National Research Ethics Committee

NREC-CT Meeting

29th May 2024

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
Ms Serena Bennett	Committee Member, NREC-CT B
Dr Andrew Lindsay	Committee Member, NREC-CT B
Dr Niall McGuinness	Committee Member, NREC-CT B
Ms Evelyn O'Shea	Committee Member, NREC-CT B
Mr Gerard Eastwood	Committee Member, NREC-CT B
Ms Deirdre Mac Loughlin	Committee Member, NREC-CT B
Ms Aileen Sheehy	Programme Manager, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Ms Rachel McDermott	Project Administrator, National Office for RECs
Ms Megan O'Neill*	Programme Officer, National Office for RECs

Apologies: Prof. Michaela Higgins, Mrs Ann Twomey, Prof. John Wells, Prof. Abhay Pandit, Prof. Catherine Hayes, Ms Jasmine Joseph, Prof. Seamus O'Reilly

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-506842-22-00
- 21-NREC-CT-065_Mod-4
- 2023-505023-31-00
- 2023-504923-20-00
- 2022-501522-38-00
- 2023-504684-16-00
- 2023-503661-28-00
- 23-NREC-CT-006_Mod-3
- AOB

- The Chair welcomed the NREC-CT B.
  - The minutes from the previous NREC-CT B meeting on 24th April 2024 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-506842-22-00

Institutions: Mater Misericordiae University Hospital, Cork University Hospital

Study title: A Phase 1, First-in-Human, Open-Label, Dose-Escalation and Expansion Study of IMGN151 (anti-FRα antibody-drug conjugate) in Adult Patients with Recurrent Endometrial Cancer and Recurrent, High-Grade Serous Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers

  - NREC-CT Decision:

- Request for further information

  - Additional Information Required RFI

Part II Considerations

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

- The NREC-CT noted the collection of data on race in the Main Consent Form pg 13. In line with GDPR special category data requirements, the NREC-CT

requested that justification for the collection of race and ethnicity data in captured in the Main Consent form.

- The NREC-CT requested further information on the processes in place for the handling and management of the data and samples obtained from participants who deemed ineligible to participate in the study following screening.

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

- The NREC-CT requested further details regarding the processes in place of the collection, use and storage of samples for patients who are screened but are not eligible for enrolment in the study.
- The NREC-CT considered the following statement in Section 4.1 of the Compliance with use of Biological Samples form; “this additional research may include studies to get more information on ovarian cancer.” The NREC-CT requested that the information given in Section 4 of the Compliance with use of Biological Samples form is modified to clearly set out what type of future research the samples are confined to, instead of use of the term “may include”.

3. **Financial arrangements**

- The NREC-CT appreciated that reimbursement is available for the travel, accommodation and meals associated with a participant’s trial activities, and requested that the Sponsor consider implementing similar reimbursement for carers travelling with the participant.

4. **Proof of insurance**

- The NREC-CT requested assurance that the insurance policy provided will be in place for the entirety of the study.

5. **Recruitment arrangements**

- The NREC-CT noted the Site Suitability form for MMUH gives 25 participants for this site, whilst the data entry on CTIS indicates 8 participants for Ireland across both sites. The NREC-CT requested that these numbers are harmonized, and if a total of 28 participants are to take part in the study from Ireland alone, please provide a comment or justification for the burden of risk on Irish patients.

