UNIVERSITY OF LONDON

Programme Specification 2018–2019

Clinical Trials

MSc
PGDip
PGCert
Short courses

Important document – please read

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Important information regarding the Programme Specification

Last revised 15 June 2018

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 2018-2019:

- PHM210 Managing Health Services is no longer being withdrawn.

- From 2018-2019, students studying modules CTM203, CTM206 and CTM209 will no longer be assessed by a written examination and an assessed assignment. Instead, students will be required to submit two assessed assignments for each module.

Title and name of awards

Programme name

Clinical Trials

Award titles

Students are registered on one of the following:

- Master of Science Clinical Trials (MSc)

- Postgraduate Diploma Clinical Trials (PGDip)

- Postgraduate Certificate Clinical Trials (PGCert)

Exit awards

- Postgraduate Diploma Clinical Trials (PGDip)

- Postgraduate Certificate Clinical Trials (PGCert)

Individual modules

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

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).

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

- MSc Clinical Trials Level 7

- PGDip Clinical Trials Level 7

- PGCert Clinical Trials Level 7

Individual modules are offered at Level 7.

Awarding body

University of London

Registering bodies

University of London and London School of Hygiene & Tropical Medicine
www.london.ac.uk;

www.lshtm.ac.uk

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.

> More details about blended learning can be found in the [Programme Regulations](#).

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

- 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

Individual modules

A selection of modules are available to be studied on an individual basis. You may take as many modules as you wish without registering for an award within the Clinical Trials programme.

> Full details of the modules available are included in the [Programme Regulations.](#)

Exit awards

Students who for academic or personal reasons are unable to complete the 180 credits required for the MSc award, or the 120 credits for the PGDip award may exit with the successful completion of 120 or 60 credits and be awarded a PGDip or PGCert respectively,

provided they fulfil the relevant criteria. Exit awards are granted at the discretion of the Board of Examiners and once a student has accepted an exit award they will not be permitted to continue their study of the same award with the University of London, unless they return the exit award prior to continuing their studies.

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 Clinical Trials	Two years	Five years
PGDip Clinical Trials	Two years	Five years
PGCert Clinical Trials	One year	Five years
Individual modules	One year	Two years

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

Credit value of modules

Further information about the credit systems used by universities in the UK and Europe is available in:

The Higher Education Credit Framework for England,
http://www.qaa.ac.uk/en/Publications/Documents/Academic-Credit-Framework.pdf

The Framework for Higher Education Qualifications in England,
http://www.qaa.ac.uk/en/Publications/Documents/Framework-Higher-Education-Qualifications-08.pdf

The European Credit Transfer and Accumulation System (ECTS),
http://ec.europa.eu/education/tools/ects_en.htm

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 for each compulsory and elective module;

- 30 UK credits for the integrating module.

Each award 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

This programme allows for recognition of prior learning.

> Details on how to apply for recognition of prior learning can be found on our website. See the General Regulations (Section 3) and Programme Regulations for further information.

Entrance requirements

Postgraduate entrance requirements

Full details of entrance requirements are provided on the website under the Requirements section.

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

English language requirements

Applicants must satisfy the English language requirements for the programme.

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.

> Detailed information on the English language requirement tests are given on the LSHTM website.

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.

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): 1GB or higher
- Hard disk space: 20GB, 5 GB free.
- DVD-ROM drive
- 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. 56K modem or higher.
- 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.

- Software:
  - 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.

- A headset/microphone may be required to participate in "real time" online discussions.

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 information, please see http://www.lshtm.ac.uk/study/funding/ and https://london.ac.uk/applications/funding-your-study

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:

- develop knowledge and understanding of the key decisions surrounding the design, delivery and assessment of clinical trials;

- encourage independent critical and evaluative skills that can be used to apply independent scientific judgment;

- teach students how to apply the conceptual and practical tools needed to initiate clinical trials;

- facilitate self-development into professionally organised and interactive individuals by practising skills of selection, assimilation and communication.

