Integration of GCP Into Clinical Research Training

An Academic Research Organization’s Perspective

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Disclaimer

The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative.
Stakeholders’ Shared Goals

- Safe & Effective Products
- Consistency in Regulatory Oversight
- Confidence in Outcomes of the Clinical Trial Process

www.ctti-clinicaltrials.org
Standard GCP Training

Fulfills the requirement

Little practical application

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Benefits of Applied GCP Training

- Opportunity for critical thinking
- Environment for questions
- Evaluation of roles and interactions of all the stakeholders in the clinical research enterprise
- Occasion to learn from the missteps/mistakes of others
- Supports strategy to reduce non-compliance

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Applied GCP Course Content

- Review Stakeholder Responsibilities
  - Sponsor/CRO Clinical Investigator Monitor/CRA
  - Clinical Investigator
  - Monitor/CRA

- Case Study Review

- Issue Escalation and Documentation Compliance

- Reflection
“THE CASE OF THE BITTER PILL STUDY XXX”

STARRING:
- THE Drug
- The Sponsor
- The CRO
- The CRA
- The PI
- The FDA
Participant Feedback

Most Effective Aspects of Training

“Group discussion and (group) work to answer questions”  “Hearing different perspectives on topics”

“I can immediately apply what I learned to my job here.”

“This was the best training workshop I’ve attended here. It was interesting, all participants were engaged and it flowed beautifully.”

“The warning letter was a perfect training tool.”
THANK YOU.

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