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The Investigator Qualification Project and Meeting Goals

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Project Team

Team Leaders	Team Members	Project Manager
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Overview

- Rather than accepting GCP training as the default solution for qualifying investigators, CTTI is working to gain a broader, evidence-based perspective to inform the efficient and effective qualification of **site investigators for the quality conduct of clinical trials.**
- Scope:
 - Specific focus on qualifying site investigators to conduct sponsored trials
 - Our view extends to investigators' delegates
 - The additional training needs of investigators developing clinical trial protocols are out of scope

Project Objectives

- Develop a framework that defines quality conduct of a clinical trial
- Describe the impact GCP training has on the quality conduct of clinical trials
- Identify gaps and redundancies in the current training of investigators in preparation for the conduct of clinical trials
- Identify key learning objectives for training to qualify investigators for the quality conduct of clinical trials

Meeting Goals

- Report evidence gathered on:
 - Critical tasks associated with clinical investigators' 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
- Evaluate proposed framework of characteristics within control of clinical investigator sites that define the quality conduct of a clinical trial.

Meeting Goals (cont.)

- Discuss how preparing clinical investigators for the quality conduct of a clinical trial could be optimized.
- Identify the recommendations and tools that sponsors and investigators could implement to better prepare clinical investigators for the quality conduct of a clinical trial. Also, pinpoint the barriers—and solutions—to implementing these recommendations.

Housekeeping

- Restrooms – past foyer, to the right (near business center)
- Parking: See registration desk for voucher
- Push to talk microphones
- State your name and organization when you speak
- Please turn phones on vibrate or silent
- Please use room Wi-Fi not personal hot-spot
- Reception dinner will be on the terrace level

THANK YOU.



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Working Group Recommendations

Key elements of GCP Training

- The 13 elements from the investigator section of the ICH E6 Good Clinical Practice Consolidated Guidance.
 - Other training topics may be considered if needed, depending on the nature and scope of proposed research
- GCP training programs should provide a framework for clinical research conduct
 - Training programs should emphasize topics that are:
 - Outside the scope of medical practice (e.g., safety reporting, IRB review, research informed consent)
 - Areas of recurring non-compliance
 - Avoid redundancy of topics covered in protocol-specific training
 - More advanced and role-based GCP training should be considered for those who have completed initial GCP training.

*** The Working Group reviewed the ICH E6 GCP Guidance and has identified 13 key elements to include in a GCP training program. Except for a few modifications, these 13 key elements were also referenced by TransCelerate's site qualification and training initiative.**

Working group Recommendations:

Training Frequency

- GCP training is recommended to occur at a minimum of every 3 years. The frequency of training should be sufficiently flexible to accommodate different experience levels, gaps in training, etc., and should not be the same course every time
- The training should be mutually accepted across organizations so that trainees may qualify for the time period without needing retraining for each new trial or sponsor

Format of GCP Training

- There are no specific recommendations on format.
- An online format may be the most practical to impart GCP training

Evidence of Training Completion:

- Satisfactory completion of a training program (such as a certificate, test score, or other formal confirmation of training received) should be documented.