Training Resources

<u>SWOG Training Resources List for Oncology Research Professionals:</u>
https://www.swog.org/media/13452





Training Resources – SWOG Learning Management System

Website	System	Function
SWOG.org (https://swog.exphosted.com) - Login with CTEP credentials	ExpertusOne	 SWOG-member-only Training Clinical Trials Training Course (CTTC) CTTC Access Instructions Advanced Practice Provider Clinical Research Workshop SWOG Oncology Research Professionals Regulatory Workshop Study Chair Workshop Early-Stage Investigator Workshop (Online portion) Investigational Agent Handling TeamScience for SWOG Members and much more – regular content additions! First time LMS access: Please see CTTC Access Instructions for general LMS system access instructions.





SWOG (ExpertusOne) Learning Management System (LMS)

- Direct link to the LMS is located on the SWOG Member-side of the website under the "Member Resources" menu,
 - Or, via direct url: <u>https://swog.exposted.com.</u>
 - Login with CTEP IAM credentials required to access.
- SWOG Member Training Courses, plus
 - Brief (5-15 minutes) modular course additions ongoing.
 - For short courses, filter by
- SWOG study-specific training is maintained in the <u>CTSU Compliance</u>, <u>Learning</u>, and <u>SOP Solutions (CLASS)</u> <u>Learning Management System [CTSU CLASS LMS]</u>; Accessible NCTN-wide to staff with CTEP IAM login.





SWOG has launched a new Learning Management System (LMS)!

THE EXPERTUSONE LMS WILL BE HOME TO ALL TRAINING THAT IS SPECIFIC TO SWOG MEMBERS.



Training certificates are viewable and printable for one year after completing a course.



Courses are available in brief 5- to 15-minute modules.



Content is regularly added and updated. See the "Announcements" window for new content.



In a user-friendly interface, you can view trainings, take surveys, and complete assessments all from one LMS content player – also available for

mobile devices.



Allows us to host virtual classes integrated with WebEx or Zoom.

NCTN-wide training — such as for protocol-specific requirements and PRO training — will remain in the CTSU CLASS system. But SWOG internal training for members and staff will be in ExpertusOne.

Some of the training content now within ExpertusOne:

- Study Chair
 Workshop
- Young Investigator Workshop Online
- Investigational Agent Handling
- Clinical Trials
 Training Course
- Team Science

Access SWOG's new LMS at swog.exphosted.com, or link from the "Training for SWOG Members" item on the "Member Resources" menu. Use your CTEP IAM credentials to log in.





SWOG (ExpertusOne) Learning Management System (LMS)

 The SWOG Learning Management System Catalog is set-up for voluntary course enrollment, by SWOG membership type.

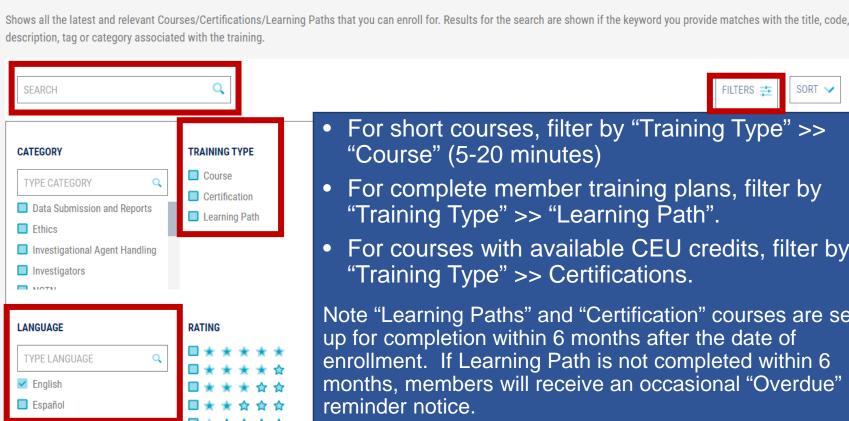
- Under the Catalog "Filters": Members can search for classes by key search term (e.g., data submission, reports, specimen, etc.), by "Training Type", or by language.
 - SWOG is in the process of adding Spanish language courses to the LMS. To search for courses available in Spanish, de-select "English" under "Language" and select "Español".



