Masters Programme in Experimental Therapeutics
Specification

1. Awarding Institution / Body: University of Oxford

2. Teaching Institution: University of Oxford, Department for Continuing Education and Department of Clinical Pharmacology

3. Programme Accredited by: University of Oxford

4. Final Award: Master of Science in Experimental Therapeutics (Postgraduate Diploma in Experimental Therapeutics (exit award only))

5. Programme Title: Master’s Programme in Experimental Therapeutics

6. UCAS Code: N/A

7. QAA Benchmarking Group: N/A

8. Date of Programme Specification/last reviewed: June 2009

9. Aims of Programme:

The MSc Experimental Therapeutics course exists in order to:

- introduce the most commonly used and most important analytical, quantitative and practical methods used in experimental therapeutics;
- enable students to understand the principles that underpin clinical research, and to enable them to translate that understanding into good clinical practice;
- enhance the quality of experimental therapeutics in the institutions to which students belong;
- enable students to undertake an original piece of research addressing an aspect of experimental therapeutics.

10. Intended Learning Outcomes and the means by which they are achieved and demonstrated:

MSc in Experimental Therapeutics

Knowledge and understanding:
At the end of the course students will be able to:

- demonstrate a knowledge of the principles, methods and techniques appropriate for solving experimental therapeutics/clinical research problems and be able to translate (through a critical comprehension of the relative advantages and disadvantages) that understanding into good clinical practice;
- manage their own learning and research and conduct independent and effective study;
- apply skills gained in techniques and practical experience from across the medical and biological sciences;
- undertake a piece of directed research in experimental therapeutics;
- develop skills in managing research-based work in experimental therapeutics;
• carry out an extended research project involving a literature review, problem specification and analysis in experimental therapeutics and write a short dissertation.

Students will know and understand:
• How drugs are developed and marketed.
• The important aspects of drug regulation.
• The pharmaceutical factors that affect drug therapy.
• Pharmacokinetics and drug metabolism.
• Pharmacogenetics.
• Pharmacodynamics (pharmacological actions of drugs) and the principles of pharmacokinetic–pharmacodynamic modelling.
• Adverse drug reactions, drug interactions, and pharmacovigilance.
• How to design phase I, II and III clinical trials for a range of novel therapeutic interventions (and imaging agents).
• Application of statistics to medicine
• Laboratory assays used to support trial end-points
• Use of non-invasive imaging in drug development.

Cognitive / Intellectual Skills:
At the end of the course students will be able to:
• understand the role of most commonly used methods appropriate for specifying translational problems through a critical comprehension of the relative advantages and disadvantages of these methods
• understand and express the main principles of some commonly applied techniques and methods
• explain the rationale for the selection of tools used in the analysis of phenomena
• undertake a piece of directed research

Research Skills:
At the end of the course students will be expected to have developed a range of transferable skills including:
• skills in managing their own learning and research and conducting independent and effective study
• skills in applying analytical techniques
• skills in analytical problem specification
• skills in applying research outputs to good clinical practice
• skills in managing research-based work
• skills in the analysis of abstract problems (identification, separation, specification and formulation)

Discipline-specific Practical Skills:
• carry out an extended research project involving a literature review, problem specification, research outputs and analysis in experimental therapeutics and write a short thesis.

Achievement of Learning Outcomes

The intended learning outcomes (above) are achieved using the following teaching and learning strategies.

Lectures and online material:
• present and explore core ideas in the subject areas of the emerging field of experimental therapeutics
• review of the current literature, including books and journals
• provide a thorough grounding in subjects that will often be new to the student (depending on the student’s background)

Practical sessions:
• provide an opportunity for students to familiarize themselves with equipment that may be used to study phenomena;
• provide a structured opportunity for students to practise techniques and methods of analysis for problems in experimental therapeutics;
• promote discussion and sharing of ideas in the practice of clinical analysis;
• provide a structured opportunity to develop analytical and numerical solutions to problems with guidance.

