National Research Ethics Committee

NREC-CT A Meeting

14th February 2024

Attendance

Name	Role
Prof. Alistair Nichol	Chairperson, NREC-CT A
Ms Caoimhe Gleeson	Deputy Chairperson, NREC-CT A
Prof. Gene Dempsey	Deputy Chairperson, NREC-CT A
Dr Darren Dahly	Committee Member, NREC-CT A
Ms Mandy Daly	Committee Member, NREC-CT A
Dr Geraldine Foley	Committee Member, NREC-CT A
Ms Muireann O'Briain	Committee Member, NREC-CT A
Dr Sean Lacey	Committee Member, NREC-CT A
Mrs Dympna Devenney	Committee Member, NREC-CT A
Prof. Aisling McMahon	Committee Member, NREC-CT A
Dr Emily Vereker	Head of Office, National Office for RECs
Dr Jane Bryant*	Project Officer, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Ms Aileen Sheehy	Programme Manager, National Office for RECs

Apologies: Dr Brian Bird, Mrs Erica Bennett, Dr Lorna Fanning, Dr Maeve Kelleher, Dr Dawn Swan

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-509472-42-00
- 2023-506091-27-00
- 2023-508341-40-00
- 22-NREC-CT-162_Mod-2
- 22-NREC-CT-177_Mod-2
- 21-NREC-CT-121_Mod-6
- 22-NREC-CT-119_Mod-3
- 22-NREC-CT-071_Mod-4
- 23-NREC-CT-011_Mod-2
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 10th January 2024 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-509472-42-00

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

Study title: A Phase 3, Randomized, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of Alnuctamab Compared to Standard of Care Regimens in Participants with Relapsed or Refractory Multiple Myeloma (RRMM) - ALUMMINATE RRMM

Dossiers for Review: Part I and II

NREC-CT Decision: Request for Further Information

Part II Considerations

1. Subject information and informed consent form

- The NREC-CT noted that the section on future research in the Main PIS/CF (Section 11.2) and Pregnant Partner PIS/CF (Page 3) 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 requested further information on the gathering of medical information on the pregnancy, birth and health of the child of a pregnant partner, specifically for how long the information will be collected for. (Pregnant Partner PISCF page 1)
- The NREC-CT recommended that the contact details of the Data Protection Commissioner (DPC) is added to the relevant sections of the PISCF documents.
- The NREC-CT requested that the consent section be unbundled, with a tick box available for each consent statement (Main PIS/CF, Pregnant Partner ICF)
- The NREC-CT noted that compensation for participants will be managed by Clincierge, who is a third party and that a separate data consent form would need to be signed. This documentation should be submitted for review. (Main PIS/CF page 28, section 4.3)

2. Suitability of the investigator

- The NREC-CT noted that GCP certification for the PI at Cork University Hospital and St James's Hospital should be updated when applicable.

2023-506091-27-00

Institutions: Children's Health Ireland

Study title: A Phase 2, Multicenter, Double-Blind, Randomized, Placebo-controlled Trial, evaluating Safety, Tolerability, and Efficacy of Subcutaneous Doses of TransCon CNP Administered Once Weekly for 52 Weeks in Infants (0 to <2 years of age) with Achondroplasia followed by an Open Label Extension (OLE) period.

Dossiers for Review: Part I and II

NREC-CT Decision: Request for Further Information

Part II Considerations

3. Compliance with national requirements on data protection

- The NREC-CT noted that the DPO had raised risks in the DPIA, and requested further information on the risk mitigation, and confirmation on whether these risks have been addressed.

4. Financial arrangements

- The Sponsor is requested to submit a statement confirming the source of funding for the trial. This statement can be submitted on headed paper and does not need to be signed.

5. Recruitment arrangements

- The NREC-CT requested confirmation on how many participants will be recruited in Ireland for the main trial, and for the volunteer MRI study.
- The NREC-CT requested clarification on whether participants who do not have English as a first language will be included in this study, and if not, that a justification is given (Section 1.8).
- The NREC-CT requested further information on how much time participants and their Parents/Guardians will have to decide to participate during the informed consent process.

6. Subject information and informed consent form

- The Sponsor is requested to add the EU CT number to the PIS and ICF documents.
- The NREC-CT recommended that a short summary PIS with graphics should be considered, including a graphic of the schedule of assessments.
- The NREC-CT requested that the following terms in the PIS be explained, or phrased in lay language; Placebo, Measurements (e.g. microgram), List of acronyms, Blinded period, Open label period, Coded data, Bone overgrowth.
- The NREC-CT requested that further information is given to participants regarding the risk of bone overgrowth, specifically what the actual risk is, and what it will mean in the long term for participants (Parent Guardian PIS, page 10).
- The NREC-CT noted that the NREC should not be contacted in the event of complaints, and that the relevant hospital complaints department contact details be given instead of those for NREC (Parent Guardian PIS, page 17).
- The NREC-CT requested an amendment to the following sentence in the Parent Guardian ICF: 'The purpose of the future research is to learn more about achondroplasia and the study medication', to include the following: *'*as it relates to achondroplasia.'
- The NREC-CT requested clarification on what data will be shared with medical authorities and collaboration partners, and if this is coded data or the participant's medical records (Parent Guardian PIS, page 11).
- The NREC-CT requested further information on the research study for MRI volunteers, specifically how this study links to the trial and how volunteers will be recruited (Volunteer PIS and ICF).
- The NREC-CT requested that the monetary amounts for reimbursement are removed from the Scout Clinical ICF (page 1).

2023-508341-40-00

Institutions: Children's Health Ireland

Study title: COACH: A Phase 2, Open-Label, Single-Arm, 156-week Trial to Investigate the Efficacy, Safety and Tolerability of Combined Once Weekly Navepegritide and Lonapegsomatropin in Children with Achondroplasia

Dossiers for Review: Part I and II

NREC-CT Decision: Request for Further Information

Part I Considerations

1. DSMB

- The Sponsor is requested to justify why a DSMB for this study will not be established.

Part II Considerations

1. Compliance with use of biological samples

- The NREC-CT requested clarification on where biological samples will be stored for the duration of the storage period (Section 4.3).

2. Recruitment arrangements

- The NREC-CT requested clarification on whether participants who do not have English as a first language will be included in this study, and if not, that a justification is given (Section 1.8).
- The NREC-CT requested further information on how much time participants and their Parents/Guardians will have to decide to participate during the informed consent process.

3. Subject information and informed consent form

- The Sponsor is requested to add the EU CT number to the PIS and ICF documents.
- The NREC-CT requested that the following terms in the PIS be explained, or phrased in lay language; Placebo, Measurements (e.g. microgram), List of acronyms, Blinded period, Open label period, Coded data, Bone overgrowth.
- The NREC-CT noted that the NREC should not be contacted in the event of complaints, and that the relevant hospital complaints department contact details be given instead of those for NREC (Parent Guardian PIS, page 13).
- The NREC-CT requested that further information is given to participants on the schedule of reimbursement and how they should claim this reimbursement if not using Scout Clinical (Parent Guardian PIS, page 9).
- The NREC-CT requested an amendment to the following sentence in the Parent Guardian ICF: ‘The purpose of the future research is to learn more about achondroplasia and the study medication’, to include the following: ‘as it relates to achondroplasia.’
- The NREC-CT requested that further information is given to participants regarding the risk of bone overgrowth, specifically what the actual risk is, and what it will mean in the long term for participants (Parent Guardian PIS, page 6).
- The NREC-CT requested that the stipend monetary amount is removed from the Scout Clinical ICF (page 1).
- The NREC-CT noted the following sentence in the PIS for children over 8 years old: ‘When blood is taken from your arm, it may sting a little bit, but this will not hurt you.’ The NREC-CT requests removal of the following part: ‘but this will not hurt you’, as it could hurt some children (Page 3).
- The NREC-CT recommended addition of a sentence on how parents/guardians can help with tests such as collection of urine samples if needed, to reduce any

anxiety for the participants around these assessments (PIS for Children over and under 8).

- The NREC-CT requested clarification on what data will be shared with medical authorities and collaboration partners, and if this is coded data or the participant's medical records (Parent Guardian PIS, page 11).

22-NREC-CT-162_Mod-2

Principal Investigator: Prof. Patrick Mallon

Study title: A randomised, controlled, parallel group, open-label trial evaluating the impact of treatment with the GLP-1 analogue semaglutide on weight loss in people living with HIV and obesity.

EudraCT: 2019-002314-39

NREC-CT Decision: Request for Further Information

- The NREC-CT requested that the information given in the original PIL and the enhanced PIL be consistent across both documents, such that participants randomised to either PIL will get the same information.
- The NREC-CT noted the PI at St Vincent's University Hospital is being replaced and requested rationale for this change, and assurances on the continued support for participants on the trial.

22-NREC-CT-177_Mod-2

Principal Investigator: Prof. Jarushka Naidoo

Study title: A Phase II, Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

EudraCT: 2021-003369-37

NREC-CT Decision: Favourable

21-NREC-CT-121_Mod-6

Principal Investigator: Prof. Ray McDermott

Study title: DASL-HiCaP: Darolutamide Augments Standard Therapy for Localised Very High-Risk Cancer of the Prostate (ANZUP1801). A randomised phase 3 double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in very high risk, clinically localised prostate cancer.

EudraCT: 2019-004818-34

NREC-CT Decision: Request for Further Information

- The NREC-CT requested confirmation that no participant-facing materials require an update as a result of the IB or Protocol update.

22-NREC-CT-119_Mod-3

Principal Investigator: Dr Declan O'Rourke

Study title: A Randomized, Double-Blind, Dose Finding and Comparison Study of the Safety and Efficacy of a High Dose of Eteplirsen, Preceded by an Open-Label Dose Escalation, in Patients with Duchenne Muscular Dystrophy With Deletion Mutations Amenable to Exon51 Skipping

EudraCT: 2018-001762-42

NREC-CT Decision: Request for Further Information

- The NREC-CT requested that the 12-14 ICF (page 6) Section "What happens if I have a baby?" be updated such that the final sentence states "*If a pregnancy should occur, the study doctor will contact the pregnant person regarding this study, and obtain consent to collect pregnancy information including, if applicable, the status of the baby*"
- The NREC-CT noted the extensive time involved in administering the IMP at site, and requested further information on whether other arrangements could be an option to ease this burden on participants and their caregivers.
- The NREC-CT requested that details of the physio / motor assessment be included in the 7-11 years and 12 years assent forms.
- The NREC-CT requested clarification on whether blood for testing can be accessed through a portacath if that is chosen to be inserted for the study.

22-NREC-CT-071_Mod-4

Principal Investigator: Prof. Brian Kirby

Study title: A Phase 3, Open-label, Parallel Group, Multicenter, Extension Study Evaluating the Long-term Treatment of Bimekizumab in Study Participants with Moderate to Severe Hidradenitis Suppurativa

EudraCT: 2020-004179-42

NREC-CT Decision: Favourable

23-NREC-CT-011_Mod-2

Principal Investigator: Dr Declan O'Rourke

Study title: A Randomized, Double-Blind, Placebo-Controlled, Multiple Ascending Dose Study Assessing Safety, Tolerability, Pharmacodynamics, Efficacy, and Pharmacokinetics of DYNE251 Administered to Participants with Duchenne Muscular Dystrophy Amenable to Exon 51 Skipping

EudraCT: 2021-005478-24

NREC-CT Decision: Request for Further Information

- The NREC-CT requested that a full rationale for all changes to the Protocol is submitted, such that these changes can be reviewed. A detailed Cover Letter should outline all changes made to the trial documentation and justification for each one given. This

includes rationales for the inclusion of the extra participant cohorts, the suicide assessment and further details on the supports and procedures.

- AOB:
  - None