# MODULE SPECIFICATION

<table>
<thead>
<tr>
<th>Academic Year (student cohort covered by specification)</th>
<th>2020-21</th>
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<tbody>
<tr>
<td>Module Code</td>
<td>CTM101</td>
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<tr>
<td>Module Title</td>
<td>Fundamentals of Clinical Trials</td>
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<tr>
<td>Module Organiser(s)</td>
<td>Susana Scott, Taemi Kawahara, Niveditha Devasenapathy</td>
</tr>
<tr>
<td>Contact Email</td>
<td><a href="mailto:CTsupport@lshtm.ac.uk">CTsupport@lshtm.ac.uk</a></td>
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| Faculty                                                 | Epidemiology and Population Health  
London School of Hygiene & Tropical Medicine  
[http://www.lshtm.ac.uk/eph/](http://www.lshtm.ac.uk/eph/) |
| FHEQ Level                                              | Level 7 |
| Credit Value                                            | CATS 15  
ECTS 7.5 |
| HECoS Code                                              | 100962 : 100473 |
| Mode of Delivery                                        | Distance Learning |
| Mode of Study                                           | Directed self-study, through online materials via the Virtual Learning Environment |
| Language of Study                                       | English |
| Pre-Requisites                                          | Prior reading is not required before registering on this module. Students will be provided with core texts at the beginning of the module. |
| Accreditation by Professional Statutory and Regulatory Body | Not currently accredited by any other body. |
| Module Cap (Maximum number of students)                 | There is no cap on the number of students who can register for this distance learning module. |
| Target Audience                                         | 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. |
| Module Description                                      | 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 observational studies. 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), how the design and analyses are implemented will be explored.

**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).

**Last Revised (e.g. year changes approved)**
2020

**Programme(s)**
This module is linked to the following programme(s)

<table>
<thead>
<tr>
<th>Programme(s)</th>
<th>Status</th>
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<tbody>
<tr>
<td>PGCert/PGDip/MSc Clinical Trials (Distance Learning - University of London Worldwide)</td>
<td>Compulsory</td>
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**Module Aim and Intended Learning Outcomes**

**Overall aim of the module**
The overall module aim is to:

- provide a student with a solid understanding of the fundamental principles in the design and interpretation of clinical trials.

**Module Intended Learning Outcomes (ILO)**
Upon successful completion of the module a student will be able to:

1. Identify key features of clinical trials
2. Distinguish key analytical concepts in clinical trials
3. Evaluate the appropriateness of various clinical trial designs in a range of contexts
4. Appraise aspects of the conduct and standardised procedures of clinical trials.

**Indicative Syllabus**

**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
Session Content

- 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 and Learning

Notional Learning Hours

<table>
<thead>
<tr>
<th>Type of Learning Time</th>
<th>Number of Hours</th>
<th>Expressed as Percentage (%)</th>
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</thead>
<tbody>
<tr>
<td>Directed self-study</td>
<td>60</td>
<td>40</td>
</tr>
<tr>
<td>Self-directed learning</td>
<td>30</td>
<td>20</td>
</tr>
<tr>
<td>Assessment, review and revision</td>
<td>60</td>
<td>40</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>150</strong></td>
<td><strong>100</strong></td>
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Teaching and Learning Strategy

Learning is self-directed against a detailed set of learning outcomes using the materials provided.

To support their self-directed learning students are strongly encouraged to

- post questions for tutors or fellow students and participate in the module-specific discussion board forums available on Moodle.
- submit a Tutor Marked Formative Assignment (TMFA), for which personalised written feedback is available. Students are provided with written feedback on submitted TMFAs.
- work through the Self Assessed Formative Assignment (SAFA), for which self-assessment tools are provided. This is not compulsory and does not contribute to the overall module grade.
- join real-time tutorials via Collaborate, available on Moodle, to obtain additional tutor support.
- make use of LSHTM online library resources.
- make use of Examiners’ Reports which include previous assessed assignment and examination questions and specimen answers.
Assessment

Assessment Strategy
The assessment strategy for CTM101 is designed to support progressive student learning through optional formative assessments, which can be self-assessed (SAFA) or tutor-marked with feedback (TMFA), and a formal examination. The FAs use scenario-based short question format to build skills, and encourage students to engage with the study materials. They encourage M-level thinking through questions which challenge students to consult study materials and to reflect and problem-solve. They support attainment of Intended learning outcomes (ILOs) by collectively testing across the range of learning outcomes. The examination questions are written to test core learning and M-level skills of criticality and reflection. For all CTM101 assessments the application of key learning to scenario-based questions encourages students to develop the skill of using core learning to respond to real-life problems encountered in the conduct and regulation of clinical trials. On this module three past examination papers, all with specimen answers, are available for practice and self-assessment.

Summative Assessment

<table>
<thead>
<tr>
<th>Assessment Type</th>
<th>Assessment Length (i.e. Word Count, Length of presentation in minutes)</th>
<th>Weighting (%)</th>
<th>Intended Module Learning Outcomes Tested</th>
</tr>
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<tbody>
<tr>
<td>Examination</td>
<td>2hrs 15mins</td>
<td>100</td>
<td>1 – 4</td>
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Resitting assessment
Resits will accord with the LSHTM’s [Resits Policy](#)
Resources

**Essential resources**
The following materials are provided to students after registration for this module once a year in October:

- Computer Assisted Learning (CAL) materials provided electronically through the online learning site Moodle, for self-directed study
- E-books as below
- Online reading as below

**E-books**

**Examples of online reading**

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 for Disabilities and Learning Differences

The module-specific site on Moodle provides students with access to the module learning materials and online reading list (containing both essential and recommended readings), and additional resources including supplementary exercises and optional lecture recordings (where appropriate). All materials posted up on Moodle areas, including computer-based sessions, have been made accessible where possible.

The LSHTM Moodle has been made accessible to the widest possible audience, using a VLE that allows for up to 300% zoom, permits navigation via keyboard and use of speech recognition software, and that allows listening through a screen reader. For students with special needs, reasonable adjustments and support can be arranged – details and how to request support can be found on the University of London Worldwide website at https://london.ac.uk/applications/how-it-works/inclusive-practice-access-arrangements