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

- The NREC-CT noted the collection of data on race in the Main Consent Form pg 13. In line with GDPR special category data requirements, the NREC-CT requested that justification for the collection of race and ethnicity data in captured in the Main Consent form.
- The NREC-CT requested that the PISCF is updated to clearly set out how long samples will be stored for and where they will be stored for future research purposes as described in Section 4 of the Collection, storage and future use of human biological samples form.
- The NREC-CT noted that travel, accommodation and meal expenses are available to participants as described in the Compensation for Trial Participants form but the PISCF only refers to reimbursement for travel. The NREC-CT requested that the PISCF is updated to reconcile this.
- The NREC-CT noted that the section on future research in the **Main PISCF (Optional Consent for Conduct of Secondary Research pg.21)** is not described in line with regulations and best practice. The Committee requested that future use of samples is sufficiently explained 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 the disease 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: HSE National Policy for Consent in Health and Social Care Research (V1.1, 2023) https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf
- The NREC-CT suggested that the PISCF may benefit from the use of diagrams or other visuals to enhance the readability of the document for participants and their understanding.
- The NREC-CT requested that further emphasis is given in the PISCF to inform potential participants that they will be foregoing standard of care treatment that is known to be beneficial should they take part in the trial.
- The NREC-CT requested that the phrasing of "combining your Coded Data with data from patients treated with other drugs" on pg. 21 of the PISCF is reconsidered so that it is clear to the reader that this pertains to participants with the same disease.
- The NREC-CT requested that the following statement on pg. 2 and 3 of the Pregnant Participant PISCF is modified to give further clarity as to how long information will be collected from the participant, "for a period following the birth of a child to the extent necessary to gather information on the effect of study drug on a child's health."
- The NREC-CT requested that the PISCF is updated to include reference to the standard agreement clauses for data that is to be transferred to a third party country.
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment.
- 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 as these documents are composed of images, rather than searchable text, and cannot be optimised for use with assistive software.

7. **Suitability of the clinical trial sites facilities**

- The NREC-CT requested that an updated Site Suitability Form for Cork University Hospital is submitted, signed by the CEO, Head of Clinic / Institution, Director of Research, Clinical Director, or delegate at each site.
- 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 as these documents are composed of images, rather than searchable text, and cannot be optimised for use with assistive software.

8. **Suitability of the investigator**

- No Considerations

21-NREC-CT-065_Mod-4

Institutions: Cork University Maternity Hospital

Study title: Phase 2b, Multicenter, Randomized, Open-label, Two-Arm Study to Evaluate the Clinical Efficacy and Safety of OHB-607 Compared to Standard Neonatal Care for the Prevention of Bronchopulmonary Dysplasia, the Most Common Cause of Chronic Lung Disease of Prematurity

- NREC-CT Decision:

- Favourable

2023-505023-31-00

Institutions: Tallaght University Hospital, Beaumont Hospital, St Vincent's Healthcare Group, Cork University Hospital

Study title: Multi-center, Double-Blind, Randomized Phase 3 Study to Compare the Efficacy and Safety of Belzutifan (MK-6482) plus Pembrolizumab (MK3475) Versus Placebo plus Pembrolizumab, in the Adjuvant Treatment of Clear Cell Renal Cell Carcinoma (ccRCC) Post Nephrectomy

- NREC-CT Decision:

- Favourable

2023-504923-20-00

Institutions: Tallaght University Hospital

Study title: A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer

- NREC-CT Decision:

- Request for further information

- Additional Information Required RFI

Part II Considerations
• **Compliance with national requirements on data protection**
• No Considerations
• **Compliance with use of biological samples**
• No Considerations
• **Financial arrangements**
• No Considerations
• **Proof of insurance**
• No Considerations
• **Recruitment arrangements**
• The NREC-CT noted the use of the abbreviation “PD-1” in the Patient Brochure and requested that this is modified to “PD-L1” to align with the abbreviation used across the Protocol and PISCF.
• **Subject information and informed consent form**

