each month
- Notifications contain a summary of delinquent forms and outstanding queries specified on the DQP
- Recipients can unsubscribe and resubscribe to these notifications via the CTSU Report and Information Subscription Portal (CRISP) on the CTSU website
- Site staff who would like to receive these notifications can also subscribe via CRISP

Recommended Process

- CTSU recommends the following process flow:

1. Review the **DQP** to identify delinquent forms and queries
2. Manage delinquent forms and queries **in Rave at the form and field levels**

- Rave Considerations
  - The Rave Task Summary and Rave folders do not always correctly reflect delinquent forms and queries that need to be managed by site staff in Rave
  - Delinquent forms and queries that require site management are always displayed at the Rave form/field level

Differences Between the DQP and Rave

- A few scenarios may yield differences between the DQP and Rave
  - DQP Delinquent Forms and Unanswered Rave Queries
    - A form is delinquent on the DQP until data entry is completed and initial "Site from System" and "Non-Conformant" queries are answered for the form in Rave. Site staff must manage these forms and queries in Rave.
  - Display of Overdue Forms and Queries in Rave
    - Overdue Forms and Queries may not always be displayed in the Rave Task Summary or at the Rave folder level. Site staff should review delinquent forms and queries in Rave at the form/field level.

Enhancements and System Refresh

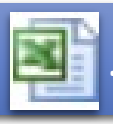
- **DQP Fixes/Enhancements:** DQP delinquent Forms and Queries that are related to released or pending DQP enhancements may still be displayed on the DQP. These forms and queries are removed from the DQP by CTSU or LPO staff as they are identified and verified.
- **REMEMBER...** the DQP system refresh runs on a nightly basis.
  - Delinquent forms will be removed from the DQP if data entry and cleaning activities have been completed by the site in Rave
  - Queries are removed from the DQP if answered by the site in Rave

Reminders

Available Reports

- **DQP Summary Table** [Provides total delinquent form/total delinquent query counts for each protocol]
- **Aging Report Summary** [Provides delinquent form/query counts for each protocol]
- **Delinquencies/Queries by Form** [Provides delinquent form/query counts for all sites and all forms for a protocol]
- **Rave Delinquencies/Queries** [Provides delinquent form/query details for a site and patient]
- **DQP Form Status Reports** [Provides 'Expected', 'Delinquent', Received' form details for a site for protocols/sites]
- **DQP Timeliness Reports** [Provides quarterly metrics of expected and received forms/queries for all protocols]
- **DQP Excel Reports** [Provides a listing of form or query delinquencies]

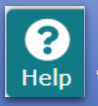
Exporting Reports

- DQP Reports can be exported via the More Commands icon  or the Excel icon  .

FAQs

- The DQP FAQs provide information on common user-reported questions and are available via the CTSU Website > Resources > Frequently Asked Questions (FAQs) > Data Quality Portal (DQP).

Help Topics

- The DQP Help Topics aid in using the DQP and are accessible via the Help Topics icon 

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FAQs

1) Why is my form still specified as delinquent on the DQP after I entered it in Rave?

- To be considered as received, 1) data entry must be complete, and 2) all initial “Site from System” and “Non-Conformant” queries on a form must be answered.
- Allow for 24 hours after entry, because DQP system refresh runs on a nightly basis to remove forms from the DQP.
- If a form is still listed as delinquent, contact the LPO-designated study data manager.

2) Why does the DQP say I have delinquent forms/queries, but none are specified in the Rave Task Summary?

- Delinquent (or Overdue, as per Rave) forms and queries may not always be displayed in the Site or Patient Rave Task Summary or at the Rave folder level.
- Always review your delinquent forms and queries in Rave **at the form/field level**, because delinquent forms and queries requiring site management are always displayed at this level.

FAQs (2)

3) Why did I receive a DQP delinquency report from the CTSU?

- The CTSU does not send out DQP delinquency reports; LPO staff may export a delinquency report from the DQP or generate a report from their own system and send it to site staff for management.
- The CTSU sends out a Delinquent Data Notification email twice a month to a site's primary contacts. These provide a summary count of delinquent forms and queries for each Rave study in which your site is participating; no specific details are provided for any delinquent forms or queries.
- Contact the LPO-designated study data manager for questions regarding delinquency reports.

4) Why does a DQP delinquency report list forms as delinquent that I previously entered and verified to have no unanswered queries in Rave?

- DQP delinquency reports age quickly, beginning approximately 24 hours from when they are created.
- Review the Delinquency Aging Report Summary on the DQP (may export data to Excel for review); if no delinquencies are specified on the DQP or in the DQP reports, you have no delinquent forms or queries to manage.
- Contact the LPO-designated study Data Manager for questions regarding delinquency reports.

FAQs (3)

5) Who receives data delinquency notification emails, how can I receive them?

- The Primary Contact(s) at a site; additional site staff can subscribe via CRISP notification on the CTSU website.

6) Where can I find refresh information on the DQP?

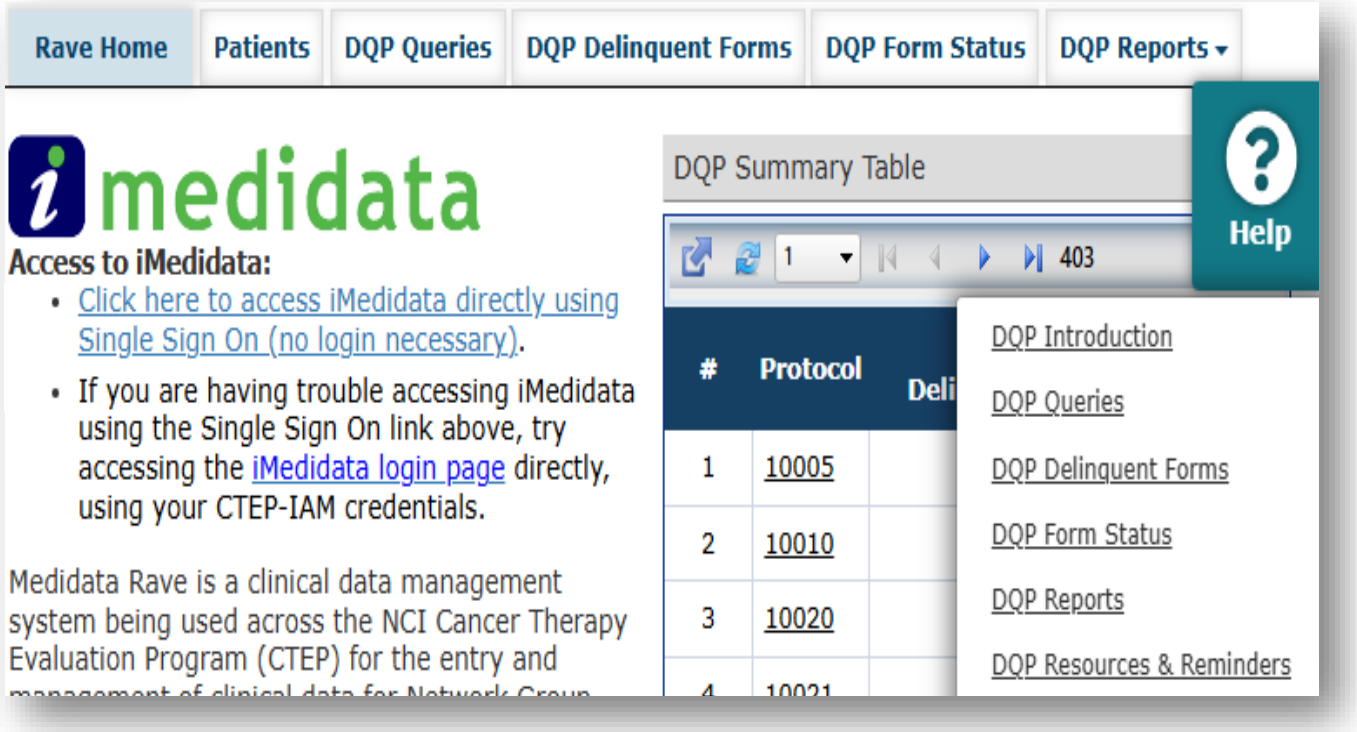
- DQP refresh date and time stamp are in the Query/Delinquency Aging Report Summary screens under the Last Refresh column.
- If updates are identified in Rave during the nightly DQP system refresh, the DQP is updated to reflect the changes in delinquent forms and/or queries for a study and the Last Refresh date/time is updated; DQP will always reflect the last time delinquent form and/or query details were updated.

7) Can date and time stamp information be specified in an exported DQP report?

- Date stamp information is included in every report exported from the DQP along with the username of the person who exported the report. Time stamp is not included in exported DQP reports. User and Date information can be deleted from exported Excel files.
- No CTSU restrictions on deleting date stamp information; a decision can be made by the LPO Data Management team to include/exclude this information.

