The Critical Need for Consistent Training for Clinical Research Professionals

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Clinical Research Training Concerns

- No formal consistent training
- No regulations controlling training
- On-the job training
- Some certification and advanced degree programs available but not consistent
- No universally accepted measure of competency across the profession

Original CTO Education Curriculum

- CITI (Biomedical Research), CITI Good Clinical Practice (GCP), HIPAA
- Tools Involving Research
- IHIS
- Components of a Research Protocol
- Departments Outside of the CTO
- SIV/Study Initiation
- OCDC/JARO
- Multi-Institution Program
- Regulatory Processes
- Informed Consent Process
- Conduct of a Study
- Medication Accountability
- Subject Safety
- Audits and DSMC
- CSRC
- Data Management

Original CTO Education Curriculum Concerns

- Flow of information not always logical
- Some information out of date
- Much of training was delivered through manuals and documents
- Not role specific
- Modules did not always clearly specify the action to be taken
- Possible inconsistencies in training from team to team

The Joint Task Force on Clinical Trial Competency (JTF) Eight Competency Domains

Uses for Eight Competency Domains Framework:

- Developing job requirements
- Assessing job candidates
- Matching employees/contractors with assignments
- **Planning training to support career paths**
- Assessing investigator qualifications
- Designing conference agendas and training programs
- **Choosing training and education events to attend.**

Revised CTO Education Curriculum Using JTF Competency Domains

Domain		
I. Scientific Concepts and Research Design	1.	Components of a Research Protocol
	2.	Clinical Scientific Review Committee (CSRC)
II. Ethical and Participant Safety Considerations	1.	CITI (Biomedical Research); CITI Good Clinical Practice (GCP); HIPAA
	2.	Informed Consent Process
	3.	Audits and Data Safety Monitoring Committee (DSMC)
III. Medicines Development and Regulation	1.	Regulatory Processes
IV. Clinical Trials Operations (GCPs)	1.	SIV/Study Implementation
	2.	Conduct of a Study
	3.	Medication Accountability
	4.	Subject Safety
V. Study and Site Management	1.	Tools Involving Research
	2.	IHIS
	3.	OCDC/JARO
VI. Data Management and Informatics	1.	Data Management
VII. Leadership and Professionalism	1.	Leadership and Professionalism
VIII. Communication and Teamwork	1.	Departments Outside of the CTO
	2.	Multi-Institution Program

Implementation of Revised CTO Education Curriculum and Onboarding

- Revised Manager and Employee Onboarding Checklists
- Revised CTO New Staff Orientation
- Revised CTO CRC/CRA Education Curriculum
- Developed RCO Education Curriculum
- Developed In-Person and Online Trainings
- **In Progress**: Revamping of team preceptor program
- **In Development**: Annual refreshers, hands on-labs