NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-CT B

2nd June 2021

Attendance

Name	Role
Dr Cliona McGovern	Chairperson, NREC CT-B
Prof John Faul	Deputy Chairperson, NREC-CT B
Dr Jean Saunders	Deputy Chairperson, NREC-CT B
Ms Serena Bennett	Committee Member, NREC-CT B
Mr Philip Berman	Committee Member, NREC-CT B
Ms Mandy Daly	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
Mr Gavin Lawler	Committee Member, NREC-CT B
Dr Mary McDonnell Naughton	Committee Member, NREC-CT B
Dr Eimear McGlinchey	Committee Member, NREC-CT B
Prof Colm O'Donnell	Committee Member, NREC-CT B
Prof Abhay Pandit	Committee Member, NREC-CT B
Ms Paula Prendeville	Committee Member, NREC-CT B
Dr Mark Robinson	Committee Member, NREC-CT B
Prof David Smith	Committee Member, NREC-CT B
Ms Aileen Sheehy*	Programme Manager, National Office for RECs
Dr Jane Bryant*	Project Officer, National Office for RECs
Dr Jennifer Ralph James	Head, National Office for RECs

*Drafted minutes

Apologies: Ms Caoimhe Gleeson

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- Application 21-NREC-CT-001
- Application 21-NREC-CT-002
- Application 21-NREC-CT-003
- AOB

- The Chair welcomed the NREC-CT B.
  - There were no Declarations of interest declared for the Applications for Review.

Applications

21-NREC-CT-001

Principal Investigator: Prof. Ray McDermott

Study title: Phase Ib/II Trial of Pembrolizumab (MK-3475) Combination Therapies in Metastatic Castration-Resistant Prostate Cancer (mCRPC) (KEYNOTE-365)

Lead institution: Tallaght University Hospital, Dublin 24

  - NREC-CT comments:
- The NREC-CT B noted that the clinical trial application represents a Phase Ib/II study unblinded open-label trial of pembrolizumab combination therapies in metastatic castrate resistant prostate cancer.
- The NREC-CT B acknowledged that while the Participant Information Leaflet (PIL) was long, it was comprehensive. The NREC-CT B noted that a summary PIL is also available.
- The NREC-CT B observed that genetic information may be processed as part of this study however it was not clear to the Committee what participants were consenting to in relation to genetic analyses.

- The NREC-CT B agreed that while some clarifications across the documentation were required, this application can be designated as Favourable with Conditions.

  - NREC-CT Decision:

- Favourable with Conditions

  - Associated Conditions:

- The NREC-CT B requested that the applicant explains the distinction between the Participant Information Leaflet and the summary Participant Information Sheet, and how each document will be used as part of the research participant recruitment process.
- The NREC-CT B suggested that the Participant Information Leaflet may benefit from removing definitions and complex information from the main body of the main PIL and adding as appendix at the end of the document.
- The NREC-CT B made a number of suggestions to the enhance the information available in the PIL.
- The NREC-CT B requested that the details of genetic analysis and any future use of genetic information are clearly outlined as part of the consent process.
- The Committee requested that country locations of data transfer are included in the consent form.
- The NREC-CT B noted that recruitment may take place over the telephone. The Committee requested explanation of why recruitment through the clinic would not always be possible as this would be a preferable option.
- The NREC-CT B suggested that the DPIA should include information around data relevant to sexual activity.
- The Committee requested further information in relation to pseudonymisation.
- The NREC-CT B acknowledged that funding is secured for the study but requests further details around the funding that is in place for this study.
- The NREC-CT B notes that while the indemnity details are provided, the length of the study surpasses the date of the insurance policy. The Committee requests that applicant clarify this discrepancy between study length and policy cover.

21-NREC-CT-002

Principal Investigator: Prof. Orla Hardiman

Study title: A Phase 3, Multi-Centre, Double-Blind, Randomised, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Reldesemtiv in Patients with Amyotrophic Lateral Sclerosis (ALS)

Lead institution: Beaumont Hospital, Dublin 9

- NREC-CT Comments:

- The NREC-CT B noted that the clinical trial application represents a Phase 3 study to assess the effect of reldesemtiv versus placebo on physical abilities in ALS patients.
- The NREC-CT B noted that while the Patient Information Leaflet (PIL) is long, it is also comprehensive.
- The NREC-CT B acknowledged the addition of optional genetic testing for participants, however some further clarification on this part of the study is required.
- The NREC-CT B agreed that while clarifications and recommendations have been made across the documentation, this application can be designated as Favourable with Conditions.

