National Research Ethics Committee

NREC-CT Meeting

2nd April 2025

Attendance

Name	Role
Prof Mary Donnelly	Chairperson, NREC-CT C
Prof John Faul	Deputy Chairperson, NREC-CT C
Dr Jean Saunders	Deputy Chairperson, NREC-CT C
Prof Austin Duffy	Committee Member, NREC-CT C
Prof Fionnuala Breathnach	Committee Member, NREC-CT C
Prof Andrew Smyth	Committee Member, NREC-CT C
Dr Steve Meaney	Committee Member, NREC-CT C
Dr Dervla Kelly	Committee Member, NREC-CT C
Dr Deborah Wallace	Committee Member, NREC-CT C
Ms Paula Prendeville	Committee Member, NREC-CT C
Mr Philip Berman	Committee Member, NREC-CT C
Ms Chita Murray	Programme Manager, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Jane Bryant	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Dr Emma Heffernan*	Project Officer, National Office for RECs
Dr Peadar Rooney	Project Officer, National Office for RECs
Ms Deirdre Ní Fhloinn	Project Officer, National Office for RECs
Ms Rachel Mc Dermott	Project Administrator, National Office for RECs

Apologies: Prof. Anne Matthews, Ms. Susan Kelly, Dr Susan Finnerty, Mr Gerry Eastwood

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2024-516020-33-00
- 2024-513682-40-01
- 2023-505850-16-00 SM-3
- 2022-500237-92-00 SM-3
- 2022-501939-16-00 SM-29
- 2022-501007-28-00 SM-9
- 2023-503614-80-00 SM-8
- 2023-507268-37-00 SM-5
- 2024-516662-11-00 SM-1
- 2022-501606-35-01 SM-4
- 2023-504931-42-00 SM-5
- AOB

- The Chair welcomed the NREC-CT C.
  - The minutes from the previous NREC-CT C meeting on 26th February 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2024-516020-33-00

Institutions: N/A

Study title: A Randomized, Double-Blind, Placebo-Controlled, Phase 2b Study to Assess the Efficacy, Safety, and Tolerability of IMVT-1402 as Treatment for Adult Patients With Graves' Disease (IMVT-1402)

Dossiers Submitted: Part I

- NREC-CT Decision:
- Favourable

- Additional Information Required
- None

2024-513682-40-01

Institutions: Beacon Hospital, Tallaght University Hospital, St James's Hospital

Study title: A Phase 3, Randomized, open-label Study of Nivolumab + Relatlimab Fixed-dose Combination with Chemotherapy Versus Pembrolizumab with Chemotherapy as First-line Treatment for Participants with Non-squamous (NSQ), Stage IV or Recurrent Non-small Cell Lung Cancer and with Tumor Cell PD-L1 expression ≥1% (RELATIVITY-1093)

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

- Additional Information Required

Part II Considerations
1. Compliance with national requirements on data protection
• No considerations raised by NREC
2. Compliance with use of biological samples
• The NREC-CT requested that the S1_Compliance with applicable rules for biological samples_IE document is updated to align with any relevant changes to the PISCF documents.
3. Financial arrangements
• No considerations raised by NREC
4. Proof of insurance

- The NREC-CT requested confirmation that insurance is in place for the duration of the trial (current certificate expires 31 May 2027).

