National Research Ethics Committee

NREC-CT B

23rd of March 2022

Attendance

Name	Role
Dr Cliona McGovern	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
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
Dr Eimear McGlinchey	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
Ms Caoimhe Gleeson	Committee Member, NREC-CT B
Prof. Abhay Pandit	Committee Member, NREC-CT B
Prof. John Faul	Committee Member, NREC-CT B
Dr Mark Robinson	Committee Member, NREC-CT B
Ms Aileen Sheehy*	Programme Manager, National Office for RECs
Dr Laura Mackey*	Project Officer, National Office for RECs
Patricia Kenny	Project Officer, National Office for RECs

NREC Meeting Minutes

*Drafted minutes

Apologies:

Prof. David Smith,

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- Application 22-NREC-CT-062
- Application 21-NREC-CT-161_AMEND-1
- Application 21-NREC-CT-163_AMEND-1
- Application 21-NREC-CT-164_AMEND-1
- Application 21-NREC-CT-092_AMEND-2
- Application 21-NREC-CT-166_AMEND-1
- AOB

- The Chair welcomed the NREC-CT B.
  - The Minutes from the NREC-CT B meeting on the 23rd of February were approved.
  - One Conflict of Interest was noted by a Committee member who recused themselves from the review of that application.

Commented [LM1]: Necessary?

Applications

22-NREC-CT-062

Principal Investigator: Dr Jarushka Naidoo

Study title: A Phase 2 Trial of MRTX849 Monotherapy and in Combination with Pembrolizumab in Patients with Advanced Non-Small Cell Lung Cancer with KRAS G12C Mutation

Lead institution: Beaumont Hospital

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a Phase 2 Trial of MRTX849 Monotherapy and in Combination with Pembrolizumab in Patients with Advanced Non-Small Cell Lung Cancer with KRAS G12C Mutation.
- The NREC-CT B agreed that additional information was required to inform its deliberations and therefore, was not yet in a position to return a final ethics decision.

  - NREC-CT Decision:

- Request for Further Information

  - Additional Information Required

- The NREC-CT B noted that the process for withdrawal has not been adequately completed under D7 of the application form and requested that this is amended.
- The NREC-CT B considered that identifying suitable participants via chart review or through multidisciplinary team meetings may be a breach of participant's confidentiality and requested clarification as to how precisely potential participants in Ireland would be identified and who would first approach potential participants about the trial. The Committee also requested clarification as to who would be on the participant's direct care team.
- The NREC-CT B considered that the content in the Participant Information Leaflets was too complex for a lay audience and requested they were revised to ensure accessibility for all participants. The Committee also requested that a brief plain English executive summary of the salient points of the study was included at the beginning of the PIL, outlining the aim of the study.
- The NREC-CT B noted that the participant materials may not adequately address the risk that some participants in the TPS<1% category may not receive pembrolizumab and requested that the materials are amended to ensure clarity around this point.
- The NREC-CT B considered that the information provided to participants on false positives to be limited and requested that this was sufficiently explained in the participant materials.
- The NREC-CT B noted that participant materials make reference to 'UK GDPR' and requested that this was amended.
- The NREC-CT B requested further clarification around the logistics of access to MUGA scans, specifically if some participants would need to travel to access these scans and if reasonable expenses for this travel would be covered. This information should also be captured in the participant materials where necessary.
- As the term 'genetic testing' has potential implications for the insurance cover of study participants, the NREC-CT B requested that this term is replaced with molecular marker testing in line with the rationale for this testing.
- The NREC-CT B requested that comprehensive CVs for the site investigators would be submitted as part the response to the request for further information.

- The NREC-CT B notes that the insurance policy would not cover the full duration of the trial and requested confirmation that adequate insurance cover would be in place for the full duration of the trial.
- Due to the volume of visits and scans included as part of the study, the NREC-CT B considered that the reimbursement of only travel expenses is inadequate and may create inclusion bias in the recruitment of participants. The Committee requested that all reasonable expenses for both participants and their carers would be covered as part of participation in the trial.
- The NREC-CT B considered that the future use of biological samples collected as part of the pre-screening process was inappropriate and requested that this was removed from the pre-screening consent form.
- For samples collected from trial participants, the NREC-CT B noted the consent process for the future use of biological samples and data was not in line with national regulations on 'explicit consent' (the Health Research Regulations 2018) and requested that the applicant provides the participant with specific choices as to how their samples and data would be used for future purposes, such as limiting future use to a specific disease area.
- Further to the above, NREC-CT B requested confirmation that any future research project using samples or data from participants involved in this study would undergo full ethics review. This should also be captured in the participant materials.
- The NREC-CT B requested that consent for future biomedical research is separated out from the main consent form.

