University of Southern California • Children's Hospital Los Angeles

SCCTSI SOUTHERN CALIFORNIA CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

Regulatory Knowledge & Support

Regulatory Science Training for Clinical Researchers

Karen Manrique, MS | Regulatory Knowledge & Support Project Administrator

USC Mann
Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences

Department of Regulatory and Quality Scienc
DK Kim International Center for Regulatory Science

Background

Education:
UC San Diego – B.S. in General Biology, Art Studio Minor
USC – M.S. in Project Management

Clinical Research:
L.A. Cardiology & Associates - Cardiology Device Trials
Doheny Eye Institute, DIRC - Ophthalmology Trials core lab
USC KSOM - Surgical Device and Drug Trials, ACRP certification

Regulatory Knowledge & Support:
SC CTSI and USC Department of Regulatory and Quality Sciences

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Regulatory Knowledge & Support

SC CTSI
Regulatory Knowledge & Support

Objective: Promote a culture of quality and streamline translation by leveraging unique USC strengths in regulatory and quality sciences to develop and disseminate best practices, conduct research, and provide direct service to clinical researchers

Specific Aims:

1) **Service**: Provide high-touch support throughout the life cycle of clinical protocols through a combination of consultation and establishment of standard best practice

2) **Education**: Expand expertise in regulatory and quality sciences in clinical research workforce through on-site education and self-study online training modules

3) **Innovation**: Conduct research to address regulatory challenges in clinical research

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Regulatory Knowledge & Support

Service: Regulatory Consultations

Provide expert consultations for researchers and investigators in product development and commercialization

- Grants: Small Business Innovative Research (SBIR)
- Meeting requests or briefing packages
- IND, IDE, Marketing Applications
- Monitoring and auditing, CRC support, protocol support
- Dietary supplement inquiries
- Device, combination product, or digital health support
- Other regulatory knowledge services

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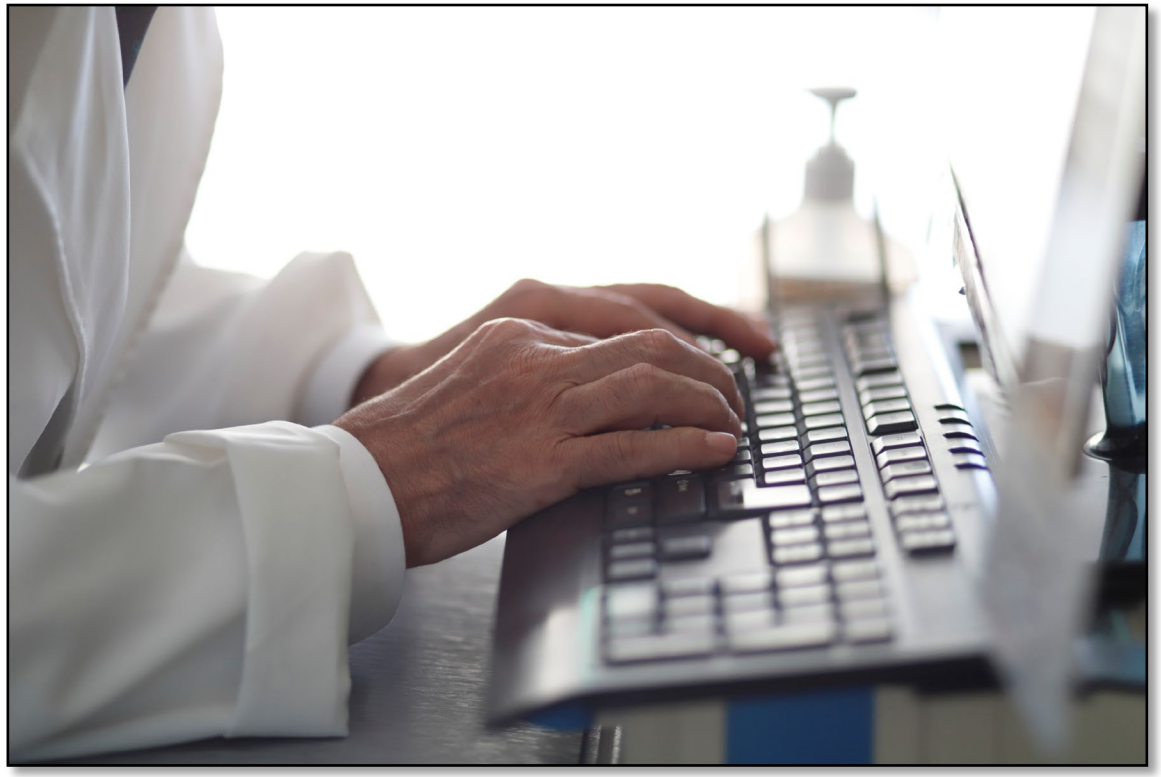
Service: Web Portal



In Development:

- One-stop shop for regulatory resources
- Streamline translation of IITs to treatment

UP-23-00757

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Regulatory Knowledge & Support

Calling all Researchers and Investigators

Help us understand your challenges in obtaining regulatory resources to advance your research

Who can participate?

- Clinical research professional
- Work in an academic institution
- ≥ 18 years old

Survey responses will be used in the creation of an interactive web portal.

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Education: Self-study Online Modules

Clinical Trial Quality Training Series

Module 1: **Monitoring** of a Clinical Trial Site + Ch.4 Addendum Remote Monitoring

Module 2: **Auditing** of a Clinical Research Site

Module 3: Site Preparedness for **FDA Inspection** **(Launching 2024)**

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Regulatory Knowledge & Support

Clinical Trial Quality Training Series

Viewed by over **1000** users in over **51** countries

Initial Launch 2018 - Survey of 204 users:

93% easy to use
95% applicable to their current work
94% lead to a change of behavior and/or practice

> This is one of the **best** courses I have ever taken. All the modules and material packaging were **excellent** precious and easy to grasp. I now feel confident to take CRA Certification exam.

