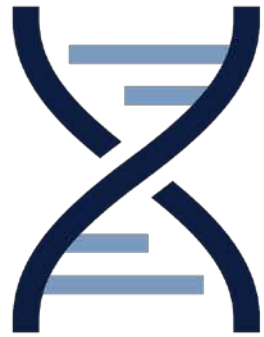# Poll Everywhere Instructions

Cell phone

1. Text **swog2024** to 22333

2. When you see the "Poll Everywhere" question screen, text the answer (i.e., A, B, C, D, E, or F) to 22333

Computer

1. In your web browser go to: **PollEv.com/swog2024**

2. When you see the "Poll Everywhere" question screen, choose the answer (i.e., A, B, C, D, E, or F)

**Oncology Research Professionals (ORP)
Site Operations Meeting**

SWOG Spring Meeting 2024

Connie Szczepanek, RN, BSN, CCRP
Liz Edwards, BA, CCRP
Caitlin Hutchinson, MS

Announcement and Updates Oncology Research Professionals (ORP) Committee

Connie Szczepanek, RN, BSN, CCRP
Chair, SWOG ORP Committee

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.

Spring Site Operations
April 3rd 5:30p-7:30p PST

Open, Welcome, and Announcements	Connie Szczepanek

General Updates	
Cancer Trials Support Unit (CTSU)	Jenny Hopkins
National Cancer Institute (NCI)	Grace Mishkin

SWOG Updates	
SWOG Network Operations Center Protocols & Membership	Dana Sparks Crystal Miwa
SWOG Network Operations Center Quality Assurance (QA)	Laura Gonzales
SWOG Network Operations Center Administration & Study Funding	Pat Mize Casey Dawson Denise Sherman
Statistics & Data Management Center (SDMC)	Cathy Rankin Chris Cook

Site Operations Support	
(Re)Igniting Leadership	Jennie Crews

Closing Remarks	Connie Szczepanek

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).

YOU are The ORP Committee!

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

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

Serving >10,000 ORPs

SWOG ORP Executive Committee
Chair: Connie Szczepanek
Vice-Chair: Dana Little

Nursing Research
Chair: Jamie Myers

ORP Liaison
Co-Chairs:
Sandy Annis
Erin Cebula

Membership
Co-Chairs:
Anthony Hicks
Lisa Stoppenhagen

Education
Co-Chairs:
Deb Bergevin
Joyce Tull

Site Operations
Co-Chairs:
Connie Szczepanek
Liz Edwards
Caitlin Hutchinson

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

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 | CANCER RESEARCH NETWORK

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

CTSU Updates

Jenny R. Hopkins

CTSU Assistant Project Director - Operations

Topics

- What's New with the Delegation of Tasks Log (DTL)?

- Site Staff Resources: What's Available and What's Coming Soon

- ID.Me Reminder

DTL Modernization

› We have modernized the DTL application!

› What does this mean?

- We rebuilt the application within a new technical framework.

- It is now a stand-alone application with its own URL (but still accessible from the CTSU Members' website).

- We have made several updates and enhancements that were driven by user input.

**Release date:
March 19, 2024**
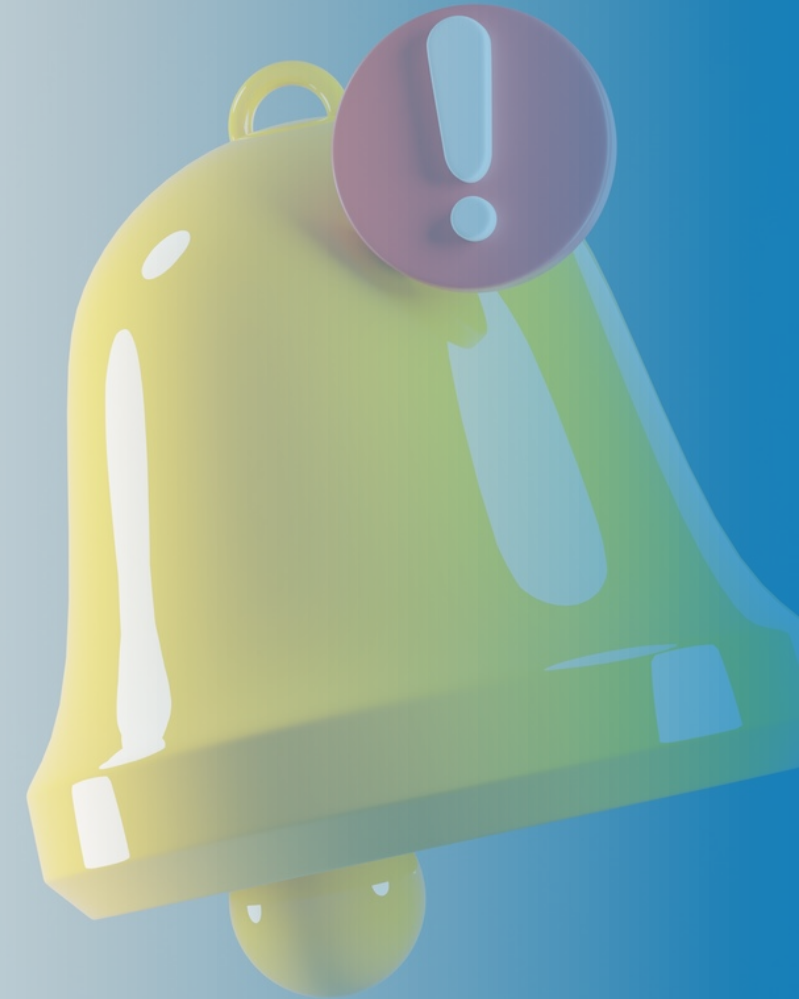
What's the Same and What's New (Key Items)

What's (Generally) the Same

› Primary DTL business rules

- DTLs are still site- and study-specific

- Must have one CI (only) and up to three DTLAs

- Must be signed by the CI at the same timepoints as before

› Main screens like Site DTL Browser, Task Assignment Browser, and DTL Approvals

› Email notifications including the bi-monthly signing notification

› Bulk functionality still available for approvals, task assignments/ inactivations, and clones

› Availability of Help Topics

What's New

› URL separate from the CTSU website

› Landing page = Dashboard

› New toggles and view options on pre-existing screens

› Cart functionality in the bulk assign/bulk inactivate operations allows submission of updates for multiple persons in one request

› New bulk operation = Submit Initiated DTLs to CI for Approval

› Increased capacity for bulk requests; all will be queued for processing

› Request Browser displays bulk requests

› Integration with CLASS for training documentation

CI = Clinical Investigator; DTLA = DTL Administrator; CLASS = Compliance, Learning, and SOP Solutions

Fresh Versions of Existing Screens

› Site DTL Browser

› Manage Site DTL

› Task Assignment Browser

› Clone DTL(s)

› DTL Approvals

› Manage Tasks

- Assign task(s) by person

- Inactivate task(s) by person
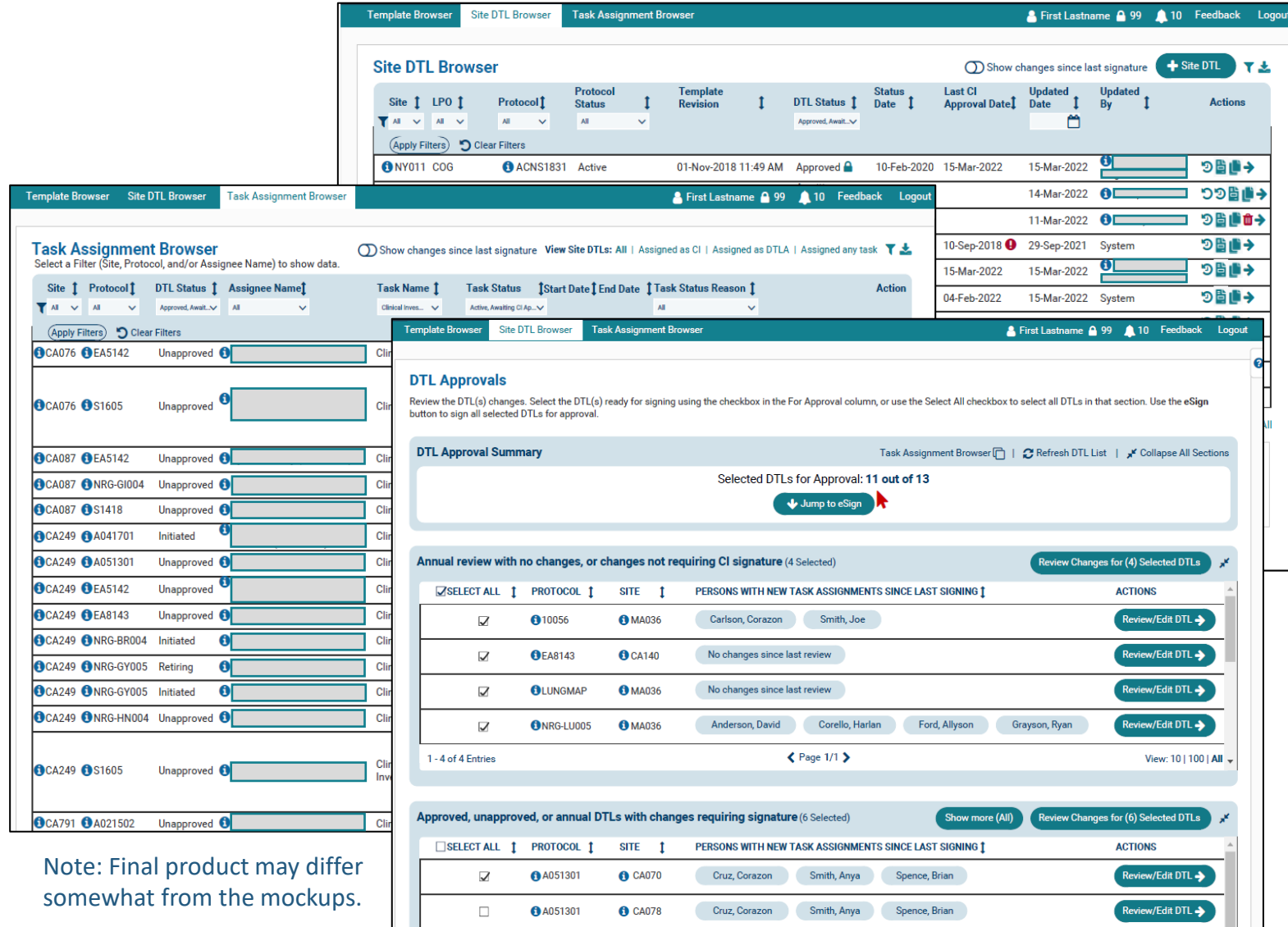
Note: Final product may differ somewhat from the mockups.

