MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2025-26
Module Code	2033
Module Title	Clinical Trials
Module Organiser(s)	Stuart Pocock, John Gregson, Matthew Dodd
Faculty	Epidemiology & Population Health
FHEQ Level	Level 7
Credit Value	**CATS:** 10 **ECTS:** 5
HECoS Code	100473 : 100962
Term of Delivery	Term 1
Mode of Delivery	For 2025-26 this module will be delivered face-to-face. Where specific teaching methods (lectures, seminars, discussion groups) are noted in this module specification, these will be delivered through face-to-face sessions. There will be a combination of live and interactive activities (synchronous learning) as well as recorded or self-directed study (asynchronous learning).
Mode of Study	Full-time
Language of Study	English
Pre-Requisites	None
Accreditation by Professional Statutory and Regulatory Body	Not currently accredited by any other body
Module Cap (Maximum number of students)	100 (numbers may be capped due to limitations in facilities or staffing)
Target Audience	The full 10-week module is compulsory for MSc students in Medical Statistics and Epidemiology. All other students with an interest in clinical trials are welcome.
Module Description	This module will introduce the main issues in the design, analysis and interpretation of clinical trials.
Duration	10 weeks at 0.5 days per week
Timetabling slot	Term 1
Last Revised (e.g. year changes approved)	June 2023

Programme(s) This module is linked to the following programme(s)	Status
MSc Medical Statistics	Compulsory
MSc Epidemiology	Compulsory

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: • Introduce the main issues in the design, analysis and interpretation of clinical trials.

Module Intended Learning Outcomes
Upon successful completion of the module a student will be able to: 1. Explain fundamental principles of comparative clinical trials in investigating and ensuring efficacy and safety of treatments 2. Describe the main features of clinical trials, including methodological and organisational considerations 3. Explore key decisions surrounding design, delivery and assessment of clinical trials 4. Explain the principles of trial conduct, reporting and meta-analyses

Indicative Syllabus

Session Content
The module is expected to cover the following topics: • General principles of comparative clinical trials • Randomization (including the rationale, organization, ethics and methods of randomization) • Size of trials (including power calculations, the need for large trials, and problems of small trials) • Data monitoring • Clinical trials reporting • Alternative trial designs • Drafting a trial protocol • Principles of meta-analysis

Teaching and Learning

Notional Learning Hours

Type of Learning Time	Number of Hours	Expressed as Percentage (%)
Contact time	25	25
Directed self-study	15	15
Self-directed learning	20	20
Assessment, review and revision	40	40
Total	**100**	**100**

Student contact time refers to the tutor-mediated time allocated to teaching, provision of guidance and feedback to students. This time includes activities that take place in face-to-face contexts such as lectures, seminars, demonstrations, tutorials, supervised laboratory workshops, practical classes, project supervision as well as where tutors are available for one-to-one discussions and interaction by email.

The division of notional learning hours listed above is indicative and is designed to inform students as to the relative split between interactive and self-directed study.

Teaching and Learning Strategy
The teaching and learning strategy is based on lectures followed by non-computer practical sessions. - In the practical sessions, students have the opportunity to discuss the concepts and methods covered immediately following the lectures. The practical sessions provide students opportunities to discuss these ideas in small groups using examples from real trials as well as undertaking specific tasks in the design and reporting of trials. For each practical, students are provided with detailed solutions to the tasks set, enabling them to check their understanding of the material. - In addition, towards the end of the course there will be a half-day session where students will work in small groups to develop the outline of a protocol and present this protocol to the other groups in their class.

Assessment

Assessment Strategy
Assessment for this module will be in the form of a written assignment. The written assignment will contain short answer questions. Students will be asked to consider various trial scenarios in relation to the topics covered on the course, for example: -trial size -randomisation -data monitoring -reporting of results and interpretation -multiplicity and subgroup analyses -alternative trial designs

Summative Assessment

Assessment Type	**Assessment Length (i.e. Word Count, Length of presentation in minutes)**	**Weighting** (%)	**Intended Module Learning Outcomes Tested**
Report	Four pages of A4	100	1-4

Resitting assessment
Resits will accord with Chapter 8a of the LSHTM Academic Manual. Resits will be in the form of a written assignment containing short answer questions (i.e. using the same format as the original assessment).

Resources

Indicative reading list
Detailed and comprehensive material is proved for the module including lecture notes, slides, practicals and solutions. Additional material is also provided in the form of self-directed practicals as well as a comprehensive reading list.

The following texts are suggested as supplementary reading:

Pocock SJ. Clinical Trials: A practical approach. Wiley (1984).

Wang D, Bakhai A. Clinical Trials: A practical guide to design, analysis, and reporting. Remedica (2006).

Teaching for Disabilities and Learning Differences

Prior to each lecture students are provided with access to lecture notes and copies of the slides used during the lecture (in pdf format). For all practical sessions students are provided with a set of solutions for the practical. In addition, supplementary materials on Stata are made available via Moodle.

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. All students have access to “SensusAccess” software which allows conversion of files into alternative formats.

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.