## Module Specification

### GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Module name</th>
<th>Fundamentals of Clinical Trials</th>
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<tbody>
<tr>
<td>Module code</td>
<td>CTM101</td>
</tr>
<tr>
<td>Module Organiser(s)</td>
<td>Niveditha Devasenapathy, Susana Scott, Taemi Kawahara</td>
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<tr>
<td>Contact email</td>
<td>The LSHTM distance learning programmes and modules are run in collaboration with the University of London (UoL). Enquiries may be made via their Student Advice Centre at: general <a href="https://london.ac.uk/contact-us">https://london.ac.uk/contact-us</a> email-form click here (Enquiries from face-to-face i.e. London-based LSHTM MSc or research students regarding study of DL modules should be emailed to <a href="mailto:CTsupport@lshtm.ac.uk">CTsupport@lshtm.ac.uk</a>)</td>
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**Home Faculty**  
Epidemiology and Population Health  
London School of Hygiene & Tropical Medicine  
http://www.lshtm.ac.uk/eph/  

**Level**  
This module is at Level 7 (postgraduate Masters level) of the QAA Framework for Higher Education Qualifications in England, Wales & Northern Ireland (FHEQ).

**Credit**  
LSHTM award 15 credits on successful completion of this module.

**Accreditation**  
Not currently accredited by any other body.

**Keywords**  
Clinical trials (including randomisation, sample size, blinding); Statistics (including stopping rules, multiplicity).

### AIMS, OBJECTIVES AND AUDIENCE

**Overall aim**  
This module will provide a student with a solid understanding of the main issues in the design and interpretation of clinical trials. The module will outline the fundamental principles of comparative clinical trials in investigating effectiveness, efficacy and safety of treatments; and compare the benefits of clinical trials in comparison to alternative study designs. The main features of clinical trials, including methodological and organisational considerations, and the principles of trial conduct and reporting will be described. Key decisions surrounding design (including sample size), delivery and assessment of clinical trials will be explored.

**Intended learning outcomes**  
By the end of this module, students should be able to:  
- Explain fundamental principles of comparative clinical trials in investigating effectiveness, efficacy and safety of interventions  
- Compare the benefits of randomised controlled clinical trials in comparison with alternative study design  
- Describe the main features of clinical trials, including methodological and organisational considerations  
- Explore key decisions surrounding the design and analysis of clinical trials  
- Explain the principles of trial conduct and reporting.
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<tr>
<th><strong>Target audience</strong></th>
<th>Compulsory module for all the students on DL PG Certificate, Diploma, MSc Clinical Trials; alternatively, it can also be taken as an individual module by any student who wishes to learn about designing, reporting and reviewing clinical trials.</th>
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<tr>
<td><strong>CONTENT</strong></td>
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| **Session content** | This module consists of 10 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows:  
• Principles of clinical trials  
• The role of observational studies  
• Randomisation  
• The use of blinding and placebos  
• Size of trials  
• Monitoring trial results  
• Reporting trial results  
• Multiplicity of data: Subgroup analysis  
• Multiplicity of data: Multiple outcomes, treatments and repeated measures  
• Alternative designs. |
| **TEACHING, LEARNING AND ASSESSMENT** |                                                                                                                                                                                                  |
| **Study resources provided or required** | The following materials are provided to students after registration for this module once a year in October:  
• CAL materials are provided electronically through the online learning site Moodle, for self-directed study  
• Online reading list (ORC).  
In addition to the materials above, students are given access to the LSHTM Virtual Learning Environment, Moodle (for online discussions forums etc.) and the LSHTM online library resources. |
| **Teaching and learning methods** | • Learning is self-directed against a detailed set of learning objectives using the materials provided.  
To support their self-directed learning:  
• Students are strongly encouraged to submit a Formative Assignment, for which personalised written feedback is available. This is not compulsory and does not contribute to the overall module grade.  
• Students are strongly encouraged to participate in the module-specific discussion board forums to post questions for tutors or fellow students.  
• There are at least two real-time tutorials available on Moodle for students to obtain additional tutor support: one for feedback on a second Formative Assignment, and one for exam revision.  
• Students are encouraged to make use of LSHTM online library resources.  
• Students are provided with Examiners’ Reports giving previous examination questions and specimen answers. |
| **Assessment details** | Formal assessment of this module is by a two-hour and fifteen minutes unseen written examination (100%).  
If students fail an examination at the first entry, they will be allowed one further attempt. |
| **Assessment dates** | The Formative Assignment for this module can be submitted only once annually, no later than 31st March and must be submitted via the online Assignment Management System. Unseen written examinations for DL modules are held once a year, in June (including resits). Examinations are normally taken in a student’s country of residence, in one of over 650 examination centres worldwide (arranged mainly through Ministries of Education or the British Council). A list of examination centres can be found at [https://london.ac.uk/current-students/examinations/examination-centres](https://london.ac.uk/current-students/examinations/examination-centres) A local fee will be payable direct to the examination centre. This fee is in addition to the programme/module fee and is set by, and paid directly to, the individual examination centres. The level of local examination centre fees varies across the world and neither the University of London nor the LSHTM have any control over the fee amount. |
| **Language of study and assessment** | English (please see ‘English language requirements’ below regarding the standard required for entry). |

