Module Specification (Distance Learning)

In collaboration with University of London International Programmes

1. Title:	**Basic Statistics for Clinical Trials**
2. Module code:	CTM102
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:	David Harrison
5. Mode of study:	Distance learning
6. Type:	Core module
7. Duration and dates:	Deadlines if taken as part of a formal award: 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) Deadlines if taken as an individual module (i.e. not registered for formal award): 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)
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):	On average the module should take about 150 hours to complete, consisting of the following: Directed self-study Computer-Assisted Learning sessions: 24 hours Additional reading time 13 hours Self-directed learning Background reading 35 hours Note-making/consolidation 10 hours Web-based discussions 20 hours Assessment, review, revision Preparation and writing of FAs/AAs/exams: 43 hours Tutor-led interactive revision sessions: 5 hours
10. Aim:	This module will introduce the basic statistical methods used in clinical trials. Students will learn how to select and apply appropriate statistical methods to analyse data from clinical trials, and how to present, interpret and discuss the analyses clearly and concisely.
11. Learning objectives:	On completing this module students should be able to: • describe the basic statistical methods used in clinical trials • select and apply appropriate statistical methods to analyse data from clinical trials • present, interpret and discuss the analyses undertaken clearly and

	concisely • explain the meaning of probability and describe examples of its use • compare and contrast normal and binomial distributions and explain their application • describe the principles of statistical inference, including point and interval estimation, and the role of sampling variation • carry out basic data analyses from clinical trials using the computer-based Stata software package.
12. Content:	This module consists of 14 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows: Introduction to basic statistics for clinical trials Types of data summary and data presentation Probability: Evaluation the role of change The normal or Gaussian distribution The binomial distribution Principles of statistical inference. Point and interval estimation Inference from a sample mean Comparison of two means Comparison of two proportions Association between two categorical variables Measures of effect in 2x2 tables Correlation and linear regression Introduction to survival analysis Allowance for baseline values The module will define probability and describe examples of its use. Normal and binomial distributions and their application will be explored, and the principles of statistical inference, including point and interval estimation, and the role of sampling variation, will be explained. As part of this introduction, a student will have the option to carry out basic data analyses from clinical trials using the computer-based Stata software package.
13. Learning methods:	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 focussed reading. 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 formative assignment. 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.
14. Assessment procedures:	Formal assessment of the module will be by one two-hour unseen written examination (100%). 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. If students fail an examination at the first entry they will be allowed one further attempt, the following year.

15. Prerequisites:	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. Students must meet the standard of English required to study this course. See http://www.lshtm.ac.uk/prospectus/english.html.
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 Clinical Trials 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.