SWOG Oncology Research Professionals

Site Operations Fall Meeting 2026

Working Smarter not Harder: Prioritizing Efforts in the Real World



Presented by:

Nikki Stover, MPP | Christina Wiess, BA, CCRP

Connie Szczepanek, RN, BSN, CCRP | Caitlin Hutchinson, MS

Please log into **Poll Everywhere** to participate in the live polling part of the session

Text swog2026 to 22333

pollev.com/swog2026

Scan QR code

We look forward to your participation!

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network | NCI Community Oncology Research Program

Photo Credit: https://static.vecteezy.com/system/resources/previews/044/601/323/large_2x/multitasking-and-effective-time-management-multitask-concept-business-woman-is-busy-doing-many-activities-with-many-hands-in-a-work-suit-design-illustration-vector.jpg

Welcome & Announcements



Presented by:

Connie Szczepanek, RN, BSN, CCRP

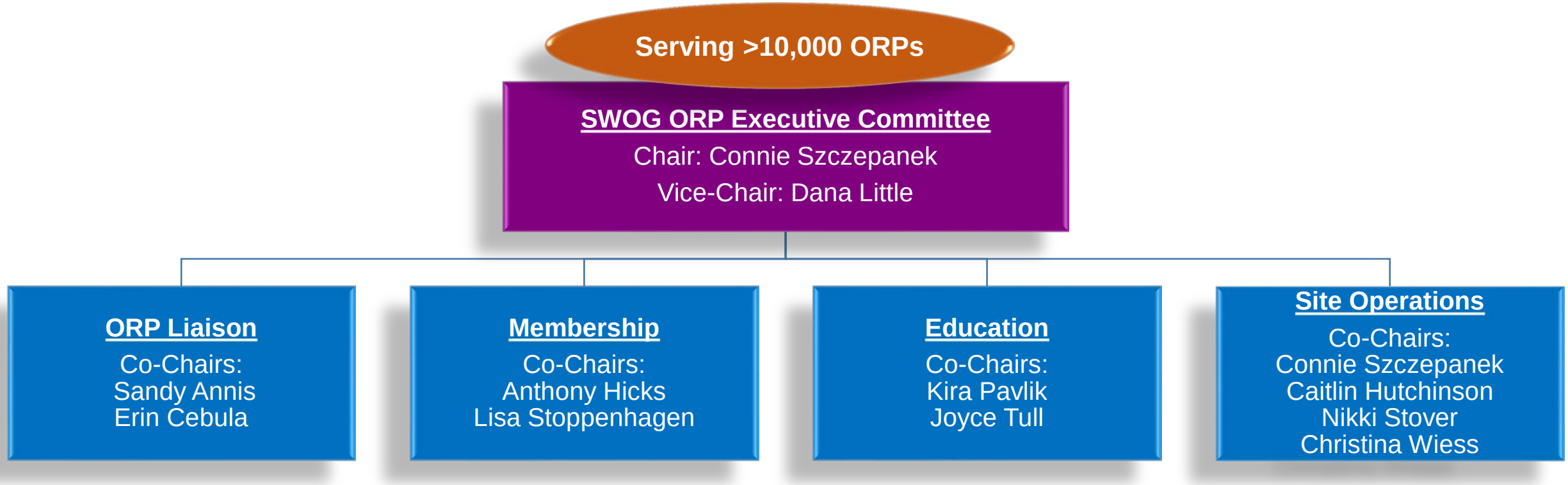
Photo Credit: https://img.freepik.com/free-vector/hand-drawn-multitask-business-woman_23-2148843890.jpg

Agenda & CE Credits

Although there are no formal CE credits for this meeting, you may submit a copy of the agenda to reflect your attendance (e.g.: SOCRA or ACRP)

Fall 2026 SWOG Site Operations Meeting Agenda Thursday, October 8, 2026 1:00 PM - 2:30 PM CT		
Open, Welcome & Announcements		Site Operations Committee
General Updates		
National Cancer Institute (NCI)		Grace Mishkin
Clinical Trials Support Unit (CTSU)		James Wise
SWOG Updates		
Statistics & Data Management Center (SDMC)		Kari Chansky
SWOG Network Operations Center	Administration & Study Funding	Pat Mize & Casey Dawson
	Quality Assurance (QA)	Laura Gonzales
	Information Systems	Cara Laubach
Closing Remarks		Site Operations Committee

SWOG ORP Committee & Sub-Committees



SWOG Cancer Research Network's Mission

To significantly improve lives through cancer clinical trials and translational research

ORP Committee's Mission

To support SWOG activities through promotion of integrity and excellence in clinical research through education, guidance, & collaborative contributions

ORP Executive Committee Members

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

Join the ORP Committee

SWOG Website:
https://www.swog.org/member-resources/membership/committee-membership

Key Involvement Opportunities:

- Disease Specific Liaisons
- Liaisons at Large
- Education Team

*"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."*

General Updates



Presented by:
Christina Wiess, BA, CCRP

Photo Credit: https://static.vecteezy.com/system/resources/thumbnails/046/418/834/small_2x/businessman-multitasking-at-workplace-busy-and-overload-man-vector.jpg

NCI Updates



Presented by:
Grace Mishkin, PhD, MPH

Photo Credit: https://static.vecteezy.com/system/resources/previews/034/882/731/large_2x/girl-in-flat-style-white-background-negotiations-business-internet-multitasking-many-hands-time-management-trendy-person-character-isolated-vector.jpg

Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Linking practice to progress



CTSU Updates

James Wise, MA

CTSU Deputy Project Director

Agenda

OPEN Modernization

Website Transformation

Disclaimer: All images in this presentation were taken from a test environment. No real production data was used.

OPEN Modernization

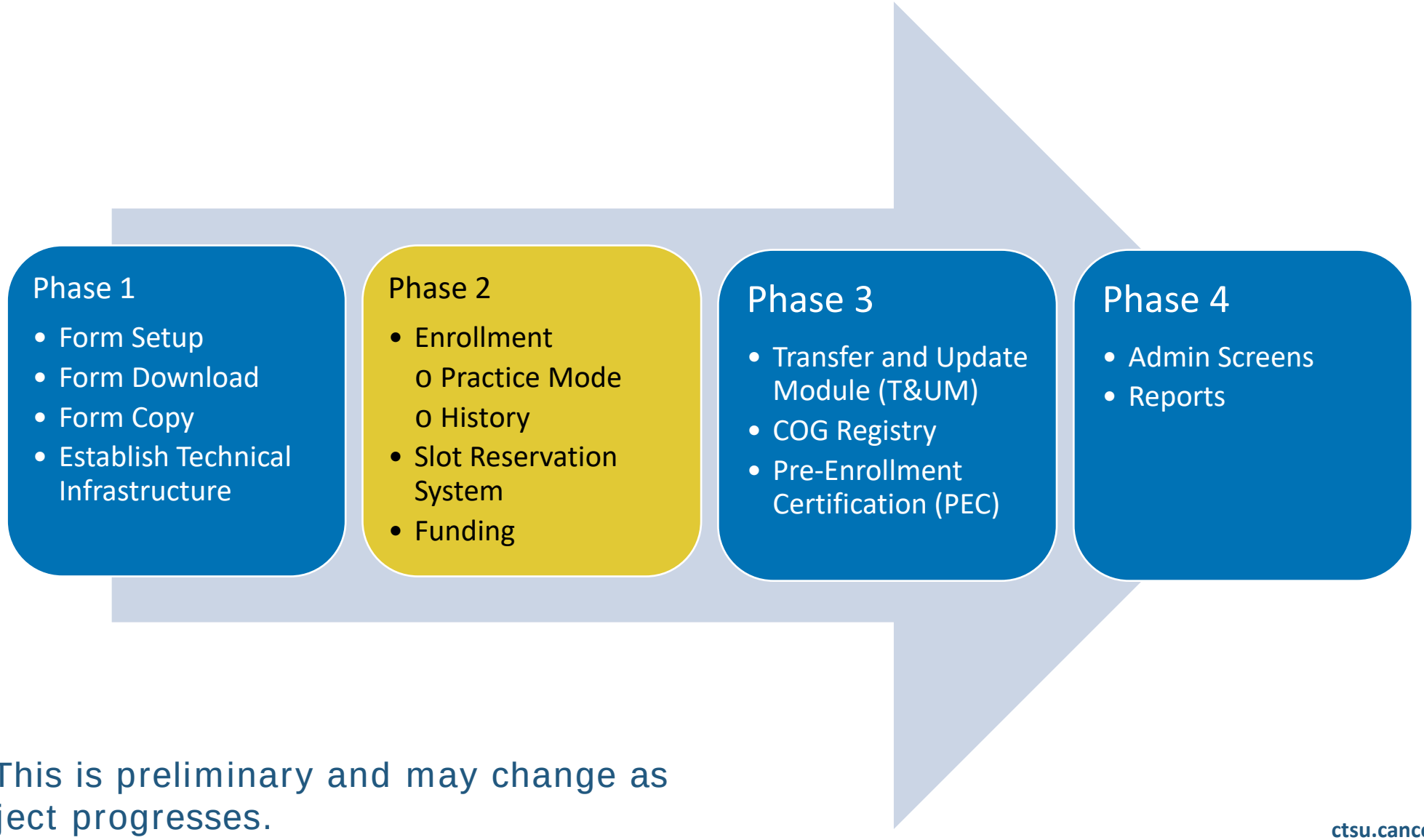


OPEN Modernization Background / Goals



- Multi-phase process, started with administrative screens
- Modernize the design and functionality
- Improve the user experience for:
  - Lead Protocol Organizations (LPOs)
  - Sites
  - CTSU Operations
- Make the entire application 508 compliant
- Retain current functionality while also enhancing it
- Set the stage for future enhancements to support cancer clinical trials

OPEN Modernization: Phased Development Approach

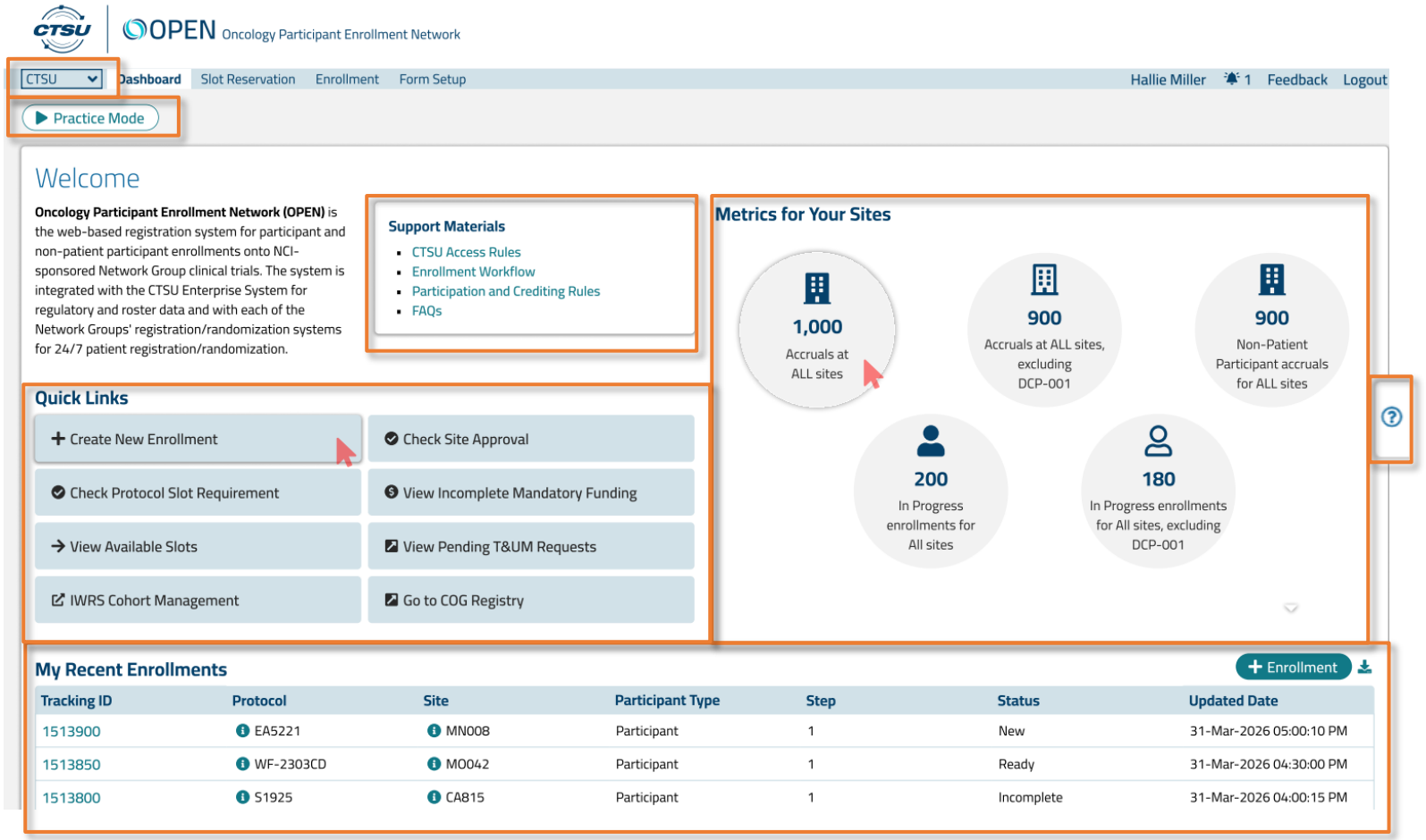


NOTE: This is preliminary and may change as the project progresses.

