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Online Courses-Classroom Seminars in Clinical Research

Nucleus Network Education offers

4 new ½ day seminars (from \$225 each)

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CLASSROOM SEMINARS



GCP Case Study Seminar

Seminar Objectives This seminar provides a series of case study opportunities to examine the typical challenges faced in daily clinical trials. Learn to apply newly gained knowledge to real life situations. In addition, gain useful working resources.
Target Audience Clinical researchers working in any area who wish to review and apply their knowledge gained in formal GCP training.

SOP Writing Seminar

Seminar Objectives The SOP Writing Seminar is a unique opportunity to gain efficiency in this sometimes overwhelming task. Ranging from understanding where to begin, what format, minimum requirements and gaining a full appreciation of the process and its components, attendees will benefit from a day with handy templates and resources.
Target Audience Clinical researchers responsible for creating their SOP and Quality System.

Budgeting, Feasibility & Finance Seminar

Seminar Objectives This seminar provides an overall understanding of financial concepts. Learn how to identify the factors in determining if a trial will break even or make a profit. Methods of maintaining cash flow and identifying which the decision makers in the process should be involved.
Target Audience Clinical researchers needing a system of financial management and project profit viability.

Research Governance Seminar

Seminar Objectives Research Governance is intrinsic to patient safety and risk management. Understanding the comprehensive key regulatory responsibilities and managing them, along with building compliant sites is the challenge for site research offices. Gain knowledge and resources to achieve this end.
Target Audience Clinical researchers responsible for research governance and compliance at their site.

These seminars complement the rigorous training of our extensive online program

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Attend one, attend all.

Buy 4, pay for 3!

Purchase online modules prior to the seminar for discounted seminar rate!

RRP:	½ day = \$365	1 Full day = \$625	1 ½ days = \$750	2 Full days = \$1050
Group Discount:	½ day = \$300	1 Full day = \$500	1 ½ days = \$600	2 Full days = \$ 900

	VIC	NSW	SA
Seminar Dates	Jun 23-24 Oct 20-21	Nov 8-9	May 6-7

For more information contact



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Courses endorsed by





ONLINE COURSES



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

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

“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 Certificate provided.

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