

E-LEARNING MODULE

UK CLINICAL TRIAL STATUTORY INSTRUMENTS FOR INVESTIGATORS AND STUDY SITE STAFF

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 Investigators and other Study Site Staff conducting trials within the UK. The module provides detailed coverage of UK Statutory Instrument (SI) legislation 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 in detail:

- The Medicines for Human Use (Clinical Trials) Regulations 2004 – SI 2004/1031
- The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 – SI 2006/1928
- The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006 – SI 2006/2984
- The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 – SI 2008/941
- The Medicines for Human Use (miscellaneous Amendments) Regulations 2009 – SI 2009/1164

Sponsors are legally required to select Investigators who have sufficient understanding of UK SIs. Using this module, Sponsors can ensure that Investigators and Study Site Staff have detailed knowledge of their legal responsibilities with regard to SI content. At the end of the module the user is automatically issued with a certificate to verify completion, which provides evidence to auditors and inspectors that SI training has been provided. 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 – please contact J3I to discuss your requirements.

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