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<th>Module Specification</th>
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### GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Module name</th>
<th>Regulatory Affairs, Good Clinical Practice and Ethics</th>
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<tbody>
<tr>
<td>Module code</td>
<td>CTM204</td>
</tr>
<tr>
<td>Module Organiser(s)</td>
<td>Claire Snowdon, Lucy Campbell, Mags Beksinska,</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>Good Clinical Practice (GCP), regulatory legislation, ethics.</td>
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### AIMS, OBJECTIVES AND AUDIENCE

| Overall aim                  | This module seeks to develop your understanding of the key features relating to the regulatory legislation and associated approvals and permissions required to conduct high quality, national and international clinical trials. Integral to the legislation is Good Clinical Practice (GCP). Students will gain a solid understanding of GCP and will explore ways of implementing GCP, including risk assessment and trial monitoring. Although the focus will be on trials of medicinal products, trials in a variety of other areas, and in different geographical settings, will be examined. Ethical issues will be considered throughout the module. Students will review the history of ethics to get an understanding of how important events and legislation have impacted upon and shaped how clinical trials are conducted today. This module consolidates and develops many of the topics introduced in the core module CTM103 Clinical Trials in Practice. |
| Intended learning outcomes  | By the end of this module, students should be able to: explain the role of regulatory affairs in the development of new medicines explain the principles of GCP demonstrate an understanding of the theoretical basis of morality discuss the issues associated with creating and setting a research agenda identify the various roles and responsibilities involved in clinical trials appraise the risks associated with clinical trials and their management describe the process of gaining ethics committee approval |
- describe the process of informed consent and treatment of vulnerable populations
- discuss issues associated with providing access to new medicinal products
- describe the mechanisms for assuring and controlling quality in clinical trials
- describe the various documents which are essential to designing and conducting clinical trials.

**Target audience**
Optional module for all the students on DL MSc Clinical Trials, PG Diploma Clinical Trials, DL MSc Epidemiology, DL PG Diploma/MSc Global Health Policy. Also open to any other student who meets pre-requisites for the module and who wishes to learn about Regulatory Affairs, GCP and Ethics.

**CONTENT**

**Session content**
The module is expected to include sessions addressing the following topics:
- Introduction
- History, Law and Ethics
- The Research Agenda
- Identifying Roles and Responsibilities
- Risks and Research
- Consent
- Access to drugs
- Quality Assurance and Control
- Essential Documents.

**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:
- Online reading.
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 FAs.
- There are at least two real-time tutorials available on Moodle for students to obtain additional tutor support: one for feedback on a second 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 marking schemes.
### Assessment details
Formal assessment of the module will be by an Assessed Assignment (AA) (20%) and by 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 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) ≈ 30 hours
- **Assessment, review and revision** ≈ 60 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. 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/), 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 40 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/MSc Clinical Trials, MSc Epidemiology, PG Diploma/MSc Global Health Policy. 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 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:** 2nd February 2017 by Claire Snowdon  
London School of Hygiene & Tropical Medicine, Keppel St., London WC1E 7HT.  
[www.lshtm.ac.uk](http://www.lshtm.ac.uk)