

**REGULATIONS FOR THE  
POSTGRADUATE DIPLOMA IN CLINICAL RESEARCH METHODOLOGY  
(PDipClinResMethodology)**

*(See also General Regulations)*

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**M.57 Admission requirements**

To be eligible for admission to the courses leading to the Postgraduate Diploma in Clinical Research Methodology, a candidate shall:

- (a) comply with the General Regulations; and
  - (b) hold a Bachelor's degree with honours or equivalent from this University or from a comparable institution accepted for this purpose.
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**M.58 Qualifying examination**

- (a) A qualifying examination may be set to test the candidate's academic ability or his or her ability to follow the course of study prescribed.
  - (b) A candidate who is required to satisfy the examiners in a qualifying examination shall not be permitted to register until he or she has satisfied the examiners in the examination.
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**M.59 Length of curriculum**

The curriculum shall extend over not less than one academic year of part-time study.

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**M.60 Completion of curriculum**

To complete the curriculum, a candidate shall:

- (a) follow instruction in the syllabuses prescribed for the course and complete satisfactorily all required written and practical work; and
  - (b) satisfy the examiners in the course by continuous assessments and by written examinations at the end of each teaching programme.
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**M.61 Examinations**

- (a) A candidate who has failed to satisfy the examiners in a course of instruction may be permitted:
  - (i) to attend a supplementary examination; or
  - (ii) to repeat the course or courses of instruction in the following academic year and to re-take the prescribed examination or examinations; or
  - (iii) to re-take the prescribed examination or examinations in the following academic year without repeating the course or courses of instruction; or
  - (iv) to undertake the study of an alternative course or courses of instruction in the following academic year and to take the prescribed examination or examinations.
- (b) A candidate who is not permitted to present himself or herself for re-examination in any subject or subjects in which he or she has failed to satisfy the examiners shall be recommended for discontinuation of studies under General Regulation G12.

**M.62 Examination results**

At the conclusion of the examination a pass list shall be published. A candidate who has shown exceptional merit in all the examinations may be awarded a mark of distinction and this mark shall be recorded on the candidate's postgraduate diploma.

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**SYLLABUS FOR THE POSTGRADUATE DIPLOMA IN CLINICAL RESEARCH METHODOLOGY**

Candidates are required to choose either of the two streams below:

**Stream I: Medical Statistics****MODULE 1 – CMED6100 Statistical Methods (20 hours)**

- Statistics in clinical practice I and II
- Measures for location and spread, normal distribution, probability and binomial distribution
- Logic in statistical inference, significance tests on the means
- Association, correlation, and simple regression analysis
- Multiple regression and analysis of variance
- Logistic regression and survival analysis
- Non-parametric methods; sample size determination

**MODULE 2 – PAED6100 Clinical Trials Research Methodology (20 hours)**

- Introduction to clinical trials
- Features of clinical trials
- Outcome measures
- Responsibilities and study documents
- Monitoring
- Ethics
- Data analysis and interpretation
- Sample size calculation
- Reports, publications and critical review
- Reviews, meta-analysis and practice

**MODULE 3 – CMED6200 Epidemiology and Critical Appraisal (20 hours)**

- Epidemiology: definitions, uses, concepts of health, disease and risk factors
- Measurements: rates, proportions, variation, validity and reliability
- Sources of information and vital statistics
- Descriptive epidemiology: person, place and time
- Study designs in epidemiology
- Screening, prevention and evaluation
- Critical appraisal, meta analysis and causality

**MODULE 4 – CTCE6010 Statistical Practice in Clinical Trials (20 hours)**

- Important concepts of medical statistics in clinical trials
- Solving of real life problems in clinical trials
- Standardisation of quality of life instruments
- Sample size determination
- Efficacy analysis
- Handling of missing values
- Safety analysis
- Brief report writing

**MODULE 5 – CTCE6020 Advanced Statistical Methods I (20 hours)**

- Data analysis using SAS/SPSS/STATA
- Analysis of variance and covariance
- Factor analysis
- Logistic regression
- Survival analysis
- Curve fitting

**MODULE 6 – CTCE6030 Advanced Epidemiological Methods (20 hours)**

- Introduction to critical appraisal
- Epidemiology survey designs and methods
- Occupational epidemiology
- Nutritional epidemiology
- Molecular and genetic epidemiology
- Randomised controlled trials
- Intervention studies
- Systematic reviews and meta-analysis

**MODULE 7 – CTCE6040 Advanced Epidemiological Methods II (20 hours)**

- Data analysis using SAS/SPSS/STATA
- Analysis for count data
- Analysis for contingency tables
- Longitudinal analysis
- Censored data analysis
- Survey data analysis