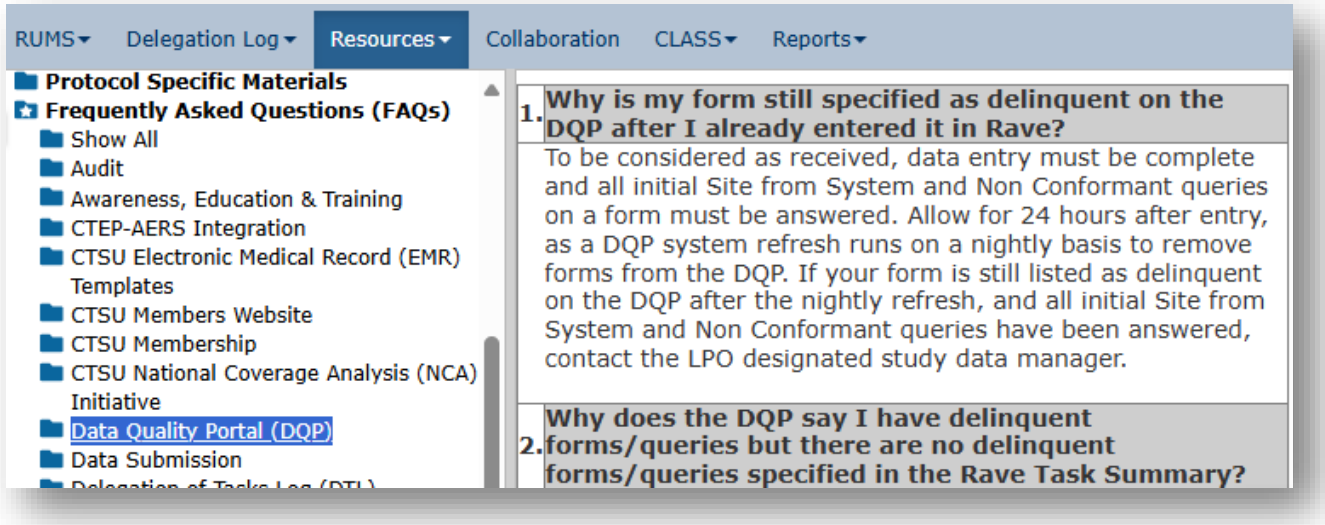
Resources (Login to CTSU Member Website Required)

- DQP Help Topics (https://www.ctsu.org/master/simplepage.aspx?ckey=HELP-DQP) are available on Data Management > Help Topics



Resources (2)

- DQP FAQs (https://www.ctsu.org/pet_main.aspx?ascx=FAQListing&category=Data+Quality+Portal+(DQP)) are available on Resources > FAQs



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OPEN

Slot Reservation for MYELOMATCH: Introduction, Process, and Resources

Introduction

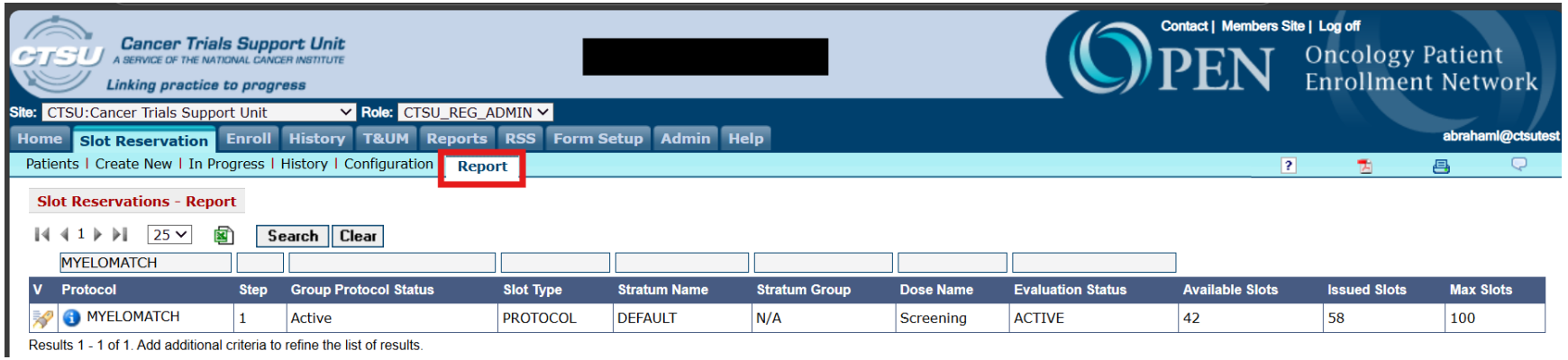
- As of March 17, 2025, slot reservation is required prior to enrolling a patient onto step 1 of MYELOMATCH
- Available slots are released daily at 8:00 AM PST
- Up to 3 slots will be released each day
- Sites must be approved to participate on the study and have the appropriate user roles to reserve a slot

Process

- Previously, sites were required to create a patient number in OPEN prior to reserving a slot
  - Patient numbers were created by entering patient demographic information
- Sites no longer need to create a patient number when reserving a slot for MYELOMATCH
- Patient demographic data will only be required at the time of enrollment

Resources - Slot Report

- Sites can refer to the OPEN Slot Reservation report to check on slot availability
- Available on OPEN > Slot Reservation > Report
- Provides real time updates
- Includes
  - Max slots
  - Available slots
  - Issued slots



Thank you!

Questions:

Contact krishnachothwani@westat.com

Thank you Krishna for the CTSU Updates!

Next up, Laura Gonzales, RN, SWOG QA Manager who comes in the spirit of ‘love and education’. Welcome Laura!

Oishi Symposium
SWOG QA Update:
CTMB Audit Guidelines
(v.15AUG2025)
Updates

Speaker

Laura Gonzales, BSN, MA, RN, OCN

SWOG Quality Assurance Manager

Updates to CTMB Auditing Guidelines by Audit Component

- Regulatory Documentation
- Pharmacy
- Participant Case

Note: This presentation is adapted from 8/8/25 ‘Upcoming Revisions to the Next Update of the CTMB Auditing Guidelines’ webinar presented by Clinical Trials Monitoring Branch (CTMB) and Pharmaceutical Management Branch (PMB)

Regulatory Documentation Component

Revision under Delegation of Tasks Log (DTL)

Major deficiency currently reads as:

Performing study-related activities without an approved DTL

Revised to:

MAJOR — Individual performing study-related activities with DTL unapproved greater than 30 calendars days

LESSER — Individual performing study-related activities with DTL unapproved 30 calendar days or less

Pharmacy Component

General Revisions under Pharmacy Component

- Description of types of DARFs available for use for NCI sponsored-studies
- Clarification with use of DARF for ‘participant returns’ of study agents
- Introduction of AURORA – NCI electronic accountability system

Types of NCI DARFs

- NCI DARF: Paper or non-NCI eDARF that prints to match NCI DARF
- NCI Oral DARF: Paper or non-NCI eDARF that prints to match NCI Oral DARF
- eDARF: AURORA accountability log

Site may choose which DARF type to use:

CTEP IND study - NCI supplied study agent	NCI DARF - *Required* (see above)
CTEP IND study – Study agent not directly supplied by NCI repository (including radiopharmaceuticals)	

Study utilizing non-CTEP IND agent and study agent not supplied by NCI	*NCI paper DARF (AURORA eDARF not available)
Study utilizing non-CTEP IND agent and study agent is supplied by NCI	

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

The following revisions apply to <u>dispensed</u> Study Agent

Revisions to Pharmacy Category

Non-Compliance - NCI DARFs Completely and Correctly Filled Out

Current wording:

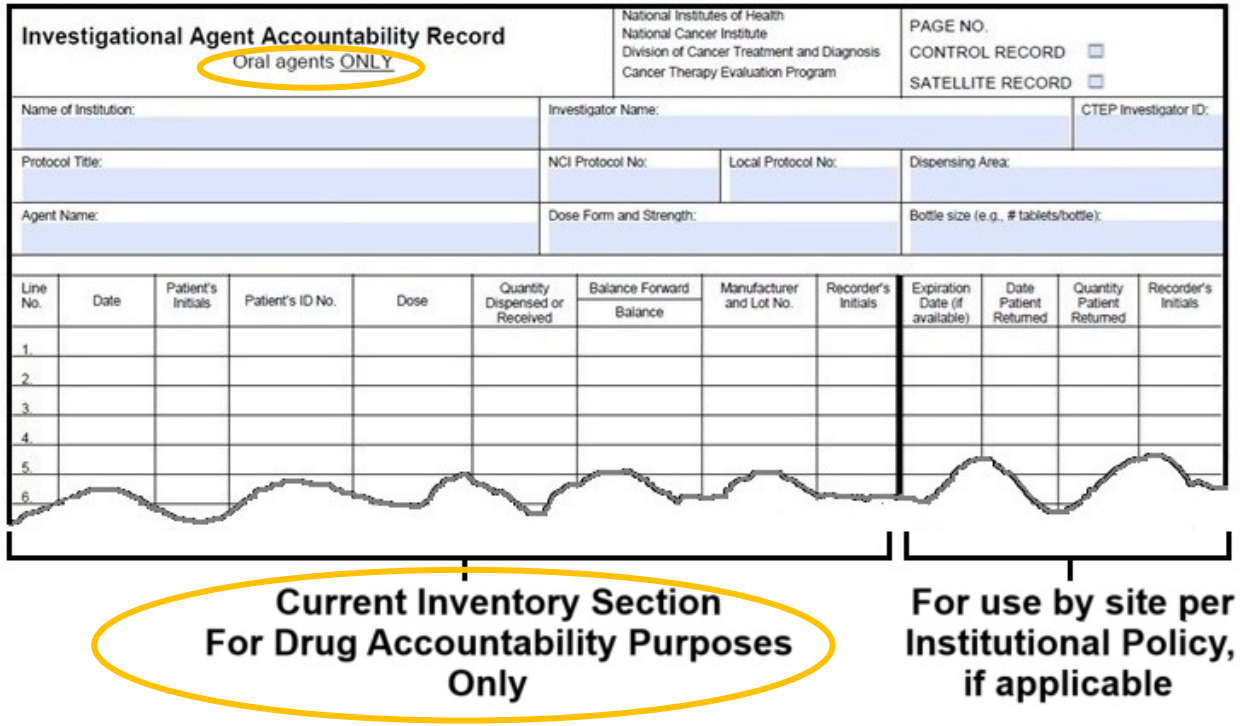
- Patient/study participant returns of oral study supplied agents not documented on the Oral DARF
- Patient/study participant returns of non-oral, non-patient-specific agent supplies are documented on the DARF
- Patient/study participant returns of non-oral, patient-specific agent supplies are not documented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

Revised to

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

[Above is abbreviated listing of non-compliance items by category]

What does Current Inventory section mean?



Investigational Agent Accountability Record
Oral agents ONLY

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

PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

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

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

Current Inventory Section For Drug Accountability Purposes Only

For use by site per Institutional Policy, if applicable

DARF is an inventory accountability log,

not a participant compliance document.

The following revisions apply to undispensed Study Agent

Revisions to Pharmacy Category

Non-Compliance - Return of Undispensed Study Agent [NCI sponsored studies]

Current wording:

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

Revised to

- Study agent is transferred to another site, investigator or protocol without NCI written approval
- Undispensed study-provided agent returned to NCI when supplied by another source
- Return Form or documentation of local destruction for undispensed inventory is not maintained
- Undispensed NCI-supplied study agent not returned, transferred or locally destroyed within 90 calendar days when requested by the NCI
- Undispensed NCI-supplied study agent remains on inventory greater than 90 days after all study participants are in follow-up, or study is closed to enrollment and no NCI-supplied study agent is being administered

[Above is completed listing of non-compliance items by category]

Revisions to Pharmacy Category

‘NCI DARFs Kept as Primary Transaction Record’ title revised to:

Non-compliance - Agent Inventory and Accountability Documentation

Current Wording

- No documentation on Control DARF of study-supplied agent transactions and local destruction

Revised to

- No documentation on Control DARF of study-supplied agent transactions including local destruction of undispensed inventory

[Above is abbreviated listing of non-compliance items]

Next Steps: Future Drug Accountability Changes

AURORA eDARF

Participant Case Component

General Revisions under Participant Case Component

- **Patient** changed to **Participant**
- Hybrid approach no longer an option in CTMB-AIS; option will only be On-site or Off-site*

** If audit is currently schedule as Hybrid in AIS for an upcoming audit, it will revert to 'No' – decide if needs updating*

General Revisions under Participant Case Component

Statements revised/added related to review of cases:

- A case may be counted towards the 10% rule if all categories are not reviewed but must have reason summarized where 'Not Reviewed' is selected in the audit report (by participant ID and by category)
- A case selected for audit that does not get reviewed (i.e., no categories reviewed) must be removed from the audit report, so it is not counted
- A case evaluated only under a 'screening step' of a study should not counted as part of the minimum 10% rule
- A case designated as 'unannounced' must have at least Informed Consent and Eligibility reviewed but cannot be counted towards the 10% rule unless it is reviewed in full (i.e., all categories reviewed) – ***Not new information***

Revisions by Categories

- Informed Consent ✓
- Eligibility ✓
- Treatment
- Disease Outcome/Response
- Adverse Event
- **Correlatives, Tests, and Procedures** New
- General Data Management Quality

✓ No changes, if any, were minor

Revisions by Category

Deficiency descriptions under these categories revised to capture deficiencies related to ‘not documented’ or ‘not reported’, rather than potentially placing deficiency under GDMQ:

- Treatment
- Disease Outcome/Response
- Adverse Event

Revisions by Category (cont…)

Audit Category	Revised Deficiency Descriptions
Treatment	Treatment/intervention not documented in source documentation; or not documented correctly
	Treatment/intervention not reported; or not reported correctly on Case Report Forms
Disease Outcome/Response	Tumor measurements/evaluation of 'status of disease' not documented in source documentation; or not documented correctly
	Tumor measurements/evaluation of 'status of disease' not reported; or not reported correctly on Case Report Forms
Adverse Event	Routine adverse events not documented in source documentation; or not documented correctly
	Adverse events not reported; or not reported correctly on Case Report Forms

Revisions by Category (cont…)

Major versus Lesser

Lesser defined as:

Finding does not have a significant impact on the outcome or interpretation of the study

Example of footnotes added under Treatment category

- Assigning a major or lesser is based on the extent of treatment data not documented; or not documented correctly
- Assigning a major or lesser is based on the extent of not reporting treatment data; or not reporting correctly

Revisions by Category (cont…)

General Data Management Quality category modified to only list deficiencies related to general data errors, missing documentation, delinquent data, etc.

Resulted in creating new category:

Correlative Studies, Tests, and Procedures

This category encompasses:

- Deficiencies related to integrated and exploratory studies including diagnostic studies, labs and related procedures
- Three deficiencies ‘word for word’ were moved from GDMQ to the new category

Revisions by Category (cont…)

Listing of Major Deficiencies

Correlative Studies, Tests, and Procedures (CTP)

- Protocol-specified laboratory tests or other parameters not done, not reported, or not documented
- Protocol-specified diagnostic studies including baseline assessments not done, not reported or not documented
- Protocol-specified research (Quality of Life forms, collection of research samples, etc.)/advanced imaging studies not done or submitted appropriately

General Data Management Quality (GDMQ)

- Recurring missing documentation in the study participant records
- Frequent data inaccuracies in primary source documentation[7]; unredacted data[8]
- Significant number of errors in submitted data[7]; data cannot be verified
- Delinquent data submission[9]

Footnotes 7, 8, and 9 above – intended to assist with assigning major vs lesser.

General Inquiries

CTMB Resources

CTMB Website: https://dctd.cancer.gov/programs/ctep/organization/ctmb

General Questions for CTMB: GeneralQuestionsforCTMB@nih.gov

Questions Related to CTMB Guidelines: QuestionsRelatedtoCTMBGuidelines@nih.gov

Reporting Research Misconduct: ReportingResearchMisconductConcerns@nih.gov

PMB Resources

PMB Website: https://dctd.cancer.gov/research/ctep-trials/for-sites/agent-management

Questions?

- QAmail@swog.org

Thank you Laura for the SWOG QA updates!

Welcome to Andrea Mongler, MPH
Plain Language Medical Writer,
SWOG Cancer Research Network

Putting It Plainly

Tips and tools for helping patients understand clinical trials

Andrea Mongler, MPH

Poll Everywhere Instructions

Join by text

Text **swog2025** to 22333

Join by QR code

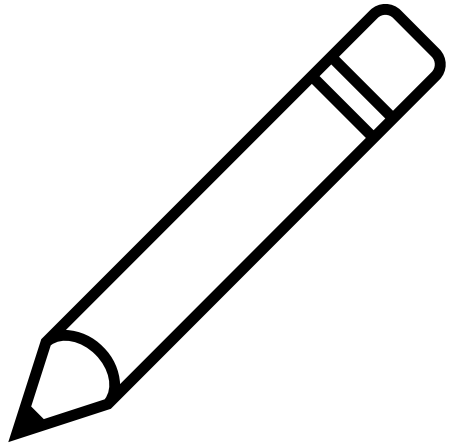
Scan with your camera app

Join by web

PollEv.com/swog2025

About me

- SWOG's plain language medical writer
- Expertise in health communication and plain language writing
- Goal: Help **you** help patients understand clinical trial info



Objectives

- Know what patient-friendly trial summaries are
- Use patient-friendly summaries with patients
- Understand key plain language best practices
- Apply those best practices in patient communications

What is plain language?

image credit: CommunicateHealth

Communication that people can understand **the first time** they read or hear it

Importance of plain language

- More than 1 in 3 adults have basic or below basic health literacy skills[1]
- People with cancer are often stressed, anxious, and overwhelmed—and that affects their ability to process information[2]
- **Everyone** benefits from plain language — even experts prefer it[3]

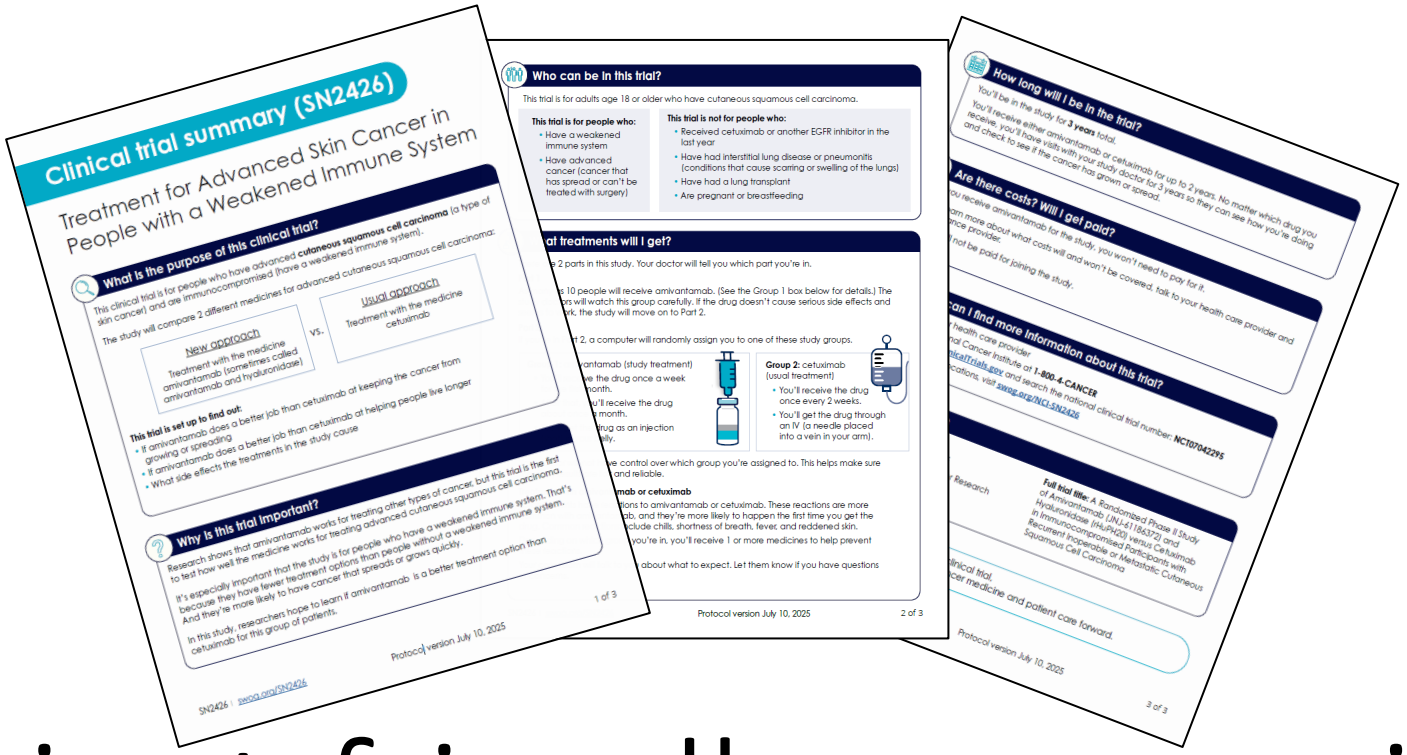
1. National Assessment of Adult Literacy: https://nces.ed.gov/pubs2006/2006483_1.pdf
2. National Cancer Institute: https://www.cancer.gov/about-cancer/treatment/side-effects/memory/cognitive-impairment-hp-pdq
3. Neilsen Norman Group: https://www.nngroup.com/articles/plain-language-experts/

Plain language in action

Protocol: Primary Objective: To compare OS in participants randomized to nivolumab + paclitaxel + ramucirumab versus those randomized to paclitaxel + ramucirumab.

Informed Consent: The study is testing if patients taking nivolumab plus the usual treatment will live longer, live the same amount of time, or live a shorter amount of time than patients taking the standard treatment alone.

Patient-friendly summary: This trial is set up to find out if adding nivolumab to the usual treatment helps people with advanced stomach or esophageal cancer live longer.

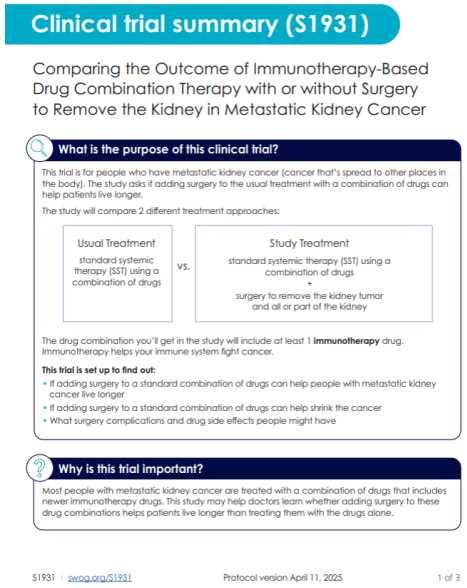


Patient-friendly summaries

Are you familiar with SWOG's patient-friendly summaries for trials?

What is a patient-friendly summary?

A short, plain language material you can use to help patients understand a clinical trial



Clinical trial summary (S1931)

Comparing the Outcome of Immunotherapy-Based Drug Combination Therapy with or without Surgery to Remove the Kidney in Metastatic Kidney Cancer

What is the purpose of this clinical trial?

This trial is for people who have metastatic kidney cancer (cancer that's spread to other places in the body). The study asks if adding surgery to the usual treatment with a combination of drugs can help patients live longer.

The study will compare 2 different treatment approaches:

Usual Treatment	vs.	Study Treatment
standard systemic therapy (SST) using a combination of drugs		standard systemic therapy (SST) using a combination of drugs + surgery to remove the kidney tumor and all or part of the kidney

The drug combination you'll get in the study will include at least 1 **immunotherapy** drug. Immunotherapy helps your immune system fight cancer.

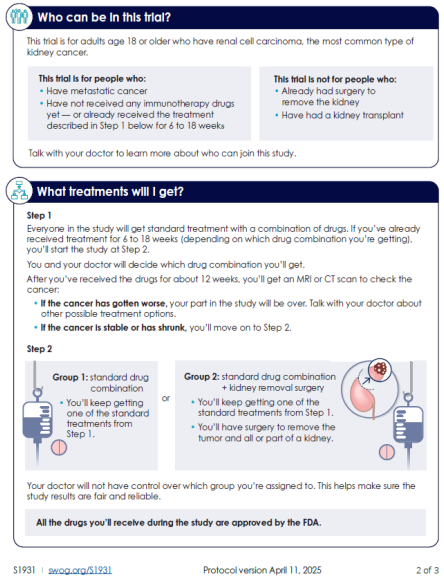
This trial is set up to find out:

- If adding surgery to a standard combination of drugs can help people with metastatic kidney cancer live longer
- If adding surgery to a standard combination of drugs can help shrink the cancer
- What surgery complications and drug side effects people might have

Why is this trial important?

Most people with metastatic kidney cancer are treated with a combination of drugs that includes newer immunotherapy drugs. This study may help doctors learn whether adding surgery to these drug combinations helps patients live longer than treating them with the drugs alone.

S1931 | swog.org/S1931 Protocol version April 11, 2025 1 of 3



Who can be in this trial?

This trial is for adults age 18 or older who have renal cell carcinoma, the most common type of kidney cancer.

This trial is for people who:

- Have metastatic cancer
- Have not received any immunotherapy drugs yet — or already received the treatment described in Step 1 below for 6 to 18 weeks

This trial is not for people who:

- Already had surgery to remove the kidney
- Have had a kidney transplant

Talk with your doctor to learn more about who can join this study.

What treatments will I get?

Step 1

Everyone in the study will get standard treatment with a combination of drugs. If you've already received treatment for 6 to 18 weeks (depending on which drug combination you're getting), you'll start the study at Step 2.

You and your doctor will decide which drug combination you'll get.

After you've received the drugs for about 12 weeks, you'll get an MRI or CT scan to check the cancer:

- **If the cancer has gotten worse,** your part in the study will be over. Talk with your doctor about other possible treatment options.
- **If the cancer is stable or has shrunk,** you'll move on to Step 2.

Step 2

Group 1: standard drug combination
- You'll keep getting one of the standard treatments from Step 1.

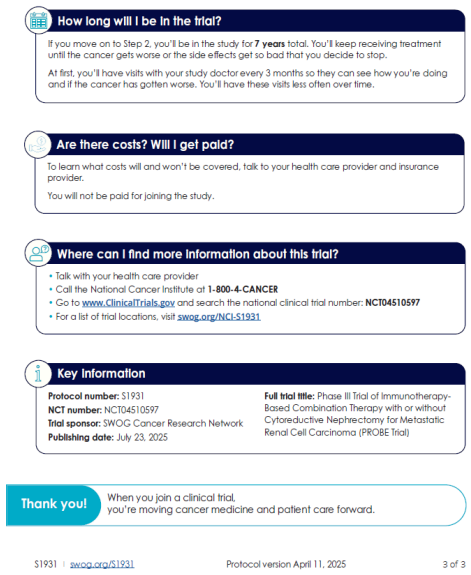
or

Group 2: standard drug combination + kidney removal surgery
- You'll keep getting one of the standard treatments from Step 1.
- You'll have surgery to remove the tumor and all or part of a kidney.

Your doctor will not have control over which group you're assigned to. This helps make sure the study results are fair and reliable.

All the drugs you'll receive during the study are approved by the FDA.

S1931 | swog.org/S1931 Protocol version April 11, 2025 2 of 3



How long will I be in the trial?

If you move on to Step 2, you'll be in the study for **7 years** total. You'll keep receiving treatment until the cancer gets worse or the side effects get so bad that you decide to stop.

At first, you'll have visits with your study doctor every 3 months so they can see how you're doing and if the cancer has gotten worse. You'll have these visits less often over time.

Are there costs? Will I get paid?

To learn what costs will and won't be covered, talk to your health care provider and insurance provider.

You will not be paid for joining the study.

Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to www.ClinicalTrials.gov and search the national clinical trial number: **NCT04510597**
- For a list of trial locations, visit swog.org/NCI-S1931

Key information

Protocol number: S1931
NCT number: NCT04510597
Trial sponsor: SWOG Cancer Research Network
Publishing date: July 23, 2025

Full trial title: Phase III Trial of Immunotherapy-Based Combination Therapy with or without Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma (PROBE Trial)

Thank you! When you join a clinical trial, you're moving cancer medicine and patient care forward.

