

# Module Specification (Distance Learning)

In collaboration with University of London International Programmes



1. Title:	<b>Fundamentals of Clinical Trials</b>
2. Module code:	CTM101
3. Institution:	Faculty of Epidemiology and Population Health London School of Hygiene & Tropical Medicine Keppel Street London WC1E 7HT <a href="http://www.lshtm.ac.uk/eph">http://www.lshtm.ac.uk/eph</a>
4. Module Organiser:	Clare Rutterford
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>On average the module should take about 150 hours to complete, consisting of the following:</p> <p><u>Directed self-study</u></p> <p>Computer-Assisted Learning sessions: 24 hours Additional reading time 13 hours</p> <p><u>Self-directed learning</u></p> <p>Background reading 35 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: 43 hours Tutor-led interactive revision sessions: 5 hours</p>
10. Aim:	This module will provide a student with a solid understanding of the main issues in the design and interpretation of clinical trials. The module will outline the fundamental principles of comparative clinical trials in investigating effectiveness, efficacy and safety of treatments; and compare the benefits of clinical trials in comparison to alternative study designs. The main features of clinical trials, including methodological and organisational considerations, and the principles of trial conduct and reporting will be described. Key decisions surrounding design (including sample size), delivery and assessment of clinical trials will be explored.

11. Learning objectives:	<p>On completing this module students should be able to:</p> <ul style="list-style-type: none"> <li>• Explain fundamental principles of comparative clinical trials in investigating effectiveness, efficacy and safety of interventions</li> <li>• Compare the benefits of randomised controlled clinical trials in comparison with alternative study design</li> <li>• Describe the main features of clinical trials, including methodology and organisational considerations</li> <li>• Explore key decisions surrounding the design and analysis of clinical trials</li> <li>• Explain the principles of trial conduct and reporting.</li> </ul>
12. Content:	<p>This module consists of 10 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows:</p> <p>Principals of clinical trials  The role of observational studies  Randomisation  The use of blinding and placebos  Size of trials  Monitoring trial results  Reporting trial results  Multiplicity of data: Subgroup analysis  Multiplicity of data: Multiple outcomes, treatments and repeated measures  Alternative designs.</p>
13. Learning methods:	<p>The course uses 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. Directed reading is provided by the module textbook.</p> <p>Self-directed learning takes place using the set of learning objectives identified in the CAL materials provided. The main forms of self-directed learning include background reading, consolidation and web-based discussions (where student support is also available from the module tutors).</p> <p>In addition a formative assignment is offered to aid revision and review of the material upon which module tutors provide written feedback.</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 <a href="http://www.londoninternational.ac.uk/current_students/general_resources/exams/exam_centres/index.shtml">http://www.londoninternational.ac.uk/current_students/general_resources/exams/exam_centres/index.shtml</a>.</p> <p>If students fail an examination at the first entry they will be allowed one further attempt, the following year.</p>
15. Prerequisites:	<p>Those wishing to study this module must have regular access to the internet to access the module study materials, and benefit from library facilities, participate in web-based discussions and submit assignments.</p> <p>Students must meet the standard of English required to study this course. See <a href="http://www.lshtm.ac.uk/prospectus/english.html">http://www.lshtm.ac.uk/prospectus/english.html</a>.</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 <u>Clinical Trials</u> courses; alternatively, it may be taken as an Individual Module.
18. Fees:	For current schedule of fees see <a href="http://www.londoninternational.ac.uk/fees/schedules/lshhtm.pdf">http://www.londoninternational.ac.uk/fees/schedules/lshhtm.pdf</a> .
19. Scholarships:	MSc only – see <a href="http://www.lshhtm.ac.uk/prospectus/funding/">http://www.lshhtm.ac.uk/prospectus/funding/</a> for details.
20. External accreditation:	None
21. Application process:	Applications are managed by the University of London International Programmes (website: <a href="http://www.londoninternational.ac.uk/">http://www.londoninternational.ac.uk/</a> ).
22. Further enquiries:	Enquiries may be emailed to <a href="mailto:distance@lshhtm.ac.uk">distance@lshhtm.ac.uk</a> .