



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

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Improving Qualification of Investigators

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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.

Agenda

➤ Introduction to CTTI

➤ Investigator Qualification Project

➤ Project Recommendations & Resources

➤ Discussion



An Introduction to CTTI

Janette Panhuis

CTTI Strengths



Public-Private Partnership
Co-founded by Duke University & FDA
Involves all stakeholders
80+ members

MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials



CTTI Membership



CTTI Projects by Topic

Quality

- ▶ Quality by Design
- ▶ Informing ICH E6 Renovation
- ▶ Analysis of ClinicalTrials.gov
- ▶ Recruitment
- ▶ Planning for Pregnancy Testing
- ▶ State of Clinical Trials Report
- ▶ Monitoring

Patient Engagement

- ▶ Patient Groups & Clinical Trials
- ▶ Patient Engagement Collaborative

Investigators & Sites

- ▶ Investigator Community
- ▶ Investigator Qualification
- ▶ GCP Training
- ▶ Site Metrics

Mobile Clinical Trials

- ▶ Novel Endpoints
- ▶ Mobile Technologies
- ▶ Decentralized Clinical Trials
- ▶ Engaging Patients and Sites

Novel Clinical Trial Designs

- ▶ Real World Evidence
- ▶ Registry Trials
- ▶ Antibacterial Drug Development
- ▶ Sentinel IMPACT-Afib Trial
- ▶ Large Simple Trials
- ▶ Using FDA Sentinel for Trials

Ethics & Human Research Protection

- ▶ Single IRB
- ▶ Data Monitoring Committees
- ▶ Informed Consent
- ▶ Safety Reporting

**As of Feb. 14, 2019; pending approval of new strategic plan*

Thank You!

Team Leaders	Team Members
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Project Managers	
Jen Goldsack (CTTI), Kirsten Wareham (CTTI)	
Social Science Lead	
Teri Swezey (CTTI)	
EC Champion	
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As well as additional experts and leaders across the clinical trials enterprise, including patients and other stakeholders

Investigator Qualification Project

The Challenge and CTTI's Solution

- ▶ FDA regulations state that sponsors are responsible for “selecting investigators qualified by training and experience”
- ▶ Challenge: A more efficient and effective means of identifying whether investigators and their delegates (site teams) are qualified is needed
- ▶ New CTTI recommendations outline how to confirm that site teams are qualified while also reducing inefficiencies in training and better preparing for the quality conduct of clinical trials

Common Clinical Investigator Deficiencies*

- ▶ Little evidence that GCP training alone sufficiently qualifies investigators
- ▶ Most common deficiencies noted during investigator inspections are directly related to GCP principles:

**Failure to follow
the investigational
plan/agreement and/or
regulations**

**Inadequate
recordkeeping**

**Inadequate
accountability for the
investigational product**

**Inadequate
communication
with the IRB**

20 years of GCP training has not fixed these issues

* Clinical Investigator (CP 7348.811) deficiencies identified in FDA Form 483 issued at close of inspections.
<https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RunningClinicalTrials/UCM604510.pdf>

A Culture Change is Needed

- Eliminate the distinction between “qualification” and “preparation”
- A successful shift depends on:
 - Investigators and their delegates assuming greater ownership of their qualification
 - Sponsors and CROs accepting documentation of relevant education and experience as evidence of qualification

If investigators are appropriately prepared for a trial, then they are qualified to conduct it

What Does Investigator Success Look Like?



Recommendations Summary

Quality Conduct by Design

- Expand qualification beyond GCP training
- Identify the unique learning requirements of each trial
- Take a targeted approach to being qualified

Improve Educational Programming

- Create educational programming with adult learners in mind, taking into account individual study roles

Specific, actionable recommendations are provided to both
1) Sponsors and CROs, and
2) Investigators and their delegates



Project Recommendations and Resources

Christine Hildebrand

Expand Qualification Beyond GCP Training

- ▶ Recognize the limits of GCP training; turn qualification from a “check-box-activity” to a valuable learning opportunity
- ▶ GCP alone is unlikely to either:
 - Adequately prepare an inexperienced member of a site team, or
 - Add value to the practice of an experienced researcher

Expand Qualification Beyond GCP Training

For Sponsors and CROs

- Move away from repetitive GCP training as the one-size-fits-all approach to qualifying.
- Develop training that is tailored to your protocol and the members of your site teams.