ALL (22) WISHLIST (0)

MY LEARNING | MY DASHBOARD





CATALOG

- For short courses, filter by "Training Type" >> "Course" (5-20 minutes)
- For complete member training plans, filter by "Training Type" >> "Learning Path".
- For courses with available CEU credits, filter by "Training Type" >> Certifications.

Note "Learning Paths" and "Certification" courses are set up for completion within 6 months after the date of enrollment. If Learning Path is not completed within 6 months, members will receive an occasional "Overdue" reminder notice.





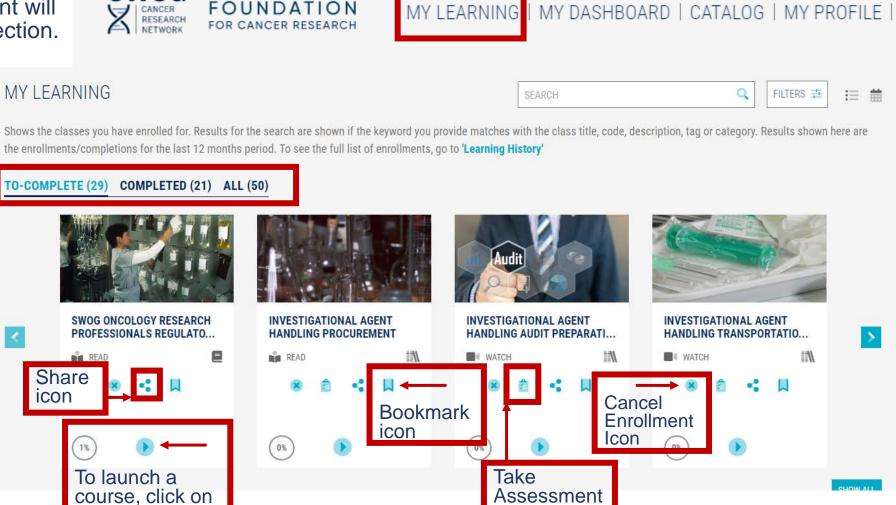
SWOG (ExpertusOne) Learning Management System (LMS)

THE HOPE

the Play icon

FOUNDATION

- After enrolling in a course, certification, or learning path, the training content will appear under the "My Learning" section.
- From the "My Learning" section, you can:
 - View course progress,
 - Launch the training content,
 - Launch the course assessment.
 - Bookmark content that you find helpful (for ease of subsequent review after completion),
 - Share (via email or messaging) system) the content with a colleague, or
 - Cancel your enrollment to the course.
 - If you click on the picture or title portion of the course, it will take you to a detail screen, where you can select and enroll in the available classes in the course or Learning Path.



icon







1 . INVESTIGATIONAL AGENT HANDLING INTRODUCTION

Investigational Agent Handling Introduction







2. INVESTIGATIONAL AGENT HANDLING PROCUREMENT

Investigational Agent Handling Procurement

CODE: IAH.PROCURE.01 | CONTACT SUPPORT: Not Available | Required | Yet To Start

HIDE CLASSES



INVESTIGATIONAL AGENT HANDLING PROCUREMENT

Investigational Agent Handling Procurement



Yet to Start

READ

: IAH.Procure.01 Class Code

: English Language

Provider : Internal

: Self Enrolled by

: Apr 18, 2023 Enrolled on Contact Support : Not Available

- This is an example of the course detail screen where you can view classes, select or launch a selected class, view class progress, and take the assessment (subsequent completion of the class content) associated with each class.
- After completion of the class, a "Completion Certificate" link will appear next to the "Take Assessment" link, where you can download a completion certificate for the class.



