



**UNIVERSITY
OF LONDON**

Programme Specification 2020–2021

Clinical Trials

MSc
PGDip
PGCert
Individual courses

Important document – please read



IMPORTANT NOTICE FOR 2020-2021 ACADEMIC YEAR

Alternative Assessments during the Coronavirus (COVID-19) Outbreak

In these unprecedented times, the University has and continues to respond quickly to the impact of COVID-19, which has resulted in changes to our assessment processes.

In line with our current General Regulations, the University may offer you alternative assessments where necessary. This includes holding online timed assessments in place of written examinations, which are usually held at examination centres. Please note that this statement replaces any published information relating to assessments or written examinations in any of our materials including the website. Previously published materials relating to examinations should therefore be read in conjunction with this statement.

The University of London continues to work towards supporting the academic progression of all its students. The University also continues to be mindful of the health and wellbeing of its students during this pandemic, whilst protecting the academic standards of its awards.

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Important information regarding the Programme Specification

Last revised 21 May 2020

About this document

The Programme Specification gives a broad outline of the structure and content of the programme, the entry level qualifications, as well as the learning outcomes students will achieve as they progress. Some of the information referred to in this programme specification is included in more detail on the University of London website. Where this is the case, links to the relevant webpage are included.

Where links to external organisations are provided, the University of London is not responsible for their content and does not recommend nor necessarily agree with opinions expressed and services provided at those sites.

If you have a query about any of the programme information provided, whether here or on the website, registered students should use the *Ask a question* tab in the [student portal](#) otherwise the *Contact Us* button on each webpage should be used.

Terminology

The following language is specific to the Clinical Trials programmes:

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.

Key revisions made

Programme specifications are revised annually. The Senate Postgraduate Teaching Committee of the London School of Hygiene & Tropical Medicine (LSHTM), as part of its annual review of standards, confirms the programme structure and the educational aims and learning outcomes, and advises on any development in student support.

Any changes that may impact on continuing students are listed below. For all new students, the programme and general information provided in this document is correct and accurate and will be applicable for the current year.

Significant changes made to the programme specification 2020-2021:

- The assessment for module CTM103 Clinical Trials in Practice has been revised to be assessed by one assessed assignment (100%). The minimum overall pass grade is GPA 2.00. A GPA of between 1.0-1.99 may be compensatable by higher grades in other modules (only one core module may be compensated in this way). If a student fails the AA with a grade point average of less than 1, the AA must be resat.
- The assessment for module CTM205 Data Management has been revised to be assessed by one assessed assignment (100%). The minimum overall pass grade is GPA 2.00. A GPA of between 1.0-1.99 may be compensatable by higher grades in other modules (only one elective module may be compensated in this way). If a student fails the AA with a grade point average of less than 1, the AA must be resat. A student registered for CTM205 who has completed one element of assessment but not the other prior to 1 September 2020, will be required to complete the existing method of assessment (the outstanding written examination or the assessed

assignment). A student who has failed the module overall and needs to resit, will need to complete the failed element(s) of the existing method of assessment.

Programme title and qualifications

Postgraduate Degrees of the University of London may be classified. The award certificate will indicate the level of the academic performance achieved by classifying the award. The classification of the degree will be based on the ratified marks from the completed assessments.

The classification system for the Clinical Trials programmes is as follows:

Distinction; Merit; Pass.

Specific rules for the classification of awards are given in the [Programme Regulations](#), under Scheme of Award.

Programme title

Clinical Trials

Qualification

Master of Science in Clinical Trials

Postgraduate Diploma in Clinical Trials

Postgraduate Certificate in Clinical Trials

Exit qualifications

Postgraduate Diploma in Clinical Trials

Postgraduate Certificate in Clinical Trials

An exit qualification is an intermediate qualification for which the student may not have registered at the outset but which may be awarded on completion of specific modules (or credit accumulated) in a longer programme of study, if the student leaves the programme.

Exit qualifications are awarded at the discretion of the Board of Examiners and once a student has accepted an exit qualification they will not normally be permitted to continue their study of the same qualification with the University of London.

Individual modules

There is also provision for individual modules to be studied on a stand-alone basis.

Qualification titles may be abbreviated as follows:

Master of Science in Clinical Trials - MSc

Postgraduate Diploma in Clinical Trials - PGDip

Postgraduate Certificate in Clinical Trials - PGCert

Level of the programmes

The Framework for Higher Education Qualifications in England, Wales and Northern Ireland (FHEQ) forms part of the UK Quality Code for Higher Education of the [Quality Assurance Agency for Higher Education](#) (QAA).

