NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

21st March 2024

Attendance

Name	Role
Prof. Barry O'Sullivan (Chair)	Chair, NREC-MD
Prof. Mary Sharp (Deputy Chair)	Deputy Chair, NREC-MD
Dr Caitriona Cahir	Deputy Chair, NREC-MD
Dr Mireille Crampe	Member, NREC-MD
Dr Ruth Davis	Member, NREC-MD
Dr Owen Doody	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Dr Gloria Kirwan	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Dr Sarah McLoughlin (PPI)	Member, NREC-MD
Prof. Therese Murphy	Member, NREC-MD
Dr Declan O'Callaghan	Member, NREC-MD
Prof. Susan O'Connell	Member, NREC-MD
Dr Clare O'Connor	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Prof. Anne Parle McDermott	Member, NREC-MD

Prof. Mahendra Varma	Member, NREC-MD
Mr Peter Woulfe	Member, NREC-MD
Dr James Gilroy	Member, NREC-MD
Prof. Cara Martin	Member, NREC-MD
Prof. Jim O'Neill	Member, NREC-MD
Ms Simone Walsh	
Dr Lucia Prihodova *	Programme Manager, National Office for Research Ethics Committees
Dr Louise Houston	Project Officer, National Office for Research Ethics Committees
Dr Emily Vereker	Head, National Office for Research Ethics Committees
Ms Ella Davis	Student Intern

*Drafted minutes. Dr Lucia Prihodova (Programme Manager, National Office for Research Ethics Committees) contributed to drafting of the minutes.

Apologies: Prof. Declan Patton, Mr Billy McCann, Prof. Tom Melvin, Dr Paul O'Connor, Prof. Anne Parle McDermott, Ms Riona Tumelty, Dr Daniel Coakley

Quorum for decisions: Yes

Agenda

1. Welcome (Chairperson)
2. Report on Committee business
3. Minutes of previous meeting
4. Declarations of interest

Responses to RFFIs

5. 23-NREC-MD-024-SM1-R1
6. 23-NREC-MD-035-R1
7. 23-NREC-MD-037-R1
8. 24-NREC-MD-004-R1
9. 23-NREC-MD-018-SM1-R1
10. 23-NREC-MD-036-R1
11. 24-NREC-MD-002-R1
12. 23-NREC-MD-006-SM1-R1

New applications:

13. 24-NREC-MD-005
14. 24-NREC-MD-006
15. 24-NREC-MD-007
16. 24-NREC-MD-008
17. 24-NREC-MD-009
18. 24-NREC-MD-010

Substantial modifications:

19. 22-NREC-MD-026-SM1
20. 23-NREC-MD-002-SM2
21. 23-NREC-MD-023-SM1
22. AOB

- The Chairperson welcomed the Committee and Dr Lucia Prihodova back as Programme Manager of the NREC-MD and Ms Ella Davis, student intern of Technological University of Dublin who is on placement at the National Office
- acknowledged apologies sent by applicable members and opened the meeting.
- NREC Committee Business Report: The Committee noted the report.
- Minutes of the previous meeting(s) (15th February 2024) were approved.
- Matters arising from the previous meeting: none
- Declarations of interest:
  - Prof. Jim O'Neill (23-NREC-MD-024-SM1-R1, 23-NREC-MD-018-SM1-R2, 24-NREC-MD-006, 24-NREC-MD-008) did not read the documentation associated with the applications and vacated the meeting while the study was under discussion.
  - Dr Ruth Davis (24-NREC-MD-007) did not read the documentation associated with application 24-NREC-MD-007 and vacated the meeting while the study was under discussion.

Applications

23-NREC-MD-024-SM1-R1

- Principal Investigator: Prof. Gabor Szeplaki
- Study title: Luma Vision's feasibility study on the VERAFEYE system (LUMINIZE).
- Lead institution: Mater Private Network, Eccles Street, Dublin 7, D07 WKW8
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - This substantial modification is submitted to and approved by the Health Products Regulatory Authority in Ireland.

23-NREC-MD-035-R1

- Principal Investigator: Dr Lisa Costelloe
- Study title: Evaluation of Novel Digital Biomarkers in a Diverse Multiple Sclerosis Cohort.
- Lead institution: Beaumont Hospital, Beaumont Road, Dublin 9, D09V2N0.

- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - A copy of the GP letter template should be provided to the National Office for Research Ethics Committees (National Office).

23-NREC-MD-037-R1

- Principal Investigator: Prof. Seamus O'Reilly
- Study title: Clinical Performance Study Plan for Ki-67 IHC MIB-1 pharmDx (Dako Omnis) on early breast cancer specimens used to identify subjects for enrolment in AstraZeneca's Phase III CAMBRIA-2 trial (D8535C00001-IVD).
- Lead institution: Cork University Hospital, Wilton, Cork, 12 DC4A. NREC-MD
- Decision

  Favourable

24-NREC-MD-004-R1

- Principal Investigator: Dr Darren Mylotte
- Study title: InvEstigation of the safety and performance of the NVT ALLEGRA Plus THV SysteM in Patients with severe aortIc stenosis or failed suRgical aortic bioprosthEsis (EMPIRE II).
- Lead institution: University Hospital Galway, Newcastle Road, Galway, H91 YR71.
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - All participants must have the ability to comprehend the nature and risks of the study. The inclusion criteria must be updated to reflect this.
  - The Participant Information Leaflet is updated to include why other doctors and nurses or other persons/entities not necessarily involved in the conduct of the study may have access to the participants personal data. A separate unbundled consent box should be included for this in the Informed Consent Form.

23-NREC-MD-018-SM1-R2

- Principal Investigator: Dr Ken McDonald
- Study title: First in Human Clinical Investigation of the FIRE1^{TM} System in Heart Failure in Patients

- Lead institution: St. Vincent's University Hospital, Elm Park, Dublin 4, D04 T6F4.
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - The NREC-MD requests that the Participant Information Leaflet is updated to provide up-front and direct knowledge to the participant, such that they are fully informed with regard to the potential implications of participation in the study, as follows:
    - The term “device fracturing” must be simplified further to ensure it is fully accessible to a layperson.
    - A statement must be included directly addressing the fact that all previously implanted Gen 1 devices fractured.
    - The long-term implications of possible blood vessel damage or organ damage in the event of device fracture device fracture must be included in the PIL.

23-NREC-MD-036-R1

- Principal Investigator: Prof. Faisal Sharif
- Study title: Distal Evaluation of Functional performance with Intravascular sensors to assess the Narrowing Effect: Guided Physiologic Stenting (DEFINE GPS).
- Lead institution: Galway University Hospital, Newcastle Rd., Galway, H91 YR71.
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - The NREC-MD requests a confirmation that participants will be given a minimum of 24 hours to consider their participation in the study.
  - In the interest of equitable access to research participation, all reasonable efforts should made to allow access to the study for participants without proficient English, or who do not speak English. Such participants should be provided with a copy of a translated Participant Information Leaflet and Informed Consent Form and the translations must be completed by a certified translation provider. Copy of translation certificates should be provided to the National Office as non-substantial amendment. In addition, when interacting with the study team, the services of interpreter should be made available to such participants.
  - The NREC-MD noted that Healthcare Resource Utilisation data will be collected in Ireland (subject to privacy laws). The NREC-MD requests clarification on what data will be collected and how it will be collected. This should be highlighted in the Participant Information Leaflet (PIL) and a separate unbundled consent box should be included for this in the Informed Consent Form.
  - The NREC-MD noted that the PIL is seeking blanket consent for future use of samples / data, for unspecified purposes, without further consent. This type of consent is not in compliance with the Data Protection Act 2018 (Section 36(2) (Health

Research) Regulations 2018), in which informed participant consent is a mandatory safeguard. The NREC-MD requests i) that consent for future use of samples is provided as a separate consent item ii) is made optional, and iii) consent can only be obtained where future use of samples and data is defined such that participants are fully informed, and/or iv) that an option is provided to enable participants to consent to be contacted with regard to future research. The NREC request confirmation that subsequent research ethics review will be sought for specific research once clearly defined.

