National Research Ethics Committee

NREC-CT A Meeting

26th July 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. David Brayden	Committee Member, NREC-CT A
Prof. Austin Duffy	Committee Member, NREC-CT A
Mr Gerard Eastwood	Committee Member, NREC-CT A
Ms Evelyn O'Shea	Committee Member, NREC-CT A
Ms Ann Twomey	Committee Member, NREC-CT A
Ms Aileen Sheehy	Programme Manager, National Office for RECs
Ms Patricia Kenny	Project Officer, National Office for RECs
Dr Jane Bryant*	Project Officer, National Office for RECs
Dr Emma Heffernan	Project Officer, National Office for RECs

*Drafted minutes

Apologies: Prof. John Wells, Prof. Tina Hickey, Dr Geraldine Foley, Prof. Catherine Hayes, Ms Muireann O'Briain, Prof. Gene Dempsey, Dr Darren Dahly

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-503661-28-00
- 2023-505268-12-00
- 21-NREC-CT-022_Mod-3
- 21-NREC-CT-173_Mod-3
- 21-NREC-CT-068_Mod-3
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 28th June 2023 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-503661-28-00

Study title: A Phase 3 Randomized, Placebo-Controlled, Double-Blind Study to Evaluate Efficacy and Safety of Upadacitinib in Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa Who Have Failed Anti-TNF Therapy

Principal Investigators & Institutions: St James's Hospital (Prof. Alan Irvine), South Infirmary Victoria University Hospital (Prof. Michelle Murphy), University Hospital Waterford (Dr Michael O'Connell), University Hospital Galway (Dr Trevor Markham), St. Vincent's University Hospital (Prof. Brian Kirby).

EU CT: 2023-503661-28-00

- 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 Further Information

- Additional Information Required:

Protocol

- The Sponsor was asked to clarify whether the blinding of participants will be maintained in Period 2 of the study.
- The Sponsor was asked to give further information on provision of rescue medications, specifically at which week of the study the participant will be offered these medications if required, and how long the rescue medications will be available for.

Recruitment arrangements

- The NREC-CT noted that advertisement material will be used to recruit participants, and requested submission of these materials for review, when available.

Subject information and informed consent form

- The NREC-CT noted that the information included on side effects in adolescents is limited, and requested that further detail be added where available (Pages 10-13, Main Adult ICF, Main Parental ICF)
- The NREC-CT requested inclusion of planned enrolment numbers for IE, across all three ICF and Assent Forms.
- The NREC-CT requested that further background information regarding the mechanism of action of the IMP, the rationale for the study and details on rescue therapy is added to Part 1 of the ICF and Assent Forms.
- The NREC-CT requested that further details are added to the sections on Optional Biomarker Research Samples, specifically around what type of biomarkers and how many additional samples and blood volume this will entail. Specific information on what disease area will be studied should also be included. (Main ICF and Assent Forms).
- The NREC-CT noted that IE law allows for the testing of HBV, HCV and HIV, and requested that 'if allowed by local law' is removed (Page 3, Main Adult ICF, Page 4 Main Parental ICF)
- The NREC-CT noted that the Local Sponsor Representative is based in the UK, and requested clarification on whether there is a separate representative for IE (Page 1, Main Adult ICF)
- The NREC-CT requested that the term 'children' found throughout the Assent (12-17) Form is amended to 'children and adolescents'.
- The NREC-CT noted that the participant's GP will be informed and requested submission of a GP letter for review.
- The NREC-CT requested clarification on whether a pregnant participant/ pregnant partner ICF will be submitted for review, and if so, that it is submitted when available.
- The NREC-CT requested that a section on data protection is added to the Assent Form, and that data retention periods are added throughout the Main ICF and Assent Forms.
- The NREC-CT recommended that participants may also have an option to give consent to be contacted in the future regarding use of their biological samples, should further tests become available.

Suitability of the investigator

- The NREC-CT requested that further information on Prof. Irvine and Prof. Kirby's previous clinical trial experience is added to their CV templates.

