STELLAR – An Interactive Web-Based Platform for Clinical Research Professionals Career Training and Advancement

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Presenters

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USC Regulatory Science | regulatory.usc.edu

SC CTSI | www.sc-ctsi.org







- USC Clinical Trial Quality Training Initiative
 - USC Monitoring Module
 - USC Regulatory Science Symposiums
- Georgia CTSA and SC CTSI Online Catalog
- STELLAR A Career Navigation System







USC Clinical Trial Quality Training Initiative

Eunjoo Pacifici, PharmD, PhD

Chair and Associate Professor, Department of Regulatory and Quality Science

Director, Regulatory Knowledge and Support (RKS), SC CTSI



USC Clinical Trial Quality Training Initiative Background

Study Monitoring is	an Essential and Rou	itine Quality Functic	on in Clinical Trials	
	IITs Lack Adequate N	Monitoring		
ICH E6 (R2) Guideline emphasizes the monitoring of critical data and processes. However, access to high	Two separate surveys of research professionals revealed that only ~65%	Lack of Resources	Lack of Approach	
quality study monitoring is often lacking in IITs conducted in academic medical centers.	reported monitoring in their investigator-initiated trials.	training resources are available, most are not readily accessible because they often require fees or institutional affiliations.	Trainings lack practical approaches to meet complex requirements of monitoring. Many academic, government, and private institutions have expressed interest in readily	

*IITs = Investigator-initiated trials



Monitoring Module

- 1. Go to: <u>https://uscregsci.remote-</u> <u>learner.net</u>
- 2. Click *create new account* (right-hand side)
- Type in your information and click *Create my new account* (bottom of page)
- 4. Open your email and click the link to confirm your account
- 5. Click *courses* (middle of page)
- Scroll down and click
 Module 1 Clinical Trial Monitoring
- 7. Click *Enroll me* (middle of page)





USC School of Pharmacy International Center for Regulatory Science

Regulatory Science Symposium





 The D.K. Kim International Center for Regulatory Science and SC CTSI hosts symposium on current regulatory science topics regarding clinical trials.

UC•IRVINE

• Designed to address the needs of the clinical research professionals, but anyone is welcome to attend.





Symposium





- Attracted more than 1,000 clinical researchers from 72 institutions.
- Occurs bi-annually in Spring and Fall.
- Future topics, content and format assessed from symposium attendees.
- Speakers from industry, consulting firms, non-profits, academia and even FDA.



Regulatory Science Virtual Symposium *Save the Date!*

Principles of Global Clinical Research for Medical Devices



Friday, April 9, 2021 9am-3pm PST

Virtual Symposium Hosted Online via Zoom



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USC School of Pharmacy International Center for Regulatory Science

> CTSA Clinical & Translational Science Awards Program

Regulatory Science Symposium

Clinical Research Career Pathways Friday, March 5, 2021 / 9am - 1pm PST



9:00 AM PST	Introduction Europo Pacifici, PharmD, PhD USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences I Associate Director, DK Kim International Center for Regulatory Science
9:15 AM PST	From Academics to Industry – A Physician Researcher Perspective Francine Koufman, MD Chief Medical Officer, Senseonics, Inc. I Distinguished Professor Emerita of Pediatrics at USC, The Center for Endocrinology, Diabetes & Metabolism, Children's Hospital Los Angeles
10:00 AM PST	Clinical Supply Chain Management: Dude, Where's My Patient Benefit? Lequino Myles, DRSc, MS, MBA, RAC, PMP, PMI-ACP Director, Quality Control at MARKEN
10:45 AM PST	Break
10:55 AM PST	Understanding Clinical Research Management at Academic Institutions Zeno Ashai, MB85, MPH Associate Director, Clinical Investigations Support Office, University of Southern California
11:30 AM PST	Roads to the Human Subjects Protection Program (OPRS and IRB) Julie Michele Sloyton, JD, PhD Director, Office for the Protection of Research Subjects (OPRS) I Clinical Professor, Rossier School of Education, University of Southern California
12:10 PM PST	Knocking on HR's Door: Do you have what it takes to be a CRP? Elaine Fisher, PhD, RN, CNE Director, Accreditation & Curriculum, Emory University, Nell Hodgson Woodruff School of Nursing Rebecca Thomas, DNP, RN Director of Clinical Research Nursing, Emory Healthcare
12:50 PM PST	Wrap-Up Eunjoo Pacifici, PharmD, PhD USC, SC-CTSI, School of Pharmacy I Chair & Associate Professor, Dept. of Reg. & Quality Sciences I Associate Director, DK Kim International Center for Regulatory Science

Please complete the course evaluation survey at the end of the symposium to receive a certificate of completion. Hours may be eligible for SoCRA and/or ACRP credit.