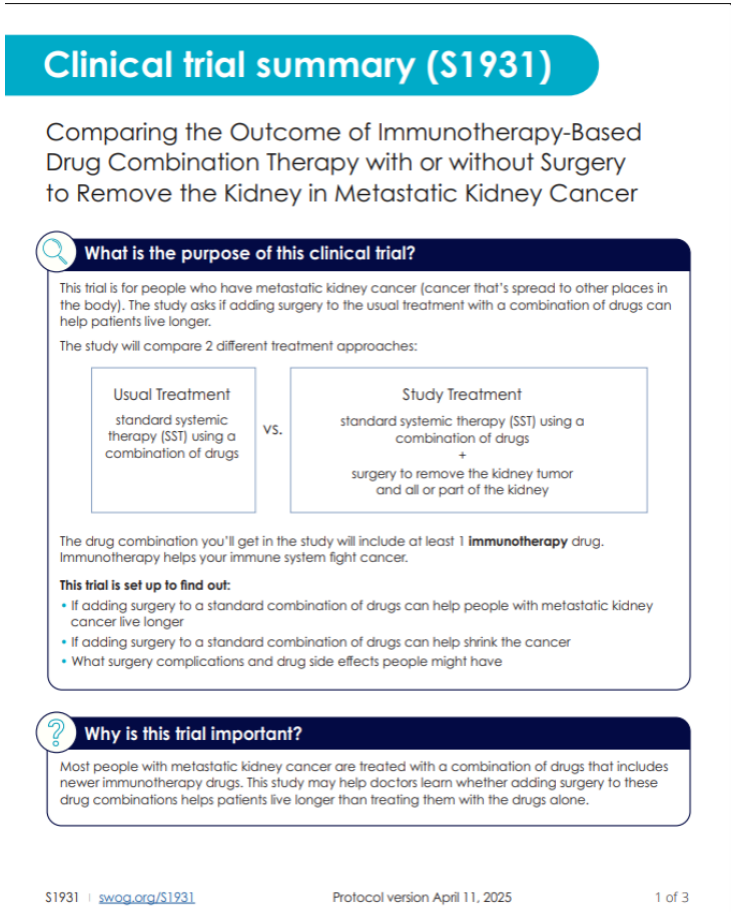
S1931 | swog.org/S1931 Protocol version April 11, 2025 3 of 3

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network NCI Community Oncology Research Program

Key facts about patient-friendly summaries

- Created for each new SWOG trial and SWOG CTP trial
- Reviewed by the study team, including the patient advocate
- Approved by the CIRB (or the WCG IRB!)
- Available online and as a printable PDF
- Usually 2 to 4 pages
- Translated into Spanish



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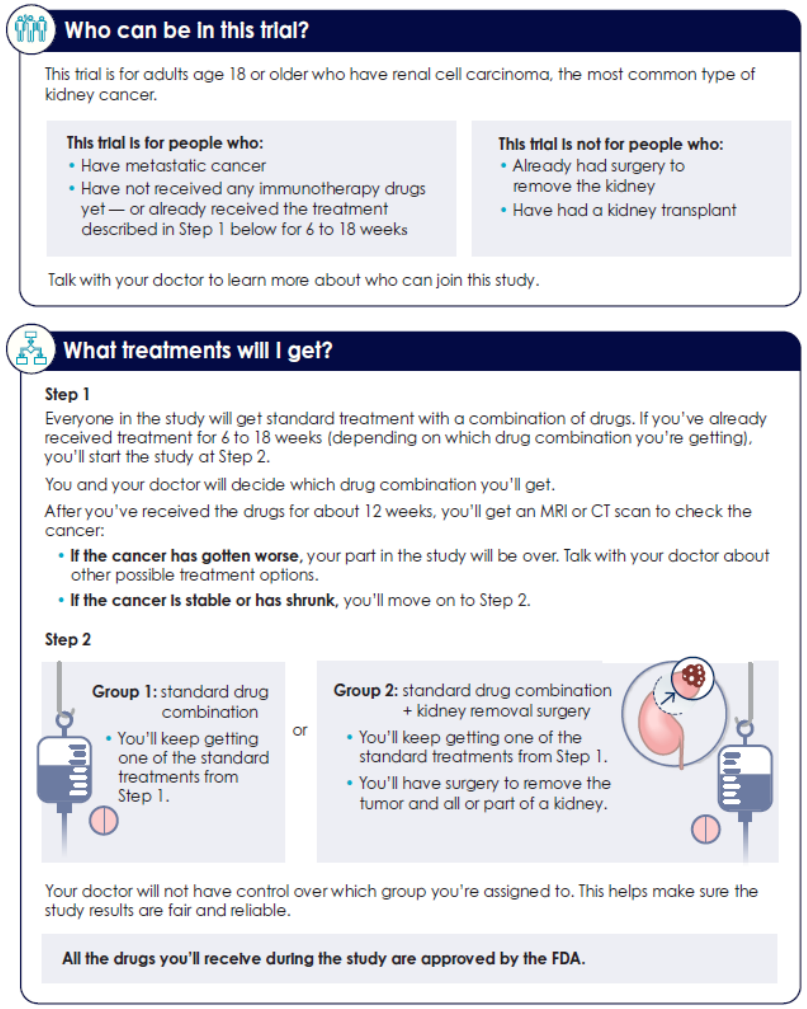
S1931 | swog.org/S1931 Protocol version April 11, 2025 1 of 3

Summary contents

- Trial purpose
- Importance of the trial
- Key inclusion/exclusion criteria
- Study groups and study treatment/intervention
- Length of study participation
- Costs/compensation
- How to learn more



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S1931 | swog.org/S1931 Protocol version April 11, 2025 2 of 3

When do you use patient-friendly summaries?

To introduce a patient to a trial

0%

Alongside the informed consent document

0%

At another time

0%

I don’t use patient-friendly summaries

0%

How do you use patient-friendly summaries?

I talk through the summary with the patient

0%

I hand the summary to the patient to review on their own

0%

I send the patient an electronic version or link to the summary

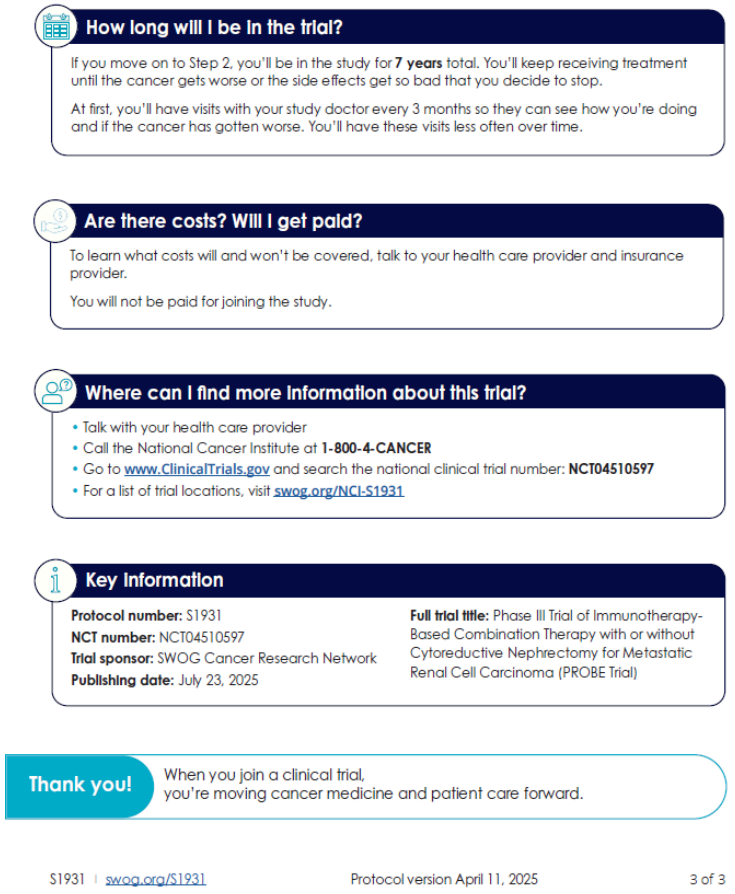
0%

I don’t use patient-friendly summaries

0%

How to use patient-friendly summaries

- Introduce patients to a trial
- Supplement the informed consent document
- Give to patients to re-review on their own — or to share with caregivers and supporters



