National Research Ethics Committee

NREC-CT B Meeting

15 March 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
Ms Serena Bennett	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
Prof. Colm O'Donnell	Committee Member, NREC-CT B
Ms Mandy Daly	Committee Member, NREC-CT B
Prof Andrew Green	Committee Member, NREC-CT B
Ms Susan Kelly	Committee Member, NREC-CT B
Ms Deirdre MacLoughlin	Committee Member, NREC-CT B
Dr Emily Vereker	Acting Head, National Office for RECs
Dr Jane Bryant	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Dr Emma Heffernan*	Project Officer, National Office for RECs
Dr Joan Devin	HRB Postdoctoral Intern

Ms Rachel Kenny	Project Administrator, National Office for RECs
Ms Bryony Milner	Administration Assistant, National Office for RECs

*Drafted minutes

Apologies: Dr Eimear McGlinchey, Prof Abhay Pandit, Dr Mark Robinson, Prof Seamus O'Reilly, Ms Caoimhe Gleeson, Mr Philip Berman, & Dr Christina Skourou

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2022-501576-25-00
- 2022-500758-41-00
- 2022-502921-16-00
- 2022-502202-33-00
- AOB

- The Chair welcomed the NREC-CT B.
  - The minutes from the previous NREC-CT B meeting on 08 February 2022 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2022-501576-25-00

Principal Investigators and Institutions: Prof. John Crown (St Vincent's University Hospital), Prof. Paul Donnellan (University Hospital Galway), Prof. Jarushka Naidoo (Beaumont Hospital), Dr Derek Power (Cork University Hospital)

Study title: A Phase 3 Trial of Fianlimab (anti-LAG-3) and Cemiplimab versus Pembrolizumab in the Adjuvant Setting in Patients with Completely Resected High-risk Melanoma

EudraCT: 2022-501576-25-00

- 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
- **Part 2 Considerations**
- The NREC-CT wishes to commend the applicants on a well-presented study. The NREC-CT requests that the language in the Assent Form for 12-17 year-old participants be made more accessible for this age group, which currently is not sufficiently edited from the adult/parent forms.
- The NREC-CT requests clarification on whether adolescents will be recruited to this study in Ireland, and if so, to clarify the pathway of care for this participants group given there are no paediatric sites or paediatricians included in the submission.

2022-500758-41-00

Principal Investigators and Institutions: Prof. Orla Hardiman (St James's Hospital)

Study title: A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Multiple Ascending Dose Study to Evaluate the Safety and Tolerability of QRL201 in Amyotrophic Lateral Sclerosis

EudraCT: 2022-500758-41-00

- 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
- **Part 1 Considerations**
- The Sponsor is asked to give further rationale for use of a placebo in this study, given the Phase I status of the study. Additionally, the EC requires further rationale on the use of placebo control for lumbar puncture, given participant burden based on the frequency, invasive nature and discomfort.
- The MHRA scientific advice states that an open label design could be acceptable provided that sound rationale is provided, the EC requests further information on the choice of the current design.
- The Sponsor is asked to give further information on safeguards that are in place for administration of the higher dose ranges of the IMP, further information on the choice of doses, given they are based on animal studies at lower doses
- **Part 2 Considerations**

- The NREC-CT notes that potential participants will need to understand English, and requests clarification if a translator will be made available for non-English speakers (Section 1.8).
- The NREC-CT noted that the PISCF for Future Scientific Research is seeking blanket consent for future / additional use of samples / data, for unspecified purposes, without further consent. This type of consent is 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 in a separate consent form.
- The NREC-CT notes that the use of the term 'leftover samples' is not appropriate and requests that this wording be amended to 'remaining samples' in the FSR PISCF, and other participant-facing material as required.
- The NREC-CT notes that recall of samples sent to third parties is not possible if the participant withdraws their consent for their use, and requests that this be enabled if consent is withdrawn. If this is not possible, a strong justification must be provided.
- The NREC-CT requests further information is given in the Pregnancy Follow Up PISCF, on the length of time that pregnant participants/ partners will be followed up for.

2022-502921-16-00

Principal Investigators and Institutions: Prof Niamh O'Connell (St James's Hospital), Dr Beatrice Nolan (CHI Crumlin)

Study title: An 18-month low-interventional prospective, multicentre study to assess joint outcomes in patients with haemophilia A or B on prophylaxis with efmoroctocog alfa or eftrenonacog alfa JOIN-us

EudraCT: 2022-502921-16-00

- 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

- **Part 2 Considerations**

- The NREC-CT wishes to commend the applicants on a well-presented study. The NREC-CT requests that the language in the Assent Form for 6-12 year-olds be made more accessible for this age group, with the addition of lay terms and visuals to aid in comprehension

2022-502202-33-00

Principal Investigators and Institutions: Dr Ciara McDonnell (CHI Temple St)

Study title: A Phase 2, Multicenter, Long-Term, Open Label Extension Trial Evaluating Safety, Tolerability, and Efficacy of Subcutaneous Doses of TransCon CNP Administered Once Weekly in Children and Adolescents with Achondroplasia

EudraCT: 2022-502202-33-00

- 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

- **Part 2 Considerations**

- The NREC-CT requests that a separate PIS and ICF is generated for a pregnant partner, as a parent could not sign an informed consent form for collection of data on a pregnant partner, only for data on their own child.

- The NREC-CT notes that both the participant's name and ID number will be present on the Parental ICF, and requests that the ID number be removed or redacted, such that this document does not create a linking sheet.

- The NREC-CT notes that there is a discrepancy in the information on the future use of biological samples between the Parental ICF and the ICF for participants reaching the age of consent. The NREC-CT requests clarification on what the samples will be used for (e.g. ACH research only, or related diseases) and that this is consistent across both documents.

- The NREC-CT requests clarification on whether a GP Letter will be used, and if so, that it be submitted for review.

- AOB: