



Oishi Symposium

Thursday, April 4, 2024

8 am – 11:30 am

Seattle, Washington

Welcome and Announcements



Connie Szczepanek, RN, BSN, CCRP
Chair, SWOG Oncology Research Professionals Committee

Deb Bergevin, BS
Co-Chair, ORP Education Subcommittee

Joyce Nancarrow Tull, MSN, RN
Co-Chair, ORP Education Subcommittee



In honor of and with
gratefulness for

Noboru Oishi MD

(1928 – 2020)

and

Jeri Oishi, RN



Logistics Details

- Please keep your phone on mute to help with sound quality.
- Questions can be submitted all throughout the meeting via the CHAT icon. We will present them to the speakers during the meeting.
- The presentations will be posted on the SWOG website within a few weeks.





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



ORP Jeri & Noboru Oishi Symposium

Thursday, April 4, 2024
8:00 AM - 11:30 AM PT

Open, Welcome, and Announcements
Connie Szczepanek, Joyce Tull

Biospecimens: Quality, Compliance, and Tips 'n Tricks
Phyllis Goodman, Cathy Rankin, Kae Tegtmeyer, Erin Cebula, Desiree Goldstein

Break

DEI Champions: Lessons Learned & Implications for Future Programming
Colmar Figueroa-Moseley

Break

SWOG QA Audits: Top Ten Deficiencies
Laura Gonzales

Break

Tour of SWOG Website
Christine Magnier

PLEASE KEEP THIS AGENDA AND USE THE FILLABLE STATEMENT BELOW TO DOCUMENT YOUR EDUCATIONAL CREDITS

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 _____

Oishi Education Sub-committee Co-Chairs:
Deb Bergevin, BS – deb.bergevin@seattlechildrens.org
Joyce Nancarrow Tull, MSN, RN – jntull@ucdavis.edu

YOU are The ORP Committee!



“SWOG holds a fundamental conviction that the Oncology Research Professionals (ORP) play a crucial role in the successful development, implementation, and analysis of any SWOG clinical trial.”



ORP Executive Committee Members

Deb Bergevin	Erin Cebula	Joyce Nancarrow-Tull
Lisa Stoppenhagen	Sandy Annis	Dana Little
Connie Szczepanek	Liz Edwards	Anthony Hicks
Annette Betley	Caitlin Hutchinson	Jamie Myers



The SWOG Oncology Research Professionals (ORP) Committee & Sub-Committees



SWOG Cancer Research Network's Mission

- To significantly improve lives through cancer clinical trials and translational research.

ORP Committee Mission

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



Quick Reference



See the ORP page on the SWOG Website:

Member Resources > Oncology Research Professionals

Quick Access to:

- Contact info of Committee Leaders
- Lead ORP (Head CRA) Training Modules
- APP Workshop

The screenshot shows the SWOG website's 'Oncology Research Professionals' page. The page header includes the SWOG logo and navigation links: About, The SWOG Network, News & Events, Clinical Trials, Member Resources, and For Patients. The main content area is titled 'Oncology Research Professionals' and contains a detailed description of the ORP committee's role. Below the text, there are sections for 'Executive Committee Leadership' and 'ORP Liaisons Leads', each listing names and contact information. A portrait photo of a woman is visible on the right side of the page. The footer of the page includes a 'New Resources' section with a link to a meeting recording.



Get Involved with ORP



Follow the link to the ORP Membership Application on the ORP Member Resources page:

To get more involved please complete the [ORP Membership Application](#).

Key Involvement Opportunities

- Disease Specific Liaisons
- Liaisons at Large
- Education Team

**SWOG ONCOLOGY RESEARCH PROFESSIONALS COMMITTEE
SUBCOMMITTEE APPLICATION FORM**

Date Submitted: _____ Date Received: _____

Name & Credentials: _____
 SWOG Roster ID: _____
 Current Position: _____
 Specialty: _____
 Member Site: _____
 Business Address: _____

 Telephone: _____ Fax: _____
 E-Mail Address: _____
 Site Principal Investigator: _____

Group Status: LAPS/Main Member NCORP Affiliate Other: _____

Subcommittee(s) or Areas of Interest:

ORP Liaison Committee Education Nursing Research
 Disease Committee _____ Membership Member at Large
 Other Committee _____ Site Operations

Requirements for ORP Subcommittee Membership:

- Be a Member of SWOG for at least 1 year
- Attendance of at least 1 out of 4 meetings
- Submission of application form and CV (resume or biosketch)
- Signature of applicant

I affirm willingness to serve in an active role on the ORP Subcommittee(s) I am invited to join.

 ORP Subcommittee Applicant Signature / Date

- Signature of Site PI or Program Administrator

I have reviewed the above application for membership in the Oncology Research Professionals Committee and recommend approval for this applicant. My signature affirms my commitment to support participation in committee activities and to provide opportunities for attendance at SWOG meetings in order to maintain membership status.

 Principal Investigator / Program Administrator Signature / Date

**PLEASE SEND COMPLETED FORM AND CV or BIOSKETCH TO THE ORP COMMITTEE MEMBERSHIP TEAM:
ORPExecs@swog.org**

09/16/2019 v

Lung-MAP Site Coordinator's Committee (SCC)

Applications Open This Spring!



What We Do:

- Represent NCTN sites currently working on Lung-MAP
 - Academic, NCORP & VA sites
 - Clinical & Regulatory Professionals
- Collaborate on a committee of 8-12 voting members
- Review & recommend strategies/materials to enhance accrual
- Provide Lung-MAP newsletter content
- Review & provide feedback on Lung-MAP protocols/materials
- Promote & represent Lung-MAP at the SWOG Group Meetings
- Serve as Lung-MAP mentors & champions at study sites

Interested in Joining?

Email SCC Chair, Stephanie Reyes (smiths1@sjchs.org) for an opportunity to shadow the April 4th Lung-MAP Site Coordinators Committee (SCC) Meeting (*Invitation & In-Person Only*)

Be on the lookout for the SWOG announcement & memo posted in CTSU!



SWOG Biospecimens:
Quality, Compliance and
Tips 'n Tricks
Phyllis Goodman, M.S.
and Kae Tegtmeier



Specimen Resources on SWOG Trials

**Phyllis Goodman, M.S.
Coordinating Statistician
Institution Performance**

**SWOG Statistics and Data Management Center
pgoodman@fredhutch.org**



Uses for Biospecimens



- Pathology review for eligibility → rarely. Currently only on S1806.
- Platform trials (Lung-MAP, MyeloMATCH, ComboMATCH, iMATCH)
 - Determine appropriate trials for participants based on bio-markers
 - Screening steps
- Determination of next step – (S1929, screening)
- Determination of stratification (S1201 ERCC1, HER2 analysis; S1418 PD-L1 evaluation)
- Endpoint determination (MRD in leukemia, myeloma)
- Translational medicine (TM) analyses
- Future research

Value of our Biospecimens

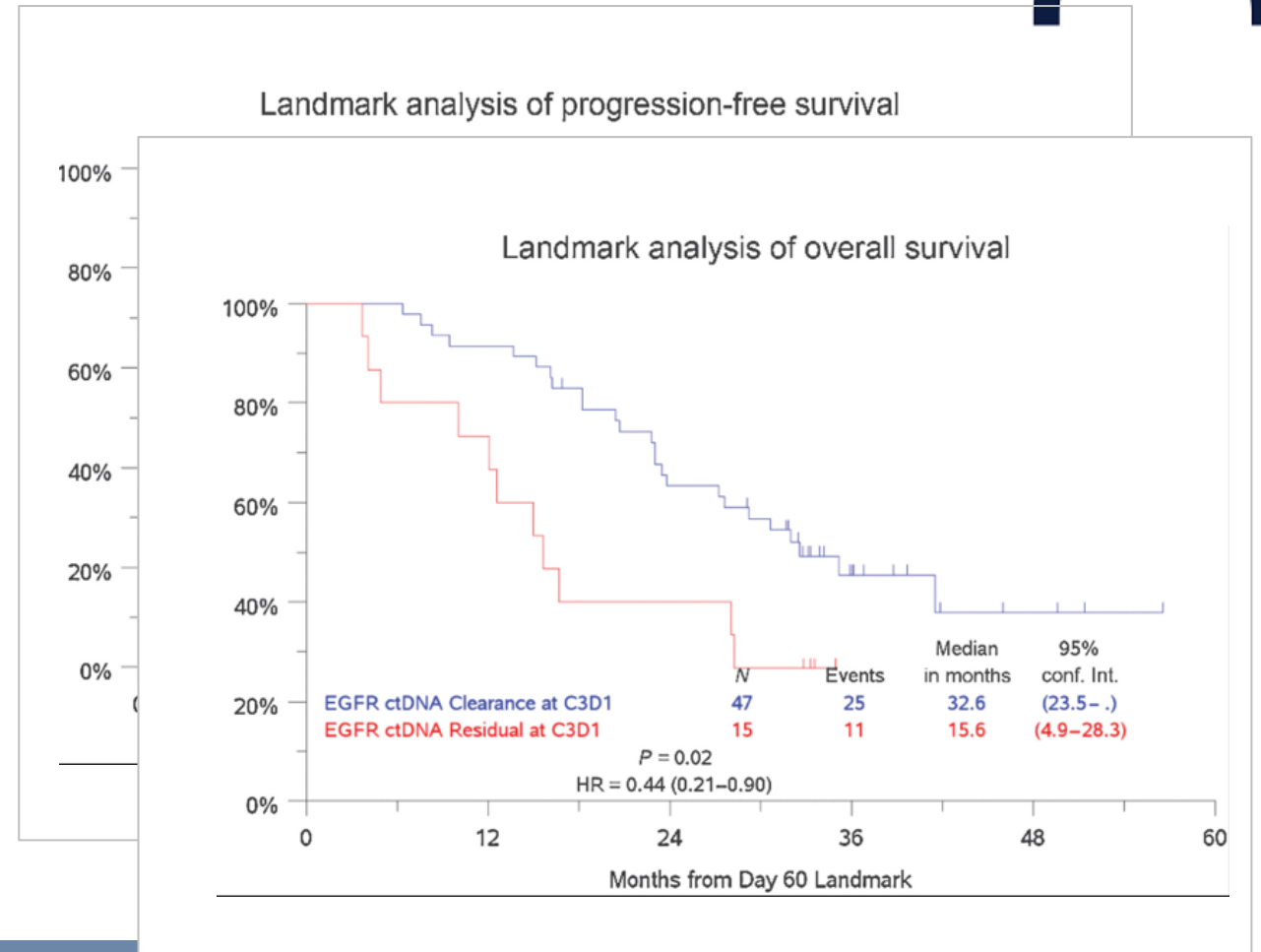


- Biologic data from our specimens
 - Blood, blood products
 - Tissue, bone marrow aspirate
 - Stool, Urine
 - Toenails???
- Linked to clinical data from our trials
 - Demographics
 - Baseline characteristics, disease characteristics
 - Quality of Life
 - Outcomes

S1403 – Circulating Tumor DNA (ctDNA)



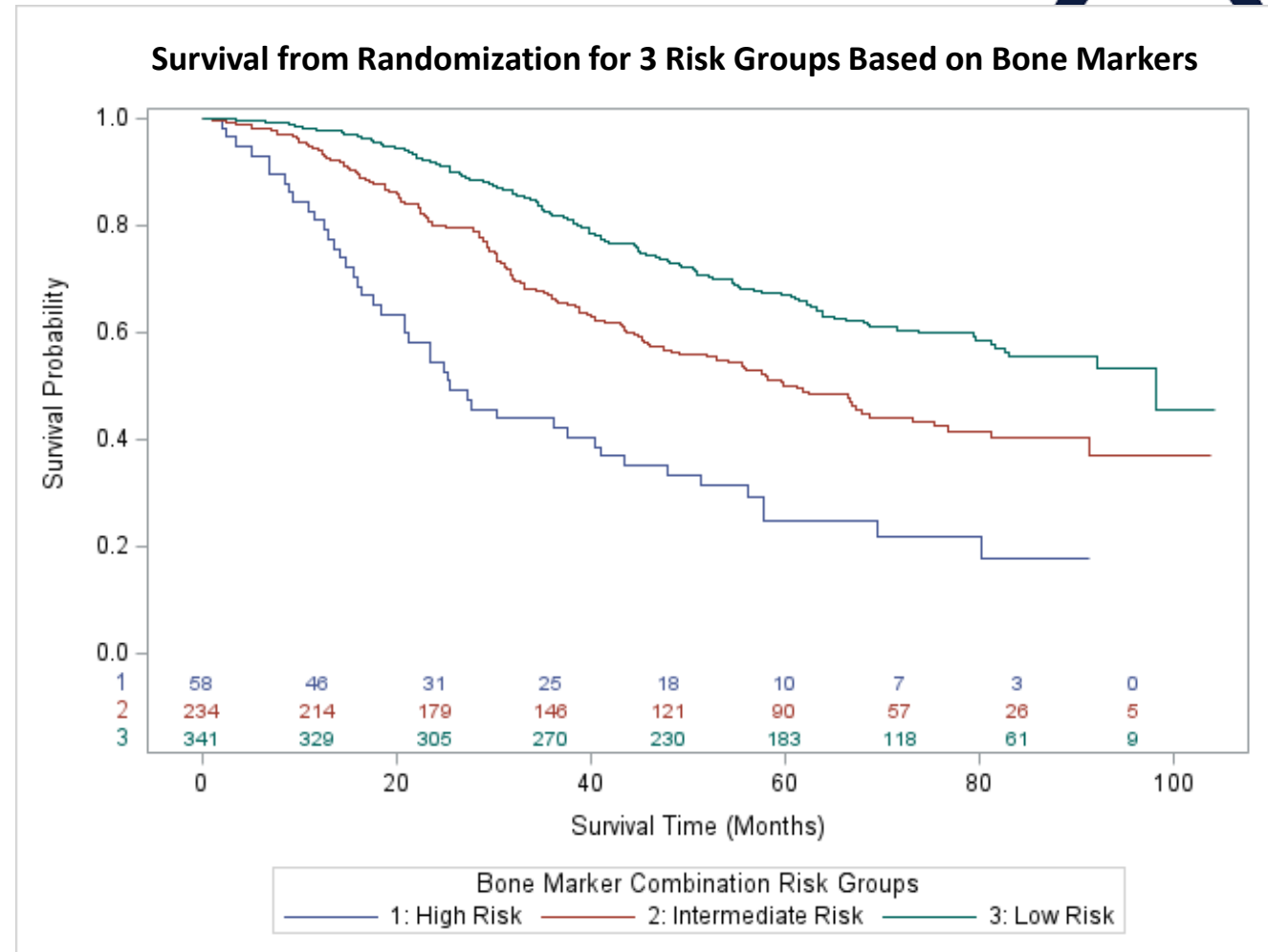
- Randomized Phase II trial in patients with EGFR Mutation Positive NSCLC
- Streck Cell-Free collection tubes at baseline, Cycle 3 Day 1 (C3D1) and progression
- Complete clearance of EGFR mutation in ctDNA by C3D1 was associated with a significant decreased risk of progression and death compared to those with persistent ctDNA at C3D1



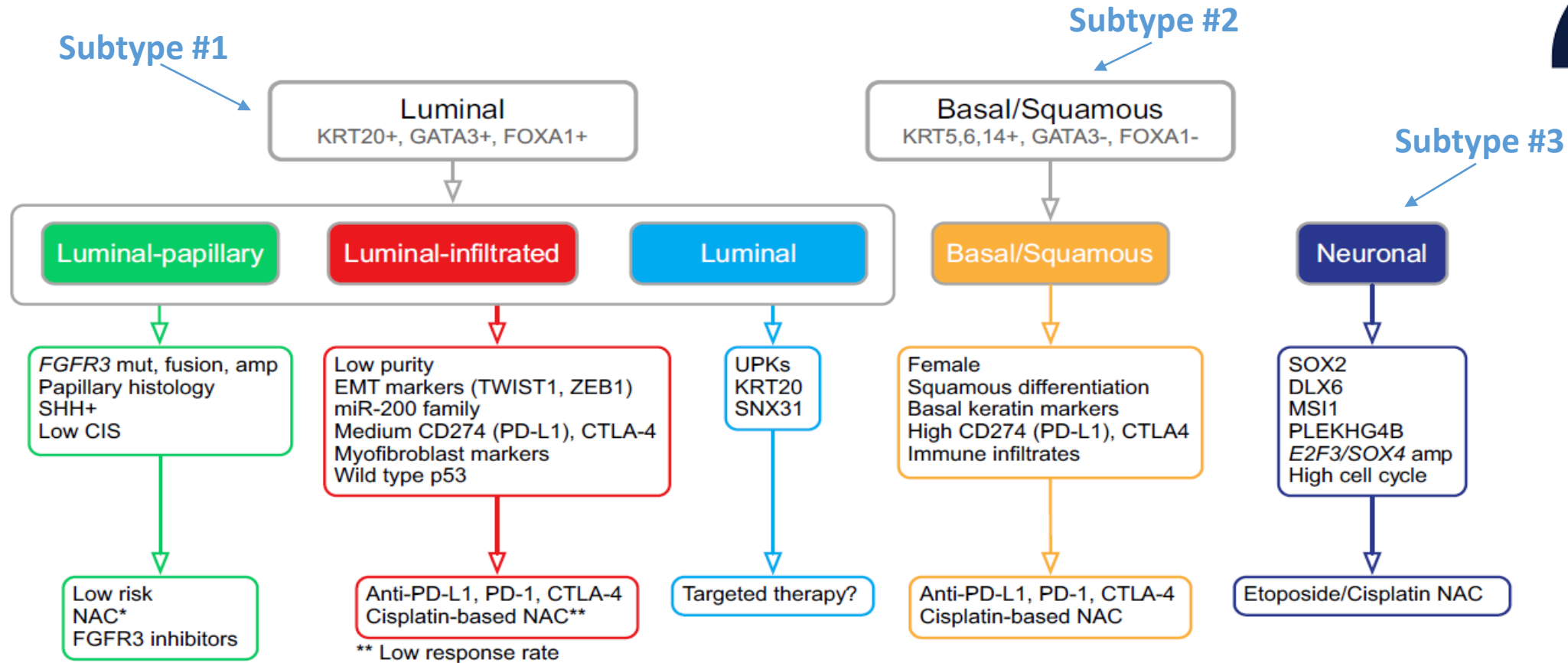
S1216 – Serum Bone Markers



- Randomized Phase III trial
- Newly diagnosed metastatic prostate cancer; majority have bone disease
- Can measuring 4 bone markers from serum (BAP, CACP, CTx, PYD) help identify survival prognosis?
- Formed 3 risk groups based on combinations of the bone markers with optimal cutpoints → Strongly correlated with survival



Schema of Expression-Based, Subtype-Stratified Therapeutic Approach as a Framework for Prospective Hypothesis Testing in Clinical Trials



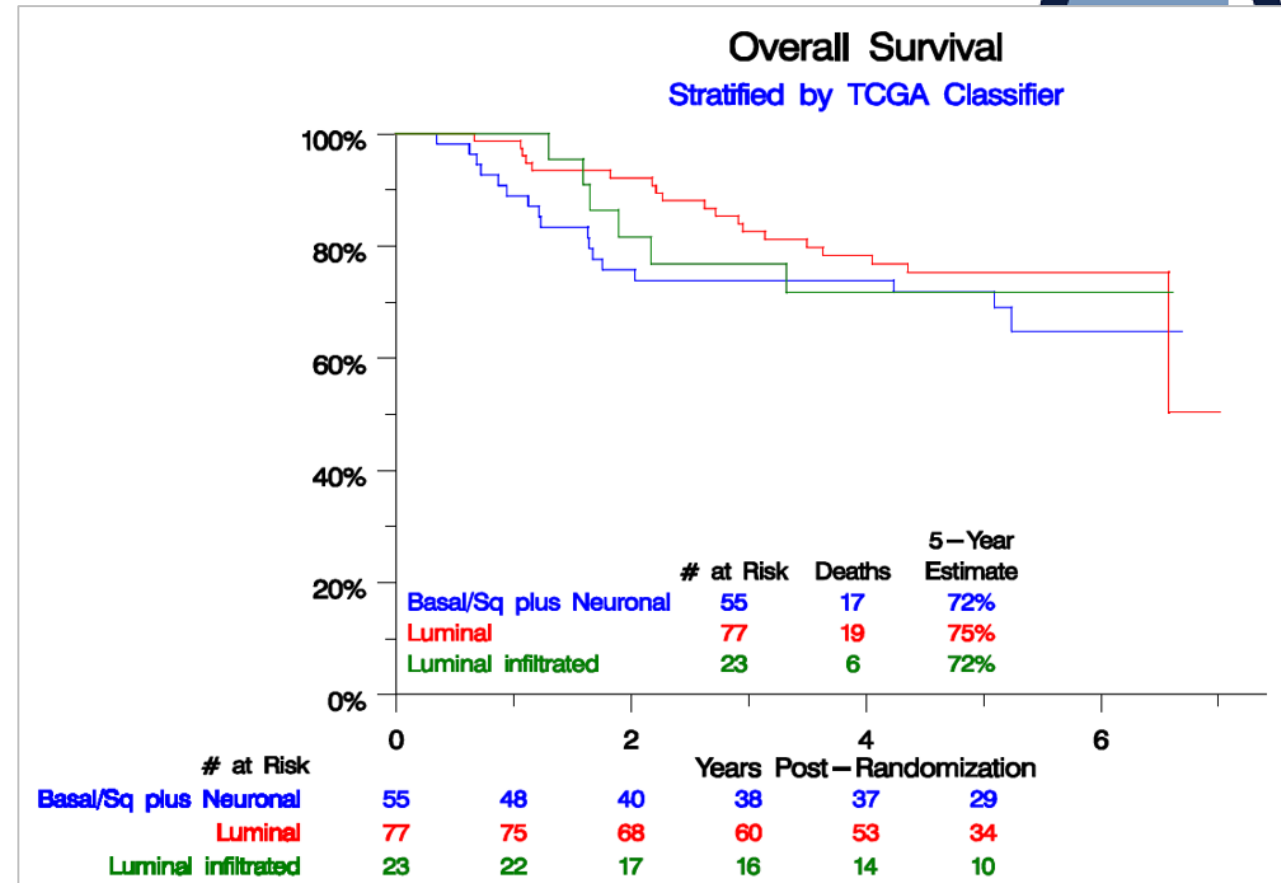
* Low predicted likelihood of response, based on preliminary data

Groupings based on mRNA from bladder cancer tissue
The Cancer Genome Atlas (TCGA)

S1314 – Bladder Tissue



- S1314 phase II trial in patients with muscle invasive bladder cancer
- TURBT = transurethral resection of bladder tumor done at study entry
- Convenient disease setting to study cancer tissue
- Performed mRNA analysis to validate prior work from TCGA and assign subtype to each patient
- Correlated subtypes with survival in S1314



So many specimens!



	NCTN (n=51 protocols)	NCORP (n=8 protocols)
# Blood samples		
Baseline, average (range)	2.1 (0-5)	2.9 (2 - 5)
Post baseline, average (range)	6.3 (0-16)	6.2 (2 - 11)
Tissue/Bone Marrow Aspirates	3.1 (0 - 11)	0.125 (0 – 1)
SWOG studies - Total expectations posted		
Bloods	87,176	36,412
Tissue	49,680	1,029
Other	3,250	9,712

Available resources



- Protocols

PRIVILEGED COMMUNICATION
FOR INVESTIGATIONAL USE ONLY

SWOG CANCER RESEARCH NETWORK

S2212. SHORTER ANTHRACYCLINE-FREE CHEMO IMMUNOTHERAPY ADAPTED TO PATHOLOGICAL RESPONSE IN EARLY TRIPLE NEGATIVE BREAST CANCER (SCARLET), A RANDOMIZED PHASE III STUDY

This trial is part of the National Clinical Trials Network (NCTN) program, which is sponsored by the National Cancer Institute (NCI). The trial will be led by SWOG with the participation of the network of NCTN organizations: Alliance for Clinical Trials in Oncology; ECOG-ACRIN Cancer Research Group; and NRG.

NCT# TBD
Study Exempt from IND Requirements per 21 CFR 312.2(b)

- CRA Workbench

SWOG CANCER RESEARCH NETWORK

Directory PHYLIS

About The SWOG Network News & Events Clinical Trials Member Resources

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CRA Workbench

Popular Resources

- OPEN Patient Registration
- Rave Data Submission
- Specimen Tracking
- SWOG QA / Audits / Monitoring

CRA Workbench

Your resource headquarters for SWOG clinical trial patient management.

Latest CRA Newsletter

- swog.org

SWOG CANCER RESEARCH NETWORK

Directory PHYLIS

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

Public Powered Cancer Research

Today

- 44 open trials
- 1,316 member sites
- 237,334 patients enrolled

- Specimen Tracking

SWOG CANCER RESEARCH NETWORK

Home

Instructions STS Specimen Tracking System

Welcome to the SWOG Specimen Tracking Website

You are logged in as a user for WA020 - University of Washington Medical Center - Montlake

Important Announcements:

3/29/2024 Specimen Labelling

- Basic Labels:** Use for fresh or frozen blood or bone marrow products (e.g., whole blood, plasma, serum, buffy coat, bone marrow and fresh or frozen urine).
- Tissue Labels:** Use for tissue specimens (FFPE or snap-frozen), including stained and unstained slides as well as blocks, scrolls, or other sections.
- Issue with Microns Labels:** Use for tissue specimens that require thickness information.
- Time-based Labels:** Use for fresh or frozen blood products where multiple samples are collected during the course of a day and the lab requires collection time to differentiate the samples for processing.

Protocol – Section 15

- Summary table with specimen requirements
 - Specimen types, timepoints
 - Mandatory vs. required with consent
 - Labelling requirement
 - Lab to ship to
- Working to get this table into every protocol with specimens
- Details in subsequent sub-sections
- Section 12 will have the how and why of pathology review (if there is) but the specimen details will be in Section 15

SUBMISSION OVERVIEW TABLE

Specimen	Collection	Timepoint	Required	Ship To
Peripheral Blood	<ul style="list-style-type: none"> • EDTA (Lavender Top) 	<ul style="list-style-type: none"> • Pre-treatment (Cycle 1, Day 1) • 40 weeks after randomization • 3 years after registration 	Required if participant consents	SWOG Biospecimen Bank
Peripheral Blood	<ul style="list-style-type: none"> • Roche cf-DNA Blood Collection Tubes 	<ul style="list-style-type: none"> • Pre-treatment (Cycle 1, Day 1) • 40 weeks after randomization • 3 years after registration • 5 years after registration 	Required if participant consents	SWOG Biospecimen Bank
Biopsy Tissue	<ul style="list-style-type: none"> • FFPE block (preferred) <p>OR</p> <ul style="list-style-type: none"> • 1 high-quality, 4–5-micron H&E slide ** and 15 unstained, 4–5 micron, positively-charged slides ** 	<ul style="list-style-type: none"> • Baseline (submitted to SWOG within 30 days after randomization) • At the time of recurrence/progression, if biopsy is performed per treating investigator preference. 	Required if participant consents	SWOG Biospecimen Bank



Biospecimen Collection and Submission Procedures

Search [] [] Directory PHYLIS []
Clinical Trials Member Resources For Patients

This webpage provides links to [specimen labeling, collection, packaging, and shipment instructions and handouts](#). For SWOG Cancer Research Network Biospecimen Bank (CB) protocols, as indicated in the protocol, these instructions may also apply to participating laboratories.

General Specimen Requirements and Instructions:

When the protocol does not provide specimen instructions (or refers to the SWOG website for instructions), follow the instructions below for the relevant specimen type(s). Each of the following webpages includes downloadable 1-page handouts for ease of site (and designated staff) use.

- For specimen instructions: First, refer to the protocol
 - Always follow protocol-specific instructions posted on the [linked resource](#). Those instructions supersede any general instructions.
 - For SWOG-led protocols: Specimen instructions are available on the [linked resource](#).

- [Specimen Labeling](#)

The complete guidelines are also posted here for [download](#).

The complete guidelines are also posted here for [download](#).

Specimen Information – CRA Workbench



SWOG CANCER RESEARCH NETWORK

Directory PHYLLIS

About The SWOG Network News & Events Clinical Trials Member Resources

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CRA Workbench

Popular Resources

- OPEN Patient Registration
- Rave Data Submission
- Specimen Tracking**
- 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
- Contact Us
- Internal Users Only

CRA Workbench

Your resource headquarters for SWOG clinical trial patient management.

[Latest CRA Newsletter](#)

[Join the CRA Mailing List](#)

Announcements

New mid-month Institution Performance Review (IPR) report

Starting this month, we have added a mid-month Institution Performance Review (IPR) report. With this report, you can monitor mid-month progress that your site is making in achieving the SWOG compliance goals. The report is located on the IPR Report page. The Monthly IPR Report metrics generated on the 2nd of every month are still the ones that will be used for assessing your sites compliance with SWOG Policy #33. [4/20/2023]

Updates to Specimen Tracking

A couple of updates have been made to the Specimen Tracking interface. In Step 2 of Logging a Specimen, the "Filter" at the top has been updated so that now at least one key filter is required before a list of samples is displayed. We are hopeful that this will make it easier to identify and select the correct specimen. Also, to avert potential problems for when the Test environment is chosen inadvertently, we have moved the "Test" button to the right side of the page and within the Test environment we have updated the banner and put a watermark on the packing list. The upcoming Winter CRA Newsletter will have more details. [12/1/2022]

SWOG EMR to EDC Project Webinar Recording

Introductory information regarding the project being developed by the SDMC using the nCartes platform can be viewed [here](#). See the May 27, 2022 [The Front Line](#) post for more information. [11/7/2022]

[SWOG Biospecimen Bank Kit Management URL](#)

- Specimen Tracking
- SWOG Best Practices

Best Practices: Specimen Submission - Guidance



Best Practices for SWOG Studies

NOTES: Specimen Submission

Unless indicated otherwise in Section 15 of the protocol, specimens should be submitted per the following guidelines:

- All specimens must be logged into the SWOG online Specimen Tracking system.
- Baseline tissue specimens must be shipped within 30 days after registration or within 30 days after surgery performed after registration unless otherwise stated in the protocol.
- Ambient temperature blood specimens must be shipped within one day of collection.
- Frozen blood and urine specimens must be shipped within 15 days of collection.
- If batch shipping of frozen specimens is allowed per protocol, they must be shipped at intervals no longer than every 3 months unless otherwise specified in the protocol. Batch shipments should include specimens for no more than 5 patients and no more than 50 individual specimens.
- Shipment of specimens greater than 3 months after the due date will result in a major data quality deficiency during an audit.

Specimen Tracking System



CANCER
RESEARCH
NETWORK

[Home](#)

[Instructions](#)



[Chooser](#)

[Log a Specimen](#)

[Specimen Manager](#)

[View/Update Consent Answers](#)

[Notify that Specimen Cannot be Submitted](#)

[Reports](#)

[Administration](#)

[Contact Us](#)

Version 3.0

Welcome to the SWOG Specimen Tracking Website

You are logged in as a user for WA020 - University of Washington Medical Center - Montlake

Important Announcements:

3/29/2024

Specimen Labelling

1. **Basic Labels:** Use for fresh or frozen blood or bone marrow products (e.g., whole blood, plasma, serum, buffy coat, bone marrow and fresh or frozen urine).
2. **Tissue Labels:** Use for tissue specimens (FFPE or snap-frozen), including stained and unstained slides as well as blocks, scrolls, or other sections.
3. **Tissue with Microns Labels:** Use for tissue specimens that require thickness information.
4. **Time-based Labels:** Use for fresh or frozen blood products where multiple samples are collected during the course of a day and the lab requires collection time to differentiate the samples for processing.

[Training module with demo](#) for using the Specimen Tracking System.

[Written Instructions](#) for using the Specimen Tracking System (English).

Specimen Can't be Submitted?

Use the *Notify that Specimen Cannot be Submitted* link at the left to let us know. Doing so will resolve the expectation.

Specimen Tracking Training



Search

Picture in picture

Specimen Tracking

Presented by
Christina
Clinical Research
SWOG Data Center

Using the SWOG Specimen Tracking System

Contents

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Specimen Manager.....	5
Notify that Specimen Cannot be Submitted	7
Reports	7
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Contact Us	9
Questions or problems?	9

0:10 / 21:43

Specimen Tracking – Log a Specimen



SWOG Patient ID: 287382 Regi
 Patient Initials: J,AM

Step 2 of 3: Choose the spec

Show: **SELECT ONE OR MORE
 CLICK APPLY TO DISPL**

Lab =

Specimen/Material Type

Submission Timepoint

Study Number: S1802

Registration Step	Submission Time
-------------------	-----------------

Please select a required filter

Registration Step	Submission Timepoint	Specimen or Material Type			Material Requirements	Lab
1	Baseline, Pre-Treatment	<input checked="" type="checkbox"/> Tissue from primary site	Blocks	FFPE	Preferred	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Pre-Treatment	<input type="checkbox"/> Tissue from primary site	Stained Slides	H&E Slides	Alternate	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Pre-Treatment	<input type="checkbox"/> Tissue from primary site	Unstained Slides		Alternate	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Pre-Treatment	<input checked="" type="checkbox"/> Metastatic tissue from distant site	Blocks	FFPE	Preferred	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Pre-Treatment	<input checked="" type="checkbox"/> Metastatic tissue from distant site	Stained Slides	H&E Slide from Metastatic Tissue	Alternate	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Pre-Treatment	<input checked="" type="checkbox"/> Metastatic tissue from distant site	Unstained Slides	Unstained Slides from Metastatic Tissue	Alternate	201 - SWOG Specimen Repository Columbus, OH
1	Relapse/progression, At Disease Progression	<input type="checkbox"/> Tissue from primary site	Blocks		Preferred	201 - SWOG Specimen Repository Columbus, OH
1	Relapse/progression, At Disease Progression	<input type="checkbox"/> Tissue from primary site	Unstained Slides		Alternate	201 - SWOG Specimen Repository Columbus, OH
1	Relapse/progression, At Disease Progression	<input type="checkbox"/> Metastatic tissue from distant site	Blocks		Preferred	201 - SWOG Specimen Repository Columbus, OH
1	Relapse/progression, At Disease Progression	<input type="checkbox"/> Metastatic tissue from distant site	Unstained Slides		Alternate	201 - SWOG Specimen Repository Columbus, OH
1	Relapse/progression, At Disease Progression	<input type="checkbox"/> Metastatic tissue from local site	Blocks		Preferred	201 - SWOG Specimen Repository Columbus, OH
1	Relapse/progression, At Disease Progression	<input type="checkbox"/> Metastatic tissue from local site	Unstained Slides		Alternate	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Pre-Registration	<input checked="" type="checkbox"/> Blood	Whole Blood	5 mL, Purple Top EDTA Tube, Room Temp.	Only option	201 - SWOG Specimen Repository Columbus, OH
1	Baseline, Step 1 Registration	<input type="checkbox"/> Blood	Whole Blood	7.5 mL, RareCyte tube, Room Temp.	Only option	181 - Amir Goldkorn Lab Los Angeles, CA
1	Baseline, Step 1 Registration	<input type="checkbox"/> Blood	Whole Blood	7.5 mL, Streck DNA tube, Room Temp.	Only option	181 - Amir Goldkorn Lab Los Angeles, CA
1	Baseline, Step 1 Registration	<input type="checkbox"/> Blood	Whole Blood	7.5 mL, PAXgene RNA tube, Room Temp.	Only option	181 - Amir Goldkorn Lab Los Angeles, CA
1	Relapse/progression, Disease Progression	<input type="checkbox"/> Blood	Whole Blood	7.5 mL, RareCyte tube, Room Temp.	Only option	181 - Amir Goldkorn Lab Los Angeles, CA
1	Relapse/progression, Disease Progression	<input type="checkbox"/> Blood	Whole Blood	7.5 mL, Streck DNA tube, Room Temp.	Only option	181 - Amir Goldkorn Lab Los Angeles, CA
1	Relapse/progression, Disease Progression	<input type="checkbox"/> Blood	Whole Blood	7.5 mL, PAXgene RNA tube, Room Temp.	Only option	181 - Amir Goldkorn Lab Los Angeles, CA
2	Pre-Randomization	<input checked="" type="checkbox"/> Tissue from primary site	Blocks	FFPE Biopsy	Preferred	201 - SWOG Specimen Repository Columbus, OH
2	Pre-Randomization	<input checked="" type="checkbox"/> Tissue from primary site	Unstained Slides	Biopsy	Alternate	201 - SWOG Specimen Repository Columbus, OH
2	Post Radical Prostatectomy	<input type="checkbox"/> Metastatic tissue from local site	Blocks	Prostate Tissue	Preferred	201 - SWOG Specimen Repository Columbus, OH
2	Post Radical Prostatectomy	<input type="checkbox"/> Metastatic tissue from local site	Unstained Slides	Prostate Tissue	Alternate	201 - SWOG Specimen Repository Columbus, OH
2	Post Radical Prostatectomy	<input type="checkbox"/> Metastatic tissue from local site	Blocks	Seminal Vesicle Tissue Block	Preferred	201 - SWOG Specimen Repository Columbus, OH
2	Post Radical Prostatectomy	<input type="checkbox"/> Metastatic tissue from local site	Unstained Slides	Seminal Vesicle Tissue	Alternate	201 - SWOG Specimen Repository Columbus, OH
2	Post Radical Prostatectomy	<input type="checkbox"/> Metastatic tissue from local site	Blocks	Positive Lymph Node Cores (if nodes dissected)	Preferred	201 - SWOG Specimen Repository Columbus, OH
2	Post Radical Prostatectomy	<input type="checkbox"/> Metastatic tissue from local site	Unstained Slides	Positive Lymph Node Cores (if nodes dissected)	Alternate	201 - SWOG Specimen Repository Columbus, OH
2	Relapse/progression, At Disease Progression	<input type="checkbox"/> Tissue from primary site	Blocks		Preferred	201 - SWOG Specimen Repository Columbus, OH

Specimen Tracking – Log a Specimen



Step 2 of 3: Choose the specimen that you are logging from the list below.

Show: **SELECT ONE OR MORE OF THESE REQUIRED FILTERS AND CLICK APPLY TO DISPLAY SPECIMEN LIST**

Lab = 201 - SWOG Biospecimen Bank ▼

Specimen/Material Type = Blood ▼




Submission Timepoint = All ▼

Optional additional filter

Registration Step = ▼

Apply Reset

Study Number: S1802

Registration Step	Submission Timepoint	Specimen or Material Type	Material Requirements	Lab
1	Baseline, Pre-Registration	 = This specimen has been logged already  = This specimen was reported as unsubmitable  Blood Whole Blood 5 mL, Purple Top EDTA Tube, Room Temp.	Only option	201 - SWOG Biospecimen Bank Columbus, OH

Specimen Tracking – Shipping



Shipment 351190 successfully recorded on 3/8/2024 5:47:23 PM (Pacific time) by Phyllis Goodman

Shipment 351190 Contents:

Patient	Study	Specimen Number	Specimen	Quantity	Timepoint	Collection Date
298270	S2104	2475196	Blood - Whole Blood	1	Other, 6 months after registration	3/8/2024
298270	S2104	2475197	Blood - Buffy coat	2	Other, 6 months after registration	3/8/2024

Specimen Label

Label to use: [Basic label](#)

Patient #: 298270

Patient Initials: M, D D

Collection Date: 3/8/2024

Specimen Type: Whole Blood

Label to use: [Basic label](#)

Patient #: 298270

Patient Initials: M, D D

Collection Date: 3/8/2024

Specimen Type: Buffy coat

Ship To: 201 - SWOG Biospecimen Bank
Address: **Standard**
Solid Tissue, Myeloma & Lymphoma Div
Nationwide Children's Hospital
700 Children's Dr, WA1340
Columbus, OH 43205

Shipment Tracking Number:
(e.g. Federal Express tracking number)

Name of Shipper: Phyllis Goodman

Shipper Phone Number: * (206) 667 - 2768 Ext.

Comments:

Shipment Date: * 3/11/2024

[Generate Shipment Label \(optional\)](#)

[View Packing List](#)

[Specimen Manager](#) [Home](#)

Summary of Contents

Blood/Whole Blood/Wren Buffer Red Top Tube Qty: 1
 Blood/Buffy coat/1ml aliquots in 2ml cryovials Qty: 2

WHEN PACKING THE SHIPMENT, REMEMBER THE FOLLOWING:

- Include a copy of this Packing List (all pages)
- Note that the expected shipping temperature for the specimen is -20C
- Confirm that all specimens listed on the following page(s) are correct. For more information see ("Label To Use")
 Label templates can be found at SWOG.org >> [Clinical Trials](#) >> [Submission Procedures](#)

Shipment Information

Shipment Tracking Number:
 Comments: (None)

Shipped date: 3/11/2024

Shipped By: Phyllis Goodman (pgoodman@fredhutchinson.org)
 Wisconsin NCI Community Oncology Research Program
 1000 North Oak Avenue
 Marshfield, WI 54449
 (206) 667-2768

SWOG Institution Head: Deanna Cole, MPH (cole.deanna@marhsfield.org)
 CRA: (715) 221-6711

Sent To: SWOG Biospecimen Bank
 Solid Tissue, Myeloma & Lymphoma Division
 Nationwide Children's Hospital
 700 Children's Dr, WA1340
 Columbus, OH 43205
 (614) 722-2865

Note to Recipient: Use this packing list to confirm the contents of the shipment. For more information on the SWOG Specimen Tracking system at <http://www.swog.org>



Packing List

Specimen: Blood / Whole Blood / Wren Buffer Red Top Tube

Timepoint: Other, 6 months after registration
Date Collected: 3/8/2024 10:00:00 AM
Quantity: 1
SWOG Specimen #: 2475196

Specimen: Blood / Buffy coat / 1mL aliquots in 2mL cryovial

Timepoint: Other, 6 months after registration
Date Collected: 3/8/2024 10:10:00 AM
Quantity: 2
SWOG Specimen #: 2475197

Shipment Contact Information

Shipped By: Phyllis Goodman (pgoodman@fredhutchinson.org)
 Wisconsin NCI Community Oncology Research Program
 1000 North Oak Avenue
 Marshfield, WI 54449
 (206) 667-2768

SWOG Institution Head: Deanna Cole, MPH (cole.deanna@marhsfield.org)
 CRA: (715) 221-6711

Specimen Label

Label to use: [Basic label](#)

Patient #: 298270
Patient Initials: M, D D
Collection Date: 3/8/2024
Specimen Type: Whole Blood

Label to use: [Basic label](#)

Patient #: 298270
Patient Initials: M, D D
Collection Date: 3/8/2024
Specimen Type: Buffy coat

Specimen Expectations - Metrics



- Baseline specimens for
 1. Eligibility, stratification or future endpoint determination
➔ Initial Forms Set metric
 2. Banking or future TM studies
➔ Specimen metric
- All other post-baseline specimens ➔ Specimen metric



Specimen Expectations – Current Report

EXPECTATIONS

Filter Criteria

SWOG Patient ID: Study: SWOG Investigator ID: Disease Type:

Registrations after: (mm/dd/yyyy) Items due*: Before After (mm/dd/yyyy) Expectation Category: IPR:

Institution CTEP ID:

[Export Report Data to Excel](#)

Data Management Institution: Upstate NCORP (UPSTATE)
Follow-up Institution: Upstate NCORP (UPSTATE)

2/9/2023 4:53:29 PM

SWOG Patient ID	Initials	Study	Institution CTEP ID	Investigator	RegDate	Last Contact Date	Status	Due Date	Expectation	Days Overdue	IPR
289123	C,JA	S1802-1	[REDACTED]	[REDACTED]	01/27/2022	01/27/2022	A	02/11/2022	Blood submission/Pre-Registration, 5 mL purple top EDTA Tube	363	SPEC
								03/24/2022	Tissue submission/Pre-Treatment Metastatic Tissue	322	SPEC
								03/24/2022	Tissue submission/Pre-Treatment Primary Tissue	322	SPEC
281933	F,PJ	S1608-1	[REDACTED]	[REDACTED]	08/13/2020	01/26/2023	A	02/28/2023	Blood submission/30-month, EDTA tubes		
								02/28/2023	Blood submission/30-month, ctDNA Streck tubes		
283163	N,KD	S1803-2	[REDACTED]	[REDACTED]	11/30/2020	01/12/2023	A	12/16/2022	Bone Marrow Aspirate/24-month, aspirate or whole blood for banking	55	SPEC
								12/16/2022	Bone Marrow Aspirate/24-month, for MRD	55	SPEC

Specimens that can't be submitted



- If a specimen cannot be submitted
 - “Notify that Specimen Cannot be Submitted” function on Specimen Tracking resolves the expectation

SWOG CANCER RESEARCH NETWORK

Home

Instructions **STS** Specimen Tracking System

Chooser

[Log a Specimen](#)

[Specimen Manager](#)

[View/Update Consent Answers](#)

[Notify that Specimen Cannot be Submitted](#)

This is the test Web site

All pages with headers in **red** act against the test database and should be used for practice only.

Welcome to the **SWOG Specimen Tracking Website**

You are logged in as a user for **WA020 - University of Washington Medical Center - Montlake**

Important Announcements:

4/1/2024

[Notify that Specimen Cannot be Submitted](#)

Version 3.0

Common reasons:

- Participant unable to come in
- Participant refused
- Staff oversight
- Collection problems

Common Specimen Expectation Problems



1. I submitted the specimen but it keeps showing up on my Expectation Report, help!
 - a. Check Specimen Manger, to confirm that the correct specimen was chosen when it was logged in.
 - b. If the **wrong Specimen Type** or **Timepoint** was chosen, you need to contact technicalquestion@crab.org to make the correction.

2. My patient changed their consent to submitting specimens, why won't the expectation go away?
 - a. Check that the consent was properly updated.
 - b. Changing consent will only stop future expectations from getting posted. If the specimen was expected prior to updating the consent, it will still appear. Use the "Notify that a specimen..." function to resolve.

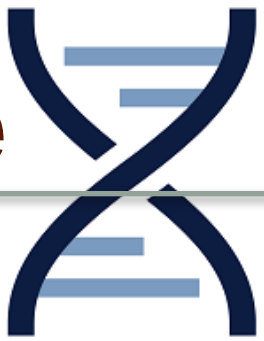
Common Specimen Expectation Problems: Progression/Relapse Specimens



1. I submitted the progression specimen, why is it still showing up on my report?
 - a. This happens if you submit a “progression” specimen prior to completing the form that indicates the patient progressed.
 - b. The form “triggers” the expectation and it should “back-resolve” but if it didn’t, contact your data coordinator at the disease-specific email.

2. My patient didn’t progress/relapse. Why are there progression specimens showing up as due (or overdue).
 - a. Progression/relapse specimens are triggered by a progression being noted in Rave. If the data is changed back to “no progression/relapse”, the expectation doesn’t resolve; you need to contact your data coordinator at the disease-specific email.

Site Tips 'n Tricks: Kaiser Permanente



New patients

- When new patients are identified for a trial, we **review the protocol study calendar and biospecimen table**
- Utilize the **Specimen Requirements Summary** to evaluate what specimens will be required and what supplies will be needed.



Existing patients

Monthly

- Centrally, we pull and send **SWOG Expectation** list and the SWOG IPR Report to our SWOG site locations.

Weekly or Bi-Weekly

- Research staff are encouraged to also check these reports often for their site and/or patients.

Processing Biospecimens: Kaiser Permanente



Prior to Visit

1. Staff maintain **patient calendars** and trackers which include specimens to be collected and upcoming visits.
2. **Weekly site meetings** used to review upcoming patients, specimens required, and specimen kits/supplies needed.
3. Prior to scheduled patient visits – **Kits are pulled and prepped** so it is ready for staff who will be completing the visit.
4. Required archival tissue is requested from our pathology departments **as early as possible**, after consent to have in hand ready to ship when due.

After patient visit

1. Collected **specimen details** including Study, Timepoint, Date and Time, Type of Specimen, Type of tubes/collection and shipping information are all **charted in the EMR and filed in the patient research chart.**
2. **Keep and file** all specimen tracking sheets, requisitions, orders, copies of shipping waybills, collection details in the patient's chart.
3. Utilize a **brief tracking list style page** in patient research shadow file charts for easy review of what date samples are completed and sent.
4. **Kit inventory is reviewed** at least monthly and kits ordered and/or prepared well in advance

Processing Biospecimens: U Rochester



Use of Research Specialists

- Ensure necessary kits are onsite when needed and are prepared for patients
- Process and ship according to protocol and IATA requirements; keep the protocol handy while processing to ensure accuracy



Research Specialists are **integrated into disease-specific Operations teams**

- Promote familiarity with disease-specific specimens
- Included in weekly team meetings to prepare for study patients
- Facilitate communication when there are last-minute changes

Site Tips 'n Tricks: U Rochester



Use of a **Shared Outlook** calendar dedicated to specimen management

- Ensures information is available to all when needed
- Facilitates coverage in the event of an unplanned absence

Success in labelling credited to:

- Detailed oriented Research Specialists who are instructed to follow the protocol “to the letter” (or comma in this case)
- Research Specialists come from the medical center processing lab and are incorporated into the team; they are invested in the research.

Conclusions



- SWOG Specimens are important!
 - Valuable resource for running trials as well as research and future trial implications
 - Most SWOG protocols now include specimen collection
- Resources available to help ORPs
 - swog.org
 - Protocol
 - CRA Workbench
 - Specimen tracking
 - Other SWOG ORPs
- Questions? Reach out to study teams or TechnicalQuestion@crab.org



Oishi Symposium: Improving Specimen Submissions to SWOG Biospecimen Bank

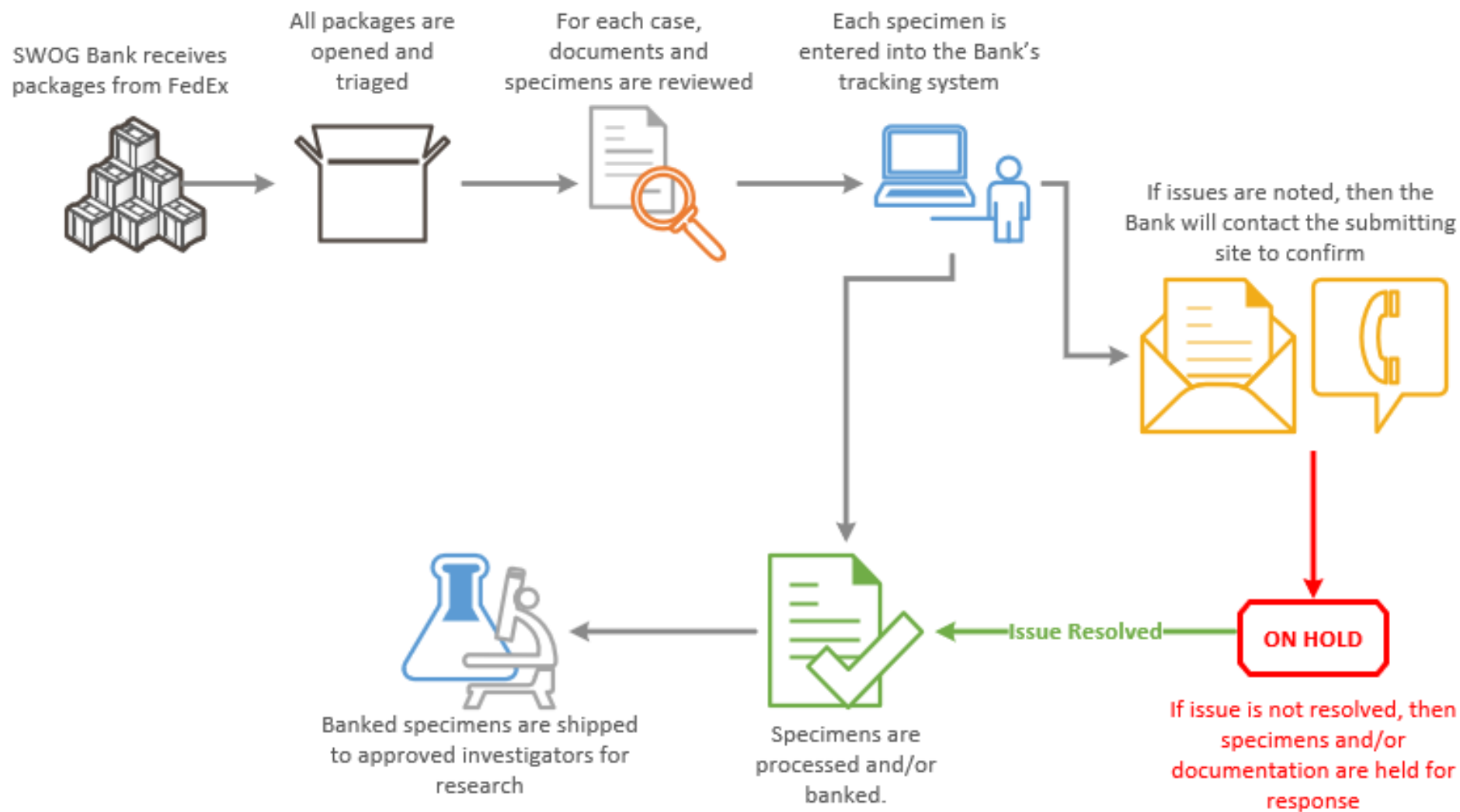
Thursday, April 4, 2024

Kae Tegtmeier

Business and Project Development Director

Biopathology Center / SWOG Biospecimen Bank

At the SWOG Biospecimen Bank





Most Common Submission Errors

1. Specimen Labeling
 - Missing required data
 - Data on specimen label discrepant with the Specimen Tracking System Packing List
 - *Note: either issue may require a waiver to resolve*
2. Missing pathology report (required for tissue submissions)
3. Quantity received is discrepant with quantity on the Packing List



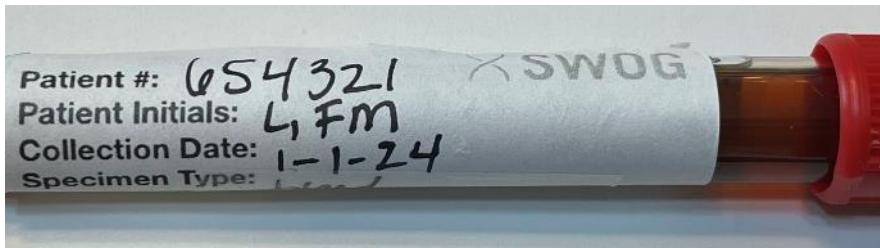
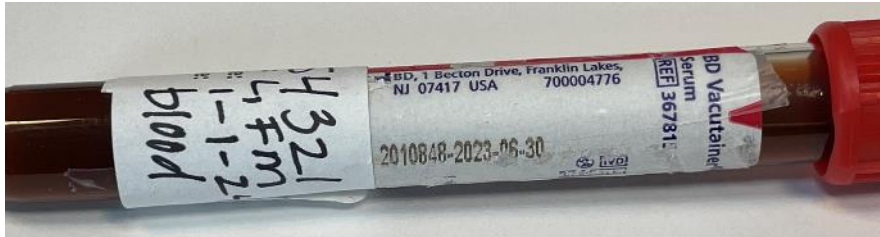
Specimen Labeling: Biofluids

Includes blood, bone marrow, plasma, serum, urine, stool, etc.

Specimen Container/Type	Required Data	Required on <i>each</i> specimen	Can be on package (e.g., plastic bag) for identical specimens
Collection tubes	<ul style="list-style-type: none">• SWOG participant ID• Participant initials• Collection date• Specimen type (blood, bone marrow, stool, etc.)	<ul style="list-style-type: none">• SWOG Participant ID• Participant initials• Specimen type• Laterality (bone marrow) – right (R) or left (L) <i>if more than one</i>	<ul style="list-style-type: none">• Collection date
Cryovial	<ul style="list-style-type: none">• SWOG participant ID• Participant initials• Collection date• Specimen type (plasma, serum, etc.)	<ul style="list-style-type: none">• SWOG Participant ID• Participant initials• Specimen type	<ul style="list-style-type: none">• Collection Date



Biofluid Labeling Examples



Blood tube

- Labeled with SWOG participant ID, initials, collection date, and specimen type
- Label placed horizontally or vertically, not covering manufacturer information and expiration date



Frozen plasma or serum

- Labeled with SWOG participant ID, initials, collection date, and specimen type
- Label wrapped around vial with a flag, or overlapping the label itself on the tube



Specimen Labeling – Tissue

Specimen Container/Type	Required Data	Required on <i>each</i> specimen	Can be on package (e.g., plastic bag) for identical specimens
FFPE Block Cassette	<ul style="list-style-type: none"> • SWOG Participant ID • Participant initials • Collection date • Surgical Pathology ID (SPID)¹ • Block Number¹ 	<ul style="list-style-type: none"> • SWOG Participant ID • Surgical Pathology ID¹ • Block number¹ 	<ul style="list-style-type: none"> • Participant initials • Collection date • Tissue type (if required) <ul style="list-style-type: none"> - Primary tumor (P) - Metastatic tumor (M) - Normal tissue (N)
FFPE Tissue Slide	<ul style="list-style-type: none"> • SWOG Participant ID • Participant initials • Collection date • Surgical Pathology ID (SPID)¹ • Block Number¹ 	<ul style="list-style-type: none"> • SWOG Participant ID • Surgical Pathology ID¹ • Block Number¹ • Tissue thickness (microns, if required) 	<ul style="list-style-type: none"> • Participant initials • Collection date • Tissue type (if required) <ul style="list-style-type: none"> - Primary tumor (P) - Metastatic tumor (M) - Normal tissue (N)

¹From the pathology report corresponding to the tissue removal procedure

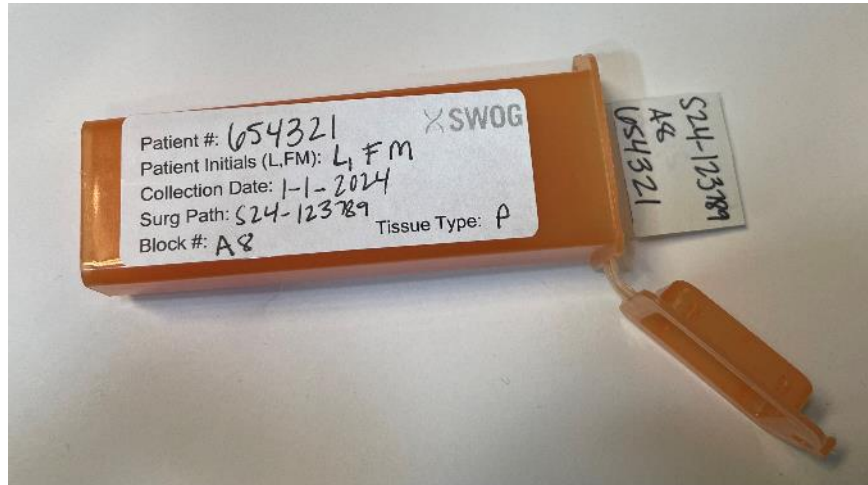
Pathology Reports and Tissue Types



- Pathology reports are **required** for formalin-fixed paraffin-embedded (FFPE) tissues – including blocks, slides, and scrolls
 - Label pathology report with the SWOG participant ID (handwritten or typed).
 - Do not redact initials, SPID/Accession #, block #, diagnosis, or collection date.
- Before distribution, a SWOG Bank pathologist confirms concordance with the institutional diagnosis
 - Quality assurance step to confirm if the tissue is acceptable for the planned research
- SWOG Bank definitions of tissue type:
 - **Primary**: the initial source of tumor tissue, including residual tumor from the primary site. Must make biological sense for tumor type (e.g., colon cancer in colon tissue).
 - **Metastatic**: tumor tissue collected at sites separate from the primary lesion, including local and distant metastatic tumor and residual tumor from the metastatic site (e.g., lung tumor biopsy for prostate cancer)
 - **Normal**: tissue that does not contain tumor, including lymph nodes negative for tumor.

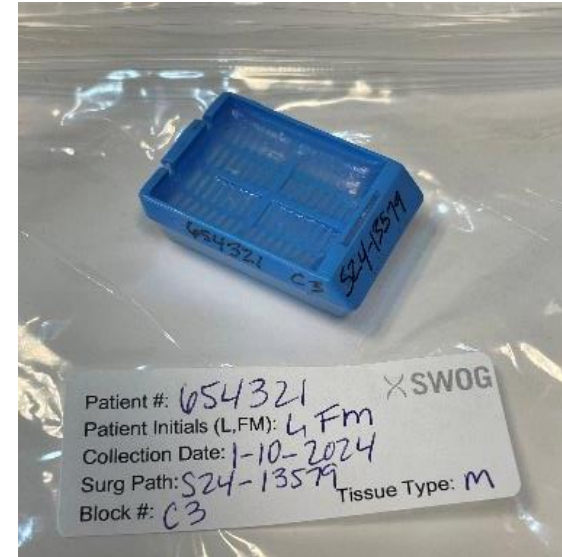


Tissue Labeling Examples



FFPE tissue slides in a slide case

- Slides labeled with SPID, Block #, and SWOG participant ID
- All other labeling requirements on slide case



FFPE tissue block

- Block labeled with SWOG participant ID, SPID, block #
- All labeling requirements on plastic bag.



Labeling Templates

Label	Example Label	Specimen type(s)
Basic labels <i>or MS Word Version for Download</i>		<ul style="list-style-type: none"> • Blood/blood products (e.g., plasma, serum, buffy coat) • Bone Marrow Aspirate and Bone Marrow Biopsy • Urine • Stool • Other biofluids
Time-based labels <i>or MS Word Version for Download</i>		<ul style="list-style-type: none"> • Specimens collected for studies where multiple samples are collected during the same day and the lab requires collection time to differentiate them for processing
Tissue Label <i>or MS Word Version for Download</i>		<ul style="list-style-type: none"> • FFPE tissue (blocks, slides, scrolls/curls) • Frozen tissue
Tissue label (with microns) <i>or MS Word Version for Download</i>		<ul style="list-style-type: none"> • FFPE tissue slides or scrolls
Basic with Laterality <i>or MS Word Version for Download</i>		<p>When the protocol requires indication of laterality, for:</p> <ul style="list-style-type: none"> • Bone Marrow Aspirate • Bone marrow Biopsy



Additional Labeling Tips

- Label tubes that will be frozen *prior* to freezing
- Printable labels that adhere to frozen surfaces are available at Labtag.com
- Acceptable initials formats:
 - Last, First Middle (L,FM) – this is the order on the Packing List
 - First Middle Last (FML)
- Do not cover or remove manufacturer labels (e.g., on collection tubes)
- Do not cover tissue (on FFPE block or slides)
- Use indelible ink for handwritten information (e.g., Moist Mark lab markers, Starstedt permanent marker pens, etc.)



Other Common Specimen Quality Issues

Issue	Prevention
Specimen that should be frozen arrived thawed or with insufficient dry ice	<ul style="list-style-type: none">• Choose an appropriately-sized container – dry ice will sublime at a rate of 5-10 lbs. every 24 hours.• Add dry ice to the bottom ~1/3, add the specimens, and then add dry ice to the top of the container.• Include lots of dry ice <i>all year round</i>.
Blood / bone marrow is hemolyzed or clotted	<ul style="list-style-type: none">• Thoroughly mix the specimen with anticoagulant immediately after collection• Do not shake or vortex, but gently invert tube 8 – 10 times after collection.
Specimen container is cracked, broken, or leaking	<ul style="list-style-type: none">• Always use plastic collection tubes if submitting frozen specimens.• Do not overfill cryovials before freezing (~1.5 mL liquid can be frozen in a 2-mL cryovial).• Package specimens carefully – if it rattles, don't ship it!• Be generous with bubble wrap – it's both a good insulator and specimen protectant.• Do not ship cracked, broken, or leaking specimens.



Common Specimen Submission Issues

Issue	Prevention
STS Packing List does not match specimens received	<ul style="list-style-type: none">• All specimen labeling information (identifiers, collection date, etc.) must correspond with the information entered in the STS.• The number of specimens (e.g., number of tubes, vials, glass slides, etc.) received must match the STS packing list. Note: number is the number of specimens, not volume (e.g., one 10-mL tube of blood is 1 specimen, two 5-mL tubes is 2 specimens)
Insufficient Dry Ice	<ul style="list-style-type: none">• Include lots of dry ice <i>all year round</i>.• Dry ice will sublimate at a rate of 5-10 lbs. every 24 hours
Incorrect specimen type received (e.g., protocol indicates to submit whole blood, and plasma is received)	<ul style="list-style-type: none">• Refer to the protocol – use the current version of the protocol• If the protocol is unclear – contact the SWOG Bank!



Website Improvements

Transitioned
content from
webpage to
printable PDF pages

Reformatting into
charts and bullet
points

Will continue to add
more pictures and
diagrams

Specimen Collection and Processing Instructions

Unless otherwise indicated in the protocol, collect and process specimens as outlined in the instructions accessible from the links below.

Important Notes:

- Prior to specimen collection: Verify that the collection tube/container (e.g., for blood, bone marrow, etc.) will not expire prior to receipt by the SWOG Biospecimen Bank (or protocol-designated laboratory).
- Always refer to the protocol for specimen collection and processing instructions.
 - When the protocol does not provide instructions (or refers to the SWOG website for specimen instructions), follow the guidelines linked below.
- The pathology report(s) corresponding to the tissue removal surgery must be included with each shipment of tissue. Pathology reports must be redacted as indicated [here](#).

Collection and Handling Instructions for FFPE Tissue, Snap-Frozen Tissue and Bone Marrow Biopsy Cores

- [Formalin-Fixed Paraffin-Embedded \(FFPE\) Tissue](#)
- [Snap-Frozen Tissue or Bone Marrow Biopsy Cores](#)

Blood Collection and Processing Instructions

- [Whole Blood](#)
- [Buffy Coat and Plasma \(from Whole Blood\)](#)
- [Serum from Whole Blood](#)

Bone Marrow Aspirate Collection and Processing Instructions

- [Bone Marrow Aspirate](#)

Specimen Collection and Processing Guidelines for Buffy Coat and Plasma

If protocol-specific collection instructions for peripheral blood and processing instructions for buffy coat and plasma are not provided in the protocol or through a linked resource (usually in Section 15 in SWOG-led protocols), then follow the instructions outlined below.

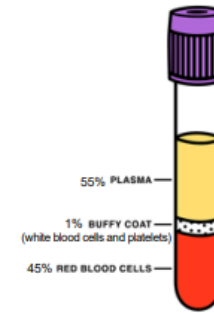
Plasma is processed from blood collected with anticoagulant (e.g. EDTA, sodium heparin, etc.). Inverting the tube immediately after collection is essential to ensure blood does not clot. Plasma and buffy coat are processed by centrifuging and removing the yellowish-clear layer (plasma) and/or the very thin white or gray-ish layer (buffy coat) – see figure. Note: after processing, plasma looks very similar to serum. If a protocol includes both plasma and serum specimens, it's imperative that each tube is labeled with the specimen type (e.g., plasma or serum).

Collecting Peripheral Blood

1. Use the protocol-specified Vacutainer tube type.
 - If the recommended size of vacutainer tube specified in the clinical trial protocol is not available, then other sized tubes may be used to collect the total volume of blood (e.g., if 10 mL of blood is requested, then two (2) 5-mL tubes may be used).
 - Pre-label vacutainer tube(s) according to [specimen labeling requirements](#).
2. Draw blood from the participant into the vacutainer tube(s). The amount of blood required will vary per protocol; refer to section 15 for the collection volume.
3. Immediately after collection, gently invert the tube 5-10 times to thoroughly mix the blood with the anticoagulant and prevent clotting.
4. Blood must be processed within 2 hours after venipuncture unless otherwise noted in the protocol. Document on the specimen shipping form if the blood was not processed within 2 hours following venipuncture.

Plasma Processing

1. Centrifuge the vacutainer tube(s) at 1200 x g for 10 minutes at room temperature.
2. Pre-label cryovials according to [specimen labeling requirements](#).
3. Using a clean disposable pipette, remove the plasma (yellow-clear liquid above the buffy coat and red blood cell layers). See Figure. No cells or debris should be present in the plasma.
4. Dispense 1 mL aliquots of plasma into the pre-labeled 2 mL-capacity cryovials and cap the tubes securely. If the aliquot volume is not specified in the protocol, use as many cryovials as needed to evenly dispense plasma into 1 mL aliquots.
 - The number of vials needed will vary based on the volume of plasma obtained but can be estimated as roughly half of the blood volume collected.
5. Immediately freeze plasma vials in an upright position, buried in dry ice or in a -70°C to -80°C freezer until ready to ship.
6. If buffy coat is also required, follow instructions below to remove buffy layer. If buffy coat is not requested, then discard remnant cells.



Buffy Coat Processing

1. Centrifuge vacutainer tube(s) at 1200 x g for 10 minutes at room temperature. *Note: if processing plasma and buffy coat, only one centrifugation is needed.*
2. Pre-label cryovials according to [specimen labeling requirements](#).
3. Using a clean pipette, slowly remove the buffy coat (the thin, cloudy pin or gray-white layer located in between the red blood cells and the plasma; refer to figure below). Avoid aspirating the red blood cells while collecting the buffy coat.
4. Split the buffy coat equally into two 2 mL cryovials.
5. Immediately freeze vials in an upright position, buried in dry ice or in a -70°C to -80°C freezer until ready to ship.

Version Date: 03/27/2024



Your feedback is important!

- Visit the SWOG Biospecimen Bank at Oishi Open Forum
- Email Training@SWOG.org

SWOG Bank Contact Information



Solid Tissue, Myeloma & Lymphoma Division

SWOG Biospecimen Bank #201
614-722-2865

bpcbank@nationwidechildrens.org

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Nationwide Children's Hospital
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Columbus, Ohio 43205

Leukemia Division

SWOG Biospecimen Bank #200
614-722-3270

bpcmlab@nationwidechildrens.org

SWOG Biospecimen Bank
Nationwide Children's Hospital
700 Children's Drive, C0825
Columbus, Ohio 43205

Questions on Biospecimens?



Don't forget to visit the Biospecimen Table at Open Forum!



BREAK TIME!

Resuming in 10 minutes



Oishi Symposium

Thursday, April 4, 2024

DEI Champions: Lessons Learned & Implications for Future Programming

Speaker

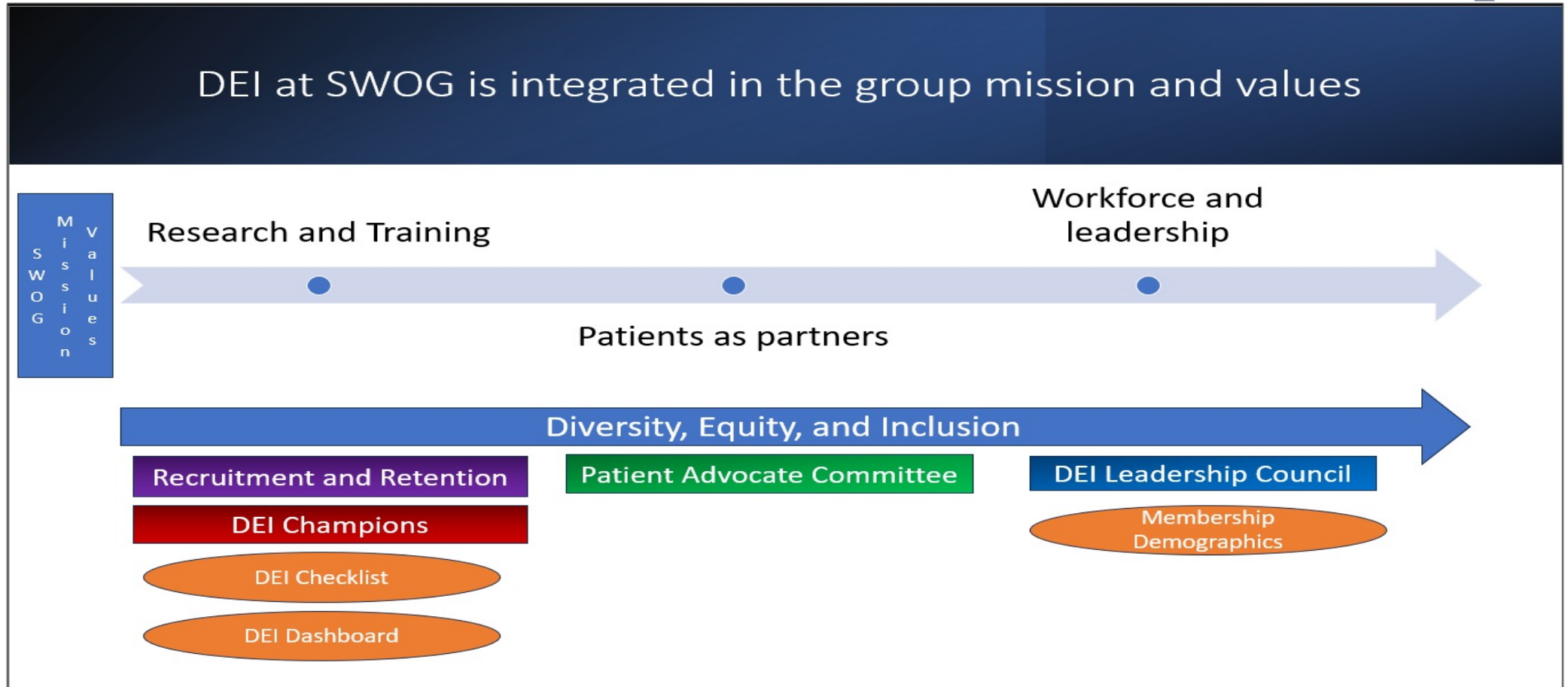
Colmar Figueroa-Moseley, Ph.D., M.P.H.
Health Equity & Research Development (HEARD)
GI Subcommittee, Co-Chair

Background



- Improving diversity and representativeness in SWOG Cancer Research Network (SWOG) clinical trials is critical for addressing disparities in prevention, detection, treatment, supportive care, and mortality among patients with cancer diagnosis.
- Understanding the needs of underrepresented groups (URGs) and building relationships and trust between these populations and researchers can help overcome barriers to study recruitment.
- SWOG developed a formal organization structure to provide evidence-based guidance for increasing diverse representation in SWOG research.

Structure



Structural Focus: DEI Champions



- 2-year funded program by Genentech and The Hope Foundation
- 5 Champions were chosen for the following committees:
 - Breast
 - Genitourinary
 - Gastrointestinal
 - Myeloma
 - Lung



Structural Focus: DEI Champions

- Champions were tasked to work with research committees and study teams to:
 - Identify action plans to increase diversity and equity in research participation
 - Provide tools, evidence, and strategies to reduce disparities and improve study outcomes
 - Implement strategies for research program modifications and policies

Factors That Affected Champion Committee Integration



- Culture
- Structure
- Readiness for Change
- Leadership



Other Champion Program Challenges



Attaching
Champions
to Poorly
Accruing
Studies

No Clear
Marching
Orders

Defining:
What is
DEI?

Statisticians

Recommendations & Opportunities



- Understand Burden of Disease in Communities of Interests (Veterans, Rural, SOGI, Women, BIPOC)
- Opening studies at sites with high rates of underrepresented groups
- Collaborate with statisticians on the Inclusion and Planned Enrollment section from capsule phase to protocol opening
- Make eligibility criteria less burdensome and inclusive
- Protocols developed with aims for specific populations

Rebranding Champion Program

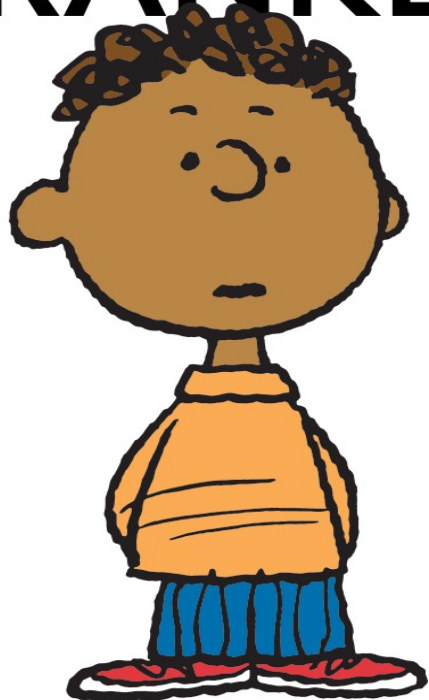


- DEI Champions program is now known as Champions of Equity & Engagement in Research (ChEER)
- Applications were due in February 2024
- Review and Interviews in April 2024
- ChEER orientation in May 2024
- Selecting 2 Champions in 2024
- Next Cohort--Lead by Champion Alumna Dr. Jessica McDermott, M.D.
- For more information:
<https://thehopefoundation.org/swog-cheer-program/>

Sometimes A New Perspective Is All We Need.



FRANKLIN



7.31.1968 DEBUT



© PNTS



Acknowledgements: Contributing Co-Authors

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THE
HOPE
FOUNDATION
A GENERATION OF IMPACT

Genentech
A Member of the Roche Group



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Questions?





BREAK TIME!

Resuming in 10 minutes



Oishi Symposium: SWOG QA Audits Top Ten Deficiencies Thursday, April 4, 2024

Speaker

Laura Gonzales, BSN, MA, RN, OCN
SWOG Quality Assurance Manager

#10 Failure to Return IND within 90 Days of End of Use



- QA recommendations:
 - Review Chapter 6 of the ORP Manual – “Drug Ordering and Maintenance”
 - Review Section in Protocol related to IND accountability
 - Develop plan to communicate study closures to pharmacy staff

#9 Failure to Implement Revision/Update with 30 days of notification



- QA recommendations:
 - Monitor CTSU Bi-Monthly Broadcast



#8 Failure to Notify Patient of New Risks

- QA recommendations:
 - Review revision/update notifications to determine if patient notification is required
 - Document patient notification in research record



#7 Treatment Not per Protocol

- QA recommendations:
 - Refer to Treatment Section in protocol for specific treatment guidelines
 - For treatment questions, refer to Protocol Contacts page or Section 7.0: “For treatment or dose modifications, contact...”

#6 QOLs/PROs Not Administered per Protocol



- QA recommendations:
 - Refer to protocol for QOL/PRO administration timepoints
 - If ePRO, document patient completion in research record
 - If patient not seen in clinic, PROs/QOLs can usually be sent to patient or administered over the phone

#5 Disease Assessments Not Performed per Protocol



- QA recommendations:
 - Refer to Disease Assessment section in protocol for timepoints
 - If disease assessment not performed, document reason in research record



#4 Late Submission of SAEs

- QA recommendations:
 - Refer to AE/SAE Section in protocol for timeline for submitting SAEs
 - If you have any questions about SAE submission, contact SWOG SAE Team at adr@swog.org

#3 Failure to Verify Eligibility Prior to Registration



- QA recommendations:
 - Refer to Eligibility Section of protocol
 - Have a second person to verify patient meets all eligibility requirements
 - Registering/Treating Investigator sign Eligibility Checklist/Affirmation of Eligibility prior to registration



#2 Delinquent Data Submission

- QA recommendations:
 - Refer to Section 14 of protocol for data submission guidelines
 - Refer to SWOG Best Practices document for data submission guidelines not covered in specific protocols
 - If any questions about data submission, contact SDMC listed on Protocol Contacts page of protocol

#1 Specimens Not Submitted per Protocol



- QA recommendations:
 - Refer to Section 15 of the protocol for specific guidelines
 - Confirm patient has consented to specimen submission and that it is reported correctly in OPEN
 - If specimen cannot be submitted, document in the research record and in Specimen Tracking

Questions?



qamail@swog.org

Questions?

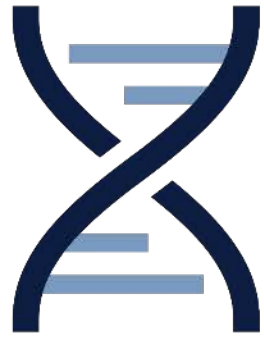


qamail@swog.org



BREAK TIME!

Resuming in 10 minutes



SWOG

CANCER
RESEARCH
NETWORK



Oishi Symposium: Tour of SWOG Website

Thursday, April 4, 2024

Tour Guide

Christine Magner,

Clinical Research Data Operations Supervisor

I need to reach out to another site. How can I find out who the Lead ORP at a SWOG site is?



- A. Google to the rescue!
- B. Use the SWOG directory
- C. Call the site in question and ask to speak to the Lead ORP at their site.
- D. Anyone remember the yellow pages?????

I need to reach out to another site. How can I find out who the Lead ORP at a SWOG site is?

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A. Google to the rescue!