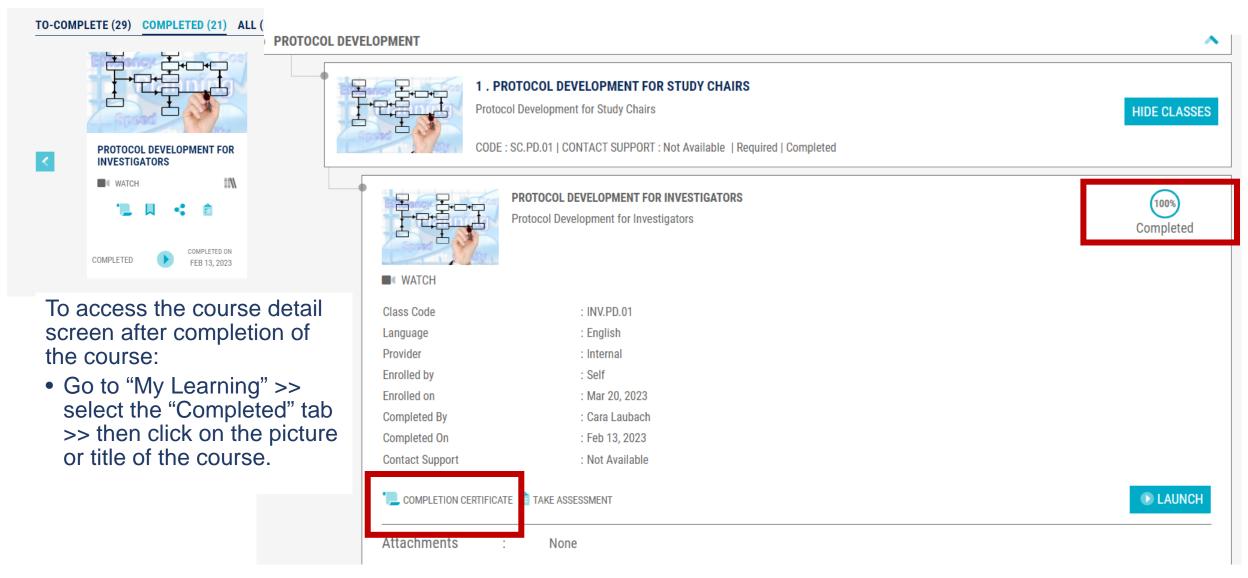
TAKE ASSESSMENT







SWOG (ExpertusOne) Learning Management System (LMS)







SWOG (ExpertusOne) Learning Management System (LMS)

• After completion of a course or entire training plan, the course completion certificate will also be available for download from the "My Certificates" section of the dashboard. Certificates are available for download for 1 year after completion of

the training.

To access the "My certificates" screen:

 Go to "My Dashboard" >> scroll right >> "My Certificates" >> then select either the "Course" or "Learning Path / Certification" tab to view certificates.







Training and Related Resources – SWOG website

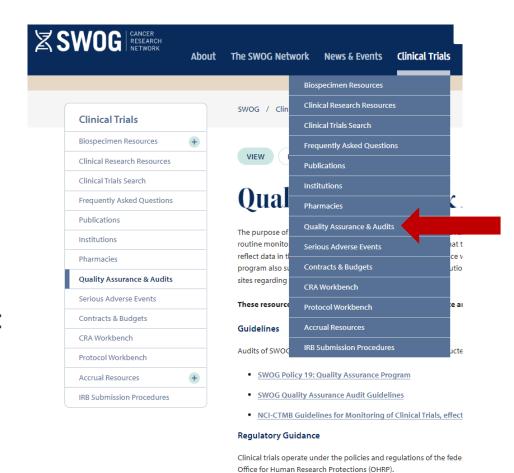
Website	Resource Topic	
SWOG.org	<u>SWOG Policies and Procedures</u>	
	<u>SWOG Oncology Research Professionals Resources</u>	
	SWOG Announcements and Current Training Opportunities	
	<u>SWOG Clinical Research Resources</u>	
	<u>SWOG Frequently Asked Questions</u>	
	SWOG Quality Assurance and Audits	
	<u>SWOG Protocol Workbench</u>	
	<u>SWOG VA Workbench</u>	
	<u>SWOG Biospecimen Processing and Submission Procedures</u>	





SWOG Quality Assurance, Auditing and Monitoring Resources

- The publicly accessible SWOG "Quality Assurance and Audits" webpage includes a collection of regulatory and accountability resources pertinent to responsible research conduct of SWOG (and NCTN) clinical trials.
- In particular, note links to:
 - SWOG Regulatory Guidance, July 2021
 - A guide to successful regulatory audit.
 - SWOG Quality Assurance Audit Guidelines
 - Guidance documents for regulatory documentation and preparation for FDA inspection and FDA registration trials:
 - Trial Master File
 - Investigational Drug Accountability
 - <u>SWOG Best Practices</u> guidance document (allowable treatment/procedure windows, specimen collection and submission, consent scenarios)
 - <u>Patient Chart Review</u> guidance document
 - Record Retention Guidance









