

# Module Specification (Distance Learning)

In collaboration with University of London International Programmes



1. Title:	<b>Protocol Development</b>
2. Module code:	CTM201
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:	Diana Elbourne
5. Mode of study:	Distance learning
6. Type:	Elective module (compulsory for MSc)
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>2 Computer-Assisted Learning (CAL) sessions: 10 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 10 hours</p> <p><u>Assessment, review, revision</u></p> <p>Groupwork 25 hours 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:	<p>The aim of this module is to be able to produce the protocol for a trial. Material in this module will build on the work of the core modules, but will go further into the steps to be taken for preparing the protocol for a trial. It is recommended that this module is taken in the same year that students attempt the last of written papers.</p> <p>Working in small groups over a 4 week period (in either autumn or spring), students will critically appraise a systematic review provided and start drafting the background section for a trial protocol. Students can then use this as a</p>

	<p>basis for developing their own draft protocol for assessment. Note that this will not be the 'final' version of the protocol, but one that would be ready for consultation with stakeholders.</p>
11. Learning objectives:	<p>On completing this module students should be able to:</p> <ul style="list-style-type: none"> <li>critically appraise a systematic review in order to develop and refine a research question to be addressed in a trial,</li> <li>understand the necessary components of a protocol for a trial,</li> <li>identify the relevant methodological and practical issues for the protocol,</li> <li>design the framework for an appropriate trial protocol, working in a group,</li> <li>appreciate the 'added value' of working in a group,</li> <li>extend this framework to produce the protocol for a trial in specific setting (individual assessment).</li> </ul>
12. Content:	<p>This module consists of 2 CAL sessions:</p> <p>Introduction to Protocol Development Components of a Protocol.</p>
13. Learning methods:	<p>Learning is self-directed against a detailed set of learning objectives, identified at the start of each session, using the Computer-Assisted Learning (CAL) materials provided to introduce and explain the principles and methods covered in the module.</p> <p>Student support is available from the module tutors through a Virtual Learning Environment discussion forum in which students are encouraged to participate. In addition, module tutors support groupwork, provide written feedback on the submitted formative and assessed assignments, respond to questions raised via the DL Student Support Office, and run interactive consolidation and revision sessions.</p>
14. Assessment procedures:	<p>Formal assessment of the module will be by an assessed assignment (80%, including 5% for contribution to groupwork) and by a two-hour unseen written examination (20%).</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>All of the Clinical Trial (CT) elective modules assume familiarity with the material and terminology introduced in the core CT modules. Students who do not have a background in clinical trials may need to spend some time familiarising themselves with terminology before they can successfully complete any of the CT elective modules.</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 <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 available to those studying the MSc <u>Clinical Trials</u> course, for which it is a compulsory module. Those studying for the PG Diploma in Clinical Trials under the credit framework scheme may also choose to study this module. 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.lshtm.ac.uk/prospectus/funding/">http://www.lshtm.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@lshtm.ac.uk">distance@lshtm.ac.uk</a> .