MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2022-23
Module Code	CTM205
Module Title	Data Management
Module Organiser(s)	Bridget Kirwan, Bhavini Ladwa, Vicky Simms
Contact Email	CTsupport@lshtm.ac.uk
Faculty	Epidemiology and Population Health London School of Hygiene & Tropical Medicine http://www.lshtm.ac.uk/eph/
FHEQ Level	Level 7
Credit Value	**CATS** 15 **ECTS** 7.5
HECoS Code	100962 : 100473 : 100755
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 ideally 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 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 submission of the assessed assignment in May.
Last Revised (e.g. year changes approved)	2021

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

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 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows: • Introduction • Principles of clinical data management • Operational infrastructure • Basic start-up considerations • Clinical data standards • Data privacy • Data Review specifications • Database set-up • Clinical Data management procedures • Common Clinical data types • Medical coding • Study closeout • Project management and metrics

Teaching and Learning

Notional Learning Hours

Type of Learning Time	**Number of Hours**	**Expressed as Percentage (%)**
Directed self-study	65	43
Self-directed learning	30	20
Assessment, review and revision	55	37
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. This is not compulsory and does not contribute to the overall module grade.
- submit a Tutor Marked Formative Assignment (TMFA), for which personalised written feedback is available.
- join real-time tutorials available on Moodle to obtain additional tutor support – a number of sessions are organized throughout the academic year
- 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 have the same word-length and 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.

NB students who enrolled on this module prior to 2020 work with the previous assessment strategy for this module i.e. one assessed assignment (20%) and a formal examination (80%). Students who need to resit or who are partially through the existing method of assessment (i.e. having sat the exam but not the AA or vice versa) will be required to still complete the existing method of assessment. Note that the Assessed Assignment (20%) and unseen written examination (80%) will only be available to take in 2020/21 and 2021/22. After this time, students who have not completed both forms of module assessment must transfer to the new method of assessment (100% AA).

Summative Assessment

Assessment Type	Assessment Length (i.e. Word Count, Length of presentation in minutes)	Weighting (%)	Submission deadline	Intended Module Learning Outcomes Tested
Assessed Assignment	The Assessed Assignment has a maximum word length of 5000 words	100	12th May	1-5

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-book as below
- Online reading as below

E-books

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

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 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 https://london.ac.uk/applications/how-it-works/inclusive-practice-access-arrangements