Selected Updates in Modernized OPEN Screens

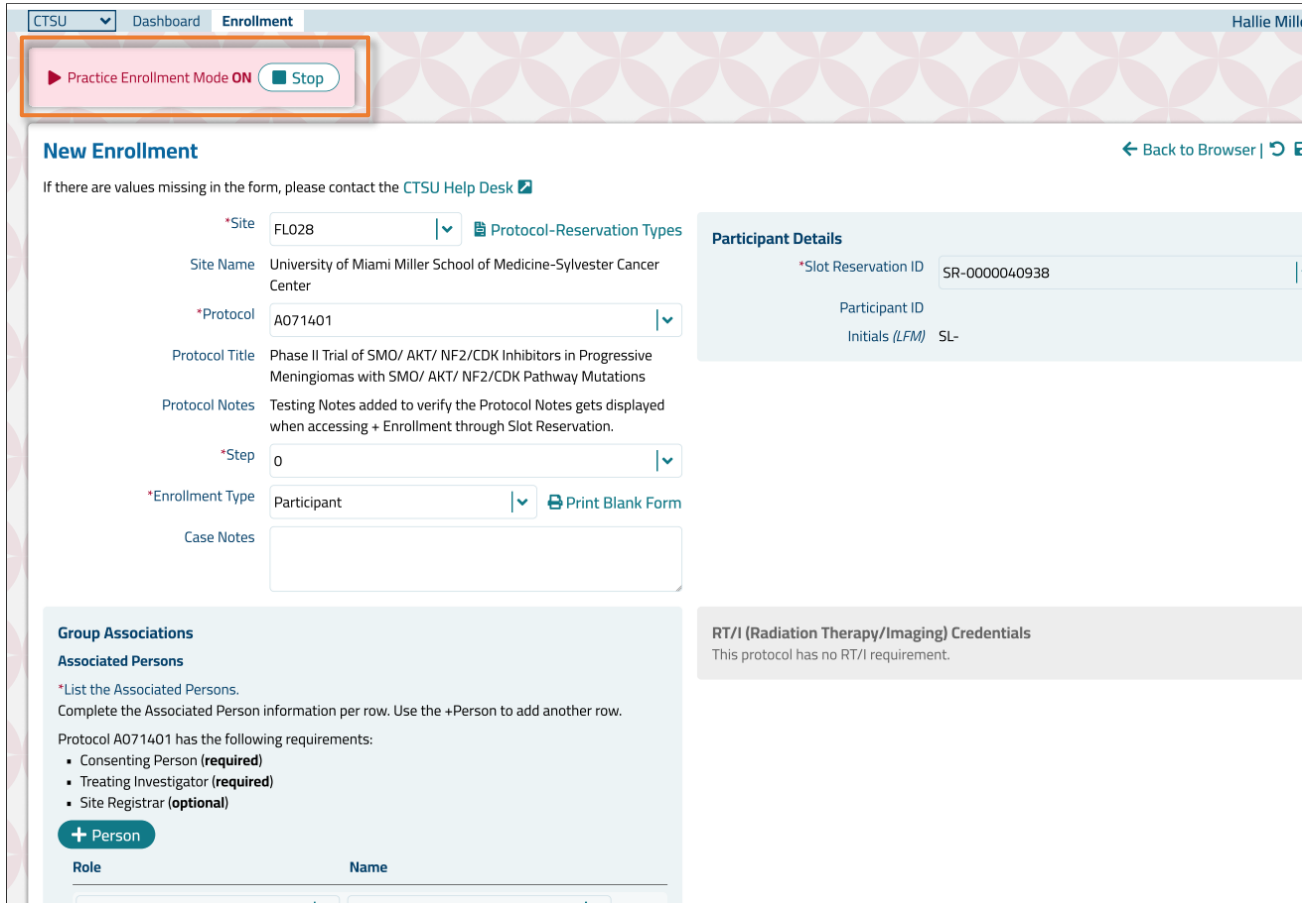
Home / Dashboard

- Simplified view
- User-specific metrics
- Begin a Practice Mode enrollment from this screen
- Quick Links revamped and grouped into single section
- Enhanced My Recent Enrollments section
- Streamlined support materials and help topics



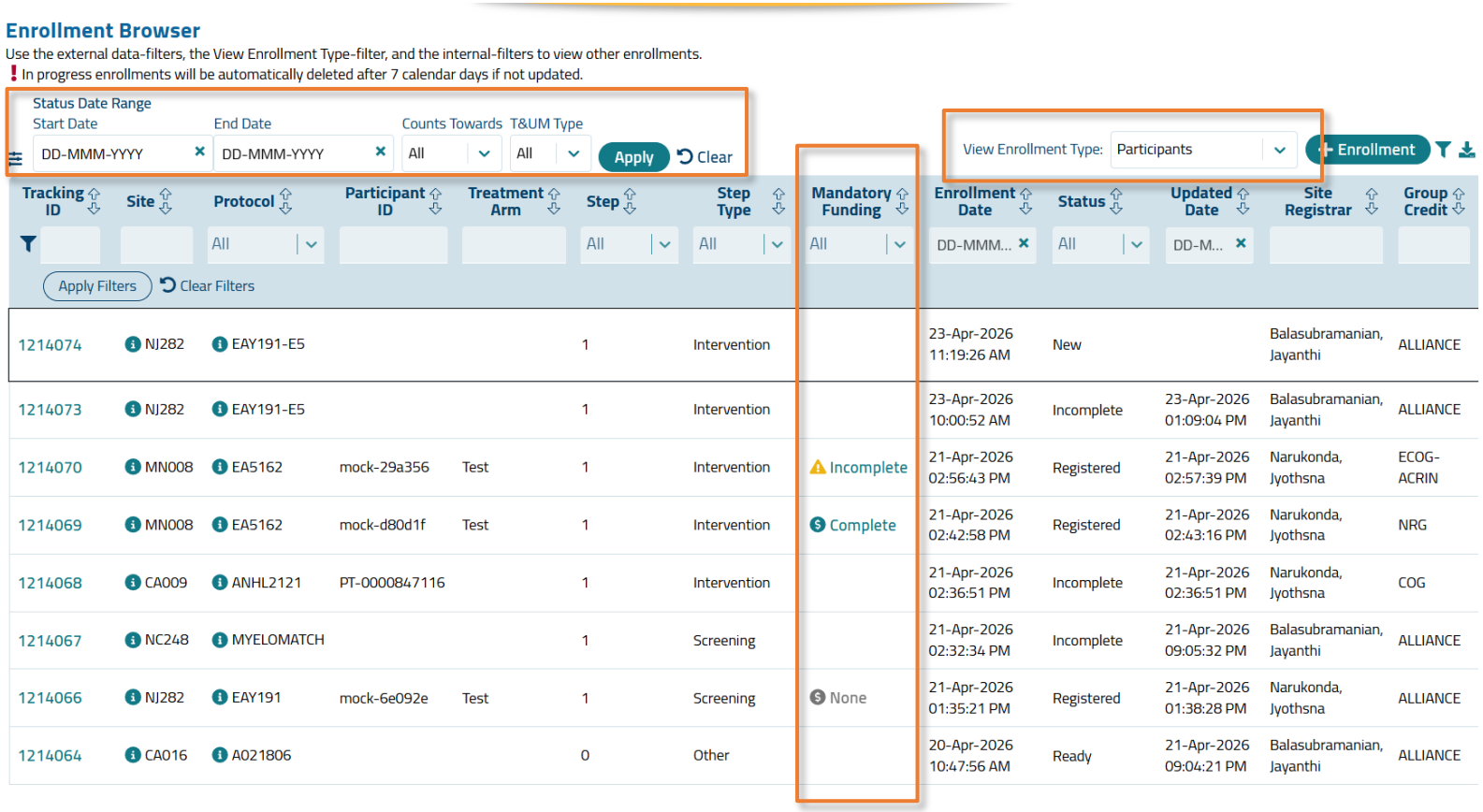
Practice Mode

- Pink patterned background
- Pink indicator box
- Stop button to exit Practice Mode



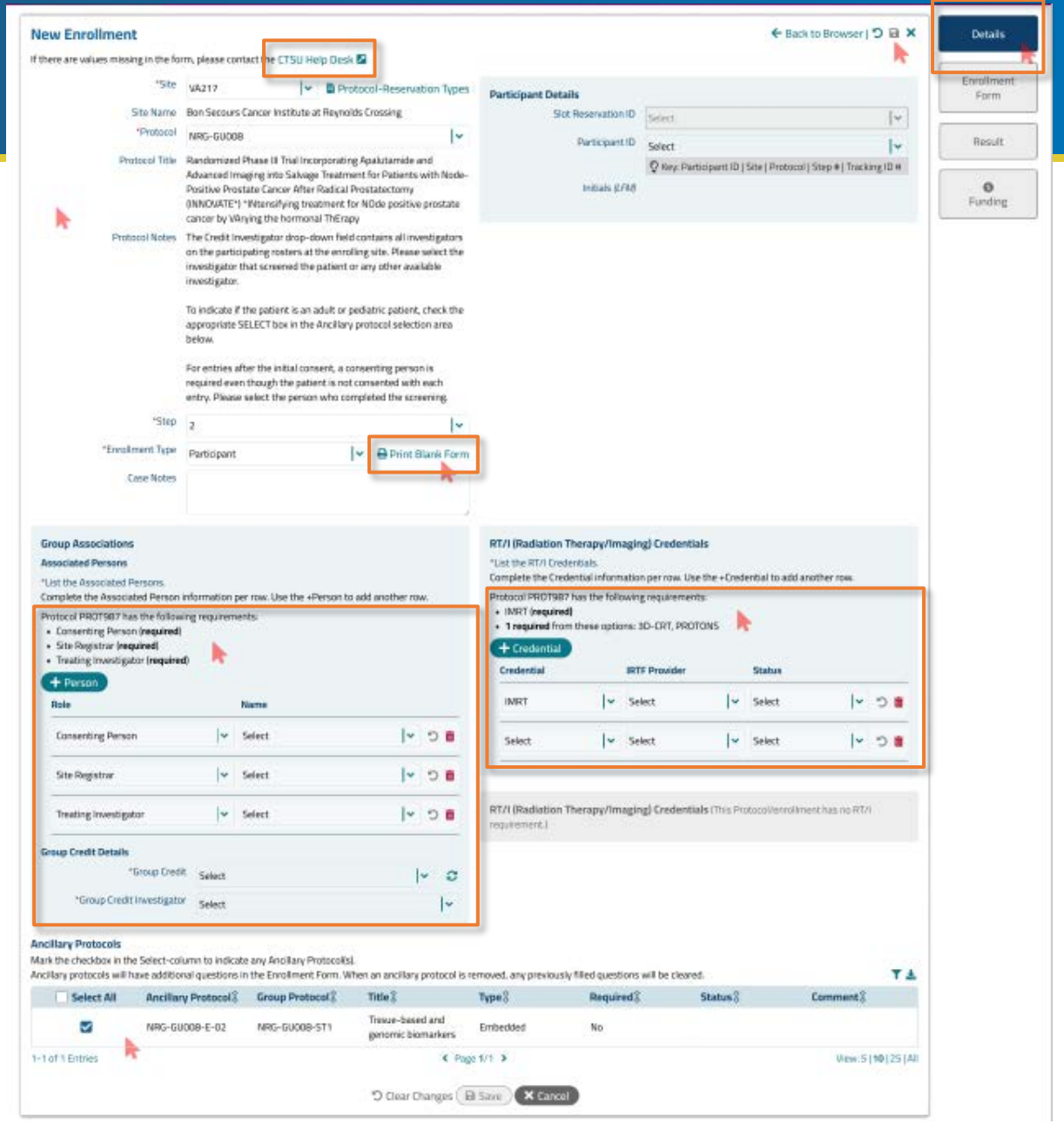
Enrollment Browser

- Single browser for all enrollments
- Participant and Non-Patient Participant enrollment view filters
- Decluttered table with external filtering
- New Mandatory Funding functionality



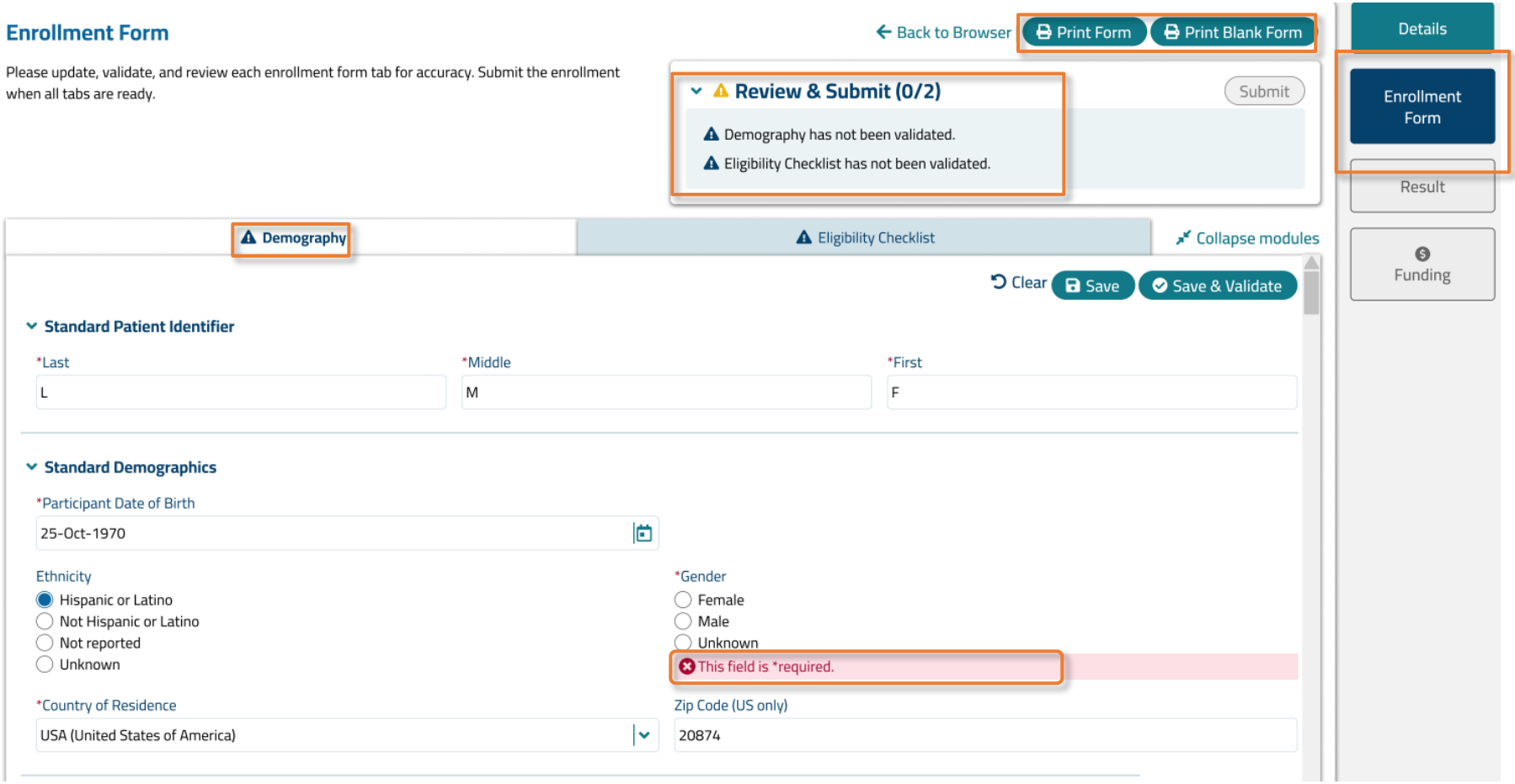
Create New Enrollment

- Details tile separated from enrollment form
- Link to the CTSU Help Desk contact page
- Pre-populated fields
- Print Blank Form feature



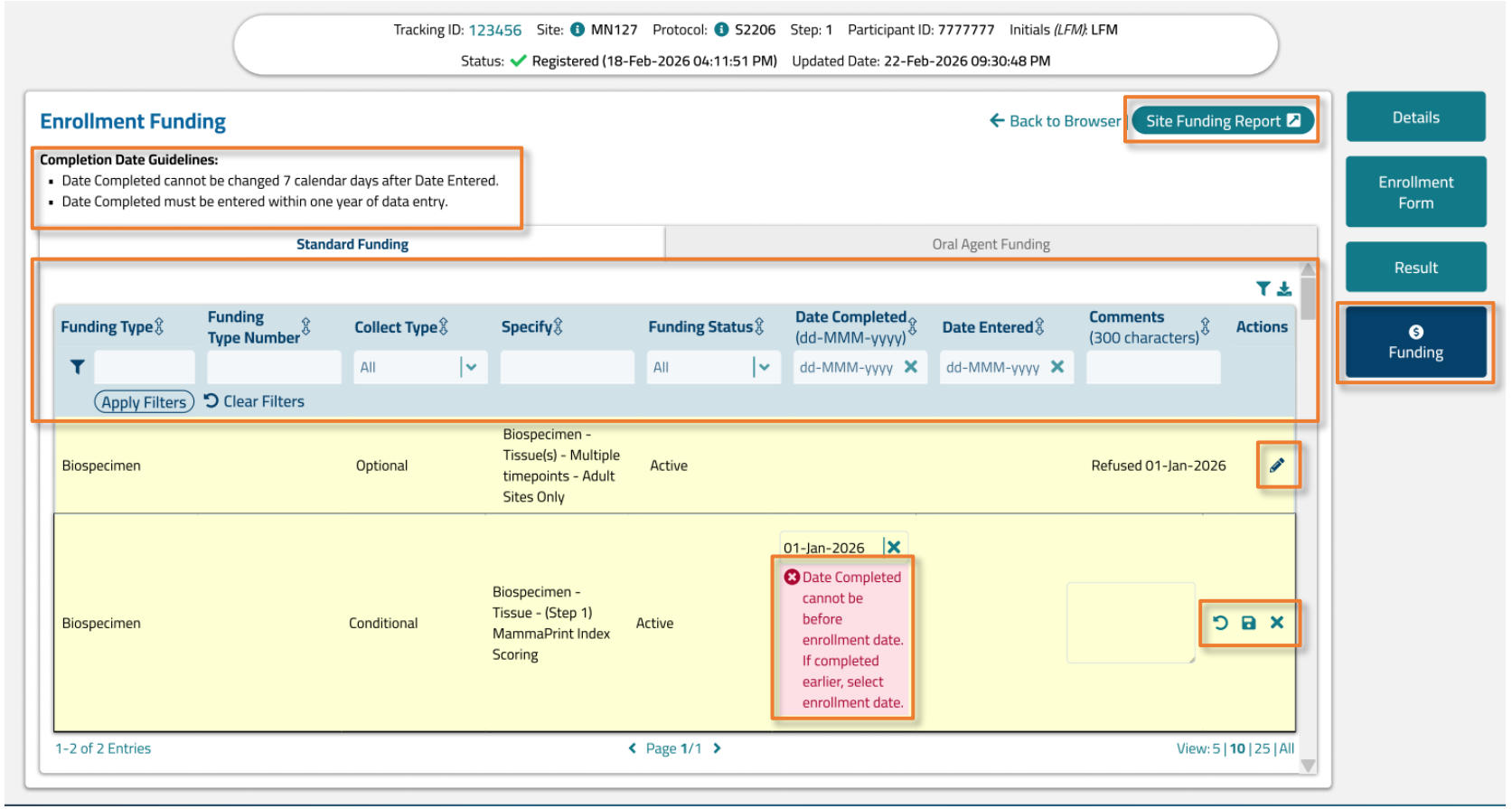
Enrollment Forms

- Enrollment Form tile contains all protocol-specific forms
- Simplified submission checklist with status icons matching tabs
- Errors appear at question level
- Print capabilities for a blank form or a form with data entered



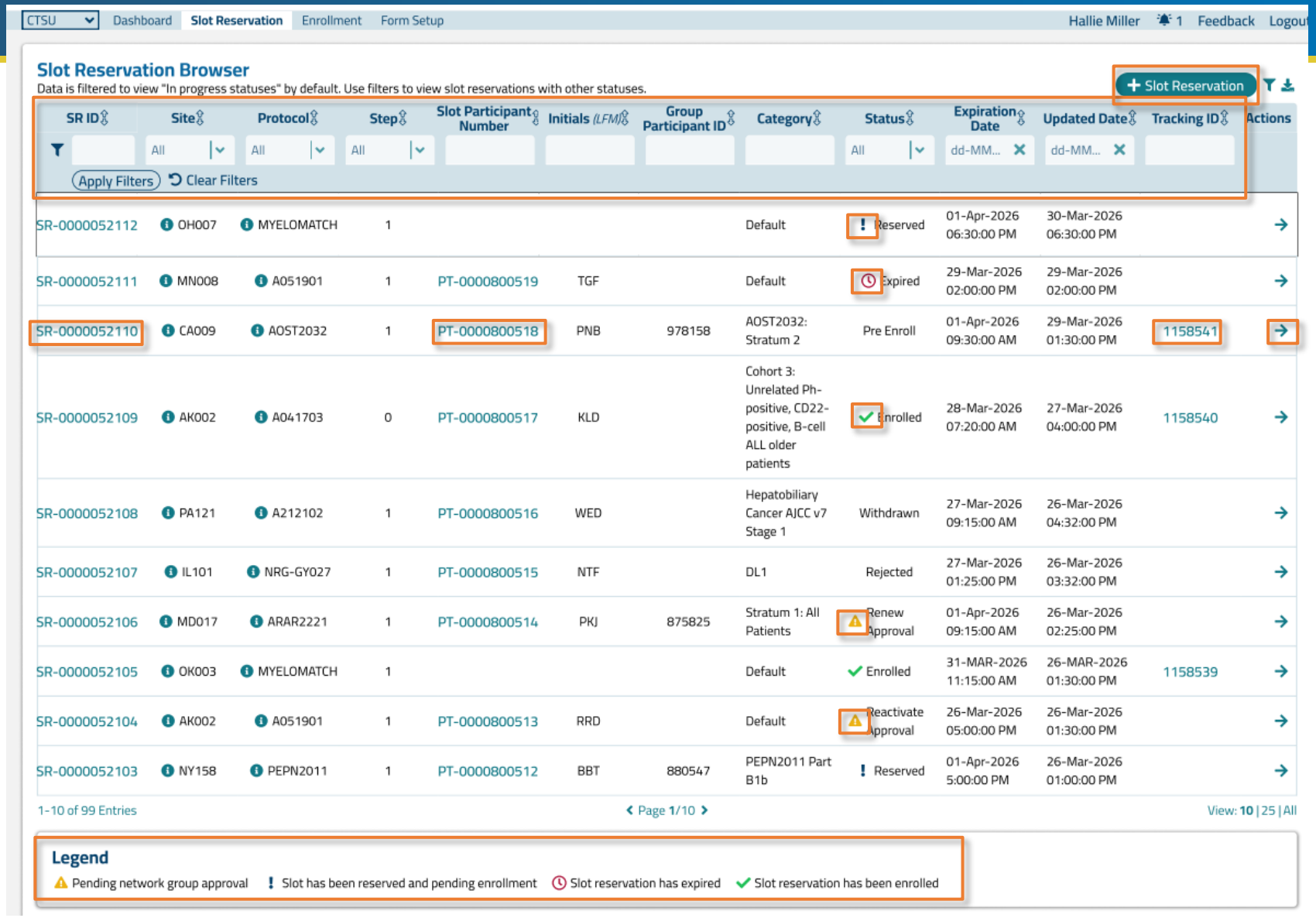
Funding

- Funding tile always present in navigation
- Funding report available for comprehensive site-level entries
- Filter functionality added
- Instructions simplified
- Single row edits and field-level error messages



Slot Reservation Browser

- Single browsers for all slot reservations
- Filters available for all columns
- Direct links to slot, participant, and enrollment
- Create a new slot using the add new button
- Visually identify select statuses with icons



Website Transformation



Member Website Transformation Background / Goals

- Multi-phase process with initial focus on most used content/tools
- Modernize the design and functionality
- Improve the user experience and streamline information retrieval and site tasks
- Updates on this effort will be communicated via the CTSU Newsletter and notifications on the existing website
- A Website Transformation Survey will gather input on current use and ideas for improvement
  - Available in fall 2026 on the website
  - Ideas can be sent at any time to the CTSU Help Desk



Questions

CTSU Help Desk

1-888-823-5923

ctsucontact@westat.com



SWOG Updates



Presented by:
Christina Wiess, BA, CCRP

Photo Credit: https://tse3.mm.bing.net/th/id/OIP.tVWN0CgSN417MPnqxG8VfgHaF7?w=215&h=184&c=7&o=5&dpr=1.1&pid=1.7

SDMC Updates

Kari Chansky, MS

Coordinating Statistician

SWOG Statistics and Data Management Center

Seattle, WA



SWOG Activations

S2419: Phase III Double Blinded Trial of Immune-Based Therapy with a Live Biotherapeutic MO-03 or Placebo for Frontline Therapy of Advanced Clear Cell Renal Cell Carcinoma [BioFront Trial]

Activated 04/22/2026 Regulatory Submission Intent

S2424CD: A Randomized Controlled Trial of an Intervention called "Algorithm-Enabled Patients Activated in Cancer Care through Teams" (A-PACT) to Improve Goals of Care Communication for People with Cancer

Activated 06/01/2026

S2504: A Randomized Phase III Study of Pirtobrutinib Plus R-CHOP vs. R-CHOP for Participants with Previously Untreated Richter Transformation (PIRAMID)

Activated: 06/01/2026

SWOG Activations

S2505: Phase III Randomized Study Testing Non-Inferiority of Short-Course Ultra-Hypofractionated Radiation (UHRT-5) Versus Standard Fractionation (RT-25) for Stage II-IIIB, Extremity, Resectable Soft Tissue Sarcoma
Activated: 07/01/2026

MM1OA-S04: A Randomized Phase II Trial of ASTX727 with Standard Duration Versus Shorter Duration of Venetoclax in Genomically Heterogenous AML Among Adults Aged 60 or Older and Less Fit for Intensive Therapy: A MyeloMATCH Substudy
Activated: 07/22/2026

SWOG Activations

S1900N: A Randomized Phase II Study of Sacituzumab Govitecan Alone, Ivonescimab Alone, or Sacituzumab Govitecan and Ivonescimab in Participants with Previously-Treated Actionable Genomic Alteration Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)
Activated: 08/03/2026

S2511: Randomized Phase III Trial of Multimodality Therapy Versus Standard of Care Systemic Therapy in HER2 Positive (HER2+) De Novo (AJCC Stage IV) Oligometastatic Breast Cancer with Response to Initial Chemotherapy
Activated: 08/18/2026 Streamlined Data Collection

SWOG Activations

S2506: MOZART MZL: A Randomized Phase II Study Evaluating Mosunetuzumab Alone and in Combination with Either Zanubrutinib or Polatuzumab Vedotin for the Treatment of Participants with Relapsed/Refractory Marginal Zone Lymphoma

Activated: 08/18/2026

S2507: A Phase II Randomized Study of Blinatumomab with or without Revumenib for Patients with KMT2A-Translocation B-cell acute lymphoblastic leukemia (ALL)/ acute leukemia with ambiguous lineage (ALAL) with persistent measurable residual disease (MRD)

Planned Activation: 09/21/2026

SWOG Activations – CTP

26CTP.LEUK02: **APEX-MF**, **A** RANDOMIZED O**P**EN LABEL TRIAL COMPARING MOM**E**LOTINIB VS DOSE-ADJUSTED RU**X**OLITINIB FOR TREATMENT-NAÏVE, CYTOPENIC **M**YELO**F**IBROSIS