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The qualifications are placed at the following Levels of the Framework for Higher Education Qualifications (FHEQ):

- MSc Level 7
- PGDip Level 7
- PGCert Level 7

Individual modules are offered at Level 7.

Relevant QAA subject benchmarks

Not applicable

Awarding body

University of London

Registering bodies

University of London and London School of Hygiene & Tropical Medicine.

Academic direction

London School of Hygiene & Tropical Medicine (LSHTM)

Accreditation by professional or statutory body

Not applicable

Language of study and assessment

English

Mode of study

Flexible and online study

Blended learning

Students may also be permitted to study up to two elective modules by blended learning in place of distance learning modules. Blended learning enables a student to combine distance learning with a period of part-time study at the London School of Hygiene & Tropical Medicine. An additional fee will be payable.

Programme structures

The **MSc Clinical Trials** consists of:

- Four compulsory CTM1 modules
- One compulsory CTM2 module
- Three elective CTM2 modules selected from a list of options
- Two additional elective modules selected from a list of options
- A compulsory integrating module

The **PGDip Clinical Trials** consists of:

- Four compulsory CTM1 modules

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- Three elective CTM2 modules selected from a list of options
- One additional elective module selected from a list of options

The **PGCert Clinical Trials** consists of:

- Four compulsory CTM1 modules

Full details of the Scheme of Award are included in the [Programme Regulations](#).

Maximum and minimum periods of registration

The maximum and minimum period of registration, from a student's 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

Study materials are made available at the start of the academic year after registration and on payment of the applicable fee.

Credit value of modules

Further information about the credit systems used by universities in the UK and Europe is provided by the [Quality Assurance Agency](#) and the [European Credit Transfer and Accumulation System](#).

Where credits are assigned to each module of a programme, credit indicates the amount of learning carried out in terms of the notional number of study hours needed, and the specified Framework for Higher Education Qualifications in England (FHEQ) credit level indicates the depth, complexity and intellectual demand of learning involved. The details below indicate the UK credits and the European Credit Transfer and Accumulation System (ECTS) values.

For the Clinical Trials programme, credits are assigned to the modules as follows:

- 15 UK credits or 7.5 ECTS for each module at FHEQ level 7;
- 30 UK credits or 15 ECTS for the integrating module at FHEQ level 7.

Each qualification equates to the following number of credits:

- MSc Clinical Trials - 180 UK credits or 90 ECTS credits
- PGDip Clinical Trials - 120 UK credits or 60 ECTS credits
- PGCert Clinical Trials - 60 UK credits or 30 ECTS credits

One UK credit equates to a notional ten hours of study.

Recognition of Prior Learning

Recognition of prior learning is a generic term for the process by which we recognise and, where appropriate, award credit for learning that has taken place at an institution other than the University of London.

See the [General Regulations](#) (Section 3) and Programme Regulations for more rules relating to prior learning.

For the Clinical Trials programmes the University of London may recognise your prior learning and allow you exemption from a compulsory module towards the qualification. This can only be considered at the point of application for the programme.

Further information on recognition of prior learning is on the [website](#).

Entrance requirements

Postgraduate entrance requirements

Applicants must submit an application in line with the procedures and deadlines set out on the University of London [website](#).

All details of the programme specific entry requirements are given on the programme page, under the [Requirements](#) tab.

English language requirements

Applicants must satisfy the English language requirements for the programme. These are set out in detail on the programme page under the [Requirements](#) tab.

Where an applicant does not meet the prescribed English language proficiency requirements but believes that they can demonstrate the requisite proficiency for admission the University may, at its discretion, consider the application.

Computer and Internet access requirements

Students will require regular access to a computer (or mobile device*) with an internet connection to use the University of London website and the Student Portal to access the LSHTM's online learning site where many of the programme's study resources are located. A webcam may be required in the event that online timed assessments (if offered) are proctored, and in such a case, it is a student's responsibility to ensure that they have a webcam.

The computer should have at least the following minimum specification:

- Processor
 - a minimum: Pentium 4 or newer with SSE2
 - recommended: 2nd-generation Core i5 (2GHz+), 3rd/4th-generation Core i5
- Memory (RAM): 2GB or higher
- Hard disk space: 20GB, 5 GB free.

