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## MODULE SPECIFICATION

<b>Academic Year (student cohort covered by specification)</b>	2020-21
<b>Module Code</b>	CTM104
<b>Module Title</b>	Reporting and Reviewing Clinical Trials
<b>Module Organiser(s)</b>	Katrin Gaardbo Kuhn, Julia Langham
<b>Contact Email</b>	<a href="mailto:CTsupport@lshtm.ac.uk">CTsupport@lshtm.ac.uk</a>
<b>Faculty</b>	Epidemiology and Population Health London School of Hygiene & Tropical Medicine <a href="http://www.lshtm.ac.uk/eph/">http://www.lshtm.ac.uk/eph/</a>
<b>FHEQ Level</b>	Level 7
<b>Credit Value</b>	<b>CATS</b> 15 <b>ECTS</b> 7.5
<b>HECoS Code</b>	100962 : 100473
<b>Mode of Delivery</b>	Distance Learning
<b>Mode of Study</b>	Directed self-study, through online materials via the Virtual Learning Environment
<b>Language of Study</b>	English
<b>Pre-Requisites</b>	Prior reading is not required before registering on this module. Students will be provided with core texts at the beginning of the module.
<b>Accreditation by Professional Statutory and Regulatory Body</b>	Not currently accredited by any other body.
<b>Module Cap (Maximum number of students)</b>	There is no cap on the number of students who can register for this distance learning module.
<b>Target Audience</b>	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.
<b>Module Description</b>	This module covers two topics related to the reporting of clinical trials:  (1) <b>Individual clinical trial reports.</b> 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) <b>Systematic reviews.</b> 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>
<b>Duration</b>	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).
<b>Last Revised (e.g. year changes approved)</b>	2020

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

## Module Aim and Intended Learning Outcomes

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

<b>Module Intended Learning Outcomes</b>
<p>Upon successful completion of the module a student will be able to:</p> <ol style="list-style-type: none"> <li>Demonstrate knowledge and understanding of the key components of, and guidelines which structure, a clinical trial report</li> <li>Critically evaluate a clinical trial report</li> <li>Demonstrate knowledge and understanding of the processes and guidelines involved in a systematic review</li> <li>Critically evaluate a systematic review.</li> </ol>



## Indicative Syllabus

### Session Content

This module consists of 13 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
<b>Total</b>	<b>150</b>	<b>100</b>

### 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.



### 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 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 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 (%)	Intended Module Learning Outcomes Tested
Examination	2hrs 15mins	100	1 – 4

### Resitting assessment

Resits will accord with the LSHTM's [Resits Policy](#)



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## 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](http://www.bmj.com/cgi/reprint/340/mar23_1/c869)
- Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement*. *PLoS Med* 6(6): e1000097. doi:10.1371/journal.pmed1000097
- 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 6.0 (updated July 2019). Cochrane, 2019. Available from <http://www.training.cochrane.org/handbook>
- Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, Cates CJ, Cheng H-Y, Corbett MS, Eldridge SM, Hernán MA, Hopewell S, Hróbjartsson A, Junqueira DR, Jüni P, Kirkham JJ, Lasserson T, Li T, McAleenan A, Reeves BC, Shepperd S, Shrier I, Stewart LA, Tilling K, White IR, Whiting PF, Higgins JPT. 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>