

University of Cambridge: Programme Specifications

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POST-GRADUATE DIPLOMA IN CLINICAL SCIENCE (TRANSLATIONAL MEDICINE AND THERAPEUTICS)

1	Awarding body	University of Cambridge
2	Teaching institution	University of Cambridge; Institute of Continuing Education*
3	Accreditation details	None
4	Name of final award	Post-graduate Diploma
5	Programme title	Clinical Science (Translational Medicine and Therapeutics)
6	JACS code(s)	None
7	Relevant QAA benchmark statement(s)	None
8	Qualifications framework level	FHEQ Level 7
9	Date specification was produced/ last revised	January 2010
10	Date specification was last reviewed	N/A

* Cognate faculty endorsement provided by the Faculty of Clinical Medicine

It is increasingly recognised in the UK that few academics pursue clinical research and drug development. This is partly driven by a lack of training in this discipline, and has recently been acknowledged by the NIHR, Wellcome Trust, BHF, Academy of Medical Sciences and other organisations which have set up funds specifically to support training in clinical research.

The Faculty of Clinical Medicine at the University of Cambridge has been awarded £5.5 million by the Wellcome Trust to set up a training programme for clinicians in Translational Medicine and Therapeutics (TMAT) as part of which a new Masters programme in TMAT was developed. However, the need for research in this area is greater than the current provision will supply, and many Allied Health Professionals and nurses are making a valuable contribution to this vital area.

Recognising this, and the different educational backgrounds of potential applicants, a new Post-graduate Diploma in Clinical Science (TMAT) has been developed that will draw on the experience from the TMAT course and Masters programme, and which is tailored specifically to the needs of individuals who may not wish to pursue a Masters course for a variety of reasons. The Department of Health recently invited discussions to establish such a course to develop the skills of Academic Clinicians, the target market for this programme.

The proposed Post-graduate Diploma incorporates a core of modules that are also open to the existing MPhil programme, allowing all students to integrate at the classroom level and provide an open flow of scientific discussion and collaboration. Post-graduate Diploma students are welcome to progress to the MPhil and are encouraged to consult with their educational supervisors regarding further graduate educational opportunities.

The Post-graduate Diploma in Clinical Science (TMAT) will be delivered by the Institute of Continuing Education (ICE) in partnership with the School of Clinical Medicine. The Post-Graduate Diploma will form part of the Institute's programme of credit-bearing professional development qualifications offered at FHEQ Level 7 offered to part-time adult students.

Aims of the Programme

The programme aims to:

1. Contribute to the commitment of the CUHNHSFT and the NIHR to continuing professional development of NHS staff in an integrated academic and clinical environment;
2. Develop a pool of highly trained research academics who will pursue clinical academic careers within academia, the NHS and industry;
3. Expand critical and current knowledge of research methodologies through an academically rigorous education programme offered in a world-leading clinical research environment.

Learning outcomes

Students who complete this programme successfully will have gained the skills and knowledge defined by the Academy of Medical Sciences. Supplementary Guidelines for the Annual Review of Competence Progression (ARCP) for Speciality Registrars undertaking joint clinical and academic training programmes (September 2007).

The ARCP requires skills and knowledge in the following areas:

1. ***Generic and applied research skills, e.g.***
 - Identifying a research topic and defining a research question
 - Data interpretation and statistical analysis
2. ***Research Governance, e.g.,***
 - Research ethics and monitoring (including COREC processes)
 - Information storage and retrieval
 - Effective networking and collaboration
3. ***Communication/Education (Transferable Skills), e.g.***
 - Writing and verbal presentation skills

Upon successful completion of the Post-graduate Diploma, graduates are expected to have developed a strong foundation in the fundamental techniques of translational research. They will be able to apply contemporary research tools to clinically relevant areas of investigation in TMAT. The Post-graduate Diploma programme will produce clinical researchers who are knowledgeable about the complex issues associated with conducting sound clinical research/trials.

On successful completion of the programme, students should be able to demonstrate the following learning outcomes:

Knowledge and understanding

1. Knowledge and critical understanding of the importance of Experimental methods in the predicting and monitoring treatment responses to specific therapies
2. Knowledge of, and practical ability in, statistical concepts - from understanding various packages to analysing data and finalising data for a scientific journal paper

3. Understanding cutting edge investigational techniques and research development skills
4. Appreciation of the importance of epidemiological research methods in aetiological epidemiology and health services research
5. Knowledge and understanding of the regulatory submission process and the requirements and knowledge of Good Clinical Practice (GCP)
6. Critical understanding of key concepts of pharmacodynamics: understanding of a dose-response curve and its determination; how to measure agonism/antagonism, potency, efficacy and selectivity
7. Critical understanding of key concepts of pharmacokinetics: understanding of half-life, other key drug properties, and how they are measured.

Cognitive/Intellectual Skills

1. Understanding of key aspects of designing and managing a pre-clinical trial
2. Critical understanding of basic principles of statistical tests and their application in conducting appropriate statistical analyses of data generated in pre-clinical trials and studies in experimental medicine
3. Ability to research and interpret data to evaluate information using a number of sources
4. Understanding of relevant summary measures relating exposures to disease risk
5. Ability to select appropriate epidemiological study designs to answer particular research questions-this is repetitive but if you want it fine
6. Understanding of the strengths and weaknesses of different epidemiological study designs
7. Ability to communicate effectively and discuss ideas and results
8. Ability to conduct computerized searches of biomedical literature and cite sources appropriately
9. Ability to acquire necessary analytical skills to appraise papers, reviews and reports in biomedical literature

Transferable Skills

1. Understanding of the key regulatory framework of clinical trials
2. Ability to apply statistical and modelling skills
3. Ability to transfer and adapt knowledge from one discipline to another
4. Ability to assess possible reasons for observed exposure-disease associations
5. Ability to research independently and within a team environment
6. Have an essential understanding of how to translate science into new drugs
7. Ability to integrate results from research with information from a wide range of sources in written reports and to give oral presentations
8. Ability to work as a member of an interdisciplinary team

Teaching and learning methods

Teaching methods will include, but not be limited to: formal lectures, interactive seminars and workshops, discussion and networking groups, structured reading and case analysis, laboratory work and presentation. Teaching sessions will set out concepts, conceptual frameworks and theory relating to the topics to be covered; other modes of teaching and learning are designed to enable participants to achieve the stated learning aims and objectives. All teaching sessions will have a feedback system in place for student's comments.

Periods of self-directed study and research between blocks of attendance will also be required; this will be enhanced through a Virtual Learning Environment (VLE), which will enable students and tutors to consolidate and expand upon the formally taught components.

Students will be expected to carry out significant in-depth research and analysis between taught sessions.

Assessment methods

The Post-graduate Diploma is assessed using multiple techniques and inter-related strategies, including written individual essays, practical assignments, case studies, active participation and the Participant Assessment Matrix (ICE). The assessment culminates in a research project, examined and supported by way of a written project report. The communication and educational components will also be assessed by a formal presentation and peer teaching component. Assessment will also be measured by: attendance at taught courses, attendance at sessions with academic supervisor, and participation in teaching at under- and post-graduate level. All assessments are supervised by an examiner's committee. The total word count for the programme is 20,000.

Programme structure: overview

The programme is offered at FHEQ Level 7 and attracts 120 credits.

The programme consists of 4 courses, attracting a total of 60 credits, plus a Research Project (60 credits). The curriculum is designed to facilitate in-depth study, independent research and critical analysis of the subject areas. All courses incorporate individual research. Besides two Post-graduate Diploma in Clinical Science generic courses, and the compulsory research project, the Post-graduate Diploma in Clinical Science (TMAT) will offer three courses of particular relevance to translational medicine and therapeutics from which two courses will be selected and completed for the Post-graduate Diploma.¹

The 5 components comprising the Post-graduate Diploma are:

1. Generic Courses (compulsory)
 - 1.2 Research Statistics and Skills
 - 1.3 Practical Aspects of Clinical Research
2. Specialist Courses (2 of 3 options)
 - 2.1 Introduction to Clinical Research
 - 2.2 Experimental Medicine methodologies
 - 2.3 Epidemiology
3. Research Project (compulsory)

The programme is offered on a part-time basis, with two intakes a year. Students will normally take a minimum of 12 months across 2 academic years to complete the Post-graduate Diploma. The maximum time for completion will normally be 24 months (ACFs may be allowed to suspend during hospital training posts and resume when returning to academic GP). Teaching is delivered throughout the year in a blended format, consisting of required intensive face-to-face sessions supported by an interactive Virtual Learning Environment (VLE).

Programme structure: detail

Generic Course 1: Research Statistics and Skills (15 credits)

¹ It will be possible to attend the third course without assessment, or other courses offered across the programme of Post-graduate Diplomas in Clinical Science.

This course enables participants to develop critical understanding of statistical methods and techniques, and, in particular, their application to the field of clinical medical research. Topics covered include non-parametric methods for skewed and ordered categorical data and small datasets; multiple and logistic regression and other methods of multivariable analysis; basic concepts in randomised controlled clinical trials and sample size; survival analysis; the use of statistical software; critical appraisal of medical literature and statistics for medical journals; and the handling of statistical data. Assessment will include, but not be limited to, practical written assignments, case studies and applied projects. Total word count is 2500.

Generic Course 2: Practical Aspects of Clinical Research (15 credits)

This course covers practical aspects of preparing grant applications, writing papers, presentation skills, reviewing papers and grants, and metrics of productivity/achievement in science. Participants will critically examine research ethics and governance issues and their significance and impact in clinical research. Key topics will include preparation of ethics and other regulatory submissions, requirements for study monitoring, data collection and analysis, and Good Clinical Practice (GCP). Assessment will include, but not be limited to, practical written assignments, case studies and applied projects. Total word count is 2500.

Specialist Course 3 (optional): Introduction to Clinical Research (15 credits)

This course provides an overview of clinical research, from principles of clinical research to integrating research into a clinical career. Participants will understand the difference between an audit and research, formulate study questions and design, understand the principles of GCP and ethics approval, critical appraisal skills, overview of research funding and writing a scientific paper. Assessment will include, but not be limited to, practical written assignments, case studies and applied projects. Total word count is 2500.

Specialist Course 4 (optional): Experimental Methodologies (15 credits)

'The new module entitled 'Experimental Medicine Methodologies' will consist of a series of lectures in the five themed areas of imaging, cardiovascular and respiratory, central nervous system, metabolic and laboratory. These lectures will cover commonly used clinical methodologies that are used for detailed patient phenotyping, for evaluating the physiological and metabolic effects of genetic disorders, and for determining the effects of dietary, pharmacological or lifestyle interventions. Such methods include functional MRI (fMRI), autonomic nerve function, cardiovascular stress testing, muscle function, energy expenditure, and clamp and stable isotope studies. This module will be of particular interest and relevance to clinical and non-clinical postgraduates embarking on or aspiring to undertake a clinical or in-vivo research programme'. Total word count is 2500.

Specialist Course 5 (optional): Epidemiology (15 credits)

This course provides a broad overview in epidemiological study designs and measures of disease risk used in aetiological epidemiology and health services research. Practical training throughout the course will give participants the basics to critically follow and conduct their own epidemiological research. The module will consist of five days with theoretical seminars in the morning and practical training in small groups in the afternoon. Assessment will include, but not be limited to, practical written assignments, case studies and applied projects. Total word count is 2500.

Research Project (60 credits)

The research project will be developed and carried out under the direction of an assigned supervisor, and will be designed to demonstrate critical understanding and application of the research principles developed in the first 4 courses. Assessment will be by way of a written research report of 10,000 words. It is likely to be embedded within on-going peer-reviewed

and externally funded programmes of work, and can lead to submission of one paper for publication.

Programme Requirements

Applications are invited from Academic Clinical Fellows (ACFs) already accepted into the NIHR ACF programme, and from those holding an upper second class 2i Bachelors degree at honours level in basic science, nursing or medicine and clinicians seeking to take time out of their training to pursue a research degree.

All students accepted onto the programme will be required to successfully complete all elements of the programme (i.e. 4 courses and the research project) to be recommended for the Post-graduate Diploma in Clinical Science (TMAT).

The Post-graduate Diploma assignments and the research project will be marked by the examination panel.

The pass mark for the Programme is 50%. Candidates who have not achieved an average mark of at least 50% in the coursework may be permitted to submit a re-sit assignment on one occasion only for each course.

All students will participate in the annual symposium where opportunities for presenting work in progress will be available and the day will include speakers across all participating disciplines and invited senior academics and our industry partner from across the globe.

Applicants to the programme will be expected to demonstrate proficiency in the English language; students whose first language is not English must be able to satisfy the current English Language Competence requirements of the University's Board of Graduate Studies in the year in which they apply for admission to the course.

Employability

Immediate career options will include doctoral training fellowships.

Career destinations will include:

- Pharmaceutical Physicians or Clinical leads in Pharmaceutical Industry
- NHS consultants
- Clinical Academics
- Clinical leads or advisors to Biotech Industry
- Clinical leads in NHS R&D
- Senior researcher
- Clinical trials managers
- Biomedical scientists
- Clinical scientists
- Nurse prescriber

Students completing the Post-graduate Diploma in Clinical Science (TMAT) will normally already be in employment or training; the Post-graduate Diploma will enable them to enhance their capacity to critically analyse and examine clinical trial issues and advances. The Post-graduate Diploma is intended to ensure that health professionals in training are able to enter full-time doctoral research in a specific, specialist area having first had some broad-based instruction on both research methodology and the translation of basic research into bedside applications.

Managing Teaching Quality and Standards

The teaching quality and standards of the course will be monitored by the Programme Advisory Committee and the Subject Moderation Panel, consisting of the University and external moderators and other Faculty and ICE members as agreed by the Education Committee.

Student Support

Advice to students is available both before and after they have registered for a course from the course director or the administrative staff assigned to the programme. All students are provided at the start of a course with the ICE Student Handbook.

Administrative staff work closely with the academic team throughout the programme, and are able to provide appropriate levels and types of student support – for instance, support in technical matters, such as using the VLE.

Periods of self-directed study and research between blocks of attendance are required; this will be enhanced through a Virtual Learning Environment (VLE), which will enable students and tutors to consolidate and expand upon the formally taught components, whilst continuing discussions related to the programme. Students will be expected to carry out significant in-depth research and analysis between taught sessions; students will be assigned a supervisor, and will be able to discuss issues with their supervisor and with the Course Director through the VLE.