National Research Ethics Committee

NREC-CT Meeting

28th May 2025

Attendance

Name	Role
Dr John Hayden	Deputy Chairperson, NREC CT-B
Prof Colm O'Donnell	Deputy Chairperson, NREC-CT B
Ms Serena Bennett	Committee Member, NREC-CT B
Dr Karina Halley	Committee Member, NREC-CT B
Prof. Michaela Higgins	Committee Member, NREC-CT B
Ms Jasmine Joseph	Committee Member, NREC-CT B
Dr Andrew Lindsay	Committee Member, NREC-CT B
Dr Niall McGuinness	Committee Member, NREC-CT B
Mr Ed Mc Donald	Committee Member, NREC-CT B
Ms Deirdre Ni Fhloinn*	Project Officer, National Office for RECs
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
Dr Emma Heffernan	Project Officer, National Office for RECs
Dr Emily Vereker	Head of Office, National Office for RECs

Apologies: Dr Cliona McGovern, Prof Seamus O'Reilly, Ms Evelyn O'Shea, Dr Aine de Róiste, Dr Ciaran Lee, Prof John Wells, Ms Ann Twomey, Ms Chita Murray

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2024-518589-29-00
- 2024-519856-94-00
- 2022-501254-10-00 SM-35
- 2022-501980-42-00 SM-14
- 2024-510742-13-00 SM-3
- 2023-508636-61-00 SM-17
- AOB

- The Chair welcomed the NREC-CT B.
  - The minutes from the previous NREC-CT B meeting on 30th April 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2024-518589-29-00

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

Study title: A Phase III, randomized, double-blind, placebo-controlled study to assess the Efficacy, Safety, and Tolerability of BI 1291583 2.5 mg administered once daily for up to 76 weeks in patients with Bronchiectasis (The AIRTIVITY® Study)

Dossiers Submitted: MSC Part 1 & 2

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Recruitment arrangements

- The NREC-CT noted that advertisement material will be used to recruit participants, and requested submission of these materials for review, when available.
- The NREC-CT noted that the Bedside Flyer contains several UK references (e.g. the MHRA, NHS and cost in Great British Pounds). The Committee requested that the Bedside Flyer is reviewed and updated to align with the Irish context.

2. Subject information and informed consent form

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment.Phase include detail of the Part 1 consideration that triggered the update to the Part 2 documentation.
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT noted that Protocol section 5.6.2 details a tokenisation process for certain sites but that an explanation and consent for tokenisation is absent from the Main PISCF. The Committee requested clarification on whether tokenisation will be implemented in the Republic of Ireland and that an explanation of the process as well as explicit consent is included in the PISCF if applicable.
- The NREC noted that the Main PISCF states ‘If you do not want to use a smartphone, you cannot participate in this study’ (pg 6), but that this exclusion criteria is not outlined in the Protocol. The Committee requested to know whether alternative methods of assessing PRO's could be provided and/or whether supports could be implemented to engage with participants who are unwilling to use a smart phone and if possible that this explained in the PISCF. If these approaches are not feasible the Committee recommends that an unwillingness to

engage with smartphones be explicitly outlined in the exclusion criteria on the study protocol.

2024-519856-94-00

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

Study title: A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate Nebulized Bacteriophage Treatment in Outpatient Adult Cystic Fibrosis (CF) Subjects with Chronic Pseudomonas aeruginosa (PsA) Pulmonary Infection

Dossiers Submitted: MSC Part 1 & 2

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS

1.

- It is noted that the dose of IMP is approximately 3.5 times higher than the dose used in the phase 1 study. In the Protocol (pg 27) it states that based on the lack of safety signals no major safety risks are considered to be associated with this dose increase. Please provide additional explanation with regard to the assessment of risk (e.g. lack of safety signals).

Part II Considerations

1. **Compliance with national requirements on data protection**

- The NREC-CT noted that the Statement of Compliance for Data Protection (pg 3) states that 'patient's privacy will be protected on an equivalent level as GDPR and Ireland laws requires' if pseudonymized data is transferred to third countries outside the European Union and the European Economic Area (EEA). However, while the Main ICF (pg 19 and 22) states that coded data and bio samples may be transferred to countries with reduced levels of data protection laws, no mitigation strategies or assurances regarding participant privacy are outlined. The Committee request 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 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.

2. **Financial arrangements**

- The NREC-CT noted that the Main ICF states that there may be reimbursement for loss of earnings for time spent at the study site (p13), however this is absent from the Compensation for Participants Form (pg1). The NREC-CT request clarification on whether participants will be reimbursed for loss of earnings, and alignment of the relevant ICF's and the Participant Compensation Form.
- The NREC-CT noted that a symbolic compensation will be offered to pregnant partners of participants. The Committee requested that the monetary amount of this symbolic compensation is specified in the Participant Compensation Form and referenced in Pregnant Partner PIL.

3. Recruitment arrangements

- The NREC-CT noted that the scientific advice from HPRA (pg16/17) and BfArM (pg 5) indicates the sponsor plans to recruit adolescents, but that the recruitment of adolescents is not mentioned in the recruitment documents. The Committee requested clarification that only adults will be recruited in Ireland.

4. Subject information and informed consent form

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment.Phase include detail of the Part 1 consideration that triggered the update to the Part 2 documentation.
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- 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. 19 of the Main 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 (please highlight this on pg 19 Main ICF)
  - 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/

2022-501254-10-00 SM-35

Institutions: St Vincent's University Hospital, Beaumont Hospital, Mater Misericordiae University Hospital, St James's Hospital, Adelaide And Meath Hospital

Study title: A Multicenter, Open-label, Phase 3 Study to Evaluate the Long-term Safety and Efficacy in Participants who are Currently on Treatment or in Follow-up in Studies That Include Pembrolizumab

Dossiers Submitted: MSC Part 1 & 2

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

1. Subject information and informed consent form

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT noted that the side effects of Pembrolizumab + Lenvatinib as combination therapy are absent in the Main Addendum for Lenvatinib ICF, but that side effects for combination therapy with Pembrolizumab + Olaparib are included in the Main Addendum for Olaparib ICF (pg 4). The Committee requested that, if available, the side effects of Pembrolizumab + Lenvatinib as a combination therapy are included in the Main Addendum for Lenvatinib ICF to maintain consistency with the Main Addendum for Olaparib ICF.
- The NREC-CT noted some typographical errors in some of the participant materials eg the word ‘very tired’ repeated in the list of side effects for Levatinib in the Main Addendum for Lenvatinib ICF (pg 3) and ‘if you able to become pregnant’ in the Main Survival Follow Up ICF (p3). The Committee requested that these are reviewed and amended to ensure readability of the PISCF’s for participants.
- The NREC-CT noted that the text regarding pregnancy/breastfeeding/ egg or sperm donation has been written in the past tense in the Main Survival Follow Up ICF (pgs.3,4) and may not be currently relevant to the participant who is post-treatment with IMP and is now in a survival ‘no treatment’ follow up period. The Committee requested that the information on pregnancy and breastfeeding as well as egg/sperm donation is reviewed, and that information is provided to reflect the current status of this patient cohort.

2022-501980-42-00 SM-14

Institutions: Children's Health Ireland (Temple Street)

Study title: A Phase 3, Open-label, Uncontrolled Study to Evaluate the Activity, Safety, Pharmacokinetics and Pharmacodynamics of Roxadustat for the Treatment of Anemia in Pediatric Participants with Chronic Kidney Disease

Dossiers Submitted: MSC Part 1 & 2

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

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

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT noted that the instruction for partners of participants to use highly effective birth control has been removed in both the Parent PISCF (p18) and Main Participant PISCF (p17). The Committee requested a justification, which satisfies the Committee, for the removal of this instruction. Alternatively please give consideration to reinstating the instruction for partners of participants to use highly effective birth control.

2024-510742-13-00 SM-3

Institutions: Children’s Health Ireland (Crumlin)

Study title: A Phase 3, Randomized, International Multicenter Trial of DAY101 Monotherapy Versus Standard of Care Chemotherapy in Patients with Pediatric Low-Grade Glioma Harboring an Activating RAF Alteration Requiring First-Line Systemic Therapy (LOGGIC/FIREFLY-2)

Dossiers Submitted: MSC Part 1 & 2

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Subject information and informed consent form

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT noted that consent for treatment after progression is included in the main consent section of the Main Parents PISCF (pg40) and the Main Adults 16+ PISCF (pg39). The Committee do not consider it appropriate for consent for treatment after progression to be obtained in advance and recommend that information regarding treatment after progression and consent for same are made into separate PISCF's to facilitate informed consent at the relevant time.
- The NREC-CT note the consent for processing of data for 16/17-year-olds in the Main Parent PISCF and Main Adults 16+ PISCF (pg40) is as previously requested by the NREC. The Committee wish to advise of a national policy change informed by discussions at a national level with relevant authorities: participants aged 16yrs+ may consent to both participation in a regulated study and associated data processing. Therefore, the consent for participation in the study and use of personal data for the study, should not be treated separately. As such, there is now no requirement to seek consent from a parent/guardian for data processing for participants aged 16 and 17. We acknowledge that this 'decoupled' change to the consent process was initially incorporated by Sponsors at the request of the NRECs. We hope this policy change is viewed as more pragmatic and facilitative for those involved in the recruitment process.
- The NREC-CT noted that the future use of data / samples (including genetic research) is not described in line with regulations / best practice in the Parents PISCF (pg 11) and the Adults 16+ PISCF (pg11). 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,

- 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/

2023-508636-61-00 SM-17

Institutions: Beaumont Hospital, St Vincent's University Hospital

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Program to Evaluate the Efficacy and Safety of Tulisokibart in Participants with Moderately to Severely Active Crohn's Disease

Dossiers Submitted: MSC Part 1 & 2

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

1. Subject information and informed consent form

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT noted that the age range for inclusion in the study is 18-80 years in the Main ICF (pg3). The Committee recommend that the age range for inclusion in the study is adjusted in the Main ICF to align with the Protocol (which stipulates 16-80 years) and to consider participants aged 16years+, as participants aged 16yrs+ may consent to both participation in a regulated study and associated data processing in the RoI.
- The NREC-CT noted that the intended use of the Optional Biopsy is very broad "your samples may be used to improve and develop tests to support clinical trials" and "will be used for research purposes" (Optional Biopsy Form pg2). The

Committee requested that use of Optional Biopsy tissue be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where use of samples and data is defined such that participants are fully informed

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- AOB:
  - None