MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2020-21
Module Code	CTM102
Module Title	Basic Statistics for Clinical Trials
Module Organiser(s)	Jennifer Nicholas, Joanna Sturgess, 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	Directed self-study, through online materials via the Virtual Learning Environment
Language of Study	English
Pre-Requisites	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.
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)	2020

Programme(s) This module is linked to the following programme(s)	**Status**
PGCert/PGDip/MSc Clinical Trials (Distance Learning - University of London Worldwide)	Compulsory

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: • 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: 1. Demonstrate understanding of fundamental principles of statistical inference   2. Identify appropriate statistical methods for analysis, summary and presentation   3. Apply appropriate basic statistical methods for analysis, summary and presentation   4. Explain the concepts of more complex methods of analysis appropriate to clinical trials   5. Interpret results from the statistical methods covered on the module.

Indicative Syllabus

Session 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

Session Content
- 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 via Collaborate, available on Moodle, to obtain additional tutor support.

Teaching and Learning Strategy
• make use of LSHTM online library resources. • 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), and a formal 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. The examination 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. On this module three past examination papers, all with specimen answers, are available for practice and self-assessment.

Summative Assessment

Assessment Type	Assessment Length (i.e. Word Count, Length of presentation in minutes)	Weighting (%)	Intended Module Learning Outcomes Tested
Examination	2hrs 15mins	100	1 – 5

Resitting assessment
Resits will accord with the LSHTM's Resits Policy

Resources

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