

## MODULE SPECIFICATION

<b>Academic Year (student cohort covered by specification)</b>	2022-23
<b>Module Code</b>	CTM203
<b>Module Title</b>	Project Management and Research Coordination
<b>Module Organiser(s)</b>	Joanna Sturgess (MO), Sue Tebbs (DMO)
<b>Contact Email</b>	<a href="mailto:CTsupport@lshtm.ac.uk">CTsupport@lshtm.ac.uk</a>
<b>Faculty</b>	Epidemiology and Population Health London School of Hygiene & Tropical Medicine <a href="http://www.lshtm.ac.uk/eph/">http://www.lshtm.ac.uk/eph/</a>
<b>FHEQ Level</b>	Level 7
<b>Credit Value</b>	<b>CATS</b> 15 <b>ECTS</b> 7.5
<b>HECoS Code</b>	100962 : 100473 : 100812
<b>Mode of Delivery</b>	Distance Learning
<b>Mode of Study</b>	Directed self-study, through online materials via the Virtual Learning Environment
<b>Language of Study</b>	English
<b>Pre-Requisites</b>	<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>Prior reading is not required before registering on this module. Students will be provided with core texts at the beginning of the module.</p>
<b>Accreditation by Professional Statutory and Regulatory Body</b>	Not currently accredited by any other body
<b>Module Cap (Maximum number of students)</b>	There is no cap on the number of students who can register for this distance learning module.
<b>Target Audience</b>	Optional module for all the students on DL MSc Clinical Trials, PG Diploma Clinical Trials, MSc Epidemiology, 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 project management and research coordination.

<b>Module Description</b>	This module will provide students with a detailed understanding of project and business management theory which is relevant for the delivery of clinical trials. A core element of the module is the exploration of the development of detailed project management schedules and budgets, the identification of key milestones and delivery plans including communication and risk management plans. The module will discuss implementation and co-ordination of the project plan with an emphasis on communication and project monitoring. It will also consider the challenges in implementation of formalised approaches to trial management.
<b>Duration</b>	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 AA submission deadline on 12th May.
<b>Last Revised (e.g. year changes approved)</b>	2021

<b>Programme(s)</b>	<b>Status</b>
This module is linked to the following programme(s)	
PGDip/MSc Clinical Trials (Distance Learning - University of London Worldwide)	Elective
PGDip/MSc Epidemiology (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

<b>Overall aim of the module</b>
<p>The overall module aim is to:</p> <ul style="list-style-type: none"> <li>equip students with the knowledge and skills to effectively project manage the delivery of clinical trials.</li> </ul>

### Module Intended Learning Outcomes

Upon successful completion of the module a student will be able to:

1. explain why the application of formalised management approaches supports better trial delivery.
2. apply best practice project management processes to develop detailed trial delivery plans.
3. assess clinical trial progress to predict performance and develop action plans for problem resolution.

## Indicative Syllabus

### Session Content

The module consists of Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows:

- The Research Agenda
- Project Planning – Scope and Quality
- Project Planning – Resources Part 1
- Project Planning – Timelines
- Project Planning – Resources Part 2
- Project Planning – Budget
- Project Planning – Understanding Stakeholders
- Project Planning and Risk
- Project Implementation and Close-Out.

## 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
<b>Total</b>	<b>150</b>	<b>100</b>

### 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.
- submit a Tutor Marked Formative Assignment (TMFA), for which personalised written feedback is available. Students are provided with written feedback on submitted TMFAs.
- 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.
- learn from written feedback from tutors on submitted AAs.
- join real-time tutorials, available on Moodle, to obtain additional tutor support: at least four tutorials are available, one focusing on formative assignments, two focusing on assessed assignments (offered across different dates) and one for exam preparation.
- make use of LSHTM online library resources.
- make use of Examiners' Reports which include previous assessed assignment questions and specimen answers.

## Assessment

### Assessment Strategy

The assessment strategy for CTM203 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 summative written assessed assignments (AAs). The FAs have a word length of 2000 words, the AA has a 5000-word limit. The FAs and AA have a 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. They support attainment of ILOs by collectively 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 limit gives sufficient text allowance to demonstrate these skills within a succinct and focused writing style. For all CTM203 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 conduct and regulation of clinical trials. On this module past AA papers, all with specimen answers, are also available for practice and self-assessment.

### Summative Assessment

Assessment Type	Assessment Length (i.e. Word Count, Length of	Weighting (%)	Submission deadline	Intended Module Learning
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	<b>presentation in minutes)</b>			<b>Outcomes Tested</b>
Assessed Assignment	Assessed Assignment has a word limit of 5000 words	100	12 <sup>th</sup> May	1,2,3

### **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

- Melton T, *Project Management Toolkit*, Butterworth Heinemann, 2007
- Brown, L, *Project Management for the Pharmaceutical Industry*, 2016
- *A Guide to the Project Management Body of Knowledge (PMBOK Guide)*, 6<sup>th</sup> edition

### Examples of online reading

- Session on CTP05 Project Management from DL MSc CT CTM103 Clinical Trials in Practice.
- Article on Managing Clinical Trials, Farrell, B, 2010
- The Guide to Efficient Trial Management – UKTMN
- Article: Financial considerations in the conduct of multi-centre randomised controlled trials: evidence from a qualitative study. Snowdon, C, 2006
- Article: Logical Framework Method for defining project success, Baccarini, D
- Article: Recruitment to randomised trials: strategies for trial enrolment and participation study: The STEPS study. Campbell, Mk, 2007
- Article: Descriptive survey of non-commercial randomised controlled trials in the United Kingdom, 1980-2002, Chalmers, I, 2003
- Article: What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. McDonald, Am, 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>