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CTTI Investigator Qualification: An Investigator’s Reflections on Training
Positive Attributes of Current Training

• **Standardized Principles**
  - Standardized GCP principles that address: Ethical conduct of studies, Patient safety, Investigator Responsibility, Data Quality and Integrity

• **Core Knowledge**
  - Represents solid core knowledge which is important particularly for those new to clinical research

• **Access**
  - Training can be accessed from anywhere at any time

• **Universal Awareness**
  - Training is widely accepted among sponsors
Shortcomings of current GCP Training

• Doesn’t address the gray areas
• Doesn’t have enough applicability to real life scenarios: *Principles are too theoretical and not applicable to daily practice*
• Is a single requirement to be done once every 2-3 years and does not satisfy the need for ongoing training throughout practice
• Not interactive
• Purely didactic in nature and does not support other methods of learning
• Very broad knowledge base without clear indication of what is the most important focus
• Too much repetition / still a requirement for multiple sponsor specific trainings which address GCP
What is Missing from GCP Training?

• Valuable training that will improve quality and efficiency of clinical trial conduct
• Training that fits the needs of Investigators across all therapeutic areas in all phases of clinical research at all levels of experience
• Ongoing support throughout clinical conduct
• Prioritization and possibly consolidation of GCP principles
• Clearer definitions of the principles that apply to actual trial conduct
• Examples and Case studies: Highlight areas of greatest risk and give practical advice on how to mitigate those risks
• Include not only what to do but guidance on how to do it
• Hands-on Real-world training