REGULATIONS FOR THE POSTGRADUATE DIPLOMA IN CLINICAL RESEARCH METHODOLOGY (PDipClinResMethodology)[1]

(See also General Regulations)

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.

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.

M.59 Length of curriculum

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

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.

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.

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[1] Not offered in 2005-2006.

(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.

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)
  - Appraising the analysis and conclusions (common pitfalls)
  - Checklist - critical review of clinical trial reports
- Statistics and Software for meta-analysis

MODULE 10 – Elective module (20 hours)

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

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- 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