B. Use the SWOG directory

C. Call the site in question and ask to speak to the Lead ORP at their site.

D. Anyone remember the yellow pages?????

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

I need to reach out to another site. How can I find out who the Lead ORP at a SWOG site is?



B. Use the SWOG directory

www.SWOG.org

↳ The SWOG Network

↳ Directory

↳ Defaulted to individual. If searching for site, click under SEARCH button

My patient is moving. How can I find other sites that have the protocol open?



- A. Google to the rescue again!
- B. Go to nih.gov and poke around
- C. Use SWOG.org
- D. Have the patient research the area for hospitals then cross reference them with the SWOG roster

My patient is moving. How can I find other sites that have the protocol open?

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A. Google to the rescue again!

B. Go to nih.gov and poke around

C. Use swog.org

D. Have the patient research the area for hospitals then cross reference them with the SWOG roster

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

My patient is moving. How can I find other sites that have the protocol open?



C. Use SWOG.org

www.SWOG.org

↳ Clinical Trials

↳ Clinical Trials Search

↳ Enter Protocol number

↳ Click on protocol title

↳ Click Trial Locations button

↳ Can enter key words or narrow down by institution type or state

↳ Contact info found by clicking site name

Cool! I found a facility for our patient to get treatment and remain on protocol down in Scottsdale. Now what?

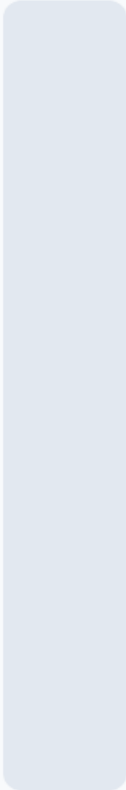


- A. Google to the rescue! Eventually this has got to be the right answer, right?
- B. Consult SWOG Policies and Procedures
- C. Use swog.org
- D. Reach out to site and see if they are accepting new patients

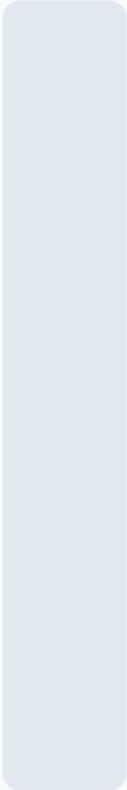
Cool! I found a facility for our patient to get treatment and remain on protocol down in Scottsdale. Now what?



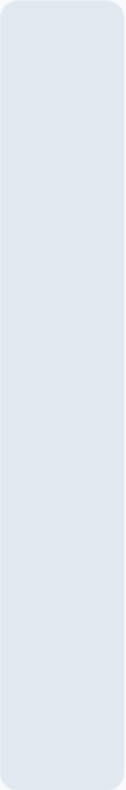
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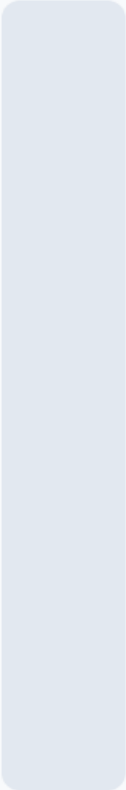
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A. Google to the rescue! Eventually this has got to be the right answer, right?

B. Consult SWOG Policies and Procedures

C. Use swog.org

D. Reach out to site and see if they are accepting new patients

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Cool! I found a facility for our patient to get treatment and remain on protocol down in Scottsdale. Now what?

B. Consult SWOG Policies and Procedures

CRA Workbench

↳ Resources

↳ SWOG Policies

↳ Policy #30 – Responsibility for Patient Follow-Up

My Lead ORP sends me the expectation report every month. I've submitted the data but how do I know if it came off the expectation report?



- A. Verify the item came off the list the following month when you receive a new report
- B. Call the Data Coordinator
- C. E-mail expectationreportquestion@crab.org
- D. Look up the current report yourself at www.swog.org

My Lead ORP sends me the expectation report every month. I've submitted the data but how do I know if it came off the expectation report?

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A. Verify the item came off the list the following month when you receive a new report

B. Call the Data Coordinator

C. E-mail expectation report question @crab.org

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



My Lead ORP sends me the expectation report every month. I've submitted the data but how do I know if it came off the expectation report?

D. Look up the current report yourself at swog.org

CRA Workbench

- ↳ Patient Reports/Data Quality
 - ↳ Expectations



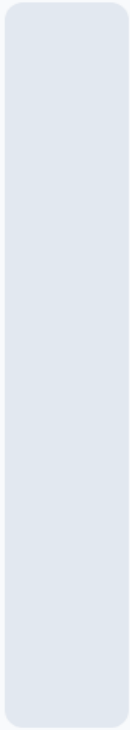
I recently received the CRA Newsletter. It sure is snazzy. I wish I hadn't waited so long to sign up to receive it. I wonder what I've missed. Do I have access to previous issues? How can my coworkers receive it?

- A. Unfortunately, no, but some info is better than none
- B. Unfortunately, no, but we're working on it
- C. Heck yes, you can sign up to receive it and view archived editions via the CRA Workbench
- D. Heck yes, just send an e-mail to CRANewsletter@crab.org

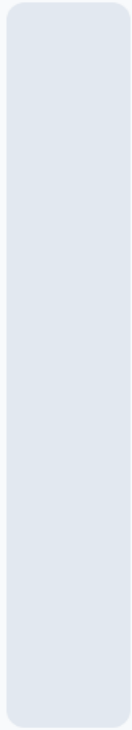
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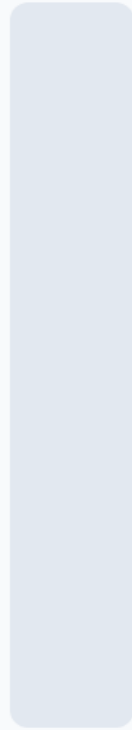
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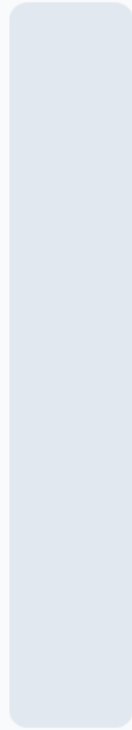
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A. Unfortunately, no, but some info is better than none

B. Unfortunately, no, but we're working on it

C. Heck yes, you can sign up to receive it and view archived editions via the CRA Workbench

D. Heck yes, just send an e-mail to CRANewsletter@crab.org

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



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C. Heck yes, you can sign up to receive it and view archived editions via the CRA Workbench

[CRA Workbench](#) *(you can view current one & join the mailing list here)*

↳ Resources

↳ CRA Newsletter Archive

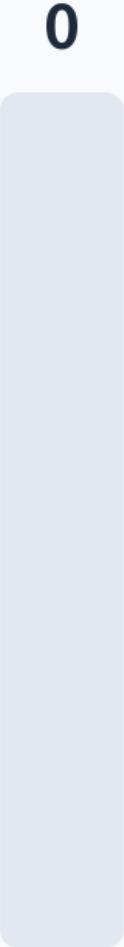
SWOG is coming for an audit. I'm trying not to freak out. What now?



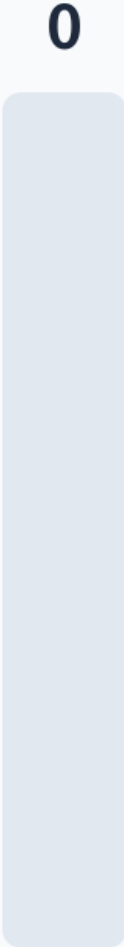
- A. SWOG CRA Workbench has a section for that
- B. Time to pray
- C. All hands on deck! Get all of your data cleaned up on all studies, just to be safe
- D. Vodka never hurt

SWOG is coming for an audit. I'm trying not to freak out. What now?

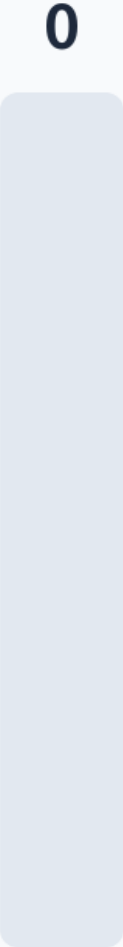
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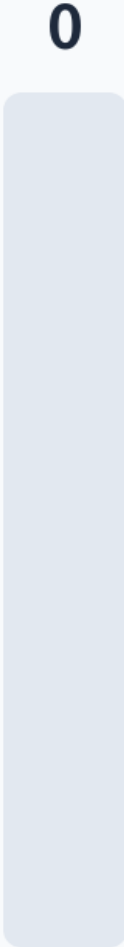
A. SWOG CRA Workbench has a section for that



B. Time to pray



C. All hands on deck! Get all of your data cleaned up on all studies, just to be safe



D. Vodka never hurt

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

SWOG is coming for an audit. I'm trying not to freak out. What now?



A. SWOG CRA Workbench has a section for that

CRA Workbench

↳ Popular Resources

↳ SWOG QA / Audits / Monitoring

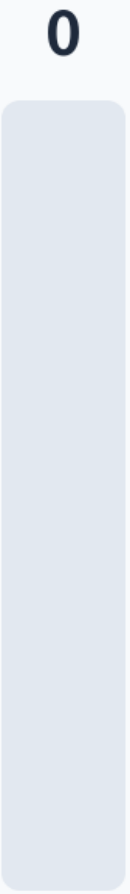
↳ 6 different categories of help including Site preparation for an Audit



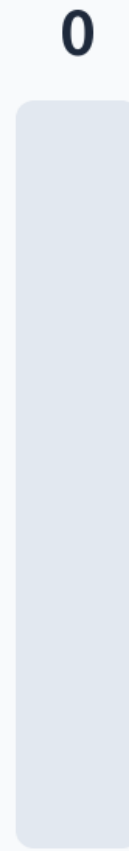
We only registered 2 pts to this study. 1 patient is deceased and the other has completed follow-up. Can we close this study out at our site?

- A. Yes, if no patients are living and/or all queries are closed and expectations resolved
- B. No, all studies must remain open through your IRB for eternity
- C. Maybe. Call your Data Coordinator and see what your options are
- D. Consult CRA Workbench to see if the study requires follow-up

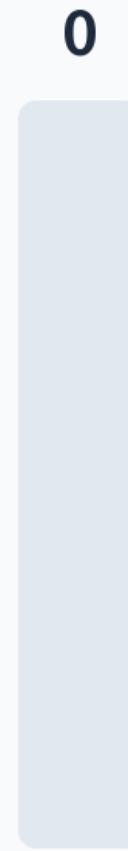
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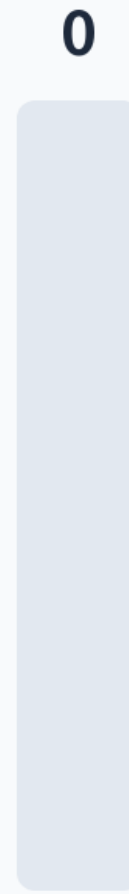
A. Yes, if no patients are living and/or all queries are closed and expectations resolved



B. No, all studies must remain open through your IRB for eternity



C. Maybe. Call your Data Coordinator and see what your options are



D. Consult CRA Workbench to see if the study requires follow-up

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We only registered 2 pts to this study. 1 patient is deceased and the other has completed follow-up. Can we close this study out at our site?

D. Consult CRA Workbench to see if the study requires follow-up

CRA Workbench

↳ Study Reports

↳ Studies with no required follow-up

My coworker attended the CTTC yesterday and got a 'cool' date wheel. How do I get one?



- A. Google to the rescue...maybe this time!
- B. You can order one through swog.org
- C. Sign up to attend next spring's CTTC
- D. You don't want one

My coworker attended the CTTC yesterday and got a 'cool' date wheel. How do I get one?

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A. Google to the rescue...maybe this time! B. You can order one through swog.org C. Sign up to attend next spring's CTTC D. You don't want one

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

My coworker attended the CTTC yesterday and got a 'cool' date wheel. How do I get one?



D. You don't want one, seriously!

CRA Workbench

↳ Tools

↳ Date Counter



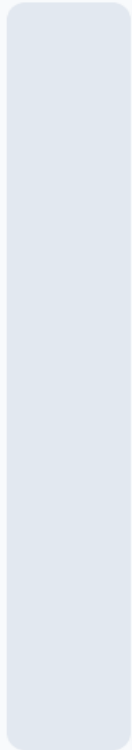
How can I make sure that I'm uploading the right document and that it will resolve the expectation?

- A. Be sure to redact all patient identifiers, both in the document and in the title of the document
- B. Do not include any special characters, especially #, to the name of any document
- C. Be certain that the correct Type of Procedure is selected
- D. Ensure that the SWOG Patient number, Pt initials and SWOG Study number is on at least one page
- E. All of the above

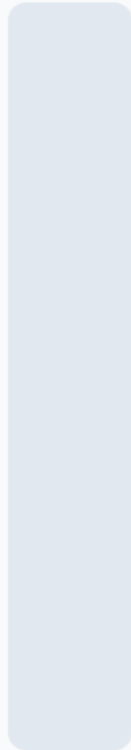
How can I make sure that I'm uploading the right document and that it will resolve the expectation?