- CD/DVD-ROM drive (some non-CT modules only)
- Operating System: (PC) Windows Vista, (Mac) OS X10.9
- Screen Resolution: 24-bit Truecolor, known as "millions of colors" on Macintosh systems.
 - For the standard design, it is recommend 1024x768px resolution.
 - For the design intended to be viewable on mobile devices it should work on screens of 320px width and above.
- Internet Connection: Email and Web access - essential.
- It is recommended that users run the latest version of Firefox.
- Cable, broadband, T1, T3 highly recommended to use Collaborate / view videos
- Printer: Either laser or ink jet.
- And the following applications installed:
 - MS Word (version compatible with .doc and .docx);
 - MS Excel;
 - a pdf reader (e.g. Adobe Acrobat).

A sound card and headset (recommended), or sound card, speakers and microphone will also be useful.

** Please note: full mobile access is not available for all modules.*

Additional requirements

- Students will need to use a calculator.

Students with access requirements

The University of London welcomes applications from disabled students and/or those who have access requirements. The University will make every effort to provide reasonable adjustments to enable those with a disability, learning difficulty or specific access requirements to have the same opportunity as all other students to successfully complete their studies.

The University is committed to managing the application procedure and the programme itself to ensure that services are accessible for all students and that an inclusive environment is created. Students with a disability or others who may need special arrangements to assist in taking examinations (such as separate room or special aids) should complete the relevant section of the application form, or contact the [Inclusive Practice Manager](#). Requests are considered by a University panel, whose purpose is to ensure that students with disabilities and/or access requirements are neither advantaged nor disadvantaged by such arrangements when compared with other students. These considerations remain separate from the academic selection processes.

For further information, see the [Inclusive Practice Policy](#).

Sources of funding and scholarships

Information about potential sources of funding and scholarships is updated annually and where available is included in the prospectus web pages.

For further information see the [website](#)

Educational aims and learning outcomes of the programmes

Clinical trials are designed to test new methods of screening, prevention, diagnosis and treatment of disease and how well these treatments or interventions will work in people. These programmes will give students a theoretical and practical understanding of the issues involved in the design, conduct, analysis and interpretation of clinical trials.

The programmes will be relevant both for those wishing to gain an overall understanding of clinical trials before moving into the field, and for those who have general or specialist experience in this area and aim to broaden their role in the design, management, analysis and reporting of clinical trials. These programmes are suitable for students working in high, middle and low income countries.

The main educational aim of these programmes is to offer a challenging, flexible scheme of study invigorated by research, which advances students' ability to develop academic and practical insights into the use of clinical trials. Students will be encouraged to develop a range of transferable and subject specific expertise using their initiative and thinking out problems themselves.

The programmes aim to equip students with the skills, knowledge and understanding to work effectively in the field of clinical trials

The intended learning outcomes of the programmes are as follows:

Knowledge, understanding, intellectual and cognitive

Students will be able to:

- Demonstrate knowledge of trial design, delivery and assessment;
- Explore theoretical and practical issues in the design and implementation of clinical trials;
- Develop skills in handling and presenting clinical trial data;
- Critically evaluate key aspects of how clinical trials are reviewed and reported.

Transferable skills

Students will be able to:

- Create, innovate, and problem solve in a range of situations;
- Communicate and discuss effectively in a variety of contexts;
- Synthesise ideas and scrutinise information in critical, evaluative and analytical ways;
- Manage their own learning, including working effectively to deadlines.

Students who pass the CTM1 core modules will have the essential introduction to a variety of methods, approaches and concepts in clinical trials. They will have a sound grasp of the fundamentals of clinical trials and will understand the key principles of scientific analysis, writing and review.

MSc students

MSc students will study modules which build on the foundations and will also choose from a range of options which further knowledge in specific areas. These students will expand knowledge on how clinical trials are planned, carried out, analysed and reported. MSc students will also apply the skills they have learnt to a particular problem and produce a written report.

Learning, teaching and assessment strategies

The programmes are primarily delivered using the internet. All the learning materials (with some minor module-specific exceptions) and study activities for the programme are available online. The online learning environment includes ‘try it yourself’ questions with hints and feedback; animations, interactive diagrams and tables; and vibrant graphics. This student-friendly format enables targeted information searches and promotes a learner-led forum for comprehension, analysis and the generation of original and thoughtful assignments. Some e-books are provided for supplementary reading and a list of other supplementary texts is also provided.

