

**CORE COMPETENCIES IN CLINICAL RESEARCH:
REAL WORLD APPLICATIONS, CONVERGENCE AND EVOLUTION OF A FRAMEWORK**

OCTOBER 19, 2016
8:00 AM – 4:00 PM
HARVARD FACULTY CLUB
READING ROOM
20 QUINCY STREET, CAMBRIDGE, MA 02138

TIME	TOPIC	PRESENTER
8:00 – 8:30	REGISTRATION & BREAKFAST	
8:30 – 8:50	REVIEW OF THE DEVELOPMENT OF THE JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY FRAMEWORK	Rebecca Li <i>MRCT Center</i>
8:50 – 9:00	UTILIZATION OF THE FRAMEWORK — RESULTS OF GLOBAL SURVEY; COMMITTEE ON ACCREDITATION OF ACADEMIC PROGRAMS IN CLINICAL RESEARCH (COAPCR); INTRODUCTION TO CASE STUDIES	Stephen Sonstein <i>Eastern Michigan University, CoAPCR, Commission on Accreditation (CoA)</i>
9:00 – 10:40	SESSION 1: FOUNDATIONAL INITIATIVES TO INTEGRATE THE CORE COMPETENCIES FRAMEWORK INTO THE CLINICAL RESEARCH ENTERPRISE	Moderator: Stephen Sonstein <i>Eastern Michigan University, CoAPCR, CoA</i>
	Mission Achievement through Competence Development	Terri Hinkley <i>Association of Clinical Research Professionals (ACRP)</i>
	Applying the Core Competency Framework of the JTF for Clinical Trial Competency to Improve the Overall Training and Career Development of Physicians in Industry Involved with Clinical Trials: A Use Case from a Biopharma Company	Subasree Srinivasan <i>Alexion; formerly Bristol-Myers-Squibb</i>
	The Use of Competencies in the Development of Job Classifications and Workforce Development Initiatives	Rebecca Brouwer <i>Duke University</i> Denise Snyder <i>Duke University</i>

	Education and Training of Clinical & Translational Study Personnel: A Competency-Based Approach	Thomas Perorazio <i>University of Michigan</i> Michelle Wartak <i>Tufts Clinical and Translational Science Institute</i>
	Moderated Discussion (20 Min.)	
10:40 – 10:50	Break	
10:50 – 12:00	SESSION 2: UTILIZATION OF COMPETENCIES FOR INNOVATIVE WORKFORCE DEVELOPMENT	Moderator: Rebecca Li <i>MRCT Center</i>
	Re-shaping an Academic Clinical Research Administration (CRA) Graduate Program Through the Application of the Harmonized Core Competencies Framework	Joan Butler <i>George Washington University</i> Beth Harper <i>George Washington University</i>
	Developing a Clinical Trials Implementation Program: One Institution's Experience	Penelope Jester <i>University of Alabama, Birmingham</i>
	Utilization of JTF Framework for CTSI Grant Renewal	Robert Kolb <i>University of Florida</i>
	Beyond Competency: Building a Professional Clinical Research Workforce for the Future	Greg Koski <i>Alliance for Clinical Research Excellence and Safety (ACRES)</i>
	Competency-Based Training for Entry-Level CRAs	Tammi Masters <i>INC Research</i>
	Moderated Discussion (20 Min.)	
12:00 – 12:30	Lunch	
12:30 – 1:40	SESSION 3: INTERNATIONAL IMPLEMENTATION	Moderator: Barbara Bierer <i>MRCT Center</i>
	The JTF Core Competencies in Latin America: Inter-Regional and Intra-Regional Differences	Honorio Silva <i>Rutgers University</i>

	Competence-Based Certification in Clinical Research in Mexico — A Proposal	Matilde Damian Jose Viramontes <i>Association of Professionals Specialists in Clinical Research (APEIC), Mexico</i>
	The Acceptance and Application of the Competencies in the EU	Esther Daemen <i>TRIUM Clinical Research Consultancy</i>
	Using the Harmonized Core Competencies to Inform the Development of an Integrated Workforce Framework in the UK	Fiona O'Neill <i>NIHR Clinical Research Network, UK</i>
	Research Essentials — Developing Excellence in Research Design and Practice. An Australian Story.	Ian Kerridge <i>PRAXIS Australia Ltd and University of Sydney</i>
	Moderated Discussion (20 Min.)	
1:40 – 3:00	<p>SESSION 4: PANEL DISCUSSION OF IMPACTS</p> <ul style="list-style-type: none"> • Sponsors • Professional Associations • Regulatory Authorities • Nonprofit Organizations • Clinical Research Organizations <p>Moderated Discussion</p>	<p>Moderator: Rebecca Li <i>MRCT Center</i></p> <p>Dirk De Naeyer (Janssen) Howard Fingert (Takeda) Margaret McCabe (IACRN) Kathryn Finch Mileham (ASCO) Robert O'Neill (FDA) Thy Pham (Gates Foundation) Richard Sax (Quintiles)</p>
3:00 – 3:50	OPEN DISCUSSION WITH AUDIENCE	Moderator: Barbara Bierer
3:50 – 4:00	NEXT STEPS	<p>Rebecca Li <i>MRCT Center</i></p> <p>Stephen Sonstein <i>Eastern Michigan University, CoAPCR, CoA</i></p>