# PROGRAMME SPECIFICATION

## 1. Overview

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| **Programme Title** | PGCert Clinical Trials |
| **Academic Year** | 2027-28 |
| **Cohort Entry Points** | Annually in October |
| **Programme Director** | 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 12 months<br>Maximum 60 months |
| **Mode of Delivery** | Distance Learning |
| **Maximum period of registration** | 5 years |
| **Language of Study** | English |
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| **Entry Requirements** | Please refer to the specific programme entry requirements here. |
| **Award Titles** | Postgraduate Certificate in Clinical Trials |
| **Total Credits** | **CATS:** 60<br>**ECTS:** 30 |
| **Accreditation by Professional Statutory and Regulatory Body** | N/A |
| **Relevant PGT QAA Benchmark Statement and/or other** | N/A |

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| **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** | Programme Periodic Review was last undertaken in June 2024 |

## 2. Programme Description, Aims & Learning Outcomes

| **Programme Description** |
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| 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 PGCert programme will provide students with a sound theoretical and practical understanding of the issues involved in the design, conduct, analysis and interpretation of clinical trials.<br><br>The programme offers the foundations of clinical trial methodology, including study design, logistics, statistical analysis, and reporting.<br><br>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. The programme is globally relevant and suitable for students working in high-, middle- and low-income countries.<br><br>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 sound 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. Demonstrate a critical awareness of trial design, delivery and assessment;
2. Explore theoretical and practical issues in the design and implementation of clinical trials;
3. Identify and apply appropriate approaches to handling and presenting clinical trial data;
4. Critically appraise key aspects of how clinical trials are reviewed and reported.

**Transferable skills**

Students will be able to:

1. Demonstrate a critical awareness of create, innovate, and problem solve in a range of situations;
2. Communicate and discuss effectively in a variety of contexts;
3. Systematically evaluate information and critically appraise ideas in analytical and evaluative ways;
4. Understand and 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.

**PGCert Clinical Trials**

Upon successful completion of the PGCert Clinical Trials programme, students will demonstrate a sound understanding of the fundamental concepts and principles of clinical trials, including their design, conduct, and analysis. 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.

**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*, 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.

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

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

The PGCert Clinical Trials consists of:

- Four compulsory CTM1 modules

| PGCert | Compulsory Modules | Elective Modules | Total Credits |
|---|---|---|---|
| Credits | 60 | 0 | 60 |

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 |

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| 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 |

**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.