- NREC-CT Decision:

- Favourable with Conditions

- Associated Conditions:

- The NREC-CT B sought assurance that the information in the Patient Information Leaflet will be verbally explained to the participant in addition to providing the PIL.
- The Committee requested that the applicant clarify the withdrawal process.
- The NREC-CT B requested that complex terminology is explained in the PIL.
- NREC-CT B requested clarity around what the broad consent will be used for. The NREC-CT B suggested a more layered approach to consent is more appropriate.
- The NREC-CT B requested further detail on the genetic testing. The NREC-CT B also requested that further information around the genetic testing is included in the PIL and consent around genetic testing is adequately elucidated for the participant.
- The NREC-CT B sought assurance that the DPO has had an opportunity to review and comment on the DPIA.
- The NREC-CT B noted that IMB is used in the documents. This should be amended to the HPRA.
- The NREC-CT B requested that the HPRA decision, if completed, is shared with the Committee.

21-NREC-CT-003

Principal Investigator: Dr Orla Killeen

Study title: An Open-label, Sequential, Ascending, Repeated Dose-finding Study of Sarilumab, Administered with Subcutaneous (SC) Injection, in Children and Adolescents, Aged 1 to 17 Years, with Systemic Juvenile Idiopathic Arthritis (sJIA), Followed by an Extension Phase

Lead institution: Children's Health Ireland at Crumlin, Dublin 12

- NREC-CT Comments:

- The NREC-CT B noted that the clinical trial application represents a Phase IIB study to describe the pharmacokinetic profile of sarilumab in patients aged 1-17 years with Systemic Juvenile Idiopathic Arthritis.
- The NREC-CT B noted that although substantial information is included around the various cohorts, additional information would be welcome for the cohort of 1-5 years.
- The NREC-CT B agreed that the Patient Information Leaflet would benefit from adjusting some of the language used in the participant materials.
- The NREC-CT B noted that there is an increased risk of infection, however no reference is made to any potential increased risk of COVID infection.
- The NREC-CT B agreed that further information and clarity are required before a final decision can be made.

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required:

- The NREC-CT B requested further explanation for the inclusion of the 1-5 years cohort in the study.
- The NREC-CT B requested clarity around the withdrawal process.
- The NREC-CT B requested further information around the arrangements in place to undertake recruitment outside of the specified site.
- The NREC-CT B requested that the language is simplified in patient-interfacing materials relevant to the specific cohorts.
- The NREC-CT B requested that the patient materials are reviewed, and any potentially coercive language or imagery, including by omission, is rectified.
- The NREC-CT B requested that all participant materials are reviewed and amended to ensure consistency where appropriate across the cohorts.
- The NREC-CT B requested that further information around genetic research is included in the participant materials, particularly around the future use of genetic data.
- The NREC-CT B suggested that more gender-neutral language is incorporated into the PIL.
- The NREC-CT B noted that the protocol requires participants not receive additional injections for the duration of the study. The NREC-CT B requested further explanation of this limitation, particularly in view of the ongoing COVID vaccine rollout.
- The NREC-CT B requested further clarity around COVID-19 infection risks.
- The NREC-CT B requested clarity around the duration of the study.

- The NREC-CT B requested further information around financial arrangements in place to cover costs of the study.
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- AOB:
  - The NREC-CT B sought clarification from the National Office regarding outcome reporting following requests for further information.
  - Clarification was sought by the Committee regarding the role of the DPIA and evidence of DPO review.
  - The NREC-CT B suggested some amendments to the NREC Assessment Report Template.
  - The NREC-CT B discussed their role in the assessment of Adverse Events.
  - Guidance on Applicant descriptions of genetic and genomic testing were discussed.

- The Chair closed the meeting.