

Module Specification (Distance Learning)

In collaboration with University of London International Programmes



1. Title:	Clinical Trials in Practice
2. Module code:	CTM103
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:	Julie Bakobaki
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</p> <p>Registration deadline: 31 August each year</p> <p>Course registration duration: Up to 5 years</p> <p>Course starts: 1 October each year</p> <p>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</p> <p>Registration deadline: 30 November each year</p> <p>Registration duration: 2 years</p> <p>Module study starts: 1 October each year</p> <p>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>Computer-Assisted Learning sessions: 12 session X 3 hours = 36 hours</p> <p>Additional reading time: 36 hours</p> <p>Assignments: 20 hours</p> <p>Self-directed learning: 26 hours prep for June exam, 2 hours unseen written examination, 3 hours per wk over 10 weeks.</p>
10. Aim:	The key steps in the logistical and practical implementation of a clinical trial are investigated in this module, including clarifying and operationalising the primary and secondary objectives of clinical trials, the implications of design choices for implementation of a trial, trial governance, clearances (including research and ethical clearance), and data collection and recruitment methods. The module will explore quality assurance and control, and investigate data processing and management issues.
11. Learning objectives:	<p>On completing this module students should be able to:</p> <ul style="list-style-type: none"> • Understand the importance of considering the practical aspects of the conduct of clinical trials • Describe the practical steps necessary before the trial starts, during the trial, and at the end of the trial • Identify the roles and responsibilities of various key players within a

	<p>trial</p> <ul style="list-style-type: none"> • Be aware of which documents are essential for the conduct of most clinical trials • Explain systems for the collection and management of the data needed for a trial • Understand the recruitment, randomisation and follow up processes in trials • Implement and evaluate the need for appropriate quality assurance and quality control • Discuss practical aspects of analysis and reporting the trial results for different audiences • Explain and utilise efficient project management techniques in the conduct of clinical trials.
12. Content:	<p>This module consists of 11 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows:</p> <p>Introduction Before the trial starts Responsibilities, roles and governance Essential documents Project management Methods of data collection Data processing and management Recruitment and randomisation GCP in relation to Quality Assurance and Quality Control Follow up Analysis, reporting and dissemination of results.</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 individualised feedback on an optional formative 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> <p>If students fail an examination at the first entry they will be allowed one further attempt, the following year.</p>

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 <u>PG Certificate/PG Diploma/MSc Clinical Trials</u> 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 .