NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-CT B

7th July 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
Ms Caoimhe Gleeson	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: Prof Colm O'Donnell

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- Application 21-NREC-CT-011
- Application 21-NREC-CT-012
- Application 21-NREC-CT-013
- Application 21-NREC-CT-014
- AOB

- The Chair welcomed the NREC-CT B.
  - Ms Lorna Fanning declared a conflict of interest for Application 21-NREC-CT-013 and did not attend the review of this application.
  - The Minutes from the NREC-CT B meeting on 2nd June 2021 were approved.

Applications

21-NREC-CT-011

Principal Investigator: Dr Jarushka Naidoo

- Study title: A phase III, multicenter, randomized, double blind, placebo-controlled study evaluating the efficacy and safety of canakinumab versus placebo as adjuvant therapy in adult subjects with stages AJCC/UICC v. 8 II-IIIA and IIIB (T>5cm N2) completely resected (R0) non-small cell lung cancer (NSCLC)

Lead institution: St. Vincent's University Hospital, Dublin 4

  - NREC-CT comments:
- The NREC-CT B noted that the clinical trial application represents a Phase III study investigating the anti-inflammatory therapy canakinumab in a placebo-controlled trial for treatment of non-small cell lung cancer.

- The NREC-CT B acknowledged that while there were some inconsistencies across documents, the language in the patient-facing materials was largely understandable and procedures well explained.
- 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 considered the Participant Information Leaflet to be comprehensive in general, but requested that further information on the participant follow-up is provided in the information materials. The Committee also strongly recommended that a 'layered' approach to consent is used.
- The NREC-CT B requested that it is clear to the participant what they are consenting to in relation to the transfer and use of their personal data, including explicitly describing the countries or jurisdictions that data may be transferred to, and which 'third parties' may have access to the data. The Committee also suggested that a hard copy of the data protection policy should be made available on request.
- The NREC-CT B requested that there is consistency across the documentation on how the drawing of blood is described, and requested further clarity on the risk of infection as described in the PIL.
- The NREC-CT B requested that the biomarker consent form is amended to clearly outline what happens to the participants' data after they withdraw from the study. The Committee also requested explanation for the rationale for the exclusion of a 'represented person' in the withdrawal process.
- The NREC-CT B requested that the applicant provides additional information on the facilities available at the site to support this study.

21-NREC-CT-012

Principal Investigator: Dr Amjad Hayat

- Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tafasitamab Plus Lenalidomide in Addition to Rituximab Versus Lenalidomide in Addition to Rituximab in Patients With Relapsed/Refractory (R/R) Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma

Lead institution: Galway University Hospital

- NREC-CT Comments:

- The NREC-CT B noted that the clinical trial application represents a Phase 3 placebo-controlled study to assess the effects of tafasitamab in combination with lenalidomide and rituximab for treatment of follicular lymphoma.
- The NREC-CT B noted that this was a well prepared study with an excellent level of information.
- 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 strongly recommended that a person other than the consultant involved in the study would lead on the recruitment of the participants, and requested further information around the timeframe that the potential participant has to consider involvement in the study before deciding.
- The NREC-CT B requested further information around the plans to support decision-making capacity should a participant be diagnosed with secondary malignancies of the brain.
- The NREC-CT B requested that the transfer of data is clearly outlined in the participant materials, and it is clear to the participant what they are consenting to in relation to the transfer and use of personal data. The Committee also requested confirmation on whether MOUs are in place between the various organisations for the transfer of data.
- The NREC-CT B requested that the Data Protection Impact Assessment is updated to reflect routine transfer of data outside of Ireland and requests assurance that participants will be clearly informed on what will happen with their personal data.

21-NREC-CT-013

Principal Investigator: Dr Patrick Hayden

- Study title: A Phase 3, Randomized, Multicenter, Open-label Study Comparing Iberdomide, Daratumumab and Dexamethasone (IberDd) versus Daratumumab, Bortezomib, and Dexamethasone (DVd) in Subjects with Relapsed or Refractory Multiple Myeloma (RRMM)

Lead institution: St James' Hospital, Dublin 8

  - NREC-CT Comments:

- The NREC-CT B noted that the clinical trial application represents a Phase III study to compare the effect of two chemotherapy regimens for treatment of multiple myeloma.
- The NREC-CT B noted that while the PIL is comprehensive and well-constructed, it is long and would benefit from a summary and appendix.
- 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 clarity on who determines the participants' tolerance to the treatment in regards to continuation of therapy.
- The NREC-CT B requested that the applicant amends the open-ended consent statement to offer participants a more suitable and informed option for future use of their samples and data.
- The NREC-CT B suggested that the Patient Information Leaflet (PIL) and the Informed Consent Form be separated into two separate documents, and requested that a plain English executive summary is included at the beginning of the PIL.
- The NREC-CT B requested further information on the options available to participants if they become pregnant during the trial and what expenses would be covered in this event.
- The NREC-CT B requested further information on the personnel capacity and the facilities available at the various sites in Ireland related to the trial. The Committee also requested confirmation that site education and policies will be in place to ensure safe handling of iberdomide by study site staff.
- The NREC-CT B requested further information on how participants will be reimbursed for expenses.
- The NREC-CT B requested confirmation that adequate insurance cover is in place for Irish participants.
- The NREC-CT B requested justification for the duration of the retention of the biological samples and related data, and further information on who in the research team will have access to participant personal information and on the contractual clauses that will be implemented to protect use of participants' data.

21-NREC-CT-014

Principal Investigator: Professor Sean Raymond McDermott

- Study title: An Open-label, Randomized, Phase 3 Study of MK-6482 in Combination with Lenvatinib (MK-7902) vs Cabozantinib for Second-line or Third-line Treatment in Participants with Advanced Renal Cell Carcinoma Who Have Progressed After Prior Anti-PD-1/L1 Therapy

Lead institution: Tallaght University Hospital, Dublin 24

- NREC-CT Comments:

- The NREC-CT B noted that the clinical trial application represents a Phase III study to compare the combination therapy of MK-6482 and MK-7902 with cabozantinib for treatment of renal cell carcinoma.
- The NREC-CT B noted that while the PIL is comprehensive, it is in places difficult to read and would benefit from a summary and appendix.
- 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 explanation of how incidental findings of the proposed genetic testing will be managed.
- The NREC-CT B requested clarity on the age cohorts included in this study.
- The NREC-CT B requested that a plain English executive summary of the salient points of the study is included at the beginning of the PIL, and that the side-effects of the treatment and survival follow-up are further elucidated in the PIL. The Committee also requested confirmation that the participants information will not be used in future studies without further consent.
- The NREC-CT B requested further information on how participants will be reimbursed for their expenses.
- The NREC-CT B requested confirmation that adequate insurance cover is in place for Irish participants.
- The NREC-CT B requested further information on the personnel capacity and the facilities available at the various sites in Ireland related to the trial.
- The NREC-CT B requested justification for the duration of the retention of data, clarity on whether MOUs will be in place for the transfer of data between the various organisations, and further information on the protections in place when transferring data to countries with potentially weaker data protection requirements.

- AOB:

- The NREC-CT B sought clarification from the National Office on operational queries.

- The National Office advised the Committee that further guidelines relating to Conflicts of Interest are in preparation.
- The NREC-CT B requested that Applicants are encouraged to use the NREC Application Form when submitting their application.

- The Chair closed the meeting.