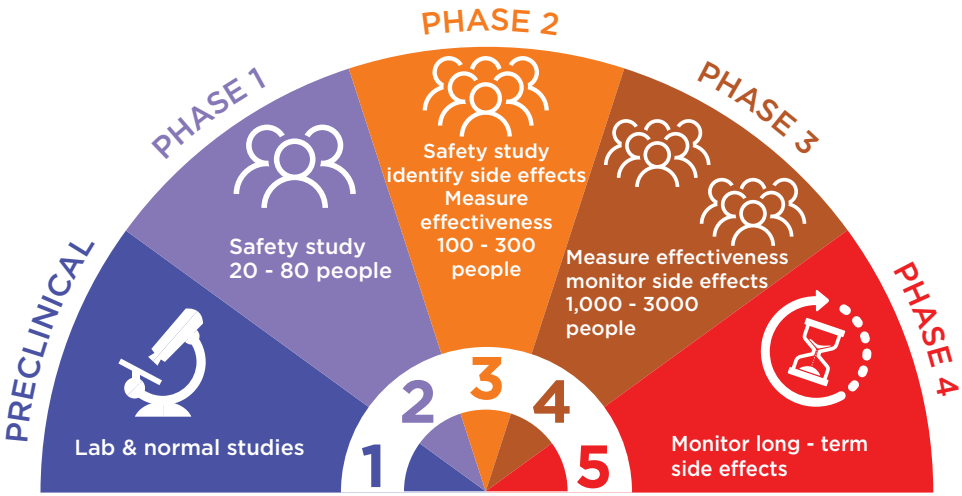
MSc CLINICAL TRIALS (ONLINE)
CKU17

CRF-C
HRB Clinical Research Facility Cork



HRB Health Research Board

CRF-C
HRB Clinical Research Facility Cork

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

School of
Public Health

next page

Description

The MSc Clinical Trials is a part-time programme delivered wholly online. The programme is designed taking into account busy working and home lives. Students can expect to devote up to 20 hours per week. Developed by the Health Research Board (HRB) Clinical Research Facility-Cork (CRF-C), this 3-year part-time (3 x 10 week semesters/year) course examines training in clinical trials and addresses the increasing need for well-informed professionals to work in all areas related to the design, conduct and analysis of clinical trials. The course should meet the needs of a wide variety of practitioners in the pharmaceutical, medical device, health, allied health and academic sectors. The variety of backgrounds and the knowledge possessed by lecturers ensures that the course has a sound mixture of the theoretical and the practical issues surrounding the conduct of clinical trials.

Programme Learning Outcomes

On successful completion of the MSc Clinical Trials, students should be able to:

- Describe the phases of clinical trials and the requirements for their conduct
- Demonstrate knowledge of effective data management practices
- Demonstrate application of complex clinical trial design and analysis
- Attain a Good Clinical Practice (GCP) certificate
- Apply clinical trial regulations to the conduct of clinical trials
- Apply key ethical principles when conducting clinical trials
- Critically evaluate all aspects of how clinical trials are managed, reviewed and reported
- Design methodologically sound clinical trials
- Write a clinical trial protocol and ethics application
- Lead a clinical trial that complies with the highest ethical, legal, regulatory and scientific standards
- Critically evaluate a published clinical trial

next page

Course Outline

PG Certificate, PG Diploma, and MSc Clinical Trials each run for three 10-week semesters, beginning in late September. Each programme comprises three modules which run over a 10-week semester; 8 teaching weeks and two weeks' reflection and absorption, one in the middle of term and one week at the end of term where no new material will be introduced

Year 1 PG Certificate (CKU17) 30 Credits Core Modules

EH6123 Fundamentals of Clinical Trials (10 credits)

- Historical development of clinical trials, phases of clinical trials, design and assessment of clinical trials, practical considerations of clinical trials, recruitment and retention; issues in the conduct of clinical trials

EH6125 Ethics Data Management and Quality in Clinical Trials (10 credits)

- History of ethics in clinical research; The Declaration of Helsinki; introduction to quality concepts (QA/QC); 13 principles of ICH-Good Clinical Practice; Good Data Management practices. GCP Certificate awarded on successful completion

EH6124 Introduction to Clinical Trial Design and Analysis (10 credits)

- Review of basic probability theory; frequentist statistical inference; causal inference in clinical trials; sample selection; randomization; allocation concealment; outcomes; baselines and covariates; sample size and power; 2-arm parallel trials; linear models; regulatory advice on trial design and analysis.

Year 2 PG Diploma (CKW03) 60 Credits Core Modules

EH6126 Advanced Clinical Trial Design and Analysis (10 credits)

- Active control equivalence designs; cross-over trials; cluster-randomized designs; longitudinal data analysis; individual responses; repeated cross-overs; N-of-1 trials; Bayesian inference; adaptive trial designs

EH6127 Regulated Clinical Trials and Pharmacovigilance (10 credits)

- Regulations in clinical trials; requirements of data management in regulated trials; investigator and sponsor responsibilities; key drug safety definitions; principles and practices of pharmacovigilance.

EH6128 Management of Multicentre Studies (10 credits)

- Introduction to the theory, principles and practice of project management; introduction to the lifecycle of clinical trials including project initiation (post funding), project setup, site setup, recruitment, analysis & trail close; application of a project management approach to clinical trials; exploration of core tasks in the clinical trial lifecycle; understanding the national clinical research Infrastructure and supports.

Year 3 MSc 90 Credits Core Modules

EH 6134 Research Methods for Clinical Trials (10 credits)

- Choosing the research question; Conducting a systematic search of the literature; determining the quality of the evidence; critical appraisal of a clinical trial using CASP; referencing using a reference manager; concepts of qualitative research

EH 6135 Embedding Research in Clinical Trials (5 credits)

- SWATs; rRCTs; Prioritising trial methodological research

EH 6131 Dissertation in Clinical Trials (15 credits)

- A taught component will provide an overview of the methodology for dissertation formats. Students will be facilitated, under supervision, in all stages of writing a clinical trial protocol.

next page

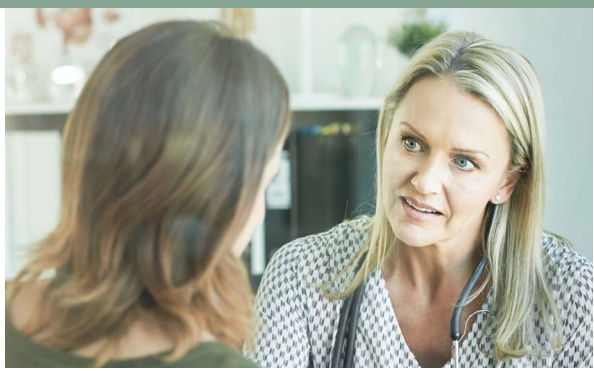
Who should apply?

PG Certificate, PG Diploma, and MSc Clinical Trials are designed to give a competitive advantage for those wishing to pursue a career in clinical trials in the pharmaceutical, medical device or academic sectors. It is the first such course in Ireland providing a pathway for progression from PG Certificate to PG Diploma and ultimately to a MSc in Clinical trials, and the only course designed and paced for the working professional. At the end of this MSc you will be trained to conduct multicentre clinical trials.

With three 10-week semesters, a week break in the middle and end to catch up and complete work, this learning experience is for the busy you. Physicians, nurses, pharmacists, managers, scientists, health scientists, and workers in the allied health professions are encouraged to apply. Experienced clinical trialists, with a practical application to teaching, coordinate and lecture on the MSc Clinical Trials. Clinical trials is a rapidly expanding discipline with exciting new job opportunities in the healthcare and pharmaceutical sectors. Join us on our journey promoting clinical trials and patient focused research to improve the health of our citizens.

Career Pathways

- Clinical Trialist
- Quality Manager
- Trial Manager
- Trial Monitor
- Data Associate
- Data Manager
- Clinical Research Nurse
- Clinical Research Associate
- Research Coordinator
- Pharmacovigilance Associate
- Regulatory Affairs Associate



next page

Fees

EU and Non-EU

PG Certificate Clinical Trials €3,600
A single module 10 credit CPD will cost €1,350

PG Diploma Clinical Trials €3,600
A single module 10 credit CPD will cost €1,350

MSc Clinical Trials €3,600
A single module 10 credit CPD will cost €1,350

Entry Requirements

Entry to the MSc is via the Postgraduate Certificate in the first instance

1. Students accepted on the Postgraduate Certificate Clinical Trials are expected to hold an honours primary degree (NFQ Level 8), minimum second class honours grade two (2.2), or equivalent, in a Science or health related discipline, or relevant subject area.
2. The Postgraduate Certificate Clinical Trials is also open to registered (not necessarily in current employment) health care professionals in Medicine, Nursing, Pharmacy, Clinical Therapies and Allied Health care disciplines who may not have a primary degree. Such applicants must provide evidence of current registration with the relevant professional regulatory body in their country (e.g. the Irish Medical Council, the Nursing and Midwifery Board of Ireland, the Pharmaceutical Society of Ireland etc. for Irish applicants).
3. All applicants will be required to write a 500 word personal statement on why they wish to pursue a career in clinical trials.
4. In exceptional circumstances, candidates with an honours primary degree (NFQ Level 8 or international equivalent) in an unrelated field, may be considered for entry to the programme, subject to the approval of the programme team.
5. Applicants may be asked to participate in an interview.
6. In all cases, decisions will be based on qualifications and quality of application.

next page

English language requirements

All applicants whose first language is not English must provide evidence of English language proficiency. Exceptions to this rule applies to applicants who have an honours degree from an English speaking country.
For further information, please go to https://www.ucc.ie/en/study/

HOW DO I APPLY?

Applications are online via PAC http://www.pac.ie/ucc

Students will also be required to submit a 500 word personal statement on why they wish to pursue a career in clinical trials

CONTACT DETAILS FOR THIS COURSE

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back to cover page