SWOG.org Clinical Research Resources Webpages



- Resources for Oncology Research Professionals
 - SWOG Data Submission Guidance, Tips, and Tricks
- Regulatory and Ethical Research Conduct References, such as the NIH Department of Bioethics Videocasts of Past Lectures
- Human Subjects Research Protection Training
- Continuing Education and Training Programs

SWOG / Clinical Trials / Clinical Research Resources

Clinical Research Resources

ANNOUNCEMENTS / CURRENT TRAINING OPPORTUNITIES

Overview. This page provides links to useful resources within the FDA, OHRP, OCR, NIH, NCI, NCTN, C professional research organizations that are pertinent to conduct of clinical trials within the National Network.

- Public Access:
 - Clinical Research and Human Subjects Research Protection Training
- *
- Clinical Investigator Resources
- Resources for Oncology Research Professionals
- Regulatory and Ethical Research Conduct References

Biospecimen Resources

Clinical Research Resources

Clinical Trials Search

Frequently Asked Questions

Publications

Institutions

Quality Assurance & Audits

Serious Adverse Events

CRA Workbench

Protocol Workbench





SWOG.org Clinical Research Resources – Regulatory References

- Clinical Research Resources | SWOG
 - Webpages devoted to onboarding resources and continuing education
 - Specifically, the <u>Clinical Research and Human Research Protection Training | SWOG</u> and <u>Regulatory and Ethical Research Conduct References | SWOG</u> pages contain a wealth of regulatory resources, such as:
 - Pertinent NCI and CIRB links, such as the <u>NCI Investigator's Handbook</u>
 - OHRP Office of Human Research Protections Human Subjects Protection Training
 - CMS HIPAA Basics for Providers guidance document
 - DHHS HIPAA for Professionals: Special Topics: Research
 - HIPAA FAQs database for Professionals
 - NIH Introduction to the Principles and Practice of Clinical Research (IPPCR)
 - Module 1 includes Research Ethics, FDA Product Regulation and Legal Issues in Clinical Research
 - Module 5 addresses Institutional Review Boards
 - FDA Overview of Drug Development (non-clinical safety assessment perspective)
 - FDA Oncology Drug Development Overview Past to Present
 - FDA Regulations: Good Clinical Practice and Clinical Trials
 - FDA Clinical Trials and Human Subject Protection
 - Most recent clinical research guidance document updates
 - FDA comprehensive list of Clinical Trials Guidance Documents
 - NIH NIAID ClinRegs: Aggregated summary of clinical research regulations by topic area





SWOG.org Frequently Asked Questions Webpages

The SWOG Network News & Events Clinical Trials **About Biospecimen Resources** The FAQs web pages provide SWOG-specific information and address the most Clinical Research Resources common site questions. Clinical Trials Search Frequently Asked Questions Frequently Asked Questions **Publications** Institutions Adverse Events, Serious Adverse Events, and External Safety Reports **Quality Assurance & Audits** Quality Assurance Serious Adverse Events Protocol Conduct **Training Resources** Data Submission Funding, Financial Agreements, and Study Payments CRA Workbench



SWOG Membership



Protocol Workbench

Training Resources – SWOG CRA Workbench

Website	System	Resource Topic
SWOG.org	CRA Workbench	ORP Manual
- Login with CTEP credentials		 Other resources Calculators and other tools CRA Newsletter CRA Resources









 Login with CTEP IAM credentials required to access

Latest CRA Newsletter

Join the CRA Mailing list

- CRA Manual for ORP
- Expectation, IPR and **Query Reports**
- Recent updates: "Announcements" and the Quarterly "CRA Newsletter"
- Helpful SWOG and **CTSU Contact** Information



Find ORP Resources on the **CRA Workbench**

Your resource headquarters for SWOG clinical trial patient management.

Study Reports

follow-up

RT Facilities

Studies with no required

Studies in Long Term Follow-

Announcements

 "Studies with no required follow-up" is a report of studies that can be terminated with the IRB of record.

