National Research Ethics Committee

NREC-CT Meeting

3rd December 2025

Attendance

Name	Role
Prof Mary Donnelly	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
Dr Deborah Wallace	Committee Member, NREC-CT C
Ms Paula Prendeville	Committee Member, NREC-CT C
Mr Gerry Eastwood	Committee Member, NREC-CT C
Mr Philip Berman	Committee Member, NREC-CT C
Prof Anne Mathews	Committee Member, NREC-CT C
Dr Juan Trujillo	Committee Member, NREC-CT C
Ms Chita Murray	Programme Manager, National Office for RECs
Patricia Kenny*	Project Officer, National Office for RECs

*Drafted minutes

Apologies: John Faul, Fionnuala Breathnach, Susan Kelly, Patrick Forde

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2024-515147-32-02
- 2025-523920-29-00
- 2023-510357-42-00 SM-9
- 2023-508323-12-00 SM-9
- 2022-502851-79-00 SM-13
- 2023-508482-32-00 SM-20
- 2024-516440-25-00 SM-3
- 2024-514173-22-00 SM-7
- 2023-504231-41-01 SM-12
- 2023-504923-20-00 SM-5
- AOB

- The Chair welcomed the NREC-CT C.
  - The minutes from the previous NREC-CT C meeting on 5th November 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2024-515147-32-02

Institutions: Wellcome HRB Clinical Research Facility, Tallaght Adult Mental Health Service

Study title: POSITRON - PsilOcybin with pSychologIcal supporT foR cOcaiNe: a randomised controlled pilot feasibility trial of psilocybin with psychological support for cocaine use disorder

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part I Considerations (RFI) for addition to CTIS

1. The Sponsor is requested to make applicable document corrections in order to align the frequency of DSMB meetings, as the protocol states that the meetings will take place every 4 months (p. 61, section 9.2) but the DSMB charter states the meetings will take place every 6 months.
2. The protocol (p. 66, section 13) states the following: “The trial may be audited by the Trinity sponsor and is open to inspection by the regulatory authority and National Research Ethics Committee (NREC)”. The Sponsor is requested to remove this wording, as the NREC does not have authority to conduct independent site inspection(s).
3. The Sponsor is requested to update the protocol to outline sample management plans for storage, analysis and/or destruction of biological samples to be collected as part of the schedule of assessments

Part II Considerations

1. Compliance with national requirements on data protection

- The NREC-CT noted that document R1_Compliance on the collection and use of personal data (section 5) document refers to a “separate PIL and ICF… for any future studies in this area (biobank)”. However, both L1_SIS and ICF Main and document S1_Compliance on the collection use and storage of biological samples indicate that no samples/data will be stored for future use. The Committee requested confirmation that no samples/data will be retained for future use and asks that the document R1_Compliance on the collection and use of personal data be updated to ensure alignment.

2. Compliance with use of biological samples

- The NREC-CT requested that document S1_Compliance with use of Biological Samples (section 3.1): be updated to clarify the location of the clinical laboratory associated to the research site where the samples will be analysed.

- The NREC-CT noted that document S1_Compliance with use of Biological Samples (section 3.5) indicates that there will be a 'direct connection' between the samples and participants. The Committee commented that pseudonymisation of samples at a minimum is a reasonable expectation, and requests a clear justification if the decision has been made not to pseudonymise samples, or an update to applicable documents.
- The NREC-CT noted that document S1_Compliance with use of Biological Samples states that samples will be destroyed after analyses. However, the SIS and ICF Adults (page 17) states that 'all data and samples collected before withdrawal will need to be stored for 25 years, after the end of the trial, to ensure the safety of the trial'. The Committee requests that the SIS and ICF Adults (page 17) be updated to ensure alignment.

3. Financial arrangements

- The NREC-CT noted that document P1_ Compensation for trial participants indicates that compensation will not be offered for meal expenses for a parent/carer. The Committee requested that consideration be given to reimbursing the cost of meals for individuals accompanying participants to trial visits.

