Master of Science in **Clinical Research** Online

CURRICULUM

WARWICK
THE UNIVERSITY OF WARWICK

iheed
Cambridge Education Group

MODULE 1
UNDERSTANDING EVIDENCE IN PRACTICE

Introductory description

This module provides students with an introductory and conceptual framework for research undertaken in clinical and medical settings. It will focus on responsible, feasible, and ethical research practices and prepare students to search for evidence, evaluate literature, and examine the design of research.

Principal module aims

This module enables students to:

- Demonstrate familiarity with different types of research.
- Articulate a research question and appreciate the ethical implications of different types of clinical studies.
- Critically appraise clinical research studies.

Learning outcomes

1. Illustrate the different types of clinical research and evaluate the characteristics of a 'good' research question.
2. Evaluate the key responsibilities of clinical researchers.
3. Appraise the stages involved in conducting clinical research.
4. Compare and contrast different types of quantitative and qualitative study designs and principles for selecting an appropriate research design to answer a research question.
5. Recognise the importance of ethics and regulation in research.
6. Evaluate the tools available to assess the quality of, and critically appraise, published research.
7. Explain and justify the mechanisms to develop and record a search strategy and effectively use online literature databases.

Outline of syllabus

This module is one of six 20-credit modules delivered over two semesters within a 12-month period.

Each module is 6 weeks in duration. This module covers such teaching topics as:

- An introduction to clinical research.
- Research ethics and governance.
- Introduction to evidence-based research and practice.
- Developing clinical research questions.
- Refining clinical research questions.
- Finding and appraising the evidence.

Assessment

Clinical Research Report (70%)

- A 2,000-word written report demonstrating the development and execution of a systematic search of the literature related to clinical research.

Clinical Research Examination (30%)

- A 60-minute examination of the fundamentals of clinical research and evaluation, comprising MCQ and Key Feature Problem questions. The examination of this module will take place at the end of the module.

MODULE 2
CLINICAL RESEARCH DESIGN

Introductory description

Undertaking clinical research with due regard for feasibility and ethics is contingent on gaining an understanding of the most appropriate study design to answer a specific research question. This module introduces students to common quantitative and qualitative study designs, along with the principles and importance of appropriate study design and methods of critically evaluating research.

Principal module aims

This module enables students to:

- Evaluate a range of potential study designs.
- Select and defend the research design most appropriate to the research question being asked.
- Critically examine published research

Learning outcomes

1. Examine the application, merits, and limits of a range of quantitative, qualitative, and mixed-methods research methods.
2. Establish a method for identifying and selecting the most appropriate study design for a given research issue.
3. Discuss issues associated with the subjects of population selection and bias within the context of study design.
4. Critically examine the effects of poor execution of study design criteria or suboptimal design selection.
5. Create a clinical research study report and justify the choice of study design.
6. Evaluate issues concerning recruitment in research.
7. Demonstrate capability in the appraisal of published research.

Outline of syllabus

Each module is 6 weeks in duration. This module covers such teaching topics as:

- An introduction to key study designs and methodologies.
- Qualitative study designs.
- Quantitative study designs.
- Population, sampling, and bias.
- Systematic reviews.
- Critical appraisal of peer-reviewed literature.

Assessment

Clinical Research Design Report (70%)

- A 2,000-word written report on the design and justification of a clinical research study.

Clinical Research Design Examination (30%)

- A 60-minute examination of the fundamentals of clinical research design, comprising MCQ and Key Feature Problem questions. The examination of this module will take place at the end of the module.

MODULE 3
CLINICAL RESEARCH ANALYSIS

Introductory description

This module introduces students to the fundamentals of data analysis within the context of clinical research. It will give a practical foundation for each form of analysis, enabling students to determine the most appropriate type of analysis for different studies.

Principal module aims

This module enables students to:

- Understand the advantages & limitations of various data analysis techniques.
- Identify data analysis strategies relevant to a given research project.
- Interpret results from data.
- Communicate complex data to others.

Learning outcomes

1. Evaluate a variety of approaches in qualitative and quantitative data analysis.
2. Evaluate strategies for selecting appropriate data analysis techniques.
3. Utilise data analysis software to interpret and explain data.
4. Explain the critical components of data integrity, such as storage, management, collation, and coding for qualitative and quantitative research.
5. Compare and contrast statistical and clinical significance, differentiating between the reliability of results, and their impact on clinical practice.
6. Demonstrate the ability to critically evaluate the validity of data outcomes reported in published research.

Outline of syllabus

Each module is 6 weeks in duration. This module covers such teaching topics as:

- Data collection and data management.
- Selection of analysis techniques.
- Qualitative data analysis.
- Quantitative data analysis.
- Describing and summarising data.
- Interpretating and displaying data.

Assessment

Clinical Research Analysis Report (70%)

A 2,000-word written report, that includes:

- A description of the rationale and justification for the selection of a data analysis technique in a given qualitative or quantitative scenario.
- A critical discussion of the data analysis techniques reported in a clinical research study.

Clinical Research Analysis Examination (30%)

- A 60-minute examination of the fundamentals of clinical research analysis, comprising MCQ and Key Feature Problem questions. The examination of this module will take place at the end of the module.

MODULE 4
DESIGN OF CLINICAL TRIALS

Introductory description

This module provides students with theoretical and practical perspectives of the design of clinical trials. Students will appraise the ethics and principles underpinning the design of clinical trials for medical and pharmaceutical research.

Principal module aims

This module enables students to:

- Evaluate key concepts in the design of clinical trials.
- Consider the most frequently utilized study designs.
- Be aware of key concerns in clinical trial management (data, people resources, safety, regulatory).

Learning outcomes

1. Critically evaluate the key concepts, structures and procedures of clinical trial management.
2. Explain the phases of clinical trials and contrast the characteristics of a randomized controlled trial (RCT) to other types of clinical trial designs.
3. Discuss the appropriateness of a trial design to answer a specific research question.
4. Critically evaluate key issues in patient and public involvement in clinical trials.
5. Appraise the challenges of involving special populations (children, elderly, adults lacking capacity etc) in clinical trials.
6. Develop appropriate techniques for attracting and retaining trial participants.
7. Estimate the resources required for development and management of clinical trials as required by regulatory agencies.
8. Evaluate methods to maximise compliance with treatment, follow-up, and safety monitoring within a clinical trial.

Outline of syllabus

Each module is 6 weeks in duration. This module covers such teaching topics as:

- Clinical trials: phases I-IV and ethical considerations.
- Types of trial design.
- Documentation: the Study Protocol, the Trial Master File (TMF), & the Case Report Form (CRF).
- Treatment allocations and eliminating bias: selection, controls and randomization.
- Investigational Medicinal Products (IMP): allocation, supply, blinding, and GMP.
- Safety reporting, adverse events, and protocol deviations.

Assessment

Randomised Control Trials – a critical review (100%)

- A 4,000-word critical review of two given published randomised control trials. The assessment will require students to consider the ethics, principles, study design and conduct of two clinical trials.

MODULE 5
MANAGEMENT OF PATIENT-CENTRED APPROACH

Introductory description

This module provides students with theoretical and practical perspectives of the conduct of patient-centred research. Students will explore issues related to the management of clinical trials, safety monitoring, regulatory issues, data analysis, reporting of trials and contemporary study designs.

Principal module aims

This module enables students to:

- Demonstrate data management and analysis approaches relevant to clinical trials.
- Consider issues of safety and regulatory obligations involved in managing clinical trials.
- Communicate effectively and clearly on clinical trial design, management, and outcomes.

Learning outcomes

1. Use appropriate project management techniques to manage clinical trials.
2. Identify and discuss important issues in data management in clinical trials.
3. Critically evaluate safety monitoring issues in clinical trials.
4. Compare and contrast local and international and global regulatory issues affecting the design and execution of clinical trials.
5. Identify the appropriate data analysis techniques appropriate to particular study objectives.
6. Evaluate the key elements of longitudinal data analysis and meta-analysis.
7. Explain contemporary clinical trial designs, including adaptive and translational study designs.
8. Demonstrate the capacity to communicate information on clinical trial design, conduct and outcomes to a range of audiences.

Outline of syllabus

Each module is 6 weeks in duration. This module covers such teaching topics as:

- Roles and responsibilities in patient-centered research
- Regulatory issues, Good Clinical Practice (GCP), and ICH E6
- Project management: initiating, running and closing a study; and reporting results.
- Clinical trials monitoring, audits, and inspections (FDA, MHRA, EMA)
- Safety reporting, adverse events, and protocol deviations
- Fraud and misconduct

Assessment

- **Presentation:** 10-minute pre-recorded presentation on the management of patient-centred research (20% of module)
- **Clinical Review Essay:** 3,200-word critical review of provided scenarios to evaluate and manage issues inherent in developing, implementing, monitoring, and reporting in patient-centred research.

MODULE 6
LEADERSHIP IN CLINICAL RESEARCH

Introductory description

Clinical Research and the successful management of clinical trials are complex undertakings that can require input from multiple stakeholders and specialities. This module explores organisational theory and leadership frameworks as they apply to those seeking to have positions of responsibility in clinical research.

The module content will be based on evidence-based theories of leadership and organisational development in the context of clinical research.

Principal module aims

This module enables students to:

- Critically evaluate their understanding of the key principles of leadership
- Consider different organisational structures and their appropriateness to different clinical research projects.
- Analyse theories of organisational culture and understand how to best approach change.
- Consider the value of mentoring in the context of clinical research.
- Apply leadership and management frameworks in different clinical research contexts.

Learning outcomes

1. Develop a critical and analytical approach to leadership in a clinical research setting.
2. Demonstrate an understanding of key theories of how organisational structure, behaviour and culture develop with reference to clinical research settings.
3. Evaluate theories of mentorship, the influence of mentorship in clinical research settings and how research mentoring differs from career mentoring.
4. Evaluate key theories of motivation with a particular reference to clinical research settings.
5. Appraise theories of change management as they relate to a clinical organisational context.
6. Demonstrate critical self-evaluation of their roles and skills as leaders and team members, through detailed understanding of relevant theoretical models and engagement with relevant leadership competency tools and frameworks.

Outline of syllabus

Each module is 6 weeks in duration. This module covers such teaching topics as:

- Effective leadership in a clinical research setting.
- Organisation behaviour and organisation culture.
- Motivating successful research teams.
- Mentorship in clinical research.
- Change management in research projects.
- Ethical issues in clinical leadership.

MODULE 6
LEADERSHIP IN CLINICAL RESEARCH

Assessment

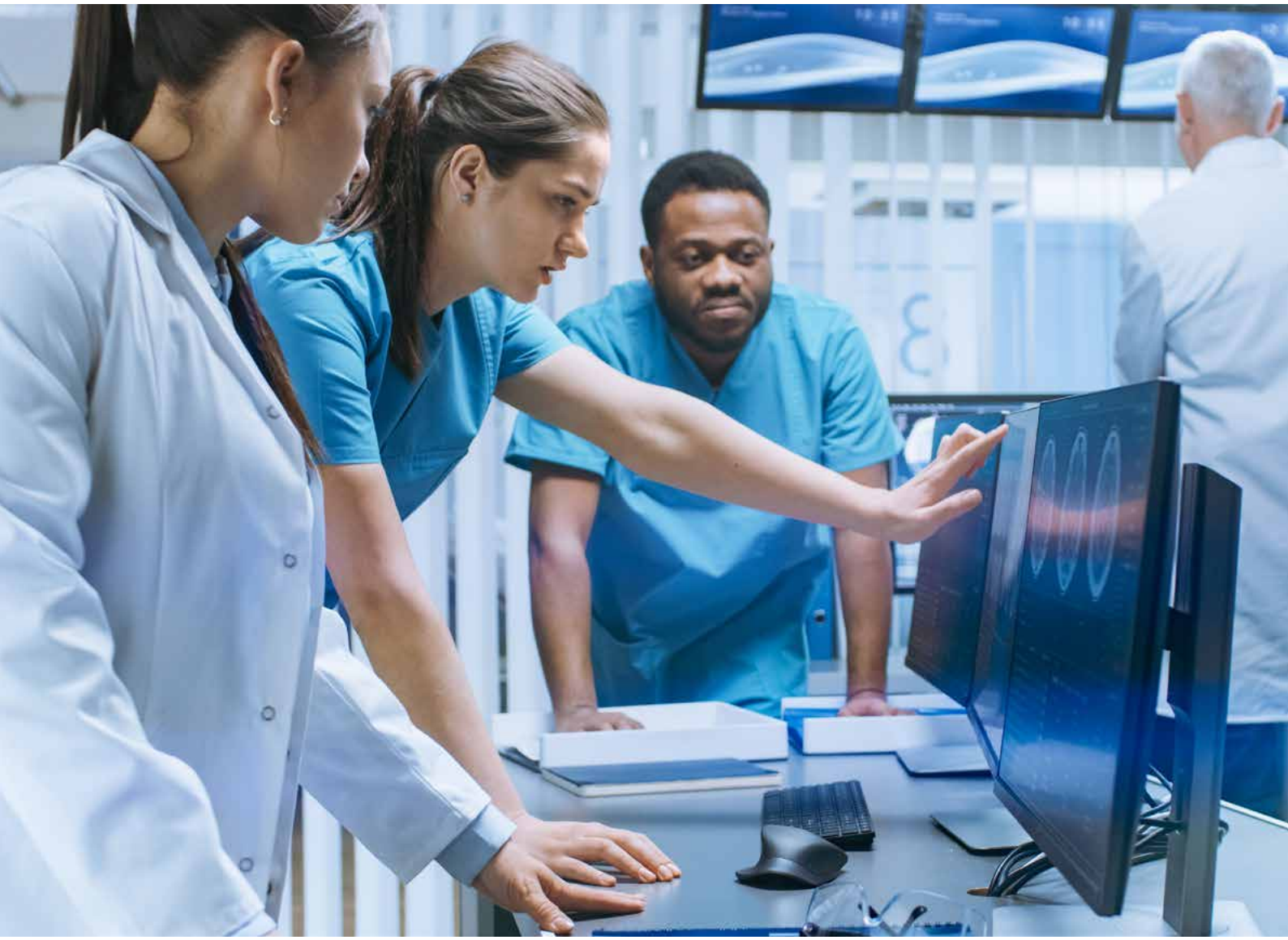
Leadership Presentation (30%)

- **A 10-minute pre-recorded presentation on clinical leadership.**

  Students identify an area for development within their organisational context, related to models of motivation, mentorship or change management and develop an evidence-based plan that could be used to enhance their organisation, demonstrating a theoretical understanding of organisational structure, leadership, and their ability to apply this in context.

Leadership in Clinical Research (70%)

- **A 3,000-word critical essay, demonstrating critical evaluation of:**
  - » Appropriate organisational theories relevant to a specific clinical research project.
  - » Leadership theories and frameworks as the apply in the context of a specific research project.



Who is iheed?

iheed is leading the way in delivering high-quality **online medical education**. Built by doctors and healthcare professionals, we have **over 30,000 users** across the globe, and believe that effective, accessible medical education is the key to providing better health outcomes worldwide. **iheed** is a division of Cambridge Education Group.

Since 1952, Cambridge Education Group has been delivering the highest quality academic programmes, providing a valuable stepping-stone for thousands of students to progress onto the world's leading universities and maximise their career opportunities.

Any questions?

Get in contact today at
clinicalresearch@iheed.org

iheed.org

facebook.com/iheedonline

twitter.com/iheed

iheed
Cambridge Education Group