MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2024-25
Module Code	CTM103
Module Title	Clinical Trials in Practice
Module Organiser(s)	Taemi Kawahara, Danielle Beaumont, Emma Beaumont
Contact Email	CTsupport@lshtm.ac.uk
Faculty	Epidemiology and Population Health London School of Hygiene & Tropical Medicine
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 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 Tuesday 1st 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 AA submission deadline on 12th May.
Last Revised (e.g. year changes approved)	March 2024

Programme(s) This module is linked to the following programme(s)	Status
PGCert/PGDip/MSc Clinical Trials (Distance Learning - University of London Worldwide)	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: 1. 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. 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	90	60
Self-directed learning	30	20
Assessment, review and revision	30	20
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. • 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.

Teaching and Learning Strategy
• 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 (FAs), 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 examination 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	5000 words	100	1 – 5

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
- 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 as below
- Online reading

E-books

- McDonald A *et al*. (2016). *A Guide to Efficient Trial Management*. Fifth Edition]. Oxford: Trial Managers Network, HMSO

Examples of online reading

- Pfeiffer J and Wells C (2017). *A practical guide to managing clinical trials.* ISBN:9781315299778
- Hulley SB *et al*. (2013). *Designing Clinical Research*. 4th Edition. Wolters Kluwer. Ebook ISBN 9781469875330

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 website at [Inclusive practice access arrangements](#)