Guided reading:
• Specify recommended texts, key articles and other materials in advance of, or following, lecture classes for the purposes of discussion and further research.

Course assignments:
• enable students to tackle problems in experimental therapeutics relevant to the analysis of data
• allow students to reflect on their learning in the context of the wider curriculum.

Expert (guest) lectures:
• provide an opportunity to enquire of the experience and knowledge of renown scientists and industrialists;
• allow an opportunity to reflect collectively upon experiences using real examples.

Workplace-based project:
• enables students to practise the application of good clinical practice in the context of their work;
• provides an opportunity for students to advocate solutions based on learnt and understanding.

Thesis:
• enables students to practise the application of research techniques
• provides an opportunity for students to study a research challenge

11. Programme structures and requirements, levels, modules, credits and awards

The MSc programme will involve the study of 8 modules and a work-based project and dissertation. Six modules will be compulsory and two will be chosen from a list of options. The research project, with an associated dissertation, will include taught material on research skills. Initially the modules will be taught in face-to-face classes; however, as the subject areas mature, these may be offered subject to their suitability as online modules.

MSc modules

Compulsory modules
Module 1: Structure of Clinical Trials and Experimental Therapeutics
☐ The history of drug discovery
☐ Modern methods of drug discovery
☐ Preclinical drug development
Module 2: The basic processes of drug therapy: pharmacokinetics
- Pharmaceutical factors in drug therapy
- Introduction to pharmacokinetics: absorption, distribution, elimination
- Zero-order and first-order kinetics; single intravenous dose kinetics
- Single oral dose kinetics
- Multiple oral dose kinetics and dosage regimens
- Systemic availability (bioavailability)
- Non-linear kinetics
- Model-independent methods

Module 3: The basic processes of drug therapy: pharmacodynamics and the principles of pharmacokinetic–pharmacodynamic modelling
- Introduction to how drugs act
- How the pharmacodynamic effect is translated into a therapeutic effect
- Drug actions on receptors and second messengers
- Drug actions on enzymes
- Drug actions on transport processes
- Drug–ligand interactions—different models
- The dose-response curve—different models
- Biomarkers and surrogate endpoints
- Pharmacokinetic-pharmacodynamic modelling

Module 4: Adverse drug reactions, drug interactions, and pharmacovigilance
- Adverse drug reactions—epidemiology and classification
- Adverse drug reactions—mechanisms
- Adverse drug reactions—monitoring and prevention
- Systematic reviews of adverse drug reactions
- Drug interactions—epidemiology and mechanisms
- Drug interactions—prevention
- Beneficial drug interactions—using combinations of drugs
- Methods of pharmacovigilance

Module 5: How to do research on therapeutic interventions: protocol preparation
- How to design pharmacokinetic experiments
- How to design pharmacodynamic experiments
- How to study drug–ligand interactions
- Evidence-based medicine
- How to design an observational (e.g. case-control) study
- How to design a clinical trial

Module 6: Biological Therapeutics
- Basic immunology
- Antibody based therapeutics
- Cell based immunotherapy
- Cancer vaccine
- Draft approaches to cancer gene therapy
- Viral vectors for gene therapy
- Non-viral vectors for gene therapy
Clinical trial design for vaccines and gene therapy

Optional modules – translational aspects of experimental medicine
The optional modules will give the student the opportunity to learn how the principles enunciated in the compulsory modules can be translated into practical actions in selected areas.

