

Module Specification (Distance Learning)

In collaboration with University of London International Programmes



1. Title:	Further Statistics for Clinical Trials
2. Module code:	CTM208
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:	Susan Charman
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>Computer-Assisted Learning (CAL) sessions: 36 hours Additional reading time: 21 hours Assignments: 14 hours Self-directed learning: 79 hours.</p>
10. Aim:	To extend students' skills and knowledge to enable them to confidently analyse individually randomised clinical trials with binary, continuous or time-to-event endpoints. This module will build on module CTM102 <i>Basic Statistics for Clinical Trials</i> to cover more advanced statistical methods used in clinical trials.
11. Learning objectives:	<p>On completing this module students should be able to:</p> <ul style="list-style-type: none"> • understand the concept of likelihood and how it is used for hypothesis testing, • perform multiple regression analyses in Stata for binary, continuous and time-to-event data, including adjustment for imbalances at baseline if appropriate, • appreciate the challenges when dealing with missing data, • decide when to use subgroup and sensitivity analyses, • appreciate the effects of repeated measures in clinical trials, and the use of statistical methods which take account of such correlation.

12. Content:	<p>Topics covered will include the concept of likelihood, the principles of regression and generalised linear models including logistic, Poisson and Cox regression. The module will also cover adjustment for covariates, analyses of repeated measures and other correlated data, missing data, sub-group analyses and sensitivity analyses. Data analyses will be carried out using Stata.</p> <p>This module consists of 9 CAL sessions:</p> <p>Introduction Principles of Regression Likelihood Logistic Regression Poisson Regression Survival Analysis Multiplicity of Data Further topics in statistics in clinical trials Summary.</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 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>CT students who wish to study advanced statistical methods are recommended to study CTM208 <i>Further Statistical Methods in Clinical Trials</i>. Students may, however, choose to study EPM304 <i>Advanced Statistical Methods in Epidemiology</i>, but must apply to the Course Director for approval and may not register for both CTM208 and EPM304 <i>Advanced Statistical Methods in Epidemiology</i>.</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 optional modules available to those studying the <u>MSc Clinical Trials</u> course but may also be studied by those registered for the <u>MSc Epidemiology</u> course, subject to Course Director approval. 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 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 .