E-LEARNING MODULE

EUROPEAN CLINICAL TRIAL DIRECTIVES

As part of an overall library forming a complete training curriculum for Clinical Trials, J3I is pleased to present an e-learning module providing detailed coverage of the European Directives and associated guidance documents most relevant to Clinical Trials with Investigational Medicinal Product. 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:

- European Legislative framework for Clinical Trials
- Overview of the content and impact of:
  - The Clinical Trial Directive 2001/20/EC
  - The GCP Directive 2005/28/EC
  - The GMP Directive 2003/94/EC
- Overview of the associated guidance documents describing applications to competent authorities, ethics committees, safety reporting and trial master filing and archiving.

This module is particularly directed at Sponsor Staff who are responsible for managing trials within the European Union. It would also be very useful to personnel who are based outside of the EU and who wish to familiarize themselves with EU requirements. The running time of this multi-media training is approximately 30 minutes and it is designed to require no user interaction throughout its progression. 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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August 2010