PROGRAMME SPECIFICATION

1. Overview

Programme Title	PGDip Clinical Trials
Academic Year	2027-28
Cohort Entry Points	Annually in October
Programme Director(s)	Claire Snowdon, Edward Stanhope, and Charles Opondo
Awarding Body	London School of Hygiene & Tropical Medicine
Teaching Institution	London School of Hygiene & Tropical Medicine
Faculty	Epidemiology and Population Health
Length of Programme	Minimum 24 months Maximum 60 months
Mode of Delivery	Distance Learning
Maximum period of registration	5 years
Language of Study	English
Entry Requirements	Please refer to the specific programme entry requirements here.
Award Titles	Postgraduate Diploma in Clinical Trials Exit awards: Postgraduate Certificate in Clinical Trials (60 credits)
Total Credits	**CATS:** 120 **ECTS:** 60
Accreditation by Professional Statutory and Regulatory Body	N/A
Relevant PGT QAA Benchmark Statement and/or	N/A

other external/internal reference points	
Framework for Higher Education Qualifications Level (FHEQ)	Level 7
Re-sit Policy	https://www.lshtm.ac.uk/sites/default/files/academic-manual-chapter-08b.pdf
Extenuating Circumstances Policy	https://www.lshtm.ac.uk/sites/default/files/academic-manual-chapter-07.pdf
Date of Introduction of Programme	First programme cohort enrolled in 2006 Programme Periodic Review was last undertaken in June 2024

2. Programme Description, Aims & Learning Outcomes

Programme Description
Clinical trials are essential for evaluating new methods of screening, prevention, diagnosis and treatment and for determining how well these treatments or interventions will work in real-world populations. This PGDip programme will provide students with a thorough appreciation for both the fundamental and specialised aspects of clinical trials. The programme offers a comprehensive curriculum covering key aspects of clinical trial methodology, including protocol development, regulatory and ethical considerations, statistical analysis, data management, and reporting. The programme is relevant for individuals new to clinical trials who wish to gain a strong foundational understanding before entering the field. It is equally well-suited for those already working in clinical trials who wish to formalise and gain recognition for their existing knowledge and skills, as well as for professionals seeking to broaden their expertise and career opportunities within the field. The programme is globally relevant and suitable for students working in high-, middle- and low-income countries. Graduates will be well prepared for careers in academia, healthcare, industry, regulatory agencies, and non-governmental organisations, with potential roles

including Chief and principal investigators, clinical trial manager/coordinator, data manager, trial statistician, among other specialist clinical trial roles.

Educational aims of the programme

The main educational aim of this programme is to offer a challenging, flexible scheme of study underpinned 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 programme aims to equip students with thorough theoretical knowledge and practical skills in the design, conduct, analysis, and interpretation of clinical trials, enabling them to contribute effectively to the development, management, and evaluation of high-quality clinical research across diverse healthcare settings globally.

Programme Learning Outcomes

The intended learning outcomes of the programmes are as follows:

Knowledge, understanding, intellectual and cognitive

Students will be able to:

1. Apply advanced knowledge of trial design, delivery and assessment;
2. Analyse complex issues in the theoretical and practical issues in the design and implementation of clinical trials;
3. Apply advanced skills in handling and presenting clinical trial data;
4. Justify key aspects of how clinical trials are reviewed and reported.

Transferable skills

Students will be able to:

1. Formulate proposals that integrate creative, innovative, and problem solving approaches in a range of trial situations;
2. Communicate and discuss effectively in a variety of contexts;
3. Apply critical, evaluative and analytical approaches to synthesising complex clinical trial information;
4. Plan and execute 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.

PGDip Clinical Trials

Upon successful completion of the PGDip Clinical Trials programme, students will develop a thorough appreciation for both the fundamental and specialised aspects of clinical trials. Students will gain practical insight into the operational aspects of running clinical trials and will be able to assess the quality and transparency of trial reporting. They will also be able to apply basic statistical methods to interpret trial data and critically evaluate clinical trial reports. In addition to this foundational knowledge, students will acquire specialist expertise in four elective areas, enabling them to tailor their learning to align with their career aspirations and develop advanced skills relevant to their chosen clinical trials focus. This qualification will prepare students for more advanced roles in clinical trial design, management, and analysis.

Teaching and Learning Strategy

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 and articles are provided for supplementary reading and a list of other supplementary material is also provided.

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.

Assessment Strategy

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.

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*, and CTM209 *Cluster Randomised Trials* each module is assessed by a time-limited examination (in part or fully) 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

Assessment criteria for the programme take into account the level at which these skills have been achieved 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 time-limited 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 is assessed by contributions to group work and one 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.

Data Monitoring and Interim Analyses is also assessed by contributions to group work and two assignments. The groupwork and related assignment allow students to give a practical demonstration of their understanding of how data monitoring committees work to make recommendations.

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

3. Programme Structure and features, modules, credit assignment and award requirements:

The PGDip Clinical Trials consists of:

- Four compulsory CTM1 modules
  AND
- Four elective CTM2 modules selected from a list of options
  OR three elective CTM2 modules selected from a list of options + one additional cross programme elective module selected from a list of options

PGDip	Compulsory Modules	Elective Modules	Total Credits
Credits	60	60	120

Module information is correct at the time of publication, but minor amendments may be made subject to approval as detailed in Chapter 3 of the LSHTM Academic Manual. Elective option modules listed are indicative and may change from year to year. https://www.lshtm.ac.uk/study/courses/changes-courses

Module Code	Module Title	Module Type	Credits (CATS)
CTM101	Fundamentals of Clinical Trials	Compulsory	15
TBD	Statistics for Epidemiology and Population Health 1	Compulsory	15
CTM103	Clinical Trials in Practice	Compulsory	15
CTM104	Reporting and Reviewing Clinical Trials	Compulsory	15
CTM201	Protocol Development	Elective	15
CTM202	Trial Designs	Elective	15
CTM203	Project management and research co-ordination	Elective	15
CTM204	Regulatory affairs, good clinical practice and ethics	Elective	15
CTM205	Data management	Elective	15
CTM206	Data monitoring and interim analyses	Elective	15
CTM208	Further statistical methods in clinical trials	Elective	15
CTM209	Design and Analysis of Cluster Randomised and Stepped Wedge Trials	Elective	15

CTM211	Introduction to Pharmacovigilance	Elective	15
TBD	Concepts in Epidemiology	Elective	15

Students wishing to study a cross programme module can find out more here: https://www.lshtm.ac.uk/study/courses/modules/distance-learning-modules/module-specifications

Contact time

Student contact time refers to the tutor-mediated time allocated to teaching, provision of guidance and feedback to students. In the context of distance learning this encompasses where tutors are available for one-to-one and group discussions online, interaction by email, discussion forums, and project supervision. Module contact time will be defined in the individual module specifications and provided to students at the start of their programme.
This definition is based on the one provided by the Quality Assurance Agency for Higher Education (QAA) Explaining contact hours (2011). Student contact time, together with time allocated for independent study and assessment, determines the total student study hours for a module or programme. Although there are separate hours allocated for each of these activities, they should always be clearly linked together to support effective learning.

The London School of Hygiene and Tropical Medicine (LSHTM) defines high quality contact time as structured, focused, purposeful and interactive.