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MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2022-23			
Module Code	CTM102			
Module Title	Basic Statistics for Clinical Trials			
Module Organiser(s)	Jennifer Nicholas, Amy Macdougall, Kelly Needham			
Contact Email	CTsupport@lshtm.ac.uk			
Faculty	Epidemiology and Population Health London School of Hygiene & Tropical Medicine http://www.lshtm.ac.uk/eph/			
FHEQ Level	Level 7			
Credit Value	CATS	15	ECTS	7.5
HECoS Code	100962 : 100473 : 101031			
Mode of Delivery	Distance Learning			
Mode of Study	Self-study, through the online Virtual Learning Environment			
Language of Study	English			
Pre-Requisites	Those wishing to study this module must have regular access to the internet to access the module study materials, participate in module-specific discussions and tutorials on Moodle, benefit from online library facilities and submit assignments. Prior reading is not required before registering on this module. Students will be provided with core texts at the beginning of the module.			
Accreditation by Professional Statutory and Regulatory Body	Not currently accredited by any other body.			
Module Cap (Maximum number of students)	There is no cap on the number of students who can register for this distance learning module. The number of students actively studying this module varies, but typically around 100 students register for the module each year.			
Target Audience	Compulsory module for all the students on DL PG Certificate, Diploma, MSc Clinical Trials; alternatively, it can also be taken as an individual module by any student who wishes to learn about basic statistics for clinical trials.			
Module Description	On this module, students will learn how to select appropriate statistical methods to analyse data from clinical trials, apply basic methods of analysis and how to present, interpret and discuss the analyses clearly and concisely. The module will define			



	probability and describe examples of its use. The normal distribution (and optionally, the binomial distribution) 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 Stata software package.
Duration	Distance learning module studies begin in early October. Students may start their studies at any time once they gain access to Moodle and therefore the study materials, and work through the material until the start of the June examinations (although assessment submission deadlines which are earlier than this must be observed).
Last Revised (e.g. year changes approved)	2021

Programme(s)	Status (<i>Compulsory/Elective</i>)
This module is linked to the following programme(s)	
PGCert/PGDip/MSc Clinical Trials (University of London Worldwide)	Compulsory

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: <ul style="list-style-type: none"> introduce the fundamental principles of statistical inference in clinical trials.

Module Intended Learning Outcomes (ILOs)
Upon successful completion of the module a student will be able to: <ol style="list-style-type: none"> Demonstrate understanding of fundamental principles of statistical inference Identify appropriate statistical methods for analysis, summary and presentation Apply appropriate basic statistical methods for analysis, summary and presentation Explain the concepts of more complex methods of analysis appropriate to clinical trials Interpret results from the statistical methods covered on the module.

Indicative Syllabus

Session Content
This module consists of Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows:



Session Content

- Introduction to basic statistics for clinical trials
- Types of data summary and data presentation
- Probability: Evaluating the role of chance
- The normal or Gaussian distribution
- The binomial distribution (optional)
- 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.

Teaching and Learning

Notional Learning Hours

Type of Learning Time	Number of Hours	Expressed as Percentage (%)
Directed self-study	60	40
Self-directed learning	30	20
Assessment, review and revision	60	40
Total	150	100

Teaching and Learning Strategy

Learning is self-directed against a detailed set of learning outcomes using the materials provided.

To support their self-directed learning students are strongly encouraged to

- post questions for tutors or fellow students and participate in the module-specific discussion board forums available on Moodle.
- submit a Tutor Marked Formative Assignment (TMFA), for which personalised written feedback is available. Students are provided with written feedback on submitted TMFAs.
- work through the Self Assessed Formative Assignment (SAFA), for which self-assessment tools are provided. This is not compulsory and does not contribute to the overall module grade.
- join real-time tutorials, available on Moodle, to obtain additional tutor support.
- make use of LSHTM online library resources.



Teaching and Learning Strategy

- make use of Examiners' Reports which include previous assessed assignment and examination questions and specimen answers.

Assessment

Assessment Strategy

The assessment strategy for CTM102 is designed to support progressive student learning through optional formative assessments, which can be self-assessed (SAFA) or tutor-marked with feedback (TMFA), an assessed assignment (AA) and an examination.

