



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

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Integration of GCP Into Clinical Research Training ***An Academic Research Organization's Perspective***

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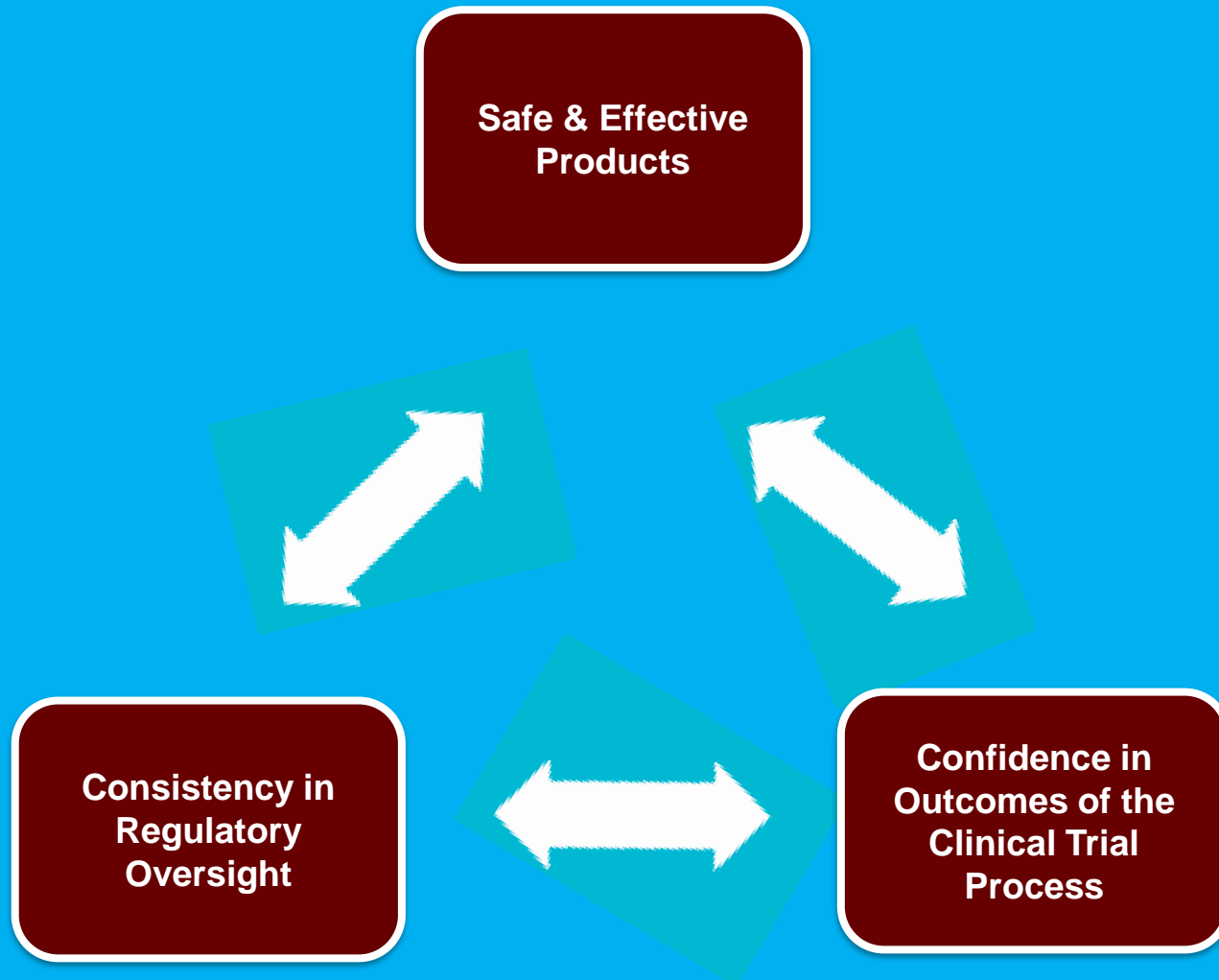
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- ▶ The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative.

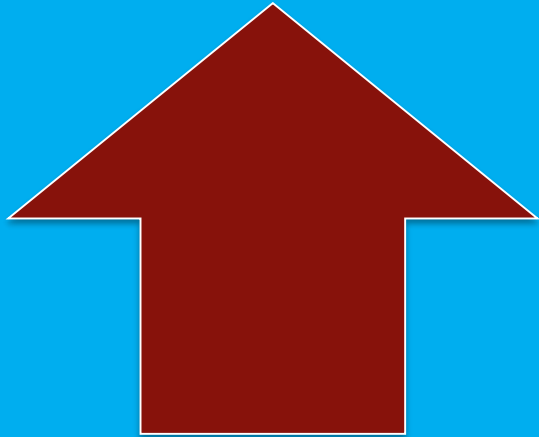
Stakeholders' Shared Goals



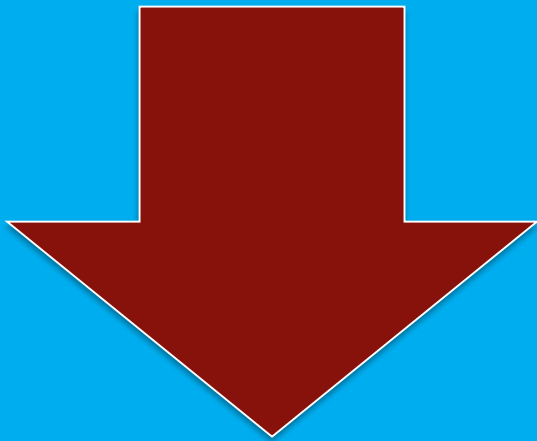




Standard GCP Training



Fulfills the
requirement



Little practical
application

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

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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