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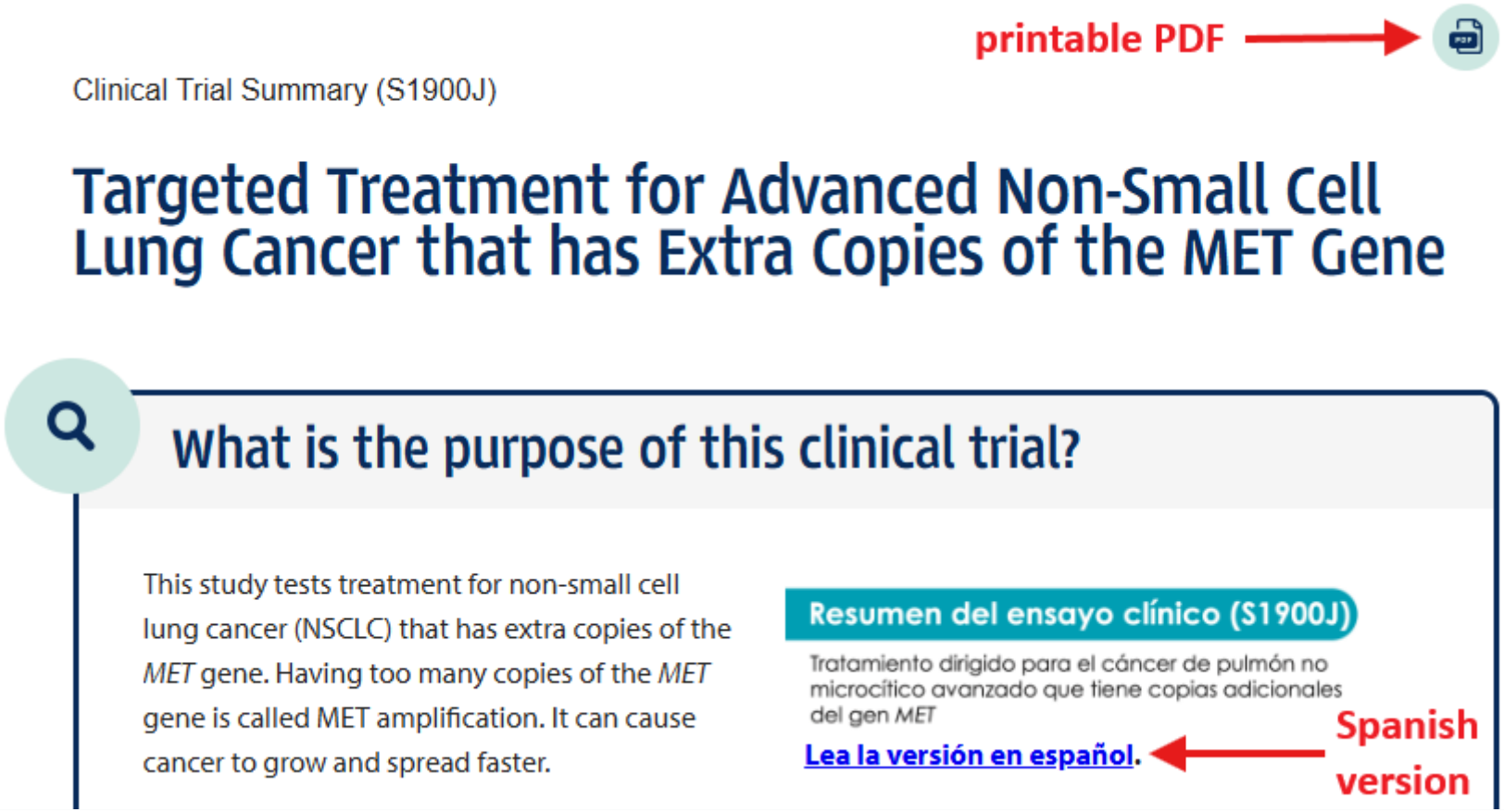
Thank you! When you join a clinical trial, you're moving cancer medicine and patient care forward.

S1931 | swog.org/S1931 Protocol version April 11, 2025 3 of 3

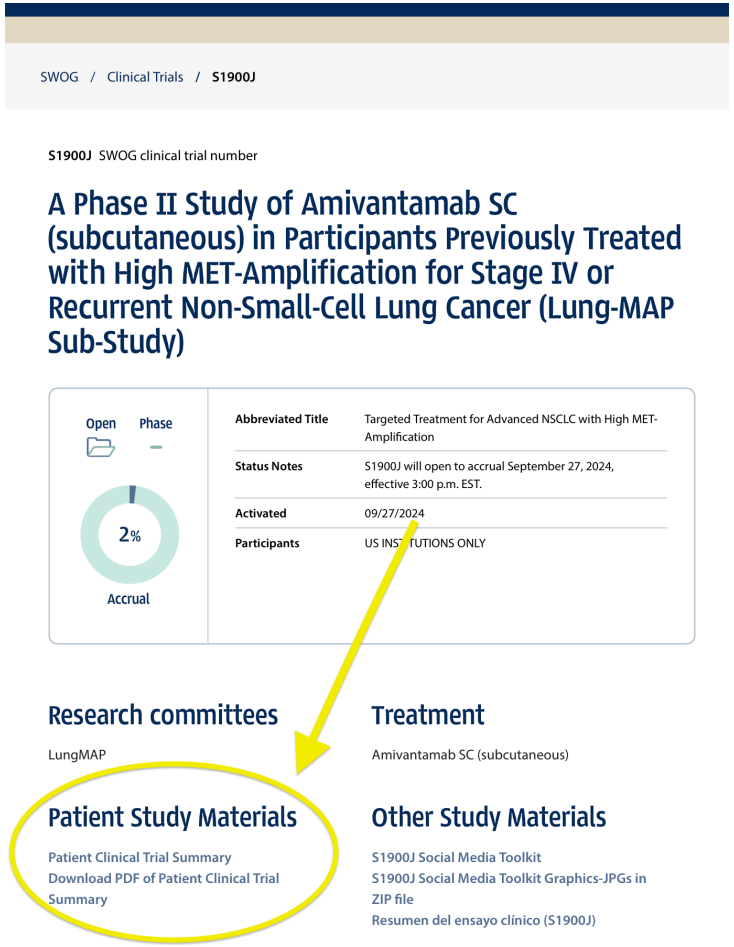
Easiest way to access a summary

swog.org/S1234 (this is publicly accessible)



