# MODULE SPECIFICATION

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| **Academic Year (student cohort covered by specification)** | 2024-25 |
| **Module Code** | CTM201 |
| **Module Title** | Protocol Development |
| **Module Organiser(s)** | Neal Alexander, Jonathan Mackinnon, Neeraj Gugnani, |
| **Contact Email** | CTsupport@lshtm.ac.uk |
| **Faculty** | Epidemiology and Population Health<br>London School of Hygiene & Tropical Medicine |
| **FHEQ Level** | Level 7 |
| **Credit Value** | **CATS** 15<br>**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. 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. For MSc CT students, it is recommended that this module is taken in the same year that students attempt the last of written examinations.<br><br>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 |

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| **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** | Compulsory module for all the students on DL MSc Clinical Trials; optional for PG Diploma Clinical Trials. Also open to any other student who meets pre-requisites for the module and who wishes to learn about developing the protocol for a trial. |
| **Module Description** | This module will build on the core CT modules (or similar material), but will go further into the steps to be taken for preparing the protocol for a trial. For MSc CT students, it is recommended that this module is taken in the same year as the last of written papers.<br>Group work is carried out in small groups over a 4-week period, in October and November, or in January and February (NB in some years the last groupwork session takes place in December or March depending on how the days of the week fall). During groupwork students will critically appraise a systematic review provided and start drafting the background section for a trial protocol. Students can then use this as a basis for developing their own draft protocol for assessment. Note that this will not be as extensive as a typical 'in use' version of a protocol, but rather a version that would be ready for consultation with stakeholders. |
| **Duration** | Distance learning module studies begin on Tuesday 1st October. Students may start their studies at any time once they gain access to Moodle and therefore the study materials; students are strongly encouraged to participate in one of the 4-week group work sessions (either in term 1 or term 2), and work through the material until the AA submission deadline on 12th May. |
| **Last Revised (e.g. year changes approved)** | March 2024 |

| **Programme(s)**<br>This module is linked to the following programme(s) | **Status** |
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| PGCert/PGDip/MSc Clinical Trials (Distance Learning - University of London Worldwide) | Compulsory for MSc<br>Elective for PGDip |

## Module Aim and Intended Learning Outcomes

| **Overall aim of the module** |
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| The overall module aim is to:<br>• produce the protocol for a trial. |

| **Module Intended Learning Outcomes** |
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| Upon successful completion of the module a student will be able to:<br>1. develop and refine a research question based on critical reading of existing literature<br>2. critically evaluate which trial design is most appropriate for a given research question<br>3. develop a trial protocol for a given design which:<br>- addresses the methodological and practical issues raised<br>- is in accordance with current applicable guidelines<br>4. achieve milestones in the development of a protocol by means of group work |

## Indicative Syllabus

| **Session Content** |
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| The module consists of 2 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows:<br>• Introduction to Protocol Development<br>• Components of a Protocol. |

## Teaching and Learning

**Notional Learning Hours**

| **Type of Learning Time** | **Number of Hours** | **Expressed as Percentage (%)** |
|---|---|---|
| Group Work | 50 | 33⅓ |
| Directed self-study | 20 | 13⅓ |
| Self-directed learning | 20 | 13⅓ |
| Assessment, review and revision | 60 | 40 |
| **Total** | **150** | **100** |

| **Teaching and Learning Strategy** |
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| Learning is oriented to a detailed set of learning outcomes using the materials provided. This learning is mostly self-directed, with group work also being an important component.<br><br>To support their self-directed learning, students are strongly encouraged to:<br>• post questions for tutors or fellow students and participate in the module-specific discussion board forums available on Moodle.<br>• take an active part in one of two 4-week group work sessions conducted on Moodle. Contribution to this group work counts towards the grade for the module.<br>• submit a Tutor Marked Formative Assignment (TMFA), for which personalised written feedback is available. Students are provided with written feedback on submitted TMFAs.<br>• Join real-time sessions on Collaborate where students may obtain additional tutor support: two prior to group work, and two after group work each term. At least eight sessions are offered.<br>• make use of LSHTM online library resources.<br>• make use of Examiners' Reports which include previous assessed assignment questions and specimen answers. |

## Assessment

| **Assessment Strategy** |
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| The assessment strategy for CTM201 is designed to support progressive student learning through groupwork, an optional formative assessment (tutor-marked with feedback, TMFA), and a written assessed assignment (AA). The groupwork and FA are designed to explicitly contribute to the AA. The FA builds on the groupwork to generate an outline trial protocol which is used, together with the feedback, to develop a fuller protocol for the AA. These activities encourage M-level thinking through questions which challenge students to consult study materials and published scientific literature, 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 limits give sufficient text allowance to demonstrate these skills within a succinct and focused writing style. For all CTM201 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 developing a protocol ("blueprint") of a clinical trial. |

**Summative Assessment**

| **Assessment Type** | **Assessment Length (i.e. Word Count, Length of presentation in minutes)** | **Weighting** (%) | **Intended Module Learning Outcomes Tested** |
|---|---|---|---|
| Group work | Group work - contributions to group work are assessed over a four-week group work period. | 20 | 1, 4 |
| Assessed Assignment | The Assessed Assignment has a maximum word length of 8000 words | 80 | 1-4 |

| **Resitting assessment** |
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| Resits will accord with the LSHTM's Resits Policy<br>For this module, the group work and the AA are not independent.<br>The group work contribution provides the foundation for the AA and so must be completed to answer the AA.<br>As the joint focus of the group work and AA change each academic year, both must be carried out in the same year.<br>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-book as below
- Online reading as below

*E-books*

- Fitzpatrick S. *The Clinical Trial Protocol*. ICR Publishing, Marlow. 2006

*Examples of online reading*

- Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gotzsche PC, Krleza-Jeric K, *et al*. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. *Ann Intern Med*. 2013; 158 3:200-7.
- Chan AW, Tetzlaff JM, Gotzsche PC, Altman DG, Mann H, Berlin JA, *et al*. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ*. 2013; 346:e7586.
- Evans JR, Solomon AW. Antibiotics for trachoma. *Cochrane Database Syst Rev*. 2011; 3:CD001860.
- Villar L, Dayan GH, Arredondo-Garcia JL, Rivera DM, Cunha R, Deseda C, *et al*. Efficacy of a Tetravalent Dengue Vaccine in Children in Latin America. *N Engl J Med*. 2015; 372 2:113-23.
- The protocol of the Villar *et al*. trial cited above.

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 website at Inclusive practice access arrangements