Activated: 06/26/2026

https://swogctp.org/trials/26ctpleuk02/

21CTP.BREAST01: MONITOR (**Mo**lecular Assessme**n**t and **I**den**t**ification of ctDNA and **O**ptimizing T**r**eatment for HR-positive, Her2-negative Metastatic Breast Cancer)

Planned Activation: Q32026

All SWOG sites are invited to consider and apply

Questions? Reach out to ctp@swog.org

MyeloMATCH – Specimen Tracking



All MyeloMATCH trials have transitioned to the SWOG Specimen Tracking System as of August 4th

- *Questions? Contact:* *myelo-match-support@nih.gov*

Data Submission Focus Areas



ORP (CRA) Workbench

- Popular Resources
  - OPEN Patient Registration
  - Rave Data Submission
  - Specimen Tracking
  - CTP Registration and Data Submission
  - SWOG QA / Audits / Monitoring
  - SWOG Best Practices
- Tools
- Resources
- CRA Manual (for Oncology Research Professionals)
- Patient Reports / Data Quality
- Study Reports
- Patient Management (Non-Rave Studies)
- Training

- Patient Reports / Data Quality
  - Expectations
  - Institution Performance Review (IPR)
  - Queries (both Rave and pre-Rave SWOG studies)
  - Ineligible Patients
  - Patients in Follow-up
  - Data Quality Portal (DQP) for Rave studies

Data Submission Focus Areas



Filter Criteria

SWOG Patient ID: | Study: | SWOG Investigator ID: | Disease Type: - ALL -

Registrations after: (mm/dd/yyyy) | Items due*: Before After (mm/dd/yyyy) *Within upcoming 90 days only | Expectation Category: - ALL - | IPR: - ALL -

Institution CTEP ID: -ALL-

Apply Reset

- ALL -
IFS
Form
Specimen
Vital Status/Follow-up

Export Report Data to Excel

Data Management Institution: Ohio State Univ (OH007)
Follow-up Institution: Ohio State Univ (OH007)

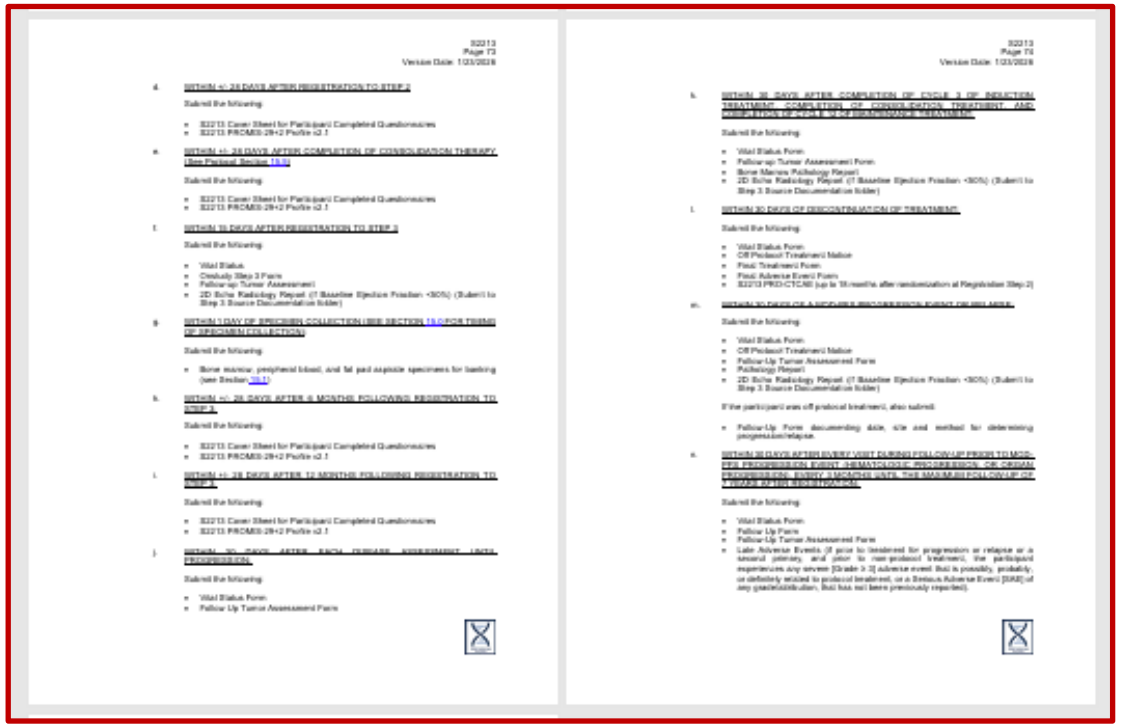
9/11/2026 1:43:03 PM

SWOG Patient ID	Initials	Study	Institution CTEP ID	Investigator	RegDate	Last Contact Date	Vital Status	Due Date	Expectation	Days Overdue	IPR
296513	H,BL	S1823-1			07/14/2023	03/04/2026	Alive	07/28/2026	Follow-up Form/At month 36	45	
								08/31/2026	Vital Status Form/Period beginning 03/05/2026	11	
295810	H,C	S1823-1			05/24/2023	10/23/2025	Alive	02/27/2026	Follow-up Form/At month 33	196	FORM
								04/21/2026	Vital Status Form/Period beginning 10/24/2025	143	FUP
								06/07/2026	Follow-up Form/At month 36	96	FORM

Data Submission Focus Areas

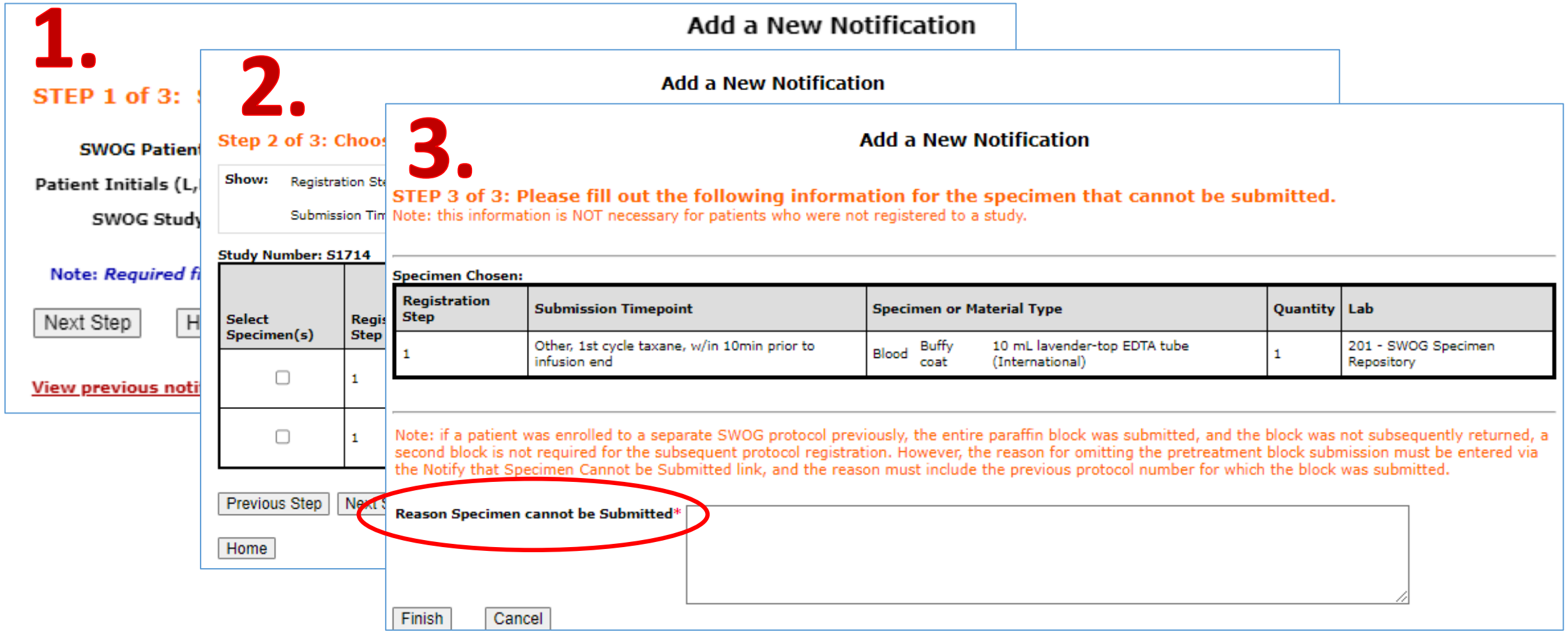
Source Documents:

*** Submit ONLY what is specified in the protocol! ***



Specimen Expectations

How to: “Notify that a Specimen Cannot be Submitted”



Data Submission Focus Areas



DQP versus Expectations

Expectation Reports

What's included in my Expectation report?
The Expectation Report gives a list of specific data items that are either overdue or are due within the next several weeks. We had been incor
what shows for data due in the future:
- For **PRO instruments**, expectations due within the upcoming **90 days** will show on the report.
- For **all other forms/specimens/source docs**, the expectation will show on the report if it is due within the upcoming **42 days**.

These changes may affect the length of your report but only because of items due in the future.

The filters at the top of the Current Expectation Report have also been renamed for clarity. You can choose to see only the Expectations count
Expectations which are negatively impacting your IPR metrics can be identified by using the "IPR" dropdown.

Data Quality Portal vs. the SWOG Expectation and Query Reports
Please take a look at the slides below that explain how the CTSU Data Quality Portal (DQP) and the SWOG Expectation System and Query R
data and responses to queries. We hope this information will answer any questions you may have about the difference between these two sys

CTSU Data Quality Portal vs SWOG Expectation and Query Reports

Data Submission Focus Areas

DQP versus Expectations

	Expectation Report	DQP
Which studies	All Rave studies + all pre-Rave studies	Rave studies WITH calendaring
What's included	Forms, vital status updates, specimens; anything else for which an expectation has been created	Forms, source document uploads and anything that has been calendared within Rave
Specimens	Included	Not included
Source documents	One expectation for each type of source doc at a given time point	One form (with log lines) which includes all relevant source docs
How to access	SWOG CRA Workbench; dynamic report updated in real time	CTSU; updated nightly

Data Submission Focus Areas



DQP versus Expectations

- We see DQP as a **tool** to help you manage data from the current Rave studies
  - ✓ All overdue data and queries in one place
  - ✓ SWOG and other Network Groups studies
- **If there is a discrepancy between DQP and Expectation Reports**, work towards the **Expectation Report** as that is how the Institution Performance Review (**IPR**) is calculated per SWOG Policy #33

CRA Newsletter – Summer and Fall



- Patient-friendly trial summaries
- NCORP Workshop
- Medidata Rave transition
- Who's who at the NOC and SDMC
- Email distribution lists

Send your ideas! CRANewsletter@crab.org



SDMC Staffing Updates





Macy Welch, B.S. Public Health
Publications Coordinator

Welcome, Macy!

SDMC Staffing Updates





Brett Hanscom, PhD
GU Committee

Welcome, Dr. Hanscom!

SDMC Staffing Updates





Megan Eisele, M.S.
Project Manager – Application Development

Welcome, Megan!

SDMC Staffing Updates





Jeri Jardine, B.S.
Data Coordinator

Welcome back, Jeri!

Contact Us



breastquestion@crab.org
cancercontrolquestion@crab.org
giquestion@crab.org
guquestion@crab.org
leukemiaquestion@crab.org
lungquestion@crab.org
lymphomaquestion@crab.org
melanomaquestion@crab.org
myelomaquestion@crab.org
raretumors@crab.org
LungMAPquestion@crab.org

SWOGComboMATCHquestion@crab.org
SWOGiMATCHquestion@crab.org
SWOGMyeloMATCHquestion@crab.org

SWOG Network Group Operations Center
Administration & Funding Updates

Presenters:
Casey Dawson, SWOG Deputy Director of Administration
Pat Mize, SWOG Assistant Director of Grants Management

SWOG Grant Transitions

SWOG NCTN Network Operations Grant

OHSU ⟹ UC Davis

03/01/2026

SWOG NCORP Research Base Grant

OHSU ⟹ The Hope Foundation

08/01/2026

Membership Association & Vendor Agreements

Membership Association Agreement

✓ Emailed

Coming Soon…

NCTN Vendor Agreement

UC Davis

- NCTN standard federal site payments
- NCTN non-standard federal site payments

NCORP Vendor Agreement

The Hope Foundation

- NCORP standard federal site payments
- NCORP non-standard federal site payments
- NCTN/NCORP pass-thru federal payments

Quality Assurance Updates



Presented by:
Laura Gonzales, BSN, MA RN, OCN

Photo Credit: https://smartbotsland.com/bots/wp-content/uploads/2022/07/Multitasking.png

Information Systems Updates



Presented by:
Cara Laubach

Photo Credit: https://img.freepik.com/premium-vector/multitask-man-computer_118813-14922.jpg

Knowledge Check Speed Round: Streamlining Your Efforts

This slide set is accessible via the SWOG website at:

Fall 2026 Oncology Research Professionals Resources

(https://www.swog.org/fall-2026-oncology-research-professionals-resources)

What needs to be documented for non-investigational medications that are included in the protocol treatment plan? (Select the best answer)

