

Delivering clinical trials – from protocol to patient



Course handbook

2024

Course Overview

Clinical trials are an exciting type of medical research which bring novel therapies to patients, resulting in improved health outcomes. This is exemplified by the recent response to the COVID-19 pandemic where randomised trials of novel therapies, and later vaccines, led to a substantial reduction in virus associated mortality.

Queen's University Belfast has established a world-renowned reputation for excellence in clinical trials, and iREACH Health will build upon this by delivering an innovative and globally competitive clinical research ecosystem here in Northern Ireland. Increasing the capacity and capability of our clinical trials workforce is essential for the sustainability of this ecosystem. This short course will introduce participants from a broad range of disciplines to the key considerations for planning and delivering clinical trials. The course is intended to be practical, focusing on the information and skills needed to take a study protocol and deliver the trial safely and effectively to participants. You will gain understanding of the regulatory processes involved and how to ensure participant safety and integrity of the trial is upheld. Practical workshops will enable students to interact with leading experts in clinical trial delivery and to learn essential skills required for successful trial protocol delivery.

Importantly, although the emphasis here is on clinical trials, the principles are the same for other types of research, for example observational studies and qualitative research. We hope that you will find the course relevant to your role in clinical trial delivery, and will give you the tools you need to be confident and competent in getting research to patients and participants.

Prof Judy Bradley (Director, iREACH)

Dr Jon Silversides (Module Co-ordinator)

Dr Adam Glass (Co-lead)

Dr Dermot Linden (Co-lead)

Course learning objectives

- To provide participants with foundational knowledge of clinical research delivery, focused on clinical trials.
- To help participants understand research delivery and regulatory infrastructure in Northern Ireland and the wider UK.
- To provide participants with necessary skills required to facilitate the set-up and successful operational delivery of a clinical trial, including screening, eligibility, consent and randomisation.
- To understand the processes involved in effective data collection, trial management and oversight.
- To understand the ethical framework involved in clinical trials, and the steps needed to ensure the safety of trial participants and delivery of the research.
- To foster the acquisition of practical skills required to manage study documentation, data entry and laboratory sample processing.

Module Specific Regulations and assessment

- The module is designed to be completed part time over 3 months and should be completed within this time.
- The programme content will be delivered in 8 sessions over 4 full days held in person in the Whitla Medical Building, Queen's University Belfast. Course dates are 17th April, 1st May, 23rd May and 26th June 2024.
- Attendance at $\geq 75\%$ of the teaching sessions is required to successfully complete the module.
- The module will also comprise self-directed learning (approximately 180 hours) from a selection of resources to include reading, e-learning, and other online courses.
- Assessment will be comprised of:
 - Self-directed learning portfolio (pass/fail)
 - MCQ exam (40%)
 - Longitudinal reflective exercise (60%) based on trial protocols

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About this handbook

This handbook describes self-directed online learning and written reflective assignments that need to be completed contemporaneously as you work your way through the course.

We strongly encourage completion of your self-directed online learning prior to each of the teaching sessions as this will enable richer discussions with the other participants and faculty members and enhance your overall learning experience. In order to successfully complete the course you will be required to submit certificates of completion for all essential online learning listed in this handbook.

Your portfolio (Appendix 1) and the written reflective group assignments are important to provide evidence of your participation in the course which you can retain for future reference. Importantly, your portfolio will contribute to the overall assessment and needs to be submitted to the faculty for review upon completion. Your course certificate can only be released for you once we have received and reviewed the portfolio.