The FAs are composed of short questions based around a clinical trial scenario to build skills and encourage deeper engagement with the study materials. They encourage M-level thinking through questions which challenge students to consult study materials and to reflect and problem-solve. They support attainment of ILOs by collectively testing across the range of learning outcomes. While these FAs are not counted towards the final overall grade point, students are particularly encouraged to submit the TMFA which will explicitly lead into the AA.

The examination and AA questions are written to test core learning and M-level skills of criticality and reflection. For all CTM102 assessments the application of key learning to scenario-based questions encourages students to develop the skill of applying their knowledge to respond to the kind of real-life situations that are encountered in the statistical aspects of clinical trials. The word limit for the AA gives sufficient text allowance to demonstrate these skills within a succinct and focused writing style. The examination questions are also written to test core learning and M-level skills and should be answered with the same criticality as should be demonstrated in the AAs.

On this module three past examination papers, all with specimen answers, are available for practice and self-assessment.

Note: The assessment for this year, 2022/23 is 60% assessed assignment (AA) and 40% exam. Prior to 2022, the assessment was 100% exam. All students who are registered on this module from 2022/23 onwards will be expected to sit the new method of assessment (60% AA and 40% exam).

Summative assessment

Assessment Type	Assessment Length (i.e. Word Count, Length of presentation in minutes)	Weighting (%)	Submission deadline	Intended Module Learning Outcomes Tested



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Summative assessment				
Assessed assignment	The Assessed Assignment has a maximum word length of 3000 words	60	12 th May	1 - 5
Examination	1hour 15mins	40	Held once per year in June	1 – 5

Timed examinations for DL modules are held once a year, in June (including resits). Examinations in 2022/23 will either be taken in a student's country of residence in one of over 650 [examination centres worldwide](#) or will be held online. If the June 2023 module exam is held at a local examination centre, a local fee will be payable direct to the exam centre. This fee will be in addition to the module fee and is set by, and paid directly to, the individual examination centre. The level of local examination centre fees varies across the world and neither the University of London nor the LSHTM have any control over the fee amount. If the June 2023 module exam is held online, no additional exam entry fee will be payable. (Note that for those resitting module assessments, a fee will be payable.)

Resitting assessment

Resits will accord with the LSHTM's [Resits Policy](#)

Resources



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Essential resources

The following materials are provided to students after registration for this module once a year in October:

- Computer Assisted Learning (CAL) materials provided electronically through the online learning site Moodle, for self-directed study
- Stata datasets
- E-books as below
- Online reading as below

E-books

- Kirkwood BR. *Essential Medical Statistics*. Malden, Mass. Blackwell 2003

Examples of online reading

- Alderson P. *Absence of evidence is not evidence of absence*. *BMJ*. 2004; 328: 476-7.
- Pocock SJ. *Statistics in practice - The simplest statistical test: how to check for a difference between treatments*. *British Medical Journal* 2006; 332(7552):1256-1258
- Bland JM & Altman DG (1998). *Statistics Notes: Time to event (survival) data*. *BMJ* 317: 468-69
- Altman DG, Doré CJ. *Randomisation and baseline comparisons in clinical trials*. *Lancet*. 1990; 335: 149-53.
- Schulz KF, Altman DG, Moher D, for the CONSORT Group. *CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials*. *BMJ*. 2010; 340: c332.

In addition to the materials above, students are given access to the LSHTM Virtual Learning Environment, Moodle (for online discussions forums etc.) and the LSHTM online library resources.

Teaching for Disabilities and Learning Differences

The module-specific site on Moodle provides students with access to the module learning materials and online reading list (containing both essential and recommended readings), and additional resources including supplementary exercises and optional lecture recordings (where appropriate). All materials posted up on Moodle areas, including computer-based sessions, have been made accessible where possible. The LSHTM Moodle has been made accessible to the widest possible audience, using a VLE that allows for up to 300% zoom, permits navigation via keyboard and use of speech recognition software, and that allows listening through a screen reader. For students with special needs, reasonable adjustments and support can be arranged – details and how to request support can be found on the University of London Worldwide website at

<https://london.ac.uk/applications/how-it-works/inclusive-practice-access-arrangements>