**TIMING AND MODE OF STUDY**

| **Duration** | Distance learning module studies begin in early October. Students may start their studies at any time once they gain access to Moodle and therefore the study materials, and work through the material until the start of the June examinations (although assessment submission deadlines which are earlier than this must be observed). |
| **Dates** | Tutorial support (via the online discussion forums or [CTsupport@lshtm.ac.uk](mailto:CTsupport@lshtm.ac.uk)) is available from the beginning of October through to the start of the exam (usually in June). |
| **Mode of study** | By distance learning. |
| **Learning time** | The notional learning time for the module totals 150 hours, consisting of:  
- **Directed self-study** (reading and working through the provided module material) ≈ 100 hours  
- **Self-directed learning** (general reading around the subject, library, Moodle discussion forums) ≈ 20 hours  
- **Assessment, review and revision** ≈ 30 hours |

**APPLICATION, ADMISSION AND FEES**

<p>| <strong>Pre-requisites</strong> | Those wishing to study this module must have regular access to the internet to access the module study materials, participate in module-specific discussions and tutorials on Moodle, benefit from online library facilities and submit assignments. |
| <strong>English language requirements</strong> | A strong command of the English language is necessary to benefit from studying the module. Applicants whose first language is not English or whose prior university studies have not been conducted wholly in English must fulfil LSHTM’s <a href="https://london.ac.uk/current-students/admissions/">English language requirements</a>, with an acceptable score in an approved test taken in the two years prior to entry. Applicants may be asked to take a test even if the standard conditions have been met. |
| <strong>Student numbers</strong> | There is no cap on the number of students who can register for this distance learning module. The number of students actively studying this module varies, but typically approx 100 students register for the module per year. |</p>
<table>
<thead>
<tr>
<th>Student selection</th>
<th>This module is available to be studied by students on the following distance learning programmes: PG Certificate, PG Diploma and MSc Clinical Trials. Alternatively, students may register for this as an “individual module”. This module is also open to LSHTM research degree students via the mixed mode study option.</th>
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<tbody>
<tr>
<td>Fees</td>
<td>The current schedule of fees can be viewed at <a href="https://www.lshtm.ac.uk/study/fees-funding/tuition-fees/tuition-fees-and-expenses-2018-19">https://www.lshtm.ac.uk/study/fees-funding/ tuition-fees/tuition-fees-and-expenses-2018-19</a></td>
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<tr>
<td>Scholarships</td>
<td>Scholarships are not available for individual modules. Some potential sources of funding are detailed on the LSHTM website.</td>
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| Admission deadlines | Applications for LSHTM distance learning programmes and modules are managed by the University of London. To apply to take either a formal award (i.e. PG Certificate, PG Diploma or MSc) or an individual module, click on the red Apply Now tab [https://london.ac.uk/courses/clinical-trials](https://london.ac.uk/courses/clinical-trials)  

Key deadlines are as follows:
- Application deadline: 31st October each year  
- Registration deadline: 30th November each year  

*Please note:* The academic year starts on Monday 1st October 2018. Students who register after 1st October should note that module welcome and Collaborate sessions held in October are recorded, but they cannot request an extension to assignment submission deadlines or apply for an examination extenuating circumstance as a result of registering later than 1st October. In-house LSHTM research degree students wishing to study this module should note information given in the mixed mode study option link at [https://lshtm.sharepoint.com/Teaching-and-Support/Pages/taught-programmes-handbooks-regulations-policies.aspx](https://lshtm.sharepoint.com/Teaching-and-Support/Pages/taught-programmes-handbooks-regulations-policies.aspx) |

**ABOUT THIS DOCUMENT**

- **This module specification applies for the academic year** 2018/19  
- **Last revised/approved:** 11th Dec 2017 by Susana Scott  
- London School of Hygiene & Tropical Medicine, Keppel St., London WC1E 7HT. [www.lshtm.ac.uk](http://www.lshtm.ac.uk)