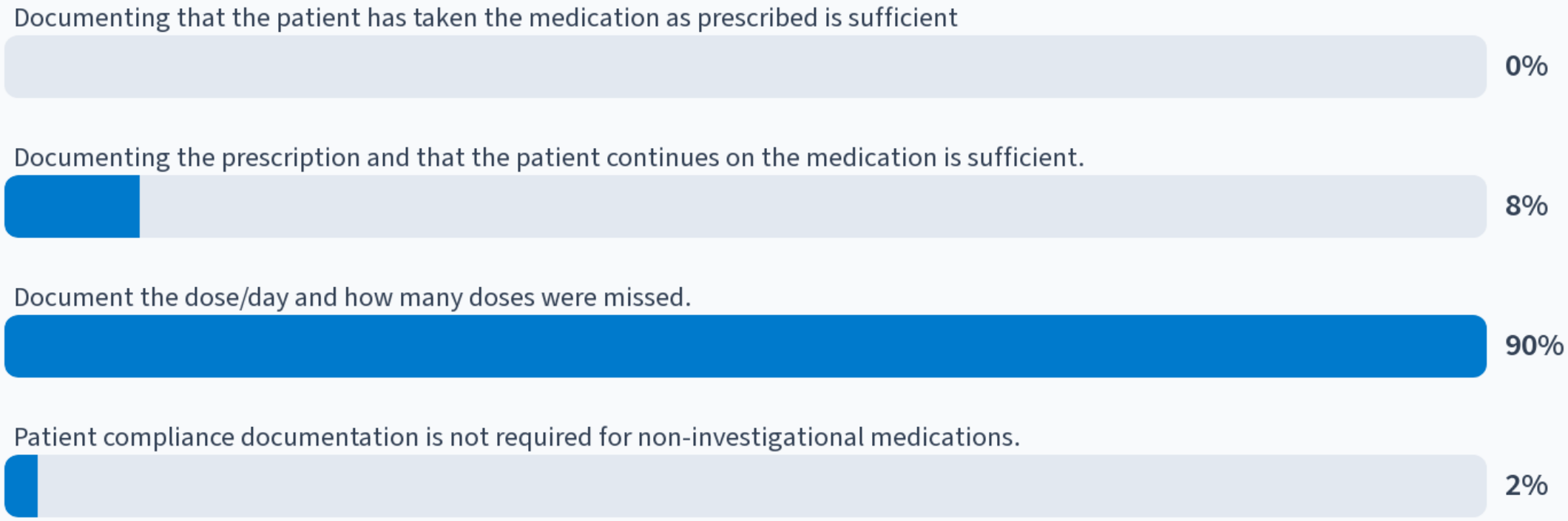
A. Documenting that the patient has taken the medication as prescribed is sufficient.

B. Documenting the prescription and that the patient continues on the medication is sufficient.

C. Document the dose/day and how many doses were missed.

D. Patient compliance documentation is not required for non-investigational medications.

What needs to be documented for non-investigational medications that are included in the protocol treatment plan? (Select the best answer)



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

What needs to be documented for non-investigational medications that are included in the protocol treatment plan?

Answer: Dose/day and how many doses were missed.

The Treatment Form in RAVE will ask you to report the total dose of all protocol treatment agents.

- If compliance has not been assessed for commercially available study agents, then there is no way to verify the total dose of the agent.

For more information refer to:

- SWOG Data Submission Guidance, Tips, and Tricks - Example Treatment Form
- SWOG ORP Manual – Chapter 16: General Forms Guidelines
- SWOG Quality Assurance & Audits – Agent Accountability and Pharmacy Operations

Related Training Course:

- SWOG Quality Assurance Webinar Safeguarding the Science: Best Practices for Investigational Drug Documentation and Management Presentation (CEU available)

A patient comes in for study treatment and starts to complete their PROs which are due in two weeks. After seeing the physician, the treatment is held for this cycle. How should the PROs be handled for this timepoint? (Select the best answer)

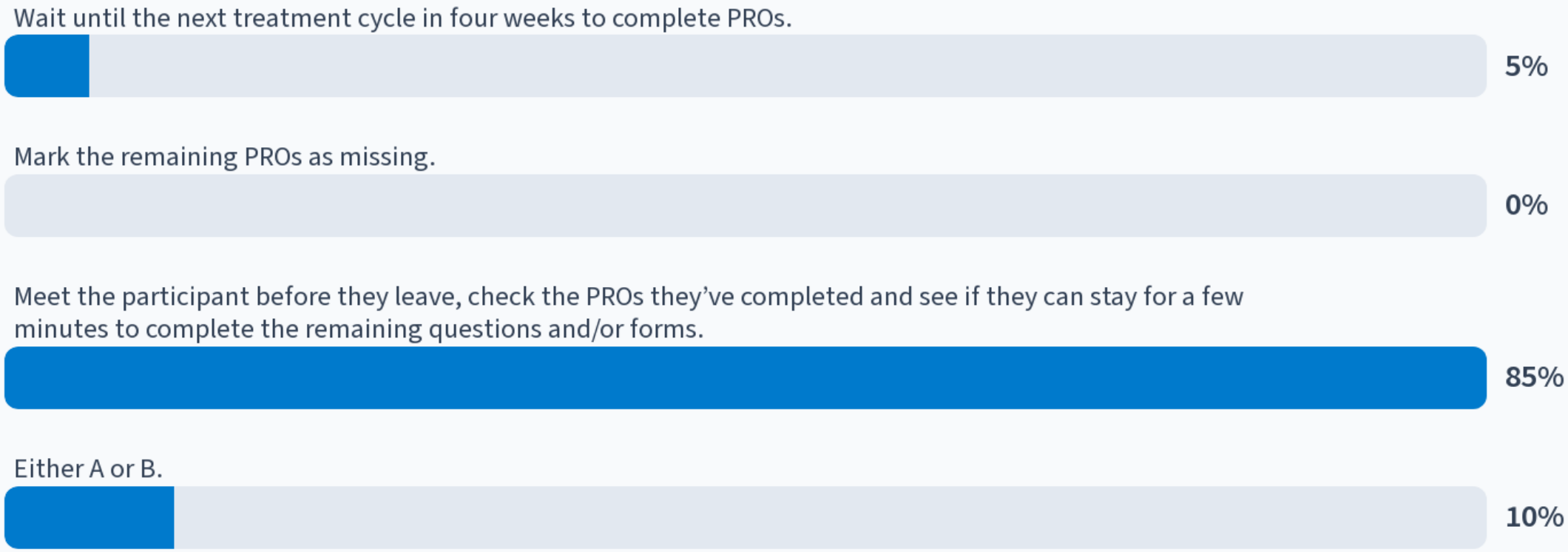
A. Wait until the next treatment cycle in four weeks to complete PROs.

B. Mark the remaining PROs as missing.

C. Meet the participant before they leave, check the PROs they've completed and see if they can stay for a few minutes to complete the remaining questions and/or forms.

D. Either A or B.

A patient comes in for study treatment and starts to complete their PROs which are due in two weeks. After seeing the physician, the treatment is held for this cycle. How should the PROs be handled for this timepoint? (Select the best answer)



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

A patient comes in for study treatment and starts to complete their PROs which are due in two weeks. After seeing the physician, the treatment is held for this cycle. How should the PROs be handled for this timepoint?

Answer:

- Meet the participant before they leave, check the PROs they've completed and see if they can stay for a few minutes to complete the remaining questions and/or forms.
  - The participant's visit is the best/most efficient timepoint to collect the PRO questionnaires that are required at that timepoint per protocol.
  - If the participant is not able to stay to complete the questionnaires, refer to the protocol for mail and/or remote administration allowances/instructions or contact the study team for further guidance.
  - Every effort should be made to collect the remaining PRO questions and/or forms within the allotted protocol-specified collection window (2 weeks in this example).

For more information refer to the following online training courses:

- Patient Reported Outcomes-Part of the SWOG Clinical Trials Training Course
- Comprehensive Overview of Patient Reported Outcomes
- Enduring SWOG Quality Assurance Webinar Patient Reported Outcomes CEU course (link accessible from: SWOG Quality Assurance Live Webinar Series)

What is the minimum information required to submit an initial Serious Adverse Event (SAE) report in CTEP-AERS?

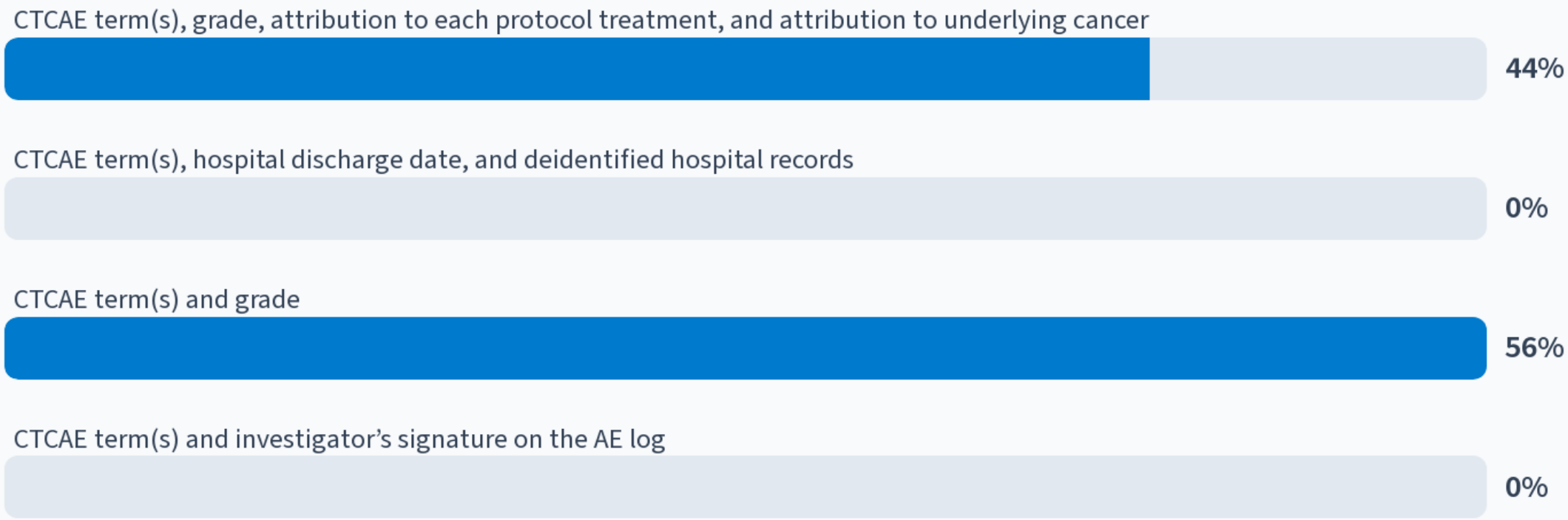
A. CTCAE term(s), grade, attribution to each protocol treatment, and attribution to underlying cancer

B. CTCAE term(s), hospital discharge date, and deidentified hospital records

C. CTCAE term(s) and grade

D. CTCAE term(s) and investigator's signature on the AE log

What is the minimum information required to submit an initial SAE report in CTEP-AERS?



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

What is the minimum information required to submit an initial Serious Adverse Event (SAE) report in CTEP-AERS?

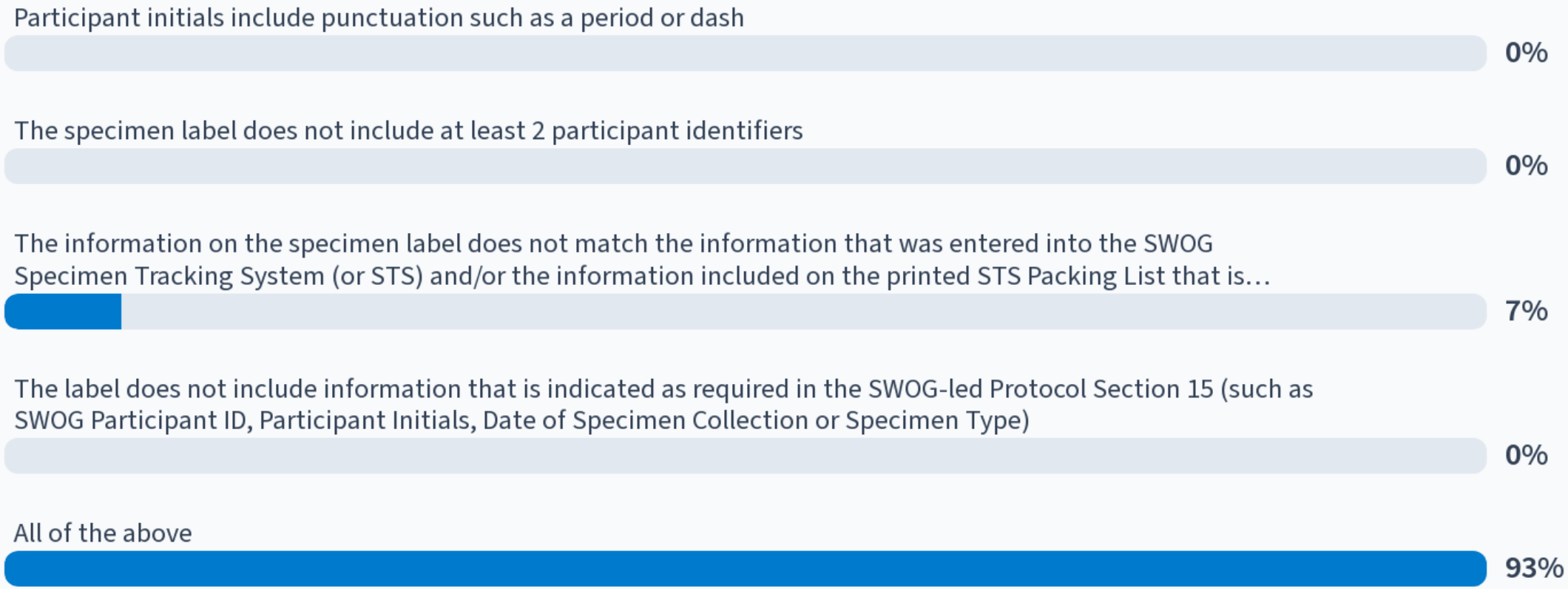
Answer: CTEP-AERS will not allow any report, including a 24-hour notification, to be submitted without the CTCAE term(s), grade, and attributions to each protocol treatment and underlying cancer.

