

# National Research Ethics Committee

## NREC-CT Meeting

11<sup>th</sup> February 2026

### 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 Áine de Róiste	Committee Member, NREC-CT B
Dr Karina Halley	Committee Member, NREC-CT B
Mr Edward McDonald	Committee Member, NREC-CT B
Ms Jasmine Joseph	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 Elizabeth O'Donnell	Committee Member, NREC-CT B
Dr Eoin Noctor	Committee Member, NREC-CT B
Dr Jane Bryant	Programme Officer, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs

Ms Chita Murray Programme Manager, National Office for RECs

Ms Deirdre Ní Fhloinn\* Project Officer, National Office for RECs

\*Drafted minutes

**Apologies:** Ms Serena Bennett, Dr Mary Anne Ryan

**Quorum for decisions:** Yes

**Conflict of Interest:** None

## Agenda

- Welcome & Apologies
- 2025-523558-14-00
- 2025-523497-16-00
- 2024-518858-17-00
- 2025-520665-47-00 SM-2
- 2023-510160-12-00 SM-5
- 2023-506669-70-00 SM-11
- 2024-510620-39-00 SM-12
- 2024-516036-94-00 SM-9
- 2024-517780-24-00 SM-6
- AOB

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- The Chair welcomed the NREC-CT B.
    - The minutes from the previous NREC-CT B meeting on 14<sup>th</sup> January 2026 were approved.
    - The NREC Business Report was discussed and noted.
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## Applications

### 2025-523558-14-00

Institutions: Beaumont Hospital

Study title: Phase 1, Open-Label, Single Ascending Dose and Multiple Dose Study to Assess Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Subcutaneously

Administered AIR-001 in Adults with Alpha-1 Antitrypsin Deficiency (AATD) Due to PiZZ Genotype

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

## Part II Considerations

### 1. Financial arrangements

- The NREC-CT noted that reimbursement for travel, meal and accommodation expenses of carers has been outlined in the Compensation Form (pg.1) but that this information is lacking in the Main PISCF. The Committee requested the Main PISCF is updated to include information regarding reimbursement of reasonable expenses for carers to align with the Compensation Form.

### 2. Subject information and informed consent form

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](mailto: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.
- The NREC-CT noted that the PISCF, while thorough, is excessively long and burdensome for potential participants, with duplication of information contained in Table 1 & Table 2 (Main PISCF pg. 16-17) and the listed schedule of procedures (Main PISCF pg. 6-15). The Committee requested that the PISCF is restructured such that the schedule of procedures is relocated to an appendix section to facilitate readability for potential participants.
  - The NREC-CT noted reference to UK data protection standards in the Main PISCF (pg.26). The Committee requested that the PISCF is updated to reflect the Irish context throughout.
  - The NREC-CT noted conflicting information in the Main PISCF (pgs. 18, 27) and the Compliance of Biological Samples Form (pg.4) regarding whether biological samples will be used for future research. The Committee requested clarification whether future use of samples is intended and that the Main PISCF and Compliance of Biological Samples Form are aligned.
  - The NREC-CT noted that carers of participants have not been included for reimbursement of travel, accommodation and meal expenses in the Compensation Form (p1). The Committee requested that reimbursement of travel, accommodation and meal expenses are considered for carers of participants and, if included, that it is elucidated in the Compensation Form and PISCF's.

**2025-523497-16-00**

Institutions: Beaumont Hospital

Study title: TSRA196-AAT-201: A Phase 1/2, Open-Label, Multi-Center, Dose Escalation, Dose Expansion, and Single Repeat Dose Study of TSRA-196 in Adults With the PiZZ Genotype Who Have Lung and/or Liver Disease Associated with Severe Alpha-1 Antitrypsin Deficiency

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

## Part II Considerations

### 3. Financial arrangements

The NREC- CT noted that carers of participants have not been included for travel, accommodation and meal expense reimbursement in the P1\_Compensation Form (p1). The Committee requested that reimbursement of travel, accommodation and meal expenses are considered for carers of participants and, if included, that it is elucidated in the Compensation Form and PISCF's.

### 4. Subject information and informed consent form

Standard Consideration:

3. 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](mailto: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.
  4. 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 PISCF states that the ethics committee (EC) 'will also have access to your information' (pg. 20). The Committee requested that the sentence is rephrased to clarify that only pseudonymised data will be provided to the EC if required under certain circumstances. Furthermore, please relocate the statement as a bullet point listed under the heading 'your coded data will be accessible by' (pg.19) to ensure continuity and clarity for prospective participants.
  - The NREC-CT noted that an optional cheek swab will be collected to explore genetic changes or differences in participants DNA but that insufficient details of

same are included in the PISCF (pg. 6). The Committee requested that the text outlining the purpose etc. of the optional cheek swab, as documented in the table on pg. 6, be included and expanded upon in an additional section of the PISCF to enhance clarity of the information provided.

- The NREC-CT noted that there is mandatory genetic testing of the SERPINA1 gene during the screening phase of the clinical trial, but that this is not sufficiently highlighted to the participant in the PISCF, merely stating that “blood will be collected to test for the following: Mutations in the SERPINA1 gene” (Main PISCF, pg.4). The Committee requested that this mandatory genetic testing is clearly emphasised and explained to the prospective participant to ensure informed consent.
- The NREC-CT noted the risk of liver injury and abnormal levels of liver enzymes associated with the study drug (Main PISCF, pg.11). The Committee requested that further information be provided in the Main PISCF regarding the potentially increased risk of severe liver injury in participants with pre-existing significant liver disease (such as participants in Part 1B and 2B of the clinical trial).
- The NREC-CT noted that the explanation regarding the risk of off-target editing associated with the IMP was inadequate (Main PISCF pg.12). The Committee requested that this section of the Main PISCF is elaborated upon to clearly explain
  - that the off-target effects of gene editing therapies are a unique type of side effect from this class of IMP
  - that each participant has unique DNA sequences and therefore their DNA could harbour unique off-target sites that were not present or detected in pre-clinical studies.
  - the risk of malignancy as outlined in the protocol (pg. 30)
  - that although these potential side effects are rare, they are likely to persist long-term after the initial treatment and are potentially permanent.
- The NREC-CT noted that sexual abstinence is acceptable as a contraceptive method for male participants only (pg. 14 Main PISCF, pg. 49 Protocol). The Committee requested clarification as to why sexual abstinence is not listed as an acceptable method of contraception for female participants.
- The NREC-CT noted that the protocol (pg.43) outlines how the planned starting dose of the IMP was chosen, but that this information is lacking in the Main PISCF. The Committee requested that the dose selection method be clearly elucidated in in the Main PISCF in plain English suitable for a lay audience such that participants are fully informed.
- The NREC-CT noted an insufficient explanation of gene editing technology in the Main PISCF (pg.2). The Committee requested that further information regarding gene editing technology be provided in the Main PISCF to enable 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.29 of the Main PISCF, as follows: “*Your samples may be analysed by Sponsor or its collaborators to contribute to the effect of TSRA-196 and/or other medicines on the body, how TSRA-196 is processed by the body, who could benefit from TSRA-196, why some people have adverse events, and understanding of AATD or other diseases, the development of related or new treatments, or research methods*”.

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,
- and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,
- 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/>

#### 5. Suitability of the clinical trial sites facilities

- The NREC-CT noted that participants will receive infusions of the IMP at St James's Hospital Welcome Centre under the supervision of [REDACTED]. Due to the nature of the intervention, the Committee requested that that a separate Site Suitability Assessment (SSA) for each site is submitted and that the structured data on CTIS is updated to include St James Hospital. In addition, SSA's signed by the Principal Investigator (PI) cannot be accepted. 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 per the SSA template. 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.

#### 2024-518858-17-00

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

Study title: The MAVRiC Study: A Phase II Study of Disease Risk Mutation-guided Finite Duration Acalabrutinib plus Venetoclax for Relapse in CLL/SLL after First-line Finite covalent BTKi plus BCL2i combination, with or without Obinutuzumab

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

#### Part II Considerations

## 1. Financial arrangements

- The NREC-CT noted that a monetary payment for participants is referenced in the Compensation Form (pg.1) but that no details are provided. The Committee requested that details of the monetary payment be provided in both the Main PISCF and Compensation Form with clear guidance regarding how these payments may be claimed.
- The NREC-CT noted that that only travel expenses will be reimbursed for participants (Compensation Form pg. 1). The Committee requested that reimbursement for all reasonable out-of-pocket expenses be considered for both participants and carers, including meals and accommodation if applicable, to ensure equity in access to clinical trials across all socioeconomic groups. This information should be provided in both the Main PISCF and Compensation Form with clear guidance regarding how reimbursement may be claimed.

## 2. Subject information and informed consent form

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](mailto: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.
- The NREC-CT noted that the study title is confusing as it appears to indicate the potential inclusion of Obinutuzumab as a component of the intervention. The Committee requested confirmation that Obinutuzumab is not part of intervention and that clarification of same be included in the Main PISCF to facilitate informed consent.
  - The NREC-CT noted that that participants may consent to notification of their general practitioner (GP) regarding participation in the study (Main PISCF, pg 24). The Committee requested that wording be inserted in the Main PISCF which strongly advises participants to allow contact with their GP considering the considerable risk of tumor lysis and teratogenicity of the study drug, including adequate reference to the potential risks.
  - The NREC-CT noted that samples will be used in 'related research activities necessary for the drug development program' (Main PISCF pg. 19) which does not align with the Compliance of Biological Samples form which states that no future research is intended with samples from participants in Ireland (Compliance of Biological Samples Form pg.4). The Committee requested confirmation that no future research of samples will be undertaken and that this is explicitly stated in the Main PISCF.
  - The NREC-CT noted reference to UK Privacy Laws and the UK Information Commission Office in the Main PISCF (pg. 29 / 21). The Committee requested that the PISCF is updated to reflect the Irish context throughout.
  - The NREC-CT noted that a PISCF for participants who become pregnant has not been submitted, which does not align with the Main PISCF which states that participants who become pregnant will be 'requested to provide information about you and your baby. This may involve a separate consent form to allow us to

monitor your baby's health and development' (Main PISCF pg.15). The Committee requested that a separate PISCF for participants who become pregnant is submitted for review or that a separate consent section detailing relevant information regarding the data to be collected be included in the Main PISCF, such that the participant is fully informed.

- The NREC-CT noted the sentence 'Your data and biological samples are needed for the Sponsor to develop the study treatment, get permission to launch and keep it on the market for CLL/SLL, monitor its safety, and be reimbursed for it, for example by governments, i.e., throughout the drug development program' (Main PISCF pg. 19). The Committee requested that the sentence is reworded with the reference to reimbursement by governments removed, to ensure accuracy of information.

### **2025-520665-47-00 SM-2**

Institutions: Royal Victoria Eye and Ear Hospital

Study title: An Open-Label Dose Escalation Study to Assess the Safety and Tolerability of a Single Intravitreal Injection of SPVN20 Gene Therapy in Subjects with No Light Perception Due to End Stage Rod Cone Dystrophy, and Who Retain Dormant Foveal Cone Photoreceptors

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

### **2023-510160-12-00 SM-5**

Institutions: Children's Health Ireland

Study title: A randomized phase 3 trial of fludarabine/cytarabine/gemtuzumab ozogamicin with or without venetoclax in children with relapsed AML

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

### **2023-506669-70-00 SM-11**

Institutions: St James's Hospital

Study title: A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of Amyloid Depletor ALXN2220 in Adult Participants with Transthyretin Amyloid Cardiomyopathy (ATTR-CM)

Dossiers Submitted: Part I & II

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

- **Additional Information Required**

## 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](mailto: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 number of participants listed as having an infusion related reaction (IRR) in earlier trials has been reduced from four down to three, but that the rationale for same is unclear (Main PISCF pg.7). The Committee requested that the number of participants who previously experienced an IRR is clarified and explained.
- The NREC-CT noted that participants will be notified regarding test results for HIV, Hepatitis B and Hepatitis C viruses (Adult PISCF pg. 5). The Committee requested that information be included in the PISCF as to what supports will be made available to participants who receive a diagnosis of these viruses.
- The NREC-CT noted that participants may withdraw consent to taking the study drug but continue participating in the study (Adult PISCF pg.14). The Committee request confirmation that participants who withdraw from the study drug but continue to participate in the study will receive reimbursement for reasonable travel costs, meal expenses and accommodation costs, as applicable.
- The NREC-CT noted that page 20 of the Adult PISCF includes a witness signature line. The NREC-CT requests information be added to all relevant PISCF's explaining the context where a witness signature would be needed (as per CTR: Annex I,L 62(b)).
- The NREC-CT noted that the Sponsor may share data from pregnant partners of study participants with other researchers, health related companies and universities (PISCF for Pregnant Partners pg.4). The Committee requested that further particulars be provided in this PISCF as to the data to be collected during pregnancy follow-up, as indicated in section 8.4.7 of the study protocol. Similarly, further details of data to be shared and the purpose of same be clearly elucidated in the PISCF as this is not included in the study protocol. If future research is to be undertaken the Committee request that future use of samples / personal data (including genetic data) is sufficiently explained to participants in the PISCF document 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/>

## **2024-510620-39-00 SM-12**

Institutions: Tallaght University Hospital

Study title: An Open-label, Randomized, Phase 3 Study of MK-6482 in Combination with Lenvatinib (MK-7902) vs Cabozantinib for Treatment in Participants with Advanced Renal Cell Carcinoma Who Have Progressed After Prior Anti-PD-1/L1 Therapy

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

### **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](mailto: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 study duration has been updated to from four to six years (Protocol, pg.5) but that there is no reference to the study duration in the Main PISCF. The Committee requested that the Main PISCF is updated to include the overall study duration such that the participant is fully informed.
- The NREC-CT noted that page 22 of the Main PISCF includes a witness signature line. The NREC-CT requests information be added to all relevant PISCF's explaining the context where a witness signature would be needed (as per CTR: Annex I,L 62(b)).

#### **2024-516036-94-00 SM-9**

Institutions: Beaumont Hospital, Tallaght University Hospital, St Vincent's University Hospital,

Study title: MK-2400-01A Substudy: A Phase 1/2, Open-label Umbrella Substudy of MK-2400-U01 Master Protocol to Evaluate the Safety and Efficacy of Ifinatumab Deruxtecan-based Treatment Combinations or Ifinatumab Deruxtecan Alone in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC) (Ideate-Prostate02)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**
- Favourable

#### **2024-517780-24-00 SM-6**

Institutions: St James's Hospital, National University of Ireland, Cork University Hospital, Mater Private Hospital, Tallaght University Hospital, St. Vincent's University Hospital, Beaumont Hospital

Study title: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab Monotherapy for the First-line Treatment of Patients with PD-L1-high Metastatic Non-small Cell Lung Cancer (ARTEMIDE-Lung04)

Dossiers Submitted: Part I & II

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

## 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](mailto: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 a list of specific, acceptable contraception methods is absent from the Main PISCF and that participants are advised to speak to their Doctor instead to obtain this information (Main PISCF pg.19). The Committee requested that a list of acceptable contraception methods be inserted in the Main PISCF such that participants are fully informed.

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- AOB: N/A