# Module Specification

## GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Module name</th>
<th>Data Monitoring and Interim Analyses</th>
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<tbody>
<tr>
<td>Module code</td>
<td>CTM206</td>
</tr>
<tr>
<td>Module Organiser(s)</td>
<td>Diana Elbourne, Elaine Pascoe</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 here  (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 in England, Wales &amp; Northern Ireland (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>
</tr>
<tr>
<td>Keywords</td>
<td>Monitoring, interim analysis, ethics, stopping guidelines, group sequential, DSMB, DMC, DAMOCLES.</td>
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## AIMS, OBJECTIVES AND AUDIENCE

### Overall aim
This module will cover issues relating to the on-going monitoring of the data in a study in order that sufficient data are available to answer the trial’s question reliably without recruiting more patients than necessary, or exposing them to unacceptable risks. The module will therefore focus on the ethical context of decisions about whether or not to continue entering patients into trials. A number of different statistical approaches will be explored, and the role and conduct of data monitoring committees (DMCs) in this process will be examined.

### Intended learning outcomes
By the end of this module, students should be able to:
- explain what is meant by data monitoring in the context of decisions about whether or not to continue to enter participants in a trial
- state ethical advantages and disadvantages for decisions about whether or not to continue to enter participants
- justify a range of reasons for stopping: including benefit, harm and futility
- show understanding of the statistical basis for decisions about whether or not to continue to enter participants
- distinguish between a range of stopping guidelines in the context of interim analyses in trials
- implement the guidelines using software provided
- describe the independent review role of DMC
- participate in a DMC
- demonstrate understanding of the economic context for decisions about whether or not to continue to enter participants
- evaluate the appropriateness of decisions about whether or not to continue to enter participants.

**Target audience**
Optional module for all the students on DL MSc Clinical Trials, PG Diploma Clinical Trials. Also open to any other student who meets pre-requisites for the module and who wishes to learn about data monitoring and interim analyses.

**CONTENT**

**Session content**
The module includes sessions addressing the following topics:

- Introduction to Data Monitoring and Interim Analysis
- Introduction to Statistical Stopping Guidelines
- Statistical Stopping Guidelines: Further considerations
- Introduction to Data Monitoring Committees
- Data Monitoring Committees: Operations and Conduct
- 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
- E-books:
  - Ellenberg S, Fleming TR, DeMets DL. *Data Monitoring Committees in Clinical Trials: A Practical Perspective*. Wiley; 2002;
- Online reading.

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

**Teaching and learning methods**
Students take part in a 2 week groupwork session conducted on Moodle. Contribution to this groupwork counts towards the grade for the module. Other 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 (FA1), 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 pairs of real-time tutorials available on Moodle for students to obtain additional tutor support: one for preparing for groupwork, and another for feedback on a 2nd Formative Assignment.
- Students are encouraged to make use of LSHTM online library resources.
- Students are provided with Examiners’ Reports giving previous AA questions and specimen answers.
### Assessment details

Formal assessment of the module will be by one assessed assignment (AA) (50%), and a second AA (50% including 20% for contribution to groupwork). This second AA needs to be completed in the same year as the groupwork. To pass the module, students will need to achieve an overall gradepoint average of 2, including at least a gradepoint of 1 in each AA. If students fail the module overall, they are allowed one further attempt at the failed element(s).

**Prior to September 2018**, students were required to sit an unseen written examination (80% of module marks) and submit an assessed assignment (20% of module marks). A student registered for CTM206 prior to 1 September 2018 who has completed one element of assessment but not the other (i.e. the unseen written examination or the assessed assignment) prior to 1 September 2018 must complete both elements of assessment. If a student registered for module CTM206 prior to 1 September 2018 and has obtained a GPA of less than 1.0 on the assessed assignment or the unseen written examination, or both, prior to 1 September 2018, then the failed element(s) must be resat.

### 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 two AAs for this module can be submitted separately at different times, or at the same time if the student prefers. The two Assessed Assignments for this module can be submitted only once annually, no later than 12th May and must be submitted via the online Assignment Management System.

### 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 participate in a 2 week groupwork (either in November/December or January/March), and work through the study materials until the assessment submission deadline on 12th May.

**Dates**

Tutorial support (via the online discussion forums or CTsupport@lshtm.ac.uk) is available from the beginning of October through to the assessment deadline.

**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) ≈ 50 hours
- **Self-directed learning** (general reading around the subject, library, Moodle discussion forums) ≈ 20 hours
- **Groupwork** ≈ 30 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, including basic statistics. 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.
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/tuition-fees/tuition-fees-and-expenses-2018-19), 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 approx. 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 and MSc Clinical Trials. 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/tuition-fees/tuition-fees-and-expenses-2018-19](https://www.lshtm.ac.uk/study/fees-funding/tuition-fees/tuition-fees-and-expenses-2018-19).

### Scholarships
Scholarships are not available for individual modules. Some potential sources of funding 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).

### ABOUT THIS DOCUMENT
This module specification applies for the academic year 2018/19

Last revised/approved 16/11/2017 by Diana Elbourne, Elaine Pascoe

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