Symposium Format

- Prior to COVID-19 an all day event and networking opportunities (plus food and raffle!)
- Lecture topics begin with broad, high-level regulations and guidance.
- Concludes with localized and grassroot perspectives.
- Interactive event with audience polling, quiz questions, and active Zoom chats.



Georgia CTSA and SC CTSI: Online Course Catalog

- Free trainings for clinical research workforce
- Free, one-time registration to the first 400 registrants
- Registration provides unlimited access to all courses and programs in the Online Course Catalog
- Participants earn a certificate or badge with contact hours upon completion of a course or program
- Contact hours can be used for CRP certification renewal
- To get started:

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





Georgia CTSA Translational Workforce Development Announces Online Course Catalog with Free Trainings for Clinical Research Professionals

The Georgia Clinical and Translational Science Alliance (Georgia CTSA) and the University of Southern California Clinical and Translational Science Institute (SC CTSI) are collaborating on an exciting new educational venture geared toward clinical research professionals at every stage of their professional development. Through this partnership, Georgia CTSA has created a new Online Course Catalog with <u>free course and program offerings</u> available to clinical research professionals and principal investigators. These courses and programs are created and vetted by experts in cross-disciplinary fields such as instructional design, technology, workforce development, regulatory science, clinical and translational science, and operations.

"We are fortunate to partner with USC SC CTSI to bring such a broad offering of high-quality trainings to our clinical research professionals."

Linda McCauley, RN, PhD, Program Director of the Georgia CTSA Translational Workforce Development and Dean of the Nell Hodgson Woodruff School of Nursing at Emory University

"This joint effort between Georgia CTSA and SC CTSI will create a wonderful resource to support training and career development of clinical research professionals at all levels. It will be a game changer, especially for people working an academic setting."

Thomas Buchanan, MD, Director & Principal Investigator of the SC Clinical and Translational Science Institute

"It has been a pleasure to partner with Georgia CTSA team in our common goal to promote life-long learning for the clinical research workforce."

Eunjoo Pacifici, PharmD, PhD, Chair and Associate Professor in the Department of Regulatory and Quality Sciences and Associate Director of the DK Kim International Center for Regulatory Science at the USC School of Pharmacy

Participants earn a certificate or badge with contact hours (continuing education) from an accredited provider upon completion of a course or a program (series of courses). Contact hours can be used to meet requirements for CRP certification renewal.

Free, one-time registration to the Georgia CTSA Online Course Catalog is available to the first 400 registrants. Registration provides unlimited access to all courses and programs in the Georgia CTSA Online Course Catalog. View the <u>Online Course Catalog</u> to get started.

The first program, *Legal Aspects for Conducting Clinical Trials*, is comprised of six courses. Individual courses in all programs receive a certificate, and completing the program earns a badge. The second program, *Clinical Trials with Medical Devices*, is comprised of seven courses of which completion of five of the seven courses will earn a badge. Be sure to check out the dashboard features as you build your professional career.

Stay Tuned for More Courses and Programs as We Develop This Free Online Course Catalog!

Content Development with Georgia CTSA







What Do We Mean by Diversity in Clinical Tria

Self-paced 0.5 credits



This course is also available in the following progra Diversity in Clinical Irials in the Time of COVID-19





- Symposium Description
- Lecture Description
- Topics
- Speaker Bios
- Learner Levels/Audience
- Continuing Education
- Quiz Questions







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CTSA Clinical & Translational Science Awards Program

One.

he Georgia Clinical & Translational Science Alliance- Georgia CTSA and Southern California Clinical and Translational Science Institute plaborated to provide free, high quality educational programs for clinical research professionals at novice to expert levels of experience. ach course or program, participants earn contact hours recognized by a conficate and/or badge.

escription: This course focuses on the importance and dimensions of diversity, exploring the current landscape of diversity in clinical tria Inical trials of recently approved drugs.

opics:

1. What is diversity?

- z Dimensions of Diversity. Race. Ethnicity, Sex, Gender, and Ancestry
- 2. Intrinsic vs. Extrinsic Factors

Georgia CTSA

- 4. Target Patient Populations
- Consideration of genetics, physiological differences, co-morbidities, geography, and multi-factors in studies for new products 5. Study Populations in Clinical Research
- a Challenges Bringing New Drug to Market
 - Regulations
 - Good laboratory practices: 21 CFR 58
 - Good manufacturing practices 21 CFR 210-211
 - Good clinical practices: 21 CFR 11, 50, 54, 56, 312, 314, 320, 812, 814
- Goal: Obtaining approved labeling
- 7. Examples: Where Differences Exist
 - + ACE inhibitors, carbamazepine, isosorbide dinitrate/hydralazine, and rasburicase
- Race and ethnic differences across drugs

Translational Workforce Development Course Catalog







Self-paced

FREE | 1.25 credits

5



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

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Learner Transcript



Envoled 6	Comp	keled	In Progress	Not Completed	Credit Earned 24.25	Credit Available 25.5		
Complete	d							
ENROLLED	COMPLETE	O COUR	SE/PROGRAM			EARNED CREDITS		
2021/01/25	2021/01/28	World I	Patient-Cente Evidence/Data	red Drug Developm	ent and Real-	5.25		
No Date Set	2021/01/27	O1/27 - Patient Centered Drug Development: History, Terms and Definitions - Patient-Focused Drug Development: Patients and Patient Advocacy Organizations						
No Date Set	2021/01/27	- Patier Advoca	nt-Focused Drug I acy Organizations	ts and Patient	1			
No Date Set	2021/01/27	- Introd	tuction to Rare Dis	Drugs	0.75			
No Date Set	2021/01/27	- From	Data, to Informati	1.25				
No Date Set	2021/01/28	- Case Survivo	Study - From Dis orship	nd	1			
2021/01/20	2021/01/24	PROGR	Quality by Der	sign in Clinical Trial		5.5		
No Date Set	2021/01/24	- What	do we mean by Q	uality by Design?		1.25		
No Date Set	2021/01/24	- Clinic Quality	al Trials Transform -by-Design (QbD)	native Initiative (CTI	 Approach to 	1.25		
No Date Set	2021/01/24	- Deve Resea	1					
No Date Set	2021/01/24	- Integ Manag	rating QbD into Te ement for Resear	am Science and Pro ch Success	sject	1		
No Date Set	2021/01/24	- Apply	ing Design for Six	Sigma		1		





STELLAR Team



Jay Rojewski, Ph.D.; Ike Choi, coPl, Ph.D.; Rebecca Thomas, DNP, RN; Linda McCauley, Pl, PhD, RN, FAAN, FAAOHN; Elaine Fisher, PhD, RN, CNE; Jasmine Choi, Ph.D.; Sejung Kwon, M.A., M.Ed.; Eunice Kim, Pharm.D.; Jeb Williams; and Janette Hill, Ph.D.







- Challenges in CRP Workforce
- Tri-Perspective Integration Model
- STELLAR Design
- Understanding Users
- Supporting Data-Driven Decision Making
- Inputs/Benefits for Users
- Next Steps



Challenges in CRP workforce

- Limited resources for **CRPs** to explore career advancement opportunities (job satisfaction & retention)
- Limited data of competency gaps to inform training needs for Training Coordinators
- High turnover rate of positions (158 CRC positions per year) and high cost to replace positions (3-5 months and \$50-60K to fill a position) for HRs
- ■Time pressure of 3-5 year grant cycles for **PIs**





Tri-Perspectives Integration Model





The Self-directed Training, Education, and Life-long Learning Advancement Resource (STELLAR) system

- Empowering individuals' in career advancement
- Efficient candidate recruitment
- Enhancing the needs-based training process







STELLAR - A Career Navigation System





Unified Metric Unit

- Meter system
- Competencies/tasks system

Map Data

- Buildings and Roads
- Jobs and Trainings





Metric Unit for Competency Gap Analysis

8 JCT Competence Domains 44 Core CRC Tasks Measuring 5 Level Proficiency Job's required competencies Job's required competencies Training's aimed competencies





