

Module Specification (Distance Learning)

In collaboration with University of London International Programmes



1. Title:	Data Monitoring and Interim Analyses
2. Module code:	CTM206
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 (MO) / Deputy MO:	Neal Alexander / Diana Elbourne
5. Mode of Study:	Distance learning
6. Type:	Elective 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>Directed self-study (68 hours)</p> <ul style="list-style-type: none"> ▪ 6 Computer-assisted learning (CAL) sessions x 10 hours ▪ Directed reading 8 hours <p>Self-directed learning (32 hours)</p> <ul style="list-style-type: none"> ▪ Background reading 2 hours ▪ Consolidating study material 20 hours ▪ Discussions on web-based discussion forum 10 hours <p>Assessment, review and revision (52 hours)</p> <ul style="list-style-type: none"> ▪ Individual revision for examinations or assignment preparation 20 hours ▪ Peer-supported revision or preparation sessions 5 hours ▪ Staff-led revision or assignment preparation sessions 5 hours ▪ Undertaking coursework or examination of various types, both formative and summative 20 hours.
10. Aim:	This module will cover issues relating to the on-going monitoring of the data in a study in order that sufficient data are available to answer the trial's question reliably without recruiting more patients than necessary, or exposing them to unacceptable risks. The module will therefore focus on the ethical context of decisions about whether or not to continue entering patients into trials. A number of different statistical approaches will be explored, and the role and conduct of data monitoring committees in this process will be examined.

11. Learning objectives:	<p>On completing this module students should be able to:</p> <ul style="list-style-type: none"> • explain what is meant by data monitoring in the context of decisions about whether or not to continue to enter participants in a trial • state ethical advantages and disadvantages for decisions about whether or not to continue to enter participants • justify a range of reasons for stopping: including benefit, harm and futility • show understanding of the statistical basis for decisions about whether or not to continue to enter participants • distinguish between a range of stopping guidelines in the context of interim analyses in trials • implement the guidelines using software provided • describe the independent review role of Data Monitoring Committee • demonstrate understanding of the economic context for decisions about whether or not to continue to enter participants • evaluate the appropriateness of decisions about whether or not to continue to enter participants.
12. Content:	<p>This module consists of 6 CAL sessions: Introduction to Data Monitoring and Interim Analysis] Introduction to Statistical Stopping Guidelines Statistical Stopping Guidelines: Further considerations Introduction to Data Monitoring Committees Data Monitoring Committees: Operations and Conduct Summary.</p>
13. Learning methods:	<p>The MSc course uses CAL material to introduce and explain the principles and methods covered in all the modules. Learning for each CT module is self-directed against a detailed set of learning objectives, identified at the start of each module (and at the start of each session of each module) using the materials provided.</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 provide written feedback on the submitted assignments, and respond to questions raised via the DL office, and run interactive consolidation and revision sessions.</p>
14. Assessment procedures:	<p>Formal assessment of the module will be by an assessed assignment (20%) and by a two-hour unseen written examination (80%).</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>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>

	Students must meet the standard of English required to study this course. http://www.lshtm.ac.uk/prospectus/english.html .
16. Attendance:	No maximum number
17. Selection, if applicable:	This module is currently only available to those studying the MSc <u>Clinical Trials</u> course; alternatively it can be taken as an Individual Module.
18. Fees:	For current schedule of fees see http://www.londoninternational.ac.uk/fees/schedules/lshhtm.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 .