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

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University of Georgia
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 USC Regulatory Science | regulatory.usc.edu
SC CTSI | www.sc-ctsi.org

TRIAL INNOVATION NETWORK

CTSA Clinical & Translational Science Awards Program
Agenda

• 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
Study Monitoring is an Essential and Routine Quality Function in Clinical Trials

ICH E6 (R2) Guideline emphasizes the monitoring of critical data and processes. However, access to high quality study monitoring is often lacking in IITs conducted in academic medical centers.

IITs Lack Adequate Monitoring

Two separate surveys of research professionals revealed that only ~65% reported monitoring in their investigator-initiated trials.

Lack of Resources

Although numerous GCP training resources are available, most are not readily accessible because they often require fees or institutional affiliations.

Lack of Approach

Trainings lack practical approaches to meet complex requirements of monitoring. Many academic, government, and private institutions have expressed interest in readily accessible tools.

*IITs = Investigator-initiated trials
Monitoring Module

1. Go to: https://uscrgsci.remotel-learner.net
2. Click *create new account* (right-hand side)
3. 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)
6. Scroll down and click *Module 1 – Clinical Trial Monitoring*
7. Click *Enroll me* (middle of page)
Developed as a clinical trial quality training initiative under the SC CTSI grant.

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

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
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 free course and program offerings 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 in 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 Pacifi, PharmD, PhD, Chair and Associate Professor in the Department of Regulatory and Quality Sciences and Associate Director of the D.K. 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 Online Course Catalog 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

- Symposium Description
- Lecture Description
- Topics
- Speaker Bios
- Learner Levels/Audience
- Continuing Education
- Quiz Questions
Translational Workforce Development Course Catalog

The Legal Aspects of Conducting Clinical Trials Program (November 2019)
This symposium is comprised of 6 sessions which review the various legal requirements for principal investigators and regulatory professionals when conducting a clinical trial.
Self-paced
FREE | 6.5 credits

Investigator Responsibilities: Industry Sponsored Trials
This course examines selected updates from the “E6(R2): Good Clinical Practice: Integrated Addendum to ICH E6(R1): Guidance for Industry applicable to industry-sponsored...
Self-paced
FREE | 0.75 credits

Investigator Responsibilities: Investigator Initiated Trials
This course discusses key roles and responsibilities of individuals associated with investigator initiated trials pertaining to 21 CFR 312.50, FDA 1572.
Self-paced
FREE | 0.5 credits

Clinical Trial Contracts
This course examines institutional clinical trial contractual agreements, and how budgets, regulations, and law compliance impacts study conduct.
Self-paced
FREE | 1.25 credits

https://twd.ce.emorynursingexperience.com/
### Learner Transcript

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Jay Rojewski, Ph.D.; Ike Choi, coPI, Ph.D.; Rebecca Thomas, DNP, RN; Linda McCauley, PI, 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.
Content

- 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

- Explore Job Market
- Identify Training Opportunities
- Efficient Recruitment
  - Candidate Recruitment
  - HR Forecasting
- Employer (PI/HR)
- Training Coordinator
- Needs-based Training
  - Trainee Recruitment
  - Training Needs Forecasting

Promoting Purposeful Training & Career Advancement

TRIAL INNOVATION NETWORK

CTSA Clinical & Translational Science Awards Program
STELLAR (Individual-Centered Approach)

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**
- **340 tasks performed by CRCs**
- **5 Level Proficiency**
- ✓ Individual’s perceived competencies
- ✓ Job’s required competencies
- ✓ Training’s aimed competencies
Matching Algorithm Explained

An Individual’s Perceived Competencies (A)

A Job’s Required Competencies (B)

A Training’s Aimed Competencies (C)

Individual & Job Match

Competencies Gap for Job

Competencies Gap & Training Match

Reciprocal Relationships

Job Matching = 
\[(A \cap B) + (A-(A \cap B)\alpha) / B\]

Training Matching = 
\[(B - (A \cap B)) \cap C\]

Filtering Factors
- Job Level, Job Location,
- Salary, Domain, Education

\(\alpha = \text{coefficient}\)
STELLAR Interface (Individual CRCs)
STELLAR Interface (Individual CRCs)

Clinical Research Coordinator I

Job Summary
Clinical Research Coordinator I
Northside Hospital
Atlanta, GA 30309
United States

Contact Information
Jane Employer
Human Resources
jane.employer@example.com

Clinical Focus
Oncology/Radiation Oncology

Training suggestions for "Clinical Research Coordinator I"

This job requires experience in specific tasks you could improve through training. Below are some recommendations based on the job requirements, your current profile, and trainings logged in the system.

* Please note these are automatically-generated suggestions, and you will need to confirm these trainings are relevant and useful to you and your future career options. View each training page for details.

<table>
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<tr>
<th>Training Opportunity</th>
<th>Method of Delivery</th>
<th>Cost?</th>
<th>Dates Available</th>
<th>Contact Inquired?</th>
<th>Institution</th>
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<td>e-Learning</td>
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STELLAR Interface (Individual CRCs)

Privacy and HIPAA: Concerns in Global Clinical Trials

Training Summary
- Privacy and HIPAA: Concerns in Global Clinical Trials
- TWD Course Catalog Partnership (Georgia CTSA & SC CTSI)
- e-Learning • 1 h 0 min • Intermediate
- This training offers contact hours.
- This training does not have an associated cost.
- This training does not offer a hard-copy certificate upon completion.

Audience
- This session is designed for Clinical Research Associates or Clinical Research Coordinators in academia, clinics, hospitals, industry, or CRO with at least 3 years of clinical research experience.
- Individuals should be experienced with research study coordination, IRB submission process, budgeting, research compliance, recruiting, enrolling, financial management, data collection and analysis.

CTSA Clinical & Translational Science Awards Program
### STELLAR Interface (Individual CRCs)

#### Filters

**LOCATION**
- □ Atlanta, GA
- □ Suwanee, GA

**CLINICAL FOCUS**
- □ Clinical Research Coordinator

**JOB LEVEL**
- □ - No selection -
- □ $20K +
- □ $30K +
- □ $40K +
- □ $50K +

**BASE SALARY LEVEL**
- □ - No selection -
- □ $20K +
- □ $30K +
- □ $40K +
- □ $50K +

#### Job Opportunities

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STELLAR Interface (Individual CRCs)
STELLAR Interface (Training Coordinators)

Welcome Test User3A!

Overview of Potential Candidates for your Trainings

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STELLAR Interface (HR & PIs)

Welcome Test User2A!

Overview of Potential Candidates for your Job Postings

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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

Wendy “One Woman Show” Smith
Satya “Do Your Best” Mishra
Stephanie “Day-to-Day Tasks” Jones
Mannara “Own the Project” Poulous
Understanding Users: Career Orientation

(N=145)

A. Positive career orientations but tentative competence

B. Optimistic and self-confident career orientations

C. Fluctuating and inconsistent career orientations

D. Restricted career orientations

Career Orientation  Competence  Individual Attributes
Supporting Data-Driven Decision Making

Job Level

Ethnicity

Age Ranges

Education Level
Supporting Data-Driven Decision Making
Inputs/Benefits (CRCs)

**Inputs**
- 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)
A. Research grant application
B. Completing a literature review to justify study background
C. Developing study designs
D. Developing study budgets
These five attributes represent the major attribute groups represented by a common psychological test known as the Big 5 (John et al., 1991). The original labels for these five traits were Openness, Conscientiousness, Extraversion, Agreeableness,
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
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<td>■ Post training profiles</td>
<td>■ Targeted list of potential trainees based on competency-job gap matching</td>
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<td>○ Task survey</td>
<td>■ Training Needs Forecasting</td>
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<td>■ Draft potential training</td>
<td>○ Explore potential trainee pool</td>
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<td>profiles</td>
<td>○ Identify gaps in trainings vs needs → guide future training development</td>
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## Development/Benefits (TWD, Policy Makers)

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<th>Benefits</th>
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| - Identifying key factors for career advancement to add to STELLAR  
  - Job satisfaction  
  - Turnover rate  
| - Coordinated effort into workforce hiring and training |
| - Further analysis to enhance STELLAR system |
| - Large-scale Competency Gap Forecasting |
| - Large-scale Training Needs Forecasting |
| - Informed Decision on Workforce Development Planning |
Next Steps

■ Launching Schedule
  ○ April - July 2021: Soft Launch for Georgia CTSA Partner Institutions
  ○ Fall 2021: Nationwide
  ○ Spring 2022: Adding Regulatory Specialists Service

■ Domain: www.stellarcareer.org – will be active in April 2021
Questions and Discussion