National Research Ethics Committee

NREC-CT Meeting

24th September 2025

Attendance

Name	Role
Dr Cliona McGovern	Chairperson, NREC-CT B
Dr John Hayden	Deputy Chairperson, NREC CT-B
Prof Colm O'Donnell	Deputy Chairperson, NREC-CT B
Dr Åine de Róiste	Committee Member, NREC-CT B
Dr Karina Halley	Committee Member, NREC-CT B
Dr Ciaran Lee	Committee Member, NREC-CT B
Dr Andrew Lindsay	Committee Member, NREC-CT B
Dr Niall McGuinness	Committee Member, NREC-CT B
Prof. Seamus O'Reilly	Committee Member, NREC-CT B
Ms Evelyn O'Shea	Committee Member, NREC-CT B
Mrs Ann Twomey	Committee Member, NREC-CT B
Mr Ed McDonald	Committee Member, NREC-CT B
Prof. John Wells	Committee Member, NREC-CT B
Dr Emily Vereker	Head of Office, National Office for RECs
Ms Chita Murray	Programme Manager, National Office for RECs
Dr Jane Bryant	Project Officer, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Ms Deirdre Ní Fhloinn*	Project Officer, National Office for RECs
Dr Peadar Rooney	Project Officer, National Office for RECs

Apologies: Prof Michaela Higgins, Ms Jasmine Joseph, Ms Serena Bennett

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2025-522598-12-00
- 2025-522056-10-01
- 2025-521661-27-00
- 2022-502202-33-00 SM-6
- 2023-508204-38-00 SM-12
- 2023-509256-34-00 SM-2
- 2023-504031-41-00 SM-27
- 2024-516609-22-00 SM-5
- AOB

- The Chair welcomed the NREC-CT B.
  - The minutes from the previous NREC-CT B meeting on 27th August 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2025-522598-12-00

Institutions: St Vincent's University Hospital

Study title: A randomized, phase 2/3 study comparing BMS-986504 in combination with Nab-paclitaxel and Gemcitabine versus placebo in combination with Nab-paclitaxel and Gemcitabine in participants with untreated metastatic pancreatic ductal adenocarcinoma harboring homozygous MTAP deletion

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 noted bundled consent in the PISCF's (Main PISCF pg 28, Additional PISCF pg 12, Optional Sample Collection PISCF pg 5, Future Research PISCF pg 6, Treatment Beyond Progression PISCF pg 3, Pregnant Partner PISCF pg 5, Pregnant Participant PISCF pg 5). The Committee requested that the consent section be unbundled in all PISCF's, with a tick box available for each consent statement.
- The NREC-CT noted the collection of data relating to race and ethnicity (Main Consent Form pg 7). The Committee requested a justification for the collection of race and ethnicity data, and the inclusion of same in all relevant PISCF's.
- The NREC-CT noted the following statement (pg. 20, Main ICF): "Even if you withdraw consent for further follow-up or contacts, your study doctor or another person or company hired by the Sponsor may continue to collect information on your health status where the law allows including asking your general practitioner (GP)". The Committee request confirmation that the Sponsor (and/or any affiliated entity) will not conduct follow-up activities on participants who withdraw consent/do not give consent for further follow-up/contacts.
- The NREC-CT noted a reference to the potential use of a third-party vendor - Mural Health (Main ICF, pg19). The Committee request the submission of applicable consenting documentation for this third-party vendor in the event that use of this service is confirmed.
- The NREC-CT noted that the future use of data / samples (including genetic research) is not described in line with regulations / best practice on pg. 2 of the Future Research PISCF. The NREC-CT 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 (pg 2

Future Research PISCF 'The results of future research can help researchers learn more about diagnosing and treating medical conditions in the future')
    - 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 states that participants may undergo whole genome / whole exome sequencing (pg 22 Main PISCF, pg 4 Optional Sample Collection PISCF pg 3, Future Research PISCF) 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 that this is elucidated in the PISCF.
    - Explicit consent, including elaborating on any potential risks associated with such analysis being performed (e.g. the possibility and management of incidental findings), is added to the PISCF.
    - Clarification is provided in the PISCF on the storage location of samples/genetic material and the 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

2025-522056-10-01

Institutions: St James's Hospital

Study title: A Prospective, Multicenter, Open-label, Phase 3 Clinical Study to Evaluate the Efficacy and Safety of Prophylactic VGA039 in Adolescent and Adult Patients with von Willebrand Disease (VIVID-6)

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 noted that the Sponsor 'is paying the Study Doctor and the study team for their work in this study' (Main PISCF pg 14). The Committee requested that further explanation of what the payment encompasses be elucidated in the PISCF to reassure patients about the impartiality of the study team.
- The NREC-CT noted the 'Mural Link Participant App' Fun Fact number 3 to be unduly influential ("Did you know that 95% of people who have participated in a clinical trial say that they would be willing to participate in another one? 91% of those participants rate their experience as excellent or good"). The Committee requested that Fun Fact number 3 be removed and/or replaced from the Mural Link to ensure non-coercive participant facing material.
- The NREC-CT noted that the FV Leiden and Prothrombin G20210A mutation status of potential participants will be assessed (Protocol pg 19) but that no genetic testing is outlined in the PISCF's. The Committee requested that if genetic testing of samples is required, this be elucidated in all relevant PISCFs. Furthermore, please note:
    - Genomic sequencing should be 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 elucidated in the PISCF.
    - Explicit consent, including outlining the risks entailed in such analysis being performed, should be included in the PISCF.
    - The possible ownership of such data by private or commercial interests should be elucidated in the PISCF.
    - The right to withdraw genetic data, and clear information on how to do so, should 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

2. Suitability of the clinical trial sites facilities

- The NREC-CT noted that adolescents may be recruited in Ireland for this study. The Committee requested clarification that St James Hospital can cater for >12 year olds (e.g. has appropriate resuscitation facilities and insurance) or confirmation that participants < 18 years old will not be enrolled in Ireland unless another site can be identified.
- Site Suitability Assessments signed by the Principal Investigator (PI) cannot be accepted by the NREC. The SSA for St James Hospital must be signed by the CEO, Head of Clinic / Institution, Director of Research, Clinical Director, or delegate at each site. As a result of a Union Controls exercise led by the European Commission, it was highlighted that the PI as a site delegate signing the SSA is a potential conflict of interest.

2025-521661-27-00

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

Study title: A Phase 2b/3 Adaptive, Randomized, Active controlled Study Evaluating the Efficacy, Safety, and Tolerability of Povetacicept Versus Calcineurin Inhibitor in the Treatment of Primary Membranous Nephropathy

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 noted that neither the Main 2b or Main 3 PISCF adequately explain that withdrawing from the study will not negatively affect the participant's ongoing

treatment (page 23 Main 2b PISCF). The Committee requested that a headed section regarding withdrawal from the clinical trial be included in the PISCFs, to clarify that withdrawal from the clinical trial would not affect the participants ongoing treatment.

- The NREC-CT noted a reference to the potential use of third-party vendors e.g. Marken and Scout (Main 2b ICF, pg. 19). The Committee requested the submission of applicable consenting documentation for these third-party vendors in the event that use of these services is confirmed.
- The NREC-CT noted that [redacted] CV states he has GCP qualification '2013-2025'. The Committee requested that details (including date obtained) of the most recent GCP course for [redacted] be provided in his CV.
- The NREC-CT noted that the consent questions in the Main 2b PISCF (pg 24) are not in correct numerical order. The Committee requested that the numerical order of the consent questions be corrected to ensure readability and informed consent.
- The NREC-CT noted that the address' of the Sponsor's headquarters are absent from the PISCF's. The Committee requested that the introduction of the PISCF's are amended to include the address' of the Sponsors headquarters both inside and outside of the EU to ensure informed consent.
- The NREC-CT noted that the locations for sample analyses and storage are absent from the PISCF's (pg 18 Main 2b PISCF, pg 20 Main 3 PISCF). The Committee requested that the locations for sample analyses and storage be included in the PISCF's to ensure informed consent.
- The NREC-CT noted that there is no provision made in the PISCF's for an impartial witness. The NREC-CT requests that an impartial witness signature line be included in all PISCF's along with an explanation of the context where a witness signature would be needed, to account for occasions when an impartial witness may assist the informed consent process (as per CTR: Annex I,L 62(b)).
- The NREC-CT noted that the side effects of the study drugs listed the Main 2b /3 PISCF's lack a standardised probability classification (e.g., 'Very Common (>10%)', 'Rare (<1%)'). The Committee requested that a standardised probability classification for all study drugs be included in the PISCF's to ensure informed consent.
- The NREC-CT noted that the future use of data / samples (including genetic research) is not described in line with regulations / best practice on pg. 18/23 of the Main 2b PISCF and pg 20/25 of the Main 3 PISCF. The NREC-CT 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 made optional
    - 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 noted the sentence 'Before the institution shares your Personal Information, the study doctor will usually replace your name with a unique code and remove information that directly identifies you' in the section of the Main 2b /3 PISCF's entitled 'Who will have access to my Personal Information and for what purpose?'. The Committee requested that the section is revised to:
  - Clarify that participants personal information will always be pseudonymised with the exception of specific, listed, circumstances.
  - Include an explicit list of potential recipients of participants coded personal information
  - Clarify that data breaches will be reported to the Data Protection Commissioner

2022-502202-33-00 SM-6

Institutions: Children's Health Ireland

Study title: A Phase 2, Multicenter, Long-Term, Open Label Extension Trial Evaluating Safety, Tolerability, and Efficacy of Subcutaneous Doses of TransCon CNP Administered Once Weekly in Children and Adolescents with Achondroplasia (AttaCH)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

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 noted duplication of text regarding allergic reactions in the Legal Age PIS Version A,B & C (page 6 & 7). The Committee requested that the duplication of text is amended or removed to ensure readability of the PIS for potential participants.
- The NREC -CT noted that NREC is described as a point of contact for questions, concerns, or complaints about the clinical trial **(**Legal Age PIS pg. 13). The committee requested that NREC be removed as a point of contact for participants in all relevant PIS. As appropriate, the Principal Investigator (PI) has been listed as the primary contact for participants with any queries, and the site Data Protection Officer/Data Protection Commission have been listed as contacts for questions or concerns regarding data protection rights.

2023-508204-38-00 SM-12

Institutions: St James's Hospital

Study title: A Phase 3, Randomized, Open-Label Study of Combination Therapy with Avutometinib plus Defactinib Versus Investigator's Choice of Treatment in Patients with Recurrent Low-Grade Serous Ovarian Cancer (LGSOC) (RAMP301)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

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 noted that the Main Adult PISCF and Adult MHI Cohort PISCF have become increasingly lengthy, text heavy documents with 89 and 55 pages respectively. While it is to be acknowledged that there is a high degree of complex information to provide to potential participants, the format is not conducive to ease of use and is burdensome. The Committee requested the inclusion of a glossary of terms and a table of contents (to include section headings and page numbers), and to consider whether any of the new information can be presented in diagram/process flow/infographic format to facilitate fully informed consent of the participants in this trial.
- The NREC-CT requested that the Main Adult PISCF and Adult MHI Cohort PISCF be updated to provide the location where the clinical trial results will be available at the end of the trial (e.g. https://euclinicaltrials.eu/)

2023-509256-34-00 SM-2

Institutions: Beaumont Hospital

Study title: A Phase 1/2 Dose-Exploration and Dose-Expansion Study to Evaluate the Safety and Efficacy of BEAM-302 in Adult Patients with Alpha-1 Antitrypsin Deficiency (AATD)-Associated Lung Disease and/or Liver Disease

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

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 noted the sentence “BEAM-302 is created by formulating all the pieces of the base editing machinery into a lipid nanoparticle (microscopic ball of

fat) that can be delivered into your blood by IV infusion" on page 2 of the Adult Main A PISCF and page 1 of the Adult Main B PISCF. The Committee requested that the above sentence (and any other technical language) be reviewed and revised in lay English to ensure informed consent.

- The NREC-CT noted the sentence "This means you may not be placed in the exact group you were first considered for" on page 4 of both the Adult Main A and B PISCF. The Committee requested further explanation is provided to the participant regarding the different patient cohorts, and allocation to same, as the meaning of the sentence is unclear.

2023-504031-41-00 SM-27

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

Study title: A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Camizestrant (AZD9833, a Next Generation, Oral Selective Estrogen Receptor Degrader) vs Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) as Adjuvant Treatment for Patients With ER+/HER2- Early Breast Cancer and an Intermediate-High or High Risk of Recurrence Who Have Completed Definitive Locoregional Treatment and Have No Evidence of Disease (CAMBRIA-2)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2024-516609-22-00 SM-5

Institutions: St Vincent's University Hospital, Connolly Hospital

Study title: A Phase 3 Randomized, Double-Blinded, Placebo-Controlled Multicenter Trial with Open-Label Extension to Evaluate the Efficacy, Safety, and Tolerability of Efgartigimod PH20 Subcutaneous Administered by Prefilled Syringe in Adult Patients with Primary Sjögren's Disease

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

- AOB:

  None