# Module Specification

## ABOUT THIS DOCUMENT

This module specification applies for the academic year 2018-19  
**Last revised**  2 August 2017 by Tim Clayton

London School of Hygiene & Tropical Medicine, Keppel St., London WC1E 7HT.  [www.lshtm.ac.uk](http://www.lshtm.ac.uk)

## GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Module name</th>
<th>Clinical Trials</th>
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<tbody>
<tr>
<td>Module code</td>
<td>2033</td>
</tr>
<tr>
<td>Module Organisers</td>
<td>Professor Stuart Pocock and Tim Clayton</td>
</tr>
<tr>
<td>Contact email</td>
<td><a href="mailto:Stuart.Pocock@lshtm.ac.uk">Stuart.Pocock@lshtm.ac.uk</a> or <a href="mailto:Tim.Clayton@lshtm.ac.uk">Tim.Clayton@lshtm.ac.uk</a></td>
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<tr>
<td>Home Faculty</td>
<td>Epidemiology &amp; Population Health</td>
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<tr>
<td>Level</td>
<td>Level 7 (postgraduate Masters ‘M’ level) of the QAA <a href="http://www.qaa.ac.uk">Framework for Higher Education Qualifications</a> in England, Wales &amp; Northern Ireland (FHEQ)</td>
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<tr>
<td>Credit</td>
<td>10 credits, within the larger 60-credit Term 1 super-module for each MSc programme. Credits are not awarded for this module individually, but only for successful completion of the Term 1 super-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>Randomization, Controlled clinical trials, Communicable diseases (in general), Non-communicable diseases (in general), Disease prevention &amp; control, Statistics</td>
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## AIMS, OBJECTIVES AND AUDIENCE

**Overall aim**  
To provide an introduction to the main issues in the design, analysis and interpretation of clinical trials

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

- Explain fundamental principles of comparative clinical trials in investigating and ensuring efficacy and safety of treatments
- Describe the main features of clinical trials, including methodological and organisational considerations
- Explore key decisions surrounding design, delivery and assessment of clinical trials
- Explain the principles of trial conduct, reporting and meta-analyses

**Target audience**  
The full 10-week module is compulsory for MSc students in Medical Statistics and Epidemiology. All other students with an interest in clinical trials are welcome.
## CONTENT

### Session content
The module is expected to include sessions addressing the following topics:
- General principles of comparative clinical trials
- Randomization (including the rationale, organization, ethics and methods of randomization)
- Size of trials (including power calculations, the need for large trials, and problems of small trials)
- Data monitoring
- Clinical trials reporting
- Alternative trial designs
- Drafting a trial protocol
- Principles of meta-analysis

## TEACHING, LEARNING AND ASSESSMENT

### Study resources provided or required
Module information can be found on the Virtual Learning Environment (Moodle) containing information about each session and key references for the module.

### Teaching and learning methods
Learning will generally be based on lectures followed by relevant.

### Assessment details
Medical Statistics students complete an assignment on aspects of trial design and/or analysis in the form of a written report. Formal assessment is by written examination. For students who are required to resit, or granted a deferral or new attempt, the task will be a written exam the following academic year.

### Assessment dates
The submission date for the assessment will be a date decided by the module Organiser, around early November. Written examinations will take place during the summer term in early/mid June. Resit/deferred/new attempts will take place during the summer term in early/mid June in the following academic year.

### Language of study and assessment
English (please see ‘English language requirements’ below regarding the standard required for entry).

## TIMING AND MODE OF STUDY

### Duration
10 weeks at 0.5 days per week

### Dates
Thursday afternoons

### Timetable slot
Term 1

### Mode of Study
The module is taught face-to-face in London. Both full-time and part-time students follow the same schedule.

### Learning time
The notional learning time for the module totals 100 hours, consisting of:
- Contact time ≈ 30 hours
- Directed self-study ≈ 15 hours
- Self-directed learning ≈ 20 hours
- Assessment, review and revision ≈ 35 hours

**APPLICATION AND ADMISSION**

<table>
<thead>
<tr>
<th>Pre-requisites</th>
<th>None</th>
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<tr>
<td><strong>English language requirements</strong></td>
<td>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 <a href="#">English language requirements</a>.</td>
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<tr>
<td>Student numbers</td>
<td>100 (numbers may be capped due to limitations in facilities or staffing)</td>
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<tr>
<td>Student selection</td>
<td>The full 10-week module is compulsory for MSc Medical Statistics and Epidemiology. Partial Registration (partial participation) by LSHTM research degree students is allowed for this module. Preference will be given to LSHTM MSc students and LSHTM research degree students. Other applicants meeting the entry criteria will usually be offered a place in the order applications are received, until any cap on numbers is reached. Applicants may be placed on a waiting list and given priority the next time the module is run.</td>
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