National Research Ethics Committee

NREC-CT Meeting

21st January 2026

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 Fionnuala Breathnach	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
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 Juan Trujillo	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
Ms Rachel Mc Dermott	Project Administrator, National Office for RECs

*Drafted minutes

Apologies: Ms Paula Prendeville, Prof Patrick Forde, Dr Dervla Kelly

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2025-520466-22-00
- 2024-517528-20-00 SM-3
- 2022-502276-23-00 SM-3
- 2024-519655-28-00 SM-3
- 2023-503772-24-00 SM-5
- 2024-512163-31-00 SM-6
- 2024-519654-37-00 SM-1
- 2025-522774-36-00 SM-1
- 2022-502705-15-00 SM-20
- 2025-521293-34-00 SM-4
- AOB

- The Chair welcomed the NREC-CT C.
  - The minutes from the previous NREC-CT C meeting on 3rd December 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2025-520466-22-00

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

Study title: Randomised, Open-label, Phase III Study of AZD5335 Versus Mirvetuximab Soravtansine in FRα-high and AZD5335 Versus Investigator's Choice Chemotherapy in FRα-low Expressing High-grade Platinum-resistant Epithelial Ovarian Cancer Patients (TREVI-OC-01)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. **Compliance with use of biological samples**

- The NREC-CT requested that section 4 of the S1_D8991C00001_IE_Compliance bio samples form is updated to align with relevant changes to the PISCF documents regarding future / secondary use of samples.

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

- The NREC-CT noted that participants may be required to undergo an optional biopsy and that this is not well described on pg. 34 of the L1_D8991C00001_IE_Main ICF. The Committee requested that the following information is added to the PISCF, using plain language suitable for a lay audience:
  - The mechanism of acquiring the biopsy.
  - Procedure related risks associated with acquiring the biopsy.
  - The type of anaesthesia that will be used to acquire the biopsy, including potential risks associated with the type of anaesthesia used.
- The NREC-CT noted that the potential side effects, including the potential side effect of eye toxicity, associated with MIRV are not elucidated in the L1_D8991C00001_IE_Main ICF. The committee requested that the potential side effects of MIRV are communicated to participants using plain language suitable for a lay audience in the L1_D8991C00001_IE_Main ICF, so they are fully informed.
- The NREC-CT noted that pg. 24 of the L1_D8991C00001_IE_Main ICF states that if participants consent, their GP "may" be informed of their participation in the study and requested that this is changed to "will", such that if participants consent, their GP will be informed of their participation in the study.
- The NREC-CT noted that a pregnant participant PISCF is included in the submission and questioned whether this is appropriate for participants undergoing treatment for recurrent ovarian cancer who have previously undergone primary

treatment. The Committee requested confirmation that pregnancy is a possibility in this cohort of participants and that the use of the pregnant participant PISCF is appropriate.

- The NREC-CT noted that pg. 13 of the L1_D8991C00001_IE_Main ICF states that 'If you have a male partner who has not had a vasectomy, he must use a condom and spermicide'. The NREC-CT requested that a rationale is provided for the requirement that male partners of participants must use a condom and spermicide, given the cohort of participants on the trial i.e. participants undergoing treatment for recurrent ovarian cancer who have previously undergone primary treatment. The PISCF should be updated accordingly.
- The NREC-CT noted that pg. 13 of the L1_D8991C00001_IE_Main ICF states 'You should also not donate or retrieve for your own use ova while receiving study treatment. Preservation of ova should be considered prior to enrolment in the study'. The Committee requested confirmation that this instruction applicable / appropriate in the context of recurrent ovarian cancer. Please updated the PISCF accordingly.
- The NREC-CT noted that the Schedule of Activities (pgs. 27 to 33) of the L1_D8991C00001_IE_Main ICF is not presented in a patient friendly format (i.e. it is laid out over 7 pages) and is in addition to a well-described narrative description of study procedures. The NREC-CT requested that this section is presented in a more condensed, patient-friendly, accessible format.
- The NREC-CT noted that the statement "Treatment is planned to continue until your cancer has worsened" on pg. 5 of the L1_D8991C00001_IE_Main ICF sounds harsh and may be distressing for participants. The committee requested that the language is softened.
- The NREC-CT noted that the Main PISCF has used a bundled approach to consent in the Informed Consent Section of the PISCF documents (pgs. 23/24 of the L1_D8991C00001_IE_Main ICF & pg. 6 of the L1_D8991C00001_IE_Optional Genomics ICF 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 (V2.1, 2025). 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 4 of the S1_D8991C00001_IE_Compliance bio samples form states that future research is not being undertaken in Ireland. This conflicts with the following statements in the PISCF documents:

- L1_D8991C00001_IE_Screening 1 PISCF;
  - pg. 5 ("Tumour samples, including from ineligible/screen fail participants, may also be tested for other biomarkers which may help improve our understanding of cancer.")
- L1_D8991C00001_IE_Main ICF PISCF

  - pg. 8 ("Your tumour tissue may also be tested for other tissue-based biomarkers related to cancer biology or the study treatments, and may include looking at DNA, RNA, and proteins)
  - pg. 18 ("The Study Sponsor may share your coded data and biosamples with its Research partners and Service providers for the purposes of the drug development programme.")
- L1_D8991C00001_IE_Optional Genomics ICF
  - pg. 1 ("Your coded data and biosamples may only be used for scientific health-related research to find new ways to detect, treat, prevent or cure health problems, or to develop new technologies and approaches that will assist with this activity, including developing machine learning and artificial intelligence technologies.")

The NREC-CT requested that future use of samples/personal data (including genetic research) 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 should be 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 noted that pg. 2 of L1_D8991C00001_IE_Optional Genomics ICF states 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 or related diseases and /or genes involved in the metabolism of the medicines being used in the trial and this is 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 (V2.1, 2025). Dublin: Health Service https://www2.healthservice.hse.ie/files/157/

Standard Consideration:

1. Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
2. All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.

3. Suitability of the clinical trial sites facilities

- The NREC-CT noted conflicting statements regarding the ocular assessments in the SSA for Cork University Hospital with text on pg. 6 stating that “Ophthalmology examination will be conducted by an external service” whereas text on pg. 8 states that “The site has an On-site Lab for safety assessments and access to an ophthalmologist / licensed eye care provider to perform the ocular assessments as required per protocol.” The Committee requested it is clarified in the SSA where ocular assessments will be performed. If participants are required to travel to another site for study related assessments, they should be informed of this in the PISCF.

4. Suitability of the investigator

- Please submit a Declaration of Interest form for [redacted]

2024-517528-20-00 SM-3

Institutions: St Vincent’s University Hospital

Study title: A Randomized, Blinded, Placebo-Controlled, Phase 2 Study of INBRX-109 in Unresectable or Metastatic Conventional Chondrosarcoma

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 NRECT-CT requested that the text on pg. 8 of the L1_SIS and ICF_Main ICF_Inhibrx Biosciences Inc_Tracked Changes PISCF is updated to remove specific reference to the study being reviewed and approved by NREC-CT B. While the initial trial was approved by NREC-CT B, subsequent Substantial Modifications may be reviewed by any of the NREC-CT committees. It is sufficient to state that that study has been reviewed and approved by NREC-CT.

Standard Consideration:

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
- All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.

2022-502276-23-00 SM-3

Institutions: Mater Misericordiae University Hospital, Cork University Hospital

Study title: Randomized, open-label, multicenter phase 3 study to assess the efficacy and safety of GIVinostat versus hydroxyurea IN JAK2V617F-positive high-risk Polycythemia Vera patients: the GIV-IN PV TRIAL

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part I Considerations (RFI) for addition to CTIS

1. Please confirm if the 14% dropout rate referred to on pgs. 42 and 118 of the D1_Italfarmaco_DSC08235732_Protocol with TC_2022-502276-23-00_EU_NotPublic is a realistic estimate based on data from previous studies or otherwise clarify how this dropout rate was calculated.

2024-519655-28-00 SM-3

Institutions: University Hospital Limerick, St James's Hospital, Mater Private Hospital, Cork University Hospital, Mater Misericordiae University Hospital, Midland Regional Hospital, University Hospital Waterford

Study title: OPTIMA YOUNG: Optimal Personalized Treatment of early breast cancer using Multi-parameter Analysis: focus on YOUNGer women

Dossiers Submitted: Part II

- **NREC-CT Decision:**

  Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

1. Subject information and informed consent form

- The NREC-CT noted that details of the performance study aspect of the trial has been integrated into the L1_SIS and ICF_main_tracked changes document. As performance studies must be assessed under the In Vitro Diagnostic Medical Devices regulation (EU No. 2017/746) and not under the Clinical Trial Regulation (EU No. 536/2014) for clinical trials of investigational medicinal products (CTIMPs), the NREC-CT requested the following:
  - Please remove all references to the performance study from the main body of the L1_SIS and ICF_main_tracked changes document, except to signpost to participants that they will need to undergo a performance study as part of the trial, and that a separate PISCF will be provided for this.
  - Please remove the title of the performance study from pg. 1 of the L1_SIS and ICF_main_tracked changes document.
  - Please remove the text ("The clinical investigation received authorisation from the HPRA on XX/XX/XXXX and a favourable opinion from the NREC-CTMD on XX/XX/XXXX.") on pg. 16 of the L1_SIS and ICF_main_tracked changes document to align with the above.
  - Please remove the explicit consent statement "and DD/MM/YYYY and DD/MM/YYYY for the performance study" from item no. 4 on pg. 26 of the Informed Consent section of the L1_SIS and ICF_main_tracked changes document as the performance study cannot be approved under the Clinical Trials Regulation (EU No. 536/2014).
  - Please note that a separate submission should be made to NREC-MD for the performance study so it can be assessed under the relevant legislation. Please see our website for details on how to make a submission to NREC-MD https://www.nrecoffice.ie/apply/apply-to-nrec-md2/
- The NREC-CT requested that the cover letter is updated as follows:
  - Please clearly state which aspects of the submission relate to the response to conditions applied to the initial approval. This should include details of