✴ New! Site Dashboard

> New landing page.

> Specific to a given user.

> Quick Links to common operations.

> My Tasks provide metrics and links to screens where you can take action.

> View options to display what you are most interested in seeing.

Welcome

View: DTLs where I am DTLA ▾

The Delegation of Tasks Log (DTL) application enables rostered site staff with appropriate access to view, create, update, and manage their site DTLs. You can use the menu items available at the top of the screen to navigate to other screens. If you prefer, the Quick Links section below provides shortcuts to common tasks associated with site DTLs. The My Tasks section enables you to view specific data for site DTLs that are relevant to you and link to screens where you can take any needed action (if applicable). Please note there is a Help icon available on the right side of every screen within the application; click on the icon to view help content related to the screen you are on.

Quick Links

➕ Create New DTL	📋 Clone DTL(s)
✏ View/Manage Single DTL	☰ Manage Tasks
→ Task Assignment Browser	→ Request Browser
✔ Submit DTLs for Approval	

My Tasks

Select a tile to view a list of the related records.
Tiles in Assignments section are calculated based on All DTLs view.

ASSIGNMENTS

2,839	0	564
My DTL Tasks	DTLs where I am Clinical Investigator (CI)	DTLs where I am DTL Administrator (DTLA)

CLINICAL INVESTIGATOR (CI)

| 1	12
Upcoming annual DTL reviews	New DTLs awaiting signature

ACTION ITEMS

1	2	1
Unapproved DTLs with patient accruals	DTLs missing required task(s)	Unapproved DTLs
2	15	1,169
Initiated DTLs	Site Registrations pending DTL requirement	Pending task assignments
1,155	184	
Tasks with suspended assignees	Tasks with unrostered assignees	

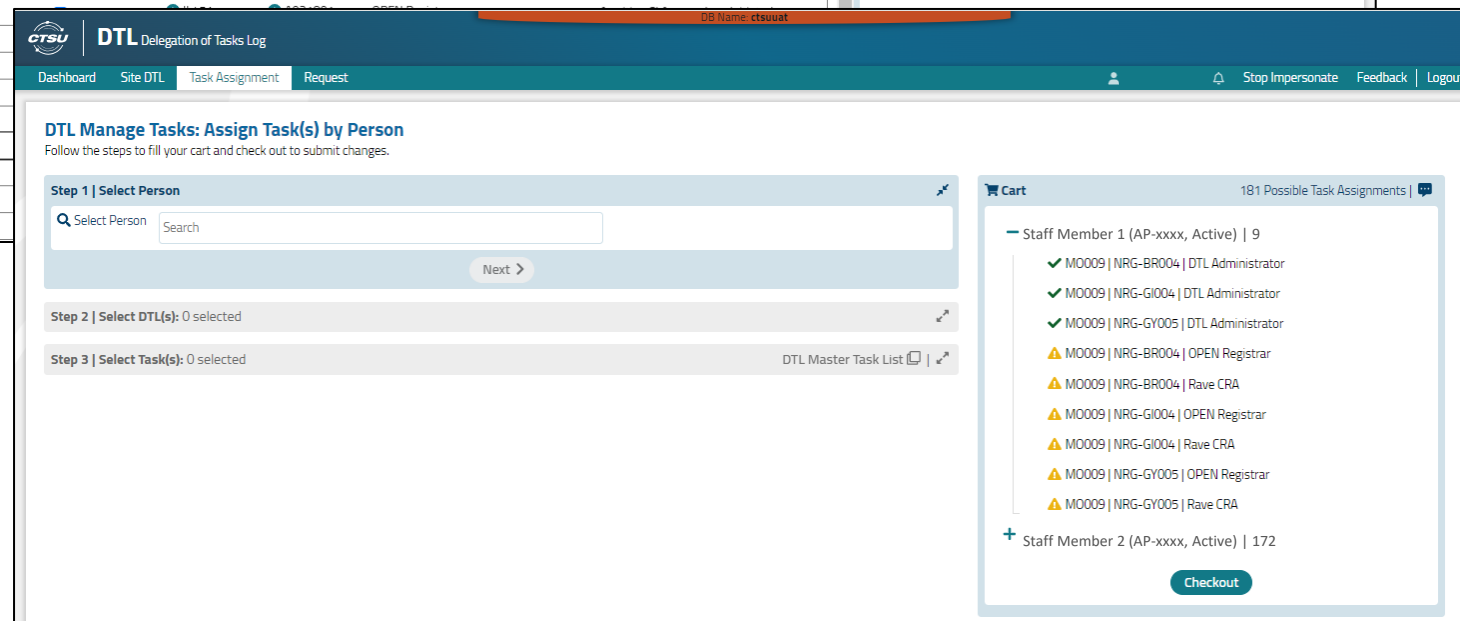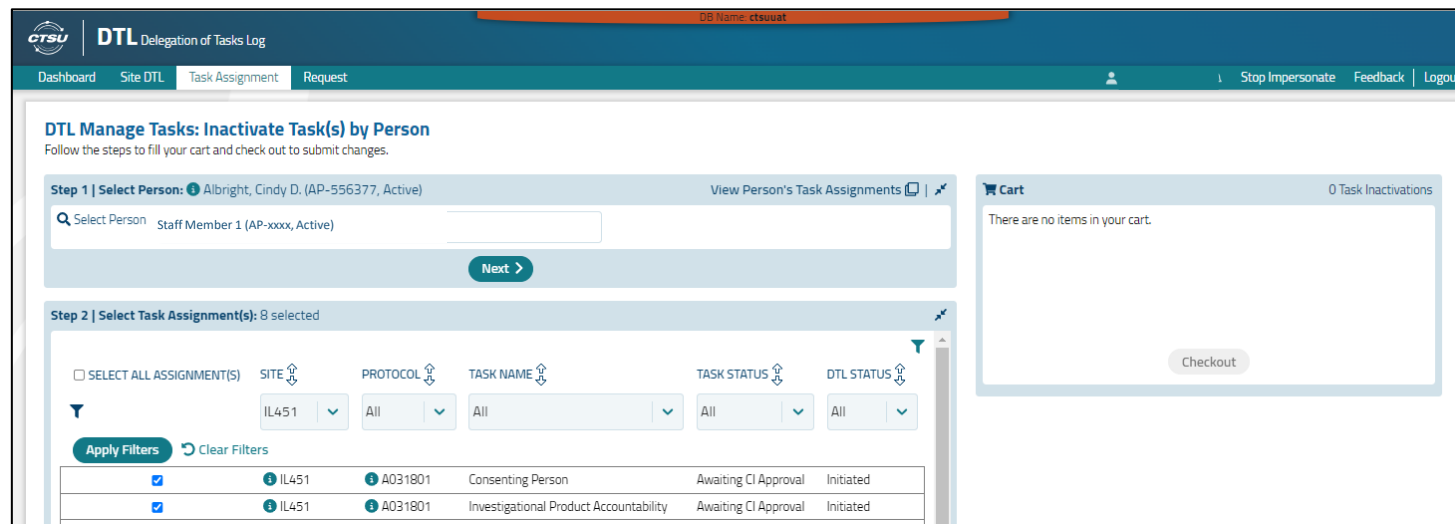# New! Cart Functionality in the Manage Tasks Screens
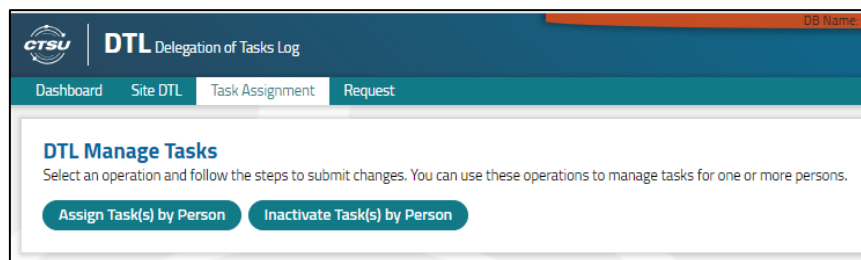
When doing bulk task assignments or bulk task inactivations, cart functionality will allow you to submit requests for multiple people.

