CLINICAL TRIALS TRANSFORMATION INITIATIVE

CTTI Recommendations: Good Clinical Practice (GCP) Training For Investigators

Recommended minimum essential elements for a GCP training program:

- 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.

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.

Training Format:

- 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.

- *These recommendations are based on results from the GCP Training Project and are aimed at investigator training, though some areas may apply to training of other site personnel.*
- *CTTI's Executive Committee approved the recommendations.*
- *Released in January 2015*