- **Please contact ADR@swog.org with any questions or issues reporting SAEs.**
- For more information refer to:
  - SWOG Serious Adverse Event Reporting-Part of the Clinical Trials Training Course
  - SWOG Policy 23, Expedited Reporting Guide, SAE Reporting Flowchart, SAE Escape Room, SAE Reporting for Lead ORPs course, Serious Adverse Event Reporting and Updates (QA webinar) course and Serious Adverse Events webpage.
  - NCI CTCAE and Adverse Event (AE) Reporting webpage, including the NCI Investigator Guidelines: AE Reporting Requirements, CTCAE resources, CTEP-AERS Training Guide, CTEP-AERS Training Slide Set, NCI Global Safety Update Memorandum, Presentation, and List of Trials Using Updated SAE Tables
  - CTEP-AERS Help webpage, Rave/CTEP-AERS integration information and FAQs

Which of the following are common specimen labelling errors for SWOG-led protocol specimen submissions that may result in queries to the site?

A. Participant initials include punctuation such as a period or dash
B. The specimen label does not include at least 2 participant identifiers
C. The information on the specimen label does not match the information that was entered into the SWOG Specimen Tracking System (or STS) and/or the information included on the printed STS Packing List that is enclosed with the specimen submission
D. The label does not include information that is indicated as required in the SWOG-led Protocol Section 15 (such as SWOG Participant ID, Participant Initials, Date of Specimen Collection or Specimen Type)
E. All of the above

Which of the following are common specimen labelling errors for SWOG-led protocol specimen submissions that may result in queries to the site?



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

Common specimen labelling errors for SWOG-led protocol specimen submissions that may result in queries to the site

- **Participant Initials will appear in L, FM (Last First Middle) format** in the SWOG Specimen Tracking System (STS).
  - **Only commas are accepted** on the label and in the STS. Any other punctuation (such as periods or dashes) is considered discrepant.
- If **2 participant identifiers** (SWOG ID, Participant Initials, Surgical Pathology ID-SPID) are not included on the specimen label or if the identifiers do not match the information that was included on the SWOG STS Packing List exactly, then a waiver will need to be completed.
- If other **labeling information** (such as collection date, specimen or tissue type) **does not match the information entered in the STS and included on the STS Packing List** or if information that is indicated as required in SWOG-led Protocol Section 15 is not included on the label, then written confirmation of the labeling information may be required.
- For more information refer to: SWOG Specimen Labeling webpage, Specimen Labeling Requirements handout, and the following courses **Specimen Labeling (New!)**, Specimen Tracking System, Tips for Specimen Submission, and QA Webinar CEU Biospecimen Collection and Submission. See also: List of Online Training

What is a SWOG patient-friendly trial summary?

A. A blurb used to raise awareness of a trial on social media

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

C. A shortened version of the informed consent document

D. A description of a clinical trial in a patient's own words

What is a SWOG patient-friendly trial summary?



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

What is a SWOG patient-friendly trial summary?

Answer: The SWOG-provided patient-friendly summary is a short, plain language material you can use to help patients understand a clinical trial

You can use the patient-friendly trial summary:

- As a supportive resource to introduce patients to a SWOG-led clinical trial
- As a (much shorter!) supplement to the informed consent document
- For patients to re-review on their own — or share with loved ones or caregivers

You can find the patient-friendly trial summaries:

- On the SWOG website at:
  - A publicly accessible link: swog.org/SXXXX (insert the trial number, e.g., swog.org/S2419)
  - swog.org/patients/trials-open-patients (a webpage where all SWOG patient-friendly summaries are available)
- On the CTSU website (after login):
  - In the Documents tab, type "summary" in the "Document Title" filter OR
  - Go to: Documents >> CIRB Approved Documents >> Support Documents, where the patient-friendly summary is usually posted as “Clinical Trial Summary”

How and when should the Vital Status Form be submitted? (Select the best answer)

A. Submit a Vital Status Form for every date of contact with the participant since the last data submission timepoint indicated in SWOG-led Protocol Section 14. Multiple Vital Status Forms may be required for submission at a single data submission timepoint specified in SWOG-led Protocol Section 14.

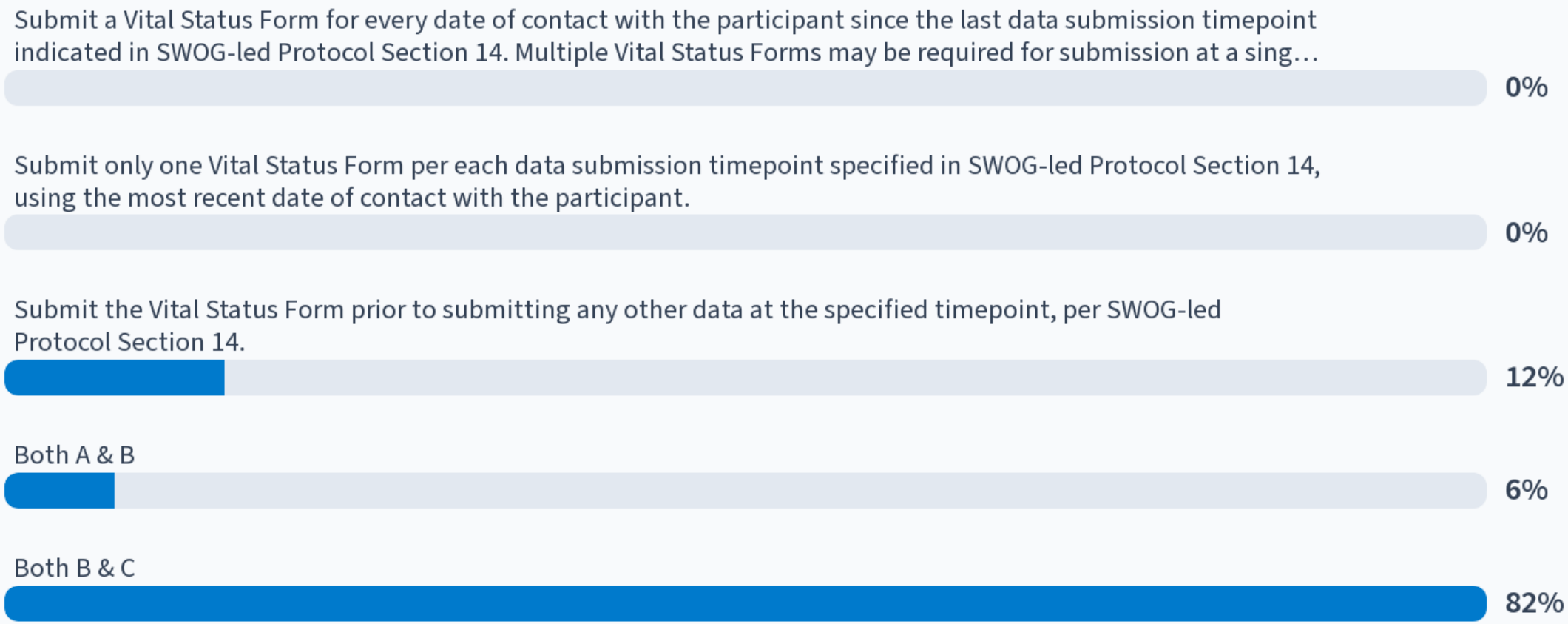
B. Submit only one Vital Status Form per each data submission timepoint specified in SWOG-led Protocol Section 14, using the most recent date of contact with the participant.

C. Submit the Vital Status Form prior to submitting any other data at the specified timepoint, per SWOG-led Protocol Section 14.

D. Both A & B

E. Both B & C

How and when should the Vital Status Form be submitted? (Select the best answer)



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

How and when should the Vital Status Form be submitted?

Answer:

Vital Status Updates are based upon when the participant was last contacted.

- Complete and submit a Vital Status Form prior to submitting any other data at that timepoint.
- Submit only 1 Vital Status form per submission timepoint, using the most recent date of contact with the participant.
- A vital status update is considered to be overdue if not submitted within 60 days after it is required per SWOG-led Protocol Section 14.

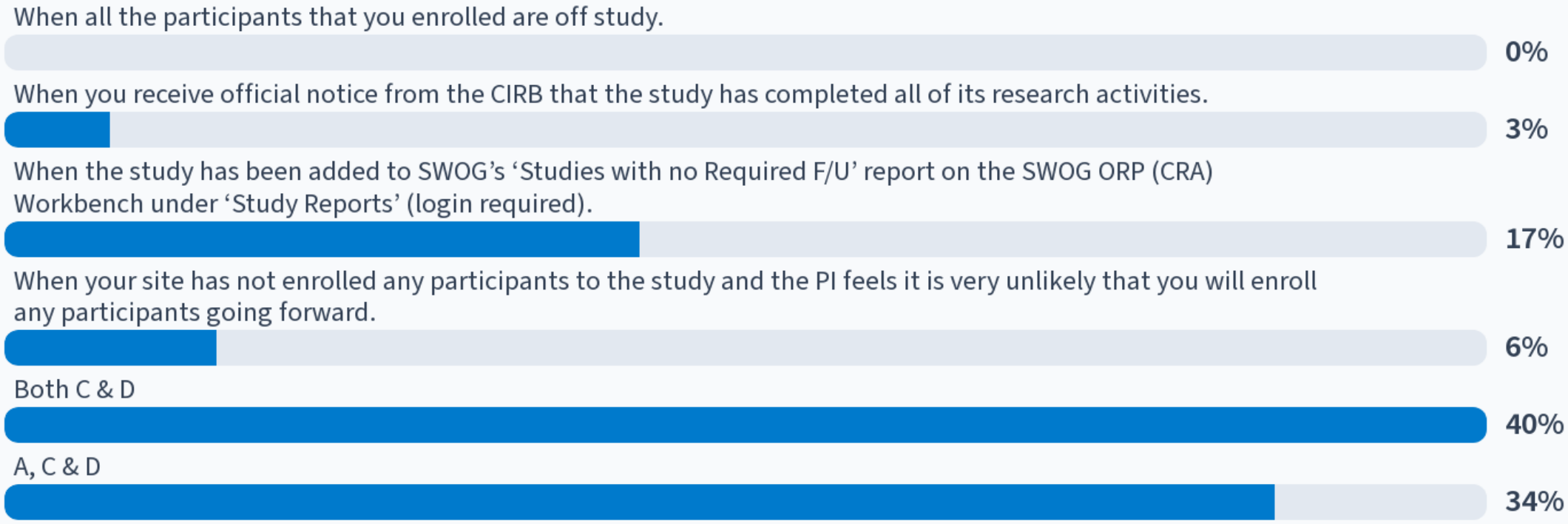
For more information refer to:

- SWOG ORP Manual – Chapter 8: Expectation Report and IPR
- SWOG ORP Manual – Chapter 16: General Forms Guidelines
- SWOG Data Submission Guidance, Tips, and Tricks - Vital Status Form

How will I know when I can submit an Early Study Closure Request to SWOG for a study we'd like to close with the CIRB?

A. When all the participants that you enrolled are off study.
B. When you receive official notice from the CIRB that the study has completed all of its research activities.
C. When the study has been added to SWOG's 'Studies with no Required F/U' report on the SWOG ORP (CRA) Workbench under 'Study Reports' (login required).
D. When your site has not enrolled any participants to the study and the PI feels it is very unlikely that you will enroll any participants going forward.
E. Both C & D
F. A, C & D

How will I know when I can submit an Early Study Closure Request to SWOG for a study we'd like to close with the CIRB?



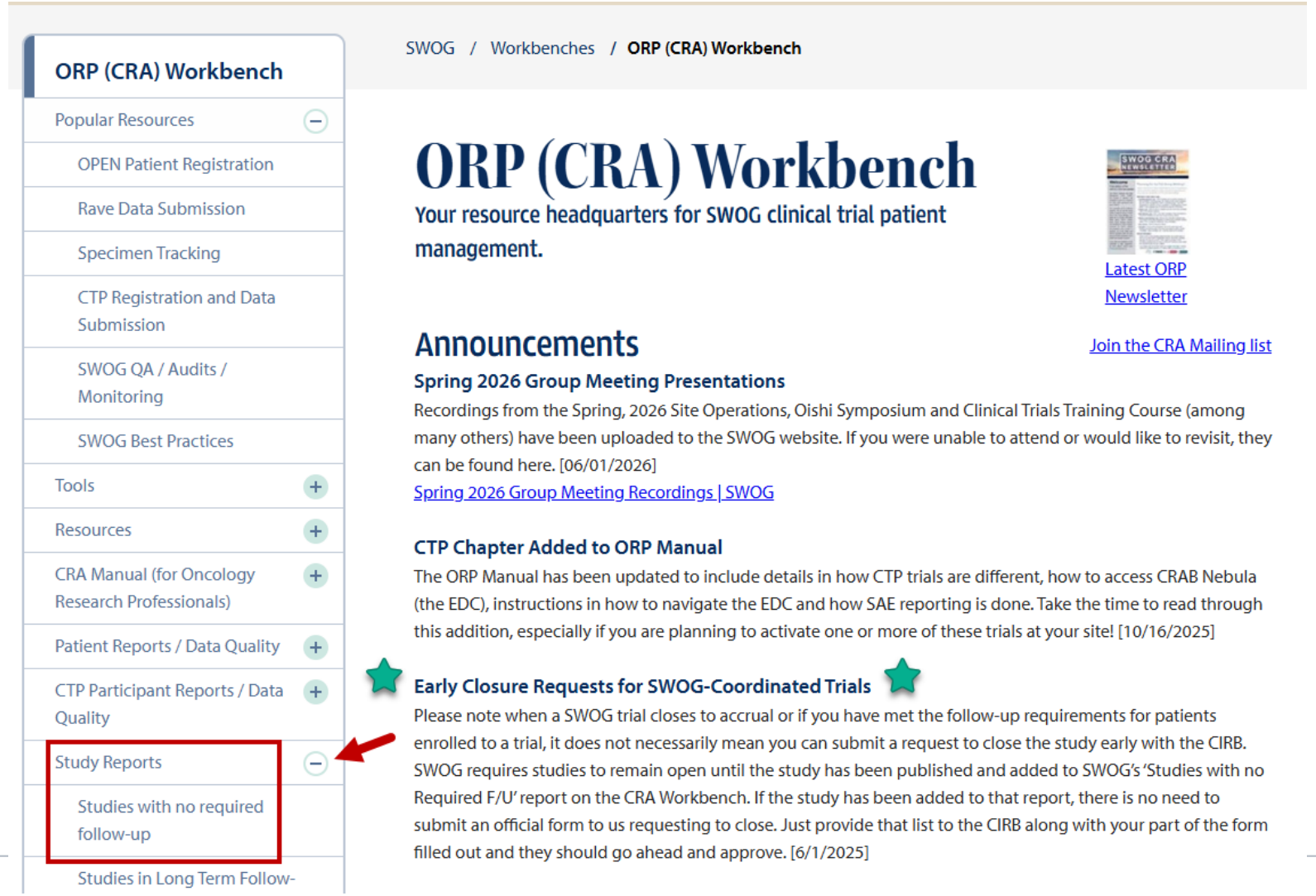
Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

How will I know when I can submit an Early Study Closure Request to SWOG for a study we'd like to close with the CIRB?