For Investigators and Their Delegates

- Recognize that GCP training in isolation is insufficient to prepare for the quality conduct of a clinical trial
- Evaluate your site team's preparedness to conduct clinical research before seeking selection as a trial site.
- Use CTTI's framework of characteristics resource.

Identify Unique Learning Requirements

- The knowledge, skills, and experience required site teams will vary with each trial
- Different study phases, disease states, protocol designs, study participant populations, and clinical settings guide unique requirements

Identify Unique Learning Requirements

For Sponsors and CROs

- Provide the completed or draft protocol to potential site teams at the beginning of the site selection process.
- Invite feedback to address feasibility issues up front.
- Complete thorough pre-study visits.

For Investigators and Their Delegates

- Request the full protocol when you are contacted about a trial.
- Assess whether you/your delegates are adequately qualified.
- Discuss your assessment findings openly with the sponsor to close any gaps in preparedness.

Take A Targeted Approach

- A targeted, risk-based approach to being qualified involves:
 - Identifying potential high risks in protocol execution, and
 - Focusing targeted, applied learning solutions toward these high-risk areas.
- Risk analyses should consider:
 - Potential challenges associated with a given protocol, and
 - Reflect the most common deviations experienced by site teams on similar protocols.

Take A Targeted Approach

For Sponsors and CROs

- Critically evaluate the skills, knowledge, and experience of site teams before:
 - site selection and
 - formulation of learning requirements.
- Discuss your evaluation of the site openly with investigators.

For Investigators and Their Delegates

- Consider your performance on past protocols to develop policies, procedures, or educational programming to improve the conduct of future studies.
- Share your findings with sponsors and CROs during the site selection process to guide effective preparation of the site team.

Improve Educational Programming

- Create training with adult learners in mind, taking into account individual study roles
- Educational programming should focus on the learning requirements of the specific trial and address the gaps in knowledge and skills
- **Active learning** encompasses a broad range of formal and informal approaches
- **Training** is one type of learning that imparts information through a structured, learner-centered approach with measurable outcomes

Improve Educational Programming:

Site-based learning activities may include:

- Mentoring
- Job-shadowing
- Virtual or in-person knowledge-sharing networks
- Mock run-throughs of study participant visits and protocol procedures

Improve Educational Programming

For Sponsors and CROs

- Recognize the value of non-traditional learning approaches.
- Accept documentation of (1) previous relevant training and (2) application of knowledge and skills as evidence of qualification.
- Define gaps in knowledge and skills.
- Create role- and protocol-specific education goals.
- Recognize that different site team members may benefit from different types of education.

For Investigators and Their Delegates

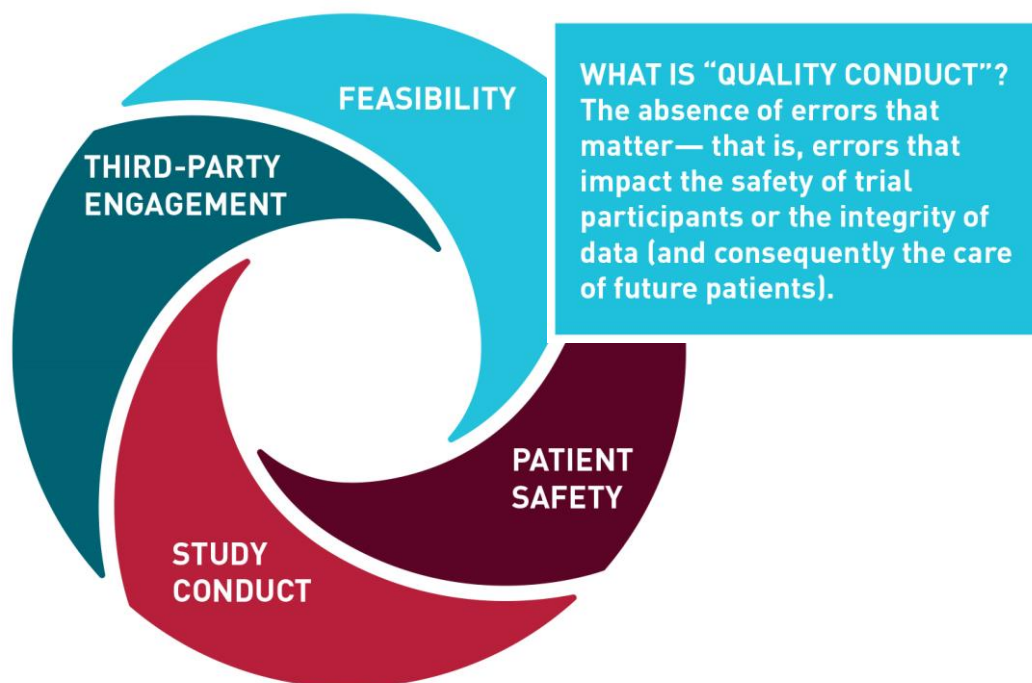
- Consider how to best meet your learning goals.
- Seek out educational offerings that meet content-specific learning goals and suit individual learning styles
- Encourage a mentoring program
- Document learning activities to serve as a record demonstrating your qualification for the conduct of clinical trials.

