NREC-MD Meeting Minutes

16th October 2025

Attendance

Name	Role	Attendance/ Apologies
Prof. Barry O'Sullivan	Chair	Attended
Prof. Mary Sharp	Deputy Chair	Attended
Prof. Declan Patton	Deputy Chair	Attended
Dr Alyson Bailey	Member	Attended
Dr Caitriona Cahir	Member	Attended
Dr Daniel Coakley	Member	Apologies
Dr Mireille Crampe	Member	Attended
Dr Ruth Davis	Member	Attended
Prof Roisin Dwyer	Member	Attended
Dr Owen Doody	Member	Attended
Dr Frank Houghton	Member	Apologies
Dr James Gilroy	Member	Apologies
Prof Suzanne Guerin	Member	Attended
Ms Orla Lane	Member	Attended
Prof. Cara Martin	Member	Attended
Mr Billy McCann	Member	Apologies
Dr Natalie McEvoy	Member	Apologies
Prof. Tom Melvin	Member	Attended
Prof. Therese Murphy	Member	Apologies
Dr Declan O'Callaghan	Member	Apologies
Dr Clare O'Connor	Member	Apologies
Prof Paul O'Connor	Member	Apologies
Dr Joanne O'Dwyer	Member	Attended
Mr Damien Owens	Member	Attended

Prof. Mahendra Varma	Member	Apologies
Mr Peter Woulfe	Member	Attended
Ms Simone Walsh	Member	Apologies
Dr Louise Houston	Project Officer, National Office for Research Ethics Committees	Attended
Dr Sarah McLoughlin	Programme Officer, National Office for Research Ethics Committees	Attended
Dr Lucia Prihodova	Programme Manager, National Office for Research Ethics Committees	Attended
Dr Emily Vereker	Head of Office, National Office for Research Ethics Committees	Apologies
Mr Ciaran Horan*	Administrative Assistant, National Office for Research Ethics Committees	Apologies
Prof Gráinne Gorman	Chief Executive of the Health Research Board	Attended

Quorum for decisions: Yes

Agenda, discussion and decisions	
1. Welcome and apologies	The Chairperson welcomed the Committee, acknowledged apologies and opened the meeting.
2. Report on Committee business	Noted
3. Minutes of previous meeting	Adopted
4. Declarations of interest	Mr Damien Owens: 22-NREC-MD-003-SM6-R1 Mr Damien Owens stepped out of the meeting for the discussion of the application.

	Prof Tom Melvin: 25-NREC-MD-025 and 25-NREC-MD-026 and 25-NREC-MD-023-R1 Prof Tom Melvin stepped out of the meeting for the discussion of the applications.
5. 22-NREC-MD-003-SM6-R1	• Principal Investigator (Lead Institution): Dr Faisal Sharif (GUH) • Sponsor: Medtronic • Study title: Global SYMPLICITY Registry (GSR) Denervation Findings in Real World (DEFINE) is referred to as the GSR DEFINE study, Including Irish Country Addendum (IMPROVE) • NREC-MD decision: Favourable with conditions • Associated conditions: 1. The NREC-MD requests that reasonable efforts are made to proactively inform the study participants of the study results.
6. 25-NREC-MD-023- R1	• Principal Investigator (Lead Institution): Prof Robert Byrne (Mater Private Hospital) • Sponsor: Boston Scientific International S.A • Study title: AGENT Drug-Coated Balloon for STent AvoidANCE in PCI for De Novo Coronary Artery Disease • NREC-MD decision: Favourable with conditions • Associated conditions: 1. The NREC-MD request that the PIL is further revised to improve accessibility and minimise technical/ legalistic language. In particular: • The section on insurance and indemnity. The PIL/ICF should be revised to outline which types of incidents are covered or not covered by the study policy, so that participants can understand this without needing to reach out to the study team. • Point 4 of the ICF on withdrawal of consent “I can take back my consent at any time without providing a reason before and during the study, without any legal consequences, and without any negative consequences or loss of benefits to which I am entitled” should be revised to clarify what the participant entitlement is. 2. The NREC-MD noted that the future use of data/samples is not described in line with regulations/best practice in the participant information leaflet and request that future use of samples/personal data is sufficiently explained to participants in the PIL/ICF so as to constitute broad informed consent, as

	required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore, • it should be made optional • it should be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed, • and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies, • optional future research is made into a separate and explicit consent item in the Informed Consent Form so it is distinct from the main consent to participate in the research, • The PIL/ICF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. For further guidance, see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biologicalsamples-and-associated-data/ - In line with Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018, the consent form needs to be revised to facilitate unbundled consent for each individual item, including optional items such as future research.
7. 25-NREC-MD-024	• Principal Investigator (Lead Institution): Dr. Rajendra Ramsamooj (Life Technologies Clinical Service Lab Inc) • Sponsor: Life Technologies Corporation, part of Thermo Fisher Scientific • Study title: Oncomine™ Dx Express Test Clinical Performance Study Protocol – FGFR Alterations in Bladder Cancer– PRJ1000701 • NREC-MD decision: Favourable

8. 25-NREC-MD-025	• Principal Investigator (Lead Institution): Dr Roisin Colleran (Mater Private Network Dublin) • Sponsor: TUM University Hospital, German Heart Center (academic), Abbott Vascular International bvba (industrial) • Study title: Intracoronary stenting and restenosis – Randomized trial of drug-eluting stent implantation or drug-coated balloon angioplasty according to neointima morphology in drug-eluting stent restenosis (ISAR-DESIRE 5) • NREC-MD decision: Request for further information • Further information requested: 1. The NREC-MD noted that Section L of the Application Form states that this study does not involve medical exposure to ionising radiation. However, the Site Suitability Form states that this study does involve exposure to ionising radiation as part of standard of care. Clarify and update the application form accordingly. 2. Complete Section K18 of the application form. 3. While the Committee noted that Dr Colleran has an excellent publication record, behind which there is clinical trial experience, the Committee requests that the PI's experience in leading clinical trials/ investigations is outlined in the CV. 4. The NREC-MD noted that participants will be recruited at the attending physician and request that in line with best practice there should be separation between clinical and research activities to minimise any confusion and potential for perceived coercion. Therefore, clarify if there is scope for participants to be approached about their participation by a research nurse or appropriate study team member. 5. The NREC-MD noted that participants who are not fluent in English are not eligible to participate in the study. The Committee request a due consideration is given to whether participation could be expanded to such participants. 6. The NREC-MD noted from Section H2 of the Application Form that "Personal correspondence during the hospital stay". Elaborate on what this entails. 7. The NREC-MD noted that the protocol (Section 8.2) lists the baseline standard of care procedures that will take place prior to randomisation and requests that this information is also included in the PIL/ICF. 8. Clarify if participation in this study does involve any risks beyond those associated with standard of care and revise the relevant section of the PIL/ICF accordingly.

	9. The NREC-MD requests that the PIL/ICF is updated to include clear information on what happens if a participant is injured as a result of taking part in the study. Specifically, the PIL should address who participants should contact, whether any associated costs will be covered, and what procedures are in place if personal data are accidentally compromised. 10. The NREC-MD requests that all relevant contact information, including for the site Principal Investigator is included on the first page of the PIL/ICF. 11. The NREC-MD noted that the first consent line of the PIL/ICF still refers to version 6 of the PIL/ICF but the current version appears to be version 7. Update this discrepancy. 12. The NREC-MD noted that the Case Report Form lists a number of biological tests however the NREC-MD Application form section K1 states that no biological samples will be processed as a part of the study. Clarify if these are collected as part of the study or standard care and if applicable, update the NREC-MD Application form. 13. The NREC-MD noted that the PIL/ICF refers to the collection of personal data from other medical examinations (Information about data protection section). • Clarify if this is an optional consent or a requirement for participation in this study. • Clarify why this additional data will be 'advantageous' to the study. • Update the documentation to clearly reflect this. 14. As data will potentially be collected from other treating doctors (PIL/ICF section on Information about data protection), the NREC-MD requests clarification as to whether a letter will be provided to request this information or inform the doctor about the participants involvement in this study. If so, provide these letters for review. 15. The NREC-MD noted some inconsistencies in the information provided in relation to the funding for this study. a. The protocol (Section 11.5) states that the total study cost is €1,000,000, however the Application Form (Section M10) states that Abbott Vascular is contributing €650,000 with other costs coming from the German Heart Center in Munich. Confirm that funding for the entire study is in place.

	b. The Clinical Trial Agreement (page 7) states that the per patient fee is €500, however Annex C states that this fee is €750. Clarify these discrepancies. 16. Clarify exactly what payments, if any, will be made to researchers as part of this study.
9. 25-NREC-MD-026	• Principal Investigator (Lead Institution): Prof Maeve Lowery (St James's Hospital) • Sponsor: Luminate Medical Inc • Study title: IMPACT: A Clinical Investigation on IMproving Peripheral Neuropathy Induced by Chemotherapy with Advanced Compression Technology – A Safety and Efficacy Study • NREC-MD decision: Request for further information • Further information requested: 1. The NREC-MD noted throughout the documentation that reference is made to the device “temporarily” reducing the symptoms of or reducing the onset of peripheral neuropathy. Clarify what is meant by a temporary reduction. 2. The NREC-MD noted that “Participants who might be considered vulnerable or needing additional considerations when consent is being sought” will be recruited for this study. Clarify if you are referring to a particular vulnerability (eg lacking capacity) are you referring to in the context of this study. If applicable, update the relevant section of the application form. 3. The NREC-MD noted that a number of additional participant documents (18.1 CLIN-72 Lilac Device How to Guide- Patient information; 18.3 CLIN-78 Lilac Gen 1 Device Introduction Video V1.0 28th August 2025; 18.5 Clin-77 IMPACT patient Brochure V1.0 25th September 2025) were provided with the submission and request clarification on their use. If appropriate, cross reference all participant facing documentation within the PIL/ICF e.g. the information video and patient brochure. 4. The NREC-MD noted that the “what to expect” section does not outline what a participant should expect from taking part in the study and suggests a heading name change.

	5. The NREC-MD requests that all exclusion criteria are included in the PIL/ICF e.g. weight exclusion and the device not fitting. 6. The NREC-MD noted that participants will have to forego any pharmacological interventions to treat neuropathy. Moreover, if pharmacological interventions are required the participant must discontinue from the study. This information along with the impact it might have to participants (particularly the sham group) should be clearly stated in the participant information leaflet / informed consent sheet (PIL/ICF). 7. Clarify if the risks to pregnant participants primarily relate to the device itself or chemotherapy treatment. Revise the PIL/ICF accordingly. 8. The NREC-MD requests that the PIL/ICF be updated to inform participants about what will happen to the data collected up to the point of their withdrawal, including how long it will be retained if they choose to withdraw from the study. 9. The NREC-MD will never request access to participant data or medical records. Remove reference to the ethics committee accessing participant data. 10. The NREC-MD noted that while transfer of data outside of the EU to the US has been described in detail in Section J5 of the Application Form, this is not the case in the PIL/ICF. Update accordingly. 11. The NREC-MD noted that the PIL/ICF states that the sponsor “may request” to maintain participant data. Clarify who will make this request and will it be made to the participant? If so, a specific consent line for this should be included in the ICF. 12. The NREC-MD noted that only data that is retained beyond 15 years will be anonymised while the rest will be destroyed. • This distinction is not clearly outlined in the PIL/ICF and should be revised. • A specific consent line should be included in the ICF to anonymise data. 13. The NREC-MD noted that the future use of data/samples is not described in line with regulations/best practice in the participant information leaflet and request that future use of samples/personal data is sufficiently explained to participants in the PIL/ICF so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,

- it should be made optional
- it should be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed,
- and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,
- optional future research is made into a separate and explicit consent item in the Informed Consent Form so it is distinct from the main consent to participate in the research,
- The PIL/ICF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. For further guidance, see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biologicalsamples-and-associated-data/ - In line with Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018, the consent form needs to be revised to facilitate unbundled consent for each individual item, including optional items such as future research.

14. The NREC-MD noted that the application form references a study coordinator throughout the document. Clarify who this will be.
15. The NREC-MD is seeking confirmation of the data controllers for this study. This information should be included in Section J1 of the Application Form.
16. The NREC-MD noted that the minimum retention period for data is 15 years. Clarify what the maximum retention period is.
17. The NREC-MD requests clarification as to what will happen to personal data held beyond the minimum 15-year period? This should be included in the PIL/ICF.
18. The NREC-MD noted that the sponsor may have access to participants medical records. Clarify for what purpose they may have access and specifically what within their medical records they may have access to. Include this information in the PIL/ICF.
19. The NREC-MD noted the large budget for this study and request further clarification on the following:

	a. what the consultancy fees comprise of b. will the Principal Investigator for the study receive a salary or any payments in relation to this study. 20. The NREC-MD noted that participants will be compensated for meals and travel costs (Section M of the Application Form). Clarify if there is a maximum amount of compensation that participants may receive or if participants will be reimbursed for all reasonable expenses.
10. 25-NREC-MD-004-SM1	• Principal Investigator (Lead Institution): Dr Emer Hanrahan (SVHG) • Sponsor: Roche • Study title: Clinical Performance Study Protocol for Use of the VENTANA PD-L1 (SP263) CDx Assay: Evaluation of PD-L1 Expression Levels in Non-small Cell Lung Cancer Specimens from Phase III Study D702GC00001 (ARTEMIDE-Lung04) • NREC-MD decision: Favourable
11. 24-NREC-MD-002-SM3	• Principal Investigator (Lead Institution): Dr Karen Cadoo (St James's Hospital) • Sponsor: AbbVie Deutschland GmbH & Co. KG • Study title: Diagnostic Protocol for Use of VENTANA FOLR1 (FOLR1-2.1) CDx Assay for ImmunoGen for Study IMGN853-0421 • NREC-MD decision: Favourable
12. 25-NREC-MD-012-SM1	• Principal Investigator (Lead Institution): Prof. Roisin Connolly (CUH) • Sponsor: Fundacio de Recerca Clinic Barcelona-Institut D'Investigacions Biomediques August Pi i Sunyer (FRCB-IDIBAPS) • Study title: The DEFINITIVE Trial: Diagnostic HER2DX-guided treatment for patients with early-stage HER2-positive breast cancer • NREC-MD decision: Favourable

13. 24-NREC-MD-020-SM2	• Principal Investigator (Lead Institution): Prof Ronan Cahill (UCD) • Sponsor: UCD • Study title: CLASSICA: Validating AI in Classifying Cancer in Real-Time Surgery • NREC-MD decision: Favourable
14. 24-NREC-MD-023-SM4	• Principal Investigator (Lead Institution): Prof Robert Byrne (Mater Private) • Sponsor: RCSI • Study title: Randomised trial of dual device treatment involving drug-coated balloon angioplasty and drug-eluting stent implantation compared to single device treatments in patients with diabetes mellitus – the DUBSTENT-DIABETES trial • NREC-MD decision: Favourable
15. AOB	• None