ICR The Institute of Cancer Research

MSc in Oncology

Including PG Certificate and PG Diploma

Research Methods

Module Guide 2017/18

Part B | Clinical Sciences

UNIVERSITY OF LONDON

Contents

Guide last amended: 22/09/2017

The information contained in this Module Guide is correct at the time of going to press. Any amendments relating to the course or changes to published dates will be announced to students via Canvas, the course virtual learning environment. Information found on Canvas will always be the most accurate and up to date information available. Where anything in this guide contradicts the ICR Academic Regulations, the ICR Academic Regulations take precedence.

1 Module details

1.1 Module overview

This module is designed to give students a fundamental appreciation of the principles of clinical research and the ethics involved in running them. Students will also be taught about trial design and the appropriate endpoints to choose, as well as developing the skills to interpret results gained in clinical trials, how to write them up into a paper, and how to consider and understand their implications for clinical practice.

The module is compulsory and is taken in Part B of the course. Lectures take place over ten weeks during the first semester, and assessment takes place at the end of the module.

1.2 Module specification

Research Methods	
Full Title:	Research Methods
Part of Course:	Part B: Clinical Sciences
Compulsory or optional:	Compulsory
ICR Reference Number:	MS2002
Academic Level:	Level 7 (Masters)
Credit Value:	10 Credits

2 Contact information

2.1 General enquires

Students are advised to contact the MSc course team regarding any administrative matters at *mscadministrator@icr.ac.uk*. Any academic matters should be forwarded to the Course Director, Module Leaders or Lecturers as appropriate.

2.2 Key people

Name	Contact Information
Course Director	
Dr David Bloomfield Consultant Clinical Oncologist, Brighton and Sussex University Hospitals	*david.bloomfield@bsuh.nhs.uk*
Module Leaders	
Mrs Jo Haviland Senior Medical Statistician, Clinical Trials and Statistics Unit, ICR	*jo.haviland@icr.ac.uk*
Dr Anna Wilkins Clinical Research Fellow, Clinical Trials and Statistics group, ICR	*anna.wilkins@icr.ac.uk*

3 Module structure and aims

3.1 Aims

This module aims to guide you in developing an appreciation of the principles and ethics of clinical research. It will help you understand trial design, including valid endpoints, and will enable you to interpret clinical trials, write a resulting paper, and consider the implications for clinical practice.

3.2 Learning objectives

This module will allow students to:

- Appreciate the use of qualitative and quantitative methodology;
- Utilise advanced reasoning skills to recognise problems in study design e.g. confounding and other biases;
- Develop an in-depth awareness of the principles of clinical trial design;
- Develop an appreciation of the process in which a trial is designed and implemented;
- Have an appreciation of the organisation of trials in the UK;
- Develop an appreciation of the rationale and principles of Good Clinical Practice (GCP), Research Governance and Ethics;
- Appreciate Public and Patient involvement in research;
- Discuss diversity and equality in research and cultural competence;
- Appreciate the process of refereeing and grant applications;
- Utilise and integrate knowledge in order to be able to act as an investigator on a clinical trial or submit a research proposal or research thesis for approval by relevant agencies.

3.3 Structure

This module is a core module for Part B of the Postgraduate Certificate / Postgraduate Diploma / MSc in Oncology course. Students should attend all lectures to prepare themselves for the end of module assessments.

Students who have taken the Part A core module Statistics for the Oncologist and/or the optional Cancer Therapies section, Experimental Cancer Pharmacology, may find some areas of overlap with this module. Due to the importance of these areas to oncological practice and the different approach to these areas taken by different teachers – this is acknowledged and considered appropriate by the teaching team.

For this module, students will prepare an essay discussing a research protocol for the summative assessment. In addition to the written submission, you will also present your discussion to your peers in a class presentation session.

A full and up to date module timetable, including presentation sessions, is available in the calendar on Canvas. Any changes to this schedule will be announced through Canvas notifications.

4 Syllabus content

4.1 Core syllabus content

The key subjects covered in this module are:

- Interventional trials, phase I, II and III;
- Observational studies;
- Qualitative studies;
- Designing a study;
- Endpoints, including Quality of Life, Translational/Biomarker and Economic;
- Writing a protocol;
- Formally writing up study results as a peer-reviewed manuscript;
- Ethics in relation to Research and Good Clinical Practice;
- Research governance;
- Data management;
- National Cancer Research Network;
- Research funding;
- Critical appraisal (checklists as used by statistical reviewers);
- Systematic reviews.