Resources CRA Manual (for Oncology Research Professionals) Patient Reports / Data Quality Study Reports Patient Management (Non-Rave +

Studies)

Training

Tools

Tools

BSA Calculator

Log (Word)

Log (PDF)

Calculator

Date Counter

Expectations

Review (IPR)

Clinical Trial Review Guide

COVID Protocol Deviation

COVID Protocol Deviation

Ideal Body Weight Calculator

Patient Reports / Data Quality

Institution Performance

Rave SWOG studies)

Ineligible Patients

Rave studies

(SDMC)

Patients in Follow-up

Queries (both Rave and pre-

Data Quality Portal (DQP) for

Contact the Statistics and

Data Management Center

Contact Reference Sheet

Creatinine Clearance

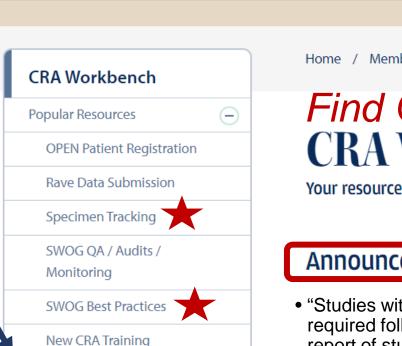
Contact Us

Course (CTTC) Your First Group Meeting Every CRA Should Know...

SWOG Clinical Trials Training

Training

SAEs for a Study S0820 Potential Patients Study-wide Unblinding Accrual by Site Accrual by Race and Sex Accrual by Disease Committee **BMT Facilities**



Training Resources – CTSU CLASS LMS

Website	System	Function
CTSU.org CTSU CLASS Learning Management System	<u>CLASS</u>	 SWOG Study-specific Training NCI Systems Training (e.g., Aurora, SDP) Other Group's Training / Study-specific Training
(under the CLASS tab)		





CTSU Compliance, Learning, and SOP Solutions (CLASS) Learning Management System



Welcome to the Compliance, Learning, and SOP Solutions (CLASS) Page

CLASS is the learning management system supported by the CTSU. It delivers several types of training courses, including:

- Protocol-specific trainings (some of which are required for site registration approval)
- · Application-specific trainings
- Role or position-specific trainings
- Membership-related trainings

Everybody with an active CTEP-IAM account can access CLASS. Access to certain training courses may be limited by roster membership, roles, and/or IRB approval or site registratic If you have questions about CLASS, please contact the CLASS Help Desk.

Resource Materials

View the CLASS User Guide here.

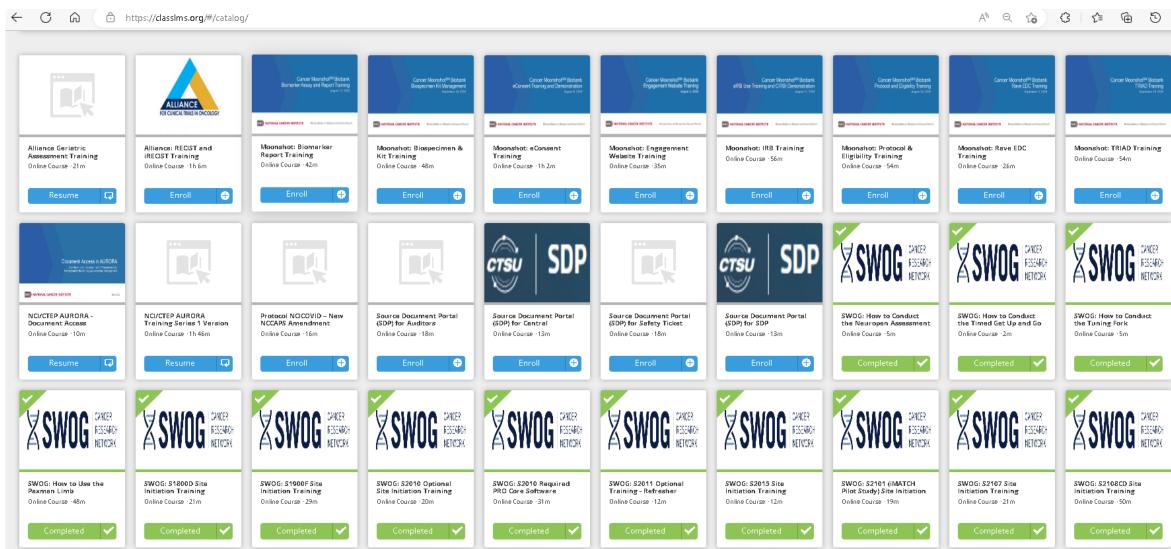
Connect to the CLASS Website





CTSU (CLASS) Example Catalog View

 Note: For ease of access/review in the catalog, the Course Name for all SWOG-provided Study Specific Training begins with "SWOG"

