National Research Ethics Committee

NREC-CT A Meeting

24 May 2023

Attendance

Name	Role
Prof. Alistair Nichol	Chairperson, NREC-CT A
Dr Heike Felzmann	Deputy Chairperson, NREC-CT A
Ms. Erica Bennett	Committee Member, NREC-CT A
Mr Gerard Daly	Committee Member, NREC-CT A
Prof. Catherine Hayes	Committee Member, NREC-CT A
Ms Muireann O'Briain	Committee Member, NREC-CT A
Prof. David Brayden	Committee Member, NREC-CT A
Dr Darren Dahly	Committee Member, NREC-CT A
Prof. Gene Dempsey	Committee Member, NREC-CT A
Prof. Austin Duffy	Committee Member, NREC-CT A
Dr Geraldine Foley	Committee Member, NREC-CT A
Ms Evelyn O'Shea	Committee Member, NREC-CT A
Ms Patricia Kenny	Project Officer, National Office for RECs
Dr Jane Bryant	Programme Officer, National Office for RECs
Ms Bryony Milner	Administrative Assistant, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Dr Emma Heffernan*	Project Officer, National Office for RECs
Ms Rachel McDermott	Project Administrator, National Office for RECs

Apologies: Mr Gerald Eastwood, Prof. Tina Hickey, Prof. Mary Donnelly, Prof. John Wells, Ms Ann Twomey

Quorum for Decisions: Yes

Agenda

- Welcome & Apologies
- 2022-502548-12-00
- 2022-502684-37-00
- 21-NREC-CT-060_Mod-3
- 22-NREC-CT-155_Mod-1
- 22-NREC-CT-143_Mod-2
- 21-NREC-CT-142_Mod-3
- 22-NREC-CT-117_Mod-1
- 21-NREC-CT-162_Mod-8
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 26 April 2023 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2022-502548-12-00

Principal Investigator: Dr Ahmed Bannaga

Study title: A Phase 3 Randomized, Open-Label, Multicenter Study of Zanubrutinib (BGB 3111) Plus Anti-CD20 Antibodies Versus Lenalidomide Plus Rituximab in Patients With Relapsed/Refractory Follicular or Marginal Zone Lymphoma

EudraCT: 2022-502548-12-00

Lead institution: University Hospital Waterford

  - NREC-CT comments:
- The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.

- **NREC-CT Decision:**

- Request for more information

- Additional Information Required

Part 2

- The NREC-CT recommends that the Main PIL and GP Letter should be split into two versions, one for each subtype cohort/study arm. This would simplify all details for both participants and their GP.
- The NREC-CT requests that the sentences and wording under 'Purpose and Design' on page 2 of the Main PIL be amended for readability; for example, shorter sentences and explanation or rewording of terms such as 'efficacy and tolerability'.
- The NREC-CT requests clarification on what the current standard of care for Arm B is in Ireland, as it is stated in the Main PIL that it is approved in the US but not in Ireland.
- The NREC-CT requests re-wording of jargon on page 33 of the Main PIL, regarding transfer of data outside of the EEA.
- The NREC-CT requests that alternative treatment options are elaborated on in the Main PIL for participants that decide not to enroll in the study, including details on current Standard of Care.
- The NREC-CT requests that additional information is given in the Main PIL on the expected length and number of site visits for participants.
- The NREC-CT would like to clarify that NREC will not request participants' coded or uncoded data and requests that this be removed from section 6.7 of the Main PIL.
- The NREC-CT requests clarification on how long participants' data will be retained for if they have withdrawn from the study.
- The NREC-CT requests that details of expense reimbursement is fully communicated to participants in the Main PIL.
- The NREC-CT requests addition of a statement on page 2 of the Optional Biopsy PIL that participants will not receive the results from this biopsy.
- The NREC-CT notes the following consent option in the Withdrawal ICF "you may not contact me or my study doctor from the date of signing" and requests clarification on whether the participant's GP should be informed if the participant is withdrawing from the study.
- The NREC-CT requests further detail on what entities will have access to the baby's data, and how long this data will be retained for (Pregnant Partner PIL, page 4).
- The NREC-CT notes that Dr Bannaga's previous clinical trials experience has been as a sub-investigator, and suggests that support be available between study sites if required.

Principal Investigator: Dr Ciara O'Hanlon Brow

Study title: A Phase 1/2 First-in-Human Study of the Safety and Efficacy of IMC-F106C as a Single Agent and in Combination with Checkpoint Inhibitors in HLA-A*02:01-Positive Participants with Advanced PRAME-Positive Cancers

EudraCT: 2022-502684-37-00

Lead institution: St James's Hospital

- **NREC-CT comments:**

- The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.

- **NREC-CT Decision:**

- Request for more information

- Additional Information Required

- The NREC-CT notes the potential of false positive results for the PRAME antigen, and requests clarification on whether there is an estimate of the frequency of false positives. If available, this information should be added to the Pre-screening ICF.
- The NREC-CT notes inclusion of NHS number in the Addendum to the Main PIL documents, and requests references to the NHS are amended for Irish sites. In addition, the consent section for data collection on all ICF documents should have one set of initials for each bullet point. Any data collection that is optional should be clarified as such in these sections.
- The NREC-CT notes in the Pregnant Partner ICF that data from the participant and their baby will be published and sent to regulatory bodies, and requests clarification on what this entails.
- The NREC-CT requests that full details on what expenses will be reimbursed to participants are added to the ICF documents, in addition to details how participants can claim this money back.

21-NREC-CT-060_Mod-3

Principal Investigator: Prof Killian Hurley

Study title: Zephyrus II: A Phase 3, Randomized, Double-Blind, Placebo Controlled Efficacy and Safety Study of Pamrevlumab in Subjects with Idiopathic Pulmonary Fibrosis (IPF

EudraCT: 2020-000697-22

Lead institution: Beamont Hospital

- **NREC-CT comments:**

- The NREC-CT A Committee agreed that this application be designated as favourable with conditions.

- **NREC-CT Decision:**

- Favourable with conditions

- Conditions of Approval

- Clarification as to whether the Home Healthcare Provider service is available in Ireland.
    - If this service is available in Ireland, then details of the specific service provider need to be added to the PISCFs, including the data protection arrangements in place.
    - If this service is to be provided in Ireland, then confirmation that participants will not be out-of-pocket should they require the use of a Home Healthcare Provider is required. It needs to be explained in the PISCF that participants will not be out-of-pocket and will be reimbursed should they require the use of this service.
- That participants requiring elective orthopaedic surgery are advised to discuss possibly delaying their surgery due to participating in the trial, with their consultant orthopaedic surgeon.
- Clarification as to why results the study results will only be available to participants at the PI's discretion (pg. 19 of the PISCF).

22-NREC-CT-155_Mod-1

Principal Investigator: Prof McKone

Study title: A Phase 3, Open-label Study Evaluating the Longterm Safety and Efficacy of VX-121 Combination Therapy in Subjects With Cystic Fibrosis

EudraCT: 2021-000713-17

Lead institution: St. Vincent's Hospital

- **NREC-CT comments:**

- The NREC-CT A Committee agreed that this application be designated as favourable with conditions.

- **NREC-CT Decision:**

- Favourable with conditions

- Conditions of Approval

- That participants who do not or cannot use a smartphone are provided with an alternative means of completing electronic forms / questionnaires, such as paper-based forms, and this is detailed in the PISCF.
- That details of the alternative arrangements in place for participants who would prefer not to use the Clinicard system are explained in the PISCF.

22-NREC-CT-143_Mod-2

Principal Investigator: Prof Donal Brennan

Study title: A double-blind, randomized, placebo-controlled multicenter study to investigate efficacy and safety of elinzanetant for the treatment of vasomotor symptoms caused by adjuvant endocrine therapy, over 52 weeks in women with, or at high risk for developing hormone-receptor positive breast cancer

EudraCT: 2022-000095-18

Lead institution: Mater Misericordiae University Hospital

- **NREC-CT comments:**

- The NREC-CT A Committee agreed that this application be designated as favourable with conditions.

- **NREC-CT Decision:**

- Favourable with conditions

- Conditions of Approval

- That details of what expenses will be covered (i.e., meals, overnight accommodation etc) is clearly stated in the PISCF (only travel is referred to in the PISCF). Details of the process involved in claiming reimbursement should also be explained.
- The NREC requested clarification on the reconsenting process for current participants and when this will occur.

21-NREC-CT-142_Mod-3

Principal Investigator: Dr Jasna Pavicic Astalos

Study title: A Phase 3b Study to Evaluate the Duration of Effect of Bimatoprost SR in Participants with Open-Angle Glaucoma or Ocular Hypertension

EudraCT: 2018-002574-52

Lead institution: University College Cork

- **NREC-CT Decision:**

- Favourable

22-NREC-CT-117_Mod-1

Principal Investigator: Dr Anne Fortune

Study title: A Phase 3, Single-Arm, Open-Label, Multicenter Study to Evaluate the Safety and Efficacy of Tafasitamab Plus Lenalidomide in Participants With Relapsed or Refractory Diffuse Large B-Cell Lymphoma

EudraCT: 2021-006049-36

Lead institution: Mater Misericordiae University Hospital

- **NREC-CT comments:**

- The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.

- **NREC-CT Decision:**

- Request for more information

- Additional Information Required

- The The NREC-CT noted that the IB states that there was one death from cardiac failure related to the trail drug and recommended that participants are informed of this is the PISCF.
- The NREC-CT queried whether photographs will be taken of Irish participants in the trial (Protocol, page 72). If so, please provide a detailed explanation to participants in the PISCF.

21-NREC-CT-162_Mod-8

Principal Investigator: Prof Michaela Higgins

Study title: A Phase III, Multicenter, Randomized, Open-Label Study Comparing Atezolizumab (Anti-PD-L1 Antibody) in Combination with Adjuvant Anthracycline/Taxane-Based Chemotherapy versus Chemotherapy Alone in Patients with Operable Triple-Negative Breast Cancer

EudraCT: 2016-003695-47

Lead institution: Mater Misericordiae University Hospital

- **NREC-CT comments:**

- The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.

- **NREC-CT Decision:**

- Request for more information

- Additional Information Required

- The NREC-CT requested that the statement that NREC will be able to access personal data is removed from the PISCF as NREC will not have access to this data (pg.38 of the PISCF).
- The NREC-CT requested that the approximate number of existing participants in Ireland is provided in the PISCF.
- The NREC-CT requested clarification as to whether the trial is expected to recommence.
- The NREC-CT requested confirmation that the current submitted PISCF will be provided to and consented by the existing participants on the trial.
- The NREC-CT requested that if/when new participants are to be recruited to the trial, the intended consent form with updated risk information (including from the analysis being undertaken) will be provided for NREC review.
- The NREC-CT requested reassurance that the Medical Monitoring Assistance available to the PIs, should they require it, will be adequate, given the extent and complexity of the amendments to appendix 9 in this application.