MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2023-24
Module Code	CTM101
Module Title	Fundamentals of Clinical Trials
Module Organiser(s)	Niveditha Devasenapathy, Siddharudha Shivalli and Sheila Harvey
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 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 time limited assessments (although assessment submission deadlines which are earlier than this must be observed).
Last Revised (e.g. year changes approved)	August 2023

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

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 • Introduction to Observational Studies • Randomisation • The use of blinding and placebos • Size of trials • Monitoring trial results

Session Content
• 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

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. • 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 time-limited assessment. 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 assessment questions are written to test core learning and M-level skills of criticality and reflection. While there is a word limit for the assessments, this is an upper limit and students will be able to answer the questions successfully in fewer words. 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

Assessment Type	**Assessment Length (i.e. Word Count, Length of presentation in minutes)**	**Weighting** (%)	**Intended Module Learning Outcomes Tested**
Time limited assessment	Assessment length TBC	100	1 – 4

Formative assignments for this module can be submitted only once annually, no later than **31 March** and must be submitted via the online Assignment Management System.

Time limited assessments for DL modules are held once a year, mostly in June (including resits).

Time limited assessments are held in accordance with University of London's annual guidance.

Please note that a separate assessment fee may be payable in addition to the module fee. Further details will be communicated as soon as the final decisions are known.

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

- Wang D and Bakhai A. (2005) *Clinical Trials- a practical guide to design, analysis and reporting*. REMEDICA

Examples of online reading

- Smith P, Morrow R & Ross D (2015). *Field Trials of Health Interventions: A Toolbox.* Oxford: Oxford University Press
- Schulz KF, Altman DG, Moher D; CONSORT Group (2010). CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *Lancet* **340**:c332
- DAMOCLES Group (2005). A proposed charter for clinical trial data monitoring committees: helping them to do their job well. *Lancet* **365**(9460): 711-22.
- Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleza-Jeric K, Laupacis A & Moher D (2013). SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* **346**:e7586. doi: 10.1136/bmj.e7586.
- UK Collaborative ECMO Trial Group (1996). UK collaborative randomised trial of neonatal extracorporeal membrane oxygenation. *Lancet* **348**(9020): 75-82
- RITA-2 trial participants (1997). Coronary angioplasty versus medical therapy for angina: the second Randomised Intervention Treatment of Angina (RITA-2) trial. *Lancet* **350**(9076): 461-8
- ISIS-2 (Second International Study of Infarct Survival) Collaborative Group (1988). Randomised trial of intravenous streptokinase, oral aspirin, both, or neither among 17,187 cases of suspected acute myocardial infarction: ISIS-2. *Lancet* **2**(8607): 349-60
- Watson-Jones D, Weiss HA, Rusizoka M, Changalucha J, Baisley K, Mugeye K, Tanton C, Ross D, Everett D, Clayton T, Balira R, Knight L, Hambleton I, Le Goff J, Belec L &Hayes R (HSV trial team; Steering and Data Monitoring Committees) (2008). Effect of herpes simplex suppression on incidence of HIV among women in Tanzania. *N Engl J Med* **358**(15):1560-71.

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 https://london.ac.uk/applications/how-it-works/inclusive-practice-access-arrangements