

## PROMOTING EXCELLENCE IN CLINICAL TRIALS

### SITE / SPONSOR /CRO COURSES

#### Site / Sponsor / CRO Personnel – Advanced GCP Training II **\$525.00 AUD**

##### Group E.1. – Data Management & Biostatistics **\$155.00 AUD**

E.1.1. Data Management	70.00
E.1.2. Introduction to Biostatistics	50.00
E.1.3. Data Analysis & Reporting	65.00

##### Group E.2. – Project Planning & Management **\$125.00 AUD**

E.2.1. Project Planning	75.00
E.2.2. Project Management	75.00

##### Group E.3. – Vendor Selection & Management **\$100.00 AUD**

E.3.1. Vendor Selection	60.00
E.3.2. Vendor Management	60.00

##### Group E.4. – Additional Topics **\$135.00 AUD**

E.4.1. Medical Terminology	35.00
E.4.3. IND Application	60.00
E.4.4. NDA Application	65.00



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together with



offer

## ONLINE TRAINING IN CLINICAL RESEARCH

**ClinfoSource**, a global online training company based in California, USA, has collaborated with **Nucleus Network Ltd** based in Victoria, Australia to jointly provide web-based training for clinical trials professionals in the Australian region.

**Tel: 03 9076 8909**

## ONLINE TRAINING FOR THE ENTIRE TEAM

**Nucleus Network Education** together with **ClinfoSource** offer you these high standard, accessible, affordable and flexible clinical research training modules.

### Program Highlights:

- Each program comprises 10 or more comprehensive topics
- Customised for the Australian clinical research regulatory environment
- The modules also contain information for the US regulatory environment as many of the trials in Australia are for international companies
- All modules are available on an individual basis, a small cluster basis or a full program certificate basis
- Completion Certificate for successful completion of online program
- Group Discounts available—contact us for more details



2008 Introductory prices

## SITE COURSES

### Site Personnel – Core GCP Training

**\$595.00 AUD**

<b>Group A.1. Introduction</b>	<b>\$255.00 AUD</b>
A.1.1. Introduction to Clinical Research	50.00
A.1.2. Principles of GCP	40.00
A.1.3. Ethical Considerations in Clinical Research	50.00
A.1.4. Clinical Trials in Australia	60.00
A.1.5. Investigator Responsibilities	50.00
A.1.6. Phases of Clinical Trials	50.00

### Group A.2. Informed Consent **\$85.00 AUD**

A.2.1. Informed Consent -- Elements and Documentation	50.00
A.2.2. Informed Consent – Process and Exceptions	50.00

### Group A.3. Study Conduct **\$255.00 AUD**

A.3.1. Site Selection, Pre-Study and Initiation Visits	50.00
A.3.2. Essential Documents in Clinical Research	50.00
A.3.3. Study Drug Accountability	50.00
A.3.4. Safety Reporting	50.00
A.3.5. Routine Site Monitoring Visits	50.00
A.3.6. Site Audits & FDA Inspections	50.00

### Site Personnel – Advanced GCP Training I

**\$465.00 AUD**

<b>Group B.1. Study Document Development</b>	<b>\$85.00 AUD</b>
B.1.1. Protocol Writing	50.00
B.1.2. CRF Design	50.00

### Group B.2. Site Contract and Budget **\$125.00 AUD**

B.2.1. Site Contract & Budget	75.00
B.2.2. Investigational Site Study Budget	70.00

### Group B.3. Ethics and Regulatory Applications **\$100.00 AUD**

B.3.1. HREC Ethical Review	60.00
B.3.2. CTN / CTX Application	60.00

### Group B.4. Additional Topics **\$155.00 AUD**

B.4.1. Subject Recruitment & Retention	50.00
B.4.2. Data Management	70.00
B.4.3. Electronic Records & Signatures	60.00

## SPONSOR / CRO COURSES

### Sponsor / CRO Personnel – Core GCP Training

**\$765.00 AUD**

<b>Group C.1. – Introduction</b>	<b>\$170.00 AUD</b>
C.1.1. Intro to Clinical Research	50.00
C.1.2. Principles of GCP	40.00
C.1.3. Ethical Considerations	50.00
C.1.4. Clinical Trials in Australia	60.00

### Group C.2. – Trial Preparation **\$225.00 AUD**

C.2.1. Phases of Clinical Trials	50.00
C.2.2. Protocol Writing	50.00
C.2.3. CRF Design	50.00
C.2.4. Informed Consent I -- Elements & Documents	50.00
C.2.5. Essential Documents in Clinical Research	50.00

### Group C.3. – Trial Start-up **\$170.00 AUD**

C.3.1. Monitoring: Site Selection	50.00
C.3.2. Monitoring: Pre-study Visits	50.00
C.3.3. Monitoring: Site Initiation	50.00
C.3.4. Informed Consent II -- Process & Exceptions	50.00

### Group C.4. – Trial Monitoring **\$225.00 AUD**

C.4.1. Routine Site Monitoring	50.00
C.4.2. Monitoring: CRF Review & SDV	50.00
C.4.3. Monitoring: Safety Reporting	50.00
C.4.4. Monitoring: Drug Accountability	50.00
C.4.5. Site Close-out	50.00

### Sponsor / CRO Personnel – Advanced GCP Training I

**\$550.00 AUD**

<b>Group D.1. – Roles &amp; Responsibilities</b>	<b>\$125.00 AUD</b>
D.1.1. Sponsor/Vendor Responsibilities	50.00
D.1.2. Investigator Responsibilities	50.00
D.1.3. HREC Ethical Review	50.00

### Group D.2. – Drug Development & Design **\$85.00 AUD**

D.2.1 Drug Discovery & Development	50.00
D.2.2. Clinical Trial Design	50.00

### Group D.3. – Regulatory Submissions **\$100.00 AUD**

D.3.1. CTN / CTX Application	60.00
D.3.2. Clinical Study Report (CSR)	60.00

### Group D.4. – Compliance & Audits **\$245.00 AUD**

D.4.1. Clinical Quality Assurance (CQA)	60.00
D.4.2. SOPs in Clinical Research	50.00
D.4.3. Sponsor Compliance & Audits	65.00
D.4.4. Site Audit	50.00
D.4.5. Electronic Records & Signatures	60.00

[www.nucleusnetwork.com.au](http://www.nucleusnetwork.com.au)

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