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**Frequency, Formats and Competency  
Measures for GCP Training Programs**

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**Moderated Session**

# *Session Goal*

**Identify suitable frequency, formats and competency measures for testing and certification**

*The literature review found little evidence for an optimum frequency, testing, or proof of GCP training*

# Frequency and Format Measures

## Training frequency

Recommendation: Tiered levels of training (role based) every 3 years

## Training format

Recommendation: The working group felt that online training may be best, but prefers to allow flexibility to the administering institution to fulfill their specific needs.

# Competency Measures

## Demonstration of competency (e.g., a quiz at the end of training)

Recommendation: The working group did not arrive at a firm conclusion on this topic and would like to pose this question at the expert meeting. The working group decided that the draft will contain verbiage stating that we recognize the benefit of testing within and across organizations, but do not have a specific recommendation for the format.

## Testing out of training?

Recommendation: Since the recommended frequency is every 3 years, the need for “testing out” does not arise. The working group will not make any recommendations for testing out, this could be raised at the expert meeting to seek opinion

# Panel Participants

- ▶ **Terri Hinkley, RN, BScN, MBA, CCRC**, Deputy Executive Director, ACRP
- ▶ **Bridget Foltz**, Health Scientist Policy Analyst, OGCP, FDA
- ▶ **Jeffrey Cooper, MD, MMM**, VP 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

▶ THANK YOU



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