1. Select a person

2. Select the DTLs (for assignments only)

3. Select the tasks

4. Add to cart

5. Select another person and repeat

6. Submit

New operation that allows site staff to submit multiple initiated DTLs to the applicable CI(s) for approval.

- DTLs must be ready for signature, i.e., all requirements are satisfied.

- Will move the DTLs to the applicable CIs' DTL Approvals screens.

Submit Initiated DTLs to CI for Approval

Select the DTL(s) ready to be submitted for approval using the checkbox, or use the Select All checkbox to select all DTLs. Use the **Submit** button to process the selected DTL(s) from Initiated to Awaiting CI Approval.

DTL Submit Summary

Selected DTLs ready to be submitted for CI approval: **13 out of 13**

[Submit]

DTLs in Initiated Status (13/13)

☑ SELECT ALL DTL(S)	SITE	LPO	PROTOCOL	PROTOCOL STATUS	ASSIGNED CI	UPDATED DATE	ACTIONS
▼	All ▼	All ▼	All ▼	All ▼	All ▼	DD-MMM-YYYY ✕	
☑	ⓘ OH086	ALLIANCE	ⓘ A021502	Closed to Accrual	ⓘ Last, First	02-Feb-2024	→
☑	ⓘ OH152	ALLIANCE	ⓘ A021502	Closed to Accrual	ⓘ Last, First	29-Nov-2023	→
☑	ⓘ OH156	ALLIANCE	ⓘ A021502	Closed to Accrual	ⓘ Last, First	22-Jan-2024	→
☑	ⓘ OH156	ALLIANCE	ⓘ A031501	Closed to Accrual	ⓘ Last, First	06-Feb-2024	→
☑	ⓘ OH415	ALLIANCE	ⓘ A021502	Closed to Accrual	ⓘ Last, First	14-Nov-2023	→
☑	ⓘ OH465	ALLIANCE	ⓘ A021502	Closed to Accrual	ⓘ Last, First	22-Jan-2024	→
☑	ⓘ OH465	ALLIANCE	ⓘ A031501	Closed to Accrual	ⓘ Last, First	06-Feb-2024	→
☑	ⓘ OH466	ALLIANCE	ⓘ A021502	Closed to Accrual	ⓘ Last, First	22-Jan-2024	→
☑	ⓘ OH467	ALLIANCE	ⓘ A021502	Closed to Accrual	ⓘ Last, First	22-Jan-2024	→
☑	ⓘ OH470	ALLIANCE	ⓘ A021502	Closed to Accrual	ⓘ Last, First	29-Nov-2023	→
☑	ⓘ OH471	ALLIANCE	ⓘ A021502	Closed to Accrual	ⓘ Last, First	22-Jan-2024	→
☑	ⓘ OH471	ALLIANCE	ⓘ A031501	Closed to Accrual	ⓘ Last, First	06-Feb-2024	→
☑	ⓘ OH472	ALLIANCE	ⓘ A021502	Closed to Accrual	ⓘ Last, First	14-Nov-2023	→

1 - 13 of 13 Entries   ‹ Page 1/1 ›   View: **All**

[Apply Filters] ↺ Clear Filters

New! Increased Capacity and Request Browser

› Increased capacity for bulk requests such as bulk cloning, bulk task assignments, bulk task inactivations, bulk submissions, and bulk approvals.

› You generally won't need to break these activities into separate batches but will need to allow time for them to process.

› A new Requests Browser will display the status of your bulk requests.

New! Integration with CLASS for Training Requirements

› For DTL tasks with training requirements, training will be managed out of the CLASS application, which is part of the CTSU enterprise.

› Once an assignee completes their training, CLASS will communicate the completion and the task assignment will become Active or Awaiting CI Approval (depending on the task and the situation).

› No need to submit or upload certificates!

› DTLAs will be able to view an assignee's training status from within the DTL application.

Resources and Help

› **DTL Help Topics** are available on every screen within the application; they are loosely context-specific.

- Look for the question mark ⑦ icon on the right.

- The full collection of site-facing help topics are available by clicking on [Compiled Site DTL Guide](#) at the bottom of the list of topics.

› There is a Feedback link available on every screen; use it to submit suggestions or questions/issues. Feedback goes to the CTSU Help Desk and is forwarded to the DTL Team when applicable.

› CTSU Help Desk

- CTSUContact@westat.com

- 888-823-5921
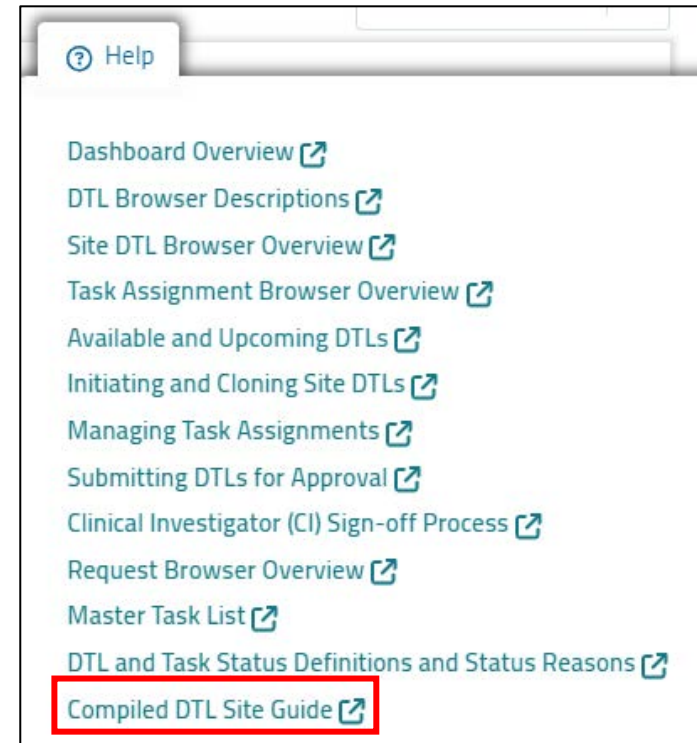
Cross-Network Training Working Group

› The CTSU has been working with members of the Cross-Network Training Working Group to expand and improve access to staff training resources.

› This includes increasing the number of resources available on the CTSU website as well as in the Compliance, Learning, and SOP Solutions (CLASS) system.

› Thanks to Cara Laubach, the SWOG representative who really spearheaded this effort.

💡 Reminder: CLASS

> CLASS is the learning management system managed by the CTSU.

Courses Available in CLASS

> CLASS has been in use for several years for trainings, including:

- Clinical Trials Monitoring Branch (CTMB) auditor training;

- Protocol-specific trainings, both purely educational as well as those associated with protocol-specific requirements (i.e., required for site registration approval); and

- Rave-related training associated with the NCICOVID study.

> More recently, a different type of training has been added to the CLASS course catalog, i.e., more general trainings that are available to site staff to help educate them on topics related to working in cancer clinical trials.

- We expect to add more of these types of trainings.

General Site Training

💡 Reminder: Checking Your Training Status

You can check your own CLASS training status in CLASS itself…

…or on the CTSU website.

⭐ Coming Soon: CLASS Training Status Report

> The CTSU is developing a **site-facing** CLASS training status report.

- • Will be available under the CLASS link on the CTSU website.

- • Part of the next CTSU website release (summer).

> Those with primary roster roles will be able to view who at their site(s) have been enrolled in training and their status.

> Can help answer a question such as: "Who at my site has started or completed the SWOG 2302 Site Initiation course?"

✴ Coming Soon: Expanded Researcher Resources

> The Cross-Network Training Working Group worked with a robust list of resources to categorize them in a way that would be useful to site research staff.

> Some of these resource are the training courses in CLASS, others are links to NCI, CTSU, and other organization materials.

> The CTSU is reworking the folders under Resources > **Researcher Resources** on the CTSU website to accommodate the topics and resources.

> A sortable version of the list itself will also be available in this location.

> Plan to have this ready this summer; will post a notice in the Bi-Monthly Broadcast.

Resources Browser

Search by Document Title ⌄

Enter search term [Go!]

- 📂 **My Protocols** ❓
- 📂 **My Favorites** [0 docs]
- ＋ 📁 **Experimental Therapeutics Clinical Trials Network (ETCTN) Program**
- 📁 **CTSU Operations Information**
- − 📂 **Researcher Resources**
  - − 📂 NCI Program and General LPO Resources
    - ＋ 📁 NIH and NCI Resources
    - ＋ 📁 LPO Resources
  - − 📂 Audit and Monitoring
    - ＋ 📁 Audit Resources
  - − 📂 Investigational Agent Management including AURORA
    - ✖ No Sub-Group found
  - − 📂 Participant Coordination and Data Management
    - ＋ 📁 Adverse Event Reporting and CTEP-AERS
    - ＋ 📁 Data Management including Rave
    - ＋ 📁 Disease-specific Training, Staging, and Assessment including RECIST
    - ＋ 📁 Laboratory Evaluations
    - ＋ 📁 Participant Registration/Transfer including OPEN
    - ＋ 📁 Recruitment and Retention
    - ＋ 📁 Specimen Management including LPO Systems
  - − 📂 Regulatory
    - ＋ 📁 Confidentiality and Privacy including HIPAA
    - ＋ 📁 Consent, Assent, and Consent Process Documentation
    - ＋ 📁 Delegation of Tasks Log (DTL) or Site Authority Log
    - ＋ 📁 General Regulatory Principles
    - ＋ 📁 IRB and NCI CIRB
    - ＋ 📁 Protocol Deviations, Unanticipated Problems, Noncompliance
  - − 📂 Site/Staff Management
    - ＋ 📁 Funding and Payment
    - ＋ 📁 General Research Training
    - ＋ 📁 Investigators
    - ＋ 📁 Patient Advocate
    - ＋ 📁 Roster Management

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💡 Reminder: Other Resources on the CTSU Website

Don't forget that most screens of the website and the modernized CTSU applications (e.g., Delegation of Tasks Log, Source Document Portal), and the Oncology Patient Enrollment Network (OPEN) contain Help Topics/user resources.

The Resources page of the website contains many resources beyond Researcher Resources, including lots of CTSU information, Frequently Asked Questions, and a Glossary!
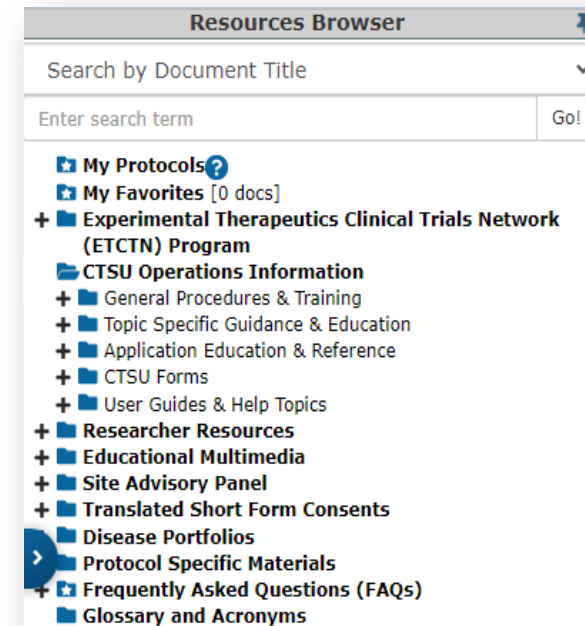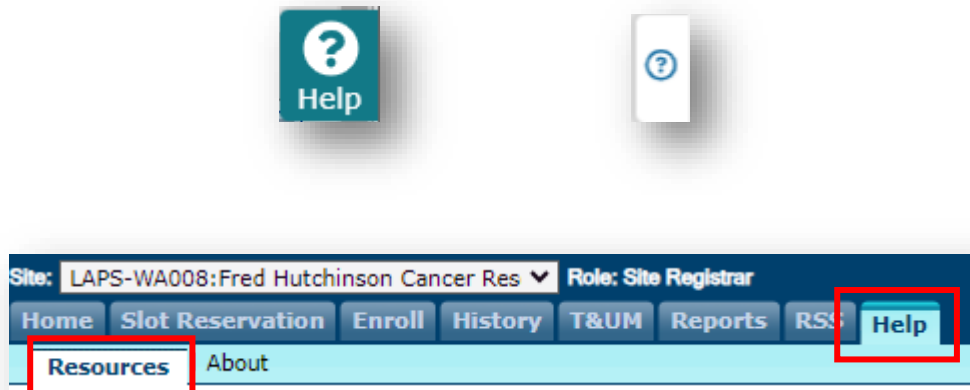
✴ Coming Soon: CTSU SAE Reporting FAQs Resource

> A comprehensive set of Serious Adverse Event (SAE) Reporting Frequently Asked Questions (FAQs) will soon be available on the <u>CTSU website > Resources > Frequently Asked Questions</u>

Read all about it!

— 📁⭐ **Frequently Asked Questions (FAQs)**
  - 📁 Show All
  - 📁 Audit
  - 📁 Awareness, Education & Training
  - 📁 CTSU Members Website
  - 📁 CTSU Membership
  - 📁 CTSU National Coverage Analysis (NCA) Initiative
  - 📁 Data Quality Portal (DQP)
  - 📁 Data Submission
  - 📁 Delegation of Tasks Log (DTL)
  - 📁 National Clinical Trials Network (NCTN)
  - 📁 Oncology Patient Enrollment Network (OPEN)
  - 📁 Patient Enrollment
  - 📁 Protocols
  - 📁 Rave
  - 📁 Regulatory - CIRB
  - 📁 Regulatory - General
  - 📁 Regulatory - local IRB
  - 📁 **Serious Adverse Event (SAE) Reporting**
  - 📁 Source Document Portal

ID.me Reminder

Current Implementation

- On August 10, 2023, a new, less stringent identity verification method was introduced.

  - U.S.-based research staff can now be verified with their cell phone number!

- U.S.-based users must complete identity verification and multi-factor authentication (MFA) with ID.me by September 30, 2024 (this is the Federal Government-imposed deadline).

CTEP IAM and ID.me
Identity Proofing and
Multi-factor Authentication:
Protecting Research Data Integrity

Making sure all users are who they say they are.

A Quick Word about International Research Staff

> Canadian investigators and staff can verify their identity by providing a driver's license or passport.

> Other international research staff are currently able to verify their identities with their passports only.

> **NCI is working towards an alternative identity verification solution for non-U.S. research staff.** Currently, such research staff have the option of using IAM or ID.me for continued access.

- "Grandfathering" for those who already have CTEP-IAM accounts; local grandfathered staff will verify new staff.

- Will still use ID.me for MFA.

> Expected to be available in early summer, stay tuned for updates!

Helpful Resources and Tips

> Remember the deadline (all research staff): September 30, 2024.

> All users, including U.S- and non-U.S.-based, must sign up with ID.me for MFA.

> For questions regarding this process, please contact the CTEP Help Desk.

> Check out the NCI and ID.me page for more information about the integration.

> Visit the dedicated page on the CTEP website for detailed instructions, FAQs, webcasts, and other helpful information.

> Compliance tracking continues via reports sent to Registration and Credential Repository (RCR) Registration Coordinators. All rostered staff can also export the Person Roster Roles Report from the Roster Update Management System (RUMS) on the CTSU website.

Thank You!!

Please note that the CTSU has a table at the Open Forum session on Thursday. Stop by with questions about these or other CTSU-related topics!

NCI Updates

Grace Mishkin

grace.Mishkin@nih.gov

New NIH and NCI Directors

Monica M. Bertagnolli, M.D., is the 17th director of the National Institutes of Health (NIH). She was nominated by President Joe Biden on May 15, 2023, confirmed by the U.S. Senate on November 7, 2023, and took office on November 9, 2023.

W. Kimryn Rathmell, M.D., Ph.D., began work December 18, 2023, as the 17th director of the National Cancer Institute (NCI), part of the National Institutes of Health (NIH).

https://www.nih.gov/about-nih/who-we-are/nih-director/nih-director-monica-m-bertagnolli-md

https://www.cancer.gov/news-events/press-releases/2023/rathmell-nci-director

Modernized DTL Browser

- New Dashboard

- New Task Status Overview

- Improved ability to manage tasks

- New submission of multiple DTLs for approval at once

- New integration between DTL and CLASS

Improvements to the DTL have been made possible by your feedback, input, and involvement in the development, as well as the hard work of the CTSU team!

CIRB Approval of Amendment Review Letters

Moving forward, clear language in the CIRB Approval of Amendment Review letter should indicate what plan was approved by the CIRB for participant notification or re-consent.

The CIRB determined that Protocol Version Date 02/26/24 does not include significant new findings that might relate to study participants' willingness to continue participation. However, the CIRB has reviewed and agrees with the Study Chair's plan for notification outlined in section 3.0 of the CIRB Amendment Application which indicated participants should be notified of changes made in the amendment.

NCI Precision Medicine Initiatives

- **ComboMATCH has been open to accrual for one year**

    - Any site successes with ComboMATCH? Challenges?

- **MyeloMATCH will be opening soon**

- **iMATCH pilot trial S2101 in progress**

NIH NATIONAL CANCER INSTITUTE

NCI Informed Consent Template Updates

- Obtained more than 500 comments and suggested revisions from all NCTN Groups, NCORP Research Bases, patient advocates, and clinical research staff

- Exploring alternatives to the Key Information section content and format

- Implementing planned and newly identified changes:

  - Language for pediatric trials

  - Ensuring gender inclusive language is used

- Released March 1: Draft Guidance from FDA and OHRP on the Informed Consent Key Information Section

  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/key-information-and-facilitating-understanding-informed-consent-guidance-sponsors-investigators-and

NCI CTAC Streamlining Clinical Trials Working Group

Plans to reduce data elements collected in IND-exempt Phase III treatment trials and work to improve EHR study implementation (including continuing the CTSU EMR Templates)

NCI Strategic Vision for Clinical Trials: 2030 and Beyond

Develop **flexible, faster, simpler, less expensive, high-impact** clinical trials that seamlessly integrate with clinical practice

Streamline processes for trial design and execution	Focus on essential endpoints
Decrease regulatory hurdles and broaden trial access	Increase efficiency of data collection

Clinical and Translational Research Advisory Committee (CTAC) Strategic Planning Working Group Report 2020
https://deainfo.nci.nih.gov/advisory/ctac/1120/SPWGreport.pdf

Streamlining Clinical Trials Working Group Focus

Limiting Data Elements Collected	Limit clinical trial data collection in late phase trials to data elements essential for primary and secondary objectives
Utilizing EHRs to Support Clinical Trials	1) Engage vendors to create mechanisms for automatically integrating study-specific documents into local implementations of their products 2) Resolve the logistical and data quality challenges of extracting clinical trial data from electronic health records

Including SWOG's work in collaboration with nCoup

Decentralized Clinical Trial Activities

- Modifications that have been implemented as permanent options for sites include:

    - Shipment of CTEP IND oral agents from the local site to the patients

    - Remote consent

    - Remote auditing option

- Sites can continue to utilize flexibilities in the regulations allowing intermittent use of local Health Care Providers (HCPs) – including local labs, imaging, routine care visits, and SOC treatments – with responsible investigator oversight

- Sites can continue to utilize virtual/telehealth visits for study visits as permitted by state licensing and study specific requirements

Decentralized Clinical Trial Activities (cont.)