**MODULE 8 – CTCE6050 Statistical Principles for Clinical Trials (20 hours)**

- Statistical principles for clinical trials (ICH GCP E9)
- Study design and considerations
- Sample size determination
- Data analysis
- Analysis of phase I studies
- Analysis of serial measurements
- Statistical reporting of clinical trials

**MODULE 9 – CTCE6060 Critical Appraisal and Meta-analysis of Clinical Trials (20 hours)**

- Critical appraisal
- Literature search (MEDLINE, Cochrane collaboration)
- Appraising the design (common pitfalls)
- Appraising the analysis and conclusions (common pitfalls)
- Checklist - critical review of clinical trial reports
- Statistics and software for meta-analysis

**MODULE 10 – Elective Modules (20 hours)**

One module should be selected from the following existing Core Modules in Biological Systems from the Master of Medical Sciences (MMedSc) programme:

- PHYO6100 Cell Biology
- BIOC6200 Genes and Gene Functions
- PHYO6200 Concepts of Human Physiology
- PHAR6100 Principles of Drug Action
- BIOC6400 Working with Genes and Proteins
- CMED6600 Biological Basis of Common Health Problems

**Stream II: Clinical Trials Research Methodology****MODULE 1 – PAED6100 Clinical Trials Research Methodology (20 hours)**

- Introduction to clinical trials
- Features of clinical trials
- Outcome measures
- Responsibilities and study documents
- Monitoring
- Ethics
- Data analysis and interpretation
- Sample size calculation
- Reports, publications and critical review
- Reviews, meta-analysis and practice

**MODULE 2 – CTCE6070 Good Clinical Practice (GCP) and Study Site Management (20 hours)**

- Introduction and overview
- About the pharmaceutical industry
- GCP players and their roles
- Responsibilities
- Investigator's meeting and GCP training
- The clinical trial protocol
- The investigator's brochure
- Case report forms
- Study organisation and planning
- The institutional review board
- Informed consent
- Recruitment of subjects
- Laboratory investigations
- Research pharmacy

- Blinding: codes and code breaking
- Adverse event detection and reporting
- Monitoring
- Data clarification
- Study closure
- Archiving
- Audits and inspections

### **MODULE 3 – CTCE6080 Clinical Trial Protocol, Study Protocol and Quality of Life (20 hours)**

- Clinical trial protocol
- Essential trial documents
- Practical site management
- Ethics committee submissions
- Quality of life

### **MODULE 4 – CTCE6090 Ethics, Law, Contracts, Budgets and Finance (20 hours)**

- IRB and ICH GCP
- Local regulatory requirements/law
- Contracts and finance
- Practice in the preparation of a study budget
- Audits and inspections
- Fraud and misconduct
- Clinical trial role play

### **MODULE 5 – CTCE6100 Study Site Management Practice (20 hours)**

- Study site initiation visit practical
- Recruitment strategy practical
- Informed consent practical
- Clinical trial role plays

### **MODULE 6 – CMED6100 Statistical Methods (20 hours)**

- Statistics in clinical practice I and II
- Measures for location and spread, normal distribution, probability and binomial distribution
- Logic in statistical inference, significance tests on the means
- Association, correlation, and simple regression analysis
- Multiple regression and analysis of variance
- Logistic regression and survival analysis
- Non-parametric methods; sample size determination

### **MODULE 7 – CTCE6010 Statistical Practice in Clinical Trials (20 hours)**

- Important concepts of medical statistics in clinical trials
- Solving of real life problems in clinical trials
- Standardisation of quality of life instruments
- Sample size determination
- Efficacy analysis
- Handling of missing values
- Safety analysis
- Brief report writing

**MODULE 8 – CMED6200 Epidemiology and Critical Appraisal (20 hours)**

- Critical appraisal, meta analysis and causality
- Descriptive epidemiology: person, place and time
- Epidemiology: definitions, uses, concepts of health, disease and risk factors
- Measurements: rates, proportions, variation, validity and reliability
- Screening, prevention and evaluation
- Sources of information and vital statistics
- Study designs in epidemiology

**MODULE 9 – CTCE6060 Critical Appraisal and Meta-analysis of Clinical Trials (20 hours)**

- Critical appraisal
- Literature search (MEDLINE, Cochrane collaboration)
- Appraising the design (common pitfalls)
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- Checklist - critical review of clinical trial reports
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**MODULE 10 – Elective module (20 hours)**

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- PHAR6100 Principles of Drug Action
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- CMED6600 Biological Basis of Common Health Problems