- Please save your portfolio (Appendix 1), to a folder on your device or to your personal 'cloud'.
- Remember to save your portfolio as you edit and make changes.
- Enter your name and email into the Personal Details section below.
- Each week there will be a pre-session online course, please ensure that you provide certificates of completion on submission of your portfolio
 - Introduction to Good Clinical Practice (GCP) or Consolidation Session
 - NIHR learn modules
 - Data Quality in Research
 - Innovations in Clinical Trial Design and Delivery for the Under-Served (INCLUDE)
 - Practical Laboratory Skills for Research Delivery Staff
- Document self-directed study undertaken throughout the course

NB. To access many of the resources for this course, you will need to sign up for an NIHR learn account – register here: <https://learn.nihr.ac.uk>

Day 1 – Wednesday 17th April, 2024 (09.30-12.30)
Seminar Room 5, 1st Floor, Whitla Medical Building

Welcome to course, assessment, and general overview of research
Dr Dermot Linden, Prof Fionnuala Lundy, Prof Judy Bradley

Session 1 learning outcomes

Following this session course participants will have:

- An understanding of the course structure and requirements
- Understanding of the fundamentals of clinical trial design and how this can influence study set-up and delivery
- Knowledge of the principles of good clinical trial conduct
- Familiarity with UK and local NI research infrastructure
- Ability to construct a schedule of events
- Ability to identify barriers, key stakeholders and essential steps to trial set-up, based on a trial protocol

Self-directed study

[Planning a Randomised Controlled Trial \(RCT\) – Points to Consider](#)

[Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects](#)

[Guideline for Good Clinical Practice ICH](#)

Example Clinical Trial Protocols – these will be assigned prior to the first session and will be available on Canvas.

Pre-session online module

Please ensure that you have either completed
[Introduction to Good Clinical Practice \(GCP\) eLearning or the GCP Consolidation Session \(if you have already completed GCP\).](#)

<https://www.nihr.ac.uk/health-and-care-professionals/training/good-clinical-practice.htm>
or <https://learn.nihr.ac.uk/course/view.php?id=1238§ion=2>

Group assignment 1

Construct a schedule of events based on your assigned trial protocol.

Day 1 – Wednesday 17th April, 2024 (13.30–16.30)
Seminar Room 2, 1st Floor, Whitla Medical Building

Setting up a Clinical Trial
Prof Judy Bradley, Roisin Martin and Sharon Carr

Session 2 learning outcomes

Following this session course participants will have critical understanding of:

- Key steps in trial planning phase including risk assessment, sponsorship, protocol development, contracts and funding/finance agreements
- Key personnel, delegation of responsibilities, study team training
- Regulatory authority approvals process (IRAS, REC, CTA submission)
- Research & Development governance approvals process

Suggested pre-session self-directed study

Prior to attending this session you should visit the online NIHR clinical trials toolkit and review the “routemap” to gain an overview of good practice and set up arrangements for clinical trials of an investigational medicinal product (CTIMP). The clinical trial toolkit can be found [here](https://www.ct-toolkit.ac.uk): <https://www.ct-toolkit.ac.uk> This website provides information on current best practice and outlines the current legal and practical requirements for conducting clinical trials. Please read through the route map and relevant sections carefully and use this as a reference when completing assignment 2.

Good Scientific Practice

Available at <https://www.ahcs.ac.uk/education-training/standards/>

Embedding a research culture

<https://www.nihr.ac.uk/health-and-care-professionals/engagement-and-participation-in-research/embedding-a-research-culture.htm>

Setting up and running research studies

<https://www.nihr.ac.uk/researchers/i-need-help-designing-my-research/setting-up-and-running-research-studies.htm>

Approvals and Governance

<https://www.nihr.ac.uk/researchers/i-need-help-designing-my-research/regulatory-approvals-and-governance.htm>

Group assignment 2

Using your example study protocol, outline the key steps needed to open this trial and expected timelines. What are the key steps to avoid delays in set up timelines?

Day 2 – Wednesday 1st May, 2024 (09.30-12.30)
Seminar Room 1, 1st Floor, Whitla Medical Building

Collecting and managing data during clinical trials
Dr Adam Glass and Joanna Shooter

Session 3 learning outcomes

Following this session course participants will understand:

- Data management processes during conduct of a clinical trial
- How to prepare an effective Case Report Form (CRF)
- Principles of data entry, processing, validation and source data verification

Pre-session online module

NIHR learn - Data Quality in Research
<https://learn.nihr.ac.uk/course/view.php?id=477#section-0>

Group assignment 3

- a. For your example trial protocol, write a reflection on how you will ensure the integrity of the trial data collected.
- b. Using the trial protocol create a CRF. This will be targeted to a specific sub-section of the trial protocol provided.
- c. What are some common pitfalls in data collection?

Day 2 – Wednesday 1st May, 2024 (13.30-16.30)
Seminar Room 1, 1st Floor, Whitla Medical Building

Managing the conduct of a trial
Prof Danny McAuley, Melanie Morris and Lynn Murphy

Session 4 learning outcomes

Following this session course participants will have gained:

- Critical understanding of the principles of trial management and monitoring including being able to identify key parties involved in clinical trial management
- Knowledge of the roles and responsibilities of Trial Management Group (TMG)
- Overview of the role, function and membership of Data Monitoring and Ethics Committee (DMEC) and Trial Steering Committee (TSC)
- Understanding of the processes pertaining to research amendments

Suggested pre-session self-directed study

[Summary of Trial Management Systems Workstream 4 Document B](#)

[Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products](#)

<https://www.ct-toolkit.ac.uk/routemap/substantial-amendments/>

<https://www.ct-toolkit.ac.uk/routemap/addition-of-new-sites-and-investigators/>

<https://www.ct-toolkit.ac.uk/routemap/urgent-safety-measures/>

[ICH guideline E2F on development safety update report](#)

Group assignment 4

- a. Using your example trial protocol, write a reflection on what measures are in place to ensure that the trial is delivered according to GCP principles.
- b. What might you need to keep under regular review?
- c. Outline team member responsibilities in terms of delivering trial to GCP principles?

Day 3 – Thursday 23rd May, 2024 (09.30-13.00)
Seminar Room 2, 1st Floor, Whitla Medical Building

Patient screening, eligibility, consent, and randomisation
Dr Jon Silversides

Session 5 learning outcomes

Following this session course participants will:

- Understand the purpose of screening and eligibility assessment
- Understand the principles and legal framework around valid, informed consent
- Recognise challenging and special situations relevant to consent (e.g. patients lacking capacity to consent)
- Be able to list common challenges with participant recruitment to trials and to suggest appropriate recruitment strategies
- Understand the need to recruit a diverse group of patients to trials
- Be able to suggest specific measures to promote participation from underserved groups
- Understand the role of patient and public representatives in trial design and delivery

Suggested pre-session self-directed study

SEAR (Screened, Eligible, Approached, Randomised) framework

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5775609/>

HRA guidance on consent and patient information:

<https://www.hra-decisiontools.org.uk/consent/principles-general.html>

NIHR clinical trials toolkit – informed consent:

<https://www.ct-toolkit.ac.uk/routemap/informed-consent/>

Dispelling the myths around health and care research:

<https://bepartofresearch.nihr.ac.uk/articles/myths-health-and-care-research/>

Pre-session online module

INCLUDE NIHR module: <https://learn.nihr.ac.uk/course/view.php?id=820>

Group assignment 5

- a. What are the factors that will impact on screening, eligibility, consent and randomisation/enrolment in your trial?
- b. What strategies could be used in your protocol to optimise recruitment to the trial to time and target?
- c. How will you ensure adequate informed consent to the trial? What are the key points for the potential participant to understand?

Day 3 – Thursday 23rd May, 2024 (14.00-16.30)
Seminar Room 2, 1st Floor, Whitla Medical Building

Managing risk and reporting adverse events
Dr Jon Silversides, Margaret McFarland

Session 6 learning outcomes

Following this session course participants will:

- Be aware of how risk is assessment and managed
- Understand the need to minimise risk to patients, staff and organisations
- Understand the ethical obligations to report adverse events
- Understand the process for reporting adverse events in clinical trials
- Be aware of the classification of adverse events and reactions, serious adverse events and reactions, serious unexpected severe adverse reactions and serious breaches, and the implications of each.

Suggested pre-session self-directed study

Good clinical practice for clinical trials - guidance
<https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials>

[Guidance for the notification of serious breaches of GCP or the trial protocol](#)

[Notification of serious breaches of GCP or the trial protocol form](#)

Safety reporting Decision Tree (in NIHR learn) <https://learn.nihr.ac.uk/course/view.php?id=496>

Group assignment 6

- a. What kind of adverse events are likely to occur in your trial, and how will you ensure prompt and accurate reporting of adverse events?
- b. What are the key ethical considerations for your trial?
- c. How will you ensure that the safety and well-being of trial participants is central to trial delivery of your chosen study?

Day 4 – Wednesday 26th June, 2024

(Group A – 9.30-12.30 / Group B – 13.30-16.30)

Laboratory, NI Clinical Research Facility, U floor, Belfast City Hospital

Introduction to basic laboratory procedures and documentation

Angelina Madden and Professor Fionnuala Lundy

Session 7 learning outcomes

Following this session course participants will:

- Understand the considerations for human biological sample collection and handling
- Understand the importance of accurate sample tracking logs
- Be aware of material transfer agreements.
- Understand the relevance of the Human Tissue Act to sample handling and storage.
- Be competent in basic sample processing procedures (centrifugation, pipetting, freezing)

Suggested pre-session self-directed study

Human tissue act training schedule. Note this needs to be booked in advance – email:

researchgovernance@qub.ac.uk

Training schedule:

<https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/FileStore/Filetoupload,1750928,en.pdf>

Thursday 11 April 2024	14.30 – 16.00	Whitla Medical Building Seminar Room 10 (WMB/SR10)
Friday 17 May 2024	10.30 – 11.30	MS Teams Session (online)
Monday 3 June 2024	10.30 – 12.00	Clinical Science A/RVH/Seminar Room 1/0G.007

International Air Transport Association training on shipping infectious substances by air (where applicable to your role). Below are 2 of the many training providers:

<https://www.eduwhere.com/coursedescription.php?courseID=41>

<https://www.imperial.ac.uk/staff-development/safety-training/safety-courses-/carriage-of-infectious-substances-by-air>

Pre-session online module

Practical Laboratory Skills for Research Delivery Staff (in NIHR Learn):

<https://learn.nihr.ac.uk/enrol/index.php?id=1304>

Day 4 – Wednesday 26th June, 2024

(Group B – 9.30-12.30 / Group A – 13.30-16.30)

Seminar Room 2, 1st Floor, Whitla Medical Building

Multiple Choice Examination

The exam will consist of a multiple choice examination on the contents of the course (including essential self-directed reading material) and will cover all aspects of the course with the exception of the practical skills module.

You will have 1 hour to complete the examination. Queen's University Belfast examination regulations will apply.

Feedback session

Following the MCQ examination, there will be opportunity for informal feedback on the course, and to address any remaining questions.

Appendix 1: Portfolio template

I confirm that I have completed the mandatory e-learning modules and that the written assessments submitted are my own work.										
Student Name:										
Student signature										
Date of signature:										
	d	d	m	m	m	y	y	y	y	

Please attach certificates for the following online courses

Week	Online course	Date completed
1	Introduction to GCP or GCP consolidation	
2	Data Quality in Research	
3	INCLUDE module	
4	Practical Laboratory Skills for Research Delivery Staff	

Please attach details of self-directed study, expand table if required

Week	Suggested self-directed study completed	Date completed

Please insert completed assignments under each heading, start a new page for each

Welcome to course, introduction to assessment, and general overview of research - Group assignment 1

Setting up a Clinical Trial - Group assignment 2

Collecting and managing data during clinical trials - Group assignment 3

Managing the conduct of a trial - Group assignment 4

Patient screening, eligibility, consent, randomisation - Group assignment 5

Managing risk and reporting adverse events - Group assignment 6