> This a **wonderful** intro to Monitoring as well as a nice refresher for those have been in QA departments a long while. I hope more courses are offered in the future!

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Clinical Trial Quality Training Series

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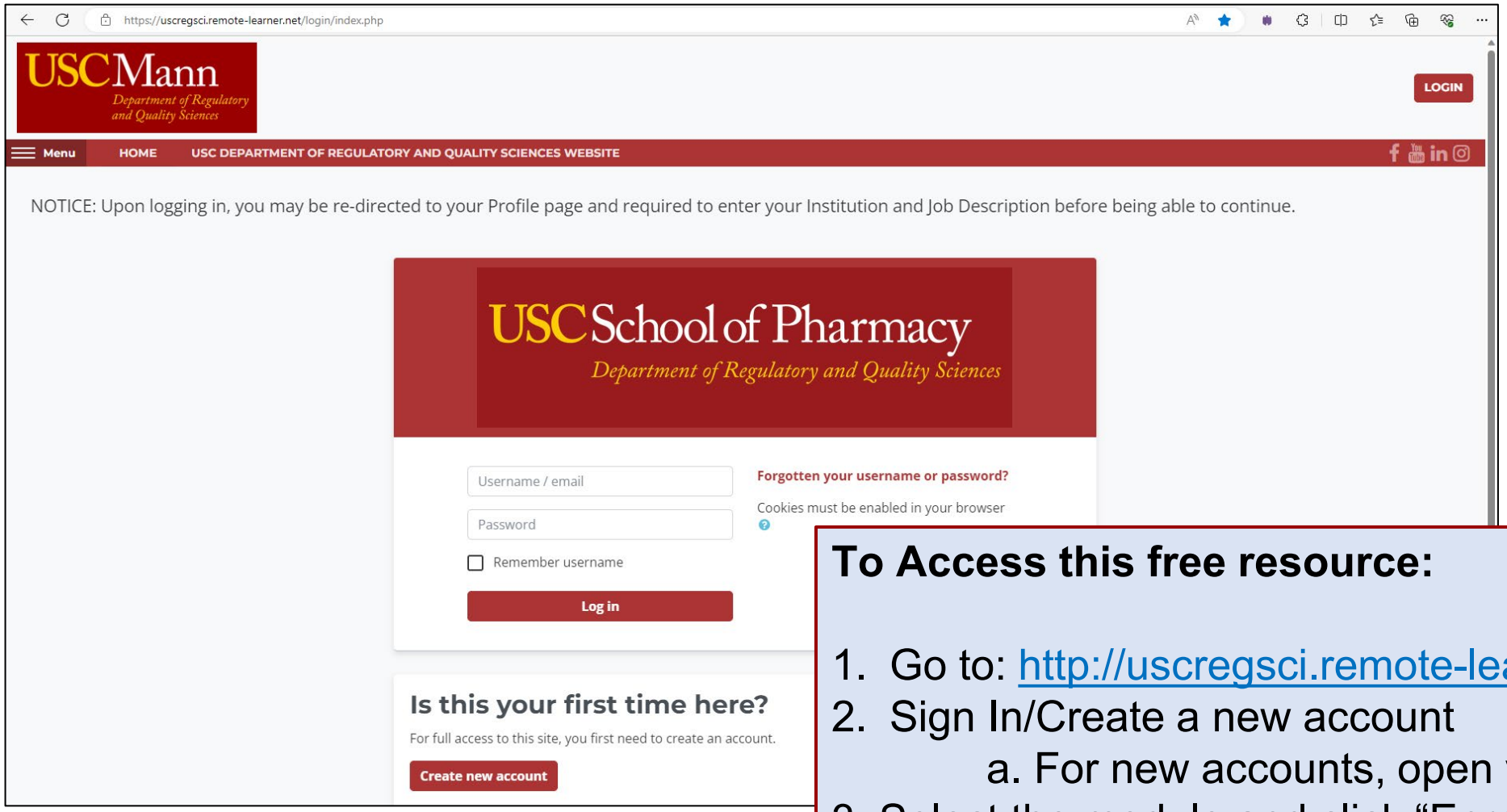
Translating Science into Solutions for Better Health



To Access this free resource:

1. Go to: http://uscregsci.remote-learner.net
2. Sign In/Create a new account
   a. For new accounts, open your email and confirm
3. Select the module and click "Enroll Me"

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https://uscregsci.remote-learner.net

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Menu | HOME | USC DEPARTMENT OF REGULATORY AND QUALITY SCIENCES WEBSITE | MY COURSES

COURSE CATALOG
Browse or search available courses
click here

MY DASHBOARD
Access all your learning needs
click here

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View your profile information
click here

WELCOME

Welcome to the University of Southern California Department of Regulatory and Quality Sciences online learning portal!

LATEST ANNOUNCEMENTS

12 Jul, 08:12
USCRegulatoryScience Admin
Planned Downtime Window
18 Dec, 10:48
USCRegulatoryScience Admin
Learning Portal Downtime
28 Feb, 22:09
USCRegulatoryScience Admin
Welcome !

My courses

Auditing of a Clinical Research Site (2024)

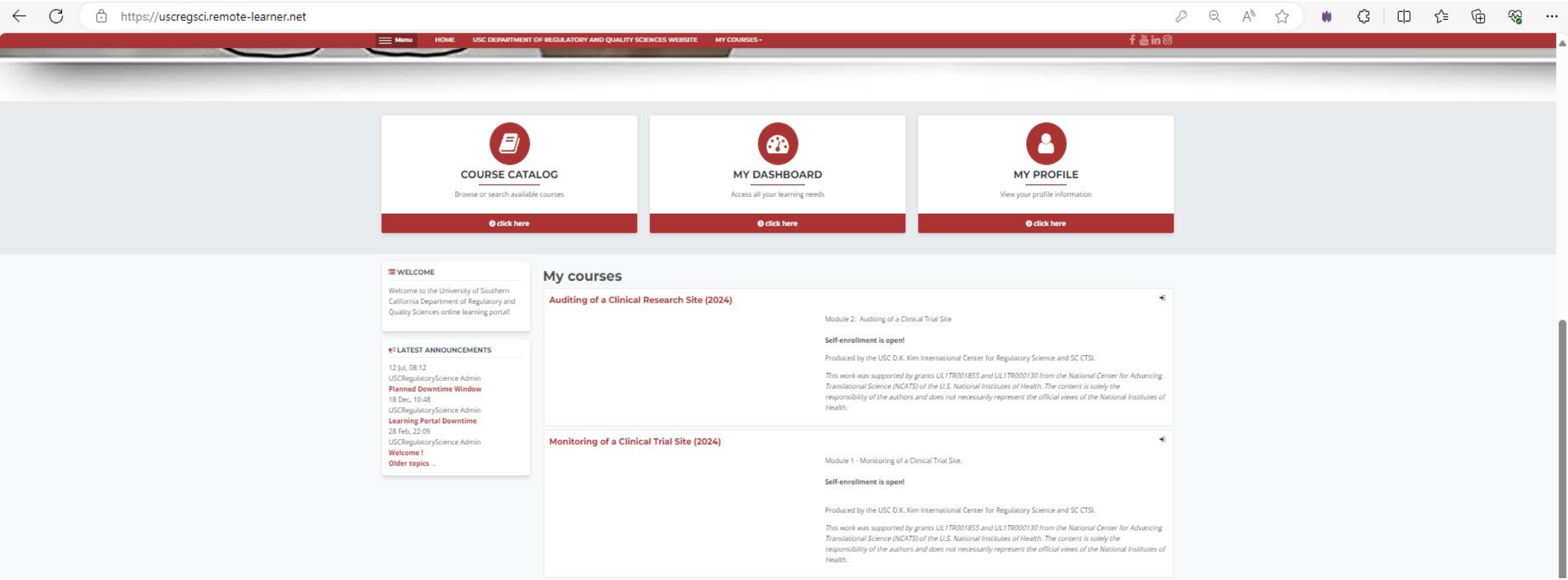
Module 2: Auditing of a Clinical Trial Site

Self-enrollment is open!

Produced by the USC D.K. Kim International Center for Regulatory Science and SC CTSI.

This work was supported by grants UL1TR001855 and UL1TR000130 from the National Center for Advancing Translational Science (NCATS) of the U.S. National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Monitoring of a Clinical Trial Site (2024)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Menu
HOME
USC DEPARTMENT OF REGULATORY AND QUALITY SCIENCES WEBSITE
MY COURSES
COURSE CATALOG
Browse or search available courses
click here
MY DASHBOARD
Access all your learning needs
click here
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Monitoring of a Clinical Trial Site (2024)
Module 1 - Monitoring of a Clinical Trial Site.
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LATEST ANNOUNCEMENTS

8 Jan, 14:16
USCRegulatoryScience Admin
Chapter 4 now working
Older topics ...

NAVIGATION

- Home
  - Dashboard
  - Site pages
  - My courses
    - Auditing 2024
    - Monitoring 2024
      - Participants
      - Badges
      - General
      - Monitoring Module Introduction (16 minutes)
      - Chapter 1: Fundamentals of Clinical Trials (34 min...
      - Chapter 2: Clinical Trial Monitoring Concepts (47 ...
      - Chapter 3: Monitoring Plans, Visits, and Reports (...
      - Chapter 4: Remote Monitoring (32 minutes)
      - End of Module Case Studies (17 min)
      - Monitoring Module Summary (16 min)
      - Survey and Feedback Forum
      - FAQs
      - Documents & Resources
      - Certificate of Completion
      - Credits
    - Auditing 2023

Welcome, Gordontest! We hope you enjoy this learning module on Clinical Trial Monitoring.

- **The intended audience for this module is all research personnel; we believe it is especially useful for CRC professional development.**
- Watch the lessons in any order. You can return as often as you like and re-watch any of the sections.
- You can receive a certificate of completion and badge after viewing all of **Module 1 Intro and Summary**, **Chapters 2, 3, 4, the End Of Module Case Studies, AND completing the course Survey**. You must also score 100% on **all four** Chapter Quizzes. Scroll down to the bottom of this page to generate your certificate.
- Chapter 1 contains basic information, and completion is not required to receive the certificate (however, scoring 100% on the chapter quiz **is required**). But it may provide a good review of foundational aspects of clinical trials.
- Toward the bottom of this page you'll find **resources** including monitoring SOPs, checklists, and templates.
- Please be sure to leave any feedback or comments you have for this course or any of the lessons in the **Feedback** forum.
- More info on playing the lessons, including activating Closed Captions, can be found in the **FAQs** at the bottom of this main page.
- Your enrollment will remain active for 1 year.

IMPORTANT: For the best playback experience, be sure to allow pop-ups in your browser for this site.

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Announcements

Open all Close all

1 **Monitoring Module Introduction (16 minutes)**

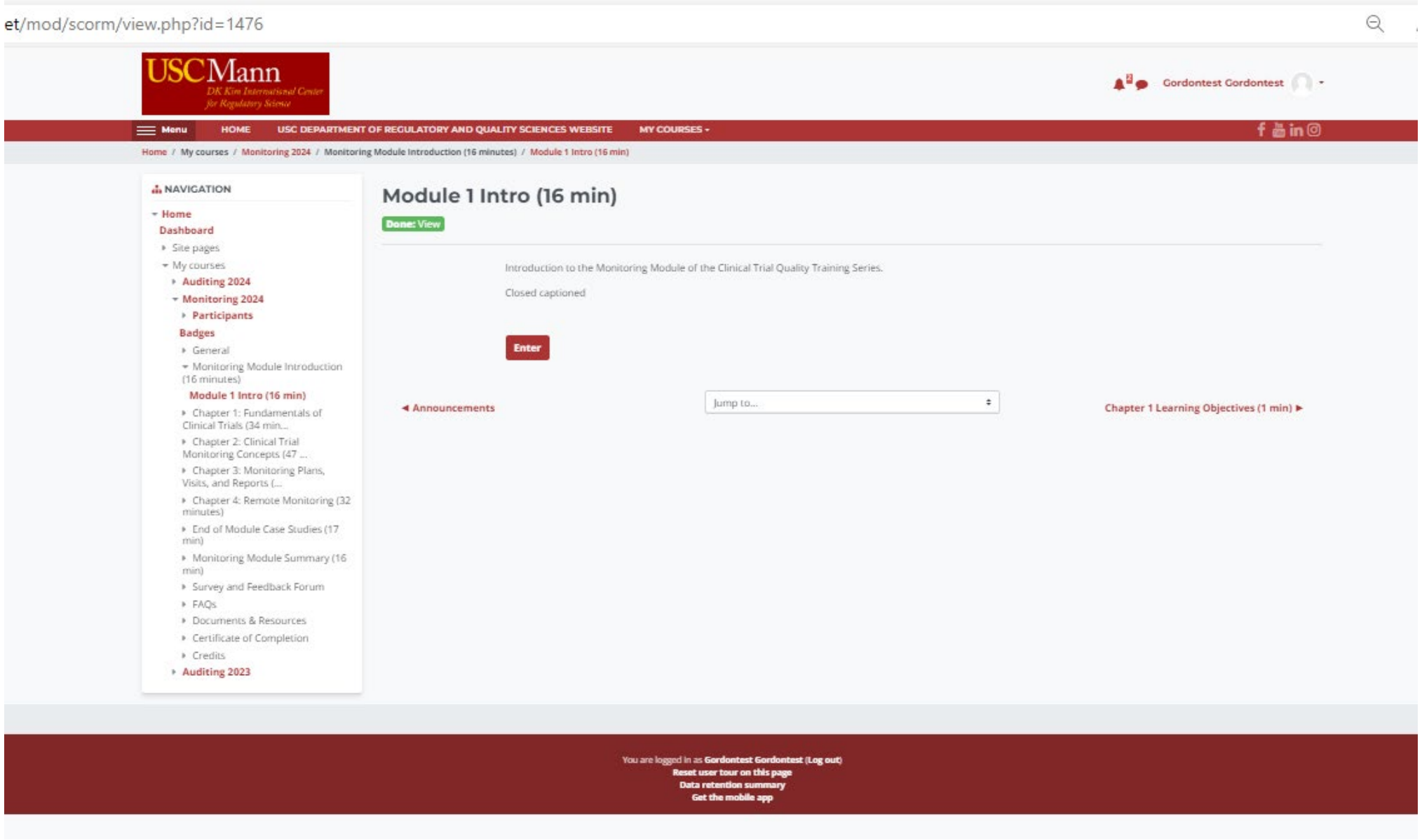
Module 1 Intro (16 min)
Done: View

2 **Chapter 1: Fundamentals of Clinical Trials (34 minutes)**

Chapter 1 Learning Objectives (1 min)
Done: View

Section A: Clinical Trial Definitions (9 min)
Done: View

Section B: Responsibilities of Clinical Trial Stakeholders (13 min)
Done: View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Menu
HOME
USC DEPARTMENT OF REGULATORY AND QUALITY SCIENCES WEBSITE
MY COURSES
Home / My courses / Monitoring 2024 / Monitoring Module Introduction (16 minutes) / Module 1 Intro (16 min)
NAVIGATION
Home
Dashboard
Site pages
My courses
Auditing 2024
Monitoring 2024
Participants
Badges
General
Monitoring Module Introduction (16 minutes)
Module 1 Intro (16 min)
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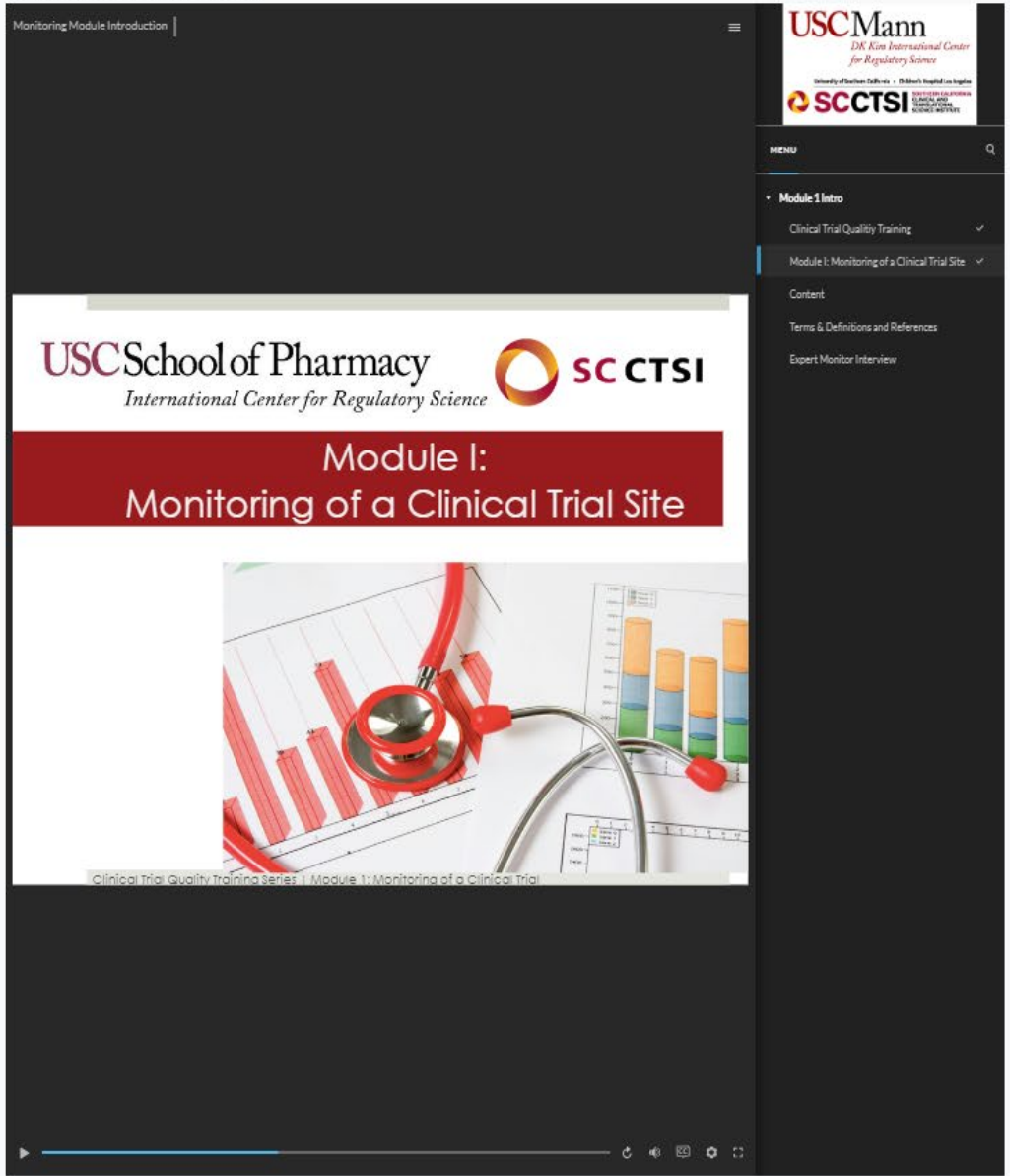
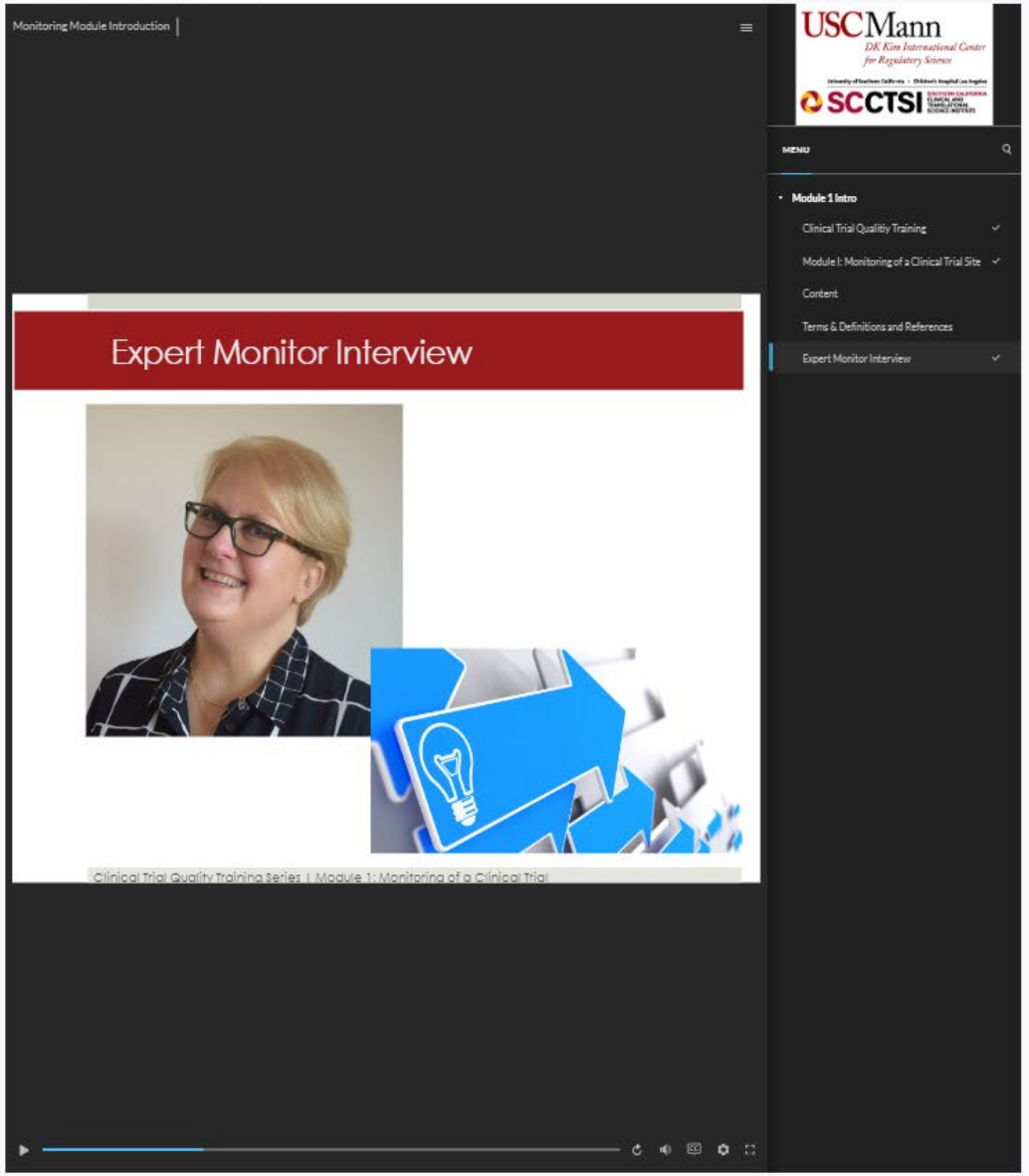
Survey and Feedback Forum
FAQs
Documents & Resources
Certificate of Completion
Credits
Auditing 2023
Module 1 Intro (16 min)
Done: View
Introduction to the Monitoring Module of the Clinical Trial Quality Training Series.
Closed captioned
Enter
◄ Announcements
Jump to...
Chapter 1 Learning Objectives (1 min) ►
You are logged in as Gordontest Gordontest (Log out)
Reset user tour on this page
Data retention summary
Get the mobile app

Module 1 Intro (16 min)



Module 1 Intro (16 min)



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- Home
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      - NIMH Repayment of Research Funding by University (...
      - Patients Missing Study Windows (4 min)
      - Investigator Not Following Protocol (6 min)
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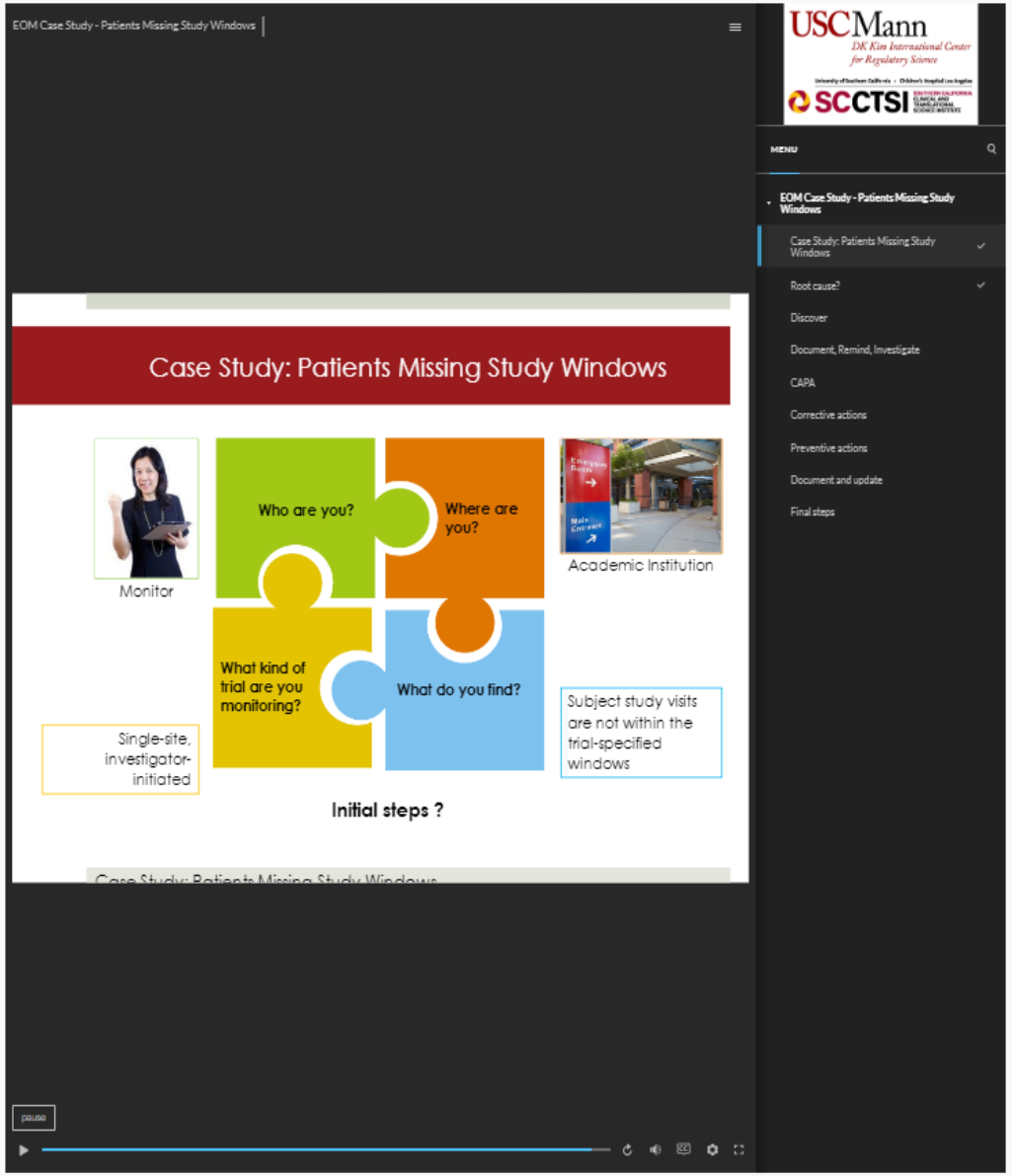