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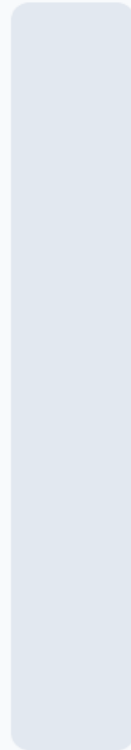
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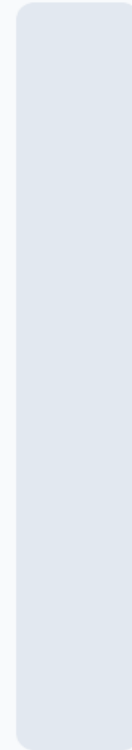
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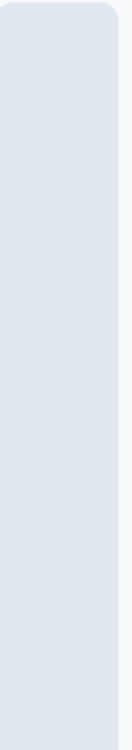
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E. All of the above

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

How can I make sure that I'm uploading the right document and that it will resolve the expectation?



E. All of the above

Let's review some examples.



DATE



PATHOLOGY REPORT

McLeod Research Center
1234 My Street
Bonney Lake, WA 98391
(253) 867 - 5309
chrism@crab.org

Patient Name:



Address: 5678 Main St
Federal Way, WA
98003
Phone: (123) 456 - 7890
MRN: FYI-86-2024



PATHOLOGY CONSULT

Interpretation:

Words, words and more words. Row, row, row your boat, gently down the stream. Merrily, merrily, merrily, merrily life is but a dream.

Clinical Information:

Brief clinical history: 51yo with a wonderful life and minimal complaints.

Procedure:

Pre-operative diagnosis: single
Post-operative diagnosis: married, child, a whole lot more responsibility and a whole lot less privacy, free time and spare money.

Gross Description:

Words, words and more words.

Comment:

Mr. Magnigorium came into clinic to have a lovely chat with our staff.
Words, words and more words. Humpty Dumpty sat on a wall. Humpty Dumpty had a great fall;
All the king's horses and all the king's men, Couldn't put Humpty together again.

Impression:

The wheels on the bus go round and round Round and round Round and round The wheels on the bus go round and round All through the town.
The wipers on the bus go swish, swish, swish Swish, swish, swish Swish, swish, swish The wipers on the bus go swish, swish, swish All through the town.
The people on the bus go chat, chat, chat Chat, chat, chat Chat, chat, chat The people on the bus go chat, chat, chat All through the town.
The horn on the bus goes beep, beep, beep Beep, beep, beep Beep, beep, beep The horn on the bus goes beep, beep, beep All through the town.
The babies on the bus go waa, waa, waa Waa, waa, waa Waa, waa, waa The babies on the bus go waa, waa, waa All through the town.

Electronically Signed by Dr. FeelGood on this date at this time.



Not So Perfect Example

- Protected Health Information (PHI) visible
- Redaction Issues
 - Inappropriate redaction method
 - Incorrect information redacted
- Missing study patient identifiers



DATE
3/11/2025

PATHOLOGY REPORT

McLeod Research Center
1234 My Street
Bonney Lake, WA 98391
(253) 867 - 5309
chrism@crab.org

Patient Name: [REDACTED]
Address: [REDACTED]
Phone
MRN: [REDACTED]

987654
GEM
S2012

PATHOLOGY CONSULT

Interpretation:

Words, words and more words. Row, row, row your boat, gently down the stream. Merrily, merrily, merrily, merrily life is but a dream.

Clinical Information:

Brief clinical history: 51yo with a wonderful life and minimal complaints.

Procedure:

Pre-operative diagnosis: single

Post-operative diagnosis: married, child, a whole lot more responsibility and a whole lot less privacy, free time and spare money.

Gross Description:

Words, words and more words.

Comment:

Mr. [REDACTED] came into clinic to have a lovely chat with our staff.

Words, words and more words. [REDACTED] sat on a wall. [REDACTED] had a great fall;

All the king's horses and all the king's men, Couldn't put [REDACTED] together again.

Impression:

The wheels on the bus go round and round Round and round Round and round The wheels on the bus go round and round All through the town.

The wipers on the bus go swish, swish, swish Swish, swish, swish Swish, swish, swish The wipers on the bus go swish, swish, swish All through the town.

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The babies on the bus go waa, waa, waa Waa, waa, waa Waa, waa, waa The babies on the bus go waa, waa, waa All through the town.

Electronically Signed by Dr. FeelGood on this date at this time.

Perfect Example

- All protected health information (PHI) redacted
- Appropriate redaction method (blackout)
- Study patient identifiers included on at least one page
 - SWOG patient number
 - Patient initials
 - SWOG study number

If a required specimen is not available for submission, you should

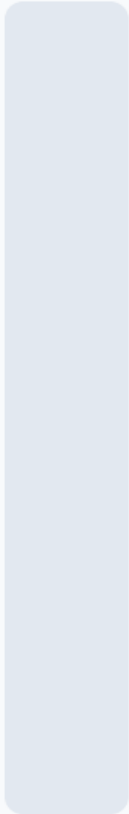


- A. Use the “notify that specimen cannot be submitted” link in the Specimen Tracking System
- B. Reach out to the Data Coordinator to ask them to remove the expectation for that specimen
- C. Do nothing. There’s no specimen to submit and therefore, nothing to enter
- D. None of these answers are correct

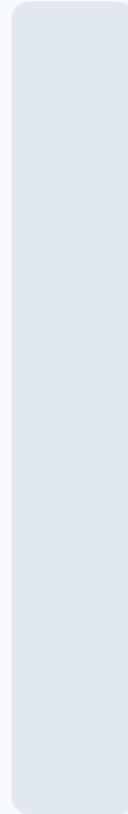
If a required specimen is not available for submission, you should



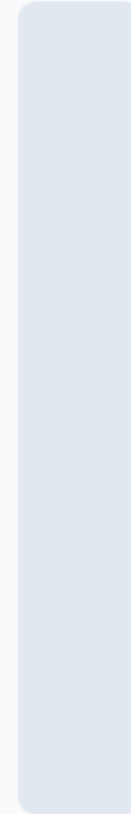
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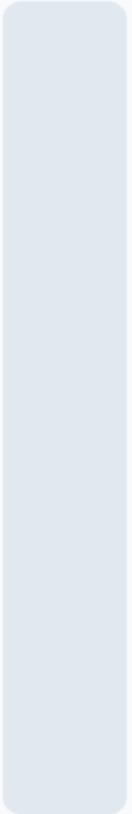
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B. Reach out to the Data Coordinator to ask them to remove the expectation for that specimen

C. Do nothing. There’s no specimen to submit and therefore, nothing to enter

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If a required specimen is not available for submission, you should

A. Use the “notify that specimen cannot be submitted” link in the Specimen Tracking System

CRA Workbench

↳ Resources

↳ SWOG Frequently Asked Questions (FAQ)

↳ Specimen Submission

↳ Item #2

The labs for my patient were reported in one-hundredth but the SWOG form is only asking for reports in tenth. Is it ok to round?



- A. No, you should report to the hundredth if the field allows, otherwise leave it blank
- B. No, you should enter the value as close as you can and specify the actual value in the Comments section of the form
- C. No, SWOG does not allow rounding. Go back to the Treating Doctor for advice on how to report
- D. None of these answers are correct

The labs for my patient were reported in one-hundredth but the SWOG form is only asking for reports in tenth. Is it ok to round?

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A. No, you should report to the hundredth if the field allows, otherwise leave it blank

B. No, you should enter the value as close as you can and specify the actual value in the Comments section of the form

C. No, SWOG does not allow rounding. Go back to the Treating Doctor for advice on how to report

D. None of these answers are correct

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

The labs for my patient were reported in one-hundredth but the SWOG form is only asking for reports in tenth. Is it ok to round?



D. None of these answers are correct because SWOG does allow rounding for tumor measurements, dosing, and labs.

CRA Workbench

- ↳ CRA Manual (for Oncology Research Professionals)
 - ↳ Chapter 16 General Forms and Guidelines
 - ↳ Page 2



My patient missed their appointment today and would like to come back on Monday for treatment. I don't see protocol windows specified in the protocol. Will this be ok?

- A. Yes, just be sure to document the reason for the missed appointment in the Comments Section of the treatment form
- B. No, if the patient missed their appointment, the cycle is considered skipped
- C. Yes, if the delay is no longer than the maximum treatment delay allowed in section 7 of the Protocol
- D. Maybe. Call the Data Coordinator for the study to find out
- E. None of these answers are correct

My patient missed their appointment today and would like to come back on Monday for treatment. I don't see protocol windows specified in the protocol. Will this be ok?

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A. Yes, just be sure to document the reason for the missed appointment in the Comments Section of the treatment form

B. No, if the patient missed their appointment, the cycle is considered skipped

C. Yes, if the delay is no longer than the maximum treatment delay allowed in section 7 of the Protocol

D. Maybe. Call the Data Coordinator for the study to find out

E. None of these answers are correct

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



My patient missed their appointment today and would like to come back on Monday for treatment. I don't see protocol windows specified in the protocol. Will this be ok?

E. None of these answers are correct because when the protocol doesn't specify protocol windows, there is a SWOG Standard available in the SWOG Best Practices Memo

[CRA Workbench](#)

↳ Resources

↳ Best Practices for SWOG Study

↳ Bottom of Page 1

I'm trying to submit data on Study S1007 and I can't find it in Rave. How am I supposed to get this follow-up form in?



- A. Reach out to CTSU to find out why you aren't seeing the study
- B. Call your Data Coordinator to find out why you aren't seeing the study
- C. This could be a Legacy study and data is not collected in Rave
- D. Ensure that the study is still open and collecting data

I'm trying to submit data on Study S1007 and I can't find it in Rave. How am I supposed to get this follow-up form in?

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A. Reach out to CTSU to find out why you aren't seeing the study

B. Call your Data Coordinator to find out why you aren't seeing the study

C. This could be a Legacy study and data is not collected in Rave

D. Ensure that the study is still open and collecting data

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

I'm trying to submit data on Study S1007 and I can't find it in Rave. How am I supposed to get this follow-up form in?



C. This could be a Legacy study and data is not collected in Rave

CRA Workbench

- ↳ Patient Management (Non-Rave Studies)
 - ↳ Data submission for Non-Rave Studies
 - ↳ Enter 1-4 SWOG Pat numbers or pull up full study or use filters for a more specific patient list

With OPEN, RAVE, and all the tools in CTSU, why is the CRA Workbench still relevant?



- A. It's the only data entry mechanism for pre-RAVE studies
- B. Reports include patients on both RAVE and pre-RAVE studies
- C. Includes critical SWOG-specific information such as CRA Manual, Best Practices, and Policies
- D. It's maintained by SWOG SCMC staff so tools and resources based largely on CRA feedback and requests
- E. All answers are correct

With OPEN, RAVE, and all the tools in CTSU, why is the CRA Workbench still relevant?

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A. It's the only data entry mechanism for pre-RAVE studies

B. Reports include patients on both RAVE and pre-RAVE studies

C. Includes critical SWOG-specific information such as CRA Manual, Best Practices, and Policies

D. It's maintained by SWOG SDMC staff so tools and resources based largely on CRA feedback and requests

E. All answers are correct

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

**With OPEN, RAVE, and all the tools in CTSU,
why is the CRA Workbench still relevant?**



E. All answers are correct!

If you need more proof, we encourage you to check it out
for yourself!

Bonus Question: Which statements are true about CLASS?

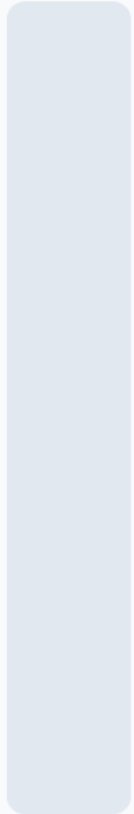


- A. CLASS is a learning management system supported by CTSU
- B. CLASS stands for Compliance, Learning and SOP Solutions
- C. Everybody with an active CTEP-IAM account can access CLASS
- D. SWOG study-specific training can be found in CLASS
- E. All statements are true

Bonus Question: Which statements are true about CLASS?

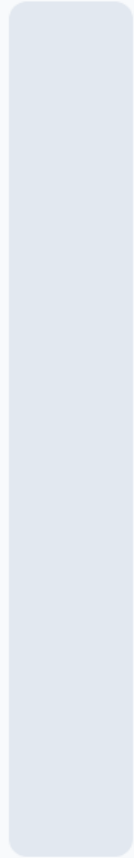
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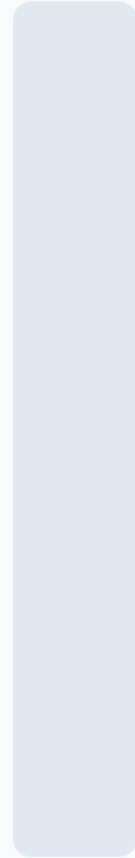
A. CLASS is a learning management system supported by CTSU

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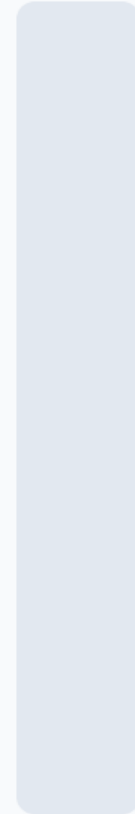
B. CLASS stands for Compliance, Learning and SOP Solutions

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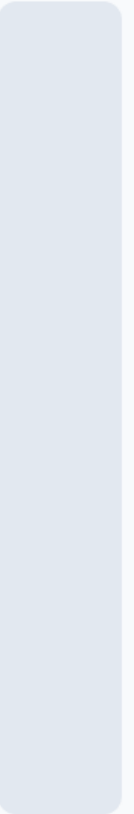
C. Everybody with an active CTEP-IAM account can access CLASS

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D. SWOG study-specific training can be found in CLASS

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E. All statements are true

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Bonus Question: Which statements are true about CLASS?



E. All answers are correct!

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↳ CLASS on Dashboard