UNIVERSITY OF LONDON

Programme Regulations 2019–2020

Clinical Trials

MSc
PGDip
PGCert
and Individual modules

Important document – please read
This document contains important information that governs your registration, assessment and programme of study

Contents

Important information regarding the Programme Regulations

Last revised 05 May 2019

As a student registered with the University of London you are governed by the current General Regulations and Programme Regulations associated with your programme of study.

These Programme Regulations are designed and developed by the LSHTM which is responsible for the academic direction of the programme. The regulations take account of any associated arrangements at LSHTM. Programme Regulations, together with the Programme Handbook, will provide the detailed rules and guidance for your programme of study.

In addition to Programme Regulations you will have to abide by the General Regulations. These regulations apply to all students registered for a programme of study with the University of London and provide the rules governing registration and assessment on all programmes; they also indicate what you may expect on completion of your programme of study and how you may pursue a complaint, should that be necessary. Programme Regulations should be read in conjunction with the General Regulations.

The relevant General Regulations and the Programme Regulations relating to your registration with us are for the current year and not the year in which you initially registered.

On all matters where the regulations are to be interpreted, or are silent, our decision will be final.

Further information about your programme of study is outlined in the Programme Specification which is available on the relevant Courses page of the website. The Programme Specification gives a broad overview of the structure and content of the programme as well as the learning outcomes students will achieve as they progress.

Terminology

The following language is specific to the Clinical Trials programme:

Modules: Individual units of the programme are called modules. Each module is a self-contained, formally structured learning experience with a coherent and explicit set of learning outcomes and assessment criteria.

Throughout the Regulations, 'we' 'us' and 'our' mean the University of London; 'you' and 'your' mean the student, or where applicable, all students.

If you have a query about any of the programme information provided please contact us. You should use the '*ask a question*' tab in the student portal.

Changes to Clinical Trials Regulations 2019-2020

- The Scheme of Award has been amended so from 2019–2020 the Consider Distinction range has risen from 4.0 – 4.29 to 4.15 – 4.29 (see Section 8: Scheme of Award)

- Elective module PHM204 will now be assessed by two written assignments weighted on the scale 30:70 with each assignment passed with a minimum GPA of 1.00.

- Elective module EPM304 will now be assessed 100% by one written assignment passed with a minimum GPA of 2.00.

1   Structure of the programmes

[Appendix A] gives the syllabuses and course outlines.

Qualification

1.1

The following named qualifications are awarded under the Clinical Trials programme:

- MSc Clinical Trials

- Postgraduate Diploma Clinical Trials (PGDip)

- Postgraduate Certificate Clinical Trials (PGCert)

Qualification structure

1.2

The **MSc Clinical Trials** consists of:

- Four compulsory CTM1 modules

- One compulsory CTM2 module (CTM201)

- Five elective modules selected from a list of options, at least three of which must be CTM2 modules.

- One compulsory integrating module (CTM210)

1.3

The **PGDip Clinical Trials** consists of:

- Four compulsory CTM1 modules

- Four elective modules selected from a list of options, at least three of which must be CTM2 modules.

1.4

The **PGCert Clinical Trials** consists of:

- Four compulsory CTM1 modules.

1.5

The Programme Director has the right to consider the suitability of your chosen modules for the MSc or PGDip and, with stated reason, may restrict your chosen options.

1.6

If you have registered for an elective module but have not attempted the assignment or unseen written examination for that module (or have obtained a fail grade for the module overall at the first attempt), you may apply to change to another elective module. If you fail the module overall at a second attempt, you will not be allowed to change to another option. If you apply to change module(s) and have entered either element of examination for the elective module concerned, you will not be able to change until after the results have been published. Up to three elective modules only may be changed in this way. If you change your choice of elective module(s), you will be required to pay the full fee for the newly chosen module.

Individual modules

1.7

You may apply to register for one or more individual module as a stand-alone module, instead of registering for the MSc, PGDip or PGCert Clinical Trials.

