Programme Title: PGDip/MSc in Clinical Drug Development

Programme Specification

<table>
<thead>
<tr>
<th>Awarding Body/Institution</th>
<th>Queen Mary, University of London</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaching Institution</td>
<td>Queen Mary, University of London</td>
</tr>
<tr>
<td>Name of Final Award and Programme Title</td>
<td>MSc/PGDip, Clinical Drug Development FT &amp; VM</td>
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<tr>
<td>Name of Interim Award(s)</td>
<td>PG Cert</td>
</tr>
<tr>
<td>Duration of Study / Period of Registration</td>
<td>1 Year Full Time &amp; 2 – 4 years Variable Mode</td>
</tr>
<tr>
<td>QM Programme Code / UCAS Code(s)</td>
<td></td>
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<tr>
<td>QAA Benchmark Group</td>
<td></td>
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<tr>
<td>FHEQ Level of Award</td>
<td>Level 7</td>
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<tr>
<td>Programme Accredited by</td>
<td></td>
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<tr>
<td>Date Programme Specification Approved</td>
<td>27 Sep 2012</td>
</tr>
<tr>
<td>Responsible School / Institute</td>
<td>William Harvey Research Institute</td>
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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 development of drugs has transformed from peripheral activities, carried out on an ad hoc basis to core activities that require trained, professional staff. However, the education and training of staff involved in drug development has not kept pace with the scientific and regulatory changes that have occurred recently. The pharmaceutical industry moves rapidly and a highly skilled personnel are required in order to adapt to this environment.

The aim of the MSc in Clinical Drug Development 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 drug development process, and provides a detailed picture of the complex and highly interrelated activities required for the development cycle for drugs and biologics, from the process of discovery to successful commercialisation.

The United Kingdom pharmaceutical industry faces one of the greatest challenges in attracting and retaining quality personnel. Moreover, in the current economic climate, demand for highly specialised employees with Postgraduate rather than Graduate Degrees is ever increasing. The MSc in Clinical Drug Development course provides participants with the opportunities to increase the likelihood of getting into the hard to enter and highly competitive pharmaceutical environment.

With the economic growth in the BRIC countries (Brazil, Russia India and China) the pharmaceutical and biotech industry is shifting research and development towards these regions. This has created a demand for skilled professionals with the
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Knowledge and expertise needed. The MSc in Clinical Drug Development provides students the edge that pharmaceutical industry requires. It also empowers the professionals working within the field with the skills and understanding required for fast progression within the industry and contract research organisations (CROs).

This programme has been running at QMUL for over ten years.

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 drug development process and obtain a higher degree before entering career in the drug development environment.

What Will You Be Expected to Achieve?

When completing the DL PGDip/MSc in Clinical Drug Development students will be expected to achieve the following learning outcomes.

Academic Content:

| A 1  | To critically evaluate the appropriateness of different approaches and demonstrate an understanding of how drugs are “discovered” |
| A 2  | Demonstrate a deep and systematic understanding of the role of pharmacokinetics in candidate optimisation |
| A 3  | Understand need for animal toxicity testing and appreciate and manage the ethical dilemmas involved |
| A 4  | Understand the role of the various methods available for assessing toxicity. |
| A 5  | Demonstrate an understanding of the financial factors and evaluate the constraints that apply to drug testing and development |
| A 6  | Understand the role of the various regulatory procedures involved in drug development |
| A 7  | Display an awareness of the strengths, weaknesses and utilization of specific study designs |
| A 8  | Maintain an objective approach to choice of study design |
| A 9  | Appreciate the role of guidelines in regulating and guiding research studies |
| A 10 | Understand the process of “first in man” studies |
| A 11 | Design simple single dose and repeat dose studies |

Disciplinary Skills - able to:

| B 1  | Understand regulatory framework governing good clinical research |
| B 2  | Integrate relevant pharmacology, pharmacokinetics and statistics related to drug development and the nature of evidence required for proof of efficacy and safety |
| B 3  | Evaluate the science, ethics and regulations pertaining to the development and review of new drug products in the UK and Europe. |
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Attributes:

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C 1</td>
<td>Can act autonomously in planning and implementing tasks at a professional or equivalent level</td>
</tr>
<tr>
<td>C 2</td>
<td>Demonstrate appropriate and comprehensive practical and theoretical skills as well as advanced communication expertise- allowing decision making in complex and unpredictable situations</td>
</tr>
<tr>
<td>C 3</td>
<td>Demonstrate autonomy in self-directed learning and realise their scope of practice</td>
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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 Pharma 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 learning environment.

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
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
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.

How is the Programme Structured?

The modular nature of the course is designed to fit in with the needs of those students who are in full time employment. To obtain an MSc award all the modules (180 credits) have to be successfully completed. To obtain a PG Dip 120 credits are needed to be completed from the taught modules (not including WHRM998). To obtain a PG Cert 4 x 15 credit modules have to be completed (60 credits, but not including WHRM998 and WHRM999). 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).

MODULE 1. Drug Discovery & Pre-Clinical Research & Development
Module Code : WHRM901

CONTENT DESCRIPTION
Following basic revision of pharmacology, the module describes the various approaches used to discover new drugs and discusses the advantages and disadvantages of the approaches. The role of pre-clinical pharmaceutical development in selecting candidate molecules is discussed. The module focuses on the selection and optimisation of drug candidates by their physiochemical properties and their drug metabolism and pharmacokinetic characteristics. The regulation of preclinical drug development and the relevant ICH guidelines are described.

AIMS
The module aims to develop the students in understanding the importance of pre-clinical research areas in pharmaceutical development.

LEARNING OUTCOMES
The learner will:
- Demonstrate an understanding of how drugs are “discovered”.
- Understand the role of pharmacokinetics in candidate optimisation.

