**Module Specification**

**GENERAL INFORMATION**

<table>
<thead>
<tr>
<th>Module name</th>
<th>Clinical Trials in Practice</th>
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<tbody>
<tr>
<td>Module code</td>
<td>CTM103</td>
</tr>
<tr>
<td>Module Organiser(s)</td>
<td>Haleema Shakur, Taemi Kawahara</td>
</tr>
<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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<tr>
<td>Home Faculty</td>
<td>Epidemiology and Population Health London School of Hygiene &amp; Tropical Medicine <a href="http://www.lshtm.ac.uk/eph/">http://www.lshtm.ac.uk/eph/</a></td>
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<tr>
<td>Level</td>
<td>This module is at Level 7 (postgraduate Masters level) of the QAA <a href="https://www.qaa.ac.uk/framework">Framework for Higher Education Qualifications</a> in England, Wales &amp; Northern Ireland (FHEQ).</td>
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<tr>
<td>Credit</td>
<td>LSHTM award 15 credits on successful completion of this module.</td>
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<tr>
<td>Accreditation</td>
<td>Not currently accredited by any other body.</td>
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<tr>
<td>Keywords</td>
<td>Clinical trials (in general), document design and generation (protocol, CRF, SOPs, Risk assessment and Data Management plans and guidelines), study planning, study set-up (site selection, multidisciplinary team, regulatory submissions), study conduct (subject randomisation and follow-up, site management, Trial Master File (TMF) management, monitoring, data management) study close out and reporting, (database lock, statistical analysis, closeout visit, report writing and publications).</td>
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**AIMS, OBJECTIVES AND AUDIENCE**

**Overall aim**

This module will cover the key steps in the logistical and practical implementation of a clinical trial, from inception to dissemination.

**Intended learning outcomes**

By the end of this module, students should be able to:

- Explain and critically evaluate how a project management team might respond to the choice of trial design in the set up and running of a clinical trial.
- Demonstrate understanding of how to plan and set up a research project so that quality and standards are promoted and maintained.
- Critically evaluate and use efficient and responsive project management techniques in the conduct of clinical trials.
- Demonstrate understanding of how data management contributes to the success of a clinical trial.
- Select and use methods for reporting trial results as appropriate for different audiences.
<table>
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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 clinical trials in practice.</th>
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<tbody>
<tr>
<td><strong>CONTENT</strong></td>
<td>In this module we discuss the various processes involved in running a clinical trial and how these can be adapted for different trial designs and scenarios. The module covers the whole life cycle of a clinical trial, including clarifying and operationalising the primary and secondary objectives, the implications of design choices for implementation of a trial, trial governance, approvals (including Regulatory and ethics committee), recruitment and data processing methods. We will also explore quality assurance and control, and investigate both data processing and data management issues. The module is expected to include sessions addressing the following topics: • Introduction • Before the trial starts • Responsibilities, roles and governance • Essential documents • Project management • Methods of data collection • Data processing and management • Recruitment and randomisation • GCP in relation to Quality Assurance and Quality Control • Follow up • Analysis, reporting and dissemination of results.</td>
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<tr>
<td><strong>TEACHING, LEARNING AND ASSESSMENT</strong></td>
<td>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 • Module reader (scanned documents provided as pdf on Moodle) including ICH E6 GCP, clinical study protocol checklist, Patient information sheet and consent form checklist, other study-related sample documentation • NIHR Trial Managers’ Network. A Guide to Efficient Trial Management. 2014 • 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.</td>
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<tr>
<td><strong>Teaching and learning methods</strong></td>
<td>• 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 (FA), for which personalised written feedback is provided the tutor team. It is not compulsory to do an FA. Marks do 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, in total, eight real-time tutorial sessions (i.e. CT Collaborate sessions) available on Moodle for students to obtain additional tutor support. The sessions are organised in December, February, April and May. • Students are encouraged to make use of LSHTM online library resources.</td>
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</table>
### Students are provided with Examiners’ Reports giving previous examination questions and marking schemes.

#### 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) 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 160 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) ≈ 30 hours
- **Assessment, review and revision** ≈ 30 hours.

### APPLICATION, ADMISSION AND FEES

#### Pre-requisites

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.

#### English language requirements

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 [English language requirements](https://london.ac.uk/current-students/examinations/examination-centres), 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.

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<tr>
<th>Student numbers</th>
<th>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.</th>
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<tbody>
<tr>
<td>Student selection</td>
<td>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 &quot;individual module&quot;. This module is also open to LSHTM research degree students via the mixed mode study option.</td>
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<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-2019-20">https://www.lshtm.ac.uk/study/fees-funding/ tuition-fees/tuition-fees-and-expenses-2019-20</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 Tuesday 1st October 2019. 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)