National Research Ethics Committee

NREC-CT Meeting

11th June 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
Dr Patrick Forde	Committee Member, NREC-CT C
Dr Juan Trujillo	Committee Member, NREC-CT C
Dr Susan Finnerty	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
Ms Susan Kelly	Committee Member, NREC-CT C
Dr Deborah Wallace	Committee Member, NREC-CT C
Mr Gerry Eastwood	Committee Member, NREC-CT C
Mr Philip Berman	Committee Member, NREC-CT C
Prof Anne Mathews	Committee Member, NREC-CT C
Dr Susan Quinn	Programme Manager, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Emma Heffernan*	Project Officer, National Office for RECs
Dr Peadar Rooney	Project Officer, National Office for RECs
Dr Emily Vereker	Head of Office, National Office for RECs

Apologies: Prof Fionnuala Breathnach, Dr Paula Prendeville

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-503711-15-00
- 2023-503699-25-00 SM-18
- 2023-508323-12-00 SM-5
- 2022-501427-24-00 SM-9
- 2022-502442-27-00 SM-4
- 2023-508922-83-00 SM-10
- 2023-509345-12-00 SM-5
- 2024-513168-24-00 SM-4
- 2023-510128-66-00 SM-4
- 2024-512998-27-00 SM-7
- 2023-507680-19-00 SM-2
- AOB

- The Chair welcomed the NREC-CT C.
  - The minutes from the previous NREC-CT C meeting on 7th May 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-503711-15-00

Institutions: Beaumont Hospital

Study title: A multi-site, open-label, sequential-group, multiple-dose trial to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamic effects of Lu AG13909 in participants with congenital adrenal hyperplasia

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. **Proof of insurance**
   - The NREC-CT noted that the insurance certificate expires on 31 May 2025 and requested confirmation that insurance is in place for the duration of the trial.
2. **Subject information and informed consent form**
   - The NREC-CT noted that the L1_SIS and ICF_Main Informed Consent Form_Part C and Treatment Extension_IE (pgs. 31, 32, 33) & the L1_SIS and ICF_Pregnant Participant Information Sheet and ICF_IE (pgs. 5/6) have used a bundled approach to consent in the Informed Consent Section of the PISCFs 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). For further information 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 noted that section 1.8 on pg. 7 of the L1_SIS and ICF_Main Informed Consent Form_Part C and Treatment Extension_IE PISCF states that participants should contact the Institutional Review Board (IRB) or Independent Ethic Committee (IEC), should they have any questions, concerns, or complaints about the study or questions while taking part in this study. The NREC-CT requested the following information should be added prior to this statement:
     - If the participant has any questions, concerns, or complaints about the study while taking part, in the first instance, they should contact the Principal/Lead Investigator (PI) and/or designated point of contact for the research study.
     - For questions or concerns regarding participants data protection rights that have not been addressed by the PI or study team, the participant should contact the Hospital site DPO and the Data Protection Commission [include details]
   - The NREC-CT noted that section 2.5.4 on pg. 19, section 9.4.1 on pg. 26 & section 9.4.2 on pg. 27 of the L1_SIS and ICF_Main Informed Consent Form_Part C and

Treatment Extension_IE PISCF state that legitimate interest is used as the basis for data processing 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 future use of data/samples is not described in line with regulations / best practice throughout the PISCF documents. For example, there are conflicting statements in the PISCF as follows: on pages. 26 and 27 of the L1_SIS and ICF_Main Informed Consent Form_Part C and Treatment Extension_IE PISCF, and page 3 of the L1_SIS and ICF_Pregnant Participant Information Sheet and ICF_IE it states: “purpose of future exploratory scientific research to gain more information and new knowledge about CAH and other diseases within Lundbeck’s area(s) of expertise”, whereas page 32 of the L1_SIS and ICF_Main Informed Consent Form_Part C and Treatment Extension_IE PISCFstates that future research will be restricted to development of the study drug, CAH, and related diseases. The NREC-CT requested that all statements regarding future research are aligned across all the PISCF documents and 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 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/
- The NREC-CT requested that the text in section 8 on pg. 25 of the L1_SIS and ICF_Main Informed Consent Form_Part C and Treatment Extension_IE PISCF is amended to inform participants that the trial has been reviewed by the National Office for Research Ethics Committees (NREC) and the Health Products Regulatory Authority (HPRA).
- The NREC-CT noted that participants are given conflicting information regarding remuneration in the L1_SIS and ICF_Main Informed Consent Form_Part C and Treatment Extension_IE PISCF - pg. 31 states that participants will not be paid for taking part in the study, except for costs covered, whereas section 2.7 on pg. 19 states “At each visit, we will provide or pay for…your time”. The NREC-CT

