

Regulatory Science Training for Clinical Researchers

Karen Manrique, MS | Regulatory Knowledge & Support Project Administrator



USCMann

Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences

*Department of Regulatory and Quality Sciences
DK Kim International Center for Regulatory Sciences*

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

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

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



Service Request Form

About You

Name*
 First Name
 Last Name

Primary Email Address*

USC Email Address (if different from primary)

Phone Number

Home Institution

I am a

Primary School/Academic Unit

Your primary area of research ☐ Clinical
☐ Basic
☐ Community
☐ Other

Have you used SCCTSI services in the past? ☐ Yes
☐ No

About Your Request

Is this request associated with a specific research project or program? ☐ Yes
☐ No

Regulatory Knowledge

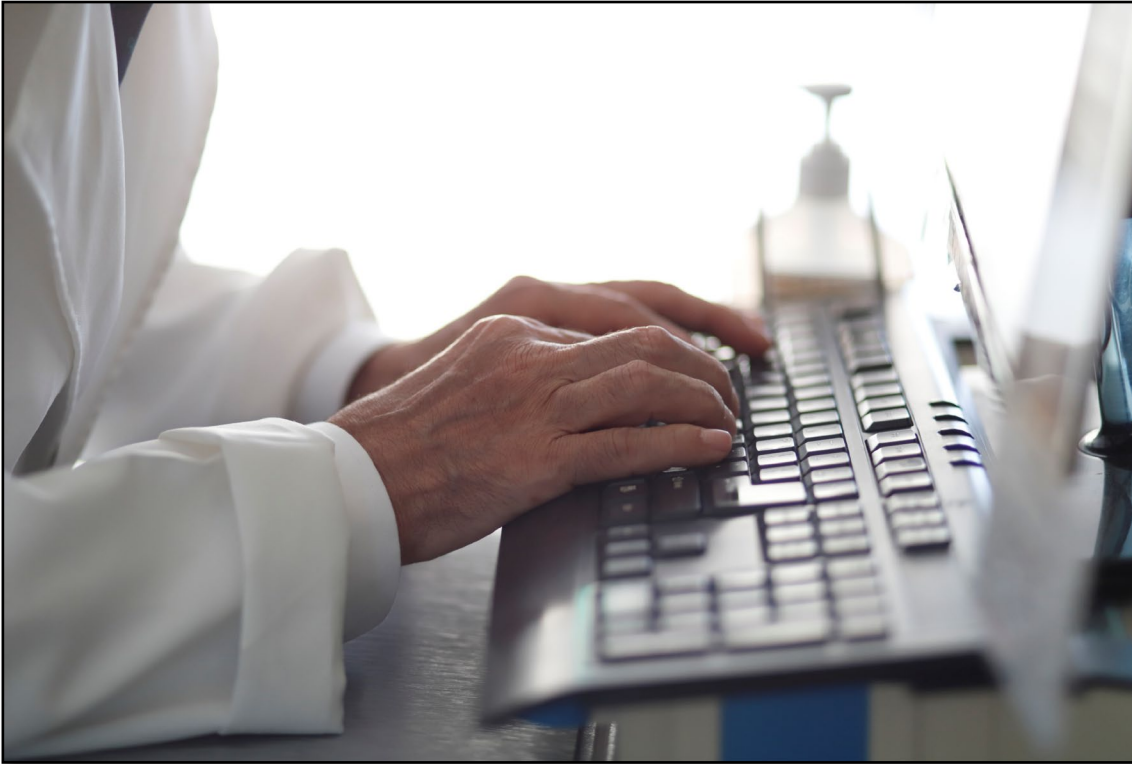
What type of assistance do you need?*

☐ Small Business Innovative Research (SBIR) Grant
☐ Other Grant
☐ Meeting Request or Briefing Package
☐ Investigational New Drug (IND) Application
☐ Investigational Device Exemption (IDE)
☐ Monitoring and Auditing
☐ Dietary Supplement Inquiries
☐ Marketing Applications
☐ CRC Support
☐ Protocol Support
☐ Other Device, Combination Product, or Digital Health Support
☐ Other regulatory knowledge services