SKILLS:
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The learner will:
• Analysis: Display an awareness of the scientific needs to support the drug discovery process.
• Synthesis: Understand preclinical studies complement phase 1 to 4 studies in man.
• Evaluation: Appreciate the need for optimisation in drug discovery and preclinical development
• Application: Maintain an objective approach to the physicochemical and in vivo characteristics required for candidate selection.

MODULE 2. Toxicology: From Molecules to Man

Module Code : WHRM902

CONTENT DESCRIPTION
The module describes the fundamentals of toxicology – animal models for drug safety testing. The variation within and between species of drug metabolism and pharmacokinetics will be discussed. The toxicity and detection of toxicity of drugs in various organ systems will be outlined together with detection carcinogenicity and mutagenicity. The concepts of post-marketing safety and pharmacovigilance will be introduced.

AIMS
The module aims to introduce the students to the processes involved in the risk assessment of pharmaceuticals.

LEARNING OUTCOMES
The learner will:
• Understand the need for animal toxicity testing
• Understand the role of the various methods available for assessing toxicity

SKILLS:
The learner will:
• Analysis: Display an awareness of the strengths, weaknesses and utility of specific toxicology testing techniques
• Synthesis: Understand how these methods can contribute to safe and effective drugs
• Evaluation: Appreciate the need for research, an evidence base, and reflective practice when making professional judgements about drug toxicity
• Application: Maintain an objective approach to choice of toxicity testing method

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

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

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

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

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.

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

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 and Elective Project
Module Code : WHRM933

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
• 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


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
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- **MODULE 9. Pharmaceutical & Healthcare Marketing**
  - Module Code: WHRM910
  - 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 10. Dissertation**
  - Module Code: WHRM911
  - 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
      - 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
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Academic Year of Study   FT - Year 1

<table>
<thead>
<tr>
<th>Module Title</th>
<th>Module Code</th>
<th>Credits</th>
<th>Level</th>
<th>Module Selection Status</th>
<th>Academic Year of Study</th>
<th>Semester</th>
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<tbody>
<tr>
<td>Drug Discovery and Pre-Clinical Research and Development</td>
<td>WHRM901</td>
<td>15</td>
<td>7</td>
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<td>Toxicology: from Molecules to Man</td>
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<td>7</td>
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<td>Semester 1</td>
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<tr>
<td>Data Management: the Interpretation of Statistics and Pharmacokinetics</td>
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<td>15</td>
<td>7</td>
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<td>Specific Topics in Clinical Trial Design and Elective Project</td>
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<td>1</td>
<td>Semester 3</td>
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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.
Also prospective students would either need to be in employment or be able to produce agreeing project supervision by a suitable supervisor.

Entry level guidelines for English Language
An ILESTS score of ≥6.5

The course is open to undergraduate medical students who wish to (and are eligible to) intercalate a Masters degree into their MBBS studies.
For these students there are entry criteria that differ from non-intercalating applicants - in addition to the equivalent English proficiency, intercalating students need to have:
1. Successfully completed at least three years of the MBBS, MbChB or equivalent medical course
   (for clinically based masters this must include the equivalent of one year of patient based teaching (in hospital/GP practices/clinics))
2. Passed year 3 or 4 exams immediately prior to entry at the first opportunity
3. Demonstrate a clear and unequivocal interest in the field by written application and/or interview

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4. For students internal and external to QMUL it is confirmed that the beginning of the first term for the following year starts after all the QMUL Masters assessments are completed

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.

All students are 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 or by phone.
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Assessment of effectiveness of student support mechanisms is evaluated with the following means:

- Continuous feedback to the students. Student feedback is an extremely important mechanism to facilitate the students learning experience. Feedback is 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.

Changes implemented following student feedback 2009-2011

- Additional lectures by the learning services team were incorporated into the timetable to give students experience from qualified staff (eg. EndNote training, medical and scientific writing).

**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 Institute level Committee will be created responsible for ongoing management of the Programmes.

**Programme-specific Rules and Facts**

**Specific Support for Disabled Students**

The Charterhouse Square Campus readily accessible to disabled students.

**Links With Employers, Placement Opportunities and Transferable Skills**

Student Employment Prospects: The employers, which include the pharmaceutical industry, NHS, etc will greatly benefit from having students who successfully completed this PGDip/MSc. With the modernisation of medical education and the fact the education and training of staff involved in drug development 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.
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MSc graduates in Clinical Drug Development will be well prepared for employment in any area of clinical drug development, clinical trial design as well as clinical trial management. This includes careers within pharmaceutical or Biotech companies, clinical research organisations (CROs), Universities as well as the Clinical Research Networks. In addition opportunities are possible within regulatory organisations worldwide working within post-market surveillance by bringing together information from different sources to evaluate the safety of newly marketed pharmaceuticals, and similarly in medical writing for medical journals.

The Institute and Centre work with the students to identify suitable opportunities and supports the job application process. Graduates continue the ‘Queen Mary experience’ after they leave by keeping in touch with the course team, colleagues and friends.

The program supports post graduates seeking careers in clinical trial design and clinical trial management within the pharmaceutical industry in the following key areas:

- Drug Design
- Pharmaceutical Analysis
- Drug safety and pharmacovigilance
- Clinical trial management e.g. (clinical research associates)
- Pharmacoeconomics
- Marketing
- Regulatory Affairs
- Quality Assurance
- Medical Writing
- Medical Sales

Programme Specification Approval

| Person completing Programme Specification | Professor Atholl Johnston |
| Person responsible for management of programme | Professor Atholl Johnston |
| Date Programme Specification approved by Taught Programmes Board | January 2017 |