Resources

- Framework of Characteristics of a Qualified Site Team: How Does Yours Measure Up?
- Documenting Qualification: A Quick Reference Guide for Investigators & their Delegates
- Documentation Template
- Resources for Training & Learning (Appendix 1)
- Mentoring & Knowledge-Sharing Examples (Appendix 2)

Framework of Characteristics of a Qualified Site Team

ABOUT THIS FRAMEWORK	
Who?	Site teams, sponsors, and contract research organizations (CROs)
What?	Gap analysis tool
When?	When assessing whether investigators and their delegates are qualified to conduct a particular trial
Where?	<ul style="list-style-type: none">- At the site, by the site team;- At the sponsor/CRO; and/or- At the site, collaboratively, by the investigator in partnership with the clinical research associate (CRA)
Why?	<ul style="list-style-type: none">- To assess a site team's current level of preparedness to conduct a particular protocol; and- To identify<ul style="list-style-type: none">• Knowledge and skills gaps• Learning/training needs



Documenting Qualification: A Quick Reference Guide

- Sponsors, CROs, and site teams should assume greater control of qualification
- Support the transfer of experience between trials while maintaining a record of qualification activities in a single document
- This will allow sponsors, CROs, and site teams to
 - Focus on addressing protocol-specific gaps in preparedness
 - Improve study execution
 - Eliminate redundant training

Documenting Qualification Template

Qualification activities are any relevant learning activities that develop your experience, knowledge, skills, or expertise

INVESTIGATORS AND THEIR DELEGATES ARE ENCOURAGED TO:

Identify and document the completion of previous relevant training and/or certification.

Maintain and update this template as new and relevant qualification activities occur.

Assess any gaps in knowledge and skills where you could benefit from further learning.

Consider your performance on past protocols to develop policies, procedures, or educational programming to improve the conduct of future studies.

SPONSORS AND CROS ARE ENCOURAGED TO:

Accept documentation of 1) the completion of previous relevant training, and/or 2) the continued application of knowledge and skills during the conduct of clinical trials as evidence that investigators and their delegates are qualified

Consider the previous application of required skills (whenever demonstrated and documented) when tailoring protocol-specific programming to meet individual learning needs.

Recognize that different members of the site team may benefit from different types of education and experience in pursuit of the same learning goal.

Resources for Training & Learning: Appendix 1

- ▶ Inventory of training, learning, and certification opportunities for site teams
- ▶ Over 100 opportunities listed
 - Free and paid opportunities
 - Online and in-person opportunities

Mentoring & Knowledge-Sharing Examples:

Appendix 2

- ▶ List of existing mentoring programs and knowledge-sharing networks to illustrate how adult learning activities are being implemented in practice
- ▶ Adult learning activities can help to address gaps in knowledge and skills through information exchange and peer support

What is adult learning?

- **Self-directed:** Empowers the learner to diagnose learning needs and formulate goals
- **Experience-based:** Leverages professional experience when introducing new material
- **Goal-oriented:** Times the delivery of information so that the learner may soon apply the skill during a trial
- **Relevant:** Emphasizes why practices are recommended or required
- **Practical:** Focuses on application of knowledge, concepts, and skills
- **Collaborative:** Creates a partnership between the learner and the instructor

Adapted from 'Malcolm Knowles'
Adult Learning Theory

Recommendations Summary

- Move away from repetitive GCP training
- A step toward targeted and effective educational programming
- A shift in the perception of qualification activities
- Recognition of previous training and experience
- Identification of gaps in knowledge or skills
- Improved understanding of how to apply GCP principles

Anticipated Impact

- A culture of collaboration
- Improved execution of study protocol
- Fewer regulatory findings
- Improved quality
- Improved efficiency
- Mentorship and knowledge-sharing platforms

Discussion

THANK YOU.



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