MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2021-22
Module Code	CTM206
Module Title	Data Monitoring and Interim Analyses
Module Organiser(s)	Diana Elbourne, Tim Collier
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
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, including basic statistics. 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 MSc Clinical Trials, PG Diploma Clinical Trials. Also open to any other student

	who meets the pre-requisites for the module and who wishes to learn about data monitoring and interim analyses.
Module Description	The module aim focuses on the on-going monitoring of the data in a study in order that sufficient data are available to answer the trial's question reliably without recruiting more patients than necessary, or exposing them to unacceptable risks. Statistical, ethical and conduct issues are considered.
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 participate in a 2-week group work (either in November/December or January/February/March), and work through the study materials until the assessment submission deadline on 12th May.
Last Revised (e.g. year changes approved)	2021

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

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: • equip students with knowledge and understanding of, and skills to address, issues relating to the on-going monitoring of the data in a study in order that sufficient data are available to answer the trial's question reliably without recruiting more patients than necessary, or exposing them to unacceptable risks.

Module Intended Learning Outcomes
Upon successful completion of the module a student will be able to: 1. explain what is meant by data monitoring in the context of decisions about whether or not to continue to enter participants in a trial 2. describe the independent review role of a Data Monitoring Committee (DMC) 3. evaluate the appropriateness of statistical, ethical and economic decisions about whether or not to continue to enter participants in a trial 4. apply a range of stopping guidelines using software provided 5. participate effectively in a DMC.

Indicative Syllabus

Session Content
The module consists of 6 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows: • Introduction to Data Monitoring and Interim Analysis • Introduction to Statistical Stopping Guidelines • Statistical Stopping Guidelines: Further considerations • Introduction to Data Monitoring Committees • Data Monitoring Committees: Operations and Conduct • Summary.

Teaching and Learning

Notional Learning Hours

Type of Learning Time	**Number of Hours**	**Expressed as Percentage (%)**
Group Work	30	20
Directed self-study	50	33
Self-directed learning	20	14
Assessment, review and revision	50	33
Total	**150**	**100**

Teaching and Learning Strategy
Students take part in a 2-week group work session conducted on Moodle. Contribution to this group work counts towards the grade for the module. Other 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. • learn from written feedback from tutors on submitted AAs. • join real-time tutorials via Collaborate available on Moodle to obtain additional tutor support: one for preparing for group work, and another for feedback on the SAFA. • 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 CTM206 is designed to support progressive student learning through optional formative assessments, which can be self-assessed (SAFA) or tutor-marked with feedback (TMFA), groupwork and two summative written assessed assignments (AAs). The FAs use a scenario-based short question format to build skills, and to encourage students to engage with the study materials. The AAs are 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. The assessments encourage M-level thinking through questions which challenge students to consult study materials and to reflect and problem-solve. They support attainment of ILOs by collectively testing across the range of learning outcomes. For all CTM206 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 the data monitoring of clinical trials. On this module two past AA papers (with specimen answers where appropriate) are also available for practice and self-assessment.

Summative Assessment

Assessment Type	**Assessment Length (i.e. Word Count, Length of presentation in minutes)**	**Weighting** (%)	**Intended Module Learning Outcomes Tested**
Coursework	Groupwork - contributions to group work are assessed over a two-week groupwork period.	20	5
Assessed Assignment: AAQ1	Assessed Assignment 1 (AA1) which follows from groupwork, has a maximum word length of 3000 words	30	3
Assessed Assignment: AAQ2	Assessed Assignment 2 (AA2) has a maximum word length of 5000 words	50	1,2,3,4

Resitting assessment
Resits will accord with the LSHTM's Resits Policy

Resitting assessment
For this module, the groupwork and AA1 are not independent. The groupwork contribution provides the foundation for AA1 and so must be completed to answer AA1. As the joint focus of the groupwork and AA1 change each academic year, both must be carried out in the same year. If one component is not completed both assessments must be resat; they cannot be resat separately.

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-books as below:
- Online reading.

E-books

- Ellenberg S, Fleming TR, DeMets DL. *Data Monitoring Committees in Clinical Trials: A Practical Perspective*. Wiley; 2002;
- Grant AM, Altman DG, Babiker AB, Campbell MK, Clemens FJ, Darbyshire JH, Elbourne DR, McLeer SK, Parmar MKB, Pocock SJ, Spiegelhalter DJ, Sydes MR, Walker AE, Wallace SA, and the DAMOCLES study group. Issues in data monitoring and interim analysis of trials. *Health Technology Assessment*. 2005;9(7).

Examples of optional online reading

- DeMets DL, Ellenberg SS. Data Monitoring Committees - Expect the Unexpected. *N Engl J Med* 2016;375:1365-71. DOI: 10.1056/NEJMra1510066
- Grant AM, Altman DG, Babiker AB, Campbell MK, Clemens F, Darbyshire JH, Elbourne DR *et al*. for the DAMOCLES Group. A proposed charter for clinical trial data monitoring committees: helping them to do their job well. *Lancet* 2005; 365(9460): 711-22 (b)
- DeMets DL, Furberg CD, Friedman LM. *Data monitoring in clinical trials. A case studies approach*. Springer (2006)

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