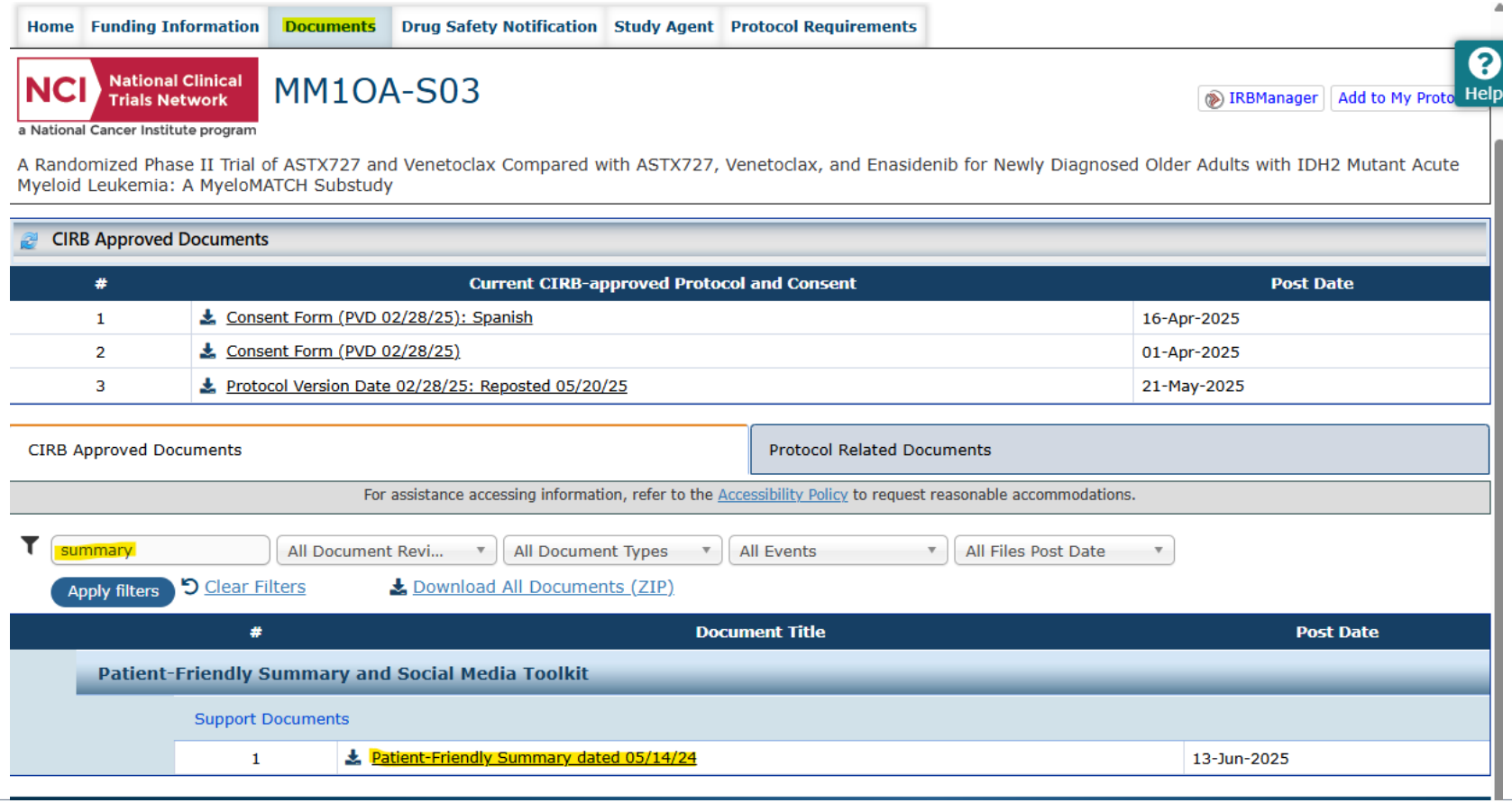
Alternate way to access a summary

swog.org/clinical-trials/S1234



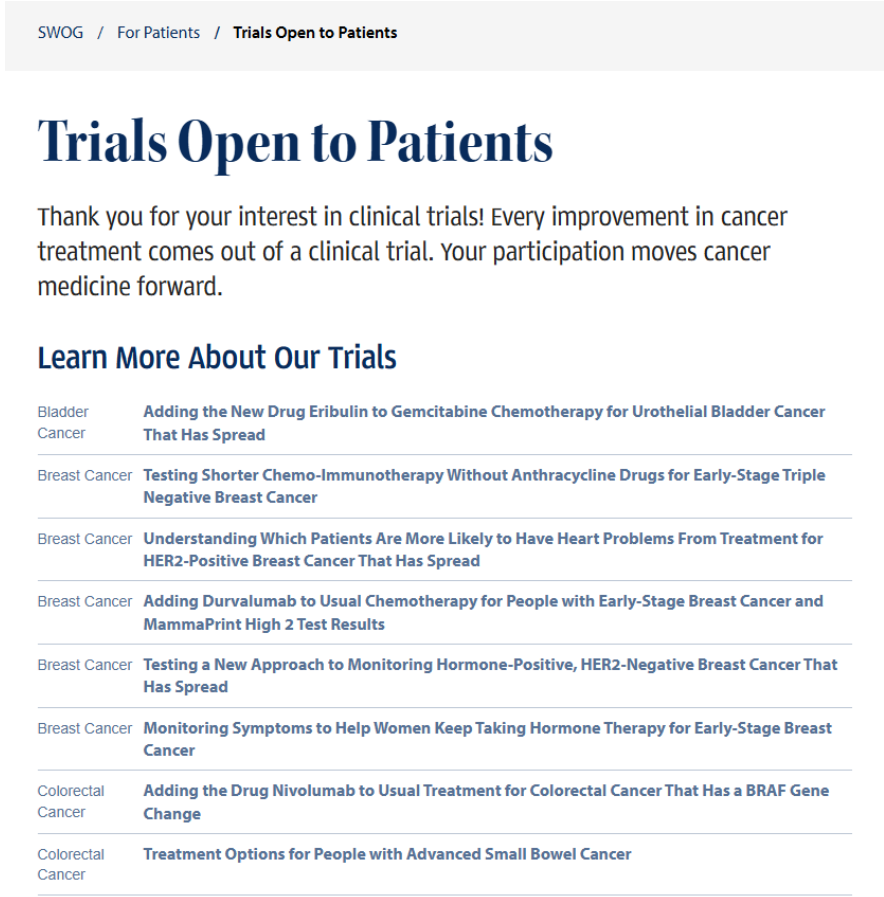
One more way to access a summary

ctsu.org: Documents tab; type “summary” in “Document Title” filter



Collection of patient-friendly summaries

- Find **printed** copies at the registration table
- Access all summaries **online** at swog.org/patients/trials-open-patients



SWOG / For Patients / **Trials Open to Patients**

Trials Open to Patients

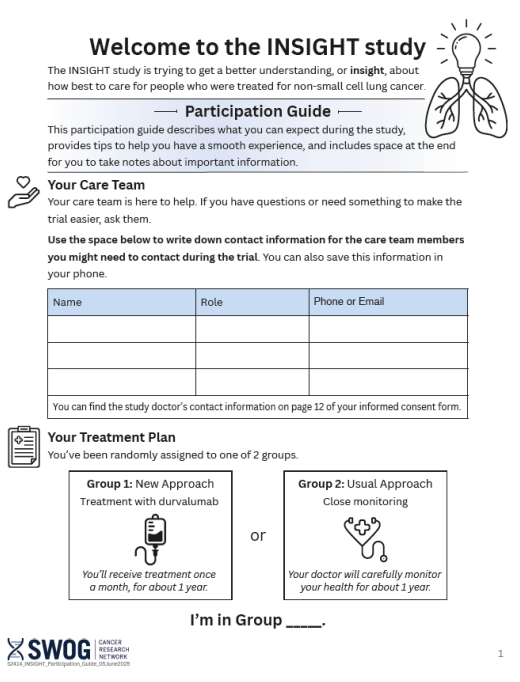
Thank you for your interest in clinical trials! Every improvement in cancer treatment comes out of a clinical trial. Your participation moves cancer medicine forward.

Learn More About Our Trials

Bladder Cancer	**Adding the New Drug Eribulin to Gemcitabine Chemotherapy for Urothelial Bladder Cancer That Has Spread**
Breast Cancer	**Testing Shorter Chemo-Immunotherapy Without Anthracycline Drugs for Early-Stage Triple Negative Breast Cancer**
Breast Cancer	**Understanding Which Patients Are More Likely to Have Heart Problems From Treatment for HER2-Positive Breast Cancer That Has Spread**
Breast Cancer	**Adding Durvalumab to Usual Chemotherapy for People with Early-Stage Breast Cancer and MammaPrint High 2 Test Results**
Breast Cancer	**Testing a New Approach to Monitoring Hormone-Positive, HER2-Negative Breast Cancer That Has Spread**
Breast Cancer	**Monitoring Symptoms to Help Women Keep Taking Hormone Therapy for Early-Stage Breast Cancer**
Colorectal Cancer	**Adding the Drug Nivolumab to Usual Treatment for Colorectal Cancer That Has a BRAF Gene Change**
Colorectal Cancer	**Treatment Options for People with Advanced Small Bowel Cancer**

Other resources

- Social media toolkits, with posts for patients and providers
- Patient fliers (e.g., Pragmatica-Lung)
- Participation guides (e.g., S2414)
- Videos (e.g., myeloMATCH)



Welcome to the INSIGHT study

The INSIGHT study is trying to get a better understanding, or **insight**, about how best to care for people who were treated for non-small cell lung cancer.

Participation Guide

This participation guide describes what you can expect during the study, provides tips to help you have a smooth experience, and includes space at the end for you to take notes about important information.

Your Care Team

Your care team is here to help. If you have questions or need something to make the trial easier, ask them.

Use the space below to write down contact information for the care team members you might need to contact during the trial. You can also save this information in your phone.

Name	Role	Phone or Email

You can find the study doctor's contact information on page 12 of your informed consent form.

Your Treatment Plan

You've been randomly assigned to one of 2 groups.

Group 1: New Approach
Treatment with durvalumab
You'll receive treatment once a month, for about 1 year.

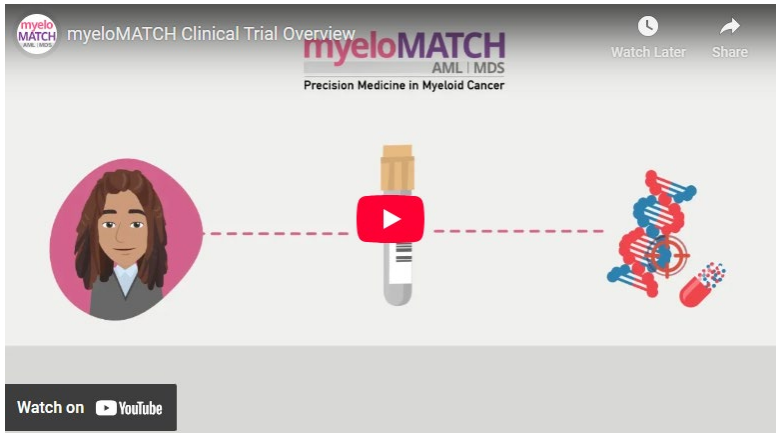
or

Group 2: Usual Approach
Close monitoring
Your doctor will carefully monitor your health for about 1 year.

I'm in Group ____.

SWOG CANCER RESEARCH NETWORK

1



Plain language best practices

Do you create educational materials for patients?

Yes!

0%

No, but this is something I'd like to start doing.

0%

I don't, but someone else on my team does.

0%

No one on my team is doing this, and we probably won't start.

0%

Choose simple terms

Pick words that people (who don't work in your field!) hear and use in everyday conversation.

Jargon	Plain language
administer	give
hypertension	high blood pressure
progression	when the cancer grows or spreads

Define technical terms people need to know

People in Group 1 will get a **placebo**. A placebo is something that looks like the study drug but doesn't contain any medicine.

Use a friendly, conversational tone

- Use “you”
- Use contractions
- Use exclamation points strategically
- Avoid directives, like “should” or “must”

Formal tone

The study team will ask patients whether they are interested in participating in an interview about their experience in the study. This is an optional interview. It is acceptable to choose not to participate. Patients may still participate in the study regardless of whether they agree to be interviewed.

Patients should discuss any questions about the interview with their doctor.

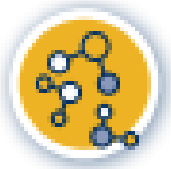
Friendly, conversational tone

The study team will ask you if you'd like to take part in an interview about your experience in the study. It's okay to say no! You can still take part in the study if you don't do the interview.

If you have any questions about the interview, talk to your doctor.

Include a clear main message at the beginning

Help people understand right away what the material is about!

