## Module Specification

### GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Module name</th>
<th>Further Statistical Methods in Clinical Trials</th>
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<tbody>
<tr>
<td>Module code</td>
<td>CTM208</td>
</tr>
<tr>
<td>Module Organiser(s)</td>
<td>Charles Opondo, Joanna Dobson, Jennifer Bell</td>
</tr>
<tr>
<td>Contact email</td>
<td>The LSHTM distance learning programmes and modules are run in collaboration with the University of London (UoL). Enquiries may be made via their Student Advice Centre at: general <a href="https://london.ac.uk/contact-us">https://london.ac.uk/contact-us</a> email-form click <a href="https://london.ac.uk/contact-us">here</a> (Enquiries from face-to-face i.e. London-based LSHTM MSc or research students regarding study of DL modules should be emailed to <a href="mailto:CTsupport@lshtm.ac.uk">CTsupport@lshtm.ac.uk</a>)</td>
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<tr>
<td>Home Faculty</td>
<td>Epidemiology and Population Health</td>
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<td></td>
<td>London School of Hygiene &amp; Tropical Medicine</td>
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<td><a href="http://www.lshtm.ac.uk/eph/">http://www.lshtm.ac.uk/eph/</a></td>
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<tr>
<td>Level</td>
<td>This module is at Level 7 (postgraduate Masters level) of the QAA Framework for Higher Education Qualifications (FHEQ).</td>
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<tr>
<td>Credit</td>
<td>LSHTM award 15 credits on successful completion of this module.</td>
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<tr>
<td>Accreditation</td>
<td>Not currently accredited by any other body.</td>
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<tr>
<td>Keywords</td>
<td>Regression; logistic; ANOVA; time-to-event; missing data; multiplicity.</td>
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### AIMS, OBJECTIVES AND AUDIENCE

**Overall 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 Basic Statistics for Clinical Trials to cover more advanced statistical methods used in clinical trials.

**Intended learning outcomes**
By the end of this module, students should be able to:
- 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.

**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.
**Session content**
The module is expected to include sessions addressing the following topics:
- 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.
This module consists of 9 CAL (Computer Assisted Learning) sessions:
- Introduction to Module
- Principles of Regression
- Linear Regression
- Likelihood
- Logistic Regression
- Poisson Regression
- Survival Analysis
- Multiplicity of Data
- Further Topics in Statistics
- Summary

**TEACHING, LEARNING AND ASSESSMENT**

**Study resources provided or required**
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
- Online reading - F05 Size of Trials from CTM101 Fundamentals of Clinical Trials
- Stata datasets

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 and learning methods**
Learning is self-directed against a detailed set of learning objectives 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.
- Students are strongly encouraged to submit a Formative Assignment (FA), for which personalised written feedback is available. This is not compulsory and does not contribute to the overall module grade.
- Students are provided with written feedback on submitted AAs.
- There are at least two real-time tutorials available on Moodle for students to obtain additional tutor support: one for feedback on a 2nd Formative Assignment, and one for exam revision.
- Students are encouraged to make use of LSHTM online library resources.
- Students are provided with Examiners’ Reports giving previous examination questions and specimen answers.

**Assessment details**
Formal assessment of the module will be by an assessed assignment (20%) and a two-hour and fifteen minutes unseen written examination (80%).
If students fail the module overall, they are allowed one further attempt at the failed element (examination and/or assignment).

| Assessment dates | The Formative Assignment for this module can be submitted only once annually, no later than 31st March and must be submitted via the online Assignment Management System. The Assessed Assignment for this module can be submitted only once annually, no later than 12th May and must be submitted via the online Assignment Management System. Unseen written examinations for DL modules are held once a year, in June (including resits). Examinations are normally taken in a student’s country of residence, in one of over 650 examination centres worldwide (arranged mainly through Ministries of Education or the British Council). A list of examination centres can be found at [https://london.ac.uk/current-students/examinations/examination-centres](https://london.ac.uk/current-students/examinations/examination-centres)
A local fee will be payable direct to the examination centre. This fee is in addition to the programme/module fee and is set by, and paid directly to, the individual examination centres. 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. |
| Language of study and assessment | English (please see ‘English language requirements’ below regarding the standard required for entry). |

**TIMING AND MODE OF STUDY**

| 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). |
| Dates | Tutorial support (via the online discussion forums or CTsupport@lshtm.ac.uk) is available from the beginning of October through to the start of the exam (usually in June). |
| Mode of study | By distance learning. |
| Learning time | The notional learning time for the module totals 150 hours, consisting of:
- **Directed self-study** (reading and working through the provided module material) ≈ 60 hours
- **Self-directed learning** (general reading around the subject, library, Moodle discussion forums) ≈ 40 hours
- **Assessment, review and revision** ≈ 50 hours. |

**APPLICATION, ADMISSION AND FEES**

| 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.

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. |
English language requirements: A strong command of the English language is necessary to benefit from studying the module. Applicants whose first language is not English or whose prior university studies have not been conducted wholly in English must fulfil LSHTM's [English language requirements](https://www.lshtm.ac.uk/study/fees-funding/), with an acceptable score in an approved test taken in the two years prior to entry. Applicants may be asked to take a test even if the standard conditions have been met.

Student numbers: 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 approximately 35 students register for the module per year.

Student selection: This module is available to be studied by students on the following distance learning programmes: PG Diploma Clinical Trials, MSc Clinical Trials, MSc Epidemiology. Alternatively, students may register for this as an "individual module".

This module is also open to students registered on LSHTM face-to-face (i.e. London-based) MSc programmes (subject to programme-specific limitations) and research degree students.

Fees: The current schedule of fees can be viewed at [https://www.lshtm.ac.uk/study/fees-funding/](https://www.lshtm.ac.uk/study/fees-funding/).

Scholarships: Scholarships are not available for individual modules. Some potential sources [of funding](https://www.lshtm.ac.uk/study/fees-funding/teachers-and-support/pages/taught-programmes-handbooks-regulations-policies.aspx) are detailed on the LSHTM website.

Admission deadlines: Applications for LSHTM distance learning programmes and modules are managed by the University of London. To apply to take either a formal award (i.e. PG Certificate, PG Diploma or MSc) or an individual module, click on the red Apply Now tab [https://london.ac.uk/courses/clinical-trials](https://london.ac.uk/courses/clinical-trials).

Key deadlines are as follows:
- Application deadline: 31st October each year
- Registration deadline: 30th November each year

*Please note:* The academic year starts on Monday 1st October 2018. Students who register after 1st October should note that module welcome and Collaborate sessions held in October are recorded, but they cannot request an extension to assignment submission deadlines or apply for an examination extenuating circumstance as a result of registering later than 1st October.

In-house LSHTM research degree students wishing to study this module should note information given in the mixed mode study option link at [https://lshtm.sharepoint.com/Teaching-and-Support/Pages/taught-programmes-handbooks-regulations-policies.aspx](https://lshtm.sharepoint.com/Teaching-and-Support/Pages/taught-programmes-handbooks-regulations-policies.aspx).