MODULE SPECIFICATION

Academic Year	2026-27
Module Code	CTM205
Module Title	Data Management
Module Organiser(s)	Bridget Kirwan & Anusiya Manivel
Contact Email	For students studying University of London Awards (initial registration 2025/2026 and prior years: Enquiries may be made via their Student Advice Centre at: Student Advice Centre. For students studying LSHTM awards (registration in 2026/2027 and onwards): Enquiries should be emailed to CTsupport@lshtm.ac.uk
Faculty	Epidemiology and Population Health
FHEQ Level	Level 7
Credit Value	**CATS** 15 **ECTS** 7.5
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 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.

Module Description	Clinical Data Management (CDM) is an indispensable part of clinical research. CDM activities should lead to the collection of reliable, high quality and statistically sound data. This module will enable students to gain a solid understanding of the best practices for developing a data management project while abiding by and applying the regulatory requirements. Throughout the sessions, we focus on practical examples, short quizzes and hands-on exercises as we explore together the best practices in data management. Students will also gain a solid understanding of the regulatory framework governing all data management activities in addition to data quality control and quality assurance activities that should be implemented to ensure that the ICH GCP and the applicable regulatory requirements with respect to data quality and integrity are met.
Duration	Distance learning module studies begin on Thursday 1st October 2026. 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 AA submission deadline on 12th May.
Last Revised (e.g. year changes approved)	April 2025

For students studying UoL awards (initial registration in 2025/2026 and prior years)

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

For students studying LSHTM awards (registration in 2026/2027 and onwards)

Programme(s) This module is linked to the following programme(s)	**Status**
PGDip Clinical Trials (Distance Learning)	Elective
MSc Clinical Trials (Distance Learning)	Elective
PGDip Global Health Policy (Distance Learning)	Elective
MSc Global Health Policy (Distance Learning)	Elective

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: • present the critical concepts and practical methods related to a data management project and to understand the role of the data management function within a clinical trial setting in addition to the regulatory environment governing the data management processes.

Module Intended Learning Outcomes
Upon successful completion of the module a student will be able to: 1. demonstrate knowledge and understanding of the role of data management within the framework of a clinical trial 2. apply fundamental practices in designing, implementing, managing and closing out a data management project 3. demonstrate knowledge and understanding of the key principles which should be implemented to deliver high quality data for statistical analysis 4. demonstrate knowledge and understanding of the regulatory framework governing the data management process 5. critically evaluate the quality control/assurance activities governing the data management process.

Indicative Syllabus

Session Content
The module consists of 9 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows: • 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 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. • work through the Self Assessed Formative Assignment (SAFA), for which self-assessment tools are provided. • submit a Tutor Marked Formative Assignment (TMFA), for which personalised written feedback is available. Students are provided with written feedback on submitted TMFAs. • join real-time webinars via Zoom on Moodle to obtain additional tutor support • to make use of LSHTM online library resources • make use of Examiners' Reports giving previous AA questions and specimen answers.

Assessment

Assessment Strategy
The assessment strategy for CTM205 is designed to support progressive student learning through optional formative assessments, which can be self-assessed (SAFA) or tutor-marked with feedback (TMFA), and one written summative assessed assignment (AA). The FAs use scenario-based question format 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 and supports attainment of ILOs by testing across the range of learning outcomes. 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 limits give sufficient text allowance to demonstrate these skills within a succinct and focused writing style. For all CTM205 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 setting up and managing clinical trial data management projects.

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 4000 words	100	1-5

Resitting assessment
Resits will accord with Chapter 8b of the LSHTM Academic Manual.

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-book as below
- Online reading as below

E-books

- Prokscha S. *Practical Guide to Clinical Data Management*. CRC Press, 3rd edition (2011)
- *Fernamdez, The Fundamentals of Clinical Data Management, Sunshine Publishers*
- SDTM-IG: Study Data Tabulation Model Implementation Guide. Various Versions. See CDISC SDTM Pages
- Clinical Data Interchange Standards Consortium (CDISC) Standards

Online resources

- Journal of the Society for Clinical Data Management https://www.jscdm.org

Examples of online reading

Sessions CTP06 (Methods of Data Collection) and CTP07 (Data Processing and Management) from Module CTM103 Clinical Trials in Practice. Session CTP06 will enable students to gain an understanding of what needs to be considered when defining the data to be collected for a clinical trial in addition the principles behind the design of a data collection instrument (i.e. eCRF or questionnaire) that will be used to collect the data. Session CTP07 (Data Processing and Management) provides an overview of the principles for the management of data collected in a clinical trial.

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 studying University of London Awards (initial registration 2025/2026 and prior years:
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: Inclusive practice and Access arrangements | University of London

For Students Studying LSHTM awards (registration 2026/2027 and onwards):
For students who require learning or assessment adjustments and support this can be arranged through the Student Support Services – details and how to request support can be found on the LSHTM Disability Support pages.