4. Proof of insurance

- The NREC-CT noted that the submitted insurance certificate indicates an expiry date of November 2025. The Committee requested that an updated insurance certificate be provided, and assurance that sufficient insurance will be in place for the duration of the trial.

5. Recruitment arrangements

- The NREC-CT noted that the GP letter includes instruction such as "The day before psilocybin administration…" and "On the morning of the psilocybin session…" etc. If/when the information applies to participants in both study arms (psilocybin and diphenhydramine), the Committee requested that the letter be amended to state "the day before administration of the allocated drug" etc., as applicable. If/when the instruction applies only to the psilocybin arm of the study, please include a statement such as "if your patient has been randomised to the psilocybin arm,…" etc.
- The NREC-CT requested that document K1_ Recruitment arrangements be updated to clarify when and how the Patient Letter will be given to the participant.
- The NREC-CT requested that document K1_ Recruitment arrangements be updated to clarify the location(s) where the recruitment advert will be displayed.
- The NREC-CT noted that the Patient Letter states "The POSITRON Clinical Trial team includes researchers at Trinity College Dublin and Tallaght University Hospital" and requests that the letter be updated to include reference to St. James's Hospital in the interests of transparency and to ensure that participants are fully informed.
- The NREC-CT requested that the GP letter be updated to replace reference to "subjects" with "participants".

6. 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 requested that document SIS and ICF Adults be updated as follows:
  - (page 4) “oocytes” should be defined in lay language
  - (page 11) remove duplication of paragraphs 1 and 2
- The NREC-CT requested that SIS and ICF Adults (page 15) be updated to provide more detail with regard to handling, storage and/or destruction of biological samples.
- The NREC-CT noted that the SIS and ICF Adults (pages 7, 8 and 9) describe the effects of the active treatment, while page 10 refers only to the effects of active placebo. The Committee advises this could potentially allow participants to deduce their treatment allocation based on side effects, which may lead to unblinding and compromise the validity of study results, and which could also influence their responses in subsequent assessments. While acknowledging it is appropriate for participants to be informed of possible effects of active treatment, the Committee requests that the SIS and ICF Adults be updated throughout to use more general language regarding treatment and potential side effects of both treatments without specifying which drug is associated with which effect to address the above concern.
- The NREC-CT noted that the protocol (page 65) states that *“Data will be entered into the encrypted electronic database located on a dedicated secure server in France”.* The Committee requests that SIS and ICF Adults (page 15) be updated to include:
  - Confirmation that the trial data will be transferred and stored in France
  - Details of what data will be stored
  - Whether the data will be identifiable or pseudonymised
  - The duration for which the data will be stored
  - What will happen to the data at the end of storage period
- The NREC-CT noted that the protocol (page 65) states that *“*All paper documents will be stored safely in a designated locked filing cabinet in Dr John R. Kelly’s locked office within Sheaf House and confidentiality will be observed at all times”. However, SIS and ICF Adults (page 16) only refers to trial data being archived by Trinity College Dublin for 25 years. The Committee requested that SIS and ICF Adults (page 16, section “How long will we keep your data for this trial”) be updated to outline that paper documents will be securely stored in a locked filing cabinet in St James Hospital, until such time that they are securely archived, in addition to the location and duration of archiving.
- The NREC-CT noted that the SIS and ICF Adults (page 15) states that “auditors and representatives from the National Office for Research Ethics Committees (NREC), may require direct access to the research dataset and your medical records”. The Committee requests that this statement be removed, and that the PISCF is amended to state that only pseudonymised data relating to safety

information may, under specific and appropriate circumstances, be shared with the NRECs, for example at the request of the Health Products Regulatory Authority.

- The NREC-CT noted that the SIS and ICF Adults (page 15) states "All staff working on trials are governed by a professional code of ethics to maintain your confidentiality" and requests that this statement be updated to include reference to adherence to the requirements of GDPR.
- The NREC-CT noted that the SIS and ICF Adults (page 1), GP letter (page 2 and 3) and Patient letter (page 2) refers to the Trial Coordinator by name (Annie Baker). The Committee requested that the documents be updated to remove the study team member's name, for the purposes of NREC review, the name can be reinserted following review.

2025-523920-29-00

Institutions: Institute of Eye Surgery Whitfield Hospital

Study title: A Phase 1b Open-Label, Randomized, Single Dose and Repeat Dose Study to Evaluate the Single and Repeat Dose Safety and Tolerability of Intravitreally Administered PYC-001 in Participants with Confirmed OPA1 Mutation-Associated Autosomal Dominant Optic Atrophy

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part I Considerations (RFI) for addition to CTIS

1. It was noted that the protocol (page 83) states that "'Compensation will only be provided on the understanding that the provision of compensation does not amount to an admission of legal liability and is participant [sic] to the proposed recipient signing a full and complete release of the company from all claims, damages, and costs." The Sponsor is required to update the applicable document(s) to provide assurance that insurance arrangements for the trial:
   - Will adequately protect the participant,
   - Will not require the participant to give "a full and complete release of the company from all claims damages and costs" if that waives legal rights or releases the sponsor/investigator from liability for negligence, and
   - Will comply with the requirements of the Clinical Trial Regulations (Article 76) as per SI 41/2022 (Reg. 19(4)(k))

Part II Considerations

1. **Financial arrangements**

- The NREC-CT noted that document ‘Patient and Caregiver Meals and Incidentals’ does not indicate the maximum allowable daily reimbursement amount for meals. The Committee requests that the document be updated to include this amount, as applicable.

2. Recruitment arrangements

- The NREC-CT noted that document ‘Recruitment and Informed Consent procedure IRL’ (Section 1.1) states “Potential participants will be identified by the clinical team involved in the treatment of these patients. Most likely via a database search and review of patients coming into routine clinics and patients' medical records”. The Committee requests clarification with regard to the term “database search”. Please confirm whether this refers to a research registry or clinical database with appropriate data protection measures, where individuals have consented to be contacted in relation to future research.

3. 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 the SIS and ICF Main (page 36, Consent / Understand Section) includes a number of consent statements. The Committee requests that these consent statements be moved to the Informed Consent Form section (pages 37-38) with signatures to ensure explicit consent.
- The NREC-CT notes inconsistencies regarding the future use of biological samples between the Biological Samples document and the SIS and ICF Main which state that no samples will be used for future research but also describes use of samples for future research or commercial profit. (SIS and ICF Main pages 28 and 32, SIS and ICF Pre-screening pages 8 and 9). Please clarify and update Compliance for use of Biological Samples document and SIS and ICFs to align, ensuring that the future use of biological samples is described in line with regulations/best practice so 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 made optional
    - 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,
- optional future research is made into a separate and explicit consent item in the Informed Consent section of the Main PISCF, with separate participant information section and 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: 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 SIS and ICF Main (page 31), and the SIS and ICF Pre-screening (page 7) includes the terms 'health insurance number' and 'NHS number'. The Committee requests that the documents be updated to remove
- these terms, as they are not relevant to participants in Ireland.
- The NREC-CT noted that the SIS and ICF Main Pregnancy (page 2) states "Compensation for Participation: You will be reimbursed for travel expenses and provided compensation". The Committee requests clarification or removal of this statement as the SIS and ICF Main Pregnancy (page 2) also states that "There will be no medical tests, procedures, or study visits as part of your and your newborn's participation in this follow-up"..
- The NREC-CT noted the use of terms in the SIS and ICF Main which may not be readily accessible to a lay audience. The Committee requests that the SIS and ICF Main be updated with lay language explanations for the following to ensure participants fully understand:
  - page 3: Background and Purpose section
  - Page 3: The term "µg"
  - Page 3: description of volume of drug being injected into eye (10, 30 and 60 micrograms) and what this means in lay terms
  - Page 9: All acronyms used such as HBV and HCV
  - Page 21: The term 'retinal detachment'
- The NREC-CT noted the statements below in the SIS and ICF Main. The Committee seeks confirmation that future research with biosamples will not take place, that commercial profit gained will be associated with trial activities only, future research, and that biosamples will be destroyed as outlined.
- Page 28: "Future Research Studies: Your private information or biospecimens collected during this study will not be used or distributed for future research studies, even if identifiers are removed.
- Page 28: "Commercial Profit: Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and you will not share in this profit"
- Page 34: "The study data will then be fully anonymized and securely archived or destroyed"

4. Suitability of the investigator

- The NREC-CT noted that the GCP certificate provided for Dr. Ng is dated 2023, while the CV provided for Dr. Ng indicates he completed this course in 2025. The

Committee requests confirmation of the date of the most recent ICH-GCP training for Dr Ng.

2023-510357-42-00 SM-9

Institutions: Mater Private Hospital, University Hospital Limerick, Beaumont Hospital, Cork University Hospital, St James's Hospital, University Hospital Waterford, St Vincent's University Hospital, Mater Misericordiae University 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 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 requests that the Main ICF Addendum 2 (page 7) be updated to include tick / initial box beside each consent statement to ensure explicit consent.

2023-508323-12-00 SM-9

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

Study title: A Phase 3 Randomized, Active-controlled, Open-label, Multicenter Study to Compare the Efficacy and Safety of MK-2870 Monotherapy Versus Treatment of

Physician's Choice as Second-line Treatment for Participants with Recurrent or Metastatic Cervical Cancer (TroFuse-020/GOG-3101/ENGOT-cx20)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2022-502851-79-00 SM-13

Institutions: Our Lady's Hospital Manorhamilton, Connolly Hospital, St Vincent's University Hospital

- Study title: A Phase 3, Single-Arm, Multicenter, Open-label Extension of Study

ARGX-113-2007 to Investigate the Long-term Safety, Tolerability, and Efficacy of Efgartigimod PH20 SC in Participants Aged 18 Years and Older With Active Idiopathic Inflammatory Myopathy

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

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 the future use of data / samples is not described in line with regulations / best practice in SIS ICF (page 8) which states that "*Samples unused in the study may be used for further nongenetic (unrelated to heredity or DNA) medical, academic, or scientific research for immunology'*)", however the term 'immunology' is considered too broad. The Committee requested that SIS and ICF (page 8) be updated such that future research is confined to a specified disease, related diseases or drug under study in this trial, as required under the

Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).

- The NREC-CT noted that SIS ICF Main (page 6) has been updated to include the statement “You must use 1 of these methods of contraception until your final dose of the study drug: *No heterosexual intercourse during the period you receive study treatment (only if this is your preferred and usual way of living*). The Committee finds this wording unclear and requests that this be reworded using plain English suitable for a lay audience.

2023-508482-32-00 SM-20

Institutions: Children’s Health Ireland

Study title: A Phase 3, randomized, double-blind, placebo-controlled, multicenter study of mavorixafor in participants with congenital and acquired primary autoimmune and idiopathic chronic neutropenic disorders who are experiencing recurrent and/or serious infections

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2024-516440-25-00 SM-3

Institutions: Mater Misericordiae University Hospital

Study title: MOONRAY-01, A Phase 1a/1b Trial of LY3962673 in Participants with KRAS G12D-Mutant Solid Tumors

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2024-514173-22-00 SM-7

Institutions: St Vincent’s University Hospital, University Hospital Limerick, Children’s Health Ireland Crumlin, Children’s Health Ireland Temple Street, Cork University Hospital

Study title: A Phase 3, Open-label Study Evaluating the Long- term Safety and Efficacy of VX-121/TEZ/D-IVA Combination Therapy in Subjects With Cystic Fibrosis

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-504231-41-01 SM-12

Institutions: University Hospital Galway, Mater Misericordiae University Hospital

Study title: A Randomized, Open-Label Phase 2/3 Study of BT8009 as Monotherapy or in Combination in Participants with Locally Advanced or Metastatic Urothelial Cancer

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-504923-20-00 SM-5

Institutions: Tallaght University Hospital

Study title: A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

- AOB:
  - None