National Research Ethics Committee

NREC-CT B

26th of January 2022

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
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
Dr Mary McDonnell Naughton	Committee Member, NREC-CT B
Dr Eimear McGlinchey	Committee Member, NREC-CT B
Prof. Abhay Pandit	Committee Member, NREC-CT B
Mr Gavin Lawler,	Committee Member, NREC-CT B
Dr Mark Robinson	Committee Member, NREC-CT B
Prof. David Smith	Committee Member, NREC-CT B
Ms Paula Prendeville	Committee Member, NREC-CT B
Ms Caoimhe Gleeson	Committee Member, NREC-CT B
Prof. Colm O'Donnell	Committee Member, NREC-CT B
Ms Aileen Sheehy*	Programme Manager, National Office for RECs
Dr Laura Mackey*	Project Officer, National Office for RECs

Dr Marta Pisarska	Postdoctoral Intern, National Office for RECs

*Drafted minutes

Apologies:

None

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- Application 22-NREC-CT-010
- Application 22-NREC-CT-011
- Application 22-NREC-CT-012
- Application 22-NREC-CT-013
- AOB

- The Chair welcomed the NREC-CT B.
  - The Minutes from the NREC-CT B meeting on the 8th if December were approved.
  - The Chair raised organisational associations with some of the investigators involved in studies due to be reviewed but declared they did not have any professional or personal connection to these investigators. The Committee considered that did not classify this as a conflict of interest.

Applications

22-NREC-CT-010

Principal Investigator: Professor Sean Raymond McDermott

Study title: A Multicenter, Double-blind, Randomized Phase 3 Study to Compare the Efficacy and Safety of Belzutifan (MK-6482) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab, in the Adjuvant Treatment of Clear Cell Renal Cell Carcinoma (ccRCC) Post Nephrectomy (MK-6482-022)

Lead institution: Tallaght University Hospital

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a Multicenter, Double-blind, Randomized Phase 3 Study to Compare the Efficacy and Safety of Belzutifan (MK-6482) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab, in the Adjuvant Treatment of Clear Cell Renal Cell Carcinoma (ccRCC) Post Nephrectomy.
- The NREC-CT B commented positively on a number of areas of this application, in particular the quality and accessibility of the participant materials.
- 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 a number of recruitment materials would be used as part of the study and sought further information on the procedures in place for handling responses to the recruitment campaign.
- The NREC-CT B requested that the additional step for participants to submit a separate request withdrawing their consent from the Future Biomedical Research (FBR) is further elucidated in the main Participant Information Leaflet (PIL).
- The NREC-CT B noted a number of discrepancies in the FBR PIL and requested that this document is revised to reflect that only left-over samples will be used as part of these studies, and that no direct harm would come to participants.
- The NREC-CT B noted that the relevant section in the application on participants lacking capacity has not been completed and requested that this section is completed, not least to provide justification for the exclusion of this cohort from the study.
- The NREC-CT B requested confirmation that both samples and the associated data transferred outside of the EEA will be stored and processed in line with EU regulations, and that it is captured in the participant materials.
- The NREC-CT B requested further information related to financial disclosures.
- The NREC-CT B requested a more detailed CV for Prof. McDermott is submitted.
- The NREC-CT B also requested that the CVs of the site PIs are submitted for review.
- Due to the high volume of additional scans as part of the project, the NREC-CT B requested that the Ionising Radiation appendix form is completed for this study and is signed by a Radiologist or Radiation Oncologist independent of the trial.
- The NREC-CT B noted that the insurance policy does not cover the duration of the trial and sought assurance from the applicant that the trial will be fully insured for the entire duration of the study.

22-NREC-CT-011

Principal Investigator: Professor Austin Duffy

Study title: PaTcH Trial: A phase 2 study to explore primary and emerging resistance mechanisms in patients with metastatic refractory Pancreatic cancer treated with Trametinib and Hydroxychloroquine

Lead institution: Mater Misericordiae University Hospital

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a phase 2 study to explore primary and emerging resistance mechanisms in patients with metastatic refractory Pancreatic cancer treated with Trametinib and Hydroxychloroquine.
- The NREC-CT B praised the quality and accessibility of the participant materials.
- 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 participants may be referred to the trial from other sites. The Committee requested further information on the process in place to inform doctors and potential participants about the study outside of the trial sites listed and additional procedures for recruitment and transfer.
- The NREC-CT B considered it unnecessary that the provision for consent includes an option for participants to provide consent for access to participant data and requested that it is removed from the PIL/ICF.
- The NREC-CT B advised that some of the terms used within the PIL could be simplified further to plain English.
- The NREC-CT B requested confirmation that when personal data is transferred outside of the EEA, a Memorandum of Understanding will be in place to ensure data will be processed and stored in line with GDPR. The Committee also requested that the Participant Information Leaflet specifies the jurisdictions where data will be transferred to.
- The NREC-CT requested CVs for both Prof. McDermott and Prof. Kolch.

