Programme Title: Distance Learning PGDip/MSc in Healthcare Research Methods

Programme Specification

Awarding Body/Institution	Queen Mary, University of London
Teaching Institution	Queen Mary, University of London
Name of Final Award and Programme Title	PG Dip Health Care Research Methods (B2D3/BB2D4) MSc Health Care Research Methods (B2S3/B2S4)
Name of Interim Award(s)	
Duration of Study / Period of Registration	1 Year Full Time
QM Programme Code / UCAS Code(s)	B2D3, B2D4, B2S3, B2S4
QAA Benchmark Group	
FHEQ Level of Award	Level 7
Programme Accredited by	
Date Programme Specification Approved	27 Sep 2012
Responsible School / Institute	William Harvey Research Institute

Schools which will also be involved in teaching part of the programme
William Harvey Research Institute

Institution(s) other than Queen Mary that will provide some teaching for the programme
N/A

Programme Outline

The aim of the Distance Learning (DL) PGDip/MSc in Healthcare Research Methods course is to provide students with a multi-disciplinary perspective to facilitate their skills. This course is designed for individuals who need an understanding of the Healthcare Research Method process and provides a detailed picture of the complex and highly interrelated activities of the development cycle for Healthcare Research Methods, from discovery to successful commercialisation.

The DL PGDip/MSc in Healthcare Research Methods course provides participants with the opportunities to, and increases the likelihood of getting into the hard to enter and highly competitive healthcare environment.

On completion of the course, successful students should have gained the following:

• To have developed an understanding of healthcare research organisation, decision making, regulatory advice, healthcare marketing and ethical issues in healthcare research and development.

• Knowledge to undertake critical appraisal of the research of others

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• To have developed the skills to formulate their own research ideas, deliver the research and analyze the data.

• Through completion of a dissertation, students should gain experience in research methodology and techniques, through literature, designing a research project, and of project data analysis and presentation.

Aims of the Programme

The aim of the course is to provide participants with a multi disciplinary perspective to facilitate the skills of post graduate students. It is intended that the course will provide a valuable opportunity for both British and overseas students who wish to gain more experience in understanding the Healthcare Research Methods process and obtain a higher degree before entering career in the Healthcare Research environment.

What Will You Be Expected to Achieve?

When completing the DL PGDip/MSc in Healthcare Research Methods students will be expected to achieve the following learning outcomes.

Academic Content:	
A1	Demonstrate knowledge and understanding of how the human body works
A2	Understand pathology, pathophysiology of all systems and organs
A3	Understand healthcare organisation and decision making
A4	Develop essential skills and knowledge of clinical design methods relevant to healthcare research
A5	Develop problem solving skills and knowledge of clinical design methods relevant to healthcare research
A6	Learn critical appraisal skills using a case study approach to identify and solve practical, theoretical and technical problems in human studies.
A7	Gain knowledge in research methodology and skills in design of a research project.
A8	Develop skills in evaluation of the process and the use of various implementations in the marketing of medicine by the pharmaceutical companies

Disciplinary Skills - able to:	
B1	Understand regulatory framework governing good clinical research
B2	Integrate relevant pharmacology, pharmacokinetics and statistics related to drug development and the nature of evidence required for proof of efficacy and safety
B3	Evaluate the science, ethics and regulations pertaining to the development and review of new drug products in the UK and Europe.

B 4	Understand and interpret pre clinical data and the phases of clinical trial design and monitoring involved in clinical trials
B 5	Understand the analysis of the factors which determine the usage of medicine and the influences of doctors, government, drug manufacturers and the public.
B 6	Examination of the regulatory and ethical issues surrounding ICH, GCP, GLP, GMP, and GXP
B 7	Understand the clinical trial protocol design for diseases effecting respiratory, nervous, cardiovascular systems, immunological disorders and malignancies.

Attributes:	
C 1	Demonstrate problem solving ability
C 2	Demonstrate appropriate practical skills
C 3	Demonstrate autonomy in self directed learning.

How Will You Learn?