2023-505268-12-00

Study title: A Phase III, multicentre, randomised, double-blind, controlled study to investigate the efficacy, safety, and tolerability of two initial administrations of COMP360 in participants with treatment-resistant depression

Principal Investigators & Institutions: La Nua Hospital Mental Health Centre (Dr Shane McInerney), Sheaf House (Dr John Kelly)

EU CT: 2023-505268-12-00

- 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 Further Information

- Additional Information Required:

Protocol

- The Sponsor was asked to clarify whether the blinding of participants will be maintained for Part B of the study, and what treatment options participants will have if they are not re-randomised.

Financial arrangements

- The NREC-CT noted in the Compensation for Trial Participants document, travel and food costs will be provided at the site's discretion. The Committee requested that out-of-pocket expenses to cover travel and food while at a site visit is provided to all participants in Ireland.

Recruitment arrangements

- The NREC-CT noted that participants 'may' be reimbursed for out-of-pocket expenses, and requests that this be amended to 'will' be reimbursed. The Committee also advised that reimbursement of out-of-pocket expenses should not be labelled as a benefit of taking part in the study. (K2 Advocacy FS_P)

Subject information and informed consent form

- The NREC-CT requested clarification on whether additional supports will be in place during the withdrawal period of the participant's usual treatment, if they do not have a caregiver available to them. The Committee sought to clarify whether there will be provision for the study team to actively check in with the participant during this period,

in addition to providing contact details for the study team. Any updates to this information should also be reflected in the ICF forms for participants.

- The NREC-CT requested further information on what out-of-hours support entails.
- The NREC-CT noted the volume of intensive forms to be completed, and requests clarification on supports available to the participant for filling these out, specifically in terms of a risk of triggering related to questionnaires on suicidal ideation. Any updates to this information should also be reflected in the ICF forms for participants.
- The NREC-CT noted the following sentence on Page 21 of the Main PIL; If the study team have any concerns about your safety from the assessments conducted in the study visits with you, they would be obliged to involve local health services to determine how best to support you. The Committee requested clarification on the phrase 'would be obliged' in terms of what process the study team will follow should they have concerns about a participant.
- The NREC-CT requested that the Main ICF includes reference to the Health Research Regulations 2018 in addition to the GDPR in the data protection section.

21-NREC-CT-022_Mod-3

Study title: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial to Evaluate the Safety and Efficacy of AMX0035 Versus Placebo for 48-week Treatment of Adult Patients with Amyotrophic Lateral Sclerosis (ALS)

Principal Investigator & Institution: Prof. Orla Hardiman, Beaumont Hospital

Eudra CT: 2021-000250-26

- NREC-CT Decision:

Favourable

21-NREC-CT-173_Mod-3

Study title: A phase IIb, double-blind, randomised, placebo-controlled trial to evaluate the efficacy and tolerability of ZED1227 in celiac disease subjects experiencing symptoms despite gluten-free diet

Principal Investigator & Institution: Prof. Valerie Byrnes, University Hospital Galway

Eudra CT: 2020-004612-97

- NREC-CT Decision:

Request for Further Information

- Additional Information Required:

- The NREC-CT requested a more detailed explanation of which types of personal information are obtained from which specific third parties. The Committee also requested clarification on which personal data types are passed on to which third parties, specifically ‘sub-contractors who sell, transfer, or merge’ (Trialbee Privacy Policy).
- The NREC-CT recommended that the Trialbee Patient Website Content, including the Privacy Policy is proofread, due to the high number of typos through the documents.

21-NREC-CT-068_Mod-3

Study title: Phase Ib of Cyclophosphamide, Pomalidomide, Dexamethasone and Daratumumab (CPD-DARA) in patients with relapsed/refractory multiple myeloma. (The CPD-DARA Study)

Principal Investigator & Institution: Dr. Janusz Krawczyk, University Hospital Galway

Eudra CT: 2019-004386-40

- NREC-CT Decision:

  Favourable

- AOB:

There was no AOB for discussion.