



WORKSHOP PROGRAMME

DAY 1

- * Registration
- * Overview of GCP Workshop & Clinical Trial
- * Overview of ICH-GCP and its difference from the Malaysian GCP
- * Ethics and the IRB/IEC
- Clinical Trial Protocol & Investigator's Brochure
- Informed Consent Process

DAY 2

- * Investigator's Responsibility
- * Role of Study Coordinator
- * Working with Sponsor (Includes Role of the Monitor)
- * Safety Monitoring and Reporting
- * Audit and Inspection

*All payment must be submitted **3 weeks** before the workshop. Cash / Cheque / Bank Draft / Postal Order / Local Order to be made payable to :*

UNIVERSITY MALAYA MEDICAL CENTRE

WORKSHOP PROGRAMME

DAY 3

- Specific Legal Issues in relation to Clinical Trials
- Regulation of Clinical Research in Malaysia
- Preparation of GCP Examination
Φ Multiple Choice Question Examination for GCP Certification

CERTIFICATES ARE ONLY AWARDED TO PARTICIPANTS UPON FULL ATTENDANCE AND A 80% PASS IN THE MCQ ASSESSMENT. THESE ARE MINISTRY OF HEALTH REQUIREMENTS.

Please submit the online form and payment to the correspondence address

CORRESPONDENCE ADDRESS

**CLINICAL INVESTIGATION CENTRE
13th FLOOR MAIN TOWER
UNIVERSITY MALAYA MEDICAL CENTRE
59100 KUALA LUMPUR.**

TEL : 03 - 7949 2886 / 2351

EMAIL: cic_staff@um.edu.my

WEBSITE: www.clinicalinvestigationcentre.com

NAME : PROF / ASSOC. PROF. / DR / MR / MRS / MS

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

IC NUMBER

INSTITUTION / DEPARTMENT / UNIT / PTj :

CONTACT ADDRESS :

TEL : _____

EMAIL : _____

SIGNATURE :

- Staff of UM/UMMC
- Student of UM/UMMC
- Others

MEAL REFERENCE:

- Vegetarian
- Non-Vegetarian



OBJECTIVES

- * To ensure that clinical research in Malaysia is conducted in accordance with international ethical and scientific standards.
- * To understand the principles underlying GCP and its specific rules of conduct.
- * To ensure that research subjects are protected.
- * To ensure data arising from clinical research is of high quality.

TARGET AUDIENCE

- * Clinical Researchers, Nurses, Pharmacists, Trial Monitors, Research Associates, Research Managers, Trial Statistician, Postgraduates candidates involved in clinical studies and other health professionals.

**GCP Course is held 4 times a year -
March, May, August & December.**

Kindly contact the Secretariat for further details on the workshop.

REGISTRATION FEES

- * RM 424 (Student of UM/UMMC)
- * RM 636 (Staff of UM/UMMC)
- * RM 848 (Others)

Registration fees includes course materials and refreshments.

CANCELLATION

Cancellation must be made in writing to the organizers. Full refund for cancellation done more than 3 weeks and 50% refund for cancellation done not less than 10 days. No refund for cancellation done less than 7 days and no show. We reserved the right to change the date(s) or speaker (s) of this course, if deem fit, without prior notice. We further reserved the right to cancel the course without liability other than return of the course fee.

ORGANISER :



GOOD CLINICAL PRACTICE WORKSHOP

DATE :

01-03 MARCH 2016

TIME :

0800 hrs - 1700 hrs

VENUE :

BILIK SEBAGUNA, 4TH FLOOR,
FACULTY OF MEDICINE
UNIVERSITY OF MALAYA

**Endorsed by the Ministry of Health
Malaysia**