Date service needed by

Submit Request

Service: Web Portal



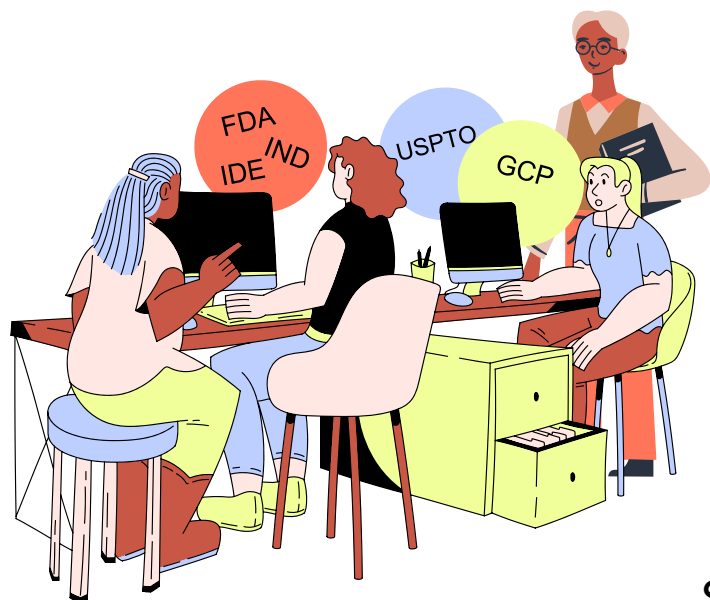
In Development:

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



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.

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)**

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!

Clinical Trial Quality Training Series

← ↻ 🔒 https://uscregsci.remote-learner.net/login/index.php

USCMann
Department of Regulatory and Quality Sciences

Menu HOME USC DEPARTMENT OF REGULATORY AND QUALITY SCIENCES WEBSITE

LOGIN

Facebook YouTube LinkedIn Instagram

NOTICE: Upon logging in, you may be re-directed to your Profile page and required to enter your Institution and Job Description before being able to continue.

USC School of Pharmacy
Department of Regulatory and Quality Sciences

☐ Remember username
Log in

Forgotten your username or password?
Cookies must be enabled in your browser

Is this your first time here?
For full access to this site, you first need to create an account.
Create new account

To Access this free resource:

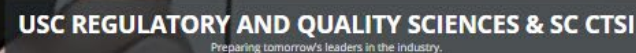
1. Go to: <http://uscregsci.remote-learner.net>
2. Sign In/Create a new account
 - a. For new accounts, open your email and confirm
3. Select the module and click “Enroll Me”



USCMann

Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences

*Department of Regulatory and Quality Sciences
DK Kim International Center for Regulatory Sciences*



USC Mann
*DK Kim International Center
for Regulatory Science*

University of Southern California • Children's Hospital Los Angeles



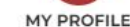
[Browse or search available courses](#)

[click here](#)



Access all your learning needs

[click here](#)

[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)

Module 1 - Monitoring of a Clinical Trial Site



COURSE CATALOG

Browse or search available courses

[click here](#)



MY DASHBOARD

Access all your learning needs

[click here](#)



MY PROFILE

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 !
[Older topics ...](#)

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)

Module 1 - Monitoring 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.

📢 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.

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.

📢 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



Gordontest Gordontest



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)