- NCI Decentralized Clinical Trials (DCT) Working Group with representatives from all NCTN Groups, NCORP Research Bases, CRPs, and CTEP/DCP, has been meeting to identify ways to implement DCT activities in trials in a consistent way and to help sites utilize DCT activities when appropriate

- Work is ongoing; goals include a resource list for sites to easily confirm what activities are generally allowed in NCTN and NCORP trials and what processes should be followed

Note on Guidance Documents

- Guidance documents are nonbinding recommendations

- All clinical trial activities should meet the requirements of the applicable statutes and regulations

- When guidance documents suggest requirements that go beyond the requirements of the applicable statutes and regulations, alternative approaches may be appropriate

Contains Nonbinding Recommendations

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

Seeking Feedback!

- **Now:** Poll Everywhere

- **Later:** Email - grace.mishkin@nih.gov

Question #1

- **Protocol variability across Groups:** If staff at your site work on protocols from multiple NCTN Groups, are there particular sections of the protocol that are challenging to use from Group to Group?

    - If so, what sections? What makes things more challenging? What is easier or harder to implement at your site? (Concrete examples are VERY HELPFUL!)

Please provide specific examples of particular protocol sections that create challenges to use from Group to Group? (sections, challenges, implementation, etc.)

Nobody has responded yet.

Hang tight! Responses are coming in.

Modernized DTL: How is it going so far?
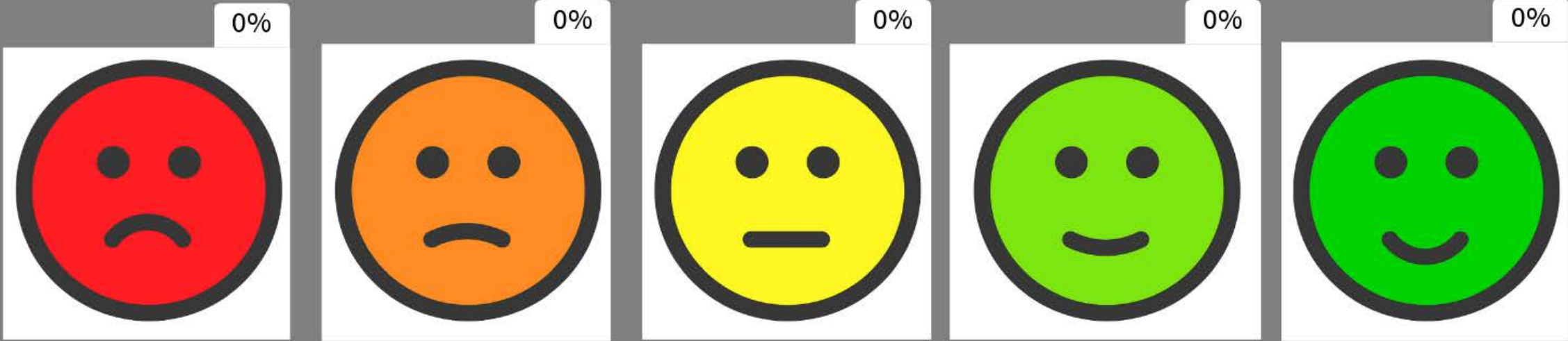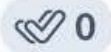
What new challenges are you facing? What haven't we talked about yet?
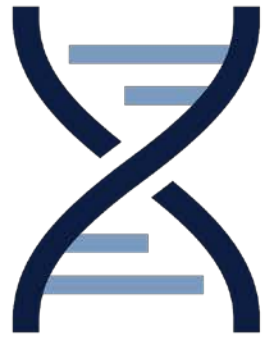
Nobody has responded yet.

Hang tight! Responses are coming in.

What is the most frustrating difference across all NCTN protocols?

♥ 0

A. Protocol layout — 0

B. Protocol content — 0

C. Data collection processes — 0

Write a single word to describe your favorite aspect of working with SWOG protocols.

♡ 0

Nobody has responded yet.

Hang tight! Responses are coming in.

Quality Assurance Updates

Presenter: Laura Gonzales, BSN, MA RN, OCN

Quality Assurance Manager

SWOG Operations Office

San Antonio TX

Upcoming QA Live Webinar

Deviations vs Deficiencies

Tuesday, June 11th, 2024 @ 11:00am Central

Registration information will be upcoming in SWOG Broadcast Emails, CTSU Broadcast Emails, and SWOG's Spring Group Meeting in Seattle.

SWOG Quality Assurance
Live Webinar Series

- **Best Practices for Informed Consent (March 15, 2024)**

- **Adverse and Serious Adverse Event Reporting (December 2023)**

- **SWOG Audits: Preparing for Success and Audit Process (October 2023)**

- **How to Develop a CAPA Plan (July 2023)**

Links to the webinar recordings, resource documents, and slide sets shared during each webinar are posted at the link below:

https://www.swog.org/swog-quality-assurance-live-webinar-series

Questions?

qamail@swog.org
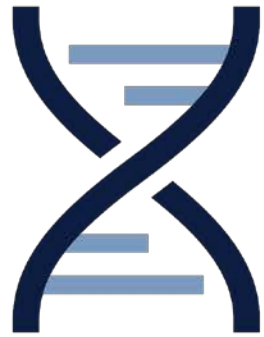
NEW SWOG Grants & Contracts Coordinator

Welcome, Denise!

NCTN Competitive Renewal Member Site Requirements

New NIH Grant Policy Terms, Section 15.2

"NIH expects recipients to ask potential subrecipients, at the application stage, to submit language in their letters of support indicating their awareness of these requirements and the subrecipient's willingness to abide by all requirements should an award be issued."
Reference: NOT-OD-23-182

<u>Note</u>: *Only applies to sites that receive standard NCTN site payments from SWOG*

NCTN Competitive Renewal
Member Site Requirements

- Letter of Intent/Support
  - Include required language
  - Signed by institutional signing official (OS)

- RR Performance Site Form

- Letter of Support from Member Site PI (Optional)

Look for Email in the Late Spring/Early Summer!

NEW Site Funding Contacts

Federal Funding	FedSitePayments@swog.org
Non-federal Funding	Finance@thehopefoundation.org
National Coverage Analysis (NCA) or General Funding Questions	Funding@swog.org

Funding Team at ORP Open Forum

Thursday, April 4th at 12:30pm – 2:00pm

Columbia C, Level 3

In Person Only

SWOG Clinical Trials Partnerships (CTP)

April 2024 Site Operations Update

SWOG Clinical Trials Partnerships
(SWOG-CTP)

Federally-funded SWOG trials

- SWOG-CTP obtains and distributes industry funding
- Drug costs, other support
- Ongoing, successful for many years

SWOG CTP-run rigorous, scientifically relevant industry supported (100%) trials*

Single SWOG Committee-initiated studies

- Previously named CTI
- Not "one-offs" like an IIT
- If successful, a broadened collaboration via other agents/designs within company may evolve

Preferred Partnerships Program (PPP)

- New mechanism
- Pipeline access – or – complex multi-arm platforms
- Joint scientific development and governance
- Dedicated CTP infrastructure

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SWOG CLINICAL TRIALS PARTNERSHIPS

*No overlap or "competition" with active federally-funded studies

Getting Started with SWOG CTP…

- SWOG Member sites will be notified about CTP studies via email
  - Study Synopsis
  - Study Feasibility Questionnaire
  - Study Calendar and Specimen Collection
  - Study Funding
- Interested sites will complete a short study feasibility questionnaire
- Once selected, sites will complete contract for the study

SWOG CTP Systems

- **Florence eTMF and eISF**
  - Sites will be given access to Florence upon completion of study contract

- **WCG IRB Central IRB**
  - Submissions through Connexus

SWOG CTP Systems

- OPEN -> Nebula
- Rave -> Nebula
- CTEP-AERS -> Nebula
- SWOG Specimen Tracking -> SWOG Specimen Tracking (same)
- SWOG Expectation and Query Reports -> SWOG Expectations and Query Reports (same)

21CTP.LEUK01: Phase 2 trial of Asciminib, Dasatinib, Prednisone and Blinatumomab for Patients with Newly Diagnosed Ph+ ALL

Anjali Advani, MD and Michaela Liedtke, MD in collaboration with Novartis

Background:

- Ph+ ALL is caused by the Bcr-Abl tyrosine kinase and is common in older adults
- Standard TKI Dasatinib is associated with high response rates but relapse is common
- Asciminib is a potent allosteric inhibitor of Bcr-Abl
- Bi-specific antibody Blinatumomab reliably eradicates Minimal Residual Disease and deepens response

Study objectives:

- Rate and depth of remission
- Disease free and overall survival
- Correlatives to study mechanisms of resistance

Statistics:

- Phase 2 study
- Hypothesis: Day 84 Major Molecular Response 52% -> 70%
- Approximately 35 patients are enrolled over 2 years

Active Industry Collaborations*

- Acute lymphocytic leukemia

- Breast cancer triple negative - adjuvant

- Breast cancer ER+ HER2 - metastatic

- Bladder cancer - neoadjuvant

- Head/neck squamous cell - advanced

  pipeline, platform, subtype

Pending Collaborations

- CNS Working Group

- Digital Engagement

- Immunotherapeutics

- Colorectal – metastatic

- Anal – locally advanced

- Several company pipelines

- SWOG VA Committee

Learn more at the ORP Open Forum!

Thursday, April 4th at 12:30pm – 2:00pm

Columbia C, Level 3

In Person Only

SWOG SDMC Updates
Spring 2024

Cathy Rankin, MS

Coordinating Statistician

SWOG SDMC

Newly Activated Trials

Study	Title	Activation
Breast S2206	Phase III Trial of Neoadjuvant Durvalumab + Chemo vs Chemotherapy Alone for MammaPrint Ultrahigh (MP2) HR+/HER2-, Stage II-III Breast Cancer	10/30/2023
Myeloma S2213	A Phase III Study of Dara-VCD Induction Followed by Autologous Stem Cell Transplant or Dara-VCD Consolidation and Dara Maintenance in Patients with Newly Diagnosed AL Amyloidosis	12/1/2023
Lung S1900K	A Randomized Phase II Study of Tepotinib with or without Ramucirumab in Participants with MET Exon 14 Skipping Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)	12/18/2023

Upcoming Trial Activations

Study	Title	Target Activation
MYELOMATCH	Master Screening and Reassessment Protocol (MSRP) for Tier Advancement in the NCI myeloMATCH Clinical Trials	Early April
MM1YA-S01	A Randomized Phase II Study Comparing Cytarabine + Daunorubicin (7+3) vs (Daunorubicin and Cytarabine) Liposome, Cytarabine + Daunorubicin + Venetoclax, Azacitidine + Venetoclax, and (Daunorubicin and Cytarabine) Liposome in Patients Aged 59 or Younger Who Are Considered High-Risk (Adverse) Acute Myeloid Leukemia as Determined by myeloMATCH	Early April
Lung - S1900J	A Phase II Study of Amivantamab-vmjw in Participants with MET Amplification-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer	4/15/2024
Leukemia - S2306	Randomized Ph 2 Trial to Evaluate the Efficacy of BCL-2 Inhibitor Therapy with Chemotherapy Compared to Chemotherapy Alone in Adult Patients with Newly Diagnosed T-Cell ALL and T-Cell Lymphoblastic Lymphoma	4/1/2024
GI - S2303	Randomized Phase II/III Trial of 2nd Line Nivolumab + Paclitaxel + Ramucirumab versus Paclitaxel + Ramucirumab in Patients with PD-L1 CPS ≥ 1 Advanced Gastric and Esophageal Adenocarcinoma	4/1/2024
Lymphoma - S2308	Randomized Phase III Study of Mosunetuzumab vs. Rituximab for Low Tumor Burden Follicular Lymphoma	5/15/2024

Early Closure Form with CIRB

- **REQUEST FOR NETWORK GROUP APPROVAL OF EARLY CLOSURE FORM** to document if network group approves early study closure at a site. Approval is not guaranteed, especially if for registration trials.

- Submit request for closure to the <u>coordinating network group</u> until the coordinating group has indicated that follow-up is complete.

Request for LPO Approval of Early Closure Form

Submit to LPO, as appropriate, per instructions on the previous page.

Institution Name*:	NCI Institution Code*:

*Supplemental Site page included below; to be used if closure rationale is the same for multiple sites.

Protocol Title (Shortened version acceptable):	Protocol Number:

Rationale for Early Closure of Study

1) No subjects were accrued at or transferred to the institution and no future accruals are anticipated.	☐
2) All subjects enrolled or transferred to the institution have completed treatment and follow-up, are off-study, or have been transferred; all patient data queries are completed; no future data queries or enrollments/transfers are anticipated.	☐
3) Other (please provide rationale):	☐

Typed name of the person completing the form:	Email Address:

Date form completed:

Early Closure Form with CIRB

- For SWOG, no need to submit if trial is already on the **Studies with No Required Follow-Up** report.
  - ➢ CRA Workbench > Study Reports

- Sites <u>do need</u> to request study closure for trials if they never enrolled any participants.

- Questions: **SWOGStudyClosureRequest@crab.org**

Policy #33
Institutional Performance Review (IPR) Revision

Going to Board of Governors this Saturday to seek approval to add **Query Metrics** to the monthly IPR metrics

Policy #33
IPR - Query Metrics

Queries posted by the SDMC, biorepository, quality assurance staff, central monitors or other non-"Site from System" queries are included in this measure.

Responsiveness to Queries: Sites are expected to respond to queries within 15 days; any query that is unresolved and 30 days past the due date is delinquent. A site is non-compliant if > 5% of the queries posted in the last 13 months are delinquent or any query posted > 13 months ago is still unresolved.

Outstanding SWOG Queries as of : 03/04/2024 5:42:06 AM

Data Management Institution:

The total number of system-generated queries in Rave is informational only and will not count against your performance.
Please note they are preventing a form from being submitted and should be addressed as soon as possible.

Institution	# Queries Posted Last 13 Months	Total # unresolved	Unresolved, <15 days overdue	Unresolved, 15-30 days overdue	Unresolved, 31-60 days overdue	Unresolved, 61-90 days overdue	Unresolved, 91 days- 13 months overdue	Unresolved, > 13 monthss overdue	Unresolved, System Queries
	143	3	3 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0	0

Site Score

SDMC is introducing a Site Score for SWOG leadership to evaluate site's overall performance compared to the Group as a whole.

- A new metric based on the quality and timeliness of data and biospecimen submissions. Data management institutions with more than 5 SWOG-credited accruals in the prior 13 months are scored on this scale.

- Weighted measure of current IPR metrics over the past 6 months.

- Soon the SDMC will begin to share individual scores with sites. Scores will be provided at the data management institution level of in.

- Emailed to sites every 6 months.

Site Score

Measure	Excellent=3	Good=2	Adequate=1	Non-compliant=0
IFS	0%	>0% - 5%	>5% - 10%	> 10% or IFS13 >0
Forms	≤ 1%	1% -2.5%	>2.5% - 5%	> 5%
FUP	≤ 5%	5% - 10%	>10 - 15%	> 15%
Specimens	0%	>0% - 5%	>5% - 10%	> 10% or SPEC13 > 0

Sum up the categories for a site to get an overall score between 0 and 12. Then calculate the average of scores over the prior 6 months.

Site Score

Overall site score is determined as follows:

Site Score	6-Month Average	# DM Institutions
Excellent	10 - 12	13
Very Good	8 - 9.9	20
Good	5 – 7.9	16
Fair	3.0 – 4.9	16
Poor	< 3	2

Data management institutions with at least 10 SWOG registrations who have **Excellent** score will be recognized by leadership at the Group Meetings and in the meeting agenda book.

Other Reminders

Best way to communicate with SDMC

Questions about study-specific requirements (eligibility, study calendar, expectations, queries, data submission, and registration procedures):

BreastQuestion@crab.org	CancerControlQuestion@crab.org
GIQuestion@crab.org	GUQuestion@crab.org
LeukemiaQuestion@crab.org	LungQuestion@crab.org
LungMAPQuestion@crab.org	LymphomaQuestion@crab.org
MelanomaQuestion@crab.org	MyelomaQuestion@crab.org
RareTumors@crab.org	SWOGComboMATCHquestion@crab.org
SWOGiMATCHquestion@crab.org	SWOGMyeloMATCHquestion@crab.org

Expectation questions for multiple studies or disease sites: ExpectationReportQuestion@crab.org

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NCI National Clinical Trials Network   NCI Community Oncology Research Program

Other Reminders

❖ CTEP-IAM authentication for CTSU will not be supported
after 9/30/2024. All users will be required to use **ID.me**

SWOG Spring 2024 Hybrid Group Meeting: Site Operations

The SWOG-nCartes Collaboration

SWOG | CANCER RESEARCH NETWORK

NCI National Clinical Trials Network   NCI Community Oncology Research Program

Current Process for Data in EDC

Data from the electronic medical record is repeatedly, redundantly, and manually transformed and entered in the EDC system

NOT
Efficient | Error-free | Timely

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network

NCI Community Oncology Research Program
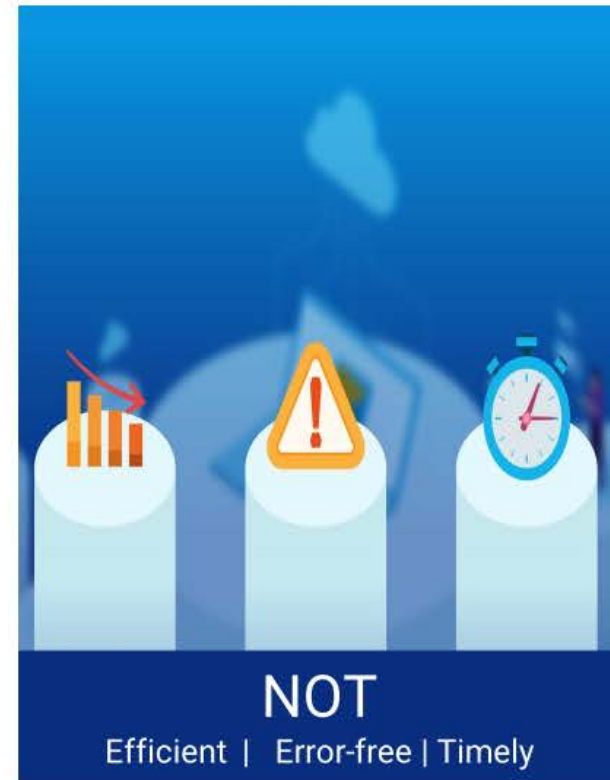
SWOG-nCartes EMR Data Supported
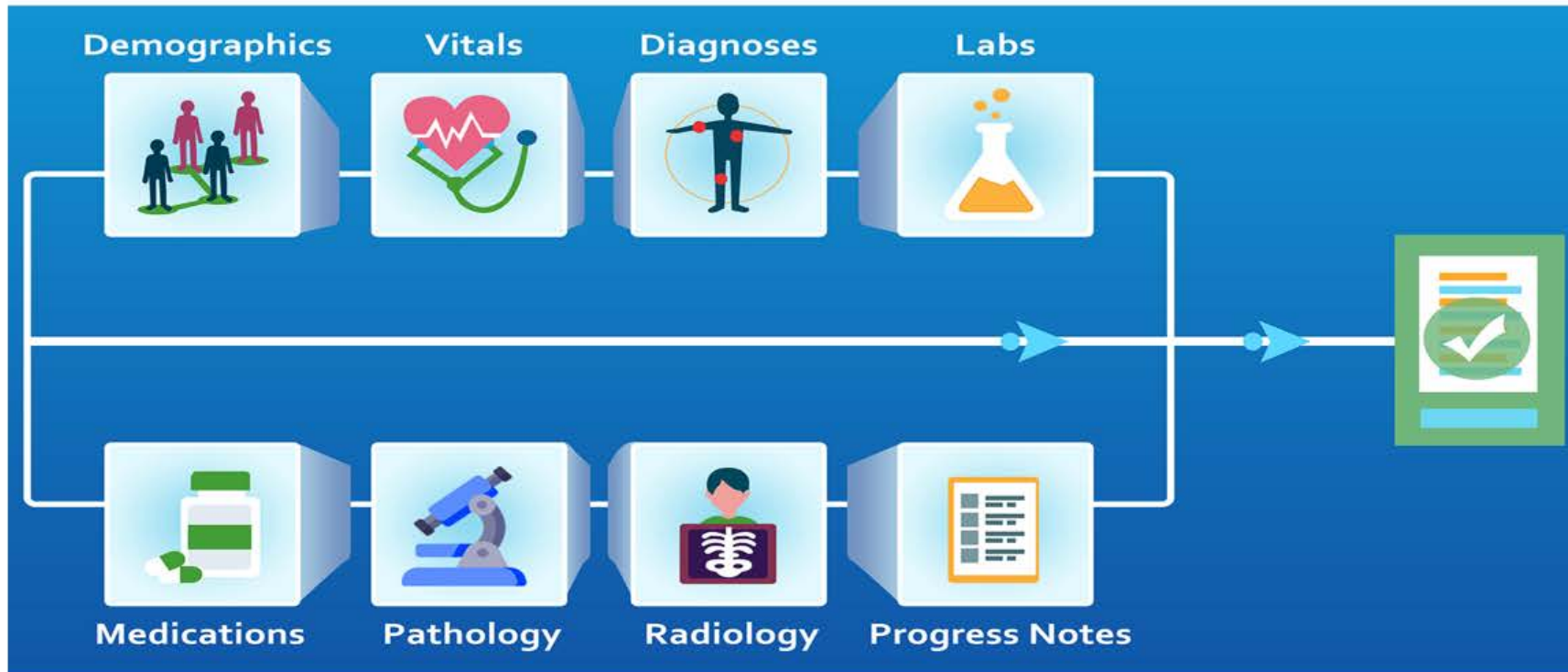
Current State

- In full production use

- Material time savings and data quality improvements for sites

- SWOG publication pending

- Ten SWOG trials are currently available on nCartes, more under consideration

- Other immediate site uses include investigator-initiated trials

- nCartes and SWOG are currently funding nCartes use on SWOG trials

SWOG-nCartes Leap Day Webinar: What SWOG Sites Are Saying

- "it's been a huge time saver for us"
- "it's been very easy for us to quickly submit lab values and complete study data entry"
- "our data managers and staff are very excited to add more of our studies to the system"
- "the error rate on data extraction was zero"

For More Information

- Visit the SWOG-nCartes Booth

SWOG-EMR-to-EDC@crab.org
or
John McIlwain (john.mcilwain@ncoup.com)

(Re)Igniting Leadership

Jennie R. Crews, MD, MMM, FACCC

ACMO Ambulatory Care, Stanford Health Care

CMO Stanford Medicine Partners

Clinical Professor, Department of Medicine, Stanford

Stanford MEDICINE | Health Care

How would you define your current role?

a. VP   b. Executive Director/ Director   c. Manager/ Supervisor   d. Individual Contributor

a National Cancer Institute program   A program of the National Cancer Institute of the National Institutes of Health

How long have you been in this role?

♥ 0

a. <1 year

0

b. 1-3 years

0

c. 3-5 years

0

d. 5-10 years

0

e. >10 years

0

What is one word to describe how you think/feel about leadership?

Nobody has responded yet.

Hang tight! Responses are coming in.

Leading

Managing

Specialist
Analyst
Tactician
Bricklayer
Problem Solver
Warrior
Diplomat
Agenda Setter
Architect
Strategist
Integrator
Generalist

Michael Watkins
How Managers Become Leaders
AAPL, February 2024

Traits we Value in Research:
- Detail oriented
- Subject matter expertise
- Task Focused
- Champion of Causes

Leading

Warrior

Diplomat

Problem Solver

Agenda Setter

Bricklayer

Architect

Tactician

Strategist

Analyst

Integrator

Specialist

Generalist

Managing

Michael Watkins
How Managers Become Leaders
AAPL, February 2024

Traits we Value in Research:
- Detail oriented
- Subject matter expertise
- Task Focused
- Champion of Causes

How do we move to this side of the path?

Leading

Warrior

Diplomat

Problem Solver

Agenda Setter

Bricklayer

Architect

Tactician

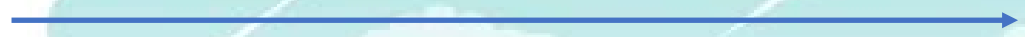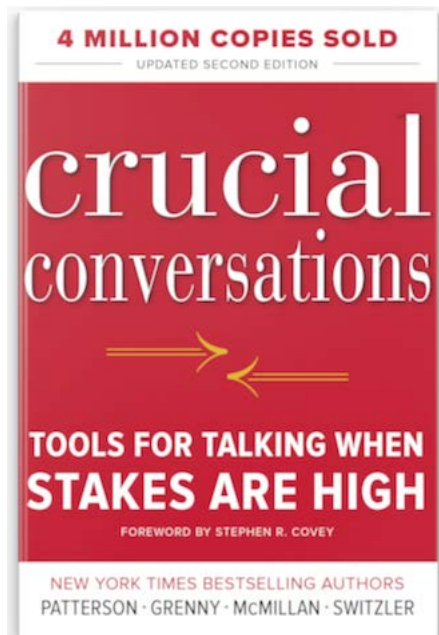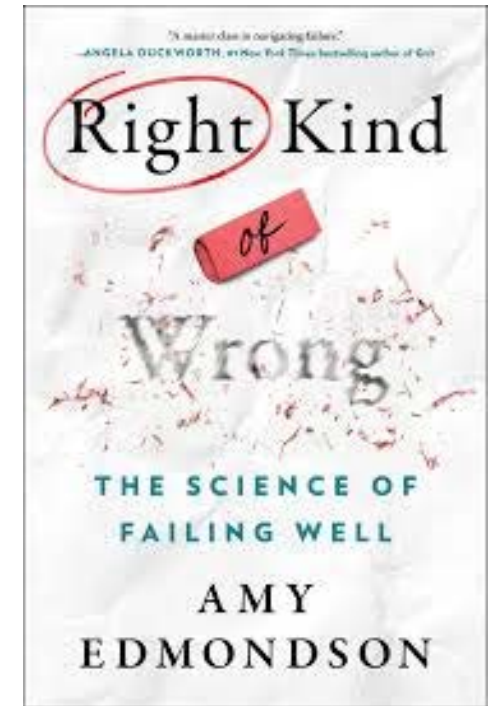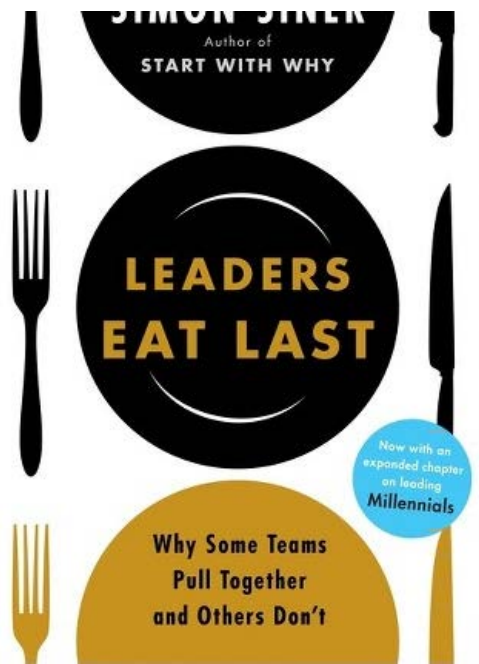Strategist

