MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2020-21
Module Code	CTM208
Module Title	Further Statistical Methods in Clinical Trials
Module Organiser(s)	Charles Opondo, Joanna Dobson, Jennifer Bell
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	10096 : 10047 : 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	All of the Clinical Trial (CT) elective modules assume familiarity with the material and terminology introduced in the core CT modules, and for this module CTM102 *Basic Statistics for Clinical Trials* is particularly relevant. 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. Students taking this module are **not** permitted to register and study both this module and EPM304, due to overlap of the content. 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	Optional module for all the students on DL MSc Clinical Trials, PG Diploma Clinical Trials, MSc Epidemiology. Also open to any other student who meets pre-requisites for the module and who wishes to learn about *Further Statistical Methods for Clinical Trials*.
Module Description	This module builds on CTM102 Basic Statistics for Clinical Trials. CTM208 covers more advanced statistical methods used in clinical trials. It extends the application of methods for the analysis of binary, continuous, and time-to-event data, and introduces methods to deal with common statistical issues in clinical trials, including repeated measurements, missing data, subgroup analyses and sensitivity analyses. Data analyses are carried out using Stata, and students learn to write Stata commands, perform analyses in Stata and interpret the output.
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**
PGDip/MSc Clinical Trials (Distance Learning - University of London Worldwide)	Elective
PGDip/MSc Epidemiology (Distance Learning - University of London Worldwide)	Elective

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: • develop students' statistical skills and knowledge to enable them to confidently analyse and interpret the results of individually randomised clinical trials.

Module Intended Learning Outcomes
Upon successful completion of the module a student will be able to: 1. Select suitable methods for the analysis of clinical trials 2. Demonstrate understanding of the concept of likelihood 3. Perform appropriate analysis of trial data using statistical software 4. Report and interpret the results of analyses of clinical trials.

Indicative Syllabus

Session Content
This module consists of 10 CAL (Computer Assisted Learning) sessions. The titles of the sessions are as follows: • Introduction to Module • Principles of Regression • Linear Regression • Likelihood • Logistic Regression • Poisson Regression • Survival Analysis • Multiplicity of Data • Further Topics in Statistics • Summary

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. • work through the Self Assessed Mock Examination (SAME), for which self-assessment tools are provided. This is not compulsory and does not contribute to the overall module grade. • learn from written feedback from tutors on submitted AAs. • join real-time tutorials via Collaborate, available on Moodle, to obtain additional tutor support: at least two tutorials are available, one focusing on assignments, and one for exam preparation. • 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 CTM208 is designed to support progressive student learning through optional formative assessments, which can be self-assessed (SAFA) or tutor-marked with feedback (TMFA), a summative written assessed assignment (AA) and a formal examination. The FAs and AA have the same word-length and scenario-based short question format to build skills, and encourage students to engage with the study materials. For both the TMFA and AA, students are provided with clinical trial data to analyse and interpret, which additionally builds data analysis and statistical software skills. The FAs and AA 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 AA is designed to test whether students are going beyond reiteration of the materials, and using M-level skills of criticality, and wider reflection. The word limit gives sufficient text allowance to demonstrate these skills within a succinct and focused writing style. The examination questions are also written to

Assessment Strategy
test core learning and M-level skills and should be answered with the same criticality as should be demonstrated in the AAs, but may be answered without recourse to the study materials. For all CTM208 assessments the application of key learning to scenario-based questions encourages students to develop the skill of using core learning to respond to real-life problems encountered in the analysis and interpretation of clinical trial data. On this module two past AA papers, and three past examination papers, all with specimen answers, are also 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**
Assessed Assignment	The Assessed Assignment has a maximum word length of 2000 words	20	1, 2, 3, 4
Examination	2 hours 15 minutes	80	1, 2, 4

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

E-books

- Kirkwood B, Sterne J. *Essential Medical Statistics*. Malden, Mass: Blackwell Science; 2003

Examples of online reading

- Pocock SJ, Assmann SE, Enos LE, Kasten LE. Subgroup analysis, covariate adjustment and baseline comparisons in clinical trial reporting: current practice and problems. Stat Med. 2002; 21: 2917-30.
- Clayton D, Hills M. Statistical Models in Epidemiology. Oxford: Oxford University Press; 1993.
- Collett D. Modelling Survival Data in Medical Research. 2nd Edition. Chapman and Hall; 2003.
- Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010; 340: c869

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