1.8

The following Clinical Trials modules are available on a stand-alone basis:

CTM101	Fundamentals of clinical trials
CTM102	Basic statistics for clinical trials
CTM103	Clinical trials in practice
CTM104	Reporting and reviewing clinical trials
CTM201	Protocol development
CTM202	Trial designs
CTM203	Project management and research co-ordination
CTM204	Regulatory affairs, good clinical practice and ethics
CTM205	Data management
CTM206	Data monitoring and interim analyses
CTM207	Design and analysis of epidemiological studies
CTM208	Further statistical methods in clinical trials
CTM209	Cluster randomised trials

1.9

Some modules may require you to have prior knowledge or experience in a particular subject area before you study the module. Information on such prerequisites is given in the individual module specifications.

1.10

Successful completion by formal assessment of an individual module may be taken into account for credit towards the MSc, PGDip or PGCert. If you transfer your registration from an individual module to the MSc, PGDip or PGCert, you must meet the rules of progression for that award.

Blended learning

1.11

Blended Learning study enables you to combine distance learning study with a period of full-time study at the LSHTM. If you have registered for the MSc degree or PGDip and have been permitted to proceed to the elective modules, you may study up to two elective modules at the LSHTM in place of distance learning elective modules. There will be restrictions on the choice of elective modules available for Blended Learning study, the period of time in which the modules must be completed and the number of students who can register for Blended Learning study each year. Modules studied by Blended Learning are subject to the LSHTM regulations.

Details related to Blended Learning study are set out in the Guidelines for Blended Learning, found on the LSHTM website, under the 'How you study' tab.

2   Registration

Effective date of registration

2.1

Your effective date of registration will be 1 September (for the MSc, PGDip, PGCert and for individual modules) in the year that you initially registered. Period of registration

2.2

The minimum and maximum periods of registration, from your effective date of registration, are:

	Minimum	**Maximum**
MSc	Two years	Five years
PGDip	Two years	Five years
PGCert	One year	Five years
Individual modules	One year	Two years

2.3

If you are registered for individual modules and have been allowed to transfer from an individual module to the PGCert, PGDip or the MSc Clinical Trials, you will be given a new period of registration beginning from the year that you register on the PGCert, PGDip or MSc Clinical Trials. The maximum period of registration will be the same for all students registered for the same programme.

2.4

If you are registered for the PGCert or PGDip Clinical Trials and progress to the PGDip or MSc Clinical Trials you will not be issued a new period of registration, your registration will continue from the year that you first registered on the PGCert or PGDip Clinical Trials. The maximum period of registration will be the same for all students registered for the same programme.

3   Recognition of prior learning and credit transfer

> To be read in conjunction with the General Regulations, Section 3.

Recognition of prior learning

3.1

Where prior learning is recognised, the decision to award credit (known as Recognition of prior learning (RPL)) shall be made by an academic appointed by the Programme Director.

3.2

Applications for RPL can only be made at the point of entry to the programme and will only apply to specific modules up to a maximum number of credits.

> Further information on the RPL policy can be found on the LSHTM website.

Credit transfer

3.3

Credit transfer for a module previously studied at LSHTM may be considered for the MSc, PGDip or the PGCert. All applications for credit transfer and recognition of prior learning will be considered on a discretionary case-by-case basis.

4   Assessment for the programme

4.1

Each CTM1 module will be assessed by a timed unseen written examination.

4.2

CTM2 modules will be assessed by a timed unseen written examination and/or by one or more written assignments.

4.3

Each EPM, IDM and PHM elective module (with the exception of PHM204 and EPM304) will normally be assessed by a timed unseen written examination and a written assignment.

Elective module PHM204 will be assessed by two written assignments weighted on the scale 30:70 with each assignment passed with a minimum GPA of 1.00. Elective module EPM304 will be assessed 100% by one written assignment passed with a minimum GPA of 2.00.

4.4

CTM210, the integrating module (MSc only), will be assessed by a written integrating report.

4.5

CTM201 Protocol development will be assessed by a written assignment

4.6

Where the assessment for a module comprises an unseen written examination and/or assessed assignment(s) you are expected to submit all the assessed assignment(s) and sit the unseen written examination for a module in the same academic year.

4.7

If you attempt only one element of the assessment for a module in a given academic year you may be permitted to carry forward the grade awarded for the element attempted for one year only. The Board of Examiners will decide if you may carry over individual element grades for longer than one year.

4.8

Assignments, reports and other similar work must be your own work and must be written without the help of other people, except where you are given permission to work in a group and submit a joint piece of work. If you are working in a group you will need to submit a declaration, confirming the nature of your contribution to the submitted work.

