

QUALIFYING INVESTIGATORS AND THEIR DELEGATES TO CONDUCT SPONSORED CLINICAL TRIALS

Expert Meeting



MEETING DETAILS | DEC. 13-14, 2017



BACKGROUND

Good clinical practice (GCP) training is widely used as the industry standard for ensuring investigators are qualified. However, little evidence has been collected to determine whether it provides the knowledge and skills necessary to support investigators and their delegates in conducting quality clinical trials.

Rather than accepting GCP training as the default solution for qualifying investigators, CTTI is working to gain a broader, evidence-based perspective that can inform the efficient and effective qualification of site investigators and their delegates—including those listed on the delegation of authority log and those making material decisions about trial conduct—for the quality conduct of clinical trials.



MEETING OBJECTIVES

During a meeting with relevant stakeholders—including those from pharmaceutical companies, government, research sites, contract research organizations, patient representatives, and other groups—experts:

- Reported evidence gathered on:
 - Critical tasks associated with the conduct of clinical trials.
 - Gaps and redundancies in training for preparing clinical investigators to conduct clinical trials.
 - Suggested knowledge and skills necessary for the quality conduct of clinical trials.
- Evaluated proposed framework of characteristics within control of clinical investigator sites that define the quality conduct of a clinical trial.
- Discussed how preparing clinical investigators for the quality conduct of a clinical trial could be optimized.
- Started to identify the recommendations and tools that sponsors and investigators could implement to better prepare clinical investigators for the quality conduct of a clinical trial, and pinpoint the barriers—and solutions—to implementing these recommendations.



MEETING THEMES

- **Look at the Whole, Not Just the Individual:** It is time to shift focus from thinking exclusively about investigator qualification, and expand the focus to the whole site team.
- **Go Beyond “Checking the Box”:** In addition to training on GCP content, additional modes of learning—including just-in-time training, learning through doing, mentorship, and peer-to-peer training and support—and role-specific skills are needed for all members of the study team to improve in their duties.
- **Build in Measurement:** Quality measures are needed to determine if new modalities of investigator qualification are working well or driving measureable improvements in the quality of trial conduct.
- **Incorporate the Patient Voice:** All training needs to evolve to be more patient-centric and include measures that matter to patients.
- **Incentives are Powerful:** An accreditation process would motivate improvement while allowing sites to meet standards in their own way. It would also allow sponsors to more readily identify sites that are prepared and qualified for quality trial conduct.
- **Communication is Key:** Communication between and within sites is critical to promoting shared learning, addressing issues and advancing education of everyone involved in conducting clinical trials.



NEXT STEPS

Meeting participants made suggestions that the CTTI project team will use as a springboard for its next step—developing recommendations and resources to improve the quality of trial conduct through optimized approaches to qualifying investigators and their delegates.



ADDITIONAL RESOURCES

- **Meeting materials**, including agenda, participant list, and presentations
- Read more about CTTI’s **Investigator Qualification Program**
- For more information, please contact Jennifer Goldsack at jennifer.goldsack@duke.edu



ABOUT CTTI

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Comprised of more than 80 member organizations, CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges. Learn more about CTTI at www.ctti-clinicaltrials.org.



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