22-NREC-CT-012

Principal Investigator: Dr Mark Doherty

Study title: A Randomized, Blinded, Placebo-controlled, Phase 2 Studyof INBRX-109 in Unresectable or Metastatic Conventional Chondrosarcoma.

Lead institution: St Vincent's University Hospital

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a Randomized, Blinded, Placebo-controlled, Phase 2 Study of INBRX-109 in Unresectable or Metastatic Conventional Chondrosarcoma.
- The NREC-CT B noted that this was a comprehensive application overall.
- 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:

- Although the Participant Information Leaflet may be necessarily long, the NREC-CT B considered the content too complex for participants and requested that the PIL is restructured to ensure that the document is accessible to all participants. The Committee also requested that a brief plain English executive summary of the salient points of the study is included at the beginning of the PIL, outlining the aim of the study.
- For future studies, the NREC-CT B suggested that the applicant seeks the involvement of a public or patient reviewer in the development of participant materials to ensure they are accessible

22-NREC-CT-013

Principal Investigator: Prof Maeve Lowery

Study title: A Randomized, Multicenter, Phase 3 Study of Zanidatamab in Combination with Chemotherapy with or without Tislelizumab in Subjects with HER2-positive Unresectable Locally Advanced or Metastatic Gastroesophageal Adenocarcinoma (GEA)

Lead institution: St James's Hospital

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a Randomized, Multicenter, Phase 3 Study of Zanidatamab in Combination with Chemotherapy with or without Tislelizumab in Subjects with HER2-positive Unresectable Locally Advanced or Metastatic Gastroesophageal Adenocarcinoma (GEA).
- 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 option of Echo or MUGA scans for participants in the trial and recommended that Echo scans are used where possible to reduce unnecessary exposure to radiation.
- The NREC-CT B noted that there are 6 consent forms associated with this study. As the consent form for the Future Biomedical Research does not directly relate to the trial at hand, the Committee requested that this consent form is clearly distinguished from the other 5 consent forms directly related to the trial.
- The NREC-CT B considered the content in the PIL too complex for a lay audience and requested that it is revised and restructured to ensure that the document is accessible to all participants. The Committee also requested that a brief plain English executive summary of the salient points of the study is included at the beginning of the PIL, outlining the aim of the study.
- For future studies, the NREC-CT B suggested that the applicant seeks the involvement of a PPI reviewer in the development of participant materials to ensure they are accessible.
- The NREC-CT B noted that HER2 assays are investigational and requests that more information on the accuracy of the assays is provided to participants.
- The NREC-CT B noted that brand names are used throughout the participant materials and requested these are replaced with generic names, and that information is included on why they will be used.
- The NREC-CT B noted that the application states results would only be given to authorities and requested that this is also outlined in the PIL.
- The NREC-CT B noted that the main PIL references patients' participation terminating when they die and requested that this is removed as it is unnecessary.
- The NREC-CT B noted that sexual abstinence is defined as refraining from "heterosexual activity" and requested that this is corrected appropriately.
- The NREC-CT B requested that the current contact details for the European Data Protection Officer included in the PIL is amended to provide details of the Irish DPO.
- In the event of a participant becoming pregnant during the trial, the NREC-CT B requested that consent is obtained for the collection of any data related to that participant.
- The NREC-CT B requested that consent is amended to be layered and specific, in line with international best practice.
- The NREC-CT B requested further information on how and when the issues related to the Clinical Research Platform will be resolved.
- In the participant materials, the NREC-CT B requested that a full list of all sites where samples will be stored is included in the relevant documents.

- In Section 4 of the PIL, the NREC-CT B noted that the first sentence refers to tests and procedures that are expanded on later and recommended adding additional explanatory words such as ‘See Below’ to highlight that more detail is available further on in the document.
- The NREC-CT B recommended the addition of a graphic on Page 11, which may enhance the accessibility of the section.
- The NREC-CT B noted the consent process for the future use of biological samples and data is 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 will 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 noted discrepancies in the documentation on whether lodgings will be covered as part of reasonable expense and requested clarity on this matter.
- The NREC-CT B requested further information on how participants can claim expenses if they are unable to access the expenses tool ‘Scout’.
- The NREC-CT B requested that a more detailed version of Prof. Lowery’s CV is submitted.

- AOB:

- The Chair provided the Committee with an update around discussions between the National Office, the NREC-CT Chairs and the Department of Health to find resolutions to the ongoing challenges around substantial amendments.
- The Chair closed the meeting.