Section 2 - Module Specification

Module Title	Clinical Trials and Regulatory Affairs	Module Code	BMD378

Credit Value	15	Level	6	Mode of Delivery	On Campus	Semester	Semester 2

Pre-requisite modules	Co-requisite modules	Overlapping modules

1) Content Description

Provide a description of the module, as it will appear in the Module Directory and on the Student Information System (approx. 70-80 words).

This module will introduce students to the whole spectrum of the clinical trials process from first-time-in-human-beings studies through to post-marketing studies that examine whether clinical trial promises translate to 'real-life' benefits for patients, with reliable evidence that benefits are likely to exceed their harms. The stringent processes for establishing and appraising the evidence with be critically discussed, together exploring the issues of the global market-place for medicines, the roles and challenges of regulators responsible for approving new drugs for public.

2) Module Aims

Specify the aims of the module, i.e. the broad educational purposes for offering this module.

This module will consider the fundamental principles of comparative clinical trials in investigating effectiveness, efficacy and safety of treatments and will include:
- the main features of clinical trials, including methodological and organisational considerations,
- the principles of trial conduct and reporting.
- the role of regulatory bodies in clinical pharmacology and drug development, both within the European system and globally.

3) Learning Outcomes

Identify the learning outcomes for this module, i.e. knowledge, skills and attributes to be developed through completion of this module. Outcomes should be referenced to the relevant QAA benchmark statements and the Framework for Higher Education Qualifications in England, Wales and Northern Ireland (2008). The SEEC Credit

* Textbook of pharmacoepidemiology, 2nd Edition, Brian L.Storm (Editor), Sean Hennessey (Editor) ISBN:978-1-118-34486-6, Wiley Blackwell
Lancet
British journal of Clinical Pharmacology

Level Descriptors for Further and Higher Education 2003 and Queen Mary Statement of Graduate Attributes should also be used as a guiding framework for curriculum design.

Academic Content:	
A1	Evaluate the role of regulatory bodies in drug development, clinical trials and drug approval
A2	Critique the rationale for and methods of Phase 1, 2 , and 3 pre-marketing clinical trials necessary for regulatory approval and marketing of new drugs
A3	Analysis of the post-Phase post licensing surveillance (4) clinical trial methodology and outcome evaluation studies and assessment of safety and efficacy.
A4	Evaluate strategies and experimental design for first-in-man studies and for clinical trials
A5	Comprehend basic statistical evaluation methods for clinical trials
Disciplinary Skills - able to:	
B1	Critically appraise the design, delivery and results of Phase 1-3 trials focusing on randomized controlled clinical trials
B2	Critically appraise the design, delivery and results of post-marketing surveillance studies focusing on non-randomized epidemiological studies
B3	Write scientific reports and present scientific data
Attributes:	
C1	Have the intellectual curiosity to learn continuously from diverse sources of information
C2	Be able to critique complex scientific concepts clearly and logically
C3	Make judgements based on evidence
C4	Effective time management and independent learning

4) Reading List

Provide an indicative reading list for the module. This should include key texts and/or journals but should not be an exhaustive list of materials.

Drug Bulletin
British Medical Journal

5) Teaching and Learning Profile

Provide details of the method of delivery (lectures, seminars, fieldwork, practical classes, etc.) used to enable the achievement of learning outcomes and an indicative number of hours for each activity to give an overall picture of the workload a student taking the module would be expected to undertake. This information will form the Key Information Set for each undergraduate programme and will be used to populate the KIS widget found on the QMUL programme information pages. More information can be found online about KIS. You may also wish to refer to the QAA guidance on contact hours when completing this section.

Activity Type	KIS Category	Time Spent (in hours)
Lecture	Scheduled	20
Tutorial	Scheduled	8
Fieldwork	Scheduled	4
Guided independent study	Independent	118
	Total	150

Specify the total module notional study hours. This should be a total of the hours given for each activity. The notional study hours for each academic credit point is 10. A 15 credit point module therefore represents 150 notional study hours.

Activity Type	Total Time Spent (in hours)	Percentage of Time Spent
Scheduled learning and teaching	32	21
Placement		
Independent Study	118	79
Total	150	100

Use the information provided in the box above to specify the total time spent and the percentage time spent in each category of teaching and learning activity.

6) Assessment Profile

Provide details of the assessment methods used to assess the achievement of learning outcomes.

Description of Assessment	Assessment Type	KIS Category	Duration / Length	% Weighting	Final element of assessment?	Qualifying Mark
Examination	In-class test	Written	90 minutes	50%	Yes	
Coursework	Report	Coursework		50%	No	

Qualifying mark: A specified minimum mark that must be obtained in one or more elements of assessment in order to pass a module. This is in addition to, and distinct from, the requirement to achieve a pass in the module mark to pass the module.

Reassessment

Provide details of the reassessment methods used, specifying whether reassessment is either standard reassessment or synoptic reassessment.

◉ Standard Reassessment ○ Synoptic Reassessment

Synoptic reassessment details (if you have indicated synoptic reassessment above, please give details)		
Brief Description of Assessment	Assessment Type	Duration / Length of Examination / Coursework
	Written Exam	3 hours
	Written assignment, inc Essay	

Section 3 - Alternative Assessment Arrangements for Associate Students

This section must only be completed if the module will be made available to associate students in Semester A and where the credit value of the "associate" version is the same as for the main version, and the main version is assessed by exam in May which is not available to the associate students. All other aspects of the module specification remain the same as indicated in Section 2 above. To add alternative assessment arrangements please click 'Add Alternative Assessment'.

Section 4a - Half Module for Associate Students (for a half module to be taught in Semester A)

This section must be completed if the proposed module will take place over 2 semesters but will be made available to single-semester associate students in a half-credit format in Semester A. Modules worth less than 30 credits taken over 2 semesters may not be made available in a half-credit format. To add details for the half module please click 'Add Half Module (Semester A)'.

Section 4b - Half Module for Associate Students (for a half module to be taught in Semester B)

This section must be completed if the proposed module will take place over 2 semesters but will be made available to single-semester associate students in a half-credit format in Semester B. Modules worth less than 30 credits taken over 2 semesters may not be made available in a half-credit format. To add details for the half module please click 'Add Half Module (Semester B)'.