Date of examinations

4.9

Timed written examinations normally take place in June each year.

> See General Regulations for Rules for taking written examinations

4.10

Assessed assignments and the integrating report (CTM210) must be received by the deadlines given in the requirements for the assignments and the LSHTM Student Handbook, both of which are available to registered students on the LSHTM Virtual Learning Environment. Assessed assignments and the integrating report must be submitted electronically (unless otherwise specified in the assignment guidelines).

4.11

Extensions to assignment deadlines will only be given in extenuating circumstances, and will only be considered if an application to the LSHTM Extenuating Circumstances Committee is made and has been received underline before the deadline. An assignment received after the deadline, without an agreed extension, will either be downgraded or will not be marked.

Materials and aids allowed in the examination room 4.12

Pre-programmable calculators may be used (see the 'Permitted materials list' that will accompany your 'Notice to candidates').

5 Number of attempts permitted at an examination

5.1

The maximum number of attempts permitted at any assessed assignment or unseen written examination is two. If you fail a module at the first attempt, you will be permitted to make a second attempt (resit). Extenuating circumstances may be taken into account which allow for more attempts.

5.2

If you fail an elective module which is assessed by two or more elements of assessment (unseen written examination and/or one or more written assignment(s)), you will normally have to resit at least one element of the module assessment, but may have to resit both or all elements.

5.3

If you fail an elective module which is assessed by two or more elements of assessment (unseen written examination and/or one or more assessed assignment(s)), having passed one element but not the other, you may only resit the failed element.

5.4

If you resit the assessed assignment element of a module assessment, you will be required to submit a fresh assignment in answer to a new question or assignment topic.

Integrating module

5.5

If you fail the integrating module report (CTM210) you must submit a fresh report in answer to a new question or report topic.

More details can be found about extenuating circumstances on the University of London website and in the General Regulations.

Details of the LSHTM resits and extenuating circumstances policies are available to registered students on the LSHTM Virtual Learning Environment.

6 Assessment offences and penalties

6.1

Penalties may be applied to assessed work that does not comply with the requirements given in programme materials or is not submitted by the stated deadlines. You should check the requirements given for individual assignments and the integrating report (CTM210) in the LSHTM Virtual Learning Environment. Penalties such as grade reductions (including reduction to a fail grade) may apply for work that is late, over-length or for poor academic quality or plagiarism.

7 Progression within the programme

See section 4 for method of assessment.

MSc Clinical Trials

7.1

You may choose to study and be assessed in a maximum of four CTM1 modules (not including resits). You must successfully complete a minimum of two CTM1 modules to be permitted to progress to elective module studies whilst you complete your remaining CTM1 modules. If you have successfully completed all CTM1 modules, you may choose to study and be assessed in six elective modules plus the integrating module (CTM210) in the same year. Resit attempts may be made in addition to the maximum number of modules stated above.

7.2

You are expected to study for the integrating module by submitting the integrating report (CTM210) in the same year that you take your last unseen written examinations or the following year. You must obtain the Programme Director's permission if you wish to submit the integrating report in an alternative year.

PGDip Clinical Trials

7.3

You may choose to study and be assessed in a maximum of four or a minimum of one CTM1 module(s) in any one year. You must successfully complete a minimum of two CTM1 modules to be permitted to progress to elective module studies whilst you complete your remaining CTM1 modules. You may choose to be assessed in the remaining CTM1 modules in the same year as up to four elective modules. Resit attempts may be made in addition to the maximum number of modules stated above.

Progression to elective module studies (PGDip and MSc only)

7.4

To proceed to the elective modules and integrating module (MSc only), you **must** pass two CTM1 modules. One of these modules must be CTM101 Fundamentals of Clinical Trials, which you must pass with a Grade Point Average (GPA) of at least 2.0.

PGCert Clinical Trials

7.5

If you are registered for the PGCert you may choose to study and be assessed in a maximum of four and a minimum of one CTM1 module(s) in any one year. Resit attempts may be made in addition to the maximum number of modules stated above.

8   Scheme of award

8.1

The Clinical Trials programmes are marked according to the following scale:

Qualification GPA	Classification
2.00 - 3.84	Pass
3.70 – 3.84	Consider merit
3.85 – 4.29	Merit
4.15 - 4.29	Consider distinction
4.30 - 5.00	Distinction

8.2

The Board of Examiners will make a decision on the final qualification classification once the criteria for that qualification have been met. Once you have met the criteria for the qualification on which you were registered, you will not be allowed to resit any failed modules or substitute any failed modules with other modules.

8.3

All unseen written examinations, assessed module assignments and the integrating report (CTM210) (MSc only) will be marked and grades combined according to the Assessment and Award Scheme on the LSHTM VLE.

8.4

The final outcome of the award of MSc, PGDip or PGCert is decided as set out in the Assessment and Award Scheme on the LSHTM VLE.

8.5

The final qualification classification will be based on the final qualification GPA, which will be calculated as set out in Section 8: Award Scheme.

8.6

In order to be awarded the MSc, PGDip or PGCert you must satisfy the Examiners in the assessment for all the necessary components of the qualification.

> See the LSHTM VLE for information on the Assessment and Award Scheme.

Exit qualifications

8.7

If you registered for the PGDip Clinical Trials or MSc Clinical Trials, an exit qualification (i.e. a related certificate or diploma) may be granted to you if you either do not satisfactorily complete, or withdraw early from, the programme you were registered on, provided that you have fully met the requirements for an exit qualification as detailed in the Assessment and Award Scheme.

The award of the PGCert Clinical Trials or PGDip Clinical Trials will be with effect from the year in which you successfully completed all components for that qualification.

Receiving related qualifications

8.8

If you successfully complete the formal assessment of individual modules, you may apply to receive a related qualification provided that you meet the requirements for that qualification and apply within three years of the successful completion of the relevant modules.

9   Transfer of registration

Transfer of registration from the PGCert or PGDip Clinical Trials to the MSc Clinical Trials

9.1

If you have passed two CTM1 modules (which must include CTM101 Fundamentals of Clinical Trials with a GPA of at least 2.00), you will be permitted to transfer registration to the MSc degree and advance to elective module studies.

9.2

If you have been awarded the PGCert or PGDip you must give up your certificate or diploma to us if you wish to transfer to the MSc degree.

Transfer of registration from the PGCert Clinical Trials to the PGDip Clinical Trials

9.3

You will be allowed to transfer registration to the PGDip and continue to the elective modules if you have passed two CTM1 modules (which must include CTM101 Fundamentals of Clinical Trials with a GPA of at least 2.00).

9.4

If you have been awarded the PGCert, you must give up your certificate on transfer to the PGDip as credit from the same modules cannot contribute to two different qualifications.

Progression and transfer of registration from an individual module

9.5

If you wish to progress from an individual module and register for the PGCert, PGDip or MSc Clinical Trials, you must follow the sequence of modules given within the individual programme structures and module specifications in Appendix A. Advice on the previous knowledge you are expected to have to undertake a particular module is also given within the module specifications.

Appendix A – Structure of the programmes

PGCert Clinical Trials

Four compulsory core modules (60 credits in total)

CTM101   Fundamentals of clinical trials [15 credits]

CTM102   Basic statistics for clinical trials [15 credits]

CTM103   Clinical trials in practice [15 credits] *

CTM104   Reporting and reviewing clinical trials [15 credits] *

PGDip Clinical Trials

Four compulsory core modules (60 credits in total)

CTM101   Fundamentals of clinical trials [15 credits]

CTM102   Basic statistics for clinical trials [15 credits]

CTM103   Clinical trials in practice [15 credits] *

CTM104   Reporting and reviewing clinical trials [15 credits] *

+

Four elective modules (60 credits in total) selected from the list of options below.

At least **three** of these must be selected from the CTM2 selection group. The remaining module can be selected from the EPM3, GHM2, IDM2, IDM3, IDM5 or PHM2 selection groups.

Credit for one module studied at LSHTM (blended learning study) may be allowed in place of one of the above elective modules, subject to module restrictions.

MSc Clinical Trials

Four compulsory core modules (60 credits in total)

CTM101   Fundamentals of clinical trials [15 credits]

CTM102   Basic statistics for clinical trials [15 credits]

CTM103   Clinical trials in practice [15 credits] *

CTM104   Reporting and reviewing clinical trials [15 credits] *

+

One compulsory module

CTM201   Protocol development [15 credits]

+

Five elective modules (75 credits in total) selected from the list of options below.

At least **three** of these must be selected from the CTM2 selection group. The remaining module can be selected from the EPM3, GHM2, IDM2, IDM3, IDM5 or PHM2 selection groups.

+

CTM210   A compulsory integrating module [30 credits]

Credit for up to two modules studied at LSHTM (blended learning study) may be allowed in place of up to two of the above elective modules, subject to module restrictions.

* You are advised to study CTM101 Fundamentals of clinical trials and CTM102 Basic statistics for clinical trials before studying these modules.

Elective modules

MSc and PGDip students must select from the following:

CTM2

CTM201   Protocol development [15 credits]

CTM202   Trial designs [15 credits]

CTM203   Project management and research co-ordination [15 credits]

CTM204   Regulatory affairs, good clinical practice and ethics [15 credits]

CTM205   Data management [15 credits]

CTM206   Data monitoring and interim analyses [15 credits]

CTM207   Design and analysis of epidemiological studies [15 credits]

CTM208   Further statistical methods in clinical trials [15 credits]

CTM209   Cluster randomised trials [15 credits]

EPM3

EPM301   Epidemiology of communicable diseases [15 credits]

EPM302   Modelling and the dynamics of infectious diseases [15 credits]

EPM304   Advanced statistical methods in epidemiology [15 credits]

EPM307   Global epidemiology of non-communicable diseases [15 credits]

GHM2

GHM201   Health Systems [15 credits]

IDM2

IDM201   Bacterial infections [15 credits]

IDM202   Nutrition and infection [15 credits]

IDM203   Parasitology [15 credits]

IDM204   Viral infections [15 credits]

IDM205   Healthcare-associated infections [15 credits]

IDM213   Immunology of infection and vaccines [15 credits]

IDM215   Water, sanitation and hygiene [15 credits]

IDM3

IDM301   Epidemiology and control of infectious diseases in developing countries [15 credits]

IDM5

IDM501	HIV [15 credits]
IDM502	Tuberculosis [15 credits]
IDM503	Malaria [15 credits]

PHM2

PHM201	Analytical models for decision making [15 credits]
PHM203	Economic analysis for health policy [15 credits]
PHM204	Economic evaluation [15 credits]
PHM205	Environmental epidemiology [15 credits]
PHM206	Environmental health policy [15 credits]
PHM207	Health care evaluation [15 credits]
PHM209	Globalisation and health [15 credits]
PHM210	Managing health services [15 credits]
PHM211	Medical anthropology in public health [15 credits]
PHM212	Organisational management [15 credits]
PHM213	Principles and practice of health promotion [15 credits]
PHM214	Conflict and health [15 credits]
PHM215	History and health [15 credits]
PHM216	Sexual health [15 credits]
PHM218	Applied communicable disease control [15 credits]

Important Notes:

- You must check each module specification prior to registration as modules may have specific prerequisites for study. In particular, many of the IDM modules require you to have a prior knowledge of basic biochemistry, cell biology, genetics and immunology in order to be able to work through and benefit fully from the module.

- Some modules have been withdrawn from study and replaced with updated versions. You may not register for or study some current modules if you have already been awarded credits and a grade for an equivalent withdrawn module - see Appendix A1.

- Students must not be registered for, and cannot study both, CTM208 and EPM304.

- Except with the special permission of the Programme Director, a student must study CTM208 *Further Statistical Methods in Clinical Trials* or EPM304 *Advanced Statistical Methods in Epidemiology* before studying CTM209.

- Except with the special permission of the Programme Director, a student must study CTM207 *Design and Analysis of Epidemiological Studies* before studying the EPM3 modules.

- Requests from students wishing to register for a module that is not on the lists above will be considered on an individual basis by the Programme Director.

- Some elective modules may not be available every year.

All module specifications can be found on the LSHTM website.

Appendix A1 – Module restrictions

Some modules have been withdrawn from study and replaced with updated versions. You may not register for or study the following currently available modules if you have already been awarded credits and a grade for the equivalent withdrawn module as follows:

Module currently available:	Previous module withdrawn:
EPM307 Global epidemiology of non-communicable diseases	EPM303 Epidemiology of non-communicable diseases
IDM215 Water, sanitation and hygiene	IDM210 Water and sanitation
PHM218 Applied communicable disease control	PHM202 Communicable disease control