4.2 NIHR training

This module also provides a formal taught course training programme suitable for NIHR Academic Clinical Fellows (ACF), as recommended by the Department of Health 2008. The training requirements for these ACFs, and where they can gain them within the module (in brackets), are as follows:

- Study design and statistics (taught lectures);
- Bioinformatics (taught lectures);
- Epidemiology (taught lectures);
- Ethical aspects of clinical research (taught lectures);
- Project design, planning, costing and management (taught lectures & student presentations);
- Research governance and the regulatory framework for governance (taught lectures);
- GCP (taught lectures on ethical principles underpinning GCP, but will not provide certified GCP training;
- Patient and public involvement in research (taught lectures);
- Refereeing of papers and grant applications (taught lectures);
- Diversity/equal opportunities in research/cultural competence (taught lectures);
- Time management/personal, effectiveness (taught lectures and student presentations);
- Leadership; practitioner, partner and leadership roles (taught lectures and student presentations).

5 Assessment

5.1 Assessment overview

Both formative and summative assessment methods will be used in this module. All students must complete both types of assignment. Please refer to the Assessment section on Canvas or in the Student Handbook for more guidance on more general aspects of assignment submission.

5.2 Formative single best answer test

For this module, all students will sit a compulsory single best answer (SBA) test. This SBA must be passed in order to pass the module overall, but the score will not contribute to the overall module mark.

The test is taken on Canvas and will consist of 25 questions, each scoring 10 points. You must score at least 50% (130 points) to pass. You have two attempts at this test and your highest score will be recorded. The SBA must be completed within 45 minutes.

5.3 Summative assignment

This module is assessed via a 'protocol development and discussion' essay of **strictly up to 1,500 words.**

This essay should be completed as a follow on from class discussions and group work that will be carried out towards the end of the module. Students will be allocated to peer-to-peer discussion groups ('action learning sets') within which you will develop a protocol relating to one of the types of trial design specified by the Module Leaders. This protocol will form the basis of your essay.

Your individual assignment submission should include a discussion of any problematic areas that were encountered as your group designed the clinical study, but should also include more detail on

any other areas that you personally feel are important and interesting.

This assignment should be written as a prose essay with:

- a short introduction to the topic;
- identification of the contentious areas of the protocol in question (these can be listed as bullet points);
- a discussion of these key issues justifying your decisions about how you would implement the study;
- overall conclusions.

Your write-up must be wholly your own work, while drawing on what you discussed and decided in group work. Any extensive similarities or cross-over with other students' write-ups will be detected by plagiarism software and may be penalised. Be sure to include relevant references to journal papers where appropriate, and **remember that penalties will apply for any work that is late, over the word limit, or includes plagiarised material.**

Submit your essay via Canvas following the instructions in the Student Handbook. Ensure you submit the same essay to both markers.

Presentations

All students will also present their discussions in a class peer group presentation session at the end of the module, before the final submission of the assignment. You do not have to have written your essay by the date of the presentations, only notes. You should take on board the comments made in the presentations and use these to refine your essay before submission.

6 Learning resources

6.1 Learning resources

The following learning resources are relevant to this module:

Key texts

You are strongly advised to read the following:

- Clinical Trials in Cancer: Principles and Practice. Girling, Parmar, Stenning, Stephens. (2003) Oxford University Press
- The Basic Science of Oncology, 4th edition. Tannock, Hill, et.al. (2004) McGraw-Hill Education

Additional reading

Students are encouraged to read these:

- Clinical Epidemiology: How to do Practice Research, 3rd edition. Section 6.30 Quality of Life. Sackett, Haynes, Guyatt, Tuqwell. (2006) Lippincott, Williams & Wilkins
- The CONSORT statement: Transparent reporting of trials (http://www.consort-statement.org/)
- The STARD statement: STAndards for the Reporting of Diagnostic accuracy studies (http://www.stard-statement.org/)
- The REMARK guidelines: REporting recommendations for tumour MARKer prognostic studies (REMARK). McShane et al. (2005) Nature Clinical Practice Oncology.2:416-422
- Patient-reported outcomes in randomized clinical trials: development of ISOQOL reporting standards. Brundage et al. (2013) Qual Life Res. 22:1161-1175

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