Module Specification (Distance Learning)

In collaboration with University of London International Programmes

1. Title:	**Regulatory Affairs, GCP and Ethics**
2. Module code:	CTM204
3. Institution:	Faculty of Epidemiology and Population Health London School of Hygiene & Tropical Medicine Keppel Street London WC1E 7HT http://www.lshtm.ac.uk/eph
4. Module Organiser:	Corinne Merle
5. Mode of study:	Distance learning
6. Type:	Elective module
7. Duration and dates:	Deadlines if taken as part of a formal award: Application deadline: 30 June each year Registration deadline: 31 August each year Course registration duration: Up to 5 years Course starts: 1 October each year Examination takes place: Usually June each year (date to be confirmed) Deadlines if taken as an individual module (i.e. not registered for formal award): Application deadline: 31 August each year Registration deadline: 30 November each year Registration duration: 2 years Module study starts: 1 October each year Examination takes place: Usually June each year (date to be confirmed).
8. Credit points:	15 credit points will be awarded on successful completion of this module at Masters level (Level 7).
9. Notional Learning Hours (NLH):	On average the module should take about 150 hours to complete, consisting of the following: Computer-Assisted Learning (CAL) sessions: 40 hours Additional reading time: 24 hours Assignments: 14 hours Self-directed learning: 72 hours.
10. 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 on how important events and legislation have impacted 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.*

11. Learning objectives:	On completing this module students should be able to: – discuss the theoretical and historical basis of morality and ethics – explain the role of regulatory affairs in the development of new medical treatments. – discuss the issues associated with creating a research agenda – explain and apply the principles of GCP when designing and conducting a clinical trial. In particular: – identify the various roles and responsibilities of key players involved in clinical trials – assess the risks associated with clinical trials and their management – describe the process of gaining ethics committees approval – describe the process of informed consent, including the process for vulnerable populations – discuss issues associated with providing access to new medicinal products – describe the mechanisms for assuring and controlling quality in clinical trials – formulate the various documents which are essential to designing and conducting clinical trials.
12. Content:	This module consists of ten CAL sessions: 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 Summary.
13. Learning methods:	Learning is self-directed against a detailed set of learning objectives, identified at the start of each chapter, using the materials provided. These consist of a module textbook which lists a range of activities including focused reading. Student support is available from the module tutors through the web-based discussion forum in which students are encouraged to participate. In addition, module tutors provide written feedback on the submitted assessed assignment. The course uses Computer-Assisted Learning (CAL) material to introduce and explain the principles and methods covered in the module. It is important that all the CAL sessions are completed and understood at each step before progressing with further sessions.
14. Assessment procedures:	Formal assessment of the module will be by an assessed assignment (20%) and by a two-hour unseen written examination (80%). Examinations are normally held in a student's country of residence, in one of over 650 examination centres worldwide. They are arranged mainly through Ministries of Education or the British Council. A local fee will be payable. A list of examination centres can be found at http://www.londoninternational.ac.uk/current_students/general_resources/exams/exam_centres/index.shtml. If students fail an examination at the first entry they will be allowed one further attempt, the following year.

15. Prerequisites:	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 as this module is taught online and through web-based discussions. Students must meet the standard of English required to study this course. See http://www.lshtm.ac.uk/prospectus/english.html.
16. Attendance:	No maximum number
17. Selection, if applicable:	This module is one of the optional modules available to those studying the MSc Clinical Trials course but may also be studied by those registered for the MSc Epidemiology course. Those studying for the PG Diploma in Clinical Trials under the credit framework scheme may also choose to study this module. Alternatively, it may be taken as an Individual Module.
18. Fees:	For current schedule of fees see http://www.londoninternational.ac.uk/fees/schedules/lshtm.pdf.
19. Scholarships:	MSc only – see http://www.lshtm.ac.uk/prospectus/funding/ for details.
20. External accreditation:	None
21. Application process:	Applications are managed by the University of London International Programmes (website: http://www.londoninternational.ac.uk/).
22. Further enquiries:	Enquiries may be emailed to distance@lshtm.ac.uk.