MASTER OF SCIENCE IN CLINICAL RESEARCH ADMINISTRATION

Master of Science in Clinical Research Administration

The MSc in Clinical Research Administration has been developed by some of the world's leading experts in the field. Its highly interactive approach and pioneering content provides graduates of health related disciplines with the advanced skills and knowledge they need to pursue a new career in clinical research administration – or broaden an existing one.

Programme outline

Our MSc in Clinical Research Administration provides an ideal foundation for a professional role in commercial and institutional organisations in a wide range of medical-related sectors.

The programmes unique interactive learning approach, incorporating rich media and a dynamic online classroom, enables you to engage fully with a range of important subject areas. Modules cover the ethical, legal and regulatory considerations that affect clinical trials, the essentials of Good Clinical Practice, the design and conduct of the clinical protocol, biostatistics, data management, product development and health economics. You will complete your degree with an original dissertation and be well versed in the principles of risk assessment and management and demonstrate an understanding of economic evaluation.

You will emerge equipped with all the tools you need for this modern discipline to coordinate and conduct a complete clinical trial, from pre-study to close-out.

Your enhanced skills in communication, teamwork, information technology and statistics will further prepare you for a career in this expanding global industry.

Programme structure

The programme comprises eight modules, culminating in a dissertation. Your first module will be 9 weeks in length where you begin with a week long brief introduction to the programme, the learning platform and then continue with the module content.

Each following module is eight weeks in length. By taking one module at a time you can explore a specific subject in depth without distractions.

A Modules

- Introduction to Clinical Research
- Ethical, Legal and Regulatory Considerations in Clinical Investigations
- Design and Conduct of the Clinical Protocol
- Good Clinical Practice in Managing and Monitoring Clinical Trials
- Biostatistics
- Information and Data Management
- Product Development in the Pharmaceutical, Biotech and Medical Device Industries
- Health Economics and Financial Management in Clinical Research Administration

B Dissertation

Students refine their dissertation topic in conjunction with their Personal Dissertation Advisor, an academic supervisor who will provide support throughout the research process.

Programme duration

The programme takes on average 30 months to complete. However, since students progress at their own pace, you may choose to complete your studies in as little as 24 months or spread them over 60 months.

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MSc in CRA Modules

Modules

Introduction to Clinical Research

Aim: To provide an in-depth and comprehensive understanding of the principles and practice of clinical research.

This module provides a thorough understanding of the history and evolution of clinical research, including examples of landmark studies and controversies. You will examine the context in which research is undertaken, types of studies, objectives and outcomes, definition and phases of protocols, and the roles and responsibilities of the clinical research team and study sponsors. You will also acquire an understanding of key medical terminology.

Ethical, Legal and Regulatory Considerations in Clinical Investigations

Aim: To provide an in-depth understanding of the ethical, legal and regulatory dimensions of clinical research.

This module offers an in-depth examination of ethical, legal and regulatory requirements and their interplay in clinical research. Subjects include recruitment and protection of subjects, diversity and vulnerable populations, informed consent, privacy/confidentiality, the role of IRB/IECs, and reporting of serious adverse events. You will explore scientific integrity and misconduct, international research, relationships with industry, conflict of interest, intellectual property, and publications and authorship.

Design and Conduct of the Clinical Protocol

Aim: To provide a systematic understanding and critical awareness of the requirements of the content of a clinical trial protocol.

This module covers specification of research design, including methods and goals, objective and hypothesis, specification of the study population, outcome measures, reliability and validity, randomisation, documentation requirements, outsourcing and multi-centre trials.

Good Clinical Practice in Managing and Monitoring Clinical Trials

Aim: To critically examine the requirements of good clinical practice.

You will acquire a firm grounding in the tenets, history and regulatory context that inform good clinical practice (GCP) as defined by the International Conference on Harmonization (ICH, from study initiation to final reports. Topics will include standard operating procedures (SOPs), recruitment, quality assurance, data safety monitoring boards (DSMBs), multi-centre/large-scale trials, protocol management and amendments, audits, and reporting.

Biostatistics

Aim: To provide an understanding of the relevance and importance of statistics to clinical research.

This module addresses the role of biostatistics in clinical research, including descriptive methodologies, statistical tests, and confidence intervals. You will examine basic concepts of data collection and analysis. The module also covers development of the Statistical Analysis Plan (SAP), preparation of the statistical report and integration in the Clinical Study Report (CSR).

Information and Data Management

Aim: To provide a critical understanding of the issues surrounding efficiency and security in the context of data management in clinical research.

You will examine the importance of information systems and information technology in increasing efficiencies in the management of clinical research data. You will consider the application of legal and ethical principles to the development of a data collection and management plan. You will also address issues of confidentiality, security of information systems and e-RDC (electronic data capture).

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Telephone: +31 (0)20 713 0000

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Product Development in the Pharmaceutical, Biotech and Medical Device Industries

Aim: To provide a systematic understanding of how industry processes drugs and devices through research and development.

This module examines current industry trends and issues with a focus on how clinical research is used to help bring products to market. It considers new drug and medical device applications, pre-market approvals, marketing authorisations, and post-marketing surveillance. In addition, it covers pharmacogenomics, pharmacoepidemiology, safety concerns, globalisation, drug pricing and healthcare reimbursement, product life-cycle management, outsourcing to developing countries, patent strategies, and accelerated approval.

Health Economics and Financial Management in Clinical Research Administration

Aim: To provide a comprehensive understanding of the economics of global clinical research and the ability to manage a clinical trial budget from planning to publication.

You will develop an understanding of economic evaluation and financial management in clinical research administration. This module gives special attention to issues such as resource scarcity and choice in the clinical research environment, cost/benefit considerations in study design and in evaluation of the clinical intervention, opportunity costs, quality of life considerations, valuation of research outcomes, and case studies from the National Institute of Clinical Excellence (NICE).

You will develop a systematic understanding of financial management in clinical research administration including estimating the full cost of a clinical protocol, the decision to outsource, calculation of direct clinical costs vs. research costs and institutional overhead, and developing and negotiating clinical trial budgets and payment terms with sponsors.

Dissertation

Aim: To undertake a piece of original research to demonstrate your mastery and integration of knowledge you have acquired during the programme.

At the culmination of the programme students undertake an original research project that applies the new knowledge and experience gained during the taught programme, including your understanding of quantitative and qualitative research methods.