▸ 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

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) ▶

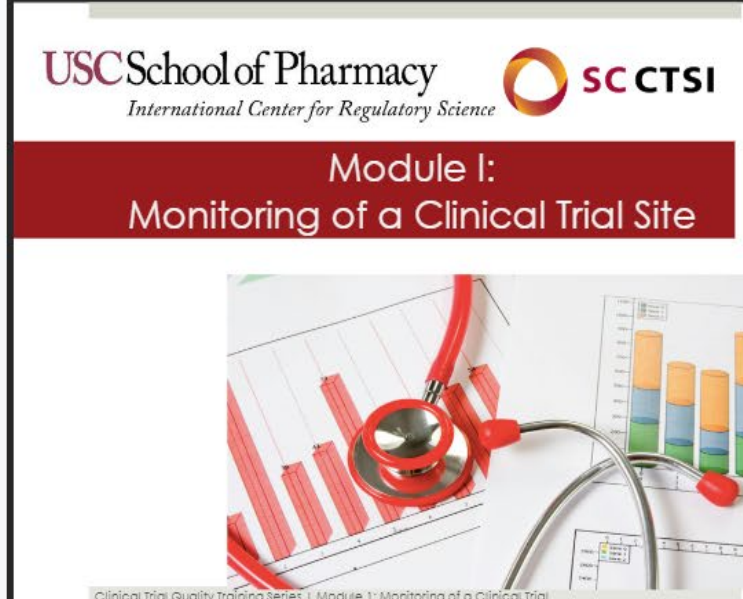
You are logged in as **Gordontest Gordontest** (Log out)[Reset user tour on this page](#)[Data retention summary](#)[Get the mobile app](#)**USC Mann**Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences*Department of Regulatory and Quality Sciences*
DK Kim International Center for Regulatory Science

📁 **NAVIGATION**

- ▼ Home
 - Dashboard
 - Site pages
 - My courses
 - ▶ **Auditing 2024**
 - ▼ **Monitoring 2024**
 - ▶ Participants
 - Badges**
 - ▶ General
 - ▼ Monitoring Module Introduction (16 minutes)
 - Module 1 Intro (16 min)**
 - ▶ 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**

Module 1 Intro (16 min)

Monitoring Module Introduction | ☰



MENU 🔍

- ▼ **Module 1 Intro**
 - Clinical Trial Quality Training ✓
 - Module I: Monitoring of a Clinical Trial Site ✓
- Content
- Terms & Definitions and References
- Expert Monitor Interview

NAVIGATION

- Home
 - Dashboard
 - Site pages
 - My courses
 - Auditing 2024
 - Monitoring 2024
 - Participants
 - Badges
 - General
 - Monitoring Module Introduction (16 minutes)
 - Module 1 Intro (16 min)
 - 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

Module 1 Intro (16 min)

Monitoring Module Introduction



MENU

- Module 1 Intro
 - Clinical Trial Quality Training ✓
 - Module 1: Monitoring of a Clinical Trial Site ✓
 - Content
 - Terms & Definitions and References
 - Expert Monitor Interview ✓

Expert Monitor Interview



Clinical Trial Quality Training Series 1 Module 1: Monitoring of a Clinical Trial

Done: View

Monitoring course survey

Done: View Done: Submit feedback

Help us improve our education initiatives by answering the survey (required for Certificate of Completion)

Forum: Please post your feedback for the course, ask a question, report a problem, or alert a misconception.

Done

FAQs

Frequently Asked Questions

Mark as done

FAQs about viewing the lessons, getting a certificate, technical issues, etc.

Documents & Resources

The documents and templates provided here are free for anyone to use, distribute, and modify.

Click the title of each resource to download it.

Guidelines for Risk-Based Monitoring Plan Development 34.4KB

Mark as done

Monitoring Plan 122.8KB

Mark as done

Query log template 9.2KB

Mark as done

Site Qualification Visit SOP 40.5KB

Mark as done

Site Qualification Visit Checklist 21.1KB

Mark as done

Site Initiation Visit SOP 40.9KB

Mark as done

Site Initiation Visit Checklist 23.9KB

Mark as done

Monitoring of a Clinical Trial Site (2024): Badges

Number of badges available: 1

Image	Name ^	Description	Criteria	Issued to me ^ v
	Monitoring of a Clinical Trial Site	Bearer has completed and passed all the requirements of the "Monitoring of a Clinical Trial Site" course of the Clinical Trial Quality Training Series, created by the USC DK Kim International Center for Regulatory and Quality Sciences, and the Southern California Clinical and Translational Science Institute.	<ul style="list-style-type: none">Users must complete the course "Monitoring of a Clinical Trial Site (2024)"	Date: 6/02/24 ✓

References 35.8KB

Mark as done

Terms and Definitions 50.9KB

Mark as done

Certificate of Completion

Once you have completed all required sections, a link will appear here to allow you to automatically generate and download a Certificate of Completion. You also will automatically receive a badge in your profile.

Requirements for certificate: view the Monitoring Module Intro, all of the lessons in Chapters 2, 3, & 4, the End Of Module Case Studies, the Monitoring Module Summary, and complete the Monitoring course survey. You must also receive a score of 100% on all 4 Chapter Quizzes, including Chapter 1 Quiz. (viewing Chapter 1 content is optional, but encouraged).

You will also automatically be awarded a digital badge of completion in your profile.

If you have any trouble accessing your Certificate, please contact the Administrator at regadmin@usc.edu.

Get your Certificate of Completion

Restricted Not available unless:

- The activity **Chapter 2 Quiz** is complete and passed
- The activity **Chapter 3 Quiz** is complete and passed
- The activity **Chapter 4 Quiz** is complete and passed

The bearer of this Certificate of Completion has met all the requirements to pass the Monitoring of a Clinical Trial site course, given by the Southern California Clinical Translational Science Institute and the USC D.K. Kim International Center for Regulatory Science.

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.

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.

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.



USC Mann

Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences

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

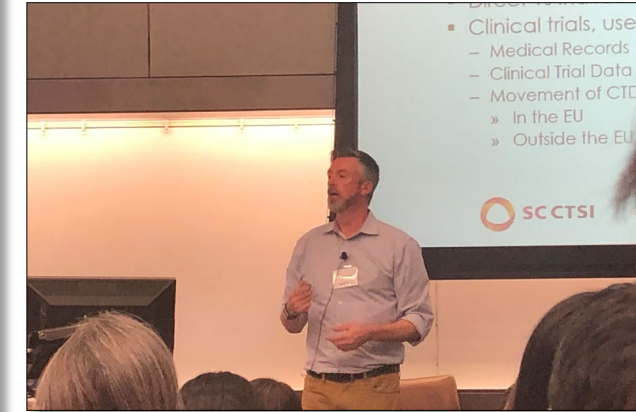
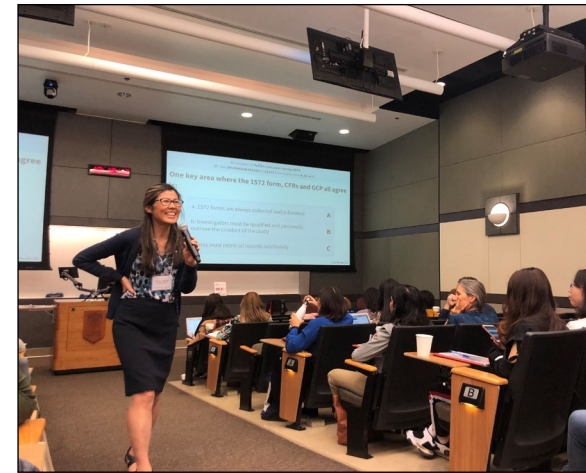
Education:

Regulatory Science Symposium

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

USCMann

Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences



Department of Regulatory and Quality Science
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

Regulatory Science Symposium – Fall 2023



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

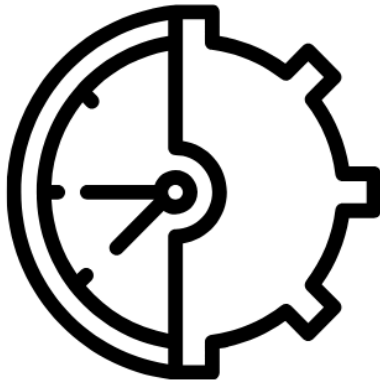
95% agreed they learned something from this event that they can use

82% agreed they will implement what they learned into their daily work activities

