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MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2022-23
Module Code	CTM204
Module Title	Regulatory Affairs, Good Clinical Practice and Ethics
Module Organiser(s)	Claire Snowdon, Mags Beksinska, Lucy Campbell
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	100962 : 100473 : 100793
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. 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. 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, 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, Good Clinical Practice (GCP) and Ethics.



Module Description	<p>This module seeks to develop 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 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.</p>
Duration	<p>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).</p>
Last Revised (e.g. year changes approved)	<p>2021</p>

Programme(s)	Status
This module is linked to the following programme	
PGDip/MSc Clinical Trials (Distance Learning - University of London Worldwide)	Elective
PGDip/MSc Epidemiology (Distance Learning - University of London Worldwide)	Elective
PGDip/MSc Global Health Policy (Distance Learning - University of London Worldwide)	Elective



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Module Aim and Intended Learning Outcomes

Overall aim of the module

The overall module aim is to:

- equip students with the skills and knowledge needed to work with guidelines and regulations governing clinical trial conduct. It will require students to engage with and apply the ethical principles underpinning those regulations.

Module Intended Learning Outcomes

Upon successful completion of the module a student will be able to:

1. explain the role of regulatory affairs in the development of new medicines
2. apply the principles of Good Clinical Practice
3. apply the ethical principles underpinning regulatory affairs.

Indicative Syllabus

Session Content

The module consists of Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows:

- Introduction
- History, Law and Ethics
- Identifying Roles and Responsibilities
- Risks and Research
- Consent
- Access to drugs
- Quality Assurance and Control
- Essential Documents.
- 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



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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, 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 CTM204 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 are used to build skills, and encourage students to engage with the study materials. They encourage M-level thinking through questions which challenge students to consult study materials and to reflect and problem-solve. 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 test core learning and M-level skills and should be answered with the same criticality as should be demonstrated in the AAs. The assessments support attainment of ILOs by collectively testing across the range of learning outcomes. For all CTM204 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 conduct and regulation of clinical trials. On this module two past AA papers, and three past examination papers, all with specimen answers, are also available for practice and self-assessment.

NB students who enrolled on this module prior to 2022 and who need to resit or who are partially through the existing method of assessment (i.e. having sat the exam but not the AA or vice versa) will be required to still complete the existing method of assessment i.e. one Assessed Assignment (20%) and a formal examination (80%). Note that the Assessed Assignment (20%) and unseen written examination (80%) will only be available



Assessment Strategy

to take in 2022/23. After this time, students who have not completed both forms of module assessment would be expected to take the new method of assessment (60% AA and 40% exam). Any student who registered for CTM204 prior to 2022/23 should contact the Module Organiser to discuss their individual assessment requirements

Summative Assessment

Assessment Type	Assessment Length (i.e. Word Count, Length of presentation in minutes)	Weighting (%)	Submission deadline	Intended Module Learning Outcomes Tested
Assessed Assignment	The Assessed Assignment has a maximum word length of 3000 words	60	12 th May	1-3
Exam	1hr 15mins	40	Held once per year in June	1-3

Timed examinations for DL modules are held once a year, in June (including resits). Examinations in 2022/23 will either be taken in a student's country of residence in one of over 650 [examination centres worldwide](#) or will be held online. If the June 2023 module exam is held at a local examination centre, a local fee will be payable direct to the exam centre. This fee will be in addition to the module fee and is set by, and paid directly to, the individual examination centre. 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. If the June 2023 module exam is held online, no additional exam entry fee will be payable. (Note that for those resitting module assessments, a fee will be payable.)

Resitting assessment

Resits will accord with the LSHTM's [Resits Policy](#)



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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
- E-books as below
- Online reading

E-books

- Michael A. Santoro, Thomas M. Gorrie. *Ethics and the Pharmaceutical Industry*, Cambridge University Press 2005.
- McDonald A et al. (2016). *A Guide to Efficient Trial Management*. Fifth Edition]. Oxford: Trial Managers Network, HMSO.

Examples of online reading

- Freedman B (1987). Equipoise and the ethics of clinical research. *New Engl J Med* 317:141–5
- International Conference for Harmonisation (2016). *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice. E6(R2)*
- Medicines and Healthcare Regulatory Authority. *Investigations into Adverse Incidents During Clinical Trials of TGN1412*
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). *The Belmont Report*, Washington, DC: DHEW Publication OS 78-0012, 1978
- Nuffield Council on Bioethics (2002). *The ethics of research related to healthcare in developing countries*. London: NCOB
- Nuremberg Code 1947
- World Medical Association (2013). *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*

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>