- The NREC-CT noted that PET scans will take place at the Beacon Hospital as set out on pg. 7 of the Main PISCF and requested clarification as to whether these scans take place at one particular Beacon Hospital site, or any of them. The PISCF should be updated to reflect which Beacon Hospital site/sites will provide PET scans.
- The NREC-CT considered the following statement on pg.9 of the PISCF, “If your tumour is not predominantly squamous histology, molecular testing for EGFR mutation is also required if the status is not already known” and requested that this is updated to reflect the information given in the protocol which indicated that “the sample can be squamous cells, or nonsquamous cells with EGFR mutation”. The Optional Limited Screening PISCF should also reflect this change.
- The NREC-CT noted it was not clear where tissue samples will be held and requested that the PISCF is modified to specify this location.
- The NREC-CT noted that pg. 10 of the PISCF refers to the transfer of samples outside the UK and recommended that this is updated to Ireland or EU.
- The NREC-CT noted that PET scans will take place at the Beacon Hospital as set out on pg. 7 of the Main PISCF and requested clarification as to whether these scans take place at one particular Beacon Hospital site, or both/either of them. The PISCF should be updated to reflect which Beacon Hospital site/sites will provide PET scans.
- 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 as these documents are composed of images, rather than searchable text, and cannot be optimised for use with assistive software.
- **Suitability of the clinical trial sites facilities**
- No Considerations
- **Suitability of the investigator**
- No Considerations

2022-501522-38-00

Institutions: Beaumont Hospital

Study title: An Extension Study of Venetoclax for Subjects Who Have Completed a Prior Venetoclax Clinical trial

- NREC-CT Decision:

- Favourable

2023-504684-16-00

Institutions: Mater Misericordiae University Hospital

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tafasitamab Plus Lenalidomide in Addition to Rituximab Versus Lenalidomide in Addition to Rituximab in Patients With Relapsed/Refractory (R/R) Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma

- NREC-CT Decision:

- Favourable

2023-503661-28-00

Institutions: St James's Hospital, South Infirmary Victoria University Hospital, University Hospital Waterford, University Hospital Galway, St. Vincent's University Hospital

Study title: A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study to Evaluate Efficacy and Safety of Upadacitinib in Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa Who Have Failed Anti-TNF Therapy

- NREC-CT Decision:

- Request for further information

- Additional Information Required RFI

Part II Considerations

- **Compliance with national requirements on data protection**
- No Considerations
- **Compliance with use of biological samples**
- No Considerations
- **Financial arrangements**
- No Considerations
- **Proof of insurance**
- No Considerations
- **Recruitment arrangements**
- No Considerations
- **Subject information and informed consent form**
- The NREC-CT noted that pg. 113 of the protocol references the completion of a paper diary by the study participants. The Committee requests that this information is captured in the participant information leaflets.
- The NREC-CT requests that the abbreviation 'TA MD' on pg. 14 of the Adult Participant Information Leaflet is further explained.
- The NREC-CT noted that all participant information leaflets provided information around the potential for retinal detachment. The Committee requests that these documents include further information around what a study participant should do in the event they experience symptoms related retinal detachment.
- The NREC-CT noted that pg. 9 of the 12-17 Assent Form states *'Some local authorities may require use of a barrier method or another method of birth control'.* The NREC-CT requests that this statement is amended to remove the word 'authorities' in line with the other participant information leaflets.
- As study participants may not know if they have an allergy or sensitivity to constituent drugs, the NREC-CT requests that the participant information leaflets are amended to state that participants should notify the study doctor of all known drug allergies or sensitivities.

- The NREC-CT requests that the following sentence on pg. 14 of the Adult Participant Information Leaflet and pg. 14 of the Parental Information Leaflet is reworded from '…*or a carcinoma in situ of the cervix if this can be successfully treated at its location'* to '…*or a carcinoma in situ of the cervix can be treated at its location'.*
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment.
- 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.
- **Suitability of the clinical trial sites facilities**
- No Considerations
- **Suitability of the investigator**
- No Considerations

23-NREC-CT-006_Mod-3

Institutions: Children's Health Ireland (Temple St)

Study title: ApproaCH: A Phase 2b, Multicenter, Double-Blind, Randomized, Placebo-controlled Trial evaluating Efficacy and Safety of Subcutaneous Doses of TransCon CNP Administered Once Weekly for 52 Weeks in Children with Achondroplasia followed by an Open Label Extension period

- NREC-CT Decision:

- Request for further information

- Additional Information Required RFI

- The NREC-CT requests further justification as to why reconsent will not be obtained from existing participants.

- AOB:
  - N/A