

REGISTRATION INFORMATION

REGISTRATION FEES

Registration Fees = RM 900

The course fee includes all supporting documentation, course materials, refreshments and lunches.

PAYMENT

Payment must be submitted at least 2 weeks before the workshops. Cheque / bank draft / local order / postal order to be made payable and send to:

CREST EVENDZ SDN BHD,
2nd Floor, MMA House,
124, Jalan Pahang,
53000 Kuala Lumpur.

BANK DETAILS

Bank Name: PUBLIC BANK BERHAD (Tiong Nam Branch)
Bank Account No.: 3-1627527-11
Account Name: CREST EVENDZ SDN BHD (922116-V)

CANCELLATION

Any cancellation must be made in writing to the organiser.

- Full refund for cancellation at least 2 weeks before date workshop;
- 50% refund for cancellation within 1 week;
- No refunds for cancellation less than 1 week or no show.

We reserve the right to change the date(s) or speaker (s) of this course, if deem fit, without prior notice. We further reserve the right to cancel the course without liability other than return of the course fee.

FOR FURTHER ENQUIRIES, PLEASE CONTACT

Ms Sayunara, Secretariat
Tel : 03-4043 3809 / 4043 9450
Fax: 03-4043 3808
Email: contact@crestevendz.com.my

REGISTRATION INFORMATION

Name: Prof/ Dr/ Mr/ Mrs/ Ms *(Please print name in block letters as you wish it to appear in the certificate)*

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IC/Passport No:

Department:

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Institution:

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Designation:

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Specialty:

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Contact Address:

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Tel: (Office)

..... (HP)

Email:

.....

Fax:

Sponsored by:

Public (Government)

Contact person:

Tel:

Private (Company Name):

Contact person:

Tel:

Self

Meal request: Vegetarian

Signature :

**Attendance is compulsory for the whole duration of workshop.*

GOOD CLINICAL PRACTICE WORKSHOP



3 - 5 April 2012

Nouvelle Hotel, Kuala Lumpur
(Kuala Lumpur-Seremban Highway,
Sungai Besi, Seri Kembangan)

CE
CREST EvendZ



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, and
2. rights, integrity and confidentiality of trial subjects are protected.



OBJECTIVES

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.



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.



COURSE CONTENTS

- Overview of ICH/GCP and Malaysian GCP
 - Clinical trials design and protocol development
 - Ethics and regulation of clinical trials
 - Role of IRB/IEC
 - Informed consent
 - Safety monitoring and reporting
 - Investigator's responsibility (study initiation, patient recruitment, CRF completion and source documents, drug accountability, role of site coordinator, essential documents, archiving at site)
 - Working with sponsor (selection of investigator/site, agreement including finance)
 - Legal aspects of clinical trials including research agreement
 - Financial aspects of clinical trials
 - Clinical trials publication*
 - GXP (good clinical data management practice, good statistical practice, good laboratory practice, good documentation practice)*
- (* optional)



WHO SHOULD PARTICIPATE?

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