The learning outcomes of the programmes are as follows:

Knowledge, understanding, intellectual and cognitive

Students will be able to:

- demonstrate understanding of issues associated with clinical trial methodology including design, delivery and assessment;

- appreciate the practical and management issues in the design and implementation of clinical trials including ethical issues, quality assurance and control;

- demonstrate basic skills in handling clinical trial data and presenting quantitative results;

- evaluate critically all aspects of how clinical trials are reviewed and reported;

- begin to develop detailed protocols for clinical trials (specific modules only);

- begin to develop appropriate designs for clinical trials (specific modules only);

- evaluate critically a completed trial or conduct further analysis of trials data and comment on results (specific modules only);

- produce a well-structured and well-written report (specific modules only).

Transferable skills

Students will be able to:

- use creativity, innovation, and problem solving skills in a range of situations;

- use fluent and effective communication and discussion skills in a written context;

- have a capacity to handle 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 award). 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 module CTM201 Protocol Development 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.

Most CTM2 modules (MSc) will be assessed by one two-hour and fifteen minute unseen written examination and written assignment(s), weighted on the scale 80:20. The compulsory CTM2 module, CTM201 *Protocol development* will be assessed by a written assignment only.

From 2018-19, 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 award.

Full details of the dates of all examinations are available on the website.

Student support and guidance

The following summarises the support and guidance available to students:

- University of London Student Guide: This provides information which is common to all students and gives information about matters of importance from the start of a student's relationship with the University of London through to their graduation.

- Programme Regulations

- The University of London Online Library: This provides access to a range of full-text, multidisciplinary databases where journal articles, book reviews and reports can be found.

- Senate House Library: Registered students may use the resources located within the University of London Senate House library

- Employability skills module – guidance on how to manage your career in the future, available through the VLE.

- A University of London email account and web area for personal information management.

Support and guidance from LSHTM

- The LSHTM Virtual Learning Environment (Moodle). This gives online access to the main module materials (which may also be sent in hard copy, depending on the module), 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.

- Distance Learning Office 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:

  o assisting in interpreting and understanding the material presented by answering queries on the online discussion forums

  o grading and providing written feedback on the assignments

  o 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 collaborates with the member institutions to deliver the University of London programmes. The policies, partnerships and systems are defined within the key documents: The Quality Framework, the Quality Assurance Schedules, Guidelines for Examinations, General Regulations and programme specific regulations for each programme.

Parity of award standards

Every programme of study is developed and approved by an academic institution of the University of London, or a consortium with representation by more than one academic institution to the same standards and requirements as would be applied in the institution/s concerned.

Learning materials are written and examinations are set and marked by academic staff who are required to apply the University's academic standards.

Review and evaluation mechanisms

Procedures are in place to assure the standards of the award and the quality of the student experience, which include programme development, delivery, management, systematic monitoring and ongoing review and enhancement of all programmes. Improvements are made as necessary to ensure that systems remain effective and rigorous.

- Annual programme reports are produced for all programmes in order to review and enhance the provision and to plan ahead;

- Every year independent external examiners submit reports to confirm that the programmes have been assessed properly and meet the appropriate academic standards;

- Annual student information statistics are produced and are referenced in all systematic reporting within the University of London;

- Periodic programme reviews are 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.

Student feedback mechanisms

The Student Experience Survey, carried out every two years, collects feedback from the student body on a range of topics relating to the student lifecycle. The results are considered in a number of different ways, including by the Pro-Vice Chancellor, the programme team, principal committees and departments at the University of London responsible for the different aspects of the student experience. Once the findings have been considered in detail, responses are published from both the University of London and from the individual Programme Directors.

Additional survey activity may also be conducted from time to time through the student portal, by email or from the programme team.

VLEs also provide the opportunity for informal feedback and discussion.

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 at https://london.ac.uk/current-students/getting-involved

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 Network

Upon graduation, students automatically become members of the University of London Alumni Network, a diverse community of over 100,000 alumni in more than 180 countries. The Alumni Network can provide past students with lifelong links to the University of London and each other. Benefits include social and networking events, access to local groups, a bi-annual magazine, social networking groups, and the opportunity to become an Alumni Ambassador for the University of London.

The London School of Hygiene and Tropical Medicine also welcomes former students to its alumni association and this is free to join.

> For further information, please see https://london.ac.uk/alumni,
> www.facebook.com/londonualumni, www.instagram.com/_londonu,
> https://www.linkedin.com/school/university-of-london/
> and also
> http://www.lshtm.ac.uk/alumni/