National Research Ethics Committee

NREC-CT A Meeting

29 March 2023

Attendance

Name	Role
Prof. Alistair Nichol	Chairperson, NREC-CT A
Dr Heike Felzmann	Deputy Chairperson, NREC-CT A
Prof. Mary Donnelly	Deputy Chairperson, NREC-CT A
Ms. Erica Bennett	Committee Member, NREC-CT A
Mr Gerard Daly	Committee Member, NREC-CT A
Prof. Catherine Hayes	Committee Member, NREC-CT A
Ms Muireann O'Briain	Committee Member, NREC-CT A
Prof. David Brayden	Committee Member, NREC-CT A
Dr Darren Dahly	Committee Member, NREC-CT A
Prof. Gene Dempsey	Committee Member, NREC-CT A
Mr Gerald Eastwood	Committee Member, NREC-CT A
Dr Geraldine Foley	Committee Member, NREC-CT A
Ms Evelyn O'Shea	Committee Member, NREC-CT A
Dr Emily Vereker	Head, National Office for RECs
Ms Patricia Kenny	Project Officer, National Office for RECs
Dr Jane Bryant	Project Manager, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Dr Emma Heffernan*	Project Officer, National Office for RECs
Dr Anne Costello	Programme Manager, National Office for RECs
Rachel McDermott	Project Administrator, National Office for RECs

Bryony Milner	Administration Assistant, National Office for RECs

*Drafted minutes

Apologies: Prof Tina Hickey, Prof. John Wells, Prof Austin Duffy, Dr Dervla Kelly & Ms Ann Twomey

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-503895-25-00
- 2022-501703-27-00
- 2023-504179-26-00
- 2022-502669-14-00
- 21-NREC-CT-090_Amend-4
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 22 February 2023 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-503895-25-00

Principal Investigator: N/A

Study title: Preventing caRdiovascular collapsE with VasoprEssors duriNg Tracheal IntubatiON: The PREVENTION Randomized Controlled Trial

EudraCT: 2023-503895-25-00

Lead institution: N/A

  - NREC-CT comments:
- The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.

- NREC-CT Decision:

- Request for more information.

- Additional Information Required

Part 1

- The Sponsor is asked to provide specific detail as to how all emergency consent procedures undertaken in comply with each part of Article 35 of S.I. No. 40/2022 – European Union (Clinical Trials on Medicinal Products for Human Use) Regulations 2022.
- EC: The protocol notes that the randomization will be restricted using random blocks and stratified by site. If this is the case, the primary analysis should then also adjust for site (see ICH E9).

2022-501703-27-00

Principal Investigator: N/A

Study title: A Randomized Open-Label Phase 3 Study of XL092 + Nivolumab vs Sunitinib in Subjects with Advanced or Metastatic Non-Clear Cell Renal Cell Carcinoma

EudraCT: 2022-501703-27-00

Lead institution: N/A

- NREC-CT Decision:

Part 1

- Favourable

2023-504179-26-00

Principal Investigator: N/A

Study title: COmparison of Bleeding Risk between Rivaroxaban and Apixaban for the treatment of acute venous thromboembolism

EudraCT: 2023-504179-26-00

Lead institution: N/A

- NREC-CT comments:

- The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.

- NREC-CT Decision:

- Request for more information

- Additional Information Required

- The The NREC-CT notes that non-English speakers will be excluded from this trial, and requests clarification if a translator will be made available for non-English speakers (Section 1.8). If not, the NREC-CT requests that rationale is provided for their exclusion
- The NREC-CT requests that further information is added to the PIL_ICF regarding the Standard of Care and what this treatment is. (Page 10)
- The NREC-CT notes that no contraceptive measures are required to be used by male participants, and requests rationale is provided as to why this is the case. Furthermore, the Committee requests appropriate advice on contraception is added to the PISCF to male participants, in line with the advice for female participants. (Page 3)
- The NREC-CT requests clarification on whether the participant will be able to choose whether their visits are in-person or by telephone, or if this is solely the decision of the Investigator. (Page 3, 4). If the visits will be solely by telephone, the NREC-CT queried whether there is sufficient oversight of participants in the event of adverse events/side effects.
- The NREC-CT requests clarification on whether there will be further visits or communication with participants after the 3 month visit. (Page 10)
- The NREC-CT notes that data will be anonymised following generation of participant codes, and queries whether this should read '…data will be pseudonymised.' (Page 12, point 2)
- The NREC-CT requests further information on how personal data will be protected following its transfer outside of the EU. (Page 13, point 15)
- The NREC-CT suggests that contact details for the Data Protection Commissioner should be added to the PIL_ICF. (Page 12, point 8)
- The NREC-CT notes that compensation for participants will not be available, and requests that rationale is provided for this. Furthermore, this must be made clear to the participant in the PIL_ICF. (Page 13, Part 3)
- The NREC-CT notes that this study has also been approved by a committee at the Mater Misericordiae University Hospital, and requests further information on the nature of this additional Committee. (Page 13, Part 3)
- The NREC-CT requests that further information is given to participants on the available alternatives, which is referenced on page 14 of the PIL_ICF, Box 5.

