National Research Ethics Committee

NREC-CT A Meeting

19th June 2024

Attendance

Name	Role
Prof. Alistair Nichol	Chairperson, NREC-CT A
Prof. Gene Dempsey	Deputy Chairperson, NREC-CT A
Ms Mandy Daly	Committee Member, NREC-CT A
Ms Muireann O'Briain	Committee Member, NREC-CT A
Dr Dawn Swan	Committee Member, NREC-CT A
Dr Maeve Kelleher	Committee Member, NREC-CT A
Mrs Dympna Devenney	Committee Member, NREC-CT A
Dr Sean Lacey	Committee Member, NREC-CT A
Dr Brian Bird	Committee Member, NREC-CT A
Dr David Byrne	Committee Member, NREC-CT A
Ms Margaret Cooney	Committee Member, NREC-CT A
Dr Jane Bryant*	Project Officer, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Ms Aileen Sheehy	Programme Manager, National Office for RECs
Ms Rachel McDermott	Project Administrator, National Office for RECs

Apologies: Dr Darren Dahly, Mrs Erica Bennett, Prof. Aisling McMahon, Ms Caoimhe Gleeson

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-508323-12-00
- 2024-511378-60-00
- 2023-505616-38-00 SM-1
- 2023-508341-40-00 SM-1
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 22nd May 2024 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-508323-12-00

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

Study title: A Phase 3 Randomized, Active-controlled, Open-label, Multicenter Study to Compare the Efficacy and Safety of MK-2870 Monotherapy Versus Treatment of Physician's Choice as Second-Line or Third-Line Treatment for Participants with Recurrent or Metastatic Cervical Cancer

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 'Health Authority in Ireland' is detailed in the Main ICF document, and requested this is corrected to the Health Products Regulatory Authority (HPRA) (Page 9).
- The NREC-CT requested that it is confirmed that to participants who wish to withdraw from the trial (Section 19) that their options are as laid out in Section 18. (Main ICF, Page 13).
- The NREC-CT noted the following sentence: *If requested, any stored blood or tissue samples that can still be identified as yours will be destroyed. Please note that we may not be able to destroy samples immediately upon request if the sample is required to maintain the scientific integrity of the trial.* The Committee requested that this is made clearer to the participant, that if the samples have already been analysed, that this information cannot be destroyed or withdrawn without impacting the overall integrity of the trial. (Main ICF, Page 13).

- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment.

2024-511378-60-00

Institution: Beaumont Hospital

Study title: A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Global Study to Evaluate the Efficacy and Safety of Intravenous AOC 1001 for the Treatment of Myotonic Dystrophy Type 1

Dossiers for Review: Part I and II

NREC-CT Decision: Request for Further Information

Part II Considerations

1. **Recruitment arrangements**

- The NREC-CT noted that the Recruitment Brochure does not give details of potential length of study visits or any information on risk/benefit. The Committee requested that this information is added for potential participants.
- The NREC-CT noted that the Participant Handbook does not contain details on safety or potential risks of the IMP or the importance of contraception. The Committee requested that this information is added for potential participants.

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

- The NREC-CT noted that the exclusion criterion 21 in the Protocol details current treatment stoppage ahead of participation, and requests that risks and potential impact associated with this is communicated to the participant in the ICF.
- The NREC-CT noted the consent for processing of data for 16/17 year olds on Page 24 of the Adult Informed Consent Form as previously requested by the NREC. The Committee wishes to advise of a recent 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 and17. The National Office is currently finalising guidance on this change. Once finalised, this guidance will be made available on the National Office website.
  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 Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment.

2023-505616-38-00 SM 1

Institutions: St Vincent's University Hospital, Mater Misericordiae University Hospital, Beaumont Hospital, Connolly Hospital, Cork University Hospital, St James's Hospital

Study title: A Phase 3b, Multicenter, Global, Interventional, Open-label Study of Trastuzumab Deruxtecan (T-DXd), an Anti-HER2-Antibody Drug Conjugate (ADC), in Subjects who Have Unresectable and/or Metastatic HER2-low or HER2 Immunohistochemistry (IHC) 0 Breast Cancer (BC) (DESTINY-Breast15)

Dossiers for Review: Part I and II

NREC-CT Decision: Request for Further Information

- The NREC-CT noted that the title has not been updated on the insurance certificate, and recommended that this be completed.
- The NREC-CT noted that the section on future research in the Biosample PISCF (Page 8), is not described in line with regulations and best practice, and should be consistent across all ICF documents. 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.
    - Optional consents should be separated out from the main consent, and designated as optional for participants.
    - 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 noted bold and capitalised sections in the ICF documents, for example on pages 4 and 6 of the Biosample ICF; and recommended that these sections be re-formatted to enhance readability.
- The NREC-CT noted reference to participants' social security numbers on page 4 of the Pregnant Partner ICF, and requested that this be amended for the Irish setting.
- The NREC-CT noted the use of 'leftover samples' throughout the ICF documents, and suggested that this be rephrased to 'remaining' samples.
- The NREC-CT requested that should a participant withdraw from the study, that it is made clearer to the participant that if their samples have already been analysed, that this information cannot be destroyed or withdrawn without impacting the overall integrity of the trial.

- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment.

2023-508341-40-00 SM 1

Institution: 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

- The NREC-CT noted the use of 'leftover samples' on page 2 of the ICF document, and suggested that this be rephrased to 'remaining' samples.
- The NREC-CT requested that should a participant withdraw from the study, that it is made clearer to the participant that if their samples have already been analysed, that this information cannot be destroyed or withdrawn without impacting the overall integrity of the trial.

AOB: None