National Research Ethics Committee

NREC-CT A Meeting

20th November 2024

Attendance

Name	Role
Prof. Alistair Nichol	Chairperson, NREC-CT A
Ms Caoimhe Gleeson	Deputy Chairperson, NREC-CT A
Prof. Gene Dempsey	Deputy Chairperson, NREC-CT A
Dr Brian Bird	Committee Member, NREC-CT A
Dr Maeve Kelleher	Committee Member, NREC-CT A
Dr Dawn Swan	Committee Member, NREC-CT A
Dr Darren Dahly	Committee Member, NREC-CT A
Prof. Aisling McMahon	Committee Member, NREC-CT A
Mrs Erica Bennett	Committee Member, NREC-CT A
Dr David Byrne	Committee Member, NREC-CT A
Ms Margaret Cooney	Committee Member, NREC-CT A
Dr Sean Lacey	Committee Member, NREC-CT A
Ms Mandy Daly	Committee Member, NREC-CT A
Ms Muireann O'Briain	Committee Member, NREC-CT A
Ms Dympna Devenney	Committee Member, NREC-CT A
Dr Emily Vereker	Head of Office, National Office for RECs
Dr Jane Bryant	Programme Officer, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs

Apologies:

Quorum for decisions:

Agenda

- Welcome & Apologies
- 2023-504751-28-00
- 2024-511754-41-00
- 2024-513429-21-00 SM-2
- 2023-504931-42-00 SM-3
- 2023-505874-14-00 SM-3
- 2023-506210-40-00 SM-1
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 16th October were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-504751-28-00

Institutions: Institute of Eye Surgery of Ireland

Study title: Vitrectomy, subretinal Tissue plasminogen activator and Intravitreal Gas for submacular haemorrhage secondary to Exudative age-Related macular degeneration (TIGER): a phase 3, pan-European, two-group, active-control, observer-masked, superiority, randomised controlled surgical trial.

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Subject information and informed consent form

- The Sponsor is requested to submit any Part 2 documentation that requires updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation.
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT requested that the SIS adults pg. 10 “What will happen to the results of the research study” be updated to provide information about the availability of the clinical trial results at the end of the trial and location of same.
- The NREC-CT requested that page 17 SIS Adult “Who has reviewed the study” be updated to refer to the National Research Ethics Committee.
- The NREC-CT noted that future research was not clearly referred to in the SIS but is referred to in the ICF page 1 and page. 2. The Committee requested that the SIS and ICF be updated to provide more information around future research for participants and whether the data being used for future research would be anonymised or pseudonymised.
    - <u>If some or all of the data is anonymised</u> the Committee requested that the ICF Adult be updated to include a consent statement for the participant to explicitly consent to the processing of their personal data from coded to anonymised data it as per Article 4 (2) and (6) General Data Protection Regulation (GDPR).

    - <u>If some or all of the data is pseudonymised</u> then this needs to be described to participants in the SIS Adult in line with regulations and best practice. Future use of data should be sufficiently explained so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018)
      Furthermore,

        - It should be made optional
        - it should be confined to the disease or drug under study in this trial. Consent can only be obtained where future use of data is defined such that participants are fully informed,
        - and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies.
        - is made into a separate and explicit consent item on consent form, with separate signatures section, so it is distinct from the main consent to participate in the research
        - The SIS should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined.

- The NREC-CT requested that the SIS and ICF be combined as one document rather than two.
- The NREC-CT requested that the SIS Adult be updated to be relevant to the Irish context rather than UK for example remove references to NHS and UK legislation and replace it with appropriate Irish legislation and references.
- The NREC-CT noted contradictions in relation to accessing/review of medical records in SIS and ICF. SIS page 15 says *"Your medical records may be reviewed by authorized representatives of Sponsors, Regulators, and the KHPCTO to verify that the study is being conducted properly. By signing the consent to the test, you authorize us to do so. Authorized representatives from KHPTO will travel to your hospital to review your medical records on site thereby providing you and other participants with greater safety during the study" h*owever the ICF Adult page 1 point 3 states *"I understand that my medical notes may be securely shared including via the Internet, with authorized persons from the research team, relevant offices, from the Study Sponsor, from King's College London or hospital, and from regulatory authorities. I give permission for these individuals to have access to my records."* The Committee requested that it is confirmed that no personal identifiable data would be transferred outside the site. Furthermore, the Committee requested that the statement in the ICF Adult be updated to remove or amend the statement to reflect this *"I understand that my medical notes may be securely shared including via the Internet with authorized persons from the research team, relevant offices, from the Study Sponsor, from King's College London or hospital, and from regulatory authorities".*
- The NREC-CT noted that the ICF page 2 states that *"I have been informed that my data will also be passed on to third countries and recipients for research purposes for which there is no adequacy decision by the European Commission and no other equivalent data protection guarantees."* The Committee requested that the ICF be updated to 1) align with the SIS which states "The United Kingdom is not a member of the EU, but for the purposes of this study, King's College London is contractually obliged to protect your data in accordance with the EU GDPR. 2) clarify if any third countries are involved and that this is clearly explained in the SIS, and consent is sought for this in the ICF.

2024-511754-41-00

Institutions: St Vincent's University Hospital

Study title: A Phase 2, Multi-Center, Randomized, Double-Blind, Controlled Trial Evaluating the Safety and Efficacy of ENV-101 in Patients with Lung Fibrosis (WHISTLE-PF Trial)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Financial arrangements

- The NREC-CT noted that the IPF carries significant morbidity so some participants may be reliant on carer support and queried whether compensation for carer's may also be provided, if required.

2. Subject information and informed consent form

- The NREC-CT noted that the Main ICF pg. 13 states that participants may need to take medication during or after the study to address side effects of therapy, and that participants may need to pay for these. The Committee noted that often trials will supply supportive care medications for conditions felt to be secondary to study treatment and queried whether this could be the case for this study.
- The NREC-CT queried whether the study drug will remain available to patients deriving clinical benefit, after study cessation. The Committee requested that the Main ICF be updated to provide this information to participants.
- The NREC-CT noted that the future use of data / samples is not described in line with regulations / best practice on pg.13 of the Main ICF which states 'sponsor may keep samples to test for indications of your disease or the amount of drug in your blood.' The Compliance with the use of biological samples document states 'sponsor will conduct future biomedical research on specimens for which consent was provided in the main ICF. This may include gene expression profiling, proteomics, metabolomincs and/or other analyses excluding DNA/genetic testing'. The NREC-CT requested that future use of personal data is sufficiently explained to participants in the PISCF documents so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,
    - it should be made optional
    - it should be confined to the disease or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed, and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies.
    - optional future research should be made into a separate and explicit consent item in the Informed Consent section of the Main PIS/CF, with separate signatures section, so it is distinct from the main consent to participate in the research
- The NREC-CT noted that the Main ICF pg. 13 states that some samples may be stored more than 2 years whereas Section 3.4 of the Compliance with the use of biological samples document states that all blood samples will be destroyed after 2 years and requested that this is updated to be aligned
- The NREC-CT noted that the Main ICF pg. 6 states that parking, meals and travel will be paid by the sponsor however there is no description of how this will be reimbursed (e.g. voucher, card, cash, bank transfer). The NREC-CT requested that this is explained clearly to participants, including any associated data processing or data transfer to 3rd parties.
- The NREC-CT noted that the Main ICF pg. 4 details PK testing however it does not detail that there will be two blood samples taken; one pre medication and one

between 1.5 and 4 hours post medication which is a long window to wait for the post medication test for people who are unwell, and the Committee requested that this is detailed to participants in the Main ICF.

- The NREC-CT noted that the Main ICF pg. 8 notes the most common side effects or side effects seen in more than 10% of participants were: altered sense of taste, muscle spasms, hairloss. The Committee noted that documents including the Investigators Brochure note these side effects as 50%. The Committee requested that this frequency of side effects is made clear to the participant in the Main ICF.
- The NREC-CT noted that the pregnant partner should learn about the study by reading the partner's PIS/CF and if that is not available, they should ask study staff for a copy. The Committee requested that a copy should be provided to the pregnant partner.
- The NREC-CT noted that the Pregnancy/Pregnant Partner ICF_ pg. 3 mentions that should they become upset or distressed, counselling will be organised by "your study doctor" which is not accurate for a pregnant partner and should refer to your partner's study doctor.
- The Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment.Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation.
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.

2024-513429-21-00 SM-2

Institutions: St Vincent's University Hospital, Mater Misericordiae University Hospital

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 Hydrochloroquine.

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-504931-42-00 SM-3

Institutions: University Hospital Limerick, Beaumont Hospital

Study title: A Phase 2 Study to Evaluate the Efficacy and Safety of MK 1026 in Participants with Hematologic Malignancies

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-505874-14-00 SM-3

Institutions: La Nua Day Hospital Mental Health Centre, Tallaght Adult Mental Health Service

Study title: A Pilot Study to Assess the Use of Methylone in the Treatment of PTSD IMPACT-1 (Investigation of Methylone for Post-Traumatic Stress Disorder [PTSD])

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS
1. The sponsor is requested to justify the removal of the sentence related to discontinuation on page 12 of the protocol synopsis.

2023-506210-40-00 SM-1

Institutions: Children's Health Ireland

Study title: A Phase 3, Single-arm, Open-label Extension of the Vericiguat VALOR Study in Pediatric Participants with Heart Failure due to Systemic Left Ventricular Systolic Dysfunction (VALOR EXT)

Dossiers Submitted: Part II

- **NREC-CT Decision:**

- Favourable

- AOB:

None