the specific conditions that are being responded to within the modification, so the committee understand the context of the requested changes.
    - Please update the text “as the same informed consent document will be used for both the clinical trial and performance study” on pg. 2 of the cover letter to make it clear that a separate and distinct PISCF document will be used as part of the submission to NREC-MD for the performance study.
- The NREC-CT noted that reference to the digital tracking sub-study has been deleted from the L1_SIS and ICF_main_tracked changes document, except from pg. 4, where it is listed in the Table of Contents. The NREC-CT requested that all references to the digital tracking sub-study are aligned in the L1_SIS and ICF_main_tracked changes document.
- Standard Consideration: All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.

2023-503772-24-00 SM-5

Institutions: Cork University Hospital, University Hospital Galway, St Vincent’s University Hospital

Study title: A Phase 2b/3, Multi-part, Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Atacicept in Subjects with IgA Nephropathy (IgAN)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2024-512163-31-00 SM-6

Institutions: Wellcome HRB Clinical Research Facility

Study title: ION363-CS1: A Phase 1-3 Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of Intrathecally Administered ION363 in Amyotrophic Lateral Sclerosis Patients with Fused in Sarcoma Mutations (FUS-ALS)

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 pgs. 18 and 19 of document L1_SIS and ICF_Adult Main ICF_Ionis Pharmaceuticals_Tracked Changes state "If the site cannot contact you or get this information from correspondence/communication with other physicians, or from review of your medical records, an independent search firm (contracted by Ionis Pharmaceuticals, Inc.), which may be located outside your home country and, thus, have different personal data protection standards, may be hired to assist the doctor and site staff in making searches using public sources (including appropriate public registries) in order to find out if you are still alive or have died". The Committee requested that the following is clarified regarding the use of an independent search firm:

- Justification as to why a third-party vendor from outside Ireland will be used.
- Please provide a more detailed account in the PISCF as to the type of assistance that will be provided by the independent search firm (see text "assist the doctor and site staff")
- Please clarify in the PISCF if the sharing of personal information with a "lost to follow up" with the independent search firm is optional or mandatory.
- Please provide the vendor details, such as name, and address (i.e. location) (if available) in the PISCF. If the vendor details are not currently available, the PISCF document should be amended to include these details when this information is available.
- Please clarify in the PISCF what, if any, participants personal information will be disclosed to the public databases and/or registers used for searches.
- Please provide information on how this data will be processed in line with GDPR.
- Explicit consent for the use of the independent search firm should be added to the Informed Consent section of the PISCF.

Standard Consideration:

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
- All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.

2024-519654-37-00 SM-1

Institutions: Beaumont Hospital, Cork University Hospital, St James's Hospital

Study title: A Multicenter, Randomized, Double-blind, Phase 2/3 Study of Ficerafusp Alfa (BCA101) or Placebo in Combination with Pembrolizumab for First-Line Treatment of PD-L1-positive, Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2025-522774-36-00 SM-1

Institutions: Mater Misericordiae University Hospital,

Study title: A Phase 1 Open-label, Multi-center Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Antitumor Activity of NDI-219216 as a Single Agent in Patients with Advanced Solid Tumors with and without Microsatellite Instability and/or Deficient Mismatch Repair

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2022-502705-15-00 SM-20

Institutions: Tallaght University Hospital, Cork University Hospital

Study title: A Phase III, Double-blind, Multicenter, Randomized study of Atezolizumab (anti-PD-L1 antibody) versus Placebo as Adjuvant therapy in Patients with High-Risk Muscle-Invasive Bladder Cancer who are CTDNA positive following cystectomy

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2025-521293-34-00 SM-4

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

Study title: A Seamless Phase 2a/2b, Randomized, Double-Blind, Placebo- and Active-Controlled, Multiple-Arm, Multiple-Stage, Adaptive Study Evaluating the Efficacy and Safety of LAD191 in Adults With Moderate-to-Severe Hidradenitis Suppurativa

Dossiers Submitted: Part II

- **NREC-CT Decision:**

- Favourable

- AOB: N/A