National Research Ethics Committee

NREC-CT A Meeting

15th October 2025

Attendance

Name	Role
Prof. Alistair Nichol	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 Darren Dahly	Committee Member, NREC-CT A
Mr Kevin Devlin	Committee Member, NREC-CT A
Ms Margaret Cooney	Committee Member, NREC-CT A
Dr Sean Lacey	Committee Member, NREC-CT A
Ms Muireann O'Briain	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
Ms Chita Murray	Programme Manager, National Office for RECs
Ms Deirdre Ní Fhloinn	Project Officer, National Office for RECs
Dr Peadar Rooney*	Project Officer, National Office for RECs

Apologies:

Name	Role
Ms Caoimhe Gleeson	Deputy Chairperson, NREC-CT A
Dr Dawn Swan	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 Mandy Daly	Committee Member, NREC-CT A

Quorum for decisions:

Agenda

- Welcome & Apologies
- 2023-510294-34-00 SM-1
- 2023-508922-83-00 SM-14
- 2023-508341-40-00 SM-3
- 2024-514208-15-00 SM-3
- 2023-506091-27-00 SM-4
- 2023-504962-52-00 SM-12
- 2025-520538-49-00 SM-1
- 2022-502215-10-00 SM-12
- 2023-509345-12-00 SM-6
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 17th September 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-510294-34-00 SM-1

Institutions: University Hospital Galway, Beaumont Hospital, Cork University Hospital, University Hospital Waterford, University Hospital Limerick, Mater Misericordiae University Hospital, St James's Hospital

Study title: A phase 3 multicenter, randomised, prospective, open-label trial of fixed-duration (12 cycles) venetoclax/ obinutuzumab vs. fixed-duration (15 cycles) venetoclax/ pirtobrutinib vs. MRD-guided venetoclax/ pirtobrutinib in patients with previously untreated chronic lymphocytic leukaemia (CLL)/ small lymphocytic lymphoma (SLL) aiming to establish measurement of individual residual disease for adjustment of treatment duration to improve outcomes (CLL18/MOIRAI)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-508922-83-00 SM-14

Institutions: University Hospital Galway, University Hospital Waterford, Tallaght University Hospital, Beaumont Hospital, St James's Hospital

Study title: A Phase 2 Trial of Adagrasib Monotherapy and in Combination with Pembrolizumab and a Phase 3 Trial of Adagrasib in Combination with Pembrolizumab versus Pembrolizumab in Patients with Advanced Non Small Cell Lung Cancer with KRAS G12C Mutation

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-508341-40-00 SM-3

Institutions: Children's Health Ireland Temple Street

Study title: COACH: A Phase 2, Open-Label, Single-Arm, 156-week Trial to Investigate the Efficacy, Safety and Tolerability of Combined Once Weekly Navepegritide and Lonapegsomatropin in Children with Achondroplasia

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

1. Subject information and informed consent form

Standard Consideration

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
- All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.
- The NREC-CT noted that on page 8 of the Parent PIS, "You should discuss any concerns with your child's study doctor. Your child's study doctor may order other medications to make side effects less serious or to make your child feel more comfortable. The most common side effects that occurred in clinical trials are listed below. These side effects were temporary/short-lived and were mild to moderate in severity". The NREC-CT requested that some further information be added to the PIS so as to advise the Parent/Guardian the likely timeframe of the common side-effects. The NREC also requested that the Parent PIS include an explanation of the course of action if the child were to develop any of the potential long-term consequences during the trial. This should clarify whether the child would be withdrawn from the study, or whether the decision to continue participation would be made collaboratively by the Principal Investigator, the parent or guardian, and the child participant.

2024-514208-15-00 SM-3

Institutions: Children's Health Ireland Temple Street

Study title: teACH: A Phase 2b, Multicenter, Double-Blind, Randomized, Placebo controlled Trial evaluating Efficacy and Safety of Subcutaneous Doses of Navepegritide Administered Once Weekly for 52 Weeks in Adolescents (12-<18 years of age) with Achondroplasia

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-506091-27-00 SM-4

Institutions: Children's Health Ireland Temple Street

Study title: A Phase 2, Multicenter, Double-Blind, Randomized, Placebo-controlled Trial, evaluating Safety, Tolerability, and Efficacy of Subcutaneous Doses of TransCon CNP Administered Once Weekly for 52 Weeks in Infants (0 to <2 years of age) with Achondroplasia followed by an Open Label Extension (OLE) period.