requested that all statements regarding remuneration are aligned across the PISCF documents for clarity and consistency.

- The NREC-CT noted the inclusion of a Columbia Suicide Severity Rating Scale on pg. 14 of the L1_SIS and ICF_Main Informed Consent Form_Part C and Treatment Extension_IE PISCF is not well foregrounded for participants and requested that a brief additional supporting narrative / explanation is added to the table.
- 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.

2023-503699-25-00 SM-18

Institutions: St Vincent's University Hospital, Connolly Hospital, Tallaght University Hospital, Our Lady of Lourdes Hospital

Study title: A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of BMS-986278 in Participants with Progressive Pulmonary Fibrosis

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-508323-12-00 SM-5

Institutions: St James's Hospital, Cork University Hospital, Mater Misericordiae University Hospital

Study title: A Phase 3 Randomized, Active-controlled, Open-label, Multicenter Study to Compare the Efficacy and Safety of MK-2870 Monotherapy Versus Treatment of Physician's Choice as Second-line Treatment for Participants with Recurrent or Metastatic Cervical Cancer (TroFuse-020/GOG-3101/ENGOT-cx20)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2022-501427-24-00 SM-9

Institutions: St James's Hospital

Study title: A Multi-Part, Randomized, Double-Blind, Placebo-Controlled Phase 2 Clinical Study of the Safety and Efficacy of CGT9486 in Subjects with NonAdvanced Systemic Mastocytosis (Summit)

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 on pg. 2 of the L1_SIS and ICF_Main ICF_Part 2_TC_Cogent PISCF regarding which part of the study participants may be enrolled in. The updated text advises participants that "Part 1 and Part 2 are not accepting new participants", whereas the subsequent sentence states "You are being asked to participate in Part 2…". The NREC-CT requested that the text is amended so it is clear to participants which parts of the study they are being asked to take part in.
   - The NREC-CT noted that the text regarding the "optional" assessments on pg. 10 of the L1_SIS and ICF_Main ICF_Part 2_TC_Cogent PISCF may be confusing for participants. The NREC-CT requested that it is made clear to participants that these assessments are at the discretion of the study doctor and will be undertaken if clinically necessary (suggest that the word "optional" is removed for 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.
2. **Suitability of the investigator**
   - The NREC-CT requested that evidence of up-to-date ICH-GCP is submitted for [redacted]. This can be via an updated CV or a certificate of ICH-GCP (within the last 3 years).

2022-502442-27-00 SM-4

Institutions: University Hospital Galway, Connolly Hospital, St Vincent's University Hospital

Study title: A Phase 3, randomised, double-blind, parallel-group, event-driven, cardiovascular safety study with BI 456906 administered subcutaneously compared with placebo in participants with overweight or obesity with established cardiovascular disease (CVD) or

chronic kidney disease, and/or at least two weight-related complications or risk factors for CVD

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-508922-83-00 SM-10

Institutions: University Hospital Waterford, Beaumont Hospital, Tallaght University Hospital, University Hospital Galway, St James's Hospital

Study title: Phase 2 Trial of Adagrasib Monotherapy and in Combination with Pembrolizumab and a Phase 3 Trial of Adagrasib in Combination with Pembrolizumab versus Pembrolizumab in Patients with Advanced Non Small Cell Lung Cancer with KRAS G12C Mutation

Dossiers Submitted: Part 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 the updated text in section 4.1 of the S1_IE_Compliance of Biological Samples_tc states that samples will not be stored for future use, and the relevant text has been removed as part of this modification. However, this does not align with the text in the L1_IE_SIS-ICF_Main Phase 3_tc PISCF (for example pg. 36 of the PISCF included the text "I agree that my coded personal information can be used for additional scientific research related to my disease or similar diseases and/or development of the study medication (but at all times in compliance with applicable law and regulation). I understand that I can still participate in the study even if do not initial this statement"). Please confirm whether optional future research will take place, and update the PISCF accordingly to remove applicable statements, if optional future research will no longer take place.
- 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.

