NREC-MD Meeting Minutes

17 April 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 Caitriona Cahir	Member	Apologies
Dr Daniel Coakley	Member	Apologies
Dr Mireille Crampe	Member	Attended
Dr Ruth Davis	Member	Apologies
Dr Owen Doody	Member	Attended
Dr Frank Houghton	Member	Attended
Dr James Gilroy	Member	Attended
Dr Gloria Kirwan	Member	Attended
Ms Orla Lane	Member	Attended
Prof. Cara Martin	Member	Attended
Mr Billy McCann (PPI)	Member	Attended
Prof. Tom Melvin	Member	Apologies
Prof. Therese Murphy	Member	Attended
Dr Declan O'Callaghan	Member	Apologies
Dr Clare O'Connor	Member	Attended
Prof Paul O'Connor	Member	Attended
Dr Joanne O'Dwyer	Member	Apologies
Mr Damien Owens	Member	Attended
Prof. Mahendra Varma	Member	Attended
Mr Peter Woulfe	Member	Attended
Ms Simone Walsh	Member	Apologies

Louise Houston*	Project Officer, National Office for Research Ethics Committees	Apologies
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	Attended
Ciaran Horan	Administrative Assistant, National Office for Research Ethics Committees	Apologies

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: 25-NREC-MD-005-R1, 25-NREC-MD-006-R1, 22-NREC-MD-003-SM5-R1, 25-NREC-MD-008 Mr Owens stepped out of the meeting when the applications were discussed Prof Tom Melvin: 25-NREC-MD-005-R1, 25-NREC-MD-007-R1
5. 25-NREC-MD-005-R1	• Principal Investigator (Lead Institution): Prof Faisal Sharif (University Hospital Galway) • Sponsor: Medtronic Vascular, Inc

	• Study title: Spyral InSight Early Clinical Feasibility Study • NREC-MD decision: Request for further information • Further information requested: The NREC-MD noted that the query relating to the risks related to exposure to ionising radiation were not adequately addressed. – The Committee noted the response that “the study procedure is a one-time event with no requirement for repeat procedures and corresponding exposure to radiation.” However as the study involves participants with a chronic disease who may need to undergo other diagnostic or interventional radiation procedures as a part of their standard care, the Committee request clarification on the following points: – Clarify why certain participants may undergo significantly higher radiation as per section O6 (d) which refers to “small % of participants.” – Quantify the “small % of participants” as best as possible. – Consider if it is feasible for participants to be exited from the study during the procedure if the exposure is reaching the point of 10 mSv dose in excess of the standard of care? – Given the statement above stating that “the study procedure is one-time event”, provide evidence that there won’t be any repeat procedures undertaken as a result of this study. – Clarify if the radiation exposure that participants undergo during the study procedure have any impact on their future health to due to the cumulative effect of radiation? – Does the radiation exposure that participants undergo during the study procedure have any impact on future diagnostic or interventional radiation procedures that participants can avail of, or on the impact they might have on the participants health? – Whilst we note that the wording in PIL has been approved by the Radiation Protection Advisor, the NREC-MD requests that information on the impact of the exposure on health and future healthcare as per point 5-6is included in the PIL/ ICF. – Include a comment from the Radiation Protection Advisor/ Radiation Safety Committee on the points above. – In light of the significant risks associated with the additional ionising radiation involved in the study, the NREC-MD requests a confirmation that the study was reviewed and approved by the Chairperson of the Radiation Safety Committee. Provide evidence of this approval.

	– Given the risks of participation, provide the terms of reference for the Data Safety Monitoring Committee. – In relation to future use of data, the NREC-MD requests clarification if there is a scope to anonymise data rather than seeking broad consent.
6. 25-NREC-MD-006-R1	• Principal Investigator (Lead Institution): Prof Faisal Sharif (University Hospital Galway • Sponsor: Medtronic Vascular, Inc • Study title: SPYRAL GEMINI Pilot Study • NREC-MD decision: Request for further information • Further information requested: – The NREC-MD requests a copy of the redlined protocol for this study with all changes highlighted. – The NREC-MD requests further information about the long-term effects/risks of hepatic denervation procedure. This information should be included in the PIL/ICF. – The NREC-MD requests that information pertaining to the Simplera sensor, how it will be used and the use of any data associated with it are included in the study protocol. – The PIL/ICF must be revised to highlight the following: o Hepatic denervation is relatively new and experimental procedure o Our knowledge on the long-term impact of hepatic denervation is currently minimal. o The catheter used for the hepatic denervation is being used outside its approved use/ CE marking. – The NREC-MD requests further information on the risks associated with repeated exposure to radiation and the cumulative effect of this. This information should be included in the PIL/ICF where appropriate. – In light of the significant risks associated with the additional ionising radiation involved in the study, the NREC-MD requests a confirmation that the study was reviewed and approved by the Chairperson of the Radiation Safety Committee. Provide evidence of this approval. – Given the risks of participation, provide the terms of reference for the Data Safety Monitoring Committee. – In relation to future use of data, the NREC-MD requests clarification if there is a scope to anonymise data rather than seeking broad consent.

7. 25-NREC-MD-007-R1	• Principal Investigator (Lead Institution): Dr Gerard O'Sullivan (University Hospital Galway) • Sponsor: Intervene • Study title: RECAN - Recana Thrombectomy Catheter for Chronic Venous Obstruction and Occlusion Study" (RECANA Study) • NREC-MD decision: Favourable with conditions • Associated conditions: – As data will be pseudonymised, the NREC-MD requests that pages 10/11 of the Participant Information Leaflet / Informed Consent Form (PIL/ICF) are revised to remove reference to anonymised data. – The NREC-MD requests that the PIL/ICF is updated to include the fact that this is a first in human study in the risks section. – The NREC-MD requests that 'first in human' is spelled out throughout the PIL/ICF and that the acronym 'FIH' is not used. – The NREC-MD requests that a specific consent box is added to the PIL/ICF stating "I understand that this is a first in human study and may not work".
8. 22-NREC-MD-003-SM5-R1	• Principal Investigator (Lead Institution): Prof Faisal Sharif (University Hospital Galway) • 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: – The remote consent procedure is utilised only after option to obtain consent in person was not possible. – Where possible and feasible, the remote consent should have a witness on both sides. – Following the receipt of signed consent form, subsequent written confirmation of enrolment to the clinical investigation is sent to the participant and witness. – The consent is confirmed with the participant next time the participant meets the PI or their delegate in person.

	– Finally, as the documentation supporting this substantial modification application refers to changes, the Committee notes that in addition to change to consent process, the only additional modification pertains to PI change and that any other changes to the PIL/ICF or protocol are subject to separate substantial modification application.
9. 25-NREC-MD-008	• Principal Investigator (Lead Institution): Prof Paul Murphy (St Vincents Hospital) • Sponsor: Medtronic • Study title: Product Surveillance Registry Platform Base Clinical Investigation Plan-Neurological • NREC-MD decision: Favourable with conditions • Associated conditions: – The NREC-MD requests that the PIL/ICF is revised to minimise technical language to increase accessibility. – The NREC-MD noted that the data retention period is listed as a range (10-15y) and requests it is specified and stated in the PIL/ICF. – The NREC-MD notes that the description of future research is very broad: : “For future compatible scientific research for similar or related medical conditions and/or therapies other than described in this document” and requests it is revised. Consent for future use of data must be limited to a particular disease area or more generally in that area or a related area of health research and must be clearly described in the Participant Information Leaflet. An example would be limiting future use of study data to the disease and / or medicinal product / device being studied. Note that any such future studies are a subject to separate REC review. – As the surveys completed by the participant might be time consuming, the NREC-MD suggests that participants be compensated for their time for this.
10. 25-NREC-MD-009	• Principal Investigator (Lead Institution): Dr Sebastian Trainor (Tallaght University Hospital) • Sponsor: Bristol-Myers Squibb Company • 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 CA2241093 (Relativity 1093) • NREC-MD decision: Request for further information

	• Further information requested: – In order to fully understand the study, the NREC-MD requests further information on recruitment processes. Provide information on: a. How potential participants will be identified b. Who will first approach the potential participants c. How will the first approach to the potential participants be conducted d. How will the sponsor ensure that potential participants do not feel compelled to participate – The NREC-MD noted that there are inconsistencies in the numbers of participants across the application documents. Confirm the number of participants in the performance study. – The NREC-MD noted that the participant's consultant and GP will not be informed about their involvement in the study and requests justification. – The NREC-MD noted that the mechanisms for participant withdrawal from the performance study are not clear and requests clarification. – The NREC-MD noted that there is no information about reporting of incidental findings. Provide information about how incidental findings will be reported. – The NREC-MD noted that biological samples (biopsies) will not be returned to participants of the performance study, even if they do not progress to the clinical trial or if they withdraw. The Committee noted that biopsy samples can be a valuable source of point-in-time information that may not be repeatable and can be important for future care of the participant and requests that samples are returned to the study sites. Alternatively, justify why samples will be retained and not returned to the participant's health care team. – The NREC-MD noted that the results of the VENTANA test will not be returned to the participants and request justification. – The application form section L8(d) refers to future use of samples that 'may include research unrelated to the study intervention(s) and/or disease under study. The research may involve genetic tests…. Or analysis of the entire genome.' However, the Section M of the NREC-MD Application form indicates that the study will not involve generation of genetic data. Clarify if any genetic or genomic testing of the samples will be carried out as a part of this or any future research.

	– The NREC-MD noted that some of the information relevant to the performance study is in the PIL/ICF for the clinical trial and vice versa. In order to facilitate informed consent these documents should include all information relevant to respective study – ie participants should receive all required information about the performance study from the performance study PIL/ICF. – The NREC-MD noted that the document '*K2. PS-25-01-050895_L1_SIS and ICF_Clinical Performance Study_IE_eng_10MAR25*' does not describe future research and instead appears to be the PIL/ICF for the performance study. The NREC-MD requests that the optional future research PIL/ICF, referred to in the application, is submitted. – Furthermore, the performance study PIL/ICF appears to be lacking key information on data process carried out as a part of the performance study and is therefore not in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018. The NREC-MD requests the document is revised accordingly. – The application form section L8(d) indicates that future research could involve genetic or genomic testing of the samples, however this is not included in the PIL/ICF. The NREC-MD requests that future genetic or genomic testing is appropriately described in the PIL for future use and that a separate optional consent line is included in the ICF for future. – Furthermore, 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, a. it should be made optional b. 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, c. and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies, d. 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,

	e. 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-biological-samples-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. – The NREC-MD noted no compensation or reimbursement will be provided to participants. Some participants will be required to undergo an additional biopsy to obtain biological samples. The NREC-MD requests that, in the instances where participants need to undergo an additional biopsy, participants are offered reimbursement for their expenses and possibly also compensated for their time. – The site suitability forms include a statement that the risk of exposure to radiation outweighs the benefits, however as per section O of the NREC-MD Application form, this performance study does not involve exposure to ionising radiation. Clarify. – The NREC-MD noted that there will be an analysis of anonymised data by Bristol Myers Squibb (application form section K18). As the data will be collected by Roche, the NREC-MD requests clarification on how the data will be anonymised, and if so, how will consent be obtained for anonymisation.
11. 24-NREC-MD-016-SM1	• Principal Investigator (Lead Institution): Prof Raymond McDermott (St Vincents Hospital) • Sponsor: Qiagen GmbH • Study title: An interventional, prospective clinical study protocol for testing RNA extracted from FFPE tumor tissue specimens taken from patients with Intermediate risk Non-Muscle-Invasive Bladder Cancer (IR-NMIBC) for FGFR alterations, using the QIAGEN therascreen® FGFR RGQ RT-PCR Kit, to determine molecular eligibility (FGFR gene alterations detected) for enrolment onto Janssen's Phase 3 clinical trial of the FGFR inhibitor, erdafitinib (MoonRISe-1 number 42756493BLC3004) • NREC-MD decision: Favourable

12. 21-NREC-MD-003-SM2	• Principal Investigator (Lead Institution): Prof Patrick Serruys (University Hospital Galway) • Sponsor: University Hospital Galway • Study title: Non-inferiority of angiography-derived physiology guidance versus usual care in an All-comers population treated with unrestricted use of Healing-Targeted Supreme stent (HT Supreme) and P2Y12 inhibitor monotherapy after 1-month of dual-antiplatelet therapy: the PIONEER IV trial • NREC-MD decision: Request for further information • Further information requested: – The NREC-MD noted that the study follow up is to be shortened from 3 to 1 year due to financial and operational concerns. However, as the clinical non-inferiority of QFR-guided PCI compared to usual care is yet to be demonstrated, the Committee request clarification on whether the shortening of follow up could pose any risks to the study participants. – The NREC-MD requests clarification if any interim additional safety measures have been put into place for existing participants given the severity of the clinical outcomes identified in the European study such as increased incidence of spontaneous myocardial infarction in the QFR group. – 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, a. it should be made optional b. 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, c. and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies, d. optional future research is made into a separate and explicit consent item in the Informed Consent section of the Main PISCF, with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research

	e. 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-biological-samples-and-associated-data/
13. AOB	• None