One of the major strengths of the course lies in the fact that the teaching staff consist of not only institute members but also involves top professionals working in the healthcare research industry and CRO-s. Our exceptional expert "panel" of internal as well as external lecturers is actively engaged with the course. Members of the WHRI who are teaching on our course are invaluable assets to the progression of the students on the course as they are not only intellectually stimulating them, but engaging them as self-directed learners, and more closely connecting them to the university and college as a community.

Teaching methods employed during this MSc course consists of lectures from the William Harvey Research Institute staff and outside experts, using well-established classic teaching methods in order to create a stimulating and effective online distance learning environment.

A note on distance learning:
The institute is aware of the difficulties some students face in finding the time and funding to come to London to study, and is planning in the immediate future to develop a distance learning programme to make widely available its highly successful healthcare research methods course. Being unable to come to London for an extended period need no longer be a barrier to obtaining an excellent qualification. The course and assessment protocols would be maintained to ensure that students achieve the same standard as those on the London-based course. The difference being the mode of delivery for the distance learning students would have to use the appropriate software to access the lectures through the internet. Access to a computer and internet will be essential. The distance learning programme will be self-taught using the fully comprehensive study materials provided. Studying through the distance learning course would provide an attractive option for those with financial constraints, commitments to work or family, or lack of local access to higher education.

Moreover, students are also involved in using new technologies (eg Blackboard, Moodle, Facebook) which allow students to discuss and exchange ideas, share knowledge as well as to review the lecture sessions in their own time and at their own pace. The programme aim is to create an environment in which all participants have the opportunity to learn and explore issues and ideas in depth, from a variety of viewpoints.

How Will You Be Assessed?

• Students will be assessed based on online submitted written assignments. The course team evaluates the progression of students on their written assignments, maintaining the highest quality of work as well as achieving the course learning objectives.

Format

The final mark will have the following components
• Continuous assessment (module assignment).
• Dissertation

Continuous assessment (module assignment)
For the continuous assessment mark, candidates will be assessed throughout the year in the form of objective assessment by written assignment.
Dissertation
Dissertation
The candidates will submit a written dissertation on a subject in which they have been supervised. The format of the dissertation will usually be literature or policy based. A viva on the dissertation may be required for borderline candidates. This will take place at the final board of Examiners meeting
All assignments will be double marked by the experts teaching on particular topics.

How is the Programme Structured?

The modular nature of the courses is designed to fit in with the needs of those students who are in full time employment. The taught element of the modules is delivered in three-day blocks every four to six weeks (approximately). For an MSc award 12 modules in total.

MODULE 1. Health and the Human Body
Module Code : WHRM912

CONTENT DESCRIPTION
The orientation module will offer participants the opportunity to revisit and develop familiar areas of human biology physiology, pathology and genetics. Particular emphasis will be placed on the importance of systemic measurements of function and evaluation of clinical laboratory investigations related to clinical trials. The lecture programme will be enhanced by student assignments that will serve to develop and integrate knowledge and understanding through group discussion and student led presentations.

AIMS
The module aims to introduce the students to the key concepts essential to understanding health and the human body. Many health professionals want to investigate their health care practice and how it could be improved to benefit their patients. Particular emphasis of this module will be placed on the importance of systematic measurements of function and evaluation of clinical laboratory investigations related to clinical trials. Moreover, health and the human body guides the students through their journey, giving detailed, step-by-step advice on planning and carrying out each stage of the research.

LEARNING OUTCOMES
The learner will:
Demonstrate the appropriate use of clinical information for management of patients. Use their knowledge of anatomy, pathology and pathophysiology as a foundation for understanding the clinical presentation and management. Identify the common sites of interest with other healthcare practices. Moreover, students will be able to communicate with physicians and healthcare professionals in a collaborative way to plan patient care.
Students will learn how to identify, monitor and manage anticipated fluctuations of healthcare quality. Furthermore, on completion of this module students will be able to apply their knowledge as a foundation for understanding of patients especially the sensitive groups such as the elderly.

MODULE 2. Healthcare organisation and Decision Making
Module Code : WHRM913

CONTENT DESCRIPTION
The main emphasis of this module is to provide students with understanding of changes and challenges within healthcare systems.

Implementation of changes, training and guidance in finding a constructive way of dealing with social and financial issues are an essential part of this module as well as ways of implementation of equality, equity and health policies.

AIMS
This module aims to enable participants in two broad areas namely health sociology and health policy/organisation. It will also provide participants with an appreciation of the broad influences on levels of health and the role of specific factors relating to major diseases. Together with the modules on research methods it will provide a basis for understanding the epidemiological techniques required to investigate the causes of disease. The scope will be both national and local and the teaching method will include practical work drawing on data available to participants in their own districts or regions.

LEARNING OUTCOMES

The learner will:
Become familiar with the concepts of health and illness, have the knowledge to perform measurement of health at local and national levels. Have a clear understanding on social production of health and illness. Implement the changes on healthcare systems. Find constructive ways of dealing with social deviance, labelling and stigma. Students will be able to contribute to development and changes in the NHS, and implement equality, equity and health changes.

Attributes:
The learner will:
• Access the learning resources available and use self-directed learning to cover the course content.
• Provide feedback to their tutor as part of a process of self-reflection
• Demonstrate autonomy in self directed learning
• Communicate effectively with the tutor, lecturer and group members
• Demonstrate problem solving ability

MODULE 3. Clinical Study Design
Module Code : WHRM903

CONTENT DESCRIPTION
The module introduces the clinical phases of drug from phase 1 through 4. The concept of Good Clinical Practice will be introduced. The types of clinical trials are discussed and how an understanding of the pre-clinical data guides trial design. The practical issues of finance, protocol development, selecting investigators, study and management, monitoring, insurance and indemnity, archiving etc, will be discussed. The role of internal and external auditing of procedures and standards will be described.

AIMS
This module introduces students to the drug testing in man and the processes involved in getting a drug to market.

LEARNING OUTCOMES
The learner will:
• Demonstrate an understanding of financial factors that contribute to drug testing and development

• Understand the role of the various regulatory procedures involved in drug development

Skills: The learner will:
• Analysis: Display an awareness of the strengths, weaknesses and utility of specific study designs
• Synthesis: Understand how these studies can contribute to clinical research
• Evaluation: Appreciate the need for research, an evidence base, and reflective practice when designing studies
• Application: Maintain an objective approach to choice of study design

Attributes:
The learner will:
• Access the learning resources available and use self-directed learning to cover the course content
• Provide feedback to their tutor as part of a process of self-reflection
• Demonstrate autonomy in self directed learning

• Communicate effectively with the tutor, lecturer and group members

MODULE 4. Practical Aspects of Clinical Research & Early Drug Development
Module Code : WHRM904

CONTENT DESCRIPTION
The course covers
ICH, ABPI and RCP Guidelines; "patients" and healthy subjects
First administration to man; toxicology and pharmacology
Single dose; choice of dose and escalation design
Repeat dose; choice of dose and design
Pharmacokinetics - Cyctochrome P450; metabolism and interactions
Safety - QTc intervals ECG etc.
Tolerability
Pharmacodynamics - surrogate markers / biomarkers
Dose response
Efficacy - Surrogates
Methods; CNS, cardiovascular (mechanical & electrical), respiratory, GI and renal

AIMS
The module aims to get students to understand the key concept in drug development of concentration-effect relationships in man.

LEARNING OUTCOMES
The learner will:
• Appreciate the role of guidelines in regulating and guiding research studies
• Understand the process of “first in man” studies
• Design simple single dose and repeat dose studies
• Integrate preclinical and clinical study information

Skills: The learner will:
• Analysis: Display an awareness of the strengths, weaknesses and utility of specific clinical pharmacology study designs
• Synthesis: Understand how these studies can contribute to “proof of concept” and guide further research studies
• Evaluation: Appreciate the need for research, an evidence base, and reflective practice when designing clinical pharmacology studies
• Application: Maintain an objective approach to choice of study design
Attributes:
The learner will:
• Access the learning resources available and use self-directed learning to cover the course content
• Provide feedback to their tutor as part of a process of self-reflection
• Demonstrate autonomy in self directed learning
• Communicate effectively with the tutor, lecturer and group members
• Demonstrate problem solving ability
• Demonstrate appropriate practical skills

MODULE 5. Ethics & Regulation in Clinical Research
Module Code : WHRM905

CONTENT DESCRIPTION
This module is taught by visiting faculty from the Medicines Healthcare products Regulatory Agency (MHRA) and the National Research Ethics Service (NRES) and includes
ICH, GCP, GLP, GMP, GXP regulations
Ethical conduct of clinical trials.
Constructing ethical applications.
Ringside at the ethics committee - lay and legal concerns.
• Informed consent.