2023-509345-12-00 SM-5

Institutions: St Vincent's University Hospital, St James's Hospital

Study title: A randomized, double-blind, double-dummy, parallel-group study, comparing the efficacy and safety of remibrutinib versus teriflunomide in participants with relapsing multiple sclerosis, followed by extended treatment with open-label remibrutinib

Dossiers Submitted: Part II

- **NREC-CT Decision:**

- Favourable

2024-513168-24-00 SM-4

Institutions: Mater Misericordiae University Hospital, St Vincent's University Hospital

Study title: A randomised, controlled, parallel group, open-label trial evaluating the impact of treatment with the GLP-1 analogue semaglutide on weight loss in people living with HIV and obesity (SWIFT Study)

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 a K1_SWAT_Protocol_V2_0_29Apr25_2024 513168 24 00 was included as part of the submission. The NREC-CT are not authorised to provide approval for the SWAT study protocol. Please provide justification as to why the sponsor has not considered the SWAT study to be a modification to the existing SWIFT clinical trial protocol (i.e. a Part 1 & Part 2 submission), as the SWAT study appears to result in a change to the current consenting process, as described in the SWIFT clinical trial protocol.
- The NREC-CT noted that a multi-media intervention will be used as part of the informed consent process and requested that all materials relating to this intervention are submitted for review. Please note that video or audio files cannot be submitted to CTIS, so transcripts of audio- video files should be submitted instead.

2. **Subject information and informed consent form**

- The NREC-CT requested confirmation that participants randomised to both arms of the SWAT study are treated equally in terms of being provided with the required clear and accessible information for participants to make a fully informed decision about participating in the trial, in line with ICH-GCP.
- The NREC-CT requested clarity is provided to the NREC-CT on what supports will be provided to participants who obtain low scores in "quality of consent" and/or "recall" as determined by the Deaconess Informed Consent Comprehension Test (DICCT) questionnaire.
- The NREC-CT noted that the L1_SWIFT_SWAT_Enhance PILICF_29April2025_For use in SWAT study only PISCF has used a bundled approach to consent in the Informed Consent Section of the PISCF documents 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
- The NREC-CT requested that the L1_SWIFT_SWAT_Enhance PILICF_29April2025_For use in SWAT study only PISCF includes details on the storage of the PISCF document. The NREC-CT requested that the "L1_SWIFT_SWAT_Enhance PILICF_29April2025_For use in SWAT study only PISCF" includes details on the storage of the PISCF document such that participants are informed.
- 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.

2023-510128-66-00 SM-4

Institutions: St James's Hospital

Study title: A Phase 3 Study of Pembrolizumab in Combination With Carboplatin/Taxane (Paclitaxel or Nab-paclitaxel) followed by Pembrolizumab With or Without Maintenance MK-2870 in the First-line Treatment of Metastatic Squamous Non-small Cell Lung Cancer

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2024-512998-27-00 SM-7

Institutions: Beaumont Hospital, University Hospital Limerick, University Hospital Waterford, St Vincent's University Hospital, St James's Hospital, Cork University Hospital

Study title: A Prospective, Open-Label, Randomized, Phase 3 Trial of Acasunlimab (GEN1046) in Combination With Pembrolizumab Versus Docetaxel in Subjects With PD-L1 Positive Metastatic Non-Small Cell Lung Cancer After Treatment With a PD-1/PD-L1 Inhibitor and Platinum-Containing Chemotherapy (ABBIL1TY NSCLC-06)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-507680-19-00 SM-2

Institutions: Our Lady's Hospital, Beaumont Hospital

Study title: A Phase 2 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of HZN-1116 in Participants With Sjögren's Syndrome

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

- AOB: