National Research Ethics Committee

NREC-CT Meeting

25th February 2026

Attendance

Name	Role
Prof David Brayden	Chairperson, NREC-CT D
Prof David Smith	Deputy Chairperson, NREC-CT D
Dr Christina Skourou	Deputy Chairperson, NREC-CT D
Prof Cathal Walsh	Committee Member, NREC-CT D
Dr Geraldine O'Dea	Committee Member, NREC-CT D
Prof Lina Zgaga	Committee Member, NREC-CT D
Mr Gerry Daly	Committee Member, NREC-CT D
Prof Geraldine O'Sullivan Coyne	Committee Member, NREC-CT D
Jennifer Linds Fennell	Observer Committee Member, NREC-CT D
Emer Hunt	Observer Committee Member, NREC-CT D
Paul Kershaw	Observer Committee Member, NREC-CT D
Ms Chita Murray	Programme Manager, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Ms Patricia Kenny*	Project Officer, National Office for RECs

*Drafted minutes

Apologies: Andrew Green, Deirdre Murray, Deirdre MacLoughlin, Mary McDonnell Naughton, Chanel Watson, Jeff Moore

Quorum for decisions: Yes

Conflict of Interest: None.

Agenda

- Welcome & Apologies
- 2025-520565-51-00
- 2025-522767-15-00
- 2025-522255-25-00
- 2022-501709-11-00 SM-15
- 2023-504962-52-00 SM-13
- 2024-518998-33-00 SM-9
- 2022-500758-41-00 SM-22
- 2023-510319-20-00 SM-6
- 2025-522400-24-00 SM-6
- AOB

- The Chair welcomed the NREC-CT D.
  - The minutes from the previous NREC-CT D meeting on 28th January 2026 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2025-520565-51-00

Institutions: Cork University Hospital

Study title: DAREON®-Lung-1: A Phase III multi-center, open-label, randomised trial of intravenous obrixtamig in combination with atezolizumab, carboplatin, and etoposide vs. atezolizumab, carboplatin, and etoposide as first-line treatment in patients with extensive-stage small cell lung cancer.

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS

1. It is noted that participants receiving obrixtamig may require dose reductions of their standard of care (SOC) chemotherapy in the event of treatment related toxicities. While such does adjustments are consistent with routine clinical practice, this may result in some participants in two study arms receiving a reduced SOC dose, which could have implications for treatment effectiveness. The sponsor is therefore requested to provide justification for this aspect of the study design including (1) further information on the clinical and scientific rationale supporting adjustment of the SOC regimen rather than reducing the IMP dose in cases of toxicity; and (2) clarification on whether SOC treatment could be discontinued entirely for some participants.

Part II Considerations

1. Financial arrangements

- The NREC-CT noted the significant study burden and requests that the sponsor assess whether compensation beyond direct reimbursement may be appropriate. This is to ensure equitable access to clinical trials across all socio-economic groups, particularly in situations where participation involves notable time commitment, inconvenience or burden. Any such compensation should remain proportionate and consistent with ethical and regulatory requirements to avoid undue influence.

2. Subject information and informed consent form

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.
- The NREC-CT noted that details of the performance study aspect of the trial has been integrated into the ICF Main. 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 ICF Main, 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 the ICF Main.
    - Please note that a separate submission should be made to the National Research Ethics Committee for Clinical Investigations of Medical Devices and Performance Studies of *In Vitro* Diagnostic Medical Devices (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 ICF Main page 11 “Will I be reimbursed for expenses” be updated to:
    - Include explicit reference to accommodation costs to ensure alignment with the Compensation for Trial participants document.
    - Provide further detail on the process by which reimbursements will be paid, including whether any third-party companies will be involved in administering these payments
    - clarify whether receipts will be required to support reimbursement claims, if so please also update Section 3 of the Compensation for Trial participants document accordingly
- The NREC-CT noted that the future use of data is not described in line with regulations / best practice on page 45 of ICF Main *“understand how the study medicine and/or other medicines work in the body, • better understand the health condition and/or other health problems”.* It is requested that page 45 ICF Main be updated to to clarify that participants’ data will be used for research confined to specified disease, related diseases or drug under study in this trial, or that an option is provided to enable participants to consent to be contacted in the future about other research studies 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). The PISCF should also make

it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined.

- The NREC-CT noted page 49 of ICF Main states the following “the sponsor shares anonymized data collected in the study”. It is requested that the ICF Main page 51 be updated to include a consent statement for the participant to explicitly consent to the processing of their personal data from pseudonymised /coded data to anonymised data as per Article 4 (2) and 6 General Data Protection Regulation (GDPR).
- The NREC-CT noted ICF Main page 47 states “We ask for your consent to transfer your personal data to countries outside the EU or EEA, which may not provide a comparable level of data protection as in the EU or EEA.” It is requested that appropriate safeguards (such as the use of standard contractual clauses) be implemented to ensure that data protection standards are equivalent to the standards of GDPR and the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) when data/samples are moved outside the EEA, and that the Statement of Compliance for Data Protection is aligned with all relevant ICF’s.
- The NREC-CT requested that ICF Main page 28 be updated to specify how imaging techniques will be used, the frequency of tumour size assessments and to specify whether the CT/PET/CT exposure is above standard of care, such that participants are informed.
- The NREC-CT requested that a lay language explanation of “Extensive stage SCLC” be provided in the ICF Main.
- The NREC-CT requested that wording on ICF Main page 7 referring to participants who “do not pass the initial screening…” be rephrased as it suggests participants may “fail” screening.
- The NREC-CT requested that stratification is explained in lay terminology in the ICF Main, page 7
- The NREC-CT requested that the ICF Main page 12 be updated to clarify the meaning of the phrase “…incorrect placement into treatment group”. It was unclear why DLL3 status determines the experimental treatment group , and further explanation is required, to ensure participants are informed.
- The NREC-CT queried the duplication of contraception information in ICF Main page 14, once for the Obrixtamig and once for standard of care. As all participants will receive standard chemotherapy, which appears to have longer contraception requirements, it is requested that the sponsor simplify the information by using the standard chemotherapy requirements alone.
- The NREC-CT requested that the ICF Pregnant partner page 2 be updated to provide an explanation for “study site” which may not be clear for the partner.
- The NREC-CT requests that Main ICF page 6 information relating to tumour tissue be updated to clearly specify the type of analysis to be performed (e.g. genetic analysis) to ensure participants are fully informed about the nature of the testing to be carried out on their samples.

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

Study title: Bleximenib or Placebo in Combination with Standard Induction and Consolidation Therapy followed by Maintenance for the Treatment of Patients with Newly Diagnosed KMT2A-rearranged or NPM1-mutant Acute Myeloid Leukemia Eligible for Intensive Chemotherapy: a double-blind phase 3 study

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Financial arrangements

- The NREC-CT noted that reimbursing study sites on a per-screened participant basis may create a risk that individuals who are unlikely to meet the eligibility criteria could undergo unnecessary screening procedures. It is requested that clarification is provided on safeguards in place to prevent over-screening and to ensure that participants are not exposed to avoidable tests or procedures.
- The NREC-CT noted that reimbursement is currently limited to visits that fall outside standard of care (SOC). However, participants may have to travel to hospitals outside their local area in order to access this clinical trial, even for SOC visits. The Sponsor should consider whether costs associated with SOC visits should also be reimbursed, to avoid disadvantaging participants who must travel long distances to attend the study site.

2. Subject information and informed consent form

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.
- The NREC-CT requested clarification on whether the tests referred to on Main ICF page 8 "The additional bone marrow and blood will be used for additional laboratory research" is part of the study endpoints or optional future research so it is clear for the participant whether these tests are optional.

- The NREC-CT requested that Main ICF page 13 be updated to clearly summarise the safeguards in place for any data transferred outside the EU.
- The NREC-CT requested clarification on the size of the patient ID card. The ID card should be small enough to fit into a wallet or phone case to ensure ease of the participant carrying it.
- The NREC-CT requested that Main ICF page 2 be updated to provide a lay language explanation of what the bone marrow test involves.
- The NREC-CT noted the statement on page 7 of Main ICF under "What is different from standard of care?" is misleading and understates the burden of participation. The NREC-CT noted for example there will be eight more bone marrow tests than standard of care. It is requested that this text is corrected or removed.
- The NREC-CT noted that on page 8 of the Main ICF participants are asked to return both unused medication and empty blister packs at each study visit. While returning unused medication is appropriate for safety and accountability purposes, the requirement to return empty blister packs may introduce unnecessary burden. If this requirement is intended to support adherence monitoring or investigational product accountability, the sponsor is requested to provide a clear rationale for its inclusion. Otherwise, the sponsor should consider removing this requirement.
- The NREC-CT requested that the Main ICF page 16 "Will you be paid if you take part in this study" be updated to:
    - Include details of what costs may be reimbursed for unscheduled hospital visits
    - Provide further detail on how these reimbursements will be paid including if third party companies will be used.
    - Clarify if receipts will be required to be provided for reimbursements, if so, please also update Section 3 of the Compensation for Trial participants document
- The NREC-CT requested that the Pregnancy ICF be updated to explicitly state how long the monitoring/ data collections will continue for the mother and in the life of the child.

2025-522255-25-00

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

Study title: FRAmework-01: A Two-Part Phase 3 Study of Sofetabart Mipitecan (LY4170156) versus Chemotherapy or Mirvetuximab Soravtansine in Platinum-Resistant Ovarian Cancer, and Sofetabart Mipitecan plus Bevacizumab versus Platinum-Based Chemotherapy plus Bevacizumab in Platinum-Sensitive Ovarian Cancer

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Financial arrangements

- The NREC-CT noted that the Clinical Trial Agreement, as referenced on page 49 (highlighted section), includes provision for the reimbursement of expenses for "caregivers." However, the Compensation for Clinical Trial Participants document does not reference reimbursement for carers. Please clarify whether expenses for participants' carers will be reimbursed, and update the Compensation for Clinical Trial Participants document accordingly.

2. Recruitment arrangements

- The NREC-CT requested that the Recruitment material poster and Recruitment material flyer be updated to provide a space for contact details for the trial study team to be inserted.

3. Subject information and informed consent form

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.
- The NREC-CT requested that the following updates be made across the Main ICF Part A, Main ICF Part B, Summary PIL Part A, Summary PIL Part B, Optional Biopsy ICF, Pre-screening ICF Part A, Pre-screening ICF Part B as relevant:
    - Provide a lay language explanation for the phrase "linker"
    - Section "Will you have costs or be reimbursed for joining the study?"" be updated to:
        - Include reference to accommodation and meal costs to align with the Compensation for Trial participants document.
        - Provide further detail on how reimbursements will be paid including if third party companies will be used.
        - Clarify if receipts will be required to be provided for reimbursements, if so, please also update Section 3 of the Compensation for Trial participants document
- The NREC-CT requested that the Main ICF Part A, Main ICF Part B, Summary PIL Part A, Summary PIL Part B, Optional Biopsy ICF, Pre-screening ICF Part A, Pre-screening ICF Part B be updated to clearly state whether it is a mandatory requirement to contact participants GPs about their involvement in

the trial. If it is not mandatory, consent to contact the participant's GP should be included.

- The NREC-CT noted that the future use of data is not described in line with regulations and best practice on page 5 of the Pre-screening ICF Part A and Pre-screening ICF Part B, where the phrase "For further medical research…the specific details of which may not be fully known at present."" is used. This wording is too broad and does not meet the requirements under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) to constitute valid broad informed consent. It is requested that the ICFs be updated to confine future use to specific disease, related diseases or drug under study in this trial and/or provide an option to enable participants to consent to be contacted in the future about other research studies outside this scope. https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/

4. Suitability of the clinical trial sites facilities

- The NREC-CT requested clarification on the number of planned participants in Ireland. The CTIs structured data indicates a total of 13 participants, whereas the Site Specific Assessments for Irish sites list a combined total of 17.

2022-501709-11-00 SM-15

Institutions: Cork University Hospital, St James's Hospital

Study title: A single arm, open-label Phase 3b study to describe the safety and tolerability of ivosidenib in combination with azacitidine in adult patients newly diagnosed with IDH1m acute myeloid leukemia (AML) ineligible for intensive induction chemotherapy

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS

1. The protocol has been updated to state that "height should be obtained only at Screening and weight will be collected as available per standard of care. Body surface area is not collected". The sponsor is requested to clarify the rationale for not recording these measurements together, as obtaining height and weight simultaneously is standard practice. In addition, given that the SmPC for Vidaga states "The recommended starting dose for the first treatment cycle, for all patients regardless of baseline hematology laboratory values, is 75 mg/m2 of body surface area, injected subcutaneously" collecting these parameters separately may introduce unnecessary variability. Please provide justification for this aspect of the study design.

Part II Considerations

3. Subject information and informed consent form

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.

2023-504962-52-00 SM-13

Institutions: Bon Secours Hospital Cork, St Vincent's University Hospital, University Hospital Galway

Study title: A Phase 3, Randomized, Open-label, Study to Compare the Efficacy and Safety of Adjuvant MK-2870 in Combination with Pembrolizumab (MK-3475) Versus Treatment of Physician's Choice (TPC) in Participants With Triple-Negative Breast Cancer (TNBC) Who Received Neoadjuvant Therapy and Did Not Achieve a Pathological Complete Response (pCR) at Surgery

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2024-518998-33-00 SM-9

Institutions: Connolly Hospital, Portiuncula University Hospital, Regional Hospital Mullingar, St Vincent's University Hospital, Our Lady of Lourdes Hospital, Beaumont Hospital

Study title: A Phase 3b, Multicenter, Randomized, Open-Label Study of Risankizumab Compared to Vedolizumab for the Treatment of Adult Subjects With Moderate to Severe Ulcerative Colitis Who are Naïve to Targeted Therapies.

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2022-500758-41-00 SM-22

Institutions: St James's Hospital

Study title: A multi-center, randomized, double-blind, placebo-controlled multiple ascending dose study to evaluate the safety and tolerability of QRL-201 in Amyotrophic Lateral Sclerosis, Followed by an Open-Label Extended Dosing Period

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Subject information and informed consent form

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.
- The NREC-CT requests clarification on whether participants' responsibilities change when they transition into the Open Label phase (Main ICF Addendum page 3 Section 5.2). If participants are expected to undertake any additional or amended responsibilities during this phase, these must be explicitly stated in the updated Informed Consent Forms (ICFs).
- The NREC-CT were unclear about the rationale for requesting participants consent to contact their GP for the purpose of future research. Please either clarify the rationale for this request or alternatively remove this consent request from the ICF.

2023-510319-20-00 SM-6

Institutions: St James's Hospital

Study title: A Randomized, Multicenter, Phase 3 Study of Zanidatamab in Combination with Chemotherapy with or without Tislelizumab in Subjects with HER2-positive Unresectable Locally Advanced or Metastatic Gastroesophageal Adenocarcinoma (GEA)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2025-522400-24-00 SM-6

Institutions: Cork University Hospital, Tallaght University Hospital

Study title: A Randomized, Open-label, Phase 2/3 trial of Izalontamab Brengitecan versus platinum-based chemotherapy for metastatic urothelial cancer in participants with disease progression on or after an immunotherapy-based treatment (IZABRIGHT-BLADDER01)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

- AOB:
  - None