

National Research Ethics Committee

NREC-CT A Meeting

26 April 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
Prof. Tina Hickey	Committee Member, NREC-CT A
Prof. John Wells	Committee Member, NREC-CT A
Mr Gerard Daly	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
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
Dr Emily Vereker	Acting Head, National Office for RECs
Dr Jane Bryant	Project Officer, National Office for RECs
Dr Emma Heffernan*	Project Officer, National Office for RECs
Rachel McDermott	Project Administrator, National Office for RECs
Bryony Milner	Administration Assistant, National Office for RECs

*Drafted minutes

Apologies: Ms. Erica Bennett, Prof. Catherine Hayes, & Dr Geraldine Foley

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-503584-42-00
- 2022-502110-85-00
- 2022-501427-24-00
- 22-NREC-CT-170
- AOB

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- The Chair welcomed the NREC-CT A.
 - The minutes from the previous NREC-CT A meeting on 29 March 2023 were approved.
 - The NREC Business Report was discussed and noted.
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Applications

2023-503584-42-00

Principal Investigator: Prof. John McDermott

Study title: An open-label, cross-over, multi-site, prospective, phase IIb study of effects on circadian rhythms and quality of life of modified-release hydrocortisone Efmody™ versus immediate-release hydrocortisone in patients with Addison's Disease

EudraCT: 2023-503584-42-00

Lead institution: Connolly Hospital

- 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 I Considerations
- The Sponsor is asked to outline the reasons as to why participants will not be randomized, and how confounding factors will be adjusted for through the open label study design.
- Part II Considerations
- The NREC-CT notes that no compensation is available for participant reimbursement and requests a justification for this.
- The NREC-CT request justification for exclusion of participants who do not have English as a first language.
- The Sponsor is requested to add the EU CT number to the PIL and ICF document.
- The NREC-CT recommends addition of a one-page summary at the start of the PIL, and/or a visualization of the timeline/schedule of activities.
- The NREC-CT requests that acronyms such as 'MD' be explained or spelled out on their first inclusion. (Page 1)
- The NREC-CT requests that the study start and end dates are updated, as April is listed as the start month. (Page 5)
- The NREC-CT requests that further information is given on the circumstances where driving should be avoided. (Page 11)
- The NREC-CT notes that any data breach will follow RCSI protocols, and requests that some further details on this process are added to this section. (Page 11)
- The NREC-CT notes that hard copies of participant data will be shredded by the Investigators after 25 years, and requests that other safeguards are put in place for the shredding of this data should either Investigator no longer work at the Institution at that time. (Page 13)
- The NREC-CT advises that NREC will not have access to participant medical records, and requests that this statement be amended. (Pages 12,18)

2022-502110-85-00

Principal Investigators: Dr. Juan Trujillo (Cork University Hospital), Prof. Jonathan Hourihane (CHI)

Study title: Phase 3, Double-blind, Placebo-controlled, Randomized Study to Assess the Efficacy and Safety of Epicutaneous Immunotherapy with DBV712 250 µg in 4-7-year-old Children with Peanut Allergy

EudraCT: 2022-502110-85-00

Lead institution: CHI Connolly

- 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 I
 - No considerations.

 - Part II Considerations
 - The NREC-CT notes that in the 'Dr to Caregiver' letter, the words 'participant' should be replaced with 'your child'.
 - The NREC-CT note that some recruitment tools are prototypes, and requests submission of the final versions for Irish sites when available.
 - The NREC-CT notes that the strategy for consenting of minors to retain their data once they reach the age of consent (18yrs) is omitted, and requests these details be added to the form.
 - The Sponsor is requested to add the EU CT number to the Participant Information Leaflets.
 - The NREC-CT notes that participants 'may' be reimbursed for expenses, and requests that this is clarified, with further information given on how the participants can claim reimbursement for expenses.
 - The NREC-CT requests that the assent form be made more accessible, through use of visuals and more accessible language.
 - The NREC-CT requests that Future Biological Research (pg. 18) is detailed in a separate PIL and ICF and is clearly optional for participants.
 - The NREC-CT notes that activities will be available for participants during some visits and requests clarification on whether they will be available for all visits.
 - The NREC-CT notes that 30% of participants will receive placebo, and requests that the need for vigilance is highlighted to caregivers.
 - The NREC-CT requests further information on Dr Trujillo's clinical trials experience, if available.

Principal Investigator: Prof. Eibhlin Conneally

Study title: A Multi-Part, Randomized, Double-Blind, Placebo-Controlled Phase 2 Clinical Study of the Safety and Efficacy of CGT9486 in Subjects with NonAdvanced Systemic Mastocytosis

EudraCT: 2022-501427-24-00

Lead institution: St James's Hospital

- 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 RFI
 - Part I Considerations
 - No Considerations

 - Part II Considerations
 - The NREC-CT notes that the format of the Main SIS and ICF should be improved to separate out consent for participants who are entering the study in Part 1 or Part 2. This would enhance clarity for participants.
 - The NREC-CT requests clarification on whether there will be any option for continued access of the IMP for participants that may be deriving benefit, following completion of the study.
 - The NREC-CT requests clarification on whether a skin biopsy is optional (Main SIS and ICF, Page 7)
 - The NREC-CT requests clarification on whether the PK study is optional. (Main SIS and ICF, Page 9)
 - The NREC-CT notes that compensation 'may' be offered for reimbursement of expenses, and requests that a list of expenses and how to claim them is added to the Main SIS and ICF. (Page 26)
 - The NREC-CT notes that consent sought for Future Biological Research (FBR) is not specific, and requests that further details are given on this FBR in the Main SIS and ICF. A request for blanket consent is not lawful under the Health Research Regulations (2018). In line with the HSE National Policy for Consent in Health and Social Care

Research, if broad consent for FBR is sought, safeguards should be put in place such as further ethics approval for FBR.

- The Committee also recommends updating of this section to include legislation relevant to the Irish sites, such as GDPR and the HRR.

22-NREC-CT-170 Response to RFI & Urgent Safety Measure

Principal Investigator: Prof Owen Smith

Study title: ALLTogether1 - A Treatment study protocol of the ALLTogether Consortium for children and young adults (0-45 years of age) with newly diagnosed acute lymphoblastic leukaemia (ALL)

EudraCT: 2018-001795-38

Lead institution: CHI Crumlin

- 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 NREC-CT requested that evidence of up-to-date ICH-GCP certification is provided for Dr Pamela Evans.
 - The NREC-CT noted that sufficient justification was not provided for non-payment of expenses and requested that participants and accompanying parents/ guardians are reimbursed for reasonable out-of-pocket expenses and that this is clearly stated in the adult and the parent / guardian PISCF. The NREC-CT also requested that the process involved in claimed reimbursement is also clearly stated in the PISCF.
 - The NREC-CT noted that randomization is not well explained in lay terms in the adult and parent / guardian PISCFs and requested that this is amended.
 - The NREC-CT noted that the procedure for withdrawal is not well described in the adolescent assent form, the adult consent form and the parent / guardian consent form and requested that the procedure for withdrawal is clearly described in these PISCFs.
 - The NREC-CT noted that the explanation provided as to why only participants with Down Syndrome are to undergo HIV testing is not sufficiently clear in the PISCF and requested that this is made clearer.

- The NREC-CT noted that parents / guardians are asked to discuss all aspects of the trial with their children and requested that a tick box with appropriate text to confirm that they have discussed all aspects of the trial with their children / guardians is added to the parent/ guardian PISCF.
 - o The NREC-CT requested that a tick box with appropriate text is also added to the 13-15 assent form so participants can confirm that all aspects of the trial have been discussed with them by their parents/ guardians.
 - o The NREC-CT requested that text is added to the assent forms for the under 6 and 7-12 in the 'my notes' section to advise them that this section can be used to make notes or drawings to describe how they are feeling.
 - The NREC-CT noted in the parent/ guardian PISCF that participants of childbearing potential who are sexually active will undergo pregnancy testing and requested clarification as to how participants are sexually active is determined.
 - o The NREC-CT requested that participants in the 13-15 assent form are advised of the importance of pregnancy avoidance.
 - o The NREC-CT requested that adults and parents / guardians are advised of the importance of pregnancy avoidance in the adult and parent/ guardian PISCFs.
 - The NREC-CT noted that the PISCF for participants with Down Syndrome was not adequately addressed in the response to RFI and requested that the language in PISCF for participants with Down Syndrome is adapted to be more appropriate for participants with Down Syndrome
 - The NREC-CT noted the submission of an Urgent Safety Measure to NREC and requested the following:
 - o Relevant details that pertain to the USM are added to the adult and parent / guardian PISCF (as per changes to the protocol as a result of the USM)
 - o Confirm details of the Substantial Amendment submitted to the HPRA as requested and provide details of communication with the HPRA prior to commencement in Ireland.
 - The NREC-CT also requested that changes made to documents as a result of this request for further information are provided for committee review in both a tracked changes and clean copy format.
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- AOB: