Evaluating Current Approaches to Preparing Investigators and Their Delegates: What is working? What is not working? What is missing?

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What is working well in current approaches to preparing investigators and their delegates?

Many GCP Principles are Valuable

- Ethics (Foundation for all GCP principles)
  - Ethical conduct of trials
  - Each individual is qualified to perform his/her tasks
  - **Informed consent from every subject prior to participation**
  - Benefits justify risks
  - **Rights, safety, and well-being of subjects prevail**
  - Medical care/decisions by qualified physician
- Protocol Compliance
  - **Compliance with a scientifically sound, detailed protocol**
  - Each individual is qualified to perform his/her tasks
  - Accurate reporting, interpretation, and verification
- Quality Control/Quality Assurance
  - Systems with procedures to ensure quality of all aspects of trial

Investigators' Attitudes about Training

- Investigators are more than willing to complete whatever training and preparations are necessary
- Training must be valuable
  - Respect their very limited time
  - Position them for the quality conduct of clinical trials
  - Protect their patients
- Current GCP training is very problematic
  - Redundant
  - Time-consuming
  - Deterrent to physician participation in clinical trials

What current approaches to preparing investigators and their delegates are not valuable?

Current Approaches are Burdensome

- Repetitive content each time
- Content is too general and not stimulating
- Just another requirement to check off
- Time-consuming and too frequent (3-5 times per year!)
- Lack of standardization

- Review of GCP
- Adverse events
- Informed consent
- Confidentiality
- Data quality and integrity
- Forms, processes, labs
- Sponsor training
- Protocol-specific training

Topics are repeated again and again in a way that is not valuable and does not improve their ability to conduct the critical tasks.

Illustrative Investigator Quote

*But **part of the problem is not that we repeat it, but we're trying to repeat everything**, and that just doesn't help, and that's where I think people get frustrated. And they find they are hearing this big message, and they can't remember any of it, and they have to hear it again. And **we're not doing a good job of communicating and prioritizing and being a little more strategic about how we communicate this information**.*

- Repetitive and ineffective content
- Need to prioritize content and present strategically

Illustrative Investigator Quote

I think some of the questions that they ask in the GCP exam are ***situational questions, and I think those are good, because they really force you to kind of think about how to apply the guidance. I also think that a lot of times the criteria aren't always black and white…***

So, I think ***instead of having 13 points that are each one sentence long, maybe some more context to it, and some examples or something with situations****. So, that when you do find yourself questioning something, you either have a place to go to ask a question, or you have some more information to read through* ***to get the right idea of what the guidance really means****.*

- Content too general
- Need more context and real world guidance

What is missing from current approaches to preparing investigators and their delegates for the quality conduct of clinical trials?

What is missing from current approaches to training?

- Interactive approaches that engage learners
  - Real-world examples - focus on application, not theory
  - Situational guidance (make the training more relevant)
  - Just-in-time approaches
- Tailored approaches
  - Content that is appropriate to knowledge and experience of trainees
  - Condense or streamline information already familiar with
- Prioritization of important topics
- Centralized method (e.g., for annual training)

Discussion