AIMS
The module aims to explain to the students the mechanisms that are in place to regulate the ethics and conduct of clinical trials in humans.
LEARNING OUTCOMES
The learner will:
• Understand the different national and international standards and requirements that govern drug research
• Appreciate the ethical issues that are involved in clinical research and why informed consent is the key to ethical research
• Be able to write a basic NRES application and understand the role of the LREC and R&D departments in research governance.

Attributes:
The learner will:
• Access the learning resources available and use self-directed learning to cover the course content
• Provide feedback to their tutor as part of a process of self-reflection.
• Demonstrate autonomy in self directed learning
• Communicate effectively with the tutor, lecturer and group members
• Demonstrate problem solving ability and appropriate practical skills

MODULE 6. Data Management: The Interpretation of Statistics & Pharmacokinetics
Module Code : WHRM906

CONTENT DESCRIPTION
Students will learn the differences between quantitative and qualitative approaches to research. What are the available the types and scales of measurement. How samples can be described using measurements of central tendency and scatter. How distributions, probability and significance relate to the differences between means and the use of basic statistical tests. The importance of statistics in the planning of research will be described. Literature searching, systematic reviews, critical appraisal of published research articles and correct reporting of research results will be discussed
AIMS
The aim of this module is to give participants the knowledge required to read critically the research of others, the skills to formulate their own research and to collect, analyse and interpret their own data. Some mathematical treatment is inevitable but participants will not be expected to memorise a lot of formulae.

LEARNING OUTCOMES
The learner will:
• Understand the difference between quantitative and qualitative research
• Choose the appropriate research method to answer a research question
• Understand the difference between nominal, ordinal, interval and ratio data
• Determine when parametric or non-parametric methods are appropriate
• Evaluate and critically appraise research findings

MODULE 7. Specific Topics in Clinical Trial Design
Module Code : WHRM907

CONTENT DESCRIPTION
This module will outline and discuss the different research designs that are needed for
• Outcome trials
• Clinical trial protocol design for diseases of the nervous system (e.g.dementias; depression; schizophrenia, epilepsy, insomnia, anxiety and Parkinson's disease)
• Clinical trial protocol design for respiratory diseases (e.g. asthma, chronic obstructive airways disease, emphysema, infections, cystic fibrosis)
• Clinical trial design for cardiovascular diseases (e.g. hypertension, ischemic heart disease, arryhthmias, cardiac failure)
• Clinical trial design in patients with malignancies and immunological disorders (e.g. AIDS)
The regulatory requirements for biotechnology products and medicinal devices will be described

AIMS
The aim of this module is to give the students examples of trials in patients rather than volunteers and to deal with the special problems that can arise in patient studies. In addition, two very specific, but increasingly important topics, biotechnology products and equivalence trials, are dealt with in more detail.

LEARNING OUTCOMES
The learner will:
• Demonstrate an understanding of the diversity of human research studies.
• Understand the problems that may arise in special patient groups
• Appreciate the significance of outcome trials in research
Skills: The learner will:
• Analysis: Display an awareness of the scientific and laboratory needs to support the clinical trials.
• Synthesis: Understand how biomarkers support clinical studies.
• Evaluation: Appreciate the need for research, an evidence base and reflective practice when making professional judgements about treatment outcomes.
• Application: Maintain an objective approach to research studies while recognising the individual nature of each patient.

MODULE 8. Elective Project
Module Code : WHRM908

CONTENT DESCRIPTION
Students have to research and present a reasoned answer to a topical controversy in medical research, treatment or practice.

AIMS
The aim of this module is to challenge the students with a contentious area of medical research, treatment or practice question which requires literature review and critical thinking to answer.