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

1. Subject information and informed consent form

Standard Consideration:

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
- All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.

- The NREC-CT noted from the protocol synopsis that “at least 6 eligible open label sentinel participants are included to evaluate the pharmacokinetic (PK) exposure and acute safety of TransCon CNP in children younger than 2 years of age”. The NREC-CT requests clarification on whether these sentinel participants have already been enrolled in the study. If they have not yet been recruited, please confirm whether any sentinel participants are planned to be recruited in Ireland.
- The NREC-CT noted on pages 2 and 3 of the Parent ICF that the limitation of future research for the child’s data, the child’s remaining biological samples and residual pharmacokinetic samples are no longer limited to Achondroplasia and/or the IMP. The NREC-CT noted that the future use of data / samples (including genetic research) is not described in line with regulations / best practice. The NREC-CT requested that future use of samples / personal data is sufficiently explained to participants in the PISCF documents 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 confined to a specified disease, related diseases 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,
    - 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: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/
- The NREC-CT noted that the conditional approval has not been fully met. The condition is to be fulfilled by approval of the accordingly updated protocol, and other applicable patient-facing documents as part of a substantial modification, prior to initiation of the present clinical trial. The NREC-CT noted that the updated ICF does not contain any reference to enrolment being limited to subjects not eligible to the licensed treatment for any reason (i.e., safety, tolerability, access to licensed product, subject/family compliance, lack of response, etc.). The NREC-CT requests that the Parent PIS be updated to clearly explain this enrolment limitation to the parent/guardian, on page 1 “introduction”.

2023-504962-52-00 SM-12

Institutions: St Vincent's University Hospital, University Hospital Galway, Bon Secours Hospital

Study title: A Phase 3, Randomized, Open-label, Study to Compare the Efficacy and Safety of Adjuvant MK-2870 in Combination with Pembrolizumab (MK-3475) Versus Treatment of Physician's Choice (TPC) in Participants With Triple-Negative Breast Cancer (TNBC) Who Received Neoadjuvant Therapy and Did Not Achieve a Pathological Complete Response (pCR) at Surgery

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2025-520538-49-00 SM-1

Institutions: Rotunda Hospital, Cork University Maternity Hospital, Coombe Women and Infants University Hospital

Study title: ACUMEN: Phase I Dose Escalation and Cohort Expansion study to affirm the safety of pharmacological doses of a novel formulation of intravenous melatonin in babies with hypoxic-ischaemic encephalopathy (HIE) to augment therapeutic hypothermia (HT) treatment; to reduce the incidence and severity of disability in babies with moderate-severe HIE.

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

1. Subject information and informed consent form

Standard Consideration:

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
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Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.

- The NREC-CT noted the conditional approval which includes reference to blood ethanol levels. The NREC-CT noted on page 4 of the Main ICF it states “In this melatonin preparation, a small amount of ethanol (alcohol) is used. This is already found in other common medicines used in newborn care (e.g., furosemide, iron, phenobarbital)” and requested that additional information be included in the Main ICF, to help contextualise the amount of ethanol used in this study. The NREC-CT requests that the ICF explain in lay terminology; the relative amount of ethanol in the melatonin formulation compared to the amounts present in other ‘commonly used’’ medications e.g. furosemide and phenobarbital, and also the total cumulative amount of ethanol that participants may receive during the study.
- The NREC-CT noted on page 5 of the Main ICF “If you decide not to take part, your baby will continue to be monitored on the hospital’s usual EEG machine, and any recordings already made on the ACUMEN machine will be deleted.” The NREC-CT noted on page 53 of the protocol “but this data can be saved for routine clinical purposes. No data from non-consented infants will be uploaded, transferred, or retained by the Sponsor”. The NREC-CT requests that the Main ICF include information that the EEG data on the ACUMEN machine recorded will be made available for clinical review by the hospital team, before deletion.

2022-502215-10-00 SM-12

Institutions: St James's Hospital

Study title: Open-label, long-term safety and efficacy study of Mim8 in participants with haemophilia A with or without inhibitors

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-509345-12-00 SM-6

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