24-NREC-MD-002-R1

- Principal Investigator: Dr Karen Cadoo
- Study title: Diagnostic Protocol for VENTANA FOLR1 (FOLR1-2.1) CDx Assay for ImmunoGen Study IMGN853-0421 IVD device manufacturer contact information.
- Lead institution: St. James's Hospital, Dublin 8, D08 NHY1.
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - The NREC-MD noted that on page 9 of the Pre-screening ICF form, the Sponsor included mention that the NREC will review future research projects. This should be amended to 'ethics committees' as the NREC only has remit over regulated areas of research.

23-NREC-MD-006-SM1-R1

- Principal Investigator: Dr Adrian Murphy
- Study title: An open-label Randomised Phase 3 Study of Tucatinib in Combination with Trastuzumab and mFOLFOX6 versus mFOLFOX6 given with or without either Cetuximab or Bevacizumab as First-line Treatment for Subjects with HER2+ Metastatic Colorectal Cancer.
- Lead institution: Beaumont Hospital, Beaumont Road, Dublin 9, D09V2N0.
- NREC-MD Decision

  Favourable

24-NREC-MD-005

- Principal Investigator: Prof. Martin O'Sullivan
- Study title ThermoBreast – Non-contact Breast Cancer Imaging using AI-enhanced Thermography
- Lead institution: Cork University Hospital, Wilton, Cork, T12 DC4A
- NREC-MD comments

- The application documentation was poorly put together, confusing and at times contradictory. The Committee spent a considerable amount of time reviewing the documentation and noted that in its current form it showed a lack of respect and candour not just for the Committee but also for prospective participants in this study.
- The study has a considerable number of objectives and while the primary objective was clear, the documentation did not detail how the secondary objectives will be met.
- The study procedure as presented in the submitted documentation were difficult to follow. It was not clear how do the procedures vary across the three participant cohorts and what study specific procedures are to be carried out at each visit.
- While the Application Form indicated that the study is carried out under Article 62 of the MDR, the protocol states that this is a medical device study under article 61 and 82 of the MDR (page 22).
- An incomplete Case Report Form was provided. It was unclear who completes the form and whether all questions relate to the participants from Ireland, eg ethnicity categories.
- A copy of user experience questionnaire and a topic guide for qualitative interviews were not provided.
- Participant facing documentation requires a substantial revision as in its present form the PIL does not have a logical flow, uses different fonts throughout, includes incomplete sentences and uses overly technical and inaccessible language. Sections of the document do not align with information provided in the application form or protocol, eg information on genetic material (page 10).
- Given the 2023 guidance issued by the FDA on thermograms in breast cancer screening, and the fact that this study involves an investigational device, and its effectiveness and safety is yet to be determined, the wording on the benefits of the device over current best practice are misleading.
- The participant documentation undermines the current best practice (mammography).
- The participant documentation includes leading statements that may cause fear and anxiety for the prospective participants and might dissuade them from undergoing mammography screening.
- While risks of participation are alluded to, they are not clearly outlined and quantified in the documentation.
- Information about the study specific procedures appear inaccurate. For example the length of the study procedure listed in the Participant Information Leaflet does not account for the time necessary for undressing and preparing for the procedure.
- It is currently unclear from the presented documentation how and when the recruitment and consenting process will take place.
- Ambiguity over who will be consenting participants due to inconsistency across the documentation.
- Lack of clarity on inclusion and exclusion criteria, the eligibility screening process and the withdrawal process (eg “if you are receiving certain treatments or preexisting conditions - you may be asked to leave study”).

- It is currently unclear how participants attending routine screening will be identified and recruited and whether there is a link between the research team and the Breastcheck unit in Cork.
- The study invitation letter is to be sent with the invitation to the medical appointment and noted that, in line with best practice, the study invitation should be sent to prospective participants separately from their medical appointment.
- In line with best practice, participants should be given sufficient (minimum 24 hours) to review and consider the Participant information Leaflet before their consent is sought.
- Lack of clarity on what approach will be taken to determine the capacity of prospective participants to provide informed consent and what supports will be available to those needing additional support to make decisions supported in
- Lack of clarity on what data, where and by whom will the participant data be processed. E.g. Section K14 of the Application Form indicates no images will be collected as a part of the study, however this requires clarification given that the primary objective is to compare the diagnostic performance of advanced image processing AI models.
- Overall lack of clarity on data processing and information on data processing presented in the participant documentation, e.g. in relation to genetic data and identifiability.
- Lack of clarity on mechanisms and data protection procedures used to collect and verify data from other sources such as GP or other treating physicians.
- The Informed consent appears to seek blanket consent for future unspecified use of data without further consent. This type of consent is not in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), in which informed consent is a mandatory safeguard. The future use of data should be clearly defined and/or participant consent to be contacted in the future to provide consent once the study area is defined should be sought. As such all future studies would be subject to a REC review.
- Lack of clarity on whether participants could be identified, ie by linking study data with genealogy services (page 10 of the Informed Consent Form)
- Overall lack of clarity over proposed analyses, e.g. how is the predictive modelling phase and a validation modelling phase being done and with what cohort of participants.
- Lack of justification for the proposed one-sided test and whether this might introduce bias in the interpretation of the findings.
- While the study procedures are to be carried out along with standard of care procedures, they pose a potential burden on participants given the length of the examination. Therefore, all reasonable expenses, e.g. parking, should be covered.
- The proposed liability insurance does not meet the requirements set out by the State Claims Agency in its State Indemnity Guidance.

- NREC-MD Decision

- Unfavourable

24-NREC-MD-006

- Principal Investigator: Prof. Gabor Szeplaki
- Study title: A Study evaluating the user experience with the FARAVIEW™ technology of the RHYTHMIA HDx™ Mapping System when used with the FARAWAVE NAV™ Pulsed Field Ablation catheter in the treatment of Atrial Fibrillation.
- Lead institution: Mater Private Hospital, Heart and Vascular Centre, 72 Eccles Street, Dublin 7, D07 RD8P.
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - The clinical investigation team to engage with the HPRA in relation to the proposed use of unapproved software in this study. An outcome of the engagement to be provided to the National Office.
  - A copy of the physician-questionnaire (page 28 of the protocol) to be provided to the National Office.
  - Participant recruitment to be performed by a suitably qualified member of the study team who is not involved in direct health care for the participant. The information on the qualifications of the appointed individual to be provided to the National Office.
  - Participants are allowed minimum 24 hours to consider their participation in the study.
  - Provide a clarification whether women of childbearing potential are included in the study as there is a discrepancy between the study protocol and the NREC-MD Application Form. If excluded, please provide justification for this approach.
  - The Participant Information Leaflet is revised to minimise technical language to increase accessibility.
  - Information on how to withdraw from the study participation is clearly stated.
  - The NREC-MD will never request access to participant's personal data and therefore the text on page 5 and page 10 of the Participant Information Leaflet shall be amended.
  - In addition to services of certified interpreter, a copy of a translated Participant Information Leaflet and Informed Consent Form should be provided to prospective participants without proficient English, and the translations must be completed by a certified translation provider. Copy of translation certificates should be provided to the National Office (G8 of the application form).
  - Table 2 of the Participant Information Leaflet is revised to clarify what risks are study specific and what risks are associated with ablation procedure. A numeric likelihood of a risk occurring should be also included in the table.

24-NREC-MD-007

- Principal Investigator: Prof. Raymond McDermott
- Study title: An Open-label, Randomized, Controlled Phase 3 Study of Disitamab Vedotin in Combination with Pembrolizumab Versus Chemotherapy in Subjects with Previously Untreated Locally Advanced or Metastatic Urothelial Carcinoma that Expresses HER2 (IHC 1+ and Greater).
- Lead institution: Tallaght University Hospital, Tallaght, Dublin 24, D24 NR0A.
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - A clarification on the total number of participants in Ireland is provided to the National Office due to discrepancy between the NREC MD application form (6 participants) and the site suitability forms (Tallaght University Hospital form: 11-20 participants, Cork University Hospital form: 3 participants).
  - Participant recruitment to be performed by a suitably qualified member of the study team who is not involved in direct health care for the participant.
  - Section L16 (h) of the NREC-MD Application Form is completed and provided to the National Office.
  - A clarification on whether the clinical performance study involves blood is provided to the National Office. Blood is noted in section L3 of the NREC-MD Application Form but not in the study protocol or participant facing documentation. If the study involves collection and processing of blood, all relevant documentation must be updated and provided to the National Office.
  - Page 35 of Protocol 2.1 states that “Blood and tissue samples donated for future research will be retained for a period of up to 25 years,” while page 4 of the Participant Information Leaflet/ Informed Consent states “We will only do tests that match the goals of this study. We will not do future research on your samples.” Clarification on the above must be provided to the National Office and all relevant documents must be revised accordingly. To ensure compliance with Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), future use of data should be clearly defined and/or participant consent to be contacted in the future to provide consent once the study area is defined should be sought. As such, all future studies would be subject to a REC review.
  - Following study withdrawal, with the exception of meeting regulatory requirements, no further testing on samples is to be carried out and information on page 4 of the Participant Information Leaflet/ Informed Consent Form is revised accordingly.
  - The PIL/ICF is revised to minimise technical language to increase accessibility.
  - The process and risks associated with having to undergo a new biopsy for the purpose of the study are clearly outlined in the PIL/ICF, including the risk that a new biopsy may not have adequate material for the evaluation.

- As participants must enrol in the Clinical Performance Study in order to be considered for the Clinical Trial, the PIL/ICF is revised to highlight that the clinical trial is randomised, and participants have a 50% chance of receiving the investigational medicinal product.
- Information on page 6 in relation to study cost is revised to reflect that participants will not be liable to any costs related to their participation in the study.
- Information on page 6 in relation to payments to the study Principal Investigator is revised for clarity.
- Information on page 7 on who to contact in relation to participant rights is revised – in the first instance, participants should be contacting the study Principal Investigator.
- The first paragraph on page 8 of the PIL/ICF is revised as the study does not collect any genetic information.
- Information on page 9 is revised as the NREC-MD will never request access to participant's personal data.
- Information on the location on sample testing (Belgium) and data sent outside EU (coded) is revised for clarity.
- An input from the lead site Data Protection Officer on the proposed processing is obtained before the study commences.
- A clarification on the duration of retention of study samples and data is provided to the National Office and aligned across participant facing documentation.
- Participants are reimbursed for all reasonable study related expenses, eg if attending the hospital for a biopsy.
- All relevant study specific, manufacturer and employer indemnity/ insurance policies as per the SIG 10: Indemnity and Insurance Arrangements for Clinical Trials Health Research Between DSA Healthcare Enterprises and Academic Institutions are in place before the clinical investigation commences.
- The NREC-MD noted that urothelial cancer is more prevalent for women than men and would encourage the Sponsor to revise the photography used in the recruitment materials to reflect this. Should any recruitment materials be updated, a copy of updated documents should be provided to the National Office.

24-NREC-MD-008

- Principal Investigator: Prof. Ivan Casserly
- Study title: Prospective, Single-arm Study to Assess the Safety and Performance of the Omega™ Left Atrial Appendage (LAA) Occluder in Patients with Non-Valvular Atrial Fibrillation and High Bleeding Risk Prospective, Single-arm Study to Assess the Safety and Performance of the Omega™ Left Atrial Appendage (LAA) Occluder in Patients with Non-Valvular Atrial Fibrillation and High Bleeding Risk.
- Lead institution: Mater Private Hospital, Heart and Vascular Centre, 72 Eccles Street, Dublin 7, D07 RD8P.
- NREC-MD Decision

- *Request for further information*

- Further information requested
  - It is currently unclear from the presented documentation how, when and by whom the recruitment and consenting process will take place.
  - It is currently unclear who will access identifiable medical information of prospective participants.
  - It is currently unclear who approach and consent prospective participants. In line with best practice, participant recruitment should be performed by a suitably qualified member of the study team who is not involved in direct health care for the participant. The information on the qualifications of the appointed individual to be provided to the National Office.
  - In line with best practice, participants should be given sufficient (minimum 24 hours) to review and consider the Participant information Leaflet before their consent is sought.
  - Justification for exclusion of pregnant or breastfeeding participants is not provided.
  - The Participant Information Leaflet is revised to minimise technical language to increase accessibility.
  - The Participant Information Leaflet and Informed Consent Form should be presented separately to prospective participants.
  - The documents appear to overstate the success of previous study on the device. While the document states that all 13 were successful the study publication states that 11/13 were procedural successes and 12/13 were technical successes.
  - Furthermore, the Participant Information Leaflet does should clearly state alternative options/ other devices on the market. The terminology in describing other devices should be revised to factual – in its current form it outlines other devices as inferior which is potentially unsubstantiated.
  - The study procedures, risks and benefits are not clearly outlined, e.g. how much time will each appointment take, what kind of recovery to expect after implantation, is there sedation as part of the transoesophageal echocardiogram and what is the recovery from that.
  - In the section ‘What risks can I expect from being in the study?’ the risks are listed however it is not clear what these risks would mean for the participant, what impact would they have on their health or life.eg ‘damage to your blood vessels, damage to the valves of your heart, infection…misplacement of the device, blood clots on the device, LAA does not completely close off the blood stream with omega device…dislodgement of device which could lead to major surgery, allergic reaction to implant materials’ what would these mean for a person? Could their heart be damaged permanently?
  - Many of the risks listed in the NREC application form F16 are not included in the consent form. All risks related to the procedure and the study device should be listed in the Participant Information Leaflet along with a numeric likelihood of them occurring.

- It is clear that a participant can withdraw if they wish, but it also states in the NREC Application form line G9 that participants will not have any further follow-up through the study if they withdraw or are withdrawn. A clarification on what follow up care will participants who withdraw from the study is necessary and should also be highlighted in participant facing documentation.
- The description of the facilities etc is very brief 'equipment is state of the art' and needs to be expanded.
- It is unclear whether participants/ participant's insurance is paying for any of the procedures related to this study.
- Participants should be reimbursed for all reasonable study related expenses.
- Please provide a declaration of interest of Principal Investigator.
- All relevant study specific, manufacturer and employer indemnity/ insurance policies as per the SIG 10: Indemnity and Insurance Arrangements for Clinical Trials Health Research Between DSA Healthcare Enterprises and Academic Institutions must be in place before the clinical investigation commences.

24-NREC-MD-009

- Principal Investigator: Prof. Jonathan Lyne
- Study title: Affera Global Registry.
- Lead institution: Beacon Hospital, Beacon Court, Bracken Rd, Sandyford Business Park, Sandyford, Dublin 18, D18 AK68.
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - A clarification on whether participant's GP will be informed of their participation in the study. If yes, a copy of the letter to GP to be provided to the National Office.
  - A clarification on whether any data will be sought from the participant's GP and if yes, by what means.
  - In relation to study procedures, a clarification on what tools will be used to assess physician perception of the performance and ease of use. A copy of any tools to be provided to the National Office.
  - Participant recruitment to be performed by a suitably qualified member of the study team who is not involved in direct health care for the participant. The information on the qualifications of the appointed individual to be provided to the National Office.
  - Participants are allowed minimum 24 hours to consider their participation in the study.
  - The Participant Information Leaflet is revised to minimise technical language to increase accessibility.

- The Participant Information Leaflet should be clear that participants can access treatment even if not taking part in the study.
- The Informed Consent Form to include an explicit consent for transfer of data outside EU.
- Information on page 10 is revised as the NREC-MD will never request access to participant's personal data.
- A detailed study budget to be provided to the National Office.
- A declaration of interest from the Principal Investigator to be provided.
- All reasonable participant expenses related to the study-specific procedures or hospital visits to be covered.
- All relevant study specific, manufacturer and employer indemnity/ insurance policies as per the SIG 10: Indemnity and Insurance Arrangements for Clinical Trials Health Research Between DSA Healthcare Enterprises and Academic Institutions are in place before the clinical investigation commences.
- In relation to section K19 of the NREC-MD Application Form, a clarification on how long data will be held for and for what purpose, to be provided.
- In relation to section K11 of the NREC-MD Application Form, a clarification on what employees does this relate to, to be provided.

24-NREC-MD-010

- Principal Investigator: Mr Barry Jones
- Study title: ProVIDE II Bridging Study.
- Lead institution: St James's Hospital, James Street, Dublin 8, D08 NHY1.
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - Participant's GP to be informed of their patient's participation in the clinical investigation. Participant's consent to share the information on their participation with their GP should be sought and a copy of the letter sent to the GP should be provided to the National Office
  - All relevant study specific, manufacturer and employer indemnity/ insurance policies as per the SIG 10: Indemnity and Insurance Arrangements for Clinical Trials Health Research Between DSA Healthcare Enterprises and Academic Institutions are in place before the clinical investigation commences.
  - The Participant Information Leaflet is revised for accessibility to minimise medical jargon.
  - Sections of the Participant Information Leaflet outlining what happens if participant decides not to participate are revised ie "if you decide not to take part it won't be held

against you" to be revised to "if you decide not to take part you will continue to receive normal care."

- The Participant Information Leaflet to include an outline of current standard of care and to highlight relevant findings from the clinical investigations undertaken with the first generation device.
- The risks of participation in the Participant Information Leaflet are quantified/ categorised based on likelihood of occurrence.
- The Informed Consent Form to include explicit consent for transfer of study data outside of the EU.
- All reasonable expenses related to participation are reimbursed to the participants.

22-NREC-MD-026-SM1

- Principal Investigator: Dr Paul Kelly
- Study title: Effectiveness of the SpaceOAR Vue System in Subjects with Prostate Cancer being Treated with Stereotactic Body Radiotherapy (SABRE).
- Lead institution: Bon Secours Radiotherapy Centre, Western Road, Galway, T12 DV56.
- NREC-MD Decision
  - *Favourable*

24-NREC-MD-010

- Principal Investigator: Mr Barry Jones
- Study title: ProVIDE II Bridging Study.
- Lead institution: St James's Hospital, James Street, Dublin 8, D08 NHY1.
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - Participant's GP to be informed of their patient's participation in the clinical investigation. Participant's consent to share the information on their participation with their GP should be sought and a copy of the letter sent to the GP should be provided to the National Office
  - All relevant study specific, manufacturer and employer indemnity/ insurance policies as per the SIG 10: Indemnity and Insurance Arrangements for Clinical Trials Health Research Between DSA Healthcare Enterprises and Academic Institutions are in place before the clinical investigation commences.
  - The Participant Information Leaflet is revised for accessibility to minimise medical jargon.
  - Sections of the Participant Information Leaflet outlining what happens if participant decides not to participate are revised ie "if you decide not to take part it won't be held

against you" to be revised to "if you decide not to take part you will continue to receive normal care."

- The Participant Information Leaflet to include an outline of current standard of care and to highlight relevant findings from the clinical investigations undertaken with the first generation device.
- The risks of participation in the Participant Information Leaflet are quantified/ categorised based on likelihood of occurrence.
- The Informed Consent Form to include explicit consent for transfer of study data outside of the EU.
- All reasonable expenses related to participation are reimbursed to the participants.

23-NREC-MD-002-SM2

- Principal Investigator: Prof. Gabor Szeplaki
- Study title: An observational post-marketing study for evaluation of ongoing safety and effectiveness of catheter mapping and ablation using commercially approved BWI medical devices for the treatment of patients with cardiac arrhythmias.
- Lead institution: Mater Private Network, Eccles Street, Dublin 7, D07 WKW8
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions
  - NREC-MD noted that Section 7.1 of the revised protocol states that "minor/underaged subjects" may be recruited for this study. It also states that the participants legally authorised representative will receive an informed consent form.
  - If minors / underaged individuals will be recruited for this study then a Substantial Modification, with all relevant associated documents, must be submitted to the National Office for Research Ethics Committee for review prior to enrolment.

22-NREC-MD-026-SM1

- Principal Investigator: Dr Dearbhaile Collins
- Study title: Clinical Performance Study Plan for FoundationOne CDX (F1CDx) used as a Clinical Trial Assay (CTA) in the Clinical Trial XPORT-EC-042 for Karyopharm Therapeutics Inc.
- Lead institution: University College Cork, Wilton, Cork, T12 DC4A.
- NREC-MD Decision
  - *Favourable*

- AOB:
- Programme Manager updated the Committee that the National Office will be shortly launching an Expression of Interest campaign for new members.
- The Chairperson thanked the Committee and closed the meeting.