MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2022-23			
Module Code	CTM202			
Module Title	Trial Designs			
Module Organiser(s)	Kerry Dwan, Edward Clarke, Edward Stanhope			
Contact Email	CTsupport@lshtm.ac.uk			
Faculty	Epidemiology and Population Health London School of Hygiene & Tropical Medicine http://www.lshtm.ac.uk/eph/			
FHEQ Level	Level 7			
Credit Value	**CATS**	15	**ECTS**	7.5
HECoS Code	100962 : 100473			
Mode of Delivery	Distance Learning			
Mode of Study	Self-study, through the online Virtual Learning Environment			
Language of Study	English			
Pre-Requisites	All of the Clinical Trial (CT) elective modules assume familiarity with the material and terminology introduced in the core CT modules, including a knowledge of basic statistics relevant to clinical trials. Students who do not have a background in clinical trials may need to spend some time familiarising themselves with terminology before they can successfully complete any of the CT elective modules. 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. 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. The number of students actively studying this module varies, but typically approx. 65 students register for the module per year.			

Target Audience	Elective module for all the students on DL MSc Clinical Trials, PG Diploma Clinical Trials, MSc Epidemiology. Also open to any other student who meets pre-requisites for the module and who wishes to learn about trial designs.
Module Description	This module seeks to develop an understanding of the key features of a variety of trial designs and provide students with the opportunity to critique their appropriate use. The appropriate application of statistical principles to trial design and analysis will be discussed. Appropriate interpretation of trial results and analysis according to the trial design are also considered.
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).
Last Revised (e.g. year changes approved)	2021

Programme(s) This module is linked to the following programme(s)	**Status** *Compulsory/Elective*
PGDip/MSc Clinical Trials (University of London Worldwide)	Elective

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: • familiarise students with a variety of trial designs and their fundamental characteristics, and provide students with the opportunity to demonstrate their appropriate use.

Module Intended Learning Outcomes
Upon successful completion of the module a student will be able to: 1. demonstrate knowledge of the key features of trial designs used to evaluate interventions 2. critically evaluate which trial design is most appropriate to the research question 3. demonstrate application of statistical principles to trial design and analysis 4. interpret the results from the analysis of trials according to the trial design.

Indicative Syllabus

Session Content
The module consists of Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows: • Introduction • Early Phase Trials • Cluster RCTs • Non-Inferiority/Equivalence Trials • Cross-Over Trials • Factorial Trials and Other Multi-Armed Trials • Adaptive Design Trials • Other Designs • Summary

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. • work through the Self Assessed Mock Examination (SAME), for which self-assessment tools are provided. This is not compulsory and does not contribute to the overall module grade. • learn from written feedback from tutors on submitted AAs.

Teaching and Learning Strategy
• join real-time tutorials, available on Moodle, to obtain additional tutor support: at least two tutorials are available, one focusing on assignments, and one for exam preparation. • 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 CTM202 is designed to support progressive student learning through optional formative assessments, which can be self-assessed (SAFA) or tutor-marked with feedback (TMFA), a summative written assessed assignment (AA) and a formal examination. The FAs are used 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 ILOs by collectively testing across the range of learning outcomes. 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 examination questions are also written to test core learning and M-level skills and should be answered with the same criticality as should be demonstrated in the AAs. For all CTM202 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 design, conduct, analysis and interpretation of different clinical trial designs. On this module two past AA papers, and three past examination papers, all with specimen answers, are also available for practice and self-assessment. *NB students who enrolled on this module prior to 2022 and who need to resit or who are partially through the existing method of assessment (i.e. having sat the exam but not the AA or vice versa) will be required to still complete the existing method of assessment i.e. one assessed assignment (20%) and a formal examination (80%). Note that the Assessed Assignment (20%) and unseen written examination (80%) will only be available to take in 2022/23. After this time, students who have not completed both forms of module assessment would be expected to take the new method of assessment (60% AA and 40% exam).* Any student who registered for CTM202 prior to 2022/23 should contact the Module Organiser to discuss their individual assessment requirements

	Summative assessment			
Assessment Type	**Assessment Length (i.e. Word Count, Length of presentation in minutes)**	**Weighting** (%)	**Submission deadline**	**Intended Module Learning Outcomes Tested**
Assessed assignment	The Assessed Assignment has a	60	12th May	**1-4**

	Summative assessment			
	maximum word length of 3000 words			
Examination	1 hour 15 minutes	40	Held once per year in June	**1-4**

Timed examinations for DL modules are held once a year, in June (including resits). Examinations in 2022/23 will either be taken in a student's country of residence in one of over 650 examination centres worldwide or will be held online. If the June 2023 module exam is held at a local examination centre, a local fee will be payable direct to the exam centre. This fee will be in addition to the module fee and is set by, and paid directly to, the individual examination centre. 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. If the June 2023 module exam is held online, no additional exam entry fee will be payable. (Note that for those resitting module assessments, a fee will be payable.)

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
- Text book as below
- E-book as below
- Online reading as below

E-books

- Senn S. *Statistical Issues in Drug Development* (3rd edition). (2021) Wiley, Chichester.

Text book

- Wang D, Bakhai A. (2005). *Clinical Trials: A Practical Guide to Design, Analysis and Reporting*. REMEDICA (*Only sent to students who did not study CTM101*.)

Examples of online reading

- Adamson J, Cockayne S, Puffer S, Torgerson DJ. Review of randomised trials using the post-randomised consent (Zelen's) design. *Contemp Clin Trials*. 2006 Aug; **27**(4): 305-19.
- Bhatt DL, Mehta C. Adaptive Designs for Clinical Trials. N Engl J Med. 2016 Jul 7;375(1):65-74. doi: 10.1056/NEJMra1510061.
- Dwan K, Li T, Altman DG, Elbourne D. CONSORT 2010 statement: extension to randomised crossover trials. BMJ, 2019; 366:14378
- Jones B, Lewis J, Ebbutt E. Trials to assess equivalence: the importance of rigorous methods. *BMJ*. 1996; **313**: 36-9
- Hayes RJ, Alexander NDE, Bennett S, Cousens SN. Design and analysis issues in cluster-randomized trials of interventions against infectious diseases. *Statistical Methods in Medical Research*. 2000; **9**(2): 95-116.
- Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials*. 2007 Feb; **28**(2): 182-91.
- Mills EJ *et al.* Design, analysis, and presentation of crossover trials. **Trials**, 2009. **10**: p. 27.
- Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJ. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. *JAMA*. 2006 Mar 8; **295**(10): 1152-60.
- Sedgwick P. Randomised controlled trials with full factorial designs *BMJ* 2012; **345** :e5114

In addition to the materials above, students are given access to the LSHTM Virtual Learning Environment, Moodle (for web-based 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 Worldwide website at
https://london.ac.uk/applications/how-it-works/inclusive-practice-access-arrangements