



Good Clinical Practice (GCP) Training: Current Practices and Challenges

January 31, 2014

Marriott North Bethesda, Bethesda, MD

Meeting Goal: To seek consensus on the key elements of GCP training and the frequency, format, and competency of training required to conduct clinical studies in the United States.

Meeting Agenda

8:30-9:00 AM

Continental Breakfast

9-9:15 AM

Pamela Tenaerts, MD, MBA, CTTI, Executive Director

Welcome

Susan Ellenberg, PhD, Professor, Department of Biostatistics and Epidemiology, U Penn

Meeting Goals and Opening Remarks

Session 1

9:15-10:15 AM

The Current Landscape for GCP Training

Session Chair: Stephanie Shapley, Health Scientist Policy Analyst, CDER, FDA

Session goal: To understand the inefficiencies in current GCP training practices that may be burdensome to investigators and to review the purpose and regulatory expectations for GCP training programs

Presentations:

Jonathan Seltzer, MD, MA, MBA, FACC, President, ACI Clinical Director, Clinical Research, Lankenau Heart Institute (Presenting on behalf of **Michael Koren, MD, FACC, CPI**, CEO, Jacksonville Center for Clinical Research)

Perspectives on "GCP" and Clinical Research Training of Physicians

Susan McHale, Sr. Director Clinical Development, AstraZeneca

The CTTI GCP Training Project and Literature Review Findings

Stephanie Shapley

GCP Training: Purpose and Expectations

Q&A for clarification

10:15-10:30 AM

Break

Session 2

10:30-Noon

Moderated Discussion: Key Elements of GCP Training Programs

Moderator and Chair: Jonathan Seltzer, MD, MBA

Session goal: To identify the minimum essential elements to include in a GCP training program that are considered adequate to promote GCP and fulfill regulatory expectations

Presentation:

Tina Chuck, MPH, Education and Policy Specialist, North Shore-LIJ Health System

Working Group Recommendations for the Key Elements of GCP

Suggested discussion points:

- Are the key elements proposed by the Working Group adequate?
 - Are there any other elements besides those proposed by the Working Group (key and additional) that should be considered?
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Noon-12:45 PM

Lunch

Session 3

12:45-1:30 PM

Moderated Discussion: Trainees and Differential Training by Job Function

Moderator and Chair: Terri Hinkley, RN, BScN, MBA, CCRC, Deputy Executive Director, Association of Clinical Research Professionals (ACRP)

Session goal: To discuss the need for differential GCP training based on job function

Presentations:

Morgean Hirt, ACA, Director of Certification, ACRP

Differential Training by Job Function: ACRP Job Analysis Results

Christine Pierre, President, Society for Clinical Research Sites

Site Perspective on Differential GCP Training

Suggested discussion points:

- Do different job functions within the clinical research enterprise require differential GCP training (e.g., PI, study coordinator)?
- What specific aspects of GCP training are applicable to each job function?
- Is it useful to provide generalized recommendations related to differential training to adopt across institutions? Or, is it more efficient for institutions to determine if differential training is desirable based on their specific need?

Meeting Agenda

Session 4
1:30-2:30 PM

Panel Discussion: Frequency, Formats, and Demonstration of Competency

Moderator and Chair: Gretchen Wild, Director Clinical Operations, St. Jude Medical

Session goal: To identify suitable frequency and formats for testing and certification

Moderated Panel Discussion:

Terri Hinkley, RN, BScN, MBA, CCRC, Deputy Executive Director, ACRP

Bridget Foltz, Health Scientist Policy Analyst, OGCP, FDA

Jeffrey Cooper, MD, MMM, Vice President Global Consulting, WIRB-Copernicus Group

Barrett Katz, MD, MBA, Executive Director, Office of Clinical Trials, Montefiore Medical Center

Sheri Jacobsen, BSN, MA, Associate Director, Global Clinical Training, AbbVie

Suggested discussion points:

- *What frequency of training is optimal?*
- *What are the recommendations for format of training? For example, traditional face-to-face with instructor, web-based, applied training workshop style.*
- *What are the recommendations for demonstration of competency?*
- *Should testing prior to training (i.e. "testing out") be an option?*

2:30-2:45 PM

Break

Session 5
3:45-4:45 PM

Integrating GCP Principles In Clinical Research Conduct

Moderator and Chair: Sabrina Comic-Savic, Sr. Director, GCP Compliance, The Medicines Company

Session goal: To discuss strategies for integrating GCP principles in clinical research

Presentations:

Lorraine Waring, Sr Director, Clinical Trial Process and Quality, Pfizer, Inc.
Integration of GCP Into Clinical Research—A Sponsor's Perspective

Benetta Walker, RAC, Sr. Learning Consultant, Organizational Learning, Duke University
Integration of GCP Into Clinical Research Training—An Academic Research Organization's Perspective

Rebecca Li, PhD, Executive Director, Multi-Regional Clinical Trials Center, Harvard U.
A Harmonized Core Competency Framework for the Clinical Research Professional Update from the Joint Task Force for Clinical Trial Competency (JTF)

Suggested discussion points:

- *How well do trainees apply what they learned?*
- *Would translating the principles of GCP to practical actions that apply to study conduct be a more effective way to train?*
- *What strategies can be adopted to integrate elements of GCP in daily aspects of clinical research?*
- *What possible 6-barriers may be faced during integration in daily clinical research activities?*

3:45-4:00 PM

Closing Remarks and Next Steps