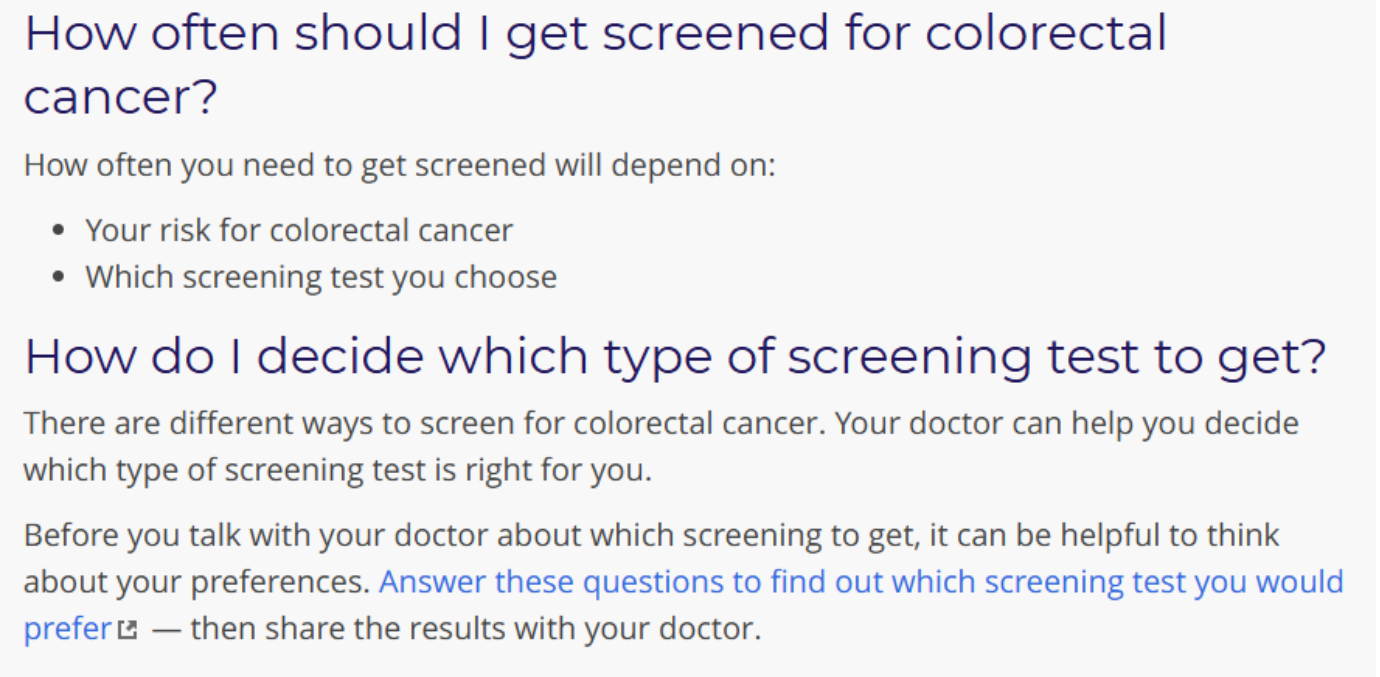


What is the purpose of this clinical trial?

This trial is for people who have head and neck cancer that came back after earlier treatment or has spread to other places in the body. **The purpose of the trial is to see if adding a medicine called amivantamab (sometimes called amivantamab hyaluronidase) to the usual chemotherapy can improve treatment for these patients.**

Break information up

- Keep sections short
- Use clear, informative headers
- Use bulleted lists
- Visually emphasize key points



How often should I get screened for colorectal cancer?

How often you need to get screened will depend on:

- Your risk for colorectal cancer
- Which screening test you choose

How do I decide which type of screening test to get?

There are different ways to screen for colorectal cancer. Your doctor can help you decide which type of screening test is right for you.

Before you talk with your doctor about which screening to get, it can be helpful to think about your preferences. Answer these questions to find out which screening test you would prefer — then share the results with your doctor.

Keep it short

Aim for no more than **20** words in a sentence, **3** sentences in a paragraph, **250** words on a page

Long sentence

It’s especially important that the study is for people who have a weakened immune system because they have fewer treatment options than people without a weakened immune system and they’re more likely to have aggressive disease (cancer that spreads or grows quickly).

Short sentences

It’s especially important that the study is for people who have a weakened immune system. That’s because they have fewer treatment options than people without a weakened immune system. And they’re more likely to have aggressive disease (cancer that spreads or grows quickly).

Use active voice

You may be asked by the study team to wear loose-fitting clothes to your appointment.

The study team may ask you to wear loose-fitting clothes to your appointment.

Make numbers easy to understand

- Use numerals
- Use whole numbers
- Provide context
- Do the math
- Help people visualize numbers

The tumor is about two centimeters.

The tumor is about 2 centimeters — about the size of a small grape. That means the tumor has shrunk.

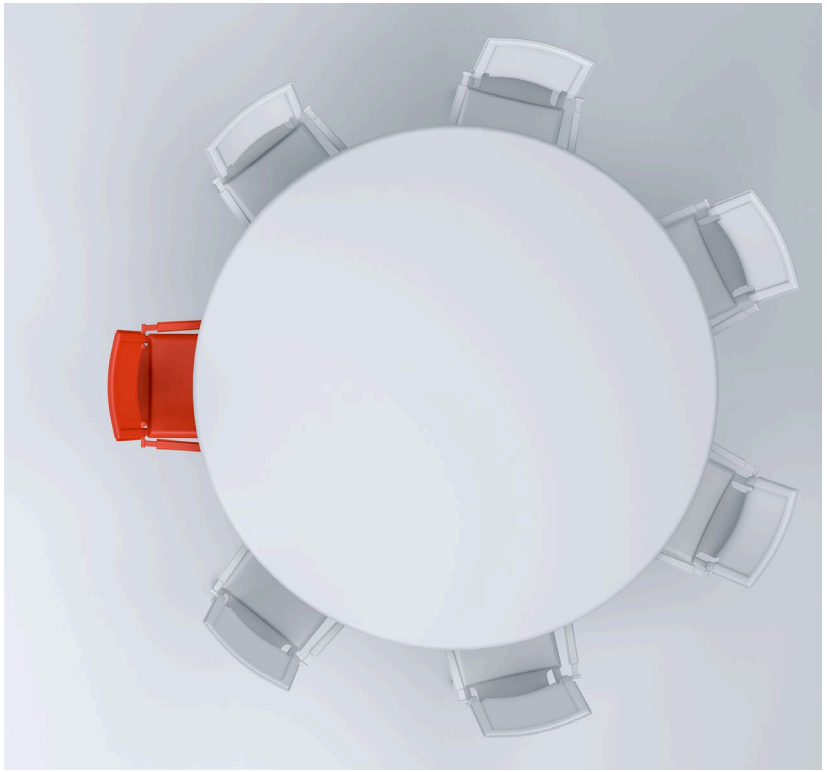
Wrap-up

Key takeaways

- **Clear communication** is key to making sure patients understand important information about trials
- Applying **plain language best practices** helps make complicated trial information understandable
- **Patient-friendly summaries** can help you communicate about trials in plain language

Come to the Open Forum!

- Share ideas for improving patient-friendly summaries
- Get a sneak peek at tools and resources SWOG is creating to help with patient communications
- Tell us what other resources/materials would be helpful for you



Questions?

- Contact me at amongler@swog.org – I'm happy to help!
- Or email communications@swog.org

Thank you Andrea for this great information!

Next Up:

Dr. Raymond Osarogiagbon

‘Life, liberty and the pursuit of happiness’: Implementing Equitable Access to Clinical Trials

Dr. Raymond Osarogiagbon

Chief Scientist, Baptist Memorial Healthcare

Director of the Multidisciplinary Thoracic Oncology Program, Baptist Cancer Center

Principal Investigator of the Baptist Health System/Mid-South Minority-Underserved Consortium NCORP

Research Professor at Vanderbilt University and member of Vanderbilt Ingram Cancer Center.

Thank you Dr. O for your outstanding presentation!

Would our panelists please join us on the stage?

Welcome to the Community Interest Panel!

- Dr. Raymond Osarogiagbon, Chief Scientist, Baptist Memorial Healthcare; Director of the Multidisciplinary Thoracic Oncology Program, Baptist Cancer Center; Principal Investigator of the Baptist Health System/Mid-South Minority-Underserved Consortium NCORP; Research Professor at Vanderbilt University and member of Vanderbilt Ingram Cancer Center.
- Christina Wiess, Senior Assistant Director of Clinical Trial Operations, Yale Cancer Center
- Amy Koffernus, Research Administrator, CROWN Consortium at HSHS St. Vincent Hospital Green Bay, WI
- Joyce Nancarrow Tull, MSN, RN; Senior Administrative Director, UC San Diego Moores Cancer Center

We have several questions we'd like the panelists to answer for the SWOG Audience:

Tell us about you, your role, and your site: the structure, organization, and details. Share with us what is special about your site?

What do you think has been your most successful effort in fueling enrollment?

What do you think has been your most successful effort in fueling outreach in the community?

Let’s talk about Outreach and Survivorship.

- What efforts are you pursuing in relation to survivorship?
- What efforts and actions does your research office participate in which fuel outreach?

Finally:

Within your site(s), what are the 2-3 experiences or strategies you would share as recommendations to other sites looking for increased success in outreach, research engagement, and enrollment?

Thank you so much for your participation in this panel!

Thank you for your attendance at the SWOG Fall Meeting 2025 Oishi Symposium

We look forward to seeing you at the SWOG Spring Meeting 2026
April 30-May 2, 2026
San Francisco, CA