# 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, Danielle Beaumont, Emma Beaumont</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 <a href="https://london.ac.uk/contact-us">here</a> (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 Framework for Higher Education Qualifications 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

The key steps in the logistical and practical implementation of a clinical trial are investigated in this module, including clarifying and operationalising the primary and secondary objectives of clinical trials, the implications of design choices for implementation of a trial, trial governance, approvals (including Regulatory and ethics committee), recruitment and data processing methods. The module will also explore quality assurance and control, and investigate both data processing and data management issues.

### Intended learning outcomes

By the end of this module, students should be able to:
- Understand the importance of considering the practical aspects when designing, setting-up, conducting and reporting clinical trials
- Describe the practical steps necessary before the trial starts, during the trial, and at the end of the trial
- Identify the roles and responsibilities of various key players within a trial
- Be aware of which documents are essential for the conduct of most clinical trials
- Explain systems for the collection and management of the data needed for a trial
- Understand the recruitment, randomisation and follow up processes in trials
- Implement and evaluate the need for appropriate quality assurance and quality control
- Discuss practical aspects of analysis and reporting the trial results for different audiences
- Explain and utilise efficient project management techniques in the conduct of clinical trials.

**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 clinical trials in practice.

## CONTENT

**Session content**
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.

## 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:
- 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
- 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 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 (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.
- 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](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 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. |
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, 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.

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.

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.

The current schedule of fees can be viewed at https://www.lshtm.ac.uk/study/fees-funding/registration-fees/registration-fees-and-expenses-2018-19

Scholarships are not available for individual modules. Some potential sources of funding are detailed on the LSHTM website.

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

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

This module specification applies for the academic year 2018/19. Please note that this Module is currently undergoing revision. Any changes will be made available before the start of the 2018-19 academic year.

Last revised/approved 29 November 2017 by Haleema Shakur-Still