Answer: Sites that have enrolled participants to a SWOG-led study must keep the protocol open at their institution until publication or once it has been added to the SWOG List of Studies with No Required Follow-Up report on the SWOG ORP (CRA) Workbench.

- **After the SWOG-led study is added to the SWOG List of Studies with No Required Follow-Up report, there is no need to submit a Request for LPO approval of Early Closure form to SWOG**.
  - Complete the site portion of the NCI CIRB Early Closure Form and attach/provide a copy of the SWOG List of Studies with No Required Follow-Up report with the submission to the NCI CIRB and the CIRB should approve the request for closure.
- If your site has NOT enrolled any participants to the study and would like to request early closure before the study is added to the SWOG List of Studies with No Required Follow-up report, then complete the site portion of the NCI CIRB Early Closure Form and E-mail the request to SWOG at SWOGStudyClosureRequest@crab.org.
- Please direct early closure requests for non-SWOG led studies to the Lead Protocol Organization for the respective study (e.g., Alliance, CCTG, COG, ECOG-ACRIN or NRG).

Where to find the SWOG List of Studies with No Required Follow-up Report



True or False?
All protocol deviations need to be reported to SWOG.

A. True

B. False

True or False?: All protocol deviations need to be reported to SWOG .



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

True or False?
All protocol deviations need to be reported to SWOG.
Answer: False

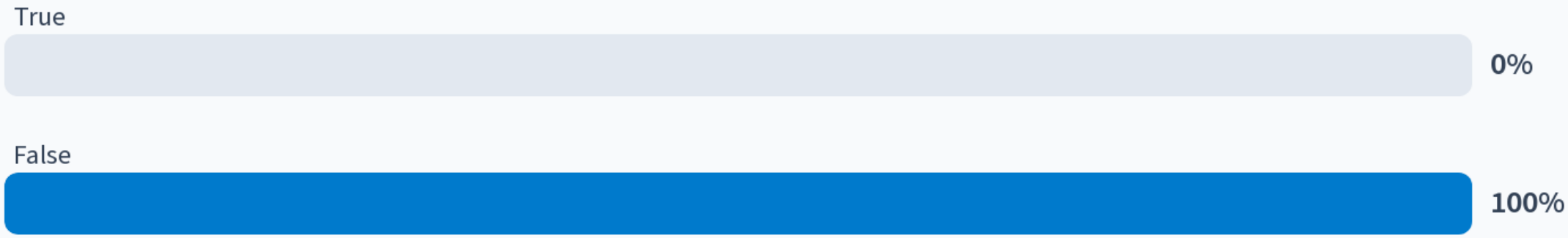
- Protocol deviations should be reported to the participating institution's IRB of record, according to the IRB's policies and procedures.
  - If the CIRB is being utilized as the IRB of record, please note the CIRB guidelines and decision tables for reporting audit findings, unanticipated problems and noncompliance, accessible from: Report A Potential Unanticipated Problem Or A Serious Or Continuing Noncompliance | NCICIRB
- **Only those deviations that meet the CIRB's definition of unanticipated or serious non-compliance should be reported to SWOG.**
  - Deviations including a corrective and preventive action plan should be reported to the SWOG Quality Assurance Department via email to: qamail@swog.org.
- For more information refer to:
  - SWOG Quality Assurance and Audits FAQs document accessible from the SWOG Quality Assurance & Audits webpage under "Additional Resources"
  - SWOG Quality Assurance Webinar Protocol Deviations vs. Deficiencies course
  - Protocol Deviations vs. Deficiencies for Lead Oncology Research Professionals - Part of the SWOG Lead ORP Workshop

True or False?
When using the 5-point Scale (Deauville Score) for disease response, it is not necessary to have documentation of the SUV max of the mediastinal blood pool or the liver.

A. True

B. False

True or False? When using the 5-point Scale (Deauville Score) for disease response, it is not necessary to have documentation of the SUV max of the mediastinal blood pool or the liver.



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

True or False?
When using the 5-point Scale (Deauville Score) for disease response, it is not necessary to have documentation of the SUV max of the mediastinal blood pool or the liver.

Answer: False

- If the study uses metabolic response based on PET scans, the auditors will need to verify the 5-point Deauville Score.
- This verification cannot be done unless the SUV max of the mediastinal blood pool and liver is provided. The Deauville Score is assigned based on the lesion's SUV in comparison to the mediastinal blood pool and liver pool.
- For more information refer to:
  - SWOG Quality Assurance Webinar Disease Assessment Presentation Slide Set
  - Lugano Response Evaluation Form
  - Lugano Disease Assessment (ORP Oishi Symposium Presentation)

When is my site considered out of compliance where overdue queries are concerned?

A. When more than 5 queries written more than 13 months ago are delinquent.
B. When more than 5% of queries written within the last 13 months are delinquent.
C. When more than 10% of queries written within the last 13 months are delinquent.
D. When any query written more than 13 months ago is delinquent.
E. Both B & D

When is my site considered out of compliance where overdue queries are concerned?



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

When is my site considered out of compliance where overdue queries are concerned?

Answer:

Sites are expected to respond to queries within 15 days.

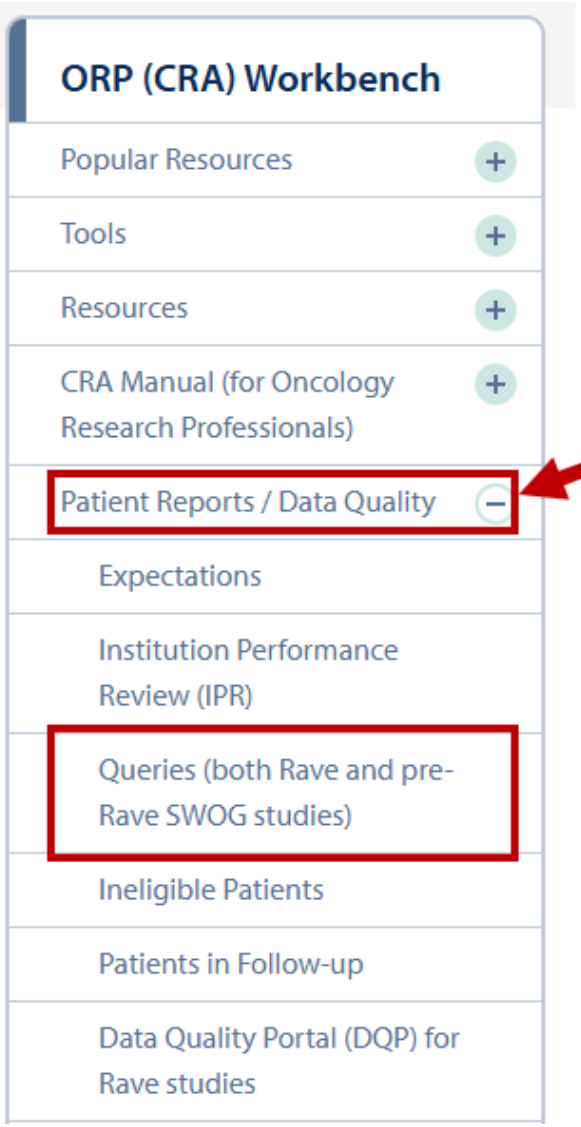
- Any query that is unresolved and is more than 30 days overdue is delinquent.

A site is non-compliant when:

- More than 5% of queries written within the last 13 months are delinquent.
- Any query written/posted more than 13 months ago is still open.

For more information refer to:

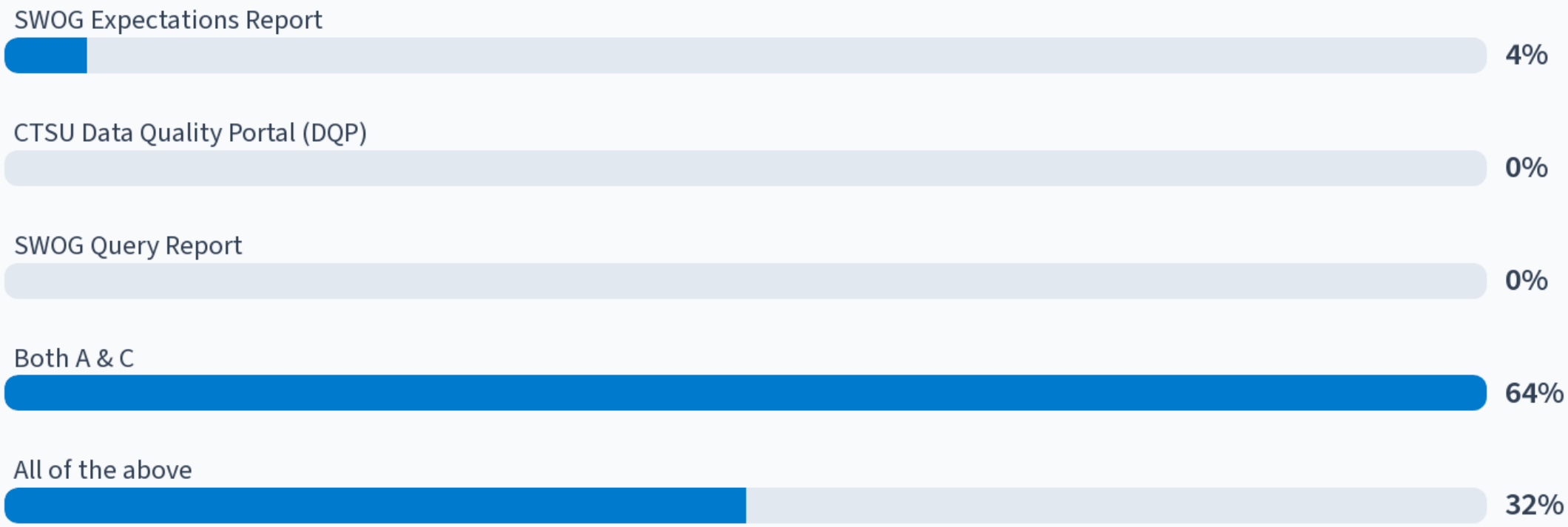
- SWOG ORP Manual – Chapter 8: Find: “Query responsiveness”
- SWOG Policy 33: Institutional Performance Review
- Reports and Tools to Support Quality Data: Expectation and IPR Reports-Part of the SWOG Clinical Trials Training Course
- Query Reports Training for Lead Oncology Research Professionals - Part of the Lead ORP Workshop



SWOG institutional performance metrics (IPR) are based off of what data quality reports?

A. SWOG Expectations Report
B. CTSU Data Quality Portal (DQP)
C. SWOG Query Report
D. Both A & C
E. All of the above

SWOG institutional performance metrics (IPR) are based off of what data quality reports?



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

SWOG institutional performance metrics (IPR) are based off of what data quality reports?

Answer:

Performance Metrics for SWOG are based off of the following reports, accessible from the SWOG ORP (CRA) Workbench:

- SWOG Expectations Report
- SWOG Query Report

SWOG recommends using the SWOG Expectation and Query Reports as the primary tool for data quality monitoring on SWOG-led studies.

For more information refer to:

- SWOG ORP Manual – Chapter 8: Expectation Report and IPR
- SWOG Policy 33: Institutional Performance Review
- Reports and Tools to Support Quality Data: Expectation and IPR Reports-Part of the SWOG Clinical Trials Training Course
- Query Reports Training for Lead Oncology Research Professionals - Part of the Lead ORP Workshop
- CTSU Data Quality Portal vs SWOG Expectation and Query Reports



What are some best practices for collecting quality Patient Reported Outcomes (PROs) data?

