Sophie Mepham GCP™

PRAXIS AUSTRALIA

Promoting Ethics and Education in Research

GOOD CLINICAL PRACTICE (GCP)
TRAINING FOR RESEARCH SITES AND STAFF

Enrol in the PRAXIS online **GCP Module C5.01** via Research Essentials

GOOD CLINICAL PRACTICE (GCP)
TRAINING FOR RESEARCH SITES AND STAFF

Working in partnership, Sophie Mepham GCP™ and PRAXIS Australia provide a TransCelerate accredited Good Clinical Practice (GCP) training tailored for all those involved in clinical research.

Welcome to the "Train the Trainer" GCP program

Good Clinical Practice (GCP) is the international standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials that involve humans. GCP also serves to protect the rights, welfare, safety and confidentiality of trial subjects. The principles of GCP have their origins in the World Medical Association's Declaration of Helsinki, first published in 1964.

It is a requirement that all staff involved in clinical research should have evidence of GCP training, and this training must be relevant and appropriate to their role. Industry, regulatory bodies and independent inspectors are also seeking assurance that research staff meet the minimum GCP training standards as defined by groups such as TransCelerate.

In 2011, the National Institute of Health Research (NIHR) in the UK developed a first-of-its-kind national GCP "Train the Trainer" program. This program supports institutions and their research staff to build the skills they need to plan and conduct their own GCP training programs, and is delivered in Australia by Dr Sophie Mepham, under exclusive license from the NIHR. The program is supported by a mentorship program, regular regulatory updates and access to real time support

Part A

Design and delivery of the GCP programs and materials

Part A of the program includes the following elements, designed and delivered to the organisation:

Design and delivery of the GCP programs	Supplied Materials
(1) Introduction to Good Clinical Practice This program is suited to all staff involved in the design and conduct of clinical trials. It includes 5 modules designed specifically for the Australian regulatory environment: 1. GCP – The Standards 2. Study Set Up 3. Informed Consent 4. Case Report Form and Data entry 5. Safety Reporting **(2) Refresher GCP** A program designed to be delivered to research staff once they have received the Introduction to Good Clinical Practice training or if staff need to have GCP training delivered quickly. Ideally suits staff who already have some knowledge of clinical trials. **(3) Nursing GCP** A short GCP program designed to be delivered to nursing/medical staff who work in clinical settings who may see research patients as they are treated as part of normal care but who are not directly involved in research. Examples include chemotherapy day unit nurses, nursing staff who may take PK blood samples and ward nurses who care for patients that are being treated on trials who require a good general understanding of the principles of GCP, but do not require full GCP training. **(4) Pharmacy GCP** A short GCP program designed to be delivered to all pharmacy staff, covering important topics such as handling, storing and dispensing of Investigational Medicinal Products. **(5) Radiology GCP** A short GCP program designed to be delivered to all radiology staff, covering important topics such adherence to protocol-specific requirements and the importance of validated testing techniques. **(5) Pathology GCP** A short GCP program designed to be delivered to all pathology staff, covering important topics such as sample integrity and the importance of using validated testing techniques.	**Web login access to the Sophie Mepham GCP members area** Login will provide access to the members area where all resources and training materials will be made available. Clients can also register to receive GCP newsletter updates from the website. Sites will be sent their website log in detail. **Workshop booklets** Introduction and refresher booklets. **Facilitator handbook** A handbook for the GCP trainers with answers to the quiz, group work and activity sessions. **Training material and activity documents** Comprehensive collection of all training material and activity documents. **Quiz sheets** A required component, necessary to attest that each student has achieved the TransCelerate minimum standard. **Certificate template** A electronic TransCelerate approved and endorsed GCP certificate template that includes the organisations own logo.
The organisation will be listed on the TransCelerate website by Sophie Mepham as a recognised GCP training program as part of the delivery of Part A.	

Part B
GCP Workshop and "Train the Trainer"

This phase comprises of the following:

GCP Workshop and "Train the Trainer"

Session One 5 - 6 hours of Introduction to GCP training provided by Sophie Mepham to the "Trainees" plus up to 50 additional attendees who require introductory GCP training. The trainees will observe Sophie Mepham deliver the training and become familiar with the handbooks, course materials, group work and scenarios and how to respond to typical audience questions and interactions.

Session Two Up to 2 - 3 hours of one on one facilitation (dependent on number of trainees) and training in how to deliver each of the GCP modules, how to engage participants and how to handle different situations that may arise during the training. The materials provided are discussed and education given on how to run the day efficiently and effectively.

Part C OPTIONAL
Ongoing mentorship and support for Trainees

The ongoing mentoring model provides the organisation and the trainees with support and mentorship.

Ongoing mentorship and support

The process of becoming a highly skilled GCP trainer can take many months. It can feel overwhelming at times , particularly with a background of changing regulations and guidelines. The mentoring model provides the organisation and the trainees with ongoing support and mentorship. It provides a safe and supportive environment for trainees to interact individually with Sophie Mepham as required.

Fees and Legal

ELEMENT	FEE (exclusive of GST)
Part A Design & delivery of all specified GCP materials Minimum # of Trainees: 2 Maximum # of Trainees: 35 Minimum # of GCP attendees: 10 Maximum # of GCP attendees: 50	**$5500 (once off)** **$750 annual licence fee** (payable up front for the first year and billable annually thereafter) **$500 graphic design fee** (payable up front) ***$500 reprinting fee** (for updates out of session)
Part B "Train the Trainer"	**$1500 per trainee** **$360pp GCP attendee**
Part C Ongoing mentoring and support	**$200per month per trainee**

Sophie Mepham GCP™

Sophie Mepham GCP™ is a consultancy business with 20 years' experience managing clinical trials across various disciplines and clinical trial "phases" in both Australia and in the UK.

Sophie is an accredited NIHR GCP program leader and is one of Australia's most well-known and respected GCP trainers.

PRAXIS AUSTRALIA

Promoting Ethics and Education in Research

PRAXIS Australia is an independent not for profit and registered charity, whose purpose is to promote the understanding and practice of ethical research for the benefit of the broader community and to support the overall quality and effectiveness of research in Australia.

For information or support
please contact us at any time.

PRAXIS Australia
Call 08 8122 4576
Email info@praxisasutralia.com.au
Click www.praxisaustralia.com.au