

Module Specification (Distance Learning)

In collaboration with University of London International Programmes



1. Title:	Data Management
2. Module code:	CTM205
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:	Andy Richardson
5. Mode of study:	Distance learning
6. Type:	Elective module
7. Duration and dates:	<p>Deadlines if taken as part of a formal award:</p> <p>Application deadline: 30 June each year</p> <p>Registration deadline: 31 August each year</p> <p>Course registration duration: Up to 5 years</p> <p>Course starts: 1 October each year</p> <p>Examination takes place: Usually June each year (date to be confirmed)</p> <p>Deadlines if taken as an individual module (i.e. not registered for formal award):</p> <p>Application deadline: 31 August each year</p> <p>Registration deadline: 30 November each year</p> <p>Registration duration: 2 years</p> <p>Module study starts: 1 October each year</p> <p>Examination takes place: Usually June each year (date to be confirmed)</p>
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):	<p>On average the module should take about 150 hours to complete, consisting of the following:</p> <p>Computer-Assisted Learning (CAL) sessions: 44 hours</p> <p>Additional reading time: 18 hours</p> <p>Assignments: 14 hours</p> <p>Self-directed learning: 74 hours</p>
10. Aim:	<p>This module is designed for students with a particular interest or need to understand in detail the principles and practices required to collect high quality clinical trial data, to prepare clinical trial data for analysis and to comply with regulatory requirements and Good Clinical Practice (GCP).</p> <p>Students will also learn how to establish the necessary infrastructure (computing environment and its controls) and the key skills and resource requirements necessary to manage a successful data management project.</p>
11. Learning objectives:	<p>On completing this module students should be able to:</p> <ul style="list-style-type: none"> • understand and discuss the key clinical data management principles, • understand the regulatory framework impacting clinical data management, • implement the processes and steps required to undertake a data management project from start to finish, • analyse and build a database to hold and manipulate a trial's clinical data (optional),

	<ul style="list-style-type: none"> • develop and specify how clinical data are to be checked and confirmed, • resource and supervise a data management project, • code and categorise clinical data in preparation for analysis, • explain and discuss common problems and solutions arising during the data management process.
12. Content:	<p>This module consists of 11 CAL sessions:</p> <p>Introduction Regulatory Environment Project Preparation Database Creation (exercises optional) Data Entry and Data Review Trial Implementation Trial Data Processing Project Close and Archive Managing Data Management Projects Establishing the Data Management Infrastructure Summary.</p>
13. Learning methods:	<p>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.</p> <p>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.</p> <p>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.</p>
14. Assessment procedures:	<p>Formal assessment of the module will be by an assessed assignment (20%) and by a two-hour unseen written examination (80%).</p> <p>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.</p> <p>If students fail an examination at the first entry they will be allowed one further attempt, the following year.</p>
15. Prerequisites:	<p>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.</p> <p>Those wishing to study this module must have regular access to the internet as this module is taught online and through web-based discussions.</p> <p>Students must meet the standard of English required to study this course. See http://www.lshtm.ac.uk/prospectus/english.html.</p>
16. Attendance:	No maximum number

17. Selection, if applicable:	This module is one of the optional modules available to those studying the MSc <u>Clinical Trials</u> 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/lshhtm.pdf .
19. Scholarships:	MSc only – see http://www.lshhtm.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@lshhtm.ac.uk .