National Research Ethics Committee

NREC-CT Meeting

14 June 2023

Attendance

Name	Role
Dr Cliona McGovern	Chairperson, NREC-CT B
Dr Jean Saunders	Deputy Chairperson, NREC CT-B
Prof. John Faul	Deputy Chairperson, NREC-CT B
Mr Philip Berman	Committee Member, NREC-CT B
Dr Enda Dooley	Committee Member, NREC-CT B
Dr Lorna Fanning	Committee Member, NREC-CT B
Dr John Hayden	Committee Member, NREC-CT B
Dr Mary McDonnell Naughton	Committee Member, NREC-CT B
Mr Gavin Lawler,	Committee Member, NREC-CT B
Ms Paula Prendeville	Committee Member, NREC-CT B
Ms Mandy Daly	Committee Member, NREC-CT B
Ms Caoimhe Gleeson	Committee Member, NREC-CT B
Ms Mandy Daly	Committee Member, NREC-CT B
Ms Susan Kelly	Committee Member, NREC-CT B
Ms Deirdre MacLoughlin	Committee Member, NREC-CT B
Dr Emily Vereker	Head, National Office for RECs
Ms Aileen Sheehy	Project Manager, National Office for RECs
Ms Rachel McDermott	Project Administrator, 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
Dr Emma Heffernan*	Project Officer, National Office for RECs

Apologies: Prof David Smith, Prof. Colm O'Donnell, Dr Eimear McGlinchey, Ms Caoimhe Gleeson, Ms Serena Bennett, Prof. Abhay Pandit, Prof Andrew Green, Dr Christina Skourou, Prof Seamus O'Reilly.

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2022-502851-79-00
- 21-NREC-CT-127_Mod-3
- 21-NREC-CT-053_Mod-4
- 21-NREC-CT-172_Mod-3
- 22-NREC-CT-164_Mod-1
- 21-NREC-CT-185_Mod-4
- 21-NREC-CT-042_Mod-6
- AOB

- The Chair welcomed the NREC-CT B.
  - The minutes from the previous NREC-CT B meeting on 23 May 2023 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2022-502851-79-00

Principal Investigator: Prof. Trevor Duffy

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

EudraCT: 2022-502851-79-00

Lead institution: Connolly Hospital

- **NREC-CT comments:**

- The NREC-CT B 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 term ‘biomarker’ is explained in the Main ICF.
- The NREC-CT requests that the optional future research is separated from the Main ICF (pg. 14) and provided to participants as a separate ICF.
- The NREC-CT requests that the reference to the NREC having access to coded data on pg. 21 of the Main ICF is removed, as the NREC does not require access to this data.
- The NREC-CT requests that it is made clearer to participants in the Main ICF that sterilization as a form of contraception is not a mandatory requirement for participation but remains optional in the Main ICF if previously performed.
- Should a participant not wish to use the Clincierge travel assistance programme, the NREC-CT requests that participants are provided with further detail in the Main ICF of alterative arrangements in place.
- The NREC-CT requests that information (if available) on safety data related to stopping the study drug / withdrawal from the study drug is added to pg. 19 of the Main ICF.
- The NREC-CT notes that photographs may be taken of participants’ injection site and requested that the rationale for this is explained in the Main ICF.
- The NREC-CT requests that details of the data protection arrangements in place for the storage of participant photos are described in the Main ICF.
- The NREC-CT requests that more detail is provided in the Main ICF on the data protection arrangements in place regarding remote monitoring. Please also state if this data will be transferred to third countries.
- The NREC-CT notes that pg. 21 of the Main ICF states that data will be stored for ‘at least 25 years’, and requests that the maximum data retention period is clearly stated in the ICF.
- The NREC-CT notes that pg. 1 of the Data Protection Notice for the Travel Assistance Programme states that data may be collected on participants’ gender, visa status and PPS. The Committee requests further information on the rationale for collection of this data.
- The NREC-CT notes that pg. 2 of the Data Protection Notice for the Travel Assistance Programme states that data may be sent to the US and requests that this is added to the consent section of the ICF (pg.24).

- The NREC-CT notes that pg. 4 of the Data Protection Notice for the Travel Assistance Programme states that 'if you do not consent to the processing of your health-related data, we will be unable to arrange wheelchair or other health-related accommodations for your transportation/lodging' and requests that this is amended in line with legislation.

21-NREC-CT-127_Mod-3

Principal Investigator: Dr Trevor Duffy

Study title: A Phase 2, Multicenter, Randomized, Double-blind, Placebo-Controlled, Study to Evaluate the Efficacy and Safety of BMS-986256 in Participants with Active Systemic Lupus Erythematosus - IM026-024

EudraCT: 2019-004021-25
Lead institution: Connolly Hospital

- **NREC-CT comments:**

- The NREC-CT B 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 noted that the tick boxes on pg.22 of the Main PISCF are not formatted correctly (tick boxes are partially duplicated) and requested that this is amended.
- The NREC-CT noted that the tick boxes on pg.25 of the Main PICSF is covering part of the text and requested that this is amended.
- The NREC-CT noted that the study insurance certificate provided does not cover the whole trial duration and requested that the insurance policy is updated to provide cover for the full duration of the study.
- The NREC-CT requested further detail is provided to participants in the PISCF regarding reimbursement of expenses, including: the process involved in submitting receipts and claiming reimbursement, whether all travel, parking and meals are included and whether overnight accommodation can be claimed, so participants are reassured that trial participation will not leave them out-of-pocket.
- The NREC-CT noted that the Study Visit Planner states that participants 'may' be reimbursed for trial related expenses and requested that this is amended to 'will' be reimbursed.

21-NREC-CT-053_Mod-4

Principal Investigator: Prof Ray McDermott

Study title: A PHASE III, DOUBLE-BLIND, MULTICENTER, RANDOMIZED STUDY OF ATEZOLIZUMAB (ANTIPD-L1 ANTIBODY) VERSUS PLACEBO AS ADJUVANT THERAPY IN PATIENTS WITH HIGH-RISK MUSCLE-INVASIVE BLADDER CANCER WHO ARE CTDNA POSITIVE FOLLOWING CYSTECTOMY

EudraCT: 2020-004418-36

- **NREC-CT comments:**

- The NREC-CT B 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 deemed that the maximum stated compensation for each trial visit is €50 which seems very low in an Irish context and may leave participants out-of-pocket. The NREC-CT requested confirmation that participants will be reimbursed for all reasonable out-of-pocket expenses. The NREC-CT requested that information is provided to participants in the PISCF regarding reimbursement of expenses, including: the process involved in submitting receipts and claiming reimbursement, whether all travel, parking and meals are included and whether overnight accommodation can be claimed, so participants are reassured that trial participation will not leave them out-of-pocket.
- The NREC-CT noted that the Surveillance PISCF is seeking blanket consent for future use of samples / data, for unspecified purposes, without further consent. This type of consent not in line with best practice, the Declaration of Taipei 2016 and not in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), where informed participant consent is a mandatory safeguard. The NREC-CT requests i) that consent for future use of samples is provided on a separate consent form and not bundled ii) is made optional, and iii) consent can only be obtained where future use of samples and data is defined such that participants are fully informed, and/or iv) that an option is provided to enable participants to consent to be contacted is provided in a separate consent form. The NREC request confirmation that subsequent research ethics review will be sought for specific research once clearly defined.

21-NREC-CT-172_Mod-3

Principal Investigator: Prof Janice Walshe

Study title: EPIK-B5: A phase III, randomized, double-blind, placebo-controlled study of alpelisib (BYL719) in combination with fulvestrant for men and postmenopausal women

with HR-positive, HER2-negative advanced breast cancer with a PIK3CA mutation, who progressed on or after aromatase inhibitor and a CDK4/6 inhibitor.

EudraCT: 2021-001966-39

Lead institution: St Vincent's University Hospital,

- **NREC-CT Decision:**

- Favourable with conditions

- **Additional conditions applied.**

- The Pg 36 of the PISCF reference made to 'Your Study Doctor will need to share some of your Personal Data (for example, your address, an email address, phone number) with people who are involved in the offsite activities as mentioned in Section 12'. The NREC-CT queried whether this is the correction section, as section 12 is not related to data protection and requested that this is clarified and corrected.
- The NREC -CT requested that the patient number is redacted or removed from pg. 29, 31, 33, 35 and 37 of the PISCF.
- The NREC-CT noted that pg. 6/7 of the PISCF has an added refence to gender, age and race being collected to section on molecular pre-screening, but removed from general section on screening period and requested that this is clarified and corrected.

22-NREC-CT-164_Mod-1

Principal Investigator: Dr Patrick Hayden

Study title: A Phase 3, Two-Stage, Randomized, Multicenter, OpenLabel Study Comparing Cc-92480, Bortezomib And Dexamethasone (480vd) Versus Pomalidomide, Bortezomib And Dexamethasone (Pvd) In Subjects With Relapsed Or Refractory Multiple Myeloma (RRMM)

EudraCT: 2021-001957-30

- **NREC-CT Decision:**

- Favourable with conditions

- **Additional conditions applied.**

- The NREC-CT requested that the updated text on p.24 regarding 'additional important precautions' in the PISCF, also includes advice to participants to contact the study team or their GP if this exposure occurs, and they have concerns they would like to discuss.

- The NREC-CT noted that the genetic testing section has been edited to remove open ended studies and requested the rationale for this.

21-NREC-CT-185_Mod-4

Principal Investigator: Dr Beatrice Nolan

Study title: ATLAS-OLE: An Open-label, Long-term Safety and Efficacy Study of Fitusiran in Patients with Hemophilia A or B, with or without Inhibitory Antibodies to Factor VIII or IX

EudraCT: 2018-002880-25

- **NREC-CT Decision:**

- Favourable

21-NREC-CT-042_Mod-6

Principal Investigator: Dr Ronan Desmond

Study title: A Phase 3, Multicenter, Randomized, Double-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy and the Safety of Efgartigimod (ARGX-113) PH20 Subcutaneous in Adult Patients With Primary Immune Thrombocytopenia

EudraCT: 2020-004032-21

- **NREC-CT Decision:**

- Favourable