MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2024-25
Module Code	CTM204
Module Title	Regulatory Affairs, Good Clinical Practice and Ethics
Module Organiser(s)	Claire Snowdon, Mags Beksinska, Lucy Campbell, Zoe Plummer
Contact Email	CTsupport@lshtm.ac.uk
Faculty	Epidemiology and Population Health London School of Hygiene & Tropical Medicine
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	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 gain 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.
Duration	Distance learning module studies begin on Tuesday 1st October 2024. Students may start their studies at any time once they gain access to Moodle and therefore the study materials, and work through the materials until the start of the June Time Limited Assessments (formative and summative assignments have earlier submission deadlines which must be observed).
Last Revised (e.g. year changes approved)	March 2024

Programme(s) This module is linked to the following programme	**Status**
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

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 9 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**

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 Time Limited Assessment (SATLA), 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 via Collaborate, available on Moodle, to obtain additional tutor support: at least two tutorials are available, one focusing on Assessed Assignments, and one for Time Limited Assessment (TLA) preparation. • make use of LSHTM online library resources. • make use of Examiners' Reports which include previous assessments questions and specimen answers.

Assessment

Assessment Strategy
The assessment strategy for CTM204 is designed to support progressive student learning through optional formative assignments, which can be self-assessed (SAFA and SATLA) or tutor-marked with feedback (TMFA), and compulsory assessments. The compulsory components are a summative written Assessed Assignment (AA) and a Time Limited Assessment (TLA) 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 TLA questions are also written to test core learning and M-level skills and should be

Assessment Strategy
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. Past AA and TLA papers, all with specimen answers, are available for practice and self-assessment.

Summative Assessment

Assessment Type	**Assessment Length (i.e. Word Count, Length of presentation in minutes)**	**Weighting** (%)	**Intended Module Learning Outcomes Tested**
Assessed Assignment	The Assessed Assignment has a maximum word length of 3000 words	60	1-3
Time Limited Assessment	The TLA has a maximum word length of 3000 words	40	1-3

Time Limited Assessments (TLAs) for DL modules are held once a year, usually in June (including resits). The assessments are held in accordance with University of London's annual guidance. Please note that for those resitting module assessments, a fee will be payable. Further details will be communicated as soon as the final decisions are known.

Resitting assessment
Resits will accord with the LSHTM's Resits Policy

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 website at Inclusive practice access arrangements