LEARNING OUTCOMES
The learner will:
• Demonstrate original thought when tackling a research question
• Systematically gather data on a particular issue
• Critically evaluate and review the issues involved in a contentious area of medical research, treatment or practice
• Develop a coherent argument for or against a contentious area of medical research, treatment or practice
• Access the learning resources available and use self-directed learning to cover the course content
• Provide feedback to their tutor as part of a process of self-reflection
• Demonstrate autonomy in self directed learning
• Communicate effectively with the tutor, lecturer and group members
• Demonstrate problem solving ability

MODULE 9. Health and Pharmaco-Economics
Module Code : WHRM909

CONTENT DESCRIPTION
This module will explore the factors that determine the usage of medicines and will concentrate on the relative influences of government, doctors, drug manufacturers and the public. These will be analysed to assess whether clients/patients are best served by current arrangements and whether people's health matches reasonable expectations. Participants will be encouraged to propose ways of tackling perceived shortcomings.
• Determining the cost of health interventions
• Measuring benefit in healthcare.
• Quality of life measures.
• Making informed choices between treatments.
• Justifying economic based decisions in healthcare

AIMS
With NICE (National Institute for Clinical Excellence) developing national clinical guidelines to secure consistent, high quality, evidence based medicine predicated on outcomes and cost, it is important that students understand the central role that pharmacoeconomics plays in these decisions.

LEARNING OUTCOMES
The learner will:
• Understand the importance of pharmacoeconomics in drug utilisation
• Appreciate the role of "quality of life" studies in outcome evaluation
• Make informed choices between treatment options based on QUALY, DALYs, etc

• Understand the differences between analysis methods
• Cost-minimization analysis (CMA)
• Cost-effectiveness analysis (CEA)
• Cost-utility analysis (CUA)
• Cost-benefit analysis (CBA)
• Discuss the role of NICE in determining treatment guideline

MODULE 10. Pharmaceutical & Healthcare Marketing
Module Code : WHRM909

CONTENT DESCRIPTION
Marketing in healthcare is contentious. This module illustrates and explains the processes that drive marketing in the healthcare setting.
• The marketing of medicines and healthcare
• Regulation of healthcare marketing
• Doctors' prescribing practices
• The role of other healthcare professionals
• The role of the patient and patient advocacy groups
• The role of government
• The use of the media in marketing healthcare
• Health promotion and disease prevention

AIMS
The aim of this module is to introduce the students to the complexity of marketing healthcare.

LEARNING OUTCOMES
The learner will:
• Appreciate the regulatory complexity of marketing healthcare interventions
• Determine who the "customer" is
• Understand the increasing role of the internet
• Appreciate the issues involved in disease screening and health promotion
• Understand the role of "ghost" writing and communication agencies in medical education

MODULE 11. Dissertation
Module Code : WHRM909

CONTENT DESCRIPTION
The project chosen must be agreed well in advance with the College tutors in order to ensure that ethics and other considerations are complied with.
The candidates will submit a written dissertation on a subject in which they have been supervised. The format of the dissertation will usually be literature or policy based. A viva on the dissertation may be required for borderline candidates. This will take place at the final board of Examiners meeting
A short pro forma with essential headings must be completed and a ~250 word summary of the proposed project provided. The project must be designed to demonstrate analytic skills and to offer opportunity for original work and for critical appraisal of relevant published work. The resulting report should be of 10,000 – 20,000 words and written in a style suitable for submission to peer review and be compatible with the Uniform Requirements for Biomedical Journals.

AIMS
The aim of this module is to give students a chance to consolidate and demonstrate their analytical and critical skills by carrying out an original research project.