Matching Algorithm Explained



Reciprocal Relationships





STELLAR	Dashl	board My Pr	rofile My R	eports Opp	ortunities •	ogout		
Good afternoon, Jane Doe	unities			Training Oppor Job Opportunit Saved Opportu	unities 2020 profile la nities	ist updated	Job Opportunities OPPORTUNITIES > JOB OPPORTUNITIES	0
Top Job Matches					٩	View all	+ JOS OPPORTUNITY	
JOB TITLE	- 1	NSTITUTION	SCORE ()	- STATUS	- LAST UPDATED		Research Assistant I	
Clinical Research Coordinator I	💽 Institut	ion Name	100%	NEW	4d ago	:	Quildianta) GA. 👩 32k - 32k	
Clinical Research Coordinator I	m Institut	tion Name	80%	NEW	Save Job Match		Save Job Match	
Clinical Research Coordinator	👗 Institut	ion Name	65%	NEW	View Recommended T	Fraining	View Recommended Training	1
	🚜 Institut	tion Name	63.3%	NEW	4d ago	_	🗸 Atlanta, GA 👩 32k - 32k	
Research Coordinator	🖺 Institut	ion Name	60.6%	NEW	4d ago	• (Research Assistant I INFECTIOUS DISEASE Ø Adente, GA 💕 32k - 32k	:
Fop Training Matches					٩	View all	Research Assistant I	
TRAINING TITLE		• PREFERRED	• STATUS		- LAST UPDATED		🗣 Atlanta, GA 📑 32x - 32k	-
Privacy and HIPAA: Concerns in Global Clinical Trials	33.8%	33.8%	NEW		4d ago	1	Research Assistant I	
Liability and Indemnification	33.8%	33.8%	NEW		4d ago		Indigen Action Internation	-
What do we mean by Quality by Design (QbD)	33.8%	33.8%	NEW		4d ago	- 7	Filter Job Opportunities	
Legal Considerations of Compassionate Use	33.8%	33.8%	NEW		4d ago			
Investigator Responsibilities: Industry Sponsored Trials	33.8%	33.8%	NEW		4d ago			

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STELLAR *	Dashboard	My Profil	e My Reports	Opportu	nities -	Log Out
Job Opportunities						
	Note: Your job op from highest mat	portunities are ch to lowest m	displayed based on th atch.(i)	e match to yo	our profile, in or	der
Atlanta, GA	JOB OPPORTUNITY	LOCATION	CLINICAL FOCUS	SALARY	SUGGESTED TRAINING(I)	SAVE
CLINICAL FOCUS JOB LEVEL BASE SALARY LEVEL	Clinical Research Coordinator I	Suwanee, GA	Infectious Disease	\$0 - \$0	Suggested Training	0
 - No selection - \$20K + \$30K + \$40K + 	Clinical Research Coordinator I	Atlanta, GA	Oncology/Radiation Oncology	\$47,000 - \$55,000	Suggested Training	•
□ \$50K +	Clinical Research Coordinator	Atlanta, GA		\$38,000 - \$65,000	Suggested Training	0
	Clinical Research	Atlanta, GA		\$40,000	Suggested Training	





STELLAR	Dashboard	My Profile	My R	Reports	Opportun	ities -	Log Out
Training Opportunitie	es						
Target Job Level	Note: Your training o order from highest r	opportunities a natch to lowes	are displayed st match.(i)	d based on	the match t	o your profile, i	n
Filters	TRAINING	METHOD OF DELIVERY	COST?	DATES AVAILABLE	CONTACT HOURS?	INSTITUTION	SAVE
OFFERS CONTACT HOURS?	Privacy and HIPAA: Concerns in	e- Learning	No		Yes	TWD Course Catalog	Ø
HAS ASSOCIATED COST?	Global Clinical Trials					Partnership (Georgia CTSA & SC CTSI)	
INSTITUTION/ORGANIZATION	Liability and Indemnification	e- Learning	No		Yes	TWD Course Catalog	Ø
 e-Learning In person training Hybrid: online and face-to-face Webingr 						Partnership (Georgia CTSA & SC CTSI)	



STELLAR Interface (Training Coordinators)

	riew Add didates Training	View V Infor	Vorkforce mation	My Profile	Log Out
Welcome Test User3A!					
Overview of Potential Candidate	s for your Trainings	0			
TRAINING TITLE		PUBLISHED?	TOTAL MATCHES		
HIPAA and CRC		×	0	View Matches	Edit Delete
Investigator Responsibilities: Industry Spons	sored Trials	×	5	View Matches	Edit Delete
Privacy and HIPAA: Concerns in Global Clini	cal Trials	×	7	View Matches	Edit Delete
Advanced International Trials with Medical I	Devices	*	1	View Matches	Edit Delete
Clinical Trials Transformative Initiative (CITT by-Design	 Approach to Quality- 	*	29	View Matches	Edit Delete
Integrating QbD into Team Science and Proj Research Success	ect Management for	*	28	View Matches	Edit Delete
Test Title Training		0	0	View Matches	Edit Delete



STELLAR Interface (HR & PIs)



Overview of Potential Candidates for your Job Postings ()

Clinical Research Coordinator III 133 View Matches Edit Delete Clinical Research Coordinator II 133 View Matches Edit Delete Clinical Research Coordinator IV 133 View Matches Edit Delete Clinical Research Coordinator IV 133 View Matches Edit Delete Lead Researcher Image: Non-text and text an	JOB TITLE	PUBLISHED?	TOTAL MATCHES	
Clinical Research Coordinator II 133 View Matches Edit Delete Clinical Research Coordinator IV 133 View Matches Edit Delete Lead Researcher Image: Algorithm of the second sec	Clinical Research Coordinator III	×	133	View Matches Edit Delete
Clinical Research Coordinator IV 133 View Matches Edit Delete Lead Researcher Image: Algorithm Comparison of the second s	Clinical Research Coordinator II	×	133	View Matches Edit Delete
Lead Researcher S 149 View Matches Edit Delete	Clinical Research Coordinator IV	×	133	View Matches Edit Delete
	Lead Researcher	0	149	View Matches Edit Delete



Understanding Users: Persona Development

- In-depth interview with individuals
 - Day-to-day tasks
 - Challenges
 - Key competencies

- Informed design decisions
 - 3 types of work levels
 - Presentation of information
 - Construction of user survey



Satya "Do Your Best" Mishra

Stephanie "Day to-Day Tasks" Jones

Mannara "Own the Project" Poulous











Understanding Users: Career Orientation



Career Orientation

Competence

Individual Attributes





Supporting Data-Driven Decision Making



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Supporting Data-Driven Decision Making

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Inputs/Benefits (CRCs)

<u>Inputs</u>

- Create and maintain personal profile
 - Tasks survey
 - Attribute survey (confidential)
 - Others (current job satisfaction)

Benefits

- Self-reflection on career status & trajectory (self-appraisal)
- Individualized information about workplace demands and availabilities
- Individualized information about training opportunities
- Integrative view of job and
 - training opportunities (intentional)

STELLAR (Individual's Professional Report)

STELLAR (Individual's Confidential Report)

Inputs/Benefits (HR/PIs)

Inputs

Post job positions

- Tasks survey
- Draft future job positions

Benefits

Targeted list of candidates based on competencies matching

■HR Forecasting

 Explore potential candidate pool for existing and anticipated openings

Inputs/Benefits (Training Coordinators)

Inputs

Post training profiles

- Task survey
- Draft potential training profiles

Benefits

Targeted list of potential trainees based on competency-job gap matching

Training Needs Forecasting

- Explore potential trainee pool
- Identify gaps in trainings vs needs → guide future training development

Development/Benefits (TWD, Policy Makers)

Further Development

- Identifying key factors for career advancement to add to STELLAR
 - Job satisfaction
 - Turnover rate
- Further analysis to enhance STELLAR system

Benefits

- Coordinated effort into workforce hiring and training
- Large-scale Competency Gap Forecasting
- Large-scale Training Needs Forecasting
- Informed Decision on Workforce Development Planning

- Launching Schedule
 - April July 2021: Soft Launch for Georgia CTSA Partner Institutions
 - Fall 2021: Nationwide
 - Spring 2022: Adding Regulatory Specialists Service
- Domain: <u>www.stellarcareer.org</u> will be active in April 2021

Questions and Discussion