The students may submit formative assignments which do not count towards the final qualification). These are marked by tutors who will provide feedback. These pave the way for examinations and for the formal assessed assignments (in some modules) which are graded and count towards accreditation.

The tutors also supervise web-based discussion groups. Students will be able to engage in dialogue, and develop and negotiate conclusions with others, which are key components in the acquisition of knowledge, understanding and transferable skills. Students may also communicate with fellow learners on a free web-based student to student network.

Advice and practical information such as study techniques, planning, preparation for assessment is available in the LSHTM programme-specific Student Handbook (which is available online to students after registration) and the [Academic Writing Handbook](#). Students manage their own learning and study schedule, but advice can be sought from the support team at any stage of the academic year.

With the exception of modules CTM103 Clinical Trials in Practice, CTM201 Protocol Development, CTM203 Project Management and Research Coordination, CTM205 Data Management, CTM206 Data Monitoring and Interim Analyses, CTM209 Cluster Randomised Trials and CTM210 the integrating module, each module is assessed by unseen written examination which will consist of questions structured to allow students to demonstrate that they have acquired the appropriate knowledge and understanding. The way that students manage data, solve problems, evaluate ideas and the organisational skills used to structure answers allows the standard of intellectual and transferable skills to be assessed.

Some modules are assessed by written assignments as well as, or instead of, by written examination. These assignments are generally scenario-led. The aim is to ensure that students can apply their “book-learning” to real-life situations. These allow a student to do a more in-depth study of the topic. Students demonstrate the skills associated with data collection, analysis, selection, reasoning and producing a well-reasoned assignment.

Protocol development (compulsory for MSc) is assessed by contributions to group work and a written assignment. This allows students to give a practical demonstration of their understanding of how trial protocols are constructed and how they can be critically analysed.

The integrating module (MSc only) brings material together from the different Clinical Trials modules and is generally taken at the time when students attempt the last of the written papers for the MSc or in the following year. It assesses not only knowledge and understanding of the modules studied, but also understanding of how the topics intersect. MSc students will submit an integrating report which will not only assess their knowledge but also their ability to plan, reason and produce a well-structured report.

Assessment criteria for the programme will show the level at which these skills have been achieved.

Assessment methods

Each compulsory **core** CTM1 module (MSc, PGDip and PGCert) will be assessed by one two-hour and fifteen minute unseen written examination with the exception of CTM103 Clinical Trials in Practice which will be assessed by one assessed assignment

CTM202, CTM204, CTM207 and CMT208 modules will be assessed by one two-hour and fifteen minute unseen written examination and written assignment(s), weighted on the scale 80:20. CTM201 and CTM205 will be assessed by one written assignment only. Modules CTM203, CTM206 and CTM209 will be assessed by two assignments for each module.

The integrating module (MSc only) on a specified topic will be assessed by the submission of a written integrating report. This module will normally be taken in the same year that students attempt the last of the written examinations.

The written examinations take place on one occasion each year, normally commencing in June. These are held at established centres worldwide.

Individual modules

A student may choose whether or not to be formally assessed in the credit bearing individual modules for which they are registered. Students who choose to be formally assessed will be examined in the same way as students studying for a full qualification.

Full details of the dates of all examinations are available on the website .
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Student support and guidance

The following summarises the support and guidance available to students:

- [Student Guide](#): This provides information which is common to all students and gives guidance on a range of issues from the start of a student's relationship with the University of London through to their graduation.
- [Programme Regulations](#)
- [The Online Library](#): This provides a range of full-text, multidisciplinary databases where journal articles, book reviews and reports can be found..
- University of London library: Registered students may use the resources located within the Senate House library.
- A University of London email account and web area for personal information management.

Support and guidance from LSHTM

- The LSHTM Moodle Virtual Learning Environment (VLE). This gives online access to the main module materials, module discussion forums, information on assignments, links to essential and recommended readings (where available), past examination papers and examiner reports, and study skills' resources.
- [LSHTM online library](#) resources.
- Student support staff are available to offer help and advice on administrative matters. Programme Directors can also be contacted for personal advice e.g. planning studies, advice on elective module options. Communication may either be via the online 'Student Support Help' discussion forum on Moodle or by email, and sometimes by Skype if needed.
- Each module has at least one Module Organiser (MO) and a team of tutors assigned to it. The tutor team provides academic support to those studying on specific modules, in the following ways:
 - assisting in interpreting and understanding the material presented by answering queries on the online discussion forums
 - grading and providing written feedback on the assignments
 - offering some real-time 'webinars' in which students are encouraged to participate.
- The tutors are specialists in their subject area.
- An LSHTM programme-specific Student Handbook, available on the LSHTM Moodle site, provides guidance on all aspects of the programme. It includes background information about the programme, advice on getting started, studying as a distance learner and organising study time, a description of the resources and programme materials available and how to access them, networking and support issues, procedures for assessment and examinations (including programme deadlines).
- Students are encouraged to exchange ideas with other students on the programme and to organise mutual support via email or other forms of communication. An online discussion forum 'Student Cafe' is available within the LSHTM Moodle site which is accessible to students only, while individual contact details can be made available through the Student Network Directory (subject to student consent). This contains contact details of other students on the programme so students can build up their own network if they wish (for example, to organise study groups).

Quality evaluation and enhancement

The University of London delivers the majority of its flexible and distance learning programmes through a collaboration between the University of London Worldwide and member institutions of the University of London. However some of the flexible and distance learning programmes draw solely on academic input from the University of London, and are delivered without academic lead by a member institutions. The policies, partnerships (where applicable) and quality assurance mechanisms applicable for the programmes are defined in the following key documents: The Quality Framework, the [Quality Assurance Schedules](#).

[Guidelines for Examinations](#), [General Regulations](#) and, for each programme, [programme specific regulations](#).

Awards standards

All University of London qualifications have to align with the [Frameworks for Higher Education Qualifications of UK Degree-Awarding Bodies](#) to assure appropriate standards for each qualification. In addition, every programme that is developed by a member institution of the University of London (or a consortium with representation by more than one member institution) will be developed to the same standard as would be applied within the institution concerned. Proportionate and robust approval procedures, including external scrutiny and student engagement are in place for all programmes. Learning materials are written and all assessments are set and marked by academic staff who are required to apply the University's academic standards.

Review and evaluation mechanisms

Some of the key mechanisms in place to assure the standards of all University of London qualifications and the quality of the student experience, include:

- Annual programme reports: produced for all programmes in order to review and enhance the provision and to plan ahead;
- Independent external examiners: submit reports every year to confirm that a programme has been assessed properly and meets the appropriate academic standards;
- Annual student information statistics: prepared for all systematic reporting within the University of London;
- Periodic programme reviews: carried out every 4-6 years to review how a programme has developed over time and to make sure that it remains current and up-to-date.

Improvements are made as necessary to ensure that systems remain effective and rigorous.

Student feedback and engagement

The principal channel for collecting feedback from students is the Student Experience Survey. Carried out every two years, this collects feedback from the student body on a range of topics relating to the student lifecycle. The results are analysed externally and then considered in a number of different ways, including by the programme team, principal committees and the senior leadership team. Details of any resulting actions taken are published on the Virtual Learning Environment and the Student Portal.

On completion of their programme of study students will be invited to take a survey that seeks to measure what they have gained from their studies. Additional survey activity may also be conducted from time to time, including a request for module specific feedback, which subsequently feeds into the annual module review process. VLEs also provide the opportunity for informal feedback and discussion.

There are also opportunities for students to get involved in governance. An undergraduate and postgraduate student member is appointed by the University to the majority of committees through an annual appointment round. Some programmes also recruit student members at the programme level. Students are frequently invited to take part in quality review processes such as Periodic Programme Reviews, Programme approval, Thematic Reviews, MOOC review panels and ad hoc focus groups. Opportunities such as these are

advertised through social media and on the website. More information can be found on the [website](#).

Students can also apply to join the Student Voice Group, which meets four times a year to consider initiatives for enhancing student experience. Notes from these meetings are published on the Student Portal.

After graduation

Further study

Successful completion of the programme may serve as preparation for students who wish to go on to take further study in the subject area.

Graduate employment routes

The programmes will be relevant both for those wishing to move into design, conduct, analysis and interpretation of clinical trials and for those who aim to broaden their role in the evaluation of interventions for screening, prevention, diagnosis and treatment of disease in people.

The Alumni Community

Upon finishing a course of study, graduates automatically become part of the University of London alumni community, a diverse global network of more than one million graduates in over 180 countries, providing lifelong links to the University and to each other.

Alumni are encouraged to keep in touch after they graduate and to become active members of the alumni community; in return they receive a number of benefits and services, including an extensive programme of events and engagement opportunities.

More information is available on the alumni [webpage](#).

Follow the alumni community on social media: Facebook , Instagram , LinkedIn
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