Analyst

Integrator

Specialist

Generalist

Managing

Michael Watkins
How Managers Become Leaders
AAPL, February 2024

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Author of START WITH WHY

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HOW THE BEST LEADERS MAKE EVERYONE SMARTER

REVISED AND UPDATED

LIZ WISEMAN

FOREWORD BY STEPHEN R. COVEY

#1 NEW YORK TIMES AND WALL STREET JOURNAL BESTSELLER

Brené Brown
PhD, MSW

dare to lead

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RULE MAKERS, RULE BREAKERS

How Tight and Loose Cultures Wire Our World

MICHELE GELFAND

"Endlessly impressive...To read this book is to see both yourself and your neighbor for the first time—guided by rules of which you've both been unaware." —SUSAN CAIN, author of *Quiet*
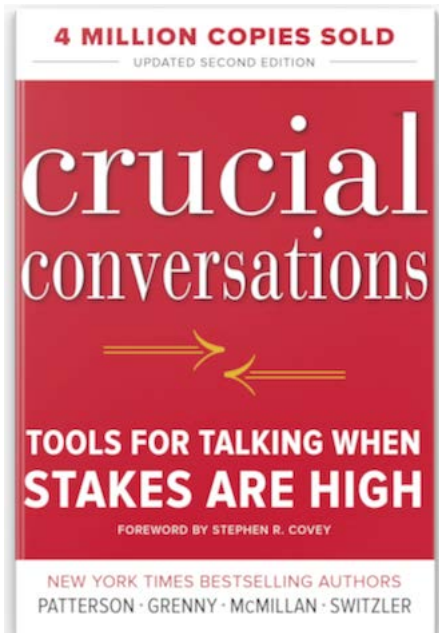
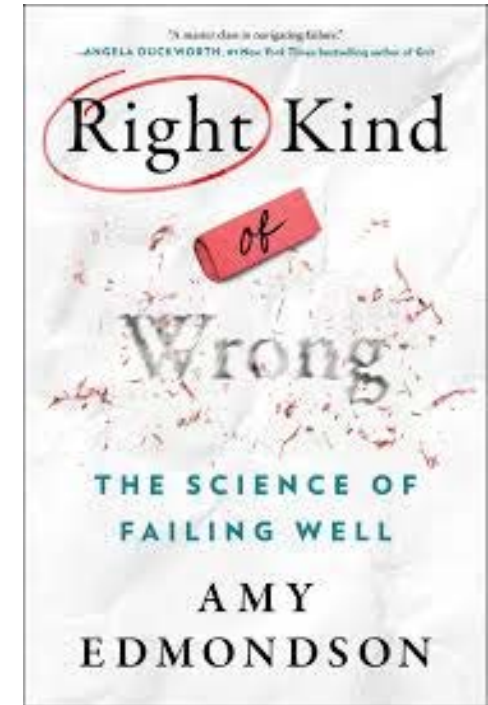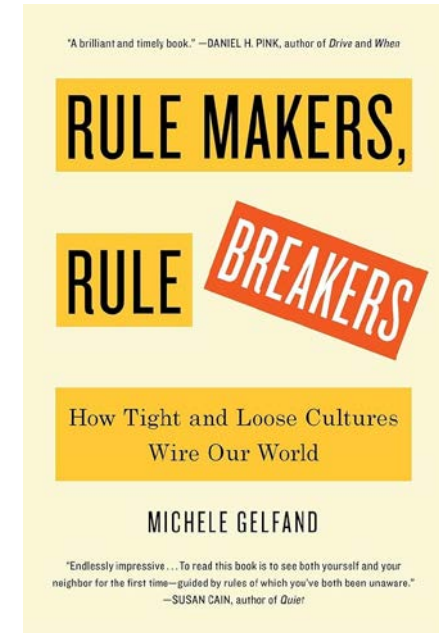Experience

Training
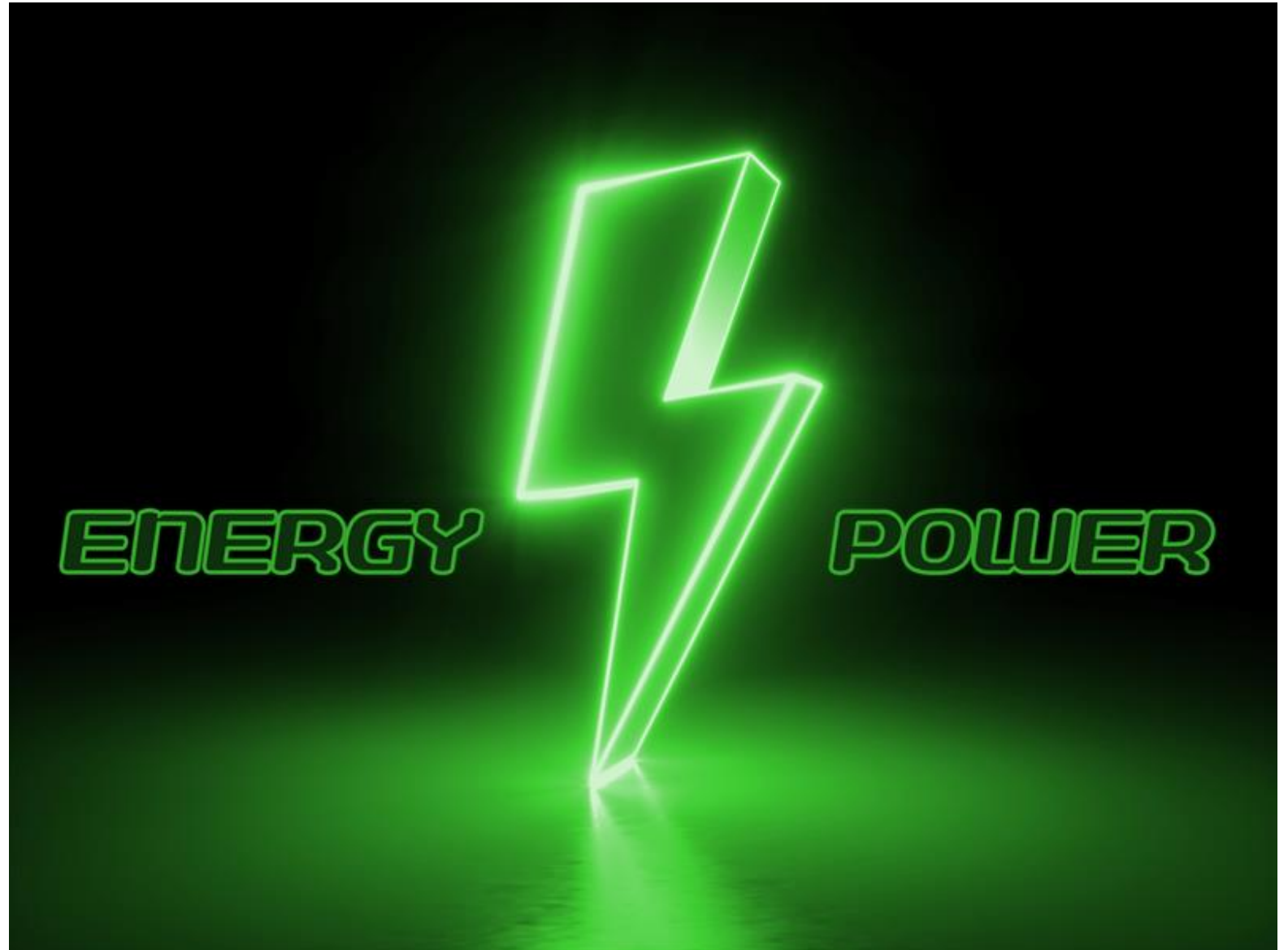
Mentorship

Observing Others

- Power =
Transfer of Energy

-Sinek

- Practice Gratitude

- Be Curious

- Fail Well

- Belonging Builds Trust

Appreciate Our Humanity

- Leadership is hard
- You are enough
- Take care of yourself
- Find support in peers

What is one word to illustrate the idea or aspect of leadership you will implement?

Nobody has responded yet.

Hang tight! Responses are coming in.

Thank you!

Jennie R. Crews, MD MMM

Jcrews@stanfordhealthcare.org

Special Thanks

- All of our Speakers

- Courtney Wille

Reminders

Tomorrow, Thursday, April 4th

- **Jeri & Noboru Oishi Symposium**, 8:00 AM – 11:00 AM PT

- **ORP Open Forum**, 12:30 PM – 2:00 PM PT

Fall 2024 SWOG Group Meeting

October 16 - 19, 2024
Hyatt Regency Chicago
Chicago, Illinois