Health Research Board
TMRN
Trials Methodology Research Network

In collaboration with...

Irish Critical Care Clinical Trials Network

UCL INSTITUTE OF CLINICAL TRIALS & METHODOLOGY

INDEPENDENT DATA MONITORING COMMITTEE (IDMC) COURSE OVERVIEW

19th, 20th and 21st of February 2024 | 10am - 1pm (UTC)

Independent Data Monitoring Committees play a critical role for any clinical trial. They are usually the only body that sees accumulating, comparative data from the trial. There have been few opportunities for people, particularly clinicians, to gain experience or much hands-on knowledge before being asked to attend as a meeting. This course fills that gap and will answer the question: "What do people who serve on them, report to them or receive reports from them need to know?"

Running virtually, it will be a mix of 3 sessions comprised of discussion, exercises and Q&A, together with pre-recorded lectures to watch between sessions. There is an optional 4th session on the 20th March that will run for one hour for any delegates who wish to discuss remaining questions that have arisen in the time following the workshop.

Places on this course are being prioritised for those in academic / clinical settings who will need to join an IDMC as part of their trial governance commitments.

Location:
Online

Places:
30
(exclusive to residents on the island of Ireland)

Cost:
Academic / Clinical Sector - €250;
Private Sector - €500

Please visit **www.hrb-tmrn.ie/training-education/** to register

Ollscoil na Gaillimhe University of Galway

University College Dublin
Ireland's Global University

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

University of Limerick
Ollscoil Luimnigh

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

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SCHEDULE

19-Feb-2024 10:00 to 13:00 (UTC) Part 1 – Live, virtual session	**Presentations, exercises, breakout discussions** • Opening Address by Dr Fiona Manning - Programme Manager: Clinical Trials and Interventions, Health Research Board (HRB) • Introduction and scene setting • What is an IDMC? How does it relate to other trial oversight committees? • Why is independent data review important? • What level of review is required for each trial?
20-Feb-2024 at own speed (UTC) Part 2 – Online	**Pre-recorded lectures & examples, & guided reading** • HPRAs perspective on IDMCs - What do the regulations & guidelines say? • What aspects of trial data need monitoring? Overview of life cycle • What does an IDMC report show? • Stopping guidelines • IDMC charters • Reading list
21-Feb-2024 10:00 to 13:00 (UTC) Part 3 – Live, virtual session	**Presentations, exercises, breakout discussions** • Choosing who sits on an IDMC • Case studies discussions: Reviewing accumulating comparative data • Making recommendations • Q&A **Post-part 3:** Relevant videos and guided reading
20-Mar-2024 10:00 to 11:00 (UTC) Optional Part 4 – Live, virtual session	**IDMC clinic:** Any remaining questions from delegates. Opportunity to discuss any issues in confidence **Subsequently...** Optional confidential discussion over next 12 months

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Professor Matt Sydes
MRC Clinical Trials Unit at UCL, UK

Matt Sydes was part of the DAMOCLES project in data good practice for Data Monitoring Committees where he undertook two reviews on DMC use and practice, and co-led the development of the IDMC charter which is now commonly used in academic trials. Matt has extensive experience of designing, running, analysing and disseminating clinical trials and associated methodology. He leads the Trial Conduct Methodology research area at MRC CTU at UCL. He has attended more than 200 IDMC and TSC meetings as an independent member, and many more as a reporting statistician.

Dr Fiona Manning
Programme Manager, Clinical Trials and Infrastructures
Health Research Board

Fiona is Programme Manager for the HRB Clinical Trials and Infrastructures portfolio. She is responsible for managing the portfolio of HRB's clinical research investments, which includes infrastructures (Clinical Research Facilities, Cancer Trials Groups and Network, Clinical Trials Networks, TMRN, NCTO) and trial activities funding programmes (DIFA). Prior to her role at HRB, Fiona was Senior Research Officer at the Office for Research and Innovation at RCSI, where she managed support for researchers for national research funding programmes, including HRB and SFI, and played a leading role in developing the university's activities in PPI in research. Fiona has held a number of research Programme Manager positions in clinical and academic settings and previously held roles in Business Development and R&D in industry. She holds a PhD and recently completed an MSc in Healthcare Management from RCSI.

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Associate Professor Sharon Love
Trial Conduct Methodology
MRC Clinical Trials Unit at UCL, UK

I worked for many years as a trial statistician and leading a team of trial statisticians in an academic clinical trials unit and now work as a researcher in trial conduct. Our trial conduct themes include monitoring, improving the implementation of novel designs, use of electronic health records in trials, increasing publication of trial experiences and data sharing. I have experience of input to more than 100 trials and presenting to more than 50 IDMC. I am/have been an IDMC member for more than 20 trials.

Elizabeth George
Senior Statistician
MRC Clinical Trials Unit at UCL, UK

I am a senior statistician at MRC CTU at UCL working on clinical trials in paediatric infections and previously in treatment for HIV in adults. My current research includes an observational study and Phase I and II clinical trials looking at severe malaria in African children as part of SMAART (Severe Malaria Africa – a consortium for Research and Trials). I have been and am currently an independent statistician on a number of IDMCs for studies based in the UK, Europe and sub-Saharan Africa and have reported to IDMCs as a trial statistician.

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Lorcan Gregorian is the GCP/ Pharmacovigilance Inspection Manager at the HPRA

Lorcan Gregorian is the GCP/Pharmacovigilance Inspection Manager at the HPRA, responsible for the development, management and operation of the national GCP and PV inspection programmes. He is a member of the HPRA Inspection Leadership Team, Irish delegate member of the EMA GCP Inspectors Working Group, and alternate member of the PV Inspectors Working Group. He holds a BSc. Pharmacology from UCD and also an MSc. Pharmaceutical Medicine from TCD. Lorcan previously held various positions in clinical research, including working as a Clinical Data Manager in Beaumont Hospital, Pharmacovigilance Associate with IQVIA and Head of Clinical Trial Specialists at Longboat Clinical.

Professor Alistair Nichol
Critical Care Medicine
University College Dublin

Professor Alistair Nichol is the Chair of Critical Care Medicine in University College Dublin and the Director of the Irish Critical Care- Clinical Trials Network and Consultant in St Vincent's University Hospital, Dublin. He has been an investigator on peer reviewed grants worth over 65 million euros from Ireland, Europe, Australia, New Zealand and Canada. He has completed the hat trick of first author publications- in NEJM, Lancet and JAMA. Currently he is completing trials in the critically ill which will randomize over 20,000 patients in the next 5 years. He has academic interests in Pandemic Preparedness, Cardiac Arrest, Trauma and Mechanical Ventilation.

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Professor Declan Devane
Health Research Methodology
University of Galway

Declan trained as a nurse and a midwife, meandered (with the help of opportunity, interest and luck) his way into trial methodology and evidence synthesis and his work now focusses on a blend across randomised trials and synthesising evidence across a number of clinical areas. Declan is the Chair in Health Research Methodology and Deputy Dean of the College of Medicine, Nursing and Health Sciences at the University of Galway. He is also the Scientific Director of the HRB-Trials Methodology Research Network, Director of Evidence Synthesis Ireland and Director of Cochrane Ireland. The has served on numerous Trial Steering Committees and Data Monitoring Committees.

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