96% would recommend this event to others

Save the Date! Spring 2024 Symposium

Keys to a Clinical Trial: Management and Operations

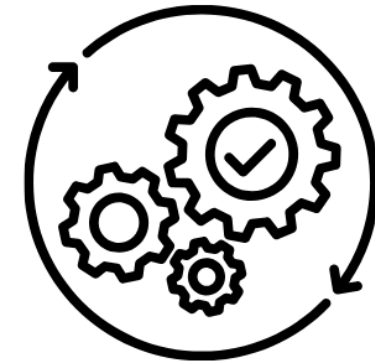


Date: Friday, April 12, 2024

Time: 9:00 am - 4:30 pm













Location: USC Health Sciences Campus

****Lunch will be provided****



Education: eMPACT

Earn CE credits with self-paced modules

FREE	FREE	FREE	FREE
			
Making Informed Decisions: Key Statistical Principles to Clinical Trial Design...	Basic Statistical Principles: Validity and Sample Size	Designing Medical Devices	Pediatric Trials
This 5-course program, features industry & academic experts discussing the role of statistics and design in medical product development. Enroll in overall program or a course(s) to earn CE/contact hrs.	The fundamental principles of statistics, including hypothesis testing, power, multiplicity, mathematical and data adjustments, and statistical confidence will be discussed. These principles...	Basic considerations for designing medical device trials such as device complexity and limitations, resource constraints, availability of a control group, and key stakeholders (i.e...	A general overview of pediatric trials, discussing pediatric subpopulations, laws related to pediatric research, the consent process, and clinical trial design considerations.
 	 	 	 
Self-paced FREE 4.1 credits	Self-paced FREE 1 credit	Self-paced FREE 0.6 credits	Self-paced FREE 0.75 credits

Access this free resource here:



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

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>

USCMann

Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences

[Apply](#)

[Impact](#)

[Give](#)



◀ DEPARTMENTS

Department of Regulatory and Quality Sciences



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

USCMann

Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences

Department of Regulatory and Quality Sciences
DK Kim International Center for Regulatory Sciences

Coming Soon! Fall 2024



New Masters Program

Clinical Trials Management

For clinical researchers

USC Mann

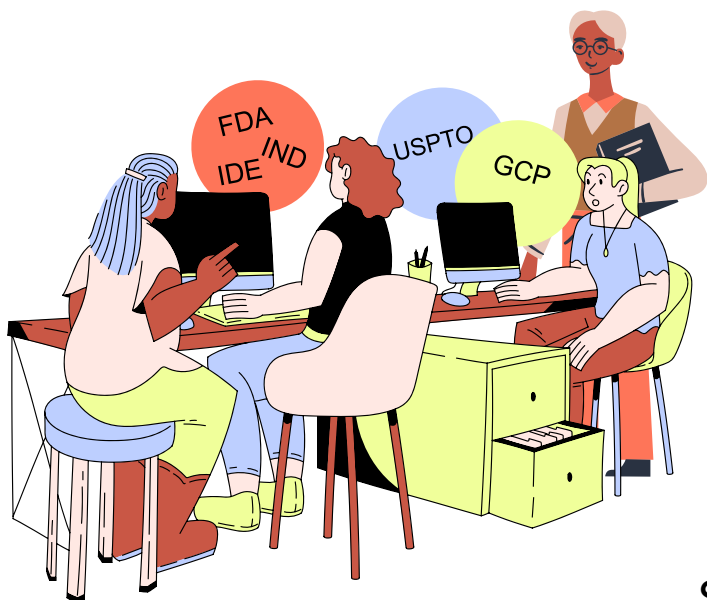
Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences

Department of Regulatory and Quality Sciences
DK Kim International Center for Regulatory Sciences



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.



sc-ctsi.org



SocalCTSI



regulatory.usc.edu



epacifici_uscregsci

THANK YOU!

Questions?

Karen Manrique
kmanriqu@usc.edu

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 | Webpage: <https://sc-ctsi.org/about/groups/clinical-research-support>