



ONLINE COURSES 2010



Course AA. Site Personnel - Core GCP Training

Group AA.1. Introduction

- Topic AA.1.1. Introduction to Clinical Research
- Topic AA.1.2. Principles of GCP
- Topic AA.1.3. Ethical Considerations in Clinical Research
- Topic AA.1.4. Clinical Trials in Australia
- Topic AA.1.5. Investigator Responsibilities
- Topic AA.1.6. Phases of Clinical Trials

Group AA.2. Informed Consent

- Topic AA.2.1. Informed Consent – Elements & Documentation
- Topic AA.2.2. Informed Consent – Process and Exceptions

Group AA.3. Study Conduct

- Topic AA.3.1. Site Selection, Pre-Study and Initiation Visits
- Topic AA.3.2. Essential Documents in Clinical Research
- Topic AA.3.3. Study Drug Accountability
- Topic AA.3.4. Safety Reporting
- Topic AA.3.5. Routine Site Monitoring Visits
- Topic AA.3.6. Site Audits

Course AB. Site Personnel - Adv GCP Training 1

Group AB.1. Study Document Development

- Topic AB.1.1. Protocol Writing
- Topic AB.1.2. CRF Design

Group AB.2. Site Contract and Budget

- Topic AB.2.1. Site Contract & Budget
- Topic AB.2.2. Investigational Site Study Budget

Group AB.3. Ethical Review and Regulatory Applications

- Topic AB.3.1. HREC Ethical Review
- Topic AB.3.2. CTN / CTX Applications

Group AB.4. Additional Topics

- Topic AB.4.1. Subject Recruitment & Retention
- Topic AB.4.2. Data Management
- Topic AB.4.3. Electronic Records & Signatures

“I have learnt a significant amount of new information despite 10 years of experience working as a research coordinator. The course has been delivered in a very informative way with many useful links.”

Course AC. Sponsor Personnel/CRA - Core GCP Training

Group AC.1. Introduction

- Topic AC.1.1. Introduction to Clinical Research
- Topic AC.1.2. Principles of GCP
- Topic AC.1.3. Ethical Considerations
- Topic AC.1.4. Clinical Trials in Australia

Group AC.2. Trial Preparation

- Topic AC.2.1. Phases of Clinical Trials
- Topic AC.2.2. Protocol Writing
- Topic AC.2.3. CRF Design
- Topic AC.2.4. Informed Consent I -- Elements & Documents
- Topic AC.2.5. Essential Documents in Clinical Research

Group AC.3. Trial Start-up

- Topic AC.3.1. Monitoring: Site Selection
- Topic AC.3.2. Monitoring: Pre-study Visits
- Topic AC.3.3. Monitoring: Site Initiation
- Topic AC.3.4. Informed Consent II -- Process & Exceptions

Group AC.4. Trial Monitoring

- Topic AC.4.1. Routine Site Monitoring
- Topic AC.4.2. Monitoring: CRF Review & SDV
- Topic AC.4.3. Monitoring: Safety Reporting
- Topic AC.4.4. Monitoring: Drug Accountability
- Topic AC.4.5. Site Close-out

Course AD. Sponsor Personnel/CRA - Adv GCP Training 1

Group AD.1. – Roles & Responsibilities

- Topic AD.1.1. Sponsor/Vendor Responsibilities
- Topic AD.1.2. Investigator Responsibilities

Group AD.2. – Drug Development & Design

- Topic AD.2.1 Drug Discovery & Development
- Topic AD.2.2. Clinical Trial Design

Group AD.3. – Regulatory Submissions

- Topic AD.3.1. CTN / CTX Application
- Topic AD.3.2. Clinical Study Report (CSR)

Group AD.4. – Compliance & Audits

- Topic AD.4.1. Clinical Quality Assurance (CQA)
- Topic AD.4.2. SOPs in Clinical Research
- Topic AD.4.3. Sponsor Compliance & Audits
- Topic AD.4.4. Site Audit
- Topic AD.4.5. Electronic Records & Signatures

Course AE. Site/Sponsor/CRA Personnel - Adv Training 2

Group AE.1. – Data Management & Biostatistics

- Topic AE.1.1. Data Management
- Topic AE.1.2. Biostatistics 1:Introduction to Biostatistics
- Topic AE.1.3. Biostatistics 2:Data analysis & reporting

Group AE.2. – Project Planning & Management

- Topic AE.2.1. Project Management Fundamentals
- Topic AE.2.2. Integrated Project Management

Group AE.3. – Vendor Selection & Management

- Topic AE.3.1. Vendor Selection
- Topic AE.3.2. Vendor Management

Group AE.4. – Additional Topics

- Topic AE.4.1. Medical Terminology
- Topic AE.4.2. IND Application
- Topic AE.4.3. NDA Application