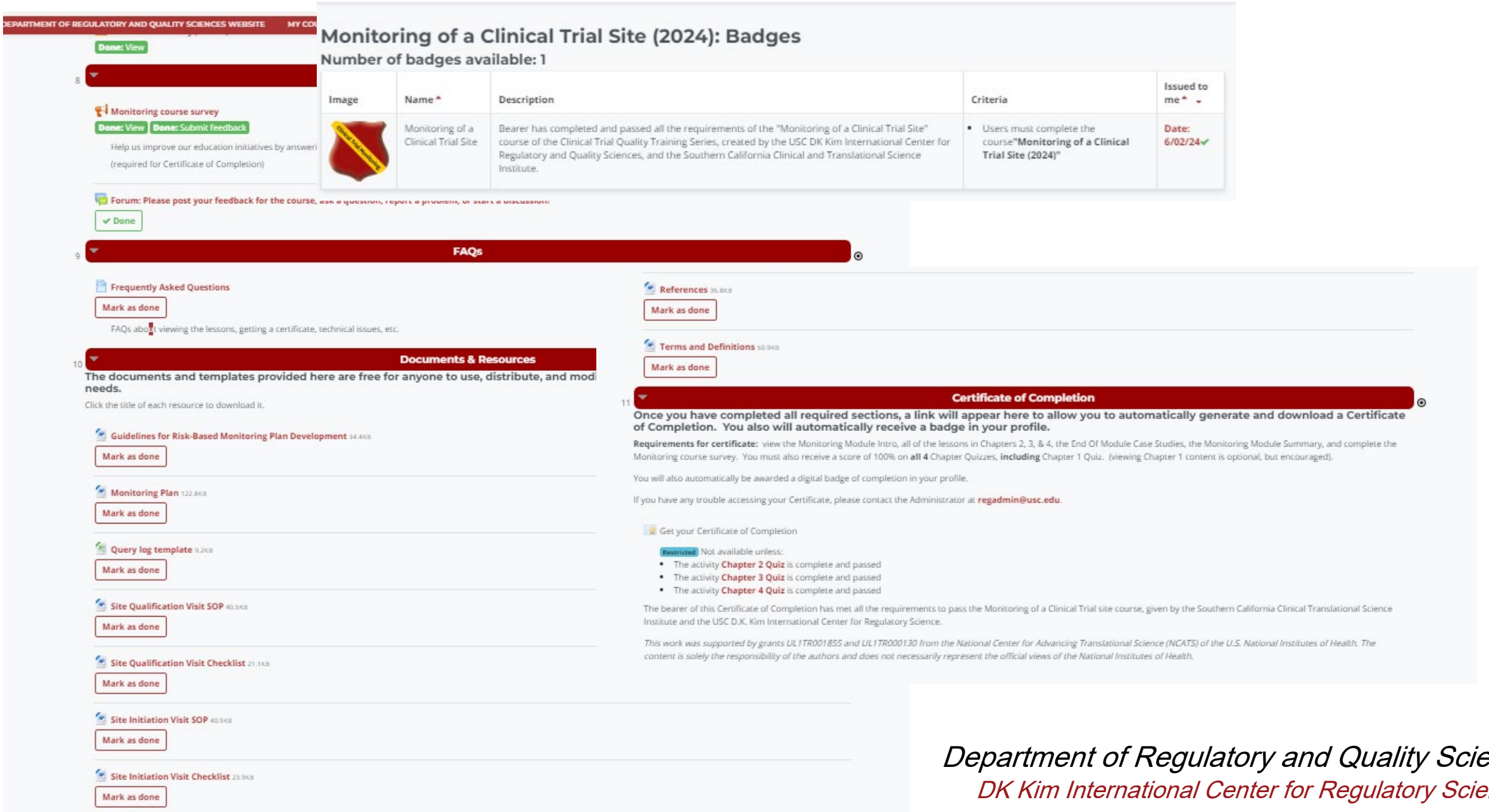

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DK Kim International Center for Regulatory Science

CERTIFICATE of COMPLETION

This is to certify that

Gordontest
Gordontest

has successfully completed the course

Monitoring of a Clinical Research Site (2024)

February 5, 2024

Course completion: 3.25 hours

Produced by the USC D.K. Kim International Center for Regulatory Science and the Southern California Clinical Translational Science Institute.

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Regulatory Knowledge & Support

Education:

Regulatory Science Symposium

- Current trends in regulatory science
- Offered 2x/year, spring and fall
- In-person, Virtual, Hybrid

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Department of Regulatory and Quality Scienc

DK Kim International Center for Regulatory Science

Regulatory Science Symposium – Spring 2023

138 total attendees, **56** survey responders:

80% agreed they learned something from this event that they can use
88% agreed they will implement what they learned into their daily work activities
96% would recommend this event to others

USC+CHLA Alpha Clinic

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SCCTSI SOUTHERN CALIFORNIA CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE
Regulatory Knowledge & Support

Regulatory Science Symposium – Fall 2023

112 total attendees, **74** survey responders:

95% agreed they learned something from this event that they can use
82% agreed they will implement what they learned into their daily work activities
96% would recommend this event to others

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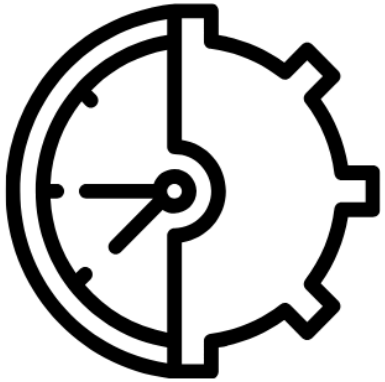
Translating Science into Solutions for Better Health

Save the Date! Spring 2024 Symposium

Keys to a Clinical Trial: Management and Operations

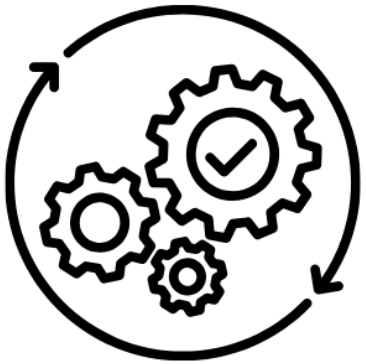


Date: Friday, April 12, 2024

Time: 9:00 am - 4:30 pm

Location: USC Health Sciences Campus

Lunch will be provided



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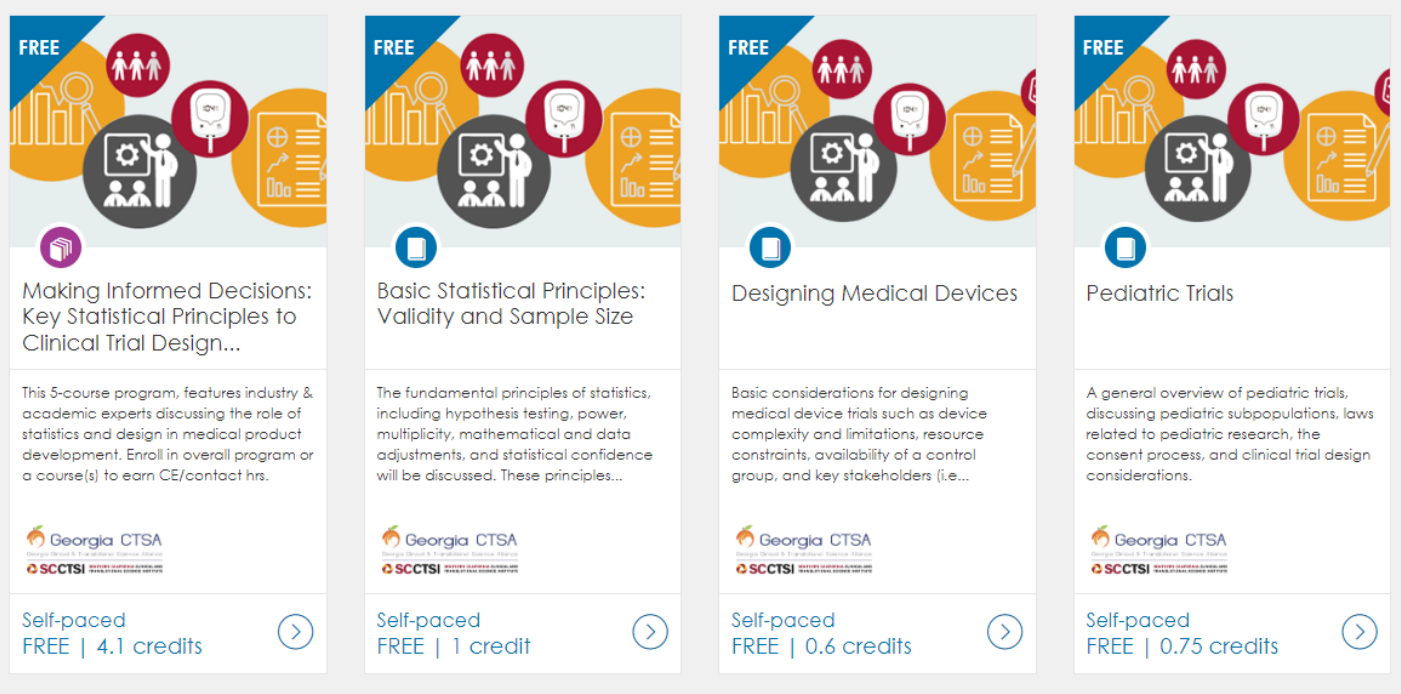
Education: eMPACT

Earn CE credits with self-paced modules



Access this free resource here:

https://twd.ce.emorynursingexperience.com

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Innovation: Research

Regulatory Science Research Team

- Student-led research: undergraduate and graduate students
- Present at conferences like ACTS, DIA, RAPS

DRSc Dissertations

- Regulatory Science

http://regulatory.usc.edu

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Apply Impact Give

Department of Regulatory & Quality Sciences

Programs

- Doctorate in Regulatory Science
- MS in Medical Product Quality
- MS in Regulatory Science
- MS in Management of Drug Development
- MS in Regulatory Management
- Graduate Certificates

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Coming Soon! Fall 2024

New Masters Program

Clinical Trials Management

For clinical researchers

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epacifici_uscregsci

THANK YOU!

Questions?

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kmanriqu@usc.edu

USC Mann
Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences

Department of Regulatory and Quality Scienc
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Q&A Post-Workshop

1. You mentioned there is a platform in development. Is that what you showed us, the educational modules ? or does the one in development have more features?

Our web portal is currently in development. It will be a repository of regulatory information and resources. A one-stop shop to find answers to general questions before requesting consultation.

2. Do you provide resources for how we can find participants for a study ?

We don't have this in RKS. If you email me some information about what you're looking for, I may be able to direct you to another core at SC CTSI. (kmanriqu@usc.edu)

3. Will the portal link to resources to CRI and biostatistics?

The portal is focused on regulatory resources and is currently in development so we appreciate any ideas and requests to see how they can be incorporated into the portal. [Feedback collected through survey administered during the workshop.]

4. Can you put up the website for trainings that count for SOCRA?

"Clinical Trial Quality Training Series" - Self-study Modules

https://sc-ctsi.org/training-education/courses/clinical-trial-monitoring-module

eMPACT Course Catalogue - Accredited Continuing Education Courses

https://twd.ce.emorynursingexperience.com/

Regulatory Science Symposia – 2 sessions a year, Spring and Fall

Join our mailing list to receive "Save the Date" and Registration Information – email kmanriqu@usc.edu or RKS@SC-ctsi.org

Recordings of past symposia

https://mann.usc.edu/departments/regulatory-quality-science-department/dk-kim-center/capacity-building/regulatory-science-bootcamps-symposia/

Please check with SOCRA guidelines to see if watching past webinars is acceptable

5. Is the service for CRC float still active? Who do we contact for that?

That service is under the Clinical Research Support Core of SC CTSI. Contact: CRS@SC-ctsi.org I Webpage: https://sc-ctsi.org/about/groups/clinical-research-support