5. Recruitment arrangements

- No considerations raised by NREC

6. Subject information and informed consent form

- The NREC-CT requested that text related to the use of an assay / the performance study / a combined trial is removed from the L1_SIS and ICF_Main PISCF, except the section on screening, as it is potentially confusing for participants. Participants should be advised that a screening test will take place and that a full explanation will be provided in a separate PISCF.
- The NREC-CT noted that the section titled 'What's the purpose?' on pg. 2 of the L1_SIS and ICF_Main PISCF is not written using a participant friendly approach and requested that this section is revised for readability and accessibility using plain English suitable for a lay audience.
- The NREC-CT requested that the text 'put in to' when describing what arm the participant has been assigned to is rephrased for clarity on pg. 4 of the L1_SIS and ICF_Main PISCF.
- The NREC-CT noted that pg. 4 of the L1_SIS and ICF_Main PISCF states 'There are also some medications that you must not take while you are on this study' and requested that prohibited medications are clearly listed, so participants are fully informed.
- The NREC-CT requested that if the results from the phase 2 study are available, they should be outlined to participants in the 'Are there benefits to my participation' section on pg. 4 of the L1_SIS and ICF_Main PISCF.
- The NREC-CT noted that pg. 4 of the L1_SIS and ICF_Main PISCF states 'The site will let very few people know your name or contact details, and only if they really need to for this study' and requested that participants are informed who specifically will have access to this information.
- The NREC-CT noted that pg. 4 of the L1_SIS and ICF_Main PISCF states 'Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules' and requested that the privacy rules referred to in this statement are clarified in the PISCF.
- The NREC-CT that pg. 9 of the L1_SIS and ICF_Main PISCF states that participants are to undergo a number of blood tests. The committee requested that participants are informed as to what blood tests will be undertaken and the purposes of these tests, so they are fully informed.
- The NREC-CT noted that pg. 10 of the L1_SIS and ICF_Main PISCF states 'A biopsy of your lymph nodes may also be needed during the screening to determine the stage of your lung cancer.' The NREC-CT requested that this statement is clarified in the PISCF as the staging of lung cancer would routinely fall under standard of care treatment.
    - Furthermore, in the context of the trial, this statement may be confusing for participants as the stage of the participants lung cancer will have been determined prior to entry to the trial.
- The NREC-CT noted that pg. 26 of the L1_SIS and ICF_Main PISCF states that if participants withdraw from the study (with no follow up) information pertaining to them may still be collected from their GP, which appears to conflict with the participants' decision to withdraw from the study. The Committee requested that

this text is amended so that if participants withdraw from the study, then no further data will be collected about them.
    - The NREC-CT requested that explicit consent is sought from participants who wish to withdraw from the study, but continue with follow up, for their GP to be contacted regarding their health status on pg. 34 of the L1_SIS and ICF_Main PISCF.
- The NREC-CT noted that pg. 26 (section 9) of the L1_SIS and ICF_Main PISCF states that 'At the end of the study, you will stop getting the study drugs. Your treating physician may offer you different drugs that are available to treat your NSCLC' which is ambiguous. The Committee requested that the word 'may' is revised.
- The NREC-CT noted that pg. 29 (section 12) of the L1_SIS and ICF_Main PISCF states that 'samples collected during the study may be stored for up to 20 years after the study ends. If the government requires it, your samples may be stored for longer than 20 years' and requested that the role of the government is clarified for participants.
- The NREC-CT noted that pgs. 10 & 28 of the L1_SIS and ICF_Main & pg. 4 of the L1_SIS and ICF_Optional Future Research PISCFs state that participants may undergo whole genome / whole exome sequencing and requested the following:
    - Genomic sequencing is confined to genes involved in the disease being treated and /or genes involved in the metabolism of the medicines being used in the trial and this elucidated in the PISCF.
    - Explicit consent, including outlining the risks entailed in such analysis being performed, is added to the PISCF.
    - The possible ownership of such data by private or commercial interests and that this elucidated in the PISCF.
    - The right to withdraw genetic data, and clear information on how to do so, must also be provided in the PISCF.
    - Clarification is provided in the PISCF on the mechanism for anonymisation, storage and security and transfer of genetic material and its associated data. For guidance, please see HSE National Policy for Consent in Health and Social Care Research (V2.0, 2024). Dublin: Health Service Executive https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-national-policy-for-consent-in-health-and-social-care-research/
- The NREC-CT noted there are conflicting statements regarding the maximum length of time samples will be retained for, on pg. 29 of the L1_SIS and ICF_Main, pg. 5 of the L1_SIS and ICF_Optional Future Research & pg. 5 of the L1_SIS and ICF_Pregnant Partner PISCFs. The NREC-CT requested that the maximum length of time samples will be retained for is aligned across the PISCF documents and the S1_Compliance with applicable rules for biological samples_IE document.
- The NREC-CT noted that pg. 6 of the L1_SIS and ICF_Optional Future Research, pg. 3 of the L1_SIS and ICF_Treatment Beyond Progression, pg. 5 of the L1_SIS and ICF_Pregnant Partner and pg. 34 / 35 of the L1_SIS and ICF_Main PISCFs have used an unlayered approach to consent in the Informed Consent Section of the PISCF and requested that a layered approach to consent is used (in that each consent item is listed and a box for participants to provide their initials is included alongside each consent item) in line with HSE policy Please see HSE National Policy for Consent in Health and Social Care Research (V2, 2024). Dublin: Health

Service Executive https://assets.hse.ie/media/documents/ncr/20250107_HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-V2.0.pdf

- The NREC-CT requested that pg. 6 of the L1_SIS and ICF_Optional Future Research. 3 of the L1_SIS and ICF_Treatment Beyond Progression, pg. 5 of the L1_SIS and ICF_Pregnant Partner and pg. 35 of the L1_SIS and ICF_Main PISCFs are updated with a placeholder for the qualification of the person performing the informed consent interview.
- The NREC-CT requested clarification as to when participants will be recruited to the optional Future research, as pg. 3 of the L1_SIS and ICF_Optional Future Research PISCF states that 'You are currently participating in the study described above'. The NREC-CT requested that this is rephrased as it appears to suggest that the participant is already enrolled in the optional future research, before they consent to participate.
- The NREC-CT noted that pg. 3 of the L1_SIS and ICF_Optional Future Research PISCF states the purpose of using the collected samples is 'to do more research in the future' and that 'The results of future research can help researchers learn more about diagnosing and treating medical conditions in the future'. The committee requested that future use of samples/personal data is sufficiently explained to participants in the PISCF documents 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 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
    - participants should be informed if future use also involves use of their data and well as their samples.
- The L1_SIS and ICF_Optional Future Research PISCF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. For further guidance, please see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/
- The NREC-CT requested that participants are informed in the L1_SIS and ICF_Optional Future Research PISCF who will have access to their samples.
- The NREC-CT noted that the text 'The biological father of your future baby is participating in the study described above. As part of this study, the father of your future baby was/is being treated with nivolumab + relatlimab fixed dose combination (BMS-986213), This drug is not approved by the Health Products Regulatory Authority (HPRA). You became pregnant while the father of your future baby was/is being treated with the study drug. You should immediately report your pregnancy to your family doctor (general practitioner - GP).' on pg. 1 of the L1_SIS and ICF_Pregnant Partner PISCF is a little alarmist and requested that this is rephrased.
- The NREC-CT noted that pregnant partners are advised on pg. 3 of the of the L1_SIS and ICF_Pregnant Partner PISCF that 'Your information and your baby's information will be shared with others as explained in this informed consent form' but this information is not well explained elsewhere in the PISCF. The Committee

requested that details as to who will have access to the pregnant partner's / baby's information is clarified in the L1_SIS and ICF_Pregnant Partner PISCF.

- The NREC-CT noted that pg. 4 of L1_SIS and ICF_Pregnant Partner PISCF the states that data will be 'shared with collaborators for additional scientific research and requested that details of who this data will be shared with is clarified.
- The NREC-CT requested that the following is clarified for participants on pg. 2 of the L1_SIS and ICF_Treatment Beyond Progression PISCF
    - How will it be decided / assessed that their condition has worsened
    - What other options they may have in terms of standard of care treatment
- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation.
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.

7. Suitability of the clinical trial sites facilities

- No considerations raised by NREC

8. Suitability of the investigator

- No considerations raised by NREC

2023-505850-16-00 SM-3

Institutions: St James's Hospital

Study title: A Phase 3 Randomized Study Comparing Bortezomib, Lenalidomide and Dexamethasone (VRd) followed by Ciltacabtagene Autoleucel, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA versus Bortezomib, Lenalidomide, and Dexamethasone (VRd) followed by Lenalidomide and Dexamethasone (Rd) Therapy in Participants with Newly Diagnosed Multiple Myeloma for Whom Hematopoietic Stem Cell Transplant is Not Planned as Initial Therapy (VRd-CAR-T)

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

- Additional Information Required
- None

2022-500237-92-00 SM-3

Institutions: St Vincent's University Hospital

Study title: A phase 3, multicenter, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of tafasitamab plus lenalidomide in addition to R-CHOP versus R CHOP in previously untreated, high-intermediate and high-risk patients with newly-diagnosed diffuse large B-cell lymphoma (DLBCL) [frontMIND]

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information
- Additional Information

Part II Considerations raised

1. Subject information and informed consent form

- The NREC-CT noted that the updated side effects listed on pg. 10 & 11 of the L1_ SIS and ICF Main_TC PISCF are described using medical terminology which may not be accessible to participants (for example, aspartate aminotransferase increased, C reactive protein levels & alanine aminotransferase increased). The committee requested that each side effect is provided with an accompanying description using plain English suitable for a lay audience.
- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.

