

Module Specification (Distance Learning)

In collaboration with University of London International Programmes



1. Title:	Reporting and Reviewing Clinical Trials
2. Module code:	CTM104
3. Institution:	Faculty of Epidemiology and Population Health London School of Hygiene & Tropical Medicine Keppel Street London WC1E 7HT http://www.lshtm.ac.uk/eph
4. Module Organiser:	Susannah Tomkins
5. Mode of study:	Distance learning
6. Type:	Core module
7. Duration and dates:	<p>Deadlines if taken as part of a formal award:</p> <p>Application deadline: 30 June each year Registration deadline: 31 August each year Course registration duration: Up to 5 years Course starts: 1 October each year Examination takes place: Usually June each year (date to be confirmed)</p> <p>Deadlines if taken as an individual module (i.e. not registered for formal award):</p> <p>Application deadline: 31 August each year Registration deadline: 30 November each year Registration duration: 2 years Module study starts: 1 October each year Examination takes place: Usually June each year (date to be confirmed).</p>
8. Credit points:	15 credit points will be awarded on successful completion of this module at Masters level (Level 7).
9. Notional Learning Hours (NLH):	<p><u>Directed self-study</u></p> <p>Computer-Assisted Learning sessions: 25 hours Additional reading time 15 hours</p> <p><u>Self-directed learning</u></p> <p>Background reading 15 hours Note-making/consolidation 10 hours Web-based discussions 20 hours</p> <p><u>Assessment, review, revision</u></p> <p>Preparation and writing of FAs/AAs/exams: 45 hours Tutor-led interactive revision sessions: 5 hours Individual and peer-supported revision sessions: 15 hours.</p>
10. Aim:	This module will cover writing up completed trials, including guidelines for authors (such as the CONSORT Statements for reporting), as well as guidelines for readers to aid their critical appraisal of trial reports. Since future policy, practice and further research will ideally be guided by the reports not merely of one trial but by the totality of the evidence, a major component of the module will therefore be the role of systematic reviews.

11. Learning objectives:	<p>On completing this module students should be able to:</p> <ul style="list-style-type: none"> • describe the key features that should appear in a trial report • understand the reasons why certain features of trials need to be reported, and the effect of these on potential bias in the results • list the main features of the CONSORT guidelines and explain their relevance • describe and understand the process required to produce a scientific publication • critically read a publication of a trial and comment on its strengths and weaknesses • critically read a systematic review and explain the processes necessary to do a high quality review (including deciding whether a meta-analysis is justified) • list the main features of the QUOROM statement and explain their relevance • understand how to search literature for relevant publications • explain the functions of a meta-analysis • understand the graphical and statistical presentation of results of trials and meta-analyses • use the Cochrane Databases to find relevant trials and systematic reviews.
12. Content:	<p>This module consists of 11 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows:</p> <p>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 Synthesis in systematic reviews.</p>
13. Learning methods:	<p>Learning is self-directed against a detailed set of learning objectives, identified at the start of each chapter, using the materials provided. These consist of a module textbook which lists a range of activities including focused reading.</p> <p>Student support is available from the module tutors through the web-based discussion forum in which students are encouraged to participate. In addition, module tutors provide written feedback on the submitted assessed assignment.</p> <p>The course uses Computer-Assisted Learning (CAL) material to introduce and explain the principles and methods covered in the module. It is important that all the CAL sessions are completed and understood at each step before progressing with further sessions.</p>
14. Assessment procedures:	<p>Formal assessment of the module will be by one two-hour unseen written examination (100%).</p> <p>Examinations are normally held in a student's country of residence, in one of over 650 examination centres worldwide. They are arranged mainly through Ministries of Education or the British Council. A local fee will be payable. A list of examination centres can be found at http://www.londoninternational.ac.uk/current_students/general_resources/exams/exam_centres/index.shtml.</p>

	If students fail an examination at the first entry they will be allowed one further attempt, the following year.
15. Prerequisites:	<p>A student is advised to study CTM101 <i>Fundamentals of Clinical Trials</i> and CTM102 <i>Basic Statistics for Clinical Trials</i> or have already studied similar syllabuses, as deemed acceptable by the Course Director, before studying this module.</p> <p>Those wishing to study this module must have regular access to the internet as this module is taught online and through web-based discussions.</p> <p>Students must meet the standard of English required to study this course. See http://www.lshtm.ac.uk/prospectus/english.html.</p>
16. Attendance:	No maximum number
17. Selection, if applicable:	This module is one of the compulsory core modules available only to those studying the PG Certificate/PG Diploma/MSc Clinical Trials courses; alternatively, it may be taken as an Individual Module.
18. Fees:	For current schedule of fees see http://www.londoninternational.ac.uk/fees/schedules/lshtm.pdf .
19. Scholarships:	MSc only – see http://www.lshtm.ac.uk/prospectus/funding/ for details.
20. External accreditation:	None
21. Application process:	Applications are managed by the University of London International Programmes (website: http://www.londoninternational.ac.uk/).
22. Further enquiries:	Enquiries may be emailed to distance@lshtm.ac.uk .