E-LEARNING MODULE

GCP FOR MONITORS

As part of an overall library forming a complete training curriculum for Clinical Trials, J3I is pleased to present an e-learning module developed especially for Monitors describing their responsibilities as specified in Good Clinical Practice (GCP). Julie Meeson of J3I has used her technical expertise in GCP, along with her considerable experience of many years of training to produce a module covering the following areas:

- Objectives and Definition of GCP
- GCP Legislative frameworks for USA, Europe and Global with interactive options
- Monitoring activities including pre-study and during-study monitoring of Investigator Sites including:
  - Delegation and Oversight of Site Staff
  - Resources
  - Informed Consent process and documentation
  - Investigational Product accountability
  - Safety
  - Source Data verification
- Handling Investigator and Study Site Staff non-compliances
- Effective reporting and follow-up of Monitoring activities

Using this module, Sponsors can ensure that Monitors have detailed understanding of their responsibilities with regard to GCP. The running time of this multi-media training is approximately 25 minutes and allows optional user interaction to include sections as required. Using a combination of visual graphics and an audio narration, the user gains a near face to face training experience right from their desktop.

This e-learning module is designed to run in a standard Web Browser, is compatible with any operating system and can be run locally or over a network. Inter-operability with standard Learning Management Systems (LMS) is available, as is dedicated corporate branding if required, Also available are options for built-in competence assessments and certification – please contact J3I to discuss your requirements.

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