LEARNING OUTCOMES
The learner will:
• Demonstrate an understanding of carrying out of a literature based research project.
• Understand the various aspects necessary to a successful scientific research project.
Skills: The learner will:
• Analysis: Display an awareness of the need for objectivity in scientific writing
• Synthesis: Understand how the results of research might be applied

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• Evaluation: Appreciate the need for maintaining an up to date knowledge of current research
• Application: Be able to present a clear rational argument to support a thesis

Attributes:
The learner will:
• Access the learning resources available and use self-directed learning to cover the course content
• Provide feedback to their tutor as part of a process of self-reflection

Academic Year of Study 1

Module Title	Module Code	Credits	Level	Module Selection Status	Academic Year of Study	Semester
Health & the Human Body		15	7	Compulsory	1	
Health Care organisation and Decision Making		15	7	Compulsory	1	
Clinical Study Design		15	7	Compulsory	1	
Practical Aspects of Clinical Research & Early Drug Devlopment		15	7	Compulsory	1	
Ethics & Regulation in Clinical Research		15	7	Compulsory	1	
Data Management: The Interpretation of Statistics & Pharmacokinetics		15	7	Compulsory	1	
Specific Topics in Clinical Trial Design		15	7	Compulsory	1	
Elective Project		15	7	Compulsory	1	
Health and Pharmaco-Economics		15	7	Compulsory	1	
Pharmaceutical & Healthcare Marketing		15	7	Compulsory	1	
Dissertation		30	7	Compulsory	1	

What Are the Entry Requirements?

Criteria for admission to the programme:
Candidates should have a degree or equivalent in an appropriate subject from an approved educational establishment.
Or
Professional qualifications or sufficient experience to satisfy the head of division and course director of the applicants fitness to pursue the course of study. The postgraduate diploma will be a prerequisite to enter the PGDip/MSc in most cases.

Entry level guidelines for English Language

An ILESTS score of ≥6.5 or a TOEFL score of ≥600 is required for this course.

How Do We Listen and Act on Your Feedback?

Students on our course are never seen as "silent partners" in the enterprise of improving teaching. One way their voices can be heard is through completion of feedback forms for each module. The feedback forms gain the students views on the clarity, style of presentation, course material, stimulation and an overall rating of the lectures (please see example of a feedback form below). Student feedback is discussed with the lecturer and is encouraged to make necessary changes following student suggestions.

Module
Lecturer Name
Class

Please rate the following aspects on a scale of 1(awful) to 5 (excellent)

Clarity (1-5)

Lecture Style (1-5)

Course Material (1-5)

Stimulation (1-5)

Overall rating (1-5)

Specific comments:

All students will be in a regular contact with members of the course team. Pastoral as well as academic support is offered on a regular basis. Students are encouraged to contact course team members via email, blackboard or by phone.

Assessment of effectiveness of student support mechanisms will be evaluated with the following means:

• Continuous feedback to the students. Student feedback is an extremely important mechanism to facilitate the students learning experience. Feedback will be offered on drafts of coursework and academic progress following formative and summative assessment.

• Staff-student liaison. Students are encouraged to keep in regular contact with the course team members to convey their experience and comments and to seek any advice or help they may need.

• Assessment of action on student feedback.

Continuous student feedback throughout the year is an essential tool with a view to maintain as well as to improve the quality and student experience of the course.

Academic Support

In addition to Staff-student liaison, all students are allocated a personal tutor who can be contacted during office hours. The role of the personal tutor is to advise the student on any issues relating to the academic aspects of the course that the student may wish to raise. A senior tutor is also available for consultation if their own tutors are not available or if for any reason unsuitable.

Also an Institute level Committee will be created and responsible for ongoing management of the Programmes.

Programme-specific Rules and Facts

Specific Support for Disabled Students

As the programme is distance learning in format it becomes readily available to disabled students who under normal circumstances would find it difficult to relocate to London.

Links With Employers, Placement Opportunities and Transferable Skills

Student employment prospects: The employers, which in this case include healthcare research organisations, and the NHS, etc will greatly benefit from having students who successfully completed this PGDip/MSc. With the modernisation of medical education and the fact that the education and training of staff involved in healthcare has not kept pace with the scientific and regulatory changes that have occurred recently, this PGDip/MSc course will help accelerate understanding and improve knowledge that is essential for building confidence and experience.

Programme Specification Approval

Person completing Programme Specification	Professor Atholl Johnston
Person responsible for management of programme	Professor Atholl Johnston
Date Programme Specification produced/amended by School Learning and Teaching Committee	
Date Programme Specification approved by Taught Programmes Board	27 Sep 2012

Queen Mary University of London