# Module Specification

## GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Module name</th>
<th>Data Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module code</td>
<td>CTM205</td>
</tr>
<tr>
<td>Module Organiser(s)</td>
<td>Bridget Kirwan, Bhavini Ladwa</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 <a href="https://london.ac.uk/contact-us">here</a> (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>
</tr>
<tr>
<td>Home Faculty</td>
<td>Epidemiology and Population Health London School of Hygiene &amp; Tropical Medicine <a href="http://www.lshtm.ac.uk/eph/">http://www.lshtm.ac.uk/eph/</a></td>
</tr>
<tr>
<td>Level</td>
<td>This module is at Level 7 (postgraduate Masters level) of the QAA <a href="https://www.qaa.ac.uk/">Framework for Higher Education Qualifications</a> in England, Wales &amp; Northern Ireland (FHEQ).</td>
</tr>
<tr>
<td>Credit</td>
<td>LSHTM awards 15 credits on successful completion of this module.</td>
</tr>
<tr>
<td>Accreditation</td>
<td>Not currently accredited by any other body.</td>
</tr>
<tr>
<td>Keywords</td>
<td>Data Management, Data Management Project, Regulatory Requirements GCP &amp; 21 CFR Part 11, Database Design, Data Review &amp; Resolution, Database Lock, Data Management Infrastructure.</td>
</tr>
</tbody>
</table>

## AIMS, OBJECTIVES AND AUDIENCE

### Overall aim
This module is designed for students with a particular interest or need to understand in detail the principles and practices required to implement a data management infrastructure to collect and manage clinical research data, to review and prepare clinical trial data for analysis in compliance with regulatory requirements and Good Clinical Practice (GCP). Students will also learn how to set-up and implement the necessary infrastructure (computing environment and its controls) as well as the key skills and resource requirements necessary to successfully manage a data management project.

### Intended learning outcomes
By the end of this module, students should be able to:
- understand and discuss the key clinical data management principles,
- understand the regulatory framework around the set-up and management of clinical research data,
- implement a project's data management processes and documentation,
- develop data management specifications,
- understand the principles and practices for the review of and cleaning of clinical research data in preparation for statistical analysis,
- Describe the procedures around the locking and unblinding of a study database.
- Detail the common problems which could arise during the lifecycle of a data management project and the associated risk mitigation planning

**Target audience**

Optional module for all the students on DL PG Diploma/MSc Clinical Trials, 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 data management.

**CONTENT**

**Session content**

The module includes the following session topics:

- Introduction to the key clinical data management principles
- The regulatory environment
- Typical Data Management Standard Operating Procedures
- Data Management Project Preparation
- Reviewing Clinical research Data (1) Principles
- Reviewing Clinical research Data (2) Specific Techniques and Standard Datatypes
- Database Lock
- Managing data management projects
- Establishing the data management infrastructure.

**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
- Online reading: including Sessions CTP06 (Methods of Data Collection) and CTP07 (Data Processing and Management) from Module CTM103 Clinical Trials in Practice.

In addition to the materials above, students are given access to the LSHTM Virtual Learning Environment, Moodle (for online discussion 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 provided. The FA is not compulsory and does not contribute to the overall module grade.
  - Students are provided with written feedback on submitted AAs.
  - There are four real-time tutorials (i.e. CT Collaborate sessions) available on Moodle for students to obtain additional tutor support.
  - Students are encouraged to make use of LSHTM online library resources.
  - Students are provided with Examiners’ Reports giving previous examination questions and specimen answers.

**Assessment details**

Formal assessment of the module will be by an assessed assignment (20%) and 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. 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 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** | 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). Tutorial support (via the online discussion forums, Collaborate sessions or CTsupport@lshtm.ac.uk) is available from the beginning of October through to the start of the exam (usually in June). By distance learning. The notional learning time for the module totals 150 hours, consisting of: • **Directed self-study** (reading and working through the provided module material) ≈ 65 hours • **Self-directed learning** (general reading around the subject, library, Moodle discussion forums) ≈ 30 hours • **Assessment, review and revision** ≈ 55 hours. |
| **APPLICATION, ADMISSION AND FEES** | 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, 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 approx. 30 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, 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/tuition-fees/tuition-fees-and-expenses-2018-19

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

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

ABOUT THIS DOCUMENT

This module specification applies for the academic year 2018/19
Last revised/approved 10 December 2017 by Bridget-Anne Kirwan
London School of Hygiene & Tropical Medicine, Keppel St., London WC1E 7HT. www.lshtm.ac.uk