2022-501939-16-00 SM-29

Institutions: The Heartbeat Trust, University College Dublin, Mater Private Hospital, Mater Private Network, St James's Hospital

Study title: Effects of ziltivekimab versus placebo on morbidity and mortality in patients with heart failure with mildly reduced or preserved ejection fraction and systemic inflammation (HERMES)

Dossiers Submitted: Part II

- NREC-CT Decision:
- Request for Further Information
- Additional Information Required

Part II Considerations raised

1. Recruitment arrangements

- The NREC-CT noted that section 1.1 of the K1_IE EX6018-4915 Recruitment procedure-TC states that participants may also be recruited through a vendor and requested that the following information is provided:
  - Justification for the use of a vendor
  - Details as to whether the payment model is per patient recruited.
  - Details as to the name and geographical location of the vendor
  - Confirmation that safeguards are in place and in compliance with all applicable regulations and legislation
  - Details as to how the vendor determines participant eligibility for the trial.
  - Details as to the qualifications (including ICH-GCP certification) and experience for the vendors
  - Details as to how the PI will be involved in the process.
  - Details as to the recruitment materials to be used by the vendor and confirmation that all recruitment materials to be used will have NREC approval
  - Details of how consent will be obtained from the potential participant for the use of their data
  - Confirmation that the Sponsor will have oversight of the vendor's activities.

2. Subject information and informed consent form

- The PISCF documents should be updated to reflect the use of a vendor to recruit participants to the trial, including assurance that the third-party vendor is acting on behalf of the Sponsor.
- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.

2022-501007-28-00 SM-9

Institutions: Beaumont Hospital, St Vincent's University Hospital, Bon Secours Hospital Cork, Beacon Hospital, St James's Hospital, Cork University Hospital, University Hospital Waterford, Sligo University Hospital, University Hospital Galway

Study title: J2J-MC-JZLH EMBER-4: A Randomized, Open-Label, Phase 3 Study of Adjuvant Imlunestrant vs Standard Adjuvant Endocrine Therapy in Patients who have Previously Received 2 to 5 years of Adjuvant Endocrine Therapy for ER+, HER2- Early Breast Cancer with an Increased Risk of Recurrence (EMBER-4)

Dossiers Submitted: Part I & II

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required

Part II Considerations raised

1. Subject information and informed consent form

- The NREC-CT noted that 'high blood levels of fat' has been added as a very common side effect on pg. 2 of the L1_ICF_CountrySpecific_Summary of Changes_V1_IE_31 Jan 2025_EN_sanitiz document. The NREC requested that the following information is added to pg. 2 of the L1_ICF_CountrySpecific_Summary of Changes_V1_IE_31 Jan 2025_EN_sanitiz document using plain English suitable for a lay audience.
  - meaning of the phrase 'high blood levels of fat' is clarified for participants (i.e. whether it refers to cholesterol and triglycerides etc)
  - the potential implications for the participant should they develop 'high blood levels of fat' is explained to participants.
- The NREC-CT noted that participants have been informed that 'Liver injury has been reported in patients taking medications that work like the study drug' and requested that they phrase 'medications that work like the study drug' is explained to participants.
- The NREC-CT noted that the Modification Description Form states that the Investigator's Brochure includes an update to the Reference Safety Information (Section 7) to include a serious adverse reaction (diarrhoea) for imlunestrant plus abemaciclib and that the EMBER-4/JZLH study does not include the combination of imlunestrant plus abemaciclib, and therefore a protocol amendment due to the IB update is not required. The NREC-CT requested clarification as to whether participants on this trial will be impacted by this update to the RSI and if diarrhoea as a potential side effect should be added to the document: L1_ICF_CountrySpecific_Summary of Changes_V1_IE_31 Jan 2025_EN_sanitiz. This document should be updated to include diarrhoea as a side effect, if participants in this trial will be impacted by the RSI
- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.

2023-503614-80-00 SM-8

Institutions: Mater Misericordiae University Hospital

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oral Inhalation of Seralutinib for the Treatment of Pulmonary Arterial Hypertension (PAH)

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

- Additional Information Required

Part II Considerations raised

1. Subject information and informed consent form

- The NREC-CT noted conflicting statements regarding future research in the L1_GB002-3101_Main ICF_IE_English_TC PISCF- pg. 24 states 'Should the Sponsor decide to do future research on your samples that is not permitted by this consent then the Sponsor may ask you to sign a further consent, which you can decline', whereas pg. 26 of the same document gives participants the option to consent to future research. This may be confusing for participants. The description of future research on pg. 26 of the L1_GB002-3101_Main ICF_IE_English_TC PISCF is not described in line with regulations/best practice. The NREC-CT requested that if future research is to be undertaken, the use of samples/personal data should be sufficiently explained to participants in the PISCF documents 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 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

  The PISCF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. For further guidance, please see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical

Character Recognition) as these documents cannot be optimised for use with assistive software.

2023-507268-37-00 SM-5

Institutions: St James's Hospital

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Crossover Study of Oral Deucrictibant Soft Capsule for On-Demand Treatment of Attacks in Adolescents and Adults with Hereditary Angioedema.

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

- Additional Information Required

Part II Considerations raised

1. Subject information and informed consent form

- The NREC-CT noted that pg. 11 of the L1_SIS and ICF_Assent12-15_Tracked_Pharvaris PISCF states 'Some of the information collected in the study may be used in another extension study if you choose to participate'.The NREC-CT requested that this is listed as a separate consent item in the ICF section of the PISCF documents, so participants / parents & guardians are clear as to the speciifc consent sought.
    - The NREC-CT also requested confirmation that any new PISCF documents related to any future studies will undergo ethical review.
- The NREC-CT noted that pg. 15 of the L1_SIS and ICF_Main_Tracked_Pharvaris and the L1_SIS and ICF_ParentGuardian_Tracked_Pharvaris PISCFs state 'When the sponsor processes information for secondary purposes, such as for additional research or continuation of studies (e.g., open-label studies you may choose to participate in), the sponsor will do so based on your consent or the sponsor's legitimate interests in conducting further scientific research' and requested that participants are informed that explicit consent is required as an additional safeguard for the processing personal data as per the Health Research Regulations 2018 (it should be made clear that legitimate interests alone are not a sufficient legal basis to process personal data as described).
- The NREC-CT noted that the terms 'open label' 'open label extension study', and 'extension study' are used interchangeably throughout the L1_SIS and ICF_Main_Tracked_Pharvaris, the L1_SIS and the ICF_ParentGuardian_Tracked_Pharvaris the ICF_Assent12-15_Tracked_Pharvaris PISCFs which may be confusing for participants / parents & guardians. The Committee requested clarification as to whether these terms are

being used to refer to the same study. If so, please align the language across all relevant PISCFs for consistency and clarity.

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.

2024-516662-11-00 SM-1

Institutions: Bon Secours Hospital Cork, University Hospital Limerick, Cork University Hospital

Study title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study in Ovarian Cancer Patients Evaluating Rucaparib and Nivolumab as Maintenance Treatment Following Response to Front-Line Platinum-Based Chemotherapy (ATHENA)

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

- Additional Information Required
- None

2022-501606-35-01 SM-4

Institutions: University Hospital Galway, Beaumont Hospital, St James's Hospital, Bon Secours Hospital Cork, Cork University Hospital, Sligo University Hospital, University Hospital Waterford

Study title: Randomized, multicenter, open-label, Phase 3 study of mirvetuximab soravtansine in combination with bevacizumab versus bevacizumab alone as maintenance therapy for patients with FRα-high recurrent platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancers who have not progressed after second-line platinum-based chemotherapy plus bevacizumab (GLORIOSA)

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

- Additional Information Required
- None

2023-504931-42-00 SM-5

Institutions: University Hospital Limerick, Beaumont Hospital

Study title: A Phase 2 Study to Evaluate the Efficacy and Safety of MK-1026 in Participants with Hematologic Malignancies

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

- Additional Information Required
- None

- AOB:
  - Prof. Austin Duffy attended his last meeting as a member of NREC-CT C. The Chair thanked him for his dedication and contribution to ethical review over the past three years as NREC committee member.