

GOOD CLINICAL PRACTICE WORKSHOP

18 - 20 MARCH 2015 | Clinical Research Centre, Level 5
Hospital Queen Elizabeth II, Sabah.

OVERVIEW

GCP is a set of rules and regulations that is provided by ICH, an international body that regulates clinical trials involving human subjects. It is a standard for the design, conduct, performance monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the

1. Data and reported results are credible and accurate
2. Rights, integrity and confidentiality of trial subjects are protected.

WHY GCP

In clinical trials, the protection of the subject is paramount especially when untested therapy is used. There must also be assurance about the conduct of clinical trials in terms of elimination of cheating, fraud or accidental error. Problems of poor study design must be avoided. Adherence to GCP is vital otherwise, subjects participating in the trials may be put at risk or the clinical trial data submitted may be rejected by health authorities and the scientific committee, if found to be unreliable. Also, the research credibility of the researcher and the research institution may be damaged. Malaysia adopted GCP in 1999, and since then doctors are required to undergo training on GCP leading to certification prior to participation in clinical trials. This course is specifically designed to meet this requirement.

OBJECTIVE

1. To understand the principles underlying GCP and its specific rules of conduct.
2. To provide experience in the key skills required through simulation in classroom setting.
3. To provide some of the resources required to design and to conduct GCP trial.
4. To achieve an overall understanding on how to conduct GCP compliant clinical trial.

WHO SHOULD PARTICIPATE?

- a) Clinicians, nurses and allied health professionals involved with research
- b) Research Associates and Study Coordinators
- c) Biomedical and research scientists
- d) Statisticians and database managers
- e) Experienced research personnel who are interested in updating their knowledge regarding GCP

REGISTRATION

- a) No Registration Fees
- b) Limited seats for 25 participants only.
- c) Dateline: 6th March 2015

CANCELLATION

- a) Any cancellation must be made in writing to the organizer.
- b) We reserve the right to change the date(s) or speaker (s) of this course, if deem fit, without prior notice.
- c) We further reserve the right to cancel the course

CONTACT

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Registration Form

Name : Prof Dr Mr Mrs Ms

(Please write name in block letters as you wish it to appear in the certificate)

IC / Passport No :

Department :

Institution :

Designation :

Specialty :

Vegetarian : Yes No

Contact Address :

Contact No (Office) :

(Mobile) :

(Fax) :

Email :