21-NREC-CT-161_AMEND-1

Principal Investigator: Professor Chris McGuigan

Study title: An open-label, single-arm 4-year study to evaluate effectiveness and safety of ocrelizumab treatment in patients with progressive multiple sclerosis

Lead institution: St Vincent's University Hospital

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a substantial amendment to an open-label, single-arm 4-year study to evaluate effectiveness and safety of ocrelizumab treatment in patients with progressive multiple sclerosis.
- The NREC-CT B noted the large number of changes included in this submission.
- The NREC-CT B agreed that additional information was required to inform its deliberations and therefore, was not yet in a position to return a final ethics decision.

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required:

- The NREC-CT B noted the addition of a lumbar puncture as part of the cerebrospinal fluid biomarker analysis but considered that the justification provided was limited and requested additional information for the inclusion of this invasive procedure. They also requested that the participant materials were amended to further highlight the justification for the process and to further explain the risk of this optional procedure.
- In relation to the CSF sampling, the NREC-CT B noted that the current language used may be misleading and personal benefit may be implied. The Committee requested that the text was amended to ensure that participants are fully informed that no personal benefit would be derived from participating in this aspect of the trial.
- The NREC-CT B requested that the following text is moved to the section on Future Biomedical Research: 'Blood samples collected during the study may be used for research related to multiple sclerosis, common pathways (links) among diseases, the use of ocrelizumab in disease therapy, and/or the development of tests or tools that help with detecting or understanding multiple sclerosis'.

21-NREC-CT-163_AMEND-1

Principal Investigator: Dr Derek Power

Study title: A Randomized, Placebo-Controlled, Double-Blind Study of Adjuvant Cemiplimab Versus Placebo After Surgery and Radiation Therapy in Patients with High Risk Cutaneous Squamous Cell Carcinoma

Lead institution: Mercy University Hospital, Cork

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a substantial amendment to a Randomized, Placebo-Controlled, Double-Blind Study of Adjuvant Cemiplimab Versus Placebo After Surgery and Radiation Therapy in Patients with High Risk Cutaneous Squamous Cell Carcinoma.
- The NREC-CT B commented that a number of changes were included in this amendment.
- The NREC-CT B agreed that additional information was required to inform its deliberations and therefore, was not yet in a position to return a final ethics decision.

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required:

- The NREC-CT B noted that the information in the CV of the Study Investigator was submitted was limited and not up to date and requested that a more comprehensive and up to date version of the CV is submitted.
- The NREC-CT B noted that consent for the main study and the 2 sub-studies have been bundled together and requested that the consent for the 2 sub-studies was separated out from the consent for the main trial.

21-NREC-CT-164_AMEND-1

Principal Investigator: Dr Glen Doherty

Study title: A Phase 3 Long-term Safety Extension Study of SHP647 in Subjects with Moderate to Severe Ulcerative Colitis or Crohn's Disease (AIDA)

Lead institution: St Vincent's University Hospital

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a substantial amendment to a Phase 3 Long-term Safety Extension Study of SHP647 in Subjects with Moderate to Severe Ulcerative Colitis or Crohn's Disease (AIDA).
- The NREC-CT B commented this a was a straightforward substantial amendment application.
- Based on the above, the NREC-CT B agreed that this substantial amendment application be designated as favourable.

- NREC-CT Decision:

- Favourable

21-NREC-CT-092_AMEND-2

Principal Investigator: Professor Maeve Lowery

Study title: A Phase III, Randomized, Double-blind Trial Comparing Trastuzumab Plus Chemotherapy and Pembrolizumab With Trastuzumab Plus Chemotherapy and Placebo as First-line Treatment in Participants With HER2 Positive Advanced Gastric or Gastroesophageal Junction Adenocarcinoma (KEYNOTE 811)

Lead institution: St James's Hospital

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a substantial amendment to a Phase III, Randomized, Double-blind Trial Comparing Trastuzumab Plus

Chemotherapy and Pembrolizumab With Trastuzumab Plus Chemotherapy and Placebo as First-line Treatment in Participants With HER2 Positive Advanced Gastric or Gastroesophageal Junction Adenocarcinoma (KEYNOTE 811).

- The NREC-CT praised the accessibility of the documentation included in this application.
- Based on the above, the NREC-CT B agreed that this substantial amendment application be designated as favourable.

- NREC-CT Decision:

- Favourable

21-NREC-CT-166_AMEND-1

Principal Investigator: Dr Emer Hanrahan

Study title: A Randomized, Double-Blind, Phase III Study of Platinum+ Pemetrexed Chemotherapy with or without Pembrolizumab (MK-3475) in First Line Metastatic Non-squamous Non-small Cell Lung Cancer Subjects (KEYNOTE-189)

Lead institution: St Vincent's University Hospital

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a substantial amendment to a A Randomized, Double-Blind, Phase III Study of Platinum+ Pemetrexed Chemotherapy with or without Pembrolizumab (MK-3475) in First Line Metastatic Non-squamous Non-small Cell Lung Cancer Subjects (KEYNOTE-189).
- The NREC-CT praised the overall quality and clarity of the submission.
- Based on the above, the NREC-CT B agreed that this substantial amendment application be designated as favourable.

- NREC-CT Decision:

- Favourable

- AOB:

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- The Chair closed the meeting.