Module 7: The principles of cancer chemotherapy
◊ Conventional cytotoxic drug families
◊ Adverse effect profiles of conventional cytotoxic drugs
◊ The efficacy toxicity ratio in cancer therapy – what good can we do and at what expense?
◊ Individualizing therapy in cancer care: pharmacogenomics
◊ Emerging biologics in cancer treatment
◊ Colorectal cancer as a case history
◊ Choosing the right statistical endpoints in cancer trials

Module 8: Structural genomics and drug discovery
◊ Introduction to protein production and engineering
◊ Basics of x-ray crystallography
◊ Nuclear magnetic resonance spectroscopy
◊ Identification of drug targets
◊ Computer modelling for drug design
◊ Elements of medicinal chemistry
◊ Toxicology packages to support drug development

Module 9: Rational Prescribing
◊ Designing a dosage regimen and individualizing therapy
◊ Monitoring drug therapy—clinical observation
◊ Monitoring drug therapy—pharmacodynamic methods
◊ Monitoring drug therapy—pharmacokinetic methods
◊ Troubleshooting failure in drug therapy
◊ Adherence to drug therapy
◊ Placebos
◊ Practical aspects of prescribing

Other optional modules will be drawn from existing CPD MSc programmes, for example, from the MSc in Evidence-Based Health Care:
• Further Practical Statistics
• Statistics for Health Research – online
• Randomised Controlled Trials
• Ethics in Health Care
• Patient-Based Evidence
• Qualitative Research Methods
• Systematic Reviews
And from the MSc in Biinformatics:
• Statistics for Biosciences – online
• Bioethics – online
• Statistical and Population Genetics
• High Throughput Experimental Techniques
• Molecular Evolution and Comparative Genetics
Dissertation
The dissertation will be based on a work-based project that will build on the material studied in the taught modules. The dissertation will begin with taught units (equivalent to one week of taught classes), which may be in an online form. The project will be supervised by an academic supervisor and employer-based mentor (who will respectively ensure that the project has sufficient academic rigour and relevance to the student’s career).

Note: A Postgraduate Diploma will be available only as an exit award to those who have not successfully completed the dissertation. To be awarded the Postgraduate Diploma, students must successfully complete all of the taught modules.

12. Support for learning

The course director and tutors undertake to:
• provide an introduction to the specialist library of learning materials for the course
• provide advice and guidance on student matters

OUDCE provides the services of a Student Advisor, experienced in the needs of part-time students, library and IT facilities, and an on-line forum for student discussion.

MSc students will have access to all University facilities and support including libraries, IT services, career and counselling services, limited child-care provision and sport and recreation. As members of a college they will benefit from pastoral support and sporting and social facilities within their college.

Students will also have access to the Oxford University Computing Services (OUCS), which includes access to IT equipment (terminals, printers and scanners), the OUCS Help Centre, the Computing Services Shop, OUCS training courses, and the personal computer maintenance service. OUCS also offers remote access services including dial-up accounts, and use of the Virtual Private Network (VPN) service.

Students may also access the University Careers Service and Language Centre.

13. Criteria for admission

The admissions policy for the course is intended to ensure that applicants are offered equality of opportunity irrespective of gender, disability, race, religion, nationality or ethnic origin.

Applicants will be assessed on their individual merits and potential. Decisions will be based on the application of selection criteria appropriate to the course of study in a competitive context. In addition, successful candidates will satisfy the requirements of the OUDCE summary admissions policy as well as the minimum required English language criteria set by the University.

All candidates will need to demonstrate:
• A first degree in a biological science or medical science subject, including pharmacy and nursing, or an equivalent level of demonstrable understanding and competence as a result of training,
• Some practical experience in research and/or development, usually via employment in a medical science-based company, research establishment or facility.
• A good working knowledge of email, internet, word processing and Windows applications (for communications with course members, course team and administration).
• Evidence of the ability to commit time to study and an employer’s commitment to make time available to study, complete course work and attend course and university events and modules

Successful candidates will normally provide evidence of all of the following:
• A general interest in experimental therapeutics, evidenced by prior experience, interest and work
• Motivation and ability to complete the course
• A clear and well argued understanding of the benefits of the course to the candidate’s current employment and future prospects

All potential applicants will receive a brochure detailing the scheme for the course and will have access to the detailed, and regularly updated, description of the course at the programme website. The admissions criteria above will be clearly stated in the brochure sent to enquiring potential students, in the Student Handbook for the programme, and in the e-handbook at the programme website.

Applications to the programme requires the completion of an application form, statements of support from three referees together with evidence of support from the candidate's company, and an interview, usually conducted face-to-face with at least two members of the teaching team. The application form includes requests for information about:
• relevant prior or current work experience
• a statement of current role and duties in their organization or, if self-employed or unemployed, details of their most recent role or experience
• details of sources of financial support (students are provided, separately, with a summary of sources of financial support from sources other than their company)
• details of any prior higher education career
• names of referees willing to offer an opinion on the suitability of the candidate for entry to the course
• evidence of employer commitment in the form of a signed statement, from a named individual within the company, of willingness to release the employee for attendance at the programme, and willingness to provide financial support
• a statement by the student of their objectives in attending the course and their reasons for seeking to register

References are secured before discussion with the applicant takes place. A telephone or face-to-face interview will be arranged for all of those who appear to fulfil the basic requirements for entry to the course. Applications may be rejected without further direct contact with the applicant, although candidates whose applications are deemed insufficient for entry to the course may, on request, receive feedback upon their application. The purpose of the interview is to:
• establish the applicant’s level of interest, motivation and potential to benefit from the course of study
• clarify any uncertainties about compliance with requirements
• ensure that candidates are fully informed of the standard of achievement and level of commitment required by the course of study

A successful candidate will normally provide evidence of all of the following:
• a demonstrated interest in experimental therapeutics
• motivation and ability to complete the course
• a clear and well argued understanding of the benefits of the course to the candidate’s current employment situation and future prospects
• prior academic achievement in mathematical or physical sciences disciplines at undergraduate or Master’s level, or practical experience in related fields
Applicants will be expected to demonstrate an approach to their study which includes demonstrable skills of critical analysis, wide contextual knowledge and the ability to manage their own time.

Formal evidence of prior academic achievement is required.

The ability of students to finance their study is not one of the criteria for academic acceptance. However, applicants may not subsequently be admitted to the course if they are unable to provide evidence of their ability to pay the course fees. In cases where students anticipate difficulties with payment, all possible information and guidance on sources of financial support will be offered.

14. Evaluation and improvement of quality & standards:

Methods for evaluating and improving quality and standards include:

- Student feedback and consultation: comments will be collected through questionnaires at least annually and through representation on committees and other informal means (specify) and considered by course directors/course teams and acted on where appropriate. Students will be informed of the outcome.

- Student destination, whether employment or further study: the course director will report on destinations in the annual report to the Board of Studies. The destinations enable some assessment of the personal development achieved by the student through the course. Information will be incorporated into the HESA survey (Destination of leavers from Higher Education survey) which must be completed in respect of part time students.

- Course team meetings will be held monthly at which course tutors consider the current course structure and delivery arrangements and make recommendations for change and improvement.

- Oxford Learning Institute participation: the Institute supports the furtherance of excellence in learning, teaching and research at the University and promotes the professional and vocational development of staff. Staff will be encouraged to attend courses provided by the Institute and by OUCS as appropriate.

- Team teaching will be used to help spread best practice for teaching and learning techniques.

- The internal examiners’ report will comment on the standards of learning and examination performance.

- The external examiner moderates work to ensure the standards of teaching and assessment are appropriate and consistent. S/he will provide an annual report which is considered by the Board of Studies, the CE Board and the Education Committee of the University.

- The Board of Examiners will meet annually to consider and agree marks, progression and awards. The Course Director’s report will review the past year, and report any developments to the Board of Studies. Detail will be provided on admissions, retention, staffing, course changes feedback and responses to feedback, student performance and any difficulties encountered with the course.
• The Board of Studies, which will include joint MSD/OUDCE membership, will receive the Course Director’s Report and the Examiners’ reports, reviews the programme of study, scrutinises and approves the course and examination arrangements.

• OUDCE and Divisional committees will consider proposals for new course or changes to courses which will, inter alia, improve and extend teaching and learning opportunities. They will advise on academic policy, quality assurance and enhancement of the course provision.

• The Education Committee bears overall responsibility for teaching, learning and assessment in the University. It has to consider and give approval for any changes to regulations.

• The CE Board (with the Divisional Board for joint courses) reviews postgraduate courses five years after implementation.

• Periodic reviews are held of groups of courses every six years

• Best practice from other HEIs is identified though reports of external examiners, attendance at conferences, reading of journals and other forms of academic communication.

• Accreditation by external organisations and an external advisory panel indicates that the course meets employers’ or outside requirements

15. Assessment Criteria:

To complete the MSc students must:
• Attend and complete the 6 compulsory modules and 2 option modules.
• Complete a project/dissertation module on research skills and a dissertation on a topic chosen in consultation with a supervisor, work-based mentor and the Course Director. The dissertation must normally be submitted at the end of two years, and it must be submitted at most, with the appropriate consents and with payment of relevant fees, at the end of four years. The dissertation should normally not exceed 20,000 words.
• attend a viva voce examination at the end of the course of studies at the discretion of the examiners.

Students will not obtain the MSc unless they complete the above requirements to the satisfaction of the examiners. In particular, failure to submit any assignment without dispensation or to submit the dissertation automatically results in overall failure. The examiners may award a distinction for exceptional performance in the MSc. Poor performance on one part of the course may, at the discretion of the examiners, be compensated for by excellent performance in the remaining parts.

The assessment of coursework and examinations in the programme is based upon recognition of the following qualities:

Knowledge, Understanding, Argument and Reasoning
• Range and depth in knowledge of the content covered in the course
• Command of appropriate analytical skills
• Logical exposition and reasoning
• Clarity, completeness and concise expression in analysis

Presentation and Deployment
• Clear demonstration of the benefit of analysis of scientific data in argument
• Clarity in written exposition
• Appropriate use of literature reviews, including correct referencing

Grading
All coursework will be assessed using the following grading scale:

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<th>Mark</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Distinction</td>
<td>70 and over</td>
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<tr>
<td>Pass</td>
<td>50 - 69</td>
</tr>
<tr>
<td>Fail</td>
<td>49 and below</td>
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</table>

Relative weights of assessments
The relative weights of the components are as follows:

<table>
<thead>
<tr>
<th>Component</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>7 assignments from 8 modules</td>
<td>120</td>
</tr>
<tr>
<td>Dissertation plus project/dissertation module</td>
<td>60</td>
</tr>
</tbody>
</table>

Cases of failure
University regulations provide that a student who has failed the overall examination for the MSc may resit at most once. This means resubmitting part of parts of the assignments and project report/dissertation, but not re-attending modules. The conventions for the course will specify in each case which parts of the assessment would need to be repeated in the event of failure and which would not.

Presentation of coursework
During each module students will be given assignments which will usually be due within four to six weeks of the end of the module. Assignments should be submitted using the CASS submission system. A marking form AM1, supplied with the notes, should be completed and returned with each assignment.

Submission of coursework
It is each student’s responsibility to ensure that assignments are submitted by the deadlines listed in the Student Handbook. These dates appear again in the notes for each module (the examiners will take exceptional circumstances into account). Assignments must be wholly the work of the student with due acknowledgement as appropriate, and must not be plagiarized. Plagiarism consists of substantial or verbatim quotation from an unacknowledged source. This includes, in particular, unacknowledged collaboration with another student. Plagiarized work will be discounted; there can be no subsequent submission of revised versions of work which has been judged to be plagiarised. For each submission made, students will be required to sign a declaration acknowledging authenticity of the work. This declaration appears on the AM1 marking form which will be included in each new set of notes.

All assignments will be first-marked, and a selection will be second-marked, by course tutors. A number of assignments (usually those receiving borderline or exceptionally high marks or where there is a large disparity between marks awarded by first and second-markers) will be sent to an external examiner for moderation, as will a complete set of a selection of individuals’ work.

Extensions
Submission of assignments and the overall appraisal by the deadline is strictly regulated. If a student cannot submit an assignment (including the dissertation) by the set deadline, they must apply in advance of the set deadline for an extension date, providing the reasons for
the request. Failure to do so may result in marks being deducted by the examiners, or the assignment being disallowed. Applications for all types of extension (see below), in accordance with Departmental policy and course conventions, are judged using the criteria below, and will in certain circumstances require approval of the Proctors. Students should be able to show that each of these criteria has been addressed.

- Whether the substantive argument for extension is associated with an unavoidable change in personal, employment or other relevant circumstances not anticipated at the outset of studies.
- The likely duration of the changed circumstances
- Whether there is clear evidence of a plan to meet the requirements for submission of assignment material within a stipulated time period.
- Ill health (medical evidence to be required if period of extension is for more than two weeks)

If a student requires an extension for an assignment (excluding the dissertation), one of procedures below must be followed depending upon the duration of the proposed extension.

For an extension of up to two weeks:
- The student’s application will be reviewed by the Course Director and if approved will be forwarded to the Department's Registry Office.

For an extension of more than two weeks:
- The application must be approved by the Chairman of the Board of Studies via the Registry Officer.

Short Dissertation Extension (days/weeks)
This type of extension is only granted in exceptional circumstances and must be approved by the University Proctors via your college. It is intended for students who suddenly find that they are unable to submit by the deadline (e.g. due to ill health).

Students who require a longer extension and who anticipate this need in advance (e.g. due to increased work load, change of job etc) should apply either for an Extension of Time or a Suspension of Status depending on their circumstances (see below).

Extension of Time
Where a student is unable to complete work within the required six terms, the student will need to seek an Extension of Time. This includes students who are unable to complete their dissertation within the final term of the course.

Extensions of Time are given out in periods of University terms and students should normally apply before the 31 August to extend/suspend the following Michaelmas Term.

An Extension of Time requires payment of additional fees for each term extended. Extension forms will be available from the Registry Office.

Suspension
Suspensions of status are periods of suspension of study used when a student’s problems have become so severe, normally for reasons such as illness or redundancy, that extensions will not help; normally in units of a term, not normally for more than three terms at a time. With a Suspension of Status, a student’s status within the University is suspended and re-started again once conditions make it possible to resume work on the course. Students on suspended status will receive no teaching or supervision during the suspension and will not pay fees for the terms of suspended status. Students will need to apply to suspend status following normal University procedure.
16. Indicators of programme quality:

Indicators of programme quality include:

- Student retention and completion rates will be analysed to assess student satisfaction and the adequacy of student support.
- Student results profiles will be analysed to assess overall achievement and progression during the course.
- Destination data will be collected to demonstrate progression from the course and market recognition of the certificate awarded. Further evidence of the quality of teaching and learning will be provided by the subsequent performance of students accepted onto full or part-time degrees courses at Oxford and other institutions.
- The annual External Examiner’s report will provide impartial feedback on the course and comparison with the standards achieved by similar courses in other institutions.
- The annual evaluation of programme quality by students will provide a ‘user assessment’ of course content and delivery.
- Accreditation: accreditation of a course indicates an impartial judgement of the quality of the course.
- Groups of courses are reviewed in detail every six years by a panel including external experts in the field.
- For new postgraduate courses the CE Board (jointly with the Divisional Board for joint courses) carries out a five year review covering student intake, student progression, aims and objectives of the course, course structure and content, resources allocated to the course and student feedback.
- Employer assessments will indicate if a student has benefited in an employment context, bringing benefits to both the individual and the organisation.
- Evidence of the quality of the Department: for example the quality of its staff (as attested by RAE, success in securing external funding, external testimony)

Please Note. This specification provides a concise summary of the main features of the programme and the learning outcomes that a typical student might reasonably be expected to achieve and demonstrate if he/she takes full advantage of the learning opportunities that are provided.

The information contained in this document is reviewed by the Continuing Education Board and may be checked by the Quality Assurance Agency for Higher Education.

AP June 2009