National Research Ethics Committee

NREC-CT Meeting

2nd October 2024

Attendance

Name	Role
Prof Mary Donnelly	Chairperson, NREC-CT C
Prof John Faul	Deputy Chairperson, NREC-CT C
Dr Jean Saunders	Deputy Chairperson, NREC-CT C
Dr Susan Finnerty	Committee Member, NREC-CT C
Prof Andrew Smyth	Committee Member, NREC-CT C
Dr Steve Meaney	Committee Member, NREC-CT C
Dr Dervla Kelly	Committee Member, NREC-CT C
Ms Susan Kelly	Committee Member, NREC-CT C
Dr Deborah Wallace	Committee Member, NREC-CT C
Ms Paula Prendeville	Committee Member, NREC-CT C
Mr Philip Berman	Committee Member, NREC-CT C
Prof Anne Mathews	Committee Member, NREC-CT C
Ms Aileen Sheehy	Programme Manager, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Dr Emma Heffernan*	Project Officer, National Office for RECs

Apologies: Prof Austin Duffy, Prof Fionnuala Breathnach, Mr Gerry Eastwood

Quorum for decisions: Yes

Conflict of Interest: 2023-508213-16-00 SM2 Philip Berman – not present for discussion of trial at meeting

Agenda

- Welcome & Apologies
- 2023-507024-24-00 SM-3
- 2023-508213-16-00 SM-2
- 2024-514173-22-00 SM-2
- 2023-510357-42-00 SM-1
- 2023-509345-12-00 SM-2
- 2022-501522-38-00 SM 3
- 2022-501606-35-01 SM 3
- 2023-506931-13-00 SM 1
- AOB

- The Chair welcomed the NREC-CT C.
  - The minutes from the previous NREC-CT C meeting on 4th September 2024 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-507024-24-00 SM-3

Institutions: University Hospital Limerick, Cork University Hospital, Tallaght University Hospital, Beaumont University Hospital, St Vincent's University Hospital

Study title: A Phase 3, Randomized, Double-blind Trial of Pembrolizumab (MK-3475) Plus Enzalutamide Plus ADT Versus Placebo Plus Enzalutamide Plus ADT in Participants With Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) (KEYNOTE-991)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. **Subject information and informed consent form**

- The NREC-CT noted that pgs. 1 & 4 of the L1_ICF_Main addendum_IRL_EN state that participants may experience dysphagia as a result of the size of the IMP, whereas pg. 142 of the IB notes it as an ADR in the gastrointestinal disorders category. Please clarify the following in the PISCF:
    - whether dysphagia is as a result of ingestion of the IMP or is also a potential side effect of the IMP.
    - detail as to the frequency / likelihood of dysphagia occurring
- 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.

2023-508213-16-00 SM-2

Institutions: Beaumont Hospital

Study title: A Phase 2, Randomized, Parallel, Open-Label Study to Investigate the Safety, Efficacy, and Pharmacokinetics of Various Dosing Regimens of Single-Agent Belantamab Mafodotin (GSK2857916) in Participants with Relapsed or Refractory Multiple Myeloma (DREAMM-14)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. **Subject information and informed consent form**

- The NREC-CT requested that the meaning of ‘albuminuria’ (as described on pg. 40 of the protocol) is clarified for participants on pg. 2 of the L1 ICF Addendum Main v1 23Jul24 using plain English suitable for a lay audience (suggest using similar approach taken for CK/CPK in the same table).

2024-514173-22-00 SM-2

Institutions: Children’s Health Ireland, Cork University Hospital, University Hospital Limerick, Our Lady’s Children’s Hospital, St Vincent’s University Hospital

Study title: A Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of VX-121 Combination Therapy in Subjects With Cystic Fibrosis (VX20-121-104)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. **Subject information and informed consent form**

- The NREC-CT noted that participants under the age of 18 at the time of signing the consent form are to undergo a series of eye exams to ensure no adverse effects of IMP and requested that the rationale for the cut off at age 18 is explained to participants in the PISCF
- 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

2023-510357-42-00 SM-1

Institutions: Beaumont Hospital, Cork University Hospital, Sligo University Hospital, University Hospital Waterford, Mater Hospital

Study title: A phase III, multicenter, randomized, open-label trial to evaluate efficacy and safety of ribociclib with endocrine therapy as an adjuvant treatment in patients with hormone receptor-positive, HER2-negative, early breast cancer (New Adjuvant TriAl with Ribociclib [LEE011]: NATALEE)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. **Subject information and informed consent form**

- The NREC-CT noted that the Main PISCF has used a bundled approach to consent in the Informed Consent Section on pg. 7 of the PISCF and requested that a layered approach to consent is used (in that each consent item is listed and a box for participants to provide their initials is included alongside each consent item) in line with HSE policy. Please see HSE National Policy for Consent in Health and Social Care Research (V1.1, 2023). Dublin: Health Service Executive https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf.
- 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.

2023-509345-12-00 SM-2

Institutions: St Vincent's University Hospital, St James's Hospital

Study title: A randomized, double-blind, double-dummy, parallel-group study, comparing the efficacy and safety of remibrutinib versus teriflunomide in participants with relapsing multiple sclerosis, followed by extended treatment with open-label remibrutinib

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2022-501522-38-00 SM-3

Institutions: Beaumont Hospital

Study title: An Extension Study of Venetoclax for Subjects Who Have Completed a Prior Venetoclax Clinical Trial

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. **Subject information and informed consent form**

- The NREC- CT noted that pg. 15, 16 and 17 refer to ‘coded data’ and requested that it is clarified in the PISCF whether this refers to future use of ‘pseudonymised’ or ‘anonymised’ data.
  If ‘coded data’ refers to anonymised data, then please:
    - Explain this to participants in the PISCF using plain English suitable for a lay audience. This should include an explanation of the term ‘anonymised’.
    - Include processing of anonymised data as an explicit consent item in the informed consent section on pg. 21 of the PISCF
- If ‘coded data’ refers to future use of pseudonymised data, then this needs to be described to participants in the PISCF 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 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.
    - is made into a separate and explicit consent item on pg. 22/ 23 of the PISCF, with separate signatures section, so it is distinct from the main consent to participate in the research

  The PISCF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. For further guidance, please see: HSE National Policy for Consent in Health and Social Care Research (V1.1, 2023) https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf

- The NREC-CT requested that the reference to ‘my witness’ on pg. 21 of the PISCF is removed, as it is not appropriate in an Irish context / under regulations.
- 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.

2022-501606-35-01 SM-3

Institutions: Cork University Hospital, University Hospital Waterford, University Hospital Galway, Bon Secours Hospital Cork, St James’s Hospital, Sligo University Hospital, Beaumont Hospital

Study title: 2022-501606-35-00 – Randomized, multicenter, open-label, Phase 3 study of mirvetuximab soravtansine in combination with bevacizumab versus bevacizumab alone as maintenance therapy for patients with FRα-high recurrent platinum-sensitive epithelial

ovarian, fallopian tube, or primary peritoneal cancers who have not progressed after second-line platinum-based chemotherapy plus bevacizumab (GLORIOSA).

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-506931-13-00 SM-1

Institutions: National University of Ireland, Mater Misericordiae University Hospital, Connolly Hospital, St Vincent's University Hospital, St James's Hospital

Study title: Efficacy and safety of cagrilintide s.c. in combination with semaglutide s.c. (CagriSema s.c.) once-weekly in participants with overweight or obesity and type 2 diabetes

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

- AOB:
  - N/A