National Research Ethics Committee

NREC-CT A Meeting

14th August 2024

Attendance

Name	Role
Prof. Alistair Nichol	Chairperson, NREC-CT A
Mrs Erica Bennett	Committee Member, 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 Darren Dahly	Committee Member, NREC-CT A
Dr Brian Bird	Committee Member, NREC-CT A
Dr David Byrne	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*	Programme Officer, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Ms Aileen Sheehy	Programme Manager, National Office for RECs
Mr Ciaran Horan	Administrative Assistant, National Office for RECs

Apologies: Dr Sean Lacey, Prof. Gene Dempsey, Ms Margaret Cooney, Ms Caoimhe Gleeson

Conflicts of Interest: Dr Maeve Kelleher declared a COI with 2023-503630-44-00, and was not present at the meeting for the discussion of this trial.

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-503630-44-00
- 2023-507680-19-00
- 2024-512279-10-00
- 2024-510730-40-00
- 2022-502851-79-00 SM-8
- 2023-510317-26-00 SM-1
- 2022-501374-19-00 SM-1
- 2023-508381-16-00 SM-1
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 19th June 2024 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-503630-44-00

Institutions: Children's Health Ireland, Cork University Hospital

Study title: A randomized, double-blind, placebo-controlled, parallel-group, multicenter, phase 3 trial to evaluate the efficacy and safety of tralokinumab in combination with topical corticosteroids in children (age 2 to <12 years) and infants (age 6 months to <2 years) with moderate-to-severe atopic dermatitis.

Dossiers for Review: Part I and II

- **NREC-CT Decision:**

  Request for further information

Part II Considerations
1. Financial arrangements
• The NREC-CT requested further information on whether the participants' caregiver will also be reimbursed for out-of-pocket expenses. If this is the case, this information should also be made clear to participants in the PISCF documents.
2. Recruitment arrangements

- The NREC-CT noted that participants who do not speak English (national language) will be excluded from the study and requests that a justification is given for this. The NREC-CT requests further justification for this exclusion criteria. The NREC-CT strongly recommends that all reasonable accommodations are made to include participants who may be eligible for participation (Section 1.8).
- The NREC-CT noted that the abbreviation TCS appears in the Participant Flyer, and requests that this is removed or explained.
- The NREC-CT noted that caregivers will be able to administer the IMP later in the trial, and requested clarification on alternative arrangements in place if the caregiver does not wish to do this (General Information for Participants and Parents).

3. Subject information and informed consent form

- The NREC-CT noted the inclusion of details on the Danish Data Protection Agency on page 12 of the PISCF for children aged 6 months to 2 years, and requested that this be amended for the Irish setting.
- The NREC-CT noted that photographic assessment is detailed in the Protocol, but not outlined in the PISCF, and requested further information on whether this is relevant for IE. If so, the NREC-CT requested further information on procedures around this assessment and processing of the data.
- The NREC-CT requested clarification on whether the participants' GP will be informed about their participation, and if so, if a GP letter is available for review.
- The NREC-CT noted that the potential for injection pain for participants is detailed in the Protocol, but not included in the PISCF documents. The Committee requests that this be added to these documents, to prepare the participants in advance of the treatment.
- The NREC-CT noted the inclusion of pregnancy wording in the Assent form for participants turning 12, and recommended that this section is revised to include more age-appropriate language (Page 5).
- The NREC-CT requested that for all consent forms, optional consents for future research be separated from the main consent, to make it clear to the participant what is part of the main study and what is optional.
- The NREC-CT requested clarification on where it would be documented if a 12 year old participant wished to withdraw their assent for participation in the study (Assent for a child turning 12, page 9).
- The NREC-CT requested further information on how parent/guardian consent will be sought to collect pregnancy data from a participant if applicable, as outlined in the Pregnancy Report forms submitted in the Part I dossier.
- The NREC-CT noted that an option for 'Yes or No' is given in the consent section of the PISCF documents for data processing, however given that this is necessary for study participation, the option to decline is confusing and should be clarified.
- The NREC-CT noted the use of the word 'subject' and requested that this is amended to 'participant' throughout the participant-facing documentation.
- The Sponsor is requested to complete the EU CT number on all the PISCF documents.
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment.

