MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2022-23
Module Code	CTM104
Module Title	Reporting and Reviewing Clinical Trials
Module Organiser(s)	Katrin Gaardbo Kuhn, Katharine Ker, Felicity Clemens
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	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 reporting and reviewing clinical trials.
Module Description	This module covers two topics related to the reporting of clinical trials: (1) **Individual clinical trial reports**. Sessions for this topic focus on guidelines for structure and content, reasons for publishing, scientific publication and, importantly, how the reader should

	critically appraise a clinical trial report. Special emphasis is placed on the CONSORT statement. (2) **Systematic reviews**. Sessions cover the processes and guidelines involved in assembling and writing a systematic review (e.g. literature searches and meta-analyses) and prepare students for critically reading and appraising a systematic review. Overall, this module joins and further explores many of the topics introduced in another core module *CTM101 Fundamentals of Clinical Trials.*
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)	2020

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: equip students with the skills and knowledge to prepare and critically appraise clinical trial reports and systematic reviews.

Module Intended Learning Outcomes
Upon successful completion of the module a student will be able to: 1. Demonstrate knowledge and understanding of the key components of, and guidelines which structure, a clinical trial report. 2. Critically appraise a clinical trial report. 3. Demonstrate knowledge and understanding of the processes and guidelines involved in a systematic review. 4. Critically appraise a systematic review.

Indicative Syllabus

Session Content
This module consists of Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows: • Introduction to Reporting and Reviewing Clinical Trials • Critical Appraisal of a Clinical Trial Report • Title, Abstract and Background for a Clinical Trial Report • Methods for a Clinical Trial Report • Results for a Clinical Trial Report • Discussion and Abstract Sections for a Clinical Trial Report • Submitting a Paper to and Dealing with a Journal, Including Peer Review • Introduction to Systematic Reviews. Why Do We Need Them and What Do They Do? • Critical Appraisal of Systematic Reviews • Systematic Reviews and Selection Bias • Systematic Reviews and Reporting Bias • Critical Appraisal of Clinical Trials Included in a Systematic Review • Synthesis in Systematic Reviews

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, 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 examination questions and specimen answers.

Assessment

Assessment Strategy
The assessment strategy for CTM104 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 formal examination. The FAs are based on published examples. They use short structured questions to encourage students to appraise different aspects of a) trials reports and b) systematic reviews in a critical manner, building their arguments as they move through the questions. They support attainment of ILOs by collectively testing across the range of learning outcomes. The examination questions are written to test core learning and M-level skills of criticality and reflection. For all CTM104 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 (%)	Submission deadline	Intended Module Learning Outcomes Tested
Examination	2hrs 15mins	100	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
- E-books as below
- Online reading

E-books

- Egger M, Smith GD, Altman DG. *Systematic Reviews in Health Care: Meta-Analysis in Context*. Blackwell Publishing; 2008

Examples of online reading

- Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, *et al.*: CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. BMJ 2010, 340:c869. http://www.bmj.com/cgi/reprint/340/mar23_1/c869
- Page MJ, Moher D, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. PRISMA 2020 explanation and elaboration: updated guidance and exemplars for reporting systematic reviews. BMJ 2021;372:n160. doi: 10.1136/bmj.n160
- Chalmers I & Altman D. Systematic Reviews. London: BMJ Books 1995.
- Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions version 6.3 (updated February 2022). Cochrane, 2022. Available from www.training.cochrane.org/handbook. Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ* 2019; **366**: l4898.

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