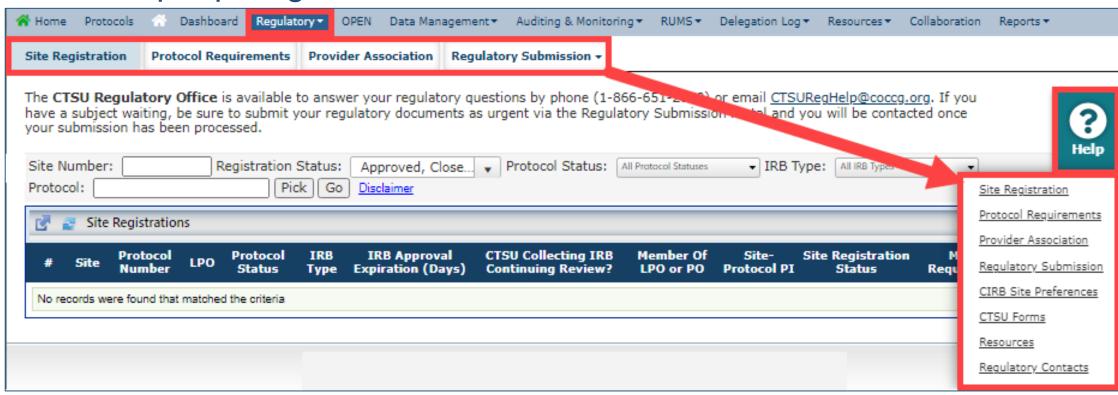


Training Resources – CTSU website

Website	Resource Topic
CTSU.org	 Help Topics (on most CTSU.org screens) Resources tab Frequently Asked Questions

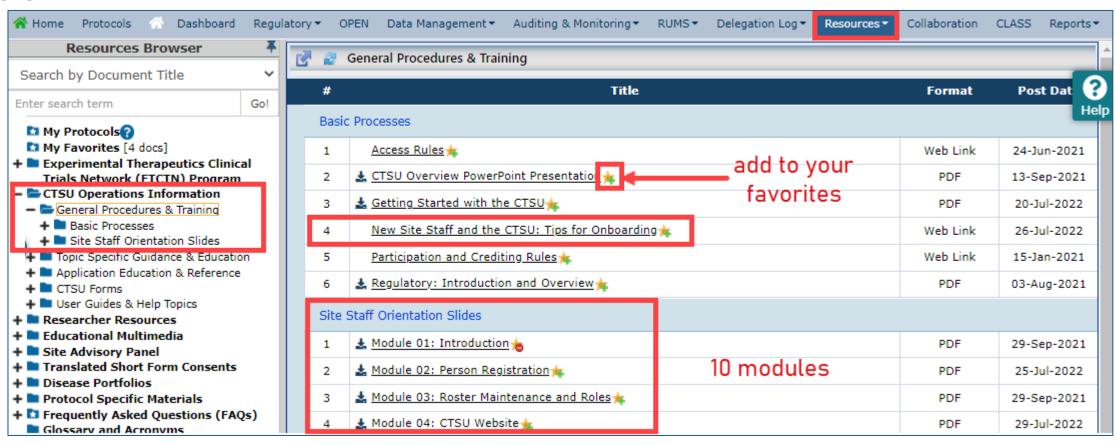
CTSU.org Help Topics

- Help topics appear on most CTSU screens, and have replaced user guides
- They are unique to the screen being viewed
- Clicking the icon shows the drop-down, a link opens the page, which has navigation
- Home help topics give an overview of the entire website



CTSU.org Resources

- Resources > CTSU Operations Information > General Procedures and Training, contains introductory materials
- Tips for Onboarding and Site Staff Orientation Slides are geared for new site staff



CTSU.org Frequently Asked Questions

Resources > FAQs

