



MODULE SPECIFICATION

Academic Year	2026-27
Module Code	CTM103
Module Title	Clinical Trials in Practice
Module Organiser(s)	Taemi Kawahara, Danielle Beaumont, Emma Beaumont
Contact Email	For students studying University of London Awards (initial registration 2025/2026 and prior years: Enquiries may be made via their Student Advice Centre at: Student Advice Centre. For students studying LSHTM awards (registration in 2026/2027 and onwards) : Enquiries should be emailed to CTsupport@lshtm.ac.uk
Faculty	Epidemiology and Population Health
FHEQ Level	Level 7
Credit Value	CATS 15 ECTS 7.5
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 clinical trials in practice.
Module Description	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.
Duration	Distance learning module studies begin on Thursday 1st October 2026. 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 AA submission deadline on 12th May.
Last Revised (e.g. year changes approved)	April 2025

For students studying UoL awards (initial registration in 2025/2026 and prior years)

Programme(s)	Status
This module is linked to the following programme(s)	
PGCert/PGDip/MSc Clinical Trials (Distance Learning - University of London Worldwide)	Compulsory

For students studying LSHTM awards (registration in 2026/2027 and onwards)

Programme(s)	Status
This module is linked to the following programme(s)	
PGCert Clinical Trials (Distance Learning)	Compulsory
PGDip Clinical Trials (Distance Learning)	Compulsory
MSc Clinical Trials (Distance Learning)	Compulsory

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: cover the key steps in the logistical and practical implementation of a clinical trial, from inception to dissemination.

Module Intended Learning Outcomes
Upon successful completion of the module a student will be able to: Critically analyse and formulate strategic project management responses to implementation of trial designs, taking into account logistical, ethical and regulatory constraints.

Module Intended Learning Outcomes

2. Demonstrate understanding of how to plan and set up a research project so that quality and standards are promoted and maintained.
3. Critically evaluate and use efficient and responsive project management techniques in the conduct of clinical trials.
4. Demonstrate understanding of how data management contributes to the success of a clinical trial.
5. Select and use methods for reporting trial results as appropriate for different audiences.

Indicative Syllabus

Session Content

This module consists of 11 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows:

- Introduction
- Before the trial starts
- Good Clinical Practice; Responsibilities, roles and governance
- Essential documents
- Project management
- Methods of data collection
- Data processing and management
- Recruitment and randomisation
- Quality Assurance and Quality Control
- Follow up
- Analysis, reporting and dissemination of results.

Teaching and Learning

Notional Learning Hours

Type of Learning Time	Number of Hours	Expressed as Percentage (%)
Directed self-study	60	40%
Self-directed learning	30	20%
Assessment, review and revision	60	40%
Total	150	100

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.

Teaching and Learning Strategy

- 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.
- join real-time tutorials via Zoom, 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 specimen answers.

Assessment

Assessment Strategy

The assessment strategy for CTM103 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 summative written assessed assignment (AA). The FAs and AAs use scenario-based short question format to build skills, and encourage students to engage with the study materials. The AA is designed to test whether students are going beyond reiteration of the materials, and using M-level skills of criticality, and wider reflection. The word limit gives sufficient text allowance to demonstrate these skills within a succinct and focused writing style. The assessments encourage M-level thinking through questions which challenge students to consult study materials and to reflect and problem-solve. They support attainment of ILOs by collectively testing across the range of learning outcomes. The assessment questions are written to test core learning and M-level skills of criticality and reflection. For all CTM103 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 practical implementation of a clinical trial, from inception to dissemination. On this module three past AA papers, all with specimen answers, are available for practice and self-assessment.

Summative Assessment

Assessment Type	Assessment Length (i.e. Word Count, Length of presentation in minutes)	Weighting (%)	Intended Module Learning Outcomes Tested
Assessed Assignment	4000 words	100	1 – 5

Resitting assessment

Resits will accord with [Chapter 8b](#) of the LSHTM Academic Manual.

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
- 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
- E-books and other Online reading as below

Examples of online reading

- The Guide to Efficient Trial Management – UKTMN
<https://www.tmn.ac.uk/resources/34-the-guide-to-efficient-trial-management>.
- 'A practical guide to managing clinical trials by Pfeiffer & Wells' ISBN 9780367497828
Published February 25, 2020 by CRC Press
- Friedman, L. M., DeMets, D. L., Furberg, C. D., Reboussin, D. M., & Granger, C. B. (2015). *Fundamentals of Clinical Trials* (5th ed.). Springer International Publishing

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 majority of the module learning materials, including a study guide and online reading list (detailing both essential and recommended readings), and additional resources including supplementary exercises, the option to listen to recordings of selected lectures taking place in London. In this module, materials provided include a textbook that is made available to students in e-format. 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. All students have access to "[SensusAccess](#)" software which allows conversion of files into alternative formats.

For Students studying University of London Awards (initial registration 2025/2026 and prior years:

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: [Inclusive practice and Access arrangements | University of London](#)

For Students Studying LSHTM awards (registration 2026/2027 and onwards):

For students who require learning or assessment adjustments and support this can be arranged through the Student Support Services – details and how to request support can be found on the [LSHTM Disability Support pages](#).