2023-507680-19-00

Institution: Our Lady's Hospital Manorhamilton, Beaumont Hospital

Study title: A Phase 2 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of HZN-1116 in Participants With Sjögren's Syndrome.

Dossiers for Review: Part I and II

- **NREC-CT Decision:**

  Request for further information

Part II Considerations

1. Financial arrangements

- The NREC-CT requested clarity on whether a participant's carer would be entitled to the same reimbursement as the participant, specifically in relation to accommodation. If this is not the case, please provide justification for this. This information should be captured in the participant materials.

2. Recruitment arrangements

- The NREC-CT requested further information is given on the recruitment arrangements, specifically; who will be accessing medical records, and more detail on what the processes will be to recruit participants.

3. Subject information and informed consent form

- The NREC-CT noted that the Main PISCF and GP letter refer to both populations in the same documents, and suggested it may be clearer to participants in either population and their GP to have a distinct set of documents applicable for each population. Additionally, the Committee recommend that the condition, Sjögren's syndrome, have a more detailed explanation in the Main PISCF.
- The NREC-CT noted that the section on confidentiality in the Main PISCF (page 22) is confusing and would benefit from editing aimed at clarifying what is personal data, coded data, pseudonymised data, and an explanation for what each type of data is. Additionally, it should be clear who will have access to each type of data, and where this will occur. The same terms for each data type should be consistent across all participant-facing information to avoid confusion. If data is to be anonymised, a separate consent line should be added to the informed consent section of the PISCF, given this is a particular form of processing and requires explicit consent under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
- The NREC-CT noted that participants will be recruited in Ireland through doctor referrals, and as such, requested justification for the use of the PatientWing recruitment company for IE. If this company is to be used, the Committee requested that a relevant DPO be consulted on the use of data by this company for their activities.
- The NREC-CT noted the overuse of exclamation marks on the concierge email templates, and suggested that these be reduced to improve the tone of the correspondence.

- The NREC-CT noted that participants will not have access to the study drug after completion of the trial and recommends that this is reconsidered, so that all participants benefiting from the study drug continue to have access.
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment.

4. Suitability of the clinical trial sites facilities

- The NREC-CT requested clarification on whether a dentist is required to be part of the site team, given the nature of the condition.

2024-512279-10-00

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

Study title: A Randomized, Open-label, Phase 3 Study of Adjuvant Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice in Patients With Triple Negative Breast Cancer Who Have Residual Invasive Disease After Surgery and Neoadjuvant Therapy

Dossiers for Review: Part I and II

- **NREC-CT Decision:**

  Request for further information

Part II Considerations

1. Compliance with use of biological samples

- The NREC-CT noted that genomic research will be performed on participant samples, and requested clarification on whether any secondary findings will be communicated to the participant and/or their GP.

2. Recruitment arrangements

- The NREC-CT noted that this document is headed as Germany, and requests clarification that the correct document for Ireland has been submitted.
- The NREC-CT noted that study posters will be supplied to potential participants, and requested that these be submitted for review when available.
- The NREC-CT noted that participants who do not speak English (national language) will be excluded from the study. The NREC-CT requested further justification for this exclusion criteria. The NREC-CT strongly recommends that all reasonable accommodations are made to include participants who may be eligible for participation (Section 1.8).

3. Subject information and informed consent form

- The NREC-CT noted the potential use for locator services to obtain participants' survival status, and requested clarification on whether this will take place in Ireland. If not, this sentence should be removed. Additionally, the NREC-CT do not think it would be appropriate to contact a participant's family in the event that a participant cannot be reached, and that a GP may be more appropriate in this case (Main PISCF, Page 7).

- The NREC-CT noted that participants will be required to complete questionnaires about health and fertility, and highlighted the sensitive nature of these topics. The Committee requested further detail on whether supports will be available to participants during completion of these questionnaires, and recommends that participants are advised of the nature of the questionnaires in the Main PISCF (Main PISCF, Page 15). Furthermore, the NREC-CT requested clarification on whether any questionnaires will be completed by male participants.
- The NREC-CT noted that participant data may be transferred outside of the EEA, and requested further clarity on which countries and for what purpose this would occur (Main PISCF, Page 33).
- The NREC-CT requested further detail on access to questionnaires, if participants do not wish to use Signant Health services (Main PISCF, Page 38).
- The NREC-CT requested that further information is given to participants in the Main PISCF about which expenses will be reimbursed, whether this is a maximum amount that can be claimed, and how they can obtain reimbursement if they do not wish to use Greenphire (Main PISCF, Page 30).
- The NREC-CT requested further detail on where the Central Laboratory for samples is located (Optional Future Research and Genomic Research PISCF, Page 5).
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment.

4. Suitability of the investigator

- The NREC-CT requested whether further detail on the trial experience of the PI at University Hospital Limerick is available, and if required, that supports are available at the site for the PI.

2024-510730-40-00

Institution: Our Lady of Lourdes Hospital, St Vincent's University Hospital, Mater Misericordiae University Hospital

Study title: A Phase 3 Multicenter, Randomized, Double-Blind Placebo-Controlled Study to Evaluate the Efficacy and Safety of Lutikizumab (ABT-981) in Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa

Dossiers for Review: Part I and II

- **NREC-CT Decision:**

  Request for further information

Part I Considerations

1. Protocol

- The Sponsor is requested to justify limiting rescue medication during the first 16 weeks of the trial given the use of placebo, and further information is requested on how participants' symptoms may be relieved if required during this period.

Part II Considerations

1. Financial arrangements

- The NREC-CT requested further information on what expenses will be reimbursed, and given that participants aged 16 and 17 are also eligible for this trial, where relevant whether their parent / guardian will also be reimbursed for expenses. This additional information should also be given to participants in the Main PISCF (Page 17).

2. Recruitment arrangements

- The NREC-CT noted that recruitment websites may be used, and requested further information on whether these will be used in Ireland. If so, the details and any recruitment material should be submitted for review when available.

3. Subject information and informed consent form

- The NREC-CT noted that participant data may be transferred to Abbvie's affiliates and research partners, and requested further detail on who this may be (Main PISCF, Pages 18-20). Additionally, the NREC-CT requested further information on how long these samples and/or data will be retained for before destruction.
- The NREC-CT noted that this study will use competitive enrolment and raised concerns about the possible undue influence this competitive approach may have on potential participants' decision-making process. The Committee requested justification for this approach. Furthermore, the NREC-CT requested confirmation that participants will not be rushed to decide on their participation, based on this enrolment approach.
- The NREC-CT requested further information on what processes, procedures and / or additional safeguards will be in place for physical examinations of participants, given the intimate areas that can be affected in this condition; for example, the potential for a chaperone if applicable.
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment.

4. Suitability of the investigator

- The NREC-CT requests further detail on the trial experience of the PI at St Vincent's University Hospital.

2022-502851-79-00 SM-8

Institution: St Vincent's University Hospital, Our Lady's Hospital Manorhamilton, Connolly Hospital

Study title: A Phase 3, Single-Arm, Multicenter, Open-label Extension of Study ARGX-113-2007 to Investigate the Long-term Safety, Tolerability, and Efficacy of Efgartigimod PH20 SC in Participants Aged 18 Years and Older With Active Idiopathic Inflammatory Myopathy

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 ICF documents for deselected subtypes have been submitted, and requested further information on which subtypes were deselected.

2023-510317-26-00 SM-1

Institution: Beaumont Hospital

Study title: A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Study to Assess the Efficacy, Safety, Tolerability, PK, and Biomarker Effects of PTC857 in Adult Subjects With Amyotrophic Lateral Sclerosis (CARDINALS)

Dossiers for Review: Part I and II

- **NREC-CT Decision:**

  Favourable

2022-501374-19-00 SM-1

Institution: St James's Hospital

Study title: A Multicenter, Open-label, Phase 2 Basket Study to Evaluate the Safety and Efficacy of MK-2140 as a Monotherapy and in Combination in Participants with Aggressive and Indolent B-cell Malignancies (waveLINE-006).

Dossiers for Review: Part I and II

- **NREC-CT Decision:**

  Favourable

2023-508381-16-00 SM-1

Institution: Tallaght Adult Mental Health Service, La Nua Day Hospital Mental Health Centre

Study title: A 52-Week, Open-Label Evaluation of the Long-term Efficacy and Safety of Single and Repeated Treatments with Methylone for the Treatment of PTSD IMPACT-EXT (Investigation of Methylone for Post-Traumatic Stress Disorder [PTSD])

Dossiers for Review: Part I and II

- **NREC-CT Decision:**

  Favourable

AOB: None