

CLINICAL RESEARCH

SITE STAFF TRAINING

2009

Introduction to Clinical Research
GCP Problem Solving Workshop
Clinical Trial Project Management
and Time Management
Courses
AUSTRALIA NEW ZEALAND



The courses will be interactive allowing participants to gain hands-on experience and will allow time for discussion, exchange of ideas and question and answer sessions.

Important Information

Fees:

The registration fee covers comprehensive course notes, lunch and refreshments.

Each attendee will receive a Certificate on completion of the course.

Withdrawals & Cancellations:

Cancellations must be received in writing 14 days prior to the course commencement date in order to receive a full refund of the registration fee.

Datapharm reserves the right to cancel the course, in which case, registrants will receive immediate notification and a full refund of the registration fee.

On Acceptance of Registration:

Details of venue and training program will be sent with notification of acceptance.

The Trainer

Eleanor Allan has worked in pharmaceutical research for 22 years, initially in drug development, followed by over 18 years in clinical research. She set up Caledonian Clinical Training in 2000 to provide specialised training for clinical research personnel. She has successfully trained sponsors, study site coordinators, investigators, academic research groups and ethics committees. Having lived and worked in Europe and Japan as well as Australia, Eleanor has an excellent grasp of international and local issues.

Eleanor has professional training qualifications and believes strongly in practical, interactive training where participants learn how to put theory into practice in realistic situations.

Datapharm Australia (CRO) works closely with investigational sites and supports the need for site staff to participate in training for their important role in clinical research. Datapharm also engages study coordinators to assist sites in times of overload.

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Want to be the best?

Be trained by the best.

CLINICAL RESEARCH

SITE STAFF TRAINING

Australian/New Zealand TIMETABLE

2009 Courses

Location	Introduction to Clinical Research	GCP Problem Solving Workshop	Clinical Trial Project Management	Time Management
Sydney	23-24 Mar 21-22 Sep	25 Mar 23 Sep	3 Nov	4 Nov
Brisbane	22-23 Jun	24 Jun	-----	-----
Melbourne	20-21 Jul	22Jul	-----	-----
Auckland NZ	12-13 Oct	14 Oct	15 Oct	16 Oct

Why?

As clinical research continues to expand in Australia and the regulatory environment changes, these courses will help ensure that site staff are equipped to handle their role. Training is essential for new staff to learn and understand key aspects of clinical research and as an important refresher for existing staff. These courses will increase the knowledge, quality and efficiency of clinical trial conduct at sites.

Who should attend?

If you
... are interested in working as part of a clinical trial site team, study coordinator or Investigator and would like to learn more about the roles

... are already part of a site team and would like to extend your knowledge and expertise in clinical trials

... have felt overwhelmed or exasperated with GCP and the regulations and would like to increase your ability to understand and interpret what is required

... would like to access tools and techniques to plan and manage your trial to meet goals and deadlines while maintaining your sanity

... feel like you never have enough time and are overwhelmed by the amount you have to do

... would like the opportunity to network with other site staff to discuss experiences and exchange ideas

...then we strongly recommend these courses.

The GCP Workshop, Clinical Trial Project Management and Time Management courses are aimed at those who already have a good understanding of clinical trial regulations, GCP and the clinical trial process.

Outline of Courses

Introduction to Clinical Research

The course will be TWO DAYS in length covering the following topics:

- Overview of the drug development process
- Overview of clinical trial regulations
- Ethics
- Informed consent
- Trial planning & management
- Source data and CRFs
- Safety reporting/adverse events

GCP Problem Solution Workshop

The course will be ONE DAY in length covering the following topics:

- Problem solving/prevention workshop
- Problem prevention improving process & quality
- Problem solving techniques relevant to Australian key clinical trial guidelines

Clinical Trial Project Management

The course will be ONE DAY in length covering the following topics:

- Work breakdown
- Scheduling/deadlines
- Personnel resource management
- Managing risk
- Tracking & controlling progress

Time Management

The course will be ONE DAY in length covering the following topics:

- Analysing your use of time
- How to set & meet goals
- Developing good time management skills
- Time management tools
- Dealing with time management problems

Registration Form

I wish to register for the following Clinical Research Site Staff Training Courses ():

- Brisbane
- Melbourne
- Sydney
- Auckland

Name: _____

Department / Hospital: _____

Postal Address: _____

Telephone: _____ Fax: _____

() _____ () _____

e-mail: _____ @ _____

Invoice to: (if not the above nominee)
Person, Company/Institution and postal address:

Payment Details

Closing date 2 weeks prior to course.
Late applications considered

Course Fees: (not including GST)

- 1) Introductory Course (2 days).....AUD \$ 900*
- 2) GCP Problem Workshop (1 day).....AUD \$ 550*
- 3) Project Management Course (1 day)..AUD \$ 550*
- 4) Time Management Course (1 day).....AUD \$ 550*

A \$50 deduction is provided for persons attending more than one course for each course attended.
* (Fees **add** 10% GST for Australian locations)
* (do **not** add 10% GST for NZ courses and pay in AUD)

Please mail or **FAX (61 2 9719 2811)** your registration form. A tax invoice will be mailed to you or your nominated company on receipt

Datapharm Australia Pty Ltd
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