2022-502669-14-00

Principal Investigator: N/A

Study title: A Randomized, Open-label, Phase 3 Study of Tarlatamab Compared With Standard of Care in Subjects With Relapsed Small Cell Lung Cancer After Platinum-based First-line Chemotherapy (DeLLphi-304)

EudraCT: 2022-502669-14-00

Lead institution: N/A

- NREC-CT comments:

- The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.

- NREC-CT Decision:

- Request for more information

- Additional Information Required

Part 1

- The Sponsor is asked for further information on the basis of inclusion of a Legal Authorised Representative, given that is stated in the inclusion criteria that participants will have provided informed consent. (Protocol, Section 8.2.1).

Part 2

- The NREC-CT requests further details on what compensation will be paid to Beaumont Hospital for provision of trial activities.
- The NREC-CT notes that individualized assistance will be provided to participants who may need it, and requests further details on the process for this assistance and the persons providing it. (Section 1.8)
- The NREC-CT notes that participants are referred to section 3a of the Main PISCF for contraception language, however there is no mention of same in section 3a, and suggests this should refer to 3g. (Main PISCF, Page 19, Section f)
- The NREC-CT notes that both the participant's name and ID number will be present on the ICF documents, and requests that the ID number be removed or redacted, such that these documents do not create linking sheets.
- The NREC-CT requests further details are given to participants on how their participation may affect their insurance. (Main PISCF, Page 14, Section a)
- The NREC-CT requests that more details are given to the participants on how to claim reimbursement for expenses. (Main PISCF, Page 22, Section 6)

- The NREC-CT notes that other risks are associated with having a biopsy done, and requests that these risks be added to the PISCF in addition to discussion with the Investigator. (Pre-screening PISCF, Page 3, Section 3)
- The NREC-CT requests clarification on why the pre-screening is optional, and how participants can still take part in the main study if they do not consent to this study. (Pre-screening PISCF)
- The NREC-CT notes that no risks are associated with participation in the PG sub-study, but suggests that there may be risks associated with genetic data collection, and that this should be communicated with participants. (PG PISCF, Page 2, Section 3a)
- The NREC-CT requests clarification on whether Section 4 of the PG PISCF pertains to Future Biological Research, or for uses that are already defined as part of the study. (PG PISCF, Page 2, Section 4)

21-NREC-CT-090_Amend-4

Principal Investigator: Dr Jarushka Naidoo

Study title: A Phase 2 Randomized Study of Relatlimab plus Nivolumab in Combination with Chemotherapy vs. Nivolumab in Combination with Chemotherapy as First Line Treatment for Participants with Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC)

EudraCT: 2020-004026-31

Lead institution: Beaumont Hospital

- NREC-CT comments:

- The NREC-CT A Committee noted that this application represents a substantial amendment to a Phase 2 Randomized Study of Relatlimab plus Nivolumab in Combination with Chemotherapy vs. Nivolumab in Combination with Chemotherapy as First Line Treatment for Participants with Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC)
- Based on the above, the NREC-CT A Committee agreed that this substantial amendment application be designated as favourable

- NREC-CT comments:

- The NREC-CT A Committee noted that this application represents a substantial amendment to a Phase 2 Randomized Study of Relatlimab plus Nivolumab in Combination with Chemotherapy vs. Nivolumab in Combination with Chemotherapy as First Line Treatment for Participants with Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC)
- Based on the above, the NREC-CT A Committee agreed that this substantial amendment application be designated as favourable

- NREC-CT Decision:

- Favourable

- AOB: