



MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2023-24
Module Code	CTM104
Module Title	Reporting and Reviewing Clinical Trials
Module Organiser(s)	Katrin Gaardbo Kuhn, Katharine Ker, Felicity Clemens
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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 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.

	<p>(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.</p> <p>Overall, this module joins and further explores many of the topics introduced in another core module <i>CTM101 Fundamentals of Clinical Trials</i>.</p>
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 assessments (although assessment submission deadlines which are earlier than this must be observed).
Last Revised (e.g. year changes approved)	August 2023

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

Module Aim and Intended Learning Outcomes

Overall aim of the module
<p>The overall module aim is to:</p> <ul style="list-style-type: none"> equip students with the skills and knowledge to prepare and critically appraise clinical trial reports and systematic reviews.

Module Intended Learning Outcomes
<p>Upon successful completion of the module a student will be able to:</p> <ol style="list-style-type: none"> Demonstrate knowledge and understanding of the key components of, and guidelines which structure, a clinical trial report. Critically appraise a clinical trial report. Demonstrate knowledge and understanding of the processes and guidelines involved in a systematic review. 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. This is not compulsory and does not contribute to the overall module grade;

Teaching and Learning Strategy

- 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 online tutorials, to obtain additional tutor support;
- make use of LSHTM online library resources;
- make use of Examiners' Reports which include previous 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 time-limited assessment. 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 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 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 (%)	Intended Module Learning Outcomes Tested
Time limited assessment	Assessment length TBC	100	1 – 4
<p>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.</p> <p>Time-limited assessments for DL modules are held once a year, mostly in June (including resits).</p> <p>Assessments are held in accordance with University of London's annual guidance but in 2023/24 they are likely to be held online.</p>			

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

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 website](#).