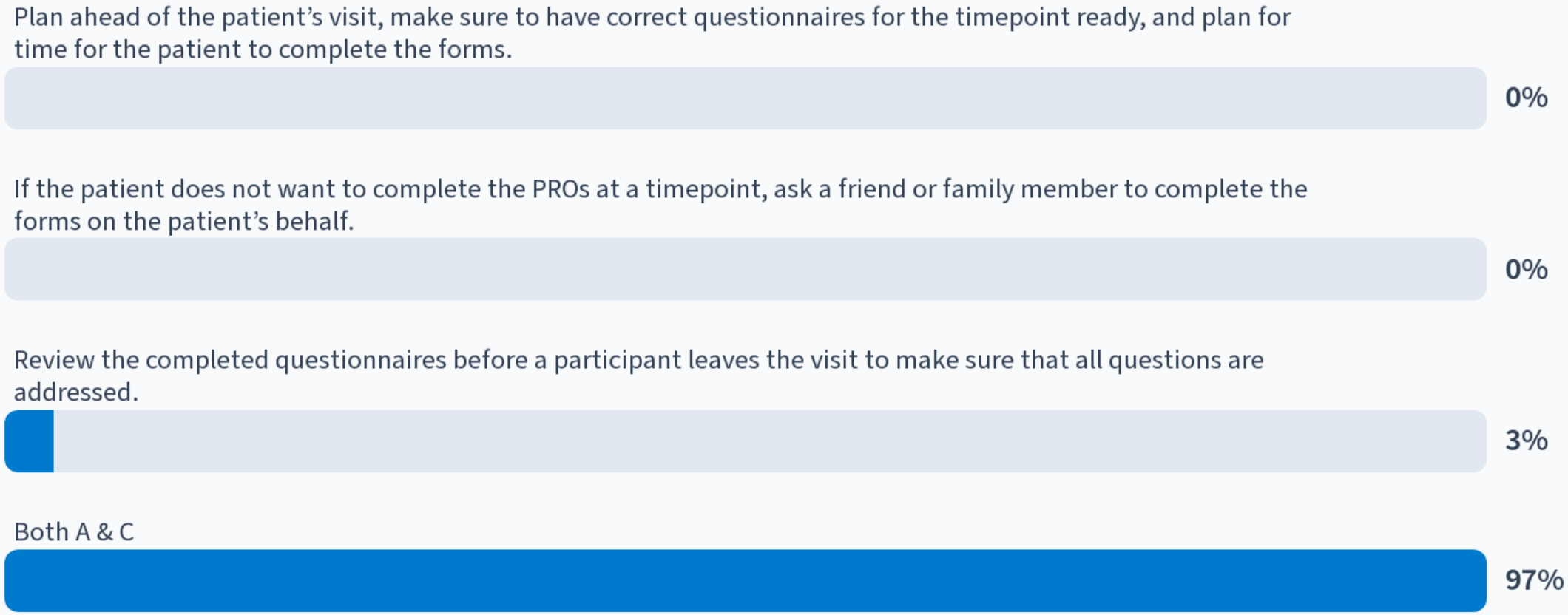
A. Plan ahead of the patient's visit, make sure to have correct questionnaires for the timepoint ready, and plan for time for the patient to complete the forms.

B. If the patient does not want to complete the PROs at a timepoint, ask a friend or family member to complete the forms on the patient's behalf.

C. Review the completed questionnaires before a participant leaves the visit to make sure that all questions are addressed.

D. Both A & C

What are some best practices for collecting quality Patient Reported Outcomes (PROs) data?



Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

What are some best practices for collecting quality Patient Reported Outcomes (PROs) data?

Answer:

- Plan ahead of the participant's visit
- Make sure to have correct questionnaires for the timepoint ready
  - Current forms are accessible from the protocol abstract page on the CTSU website (login required) under Documents >> CIRB Approved Documents (under "Support documents" with the PRO instrument name or descriptor as the document title, e.g.: "PRO Packet" or "PRO-CTCAE form(s)"
  - Refer to protocol Section 15 (of SWOG-led protocols) for timepoints
- Plan / allow time within the scheduled visit for the participant to complete the forms.
- Review the completed questionnaires before a participant leaves the visit to make sure that all questions are addressed.

For more information refer to the following online training courses:

- Patient Reported Outcomes - Part of the SWOG Clinical Trials Training Course
- Comprehensive Overview of Patient Reported Outcomes
- Enduring SWOG Quality Assurance Webinar Patient Reported Outcomes CEU course, in CTSU CLASS accessible from: SWOG Quality Assurance Live Webinar Series

Where can SWOG-provided Educational and Training Resources be found?

A. CTSU Researcher Resources
B. SWOG.org website
C. CTSU CLASS Learning Management System
D. SWOG ExpertusOne Learning Management System
E. SWOG ORP (CRA) Workbench
F. CTSU protocol abstract page
G. All of the above

Where can SWOG-provided Educational and Training Resources be found?

CTSU Researcher Resources 0%

SWOG.org website 0%

CTSU CLASS Learning Management System 0%

SWOG ExpertusOne Learning Management System 0%

SWOG ORP (CRA) Workbench 0%

CTSU protocol abstract page 0%

All of the above 0%

Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

Where can SWOG-provided Educational and Training Resources be found?

- SWOG.org website (throughout the website, relevant to respective topic)
  - In particular, refer to: SWOG Training Resources, Current List of Online Training Courses, Announcements-Upcoming and Recently Posted Training, SWOG Quality Assurance Live Webinar Series, Frequently Asked Questions, Clinical Research Resources and Resources for Oncology Research Professionals
- CTSU CLASS Learning Management System (search by Clinical Trial Number or "SWOG")
- SWOG ExpertusOne Learning Management System (use the Universal Search bar to search by keyword. For access assistance, contact LMSsupport@swog.org)
- SWOG ORP (CRA) Workbench
  - In particular (after login), refer to the resources included under the following navigational menus: Tools, Resources, CRA Manual (for Oncology Research Professionals), Training and Contact Us
- CTSU protocol abstract page (after login, located on the respective protocol abstract page under Documents>>Protocol-Related Documents>>Education and Promotion)
- CTSU Researcher Resources (accessible via CTSU.org after login under the Resources menu)

SWOG Training & Resource Announcements:

Reminders:

- **The SWOG ExpertusOne Learning Management System has moved to a new URL:**
  https://swog.expertusone.cloud/learner/swog/
  (login with ID.me credentials used to access NCI/CTSU secure IT systems)

- **SWOG posts trimmed versions of the SWOG Oishi Symposium, Site Operations Meeting, NCORP Workshop and Take Action Symposium Meetings via ExpertusOne.**
  - Meeting materials are posted via ExpertusOne ~4 weeks after each Group Meeting.
  - After review, SWOG members can download a completion certificate to document their review.
  - You can locate online resources via keyword search within the ExpertusOne system, or
    - Refer to the: Fall 2026 Oncology Research Professionals Resources (https://www.swog.org/fall-2026-oncology-research-professionals-resources) for forthcoming Fall 2026 Site Operations and Oishi Symposium enduring course links.
    - Refer to the Current List of Online Training Courses webpage for forthcoming Fall 2026 NCORP Workshop enduring course links. Here, you can also find links to prior Group meeting materials.

Featured new online training course:

- **SWOG Specimen Labeling**
  - An overview of specimen labeling (for submissions to the SWOG Biospecimen Bank)



...for all you do

Closing Remarks



Presented by:
Christina Wiess, BA, CCRP

Photo Credit: https://i.pinimg.com/736x/f8/ba/76/f8ba761eba4ba5ed97bc2b5e3d5aadc0.jpg

Get help with patient education materials

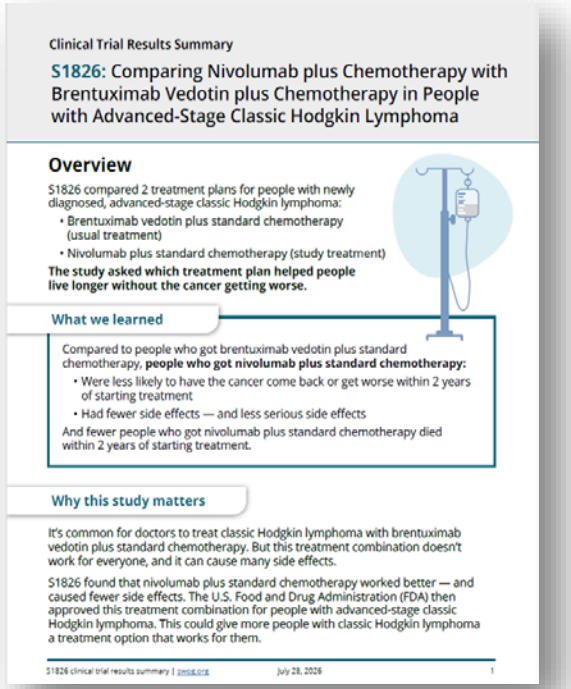
SWOG's Plain Language Communications Expert is providing one-on-one support and group sessions. You might choose:

- **An on-demand phone call or video visit** for help with a specific material or project
- **A scheduled training** to provide your team with guidance on creating clear, effective, accessible patient materials



Interested? Email Andrea Mongler at amongler@swog.org.

Check it out: Patient-friendly results summaries



Clinical Trial Results Summary

S1826: Comparing Nivolumab plus Chemotherapy with Brentuximab Vedotin plus Chemotherapy in People with Advanced-Stage Classic Hodgkin Lymphoma

Overview

S1826 compared 2 treatment plans for people with newly diagnosed, advanced-stage classic Hodgkin lymphoma:

- Brentuximab vedotin plus standard chemotherapy (usual treatment)
- Nivolumab plus standard chemotherapy (study treatment)

The study asked which treatment plan helped people live longer without the cancer getting worse.

What we learned

Compared to people who got brentuximab vedotin plus standard chemotherapy, **people who got nivolumab plus standard chemotherapy:**

- Were less likely to have the cancer come back or get worse within 2 years of starting treatment
- Had fewer side effects — and less serious side effects

And fewer people who got nivolumab plus standard chemotherapy died within 2 years of starting treatment.

Why this study matters

It's common for doctors to treat classic Hodgkin lymphoma with brentuximab vedotin plus standard chemotherapy. But this treatment combination doesn't work for everyone, and it can cause many side effects.

S1826 found that nivolumab plus standard chemotherapy worked better — and caused fewer side effects. The U.S. Food and Drug Administration (FDA) then approved this treatment combination for people with advanced-stage classic Hodgkin lymphoma. This could give more people with classic Hodgkin lymphoma a treatment option that works for them.

S1826 clinical trial results summary | swog.org July 28, 2026 1

SWOG is now creating a **plain language summary** of the primary results of each phase 2 or 3 trial. The priority audience is trial participants (and families/caregivers).

- Access all existing results summaries at swog.org/patients/trial-results.

Site Operations Session Feedback

Let us know what we can do to continue to support your site's operational needs



Click here:
Survey Link

Photo credit: https://www.wa.gov.au/system/files/styles/crop_feature_large/private/2023-10/shutterstock_1812205510.jpg?h=b903c632&itok=IJ52upph

Special Thanks

- Each of our speakers
- Courtney Wille
- Hyatt staff
- Audio/visual team



Photo Credit: https://www.pinterest.com/pin/yellow-sticky-notes-with-thank-you-message-and-smile--763289836822503350/

Reminders

Spring 2027 SWOG Group Meeting

April 15-17, 2027
Hyatt Regency San Francisco
San Francisco, CA



Photo Credit https://static.vecteezy.com/system/resources/previews/040/963/981/non_2x/businesswoman-meditates-at-her-office-desk-with-work-stuff-and-papers-flying-illustrating-employee-wellbeing-and-comfortable-workspace-concept-of-relaxation-and-balance-in-workplace-vector.jpg:

CTSU Data Quality Portal vs. SWOG Expectation and Query Reports

Cathy Rankin, M.S.
Coordinating Statistician
Institution Performance
SWOG Statistics and Data Management Center

April 2026

Expectation Report vs. DQP Delinquency Report

	Expectation Report	DQP
What's posted?	Overdue and upcoming forms due within next 90 days	Overdue forms. Reports also available where up to a 1 year timeframe can be specified
Due date	Based on cycle length, doesn't take treatment delays into account	Based on cycle length. May take into account treatment delays on older trials
Overdue definition	Baseline: > 30 days from due date Post-baseline: > 60 days from due date	Overdue if > 15 days late for baseline data, > 30 days for on-treatment data; > 60 days late for off treatment data

Expectation Report vs. DQP Delinquency Report (continued)

	Expectation Report	DQP
Which studies	All Rave studies + all pre-Rave studies	Rave studies WITH calendaring
What's included	Forms, source document uploads, and specimens; anything else for which an expectation has been created	Forms, source document uploads and anything that has been calendared within Rave
Specimens	Included	Not included
Source documents	One expectation for each type of source doc at a given time point	One form (with log lines) which includes all relevant source docs
How to access	SWOG CRA Workbench; dynamic report updated in real time*	CTSU; updated nightly

* Data submitted in Rave are applied to the SWOG database overnight.

Calendared Studies

- All SWOG studies in Rave except for the following are calendared, i.e., DQP will NOT show delinquent data for this trial.
  - S1207
- All other Rave studies and all future SWOG studies will be calendared

SWOG Query Report vs. DQP Queries

	SWOG Query Report	DQP
What's posted?	All queries	All queries
Which studies?	All Rave studies + All pre-Rave studies	All Rave studies
Overdue definition	Calculated from date posted; overdue if > 15 days from posting and not answered	Calculated from date posted; overdue if > 15 days from posting and not answered
What's included?	Queries written by Data Coordinators, Auditors/Monitors and other personnel. **Medidata Rave System queries + non-conformant data sent by email.**	Queries written by Data Coordinators, Auditors/Monitors and other personnel. **Medidata Rave System queries + non-conformant data**
How to access	SWOG CRA Workbench	CTSU

Comments

- Calendared vs. Not Calendared
  - You will not see overdue forms on studies that aren't calendared (S1207); you will still see outstanding queries regardless of calendaring.
- We see DQP as a tool to help you manage data from the current Rave studies
  - All overdue data and queries in one place
  - SWOG and other Network Groups studies
- If there is a discrepancy between DQP and Expectation Reports, work towards the Expectation Report as that is how the Institution Performance Review (IPR) is calculated per SWOG Policy #33.

Questions

- If you have questions, please contact Cathy Rankin at crankin@fredhutch.org.