National Research Ethics Committee

NREC-CT A Meeting

16th October 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
- 2023-510292-65-00
- 2023-509859-13-00 SM-1
- 2023-505678-14-00 SM-10
- 2023-505617-24-00 SM-1
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 18th September were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-510292-65-00

Institutions: St James's Hospital

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Axatilimab (INCA034176) and Corticosteroids as Initial Treatment for Chronic Graft-Versus Host Disease.

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Recruitment arrangements

- The NREC-CT noted that this trial includes minors (i.e., ≥12 years); however, no paediatric site is listed for Ireland and no relevant documentation is included in the Part II dossier. It is requested that the sponsor clarifies whether minors (i.e., aged 12 to 15 years) will be included in the study. Please note that participants aged 16+ years are capable of consenting on their own behalf, and therefore, assent forms are not required.

2. Subject information and informed consent form

- The NREC-CT noted that in the assent form for 12 to 16 year olds that the information provided about the following areas is inappropriate and that suitable language and terminology for this age group must be incorporated:
    1. Information about GVHD
    2. What a trial is and why this drug is being studied
    3. What steroids are and why a different treatment might be better
    4. Explanation on trial periods, specifically the screening period and consenting process
- The NREC-CT requested that the Assent ICF form is updated to '12 to 15' year olds as participants aged 16 and above can provide consent for participation. Please note that participants aged 16+ years are capable of consenting on their own behalf, and therefore, assent forms are not required for this age group.
- The NREC-CT requested that a clearer explanation about GVHD and why the study drug is being investigated should be incorporated into the Parental ICF.
- The NREC-CT noted in all SIS-ICF documents (i.e., Assent ICF, Main ICF, Parental ICF) that the current presentation of information about study site visits is unclear and difficult to read. The Committee requested that this section in all the PIL-ICF documents is redesigned into a table or infographic format and that further explanation is provided as to why the significant number of visits (i.e., 66) are required.
- The NREC-CT noted that best practice for presenting side effects is to use lay terminology first, and then follow up with the medical term in brackets. It is requested that the sponsor updates all SIS-ICFs are updated accordingly.
- The NREC-CT noted that on page 9 of the Assent ICF, page 13 of the Main and Parental ICF documents, that it states that participants 'may' be reimbursed. It is requested that the word 'may' is changed to 'will' to align with the information in the Compensation for Trial Participants document.
- The NREC-CT requested that the Glossary of Terms in all SIS-ICF documents is moved so that it appears before the request to sign, so that the participants are fully informed of the acronyms used throughout the document in advance of providing their consent.
- 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.

2023-509859-13-00 SM-1

Institutions: University Hospital Galway, St James's Hospital, Cork University Hospital

Study title: A Phase 3, Two-Stage, Randomized, Multicenter, Open-Label Study Comparing Mezigdomide (CC-92480), Bortezomib And Dexamethasone (MeziVd) Versus Pomalidomide, Bortezomib And Dexamethasone (PVd) In Subjects With Relapsed Or Refractory Multiple Myeloma (RRMM): Successor-1

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations
1. Recruitment arrangements
• The NREC-CT recommended that the document K2_Recruitment Materials_IE_Patient Brochure.PDF should mention withdrawal and data management.
2. Subject information and informed consent form
• The NREC-CT noted that in the document L1_SIS and ICF_IE_Main_ENG_Tracked.PDF it is stated that scans "may be submitted to a company that may review your images". The NREC-CT requested that further information is provided to participant regarding the period of storage of these images, and the data sharing agreement between external company and researchers.

2023-505678-14-00 SM-10

Institutions: Beaumont Hospital, St Vincent's University Hospital

Study title: A Multicenter, Randomized Study to Evaluate the Safety and Efficacy of Lutikizumab for Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis

Dossiers Submitted: Part II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. **Recruitment arrangements**

- The NREC-CT requested that in the document K2_M23-703_Patient Brochure_Public.PDF, information should be provided on the right to withdraw, and on data storage and management.
- The NREC-CT requested that in the document K2_M23-703_Patient Brochure_Public.PDF, the wording that participants "may be paid back (reimbursed) for reasonable travel costs" is amended to "will be paid back (reimbursed)" for reasonable travel costs.

2023-505617-24-00 SM-1

Institutions: Bon Secours Hospital Cork, Beaumont Hospital, St James's Hospital, Mater Misericordiae University Hospital

Study title: A Randomized Phase 2 Study of Ocular Toxicity Evaluation and Mitigation During Treatment with Mirvetuximab Soravtansine in Patients with Recurrent Ovarian Cancer with High Folate Receptor-Alpha Expression

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. **Suitability of the clinical trial sites facilities**

- The NREC-CT noted the addition of two additional sites to this study. The NREC-CT noted the lack of uniformity between the responses to Question 5 on the Site Suitability forms (Is the exposure to ionising radiation at this site above what is required for standard of care?) and requested clarity is provided regarding this response. The NREC-CT requested reassurance that this discrepancy will not affect the quality of the trial or the risk to participants.

- AOB: