MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2020-21
Module Code	2033
Module Title	Clinical Trials
Module Organiser(s)	Stuart Pocock and Tim Clayton
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 2020-21 this module will be delivered online only. Where specific teaching methods (lectures, seminars, discussion groups) are noted in this module specification these will be delivered using an online platform. 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 provide an introduction to 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/2020

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. Student contact time also includes tutor-mediated activities that take place in online environments, which may be synchronous (using real-time digital tools such as Zoom or Blackboard Collaborate Ultra) or asynchronous (using digital tools such as tutor-moderated discussion forums or blogs often delivered through the School's virtual learning environment, Moodle).

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 in the lectures immediately following the lectures. The practicals provide students 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
MSc Medical Statistics students complete a summative assessment in the form of a written report. In the report students are asked to consider a trial scenario, are asked to calculate sample sizes, and to comment on changes to the scenario and its findings. Formal assessment for both MSc Medical Statistics and MSc Epidemiology students is by written examination, which will be online.

Summative Assessment

Assessment Type	**Assessment Length (i.e. Word Count, Length of presentation in minutes)**	**Weighting** (%)	**Intended Module Learning Outcomes Tested**
Report*	Three pages of A4	See 8a.6.22 in Chapter 8a	1-4
Exam (Paper 1)*	Various	See 8a.6.22 in Chapter 8a	1-4
Exam (Paper 1)**	1 question	100	1-4

* MSc Medical Statistics students only

** MSc Epidemiology students only

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

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). All lectures are recorded and made available on Moodle as soon as possible after each session. 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 module-specific site on Moodle provides students with access to lecture notes and copies of the slides used during the lecture prior to the lecture (in pdf format). All lectures are recorded and made available on Moodle as quickly as possible. 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. 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.