National Research Ethics Committee

NREC-CT Meeting

12th November 2025

Attendance

Name	Role
Prof David Brayden	Chairperson, NREC-CT D
Prof David Smith	Deputy Chairperson, NREC-CT D
Dr Christina Skourou	Deputy Chairperson, NREC-CT D
Prof Andrew Green	Committee Member, NREC-CT D
Prof Cathal Walsh	Committee Member, NREC-CT D
Dr Geraldine O'Dea	Committee Member, NREC-CT D
Prof Lina Zgaga	Committee Member, NREC-CT D
Dr Mary McDonnell Naughton	Committee Member, NREC-CT D
Prof Geraldine O'Sullivan Coyne	Committee Member, NREC-CT D
Ms Chanel Watson	Committee Member, NREC-CT D
Dr Jeff Moore	Committee Member, NREC-CT D
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Jane Bryant	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Ms Patricia Kenny*	Project Officer, National Office for RECs
Rachel McDermott	Project Administrator, National Office for RECs

*Drafted minutes

Apologies: Deirdre Murray, Gerry Daly, Deirdre MacLoughlin

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2024-518819-19-00
- 2025-523530-30-00
- 2024-518895-30-00
- 2024-517422-25-00 SM-1
- 2023-504931-42-00 SM-9
- 2023-507890-17-00 SM-11
- 2023-509877-22-00 SM-5
- AOB

- The Chair welcomed the NREC-CT D.
  - The minutes from the previous NREC-CT D meeting on 8th October 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2024-518819-19-00

Institutions: St Vincent's University Hospital

Study title: Phase II Study of datopotamab-deruxtecan (Dato-DXd; DS-1026a) in triplenegative breast cancer patients with newly Diagnosed or progressing brain metastases

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**
- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. **Compliance with national requirements on data protection**

- The NREC-CT requests that Section 2 (Legislative compliance) in the NREC Statement of Compliance document be updated to make reference to the Irish Data Protection Commission and include details of how to contact them.

2. **Compliance with use of biological samples**

- The NREC-CT notes that biological samples are being collected and requests that the form "S1_Compliance with use of human biological samples template" be completed and submitted for review. Please note that this form must be completed and submitted regardless of whether biological samples are being collected or not. If biological samples will be stored for future use this must be clearly stated in SIS and ICF and should include the following details::
    - that future use is confined to a specified disease, related diseases or drug under study in this trial
    - if future research is not confined as above participants should be asked to consent to being contacted in the future when research is defined,
    - it should be clear to participants that subsequent research ethics review will be sought for all future research studies.
    - information should be provided on how long samples will be stored, where they will be stored and who will have access to the samples.
    - Please refer to NREC guidance on use of biological samples and associated data for further information https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/

3. **Financial arrangements**

- It was unclear to NREC-CT whether participants lacking capacity will be enrolled in the trial, as the Compensation for trial participants refers to reimbursement for legal representatives, however the SIS and ICF contains no mention of legal representatives. The NREC-CT requests that either the Compensation for trial participants or SIS and ICF be updated to clarify this point.

- The NREC-CT requests that a separate document with sponsor logo be provided confirming source of funding for trial. We cannot accept the wording added to the end of the Compensation for trial participants document.
- The NREC-CT requests that Compensation for trial participants document Section 3 be completed.
- The NREC-CT notes that Compensation for participants document advises that only travel expenses will be reimbursed however the study protocol page 39 states "*reimbursement of travel expenses, all reasonable out of pocket expenses and compensation for time and inconvenience*" may be paid. The Committee requests that the Compensation for participants document and SIS and ICF be updated to include reimbursement for reasonable out of pocket expenses (including the mouthwash which is a requirement of trial participation) and time and inconvenience, and provide clear details on the process for reimbursement, to align with the protocol, and to ensure equity in access to clinical trials across all socioeconomic groups.

4. 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 the SIS and ICF page 1 be updated to include the EU trial number for participants.
- The NREC-CT requests that the SIS and ICF page 11 consent statement *"I have also read the text of this patient information and consent form, which comprises a total of 11 pages"* be updated to include that the participant understands the information.
- The NREC-CT notes on page 3 SIS and ICF End of treatment and follow up. section "*You will then be contacted after 3, 9, 18 and 30 months to see how you are feeling, subject to your consent."* It was unclear to the Committee how participants provide consent for this follow up. The Committee requests the SIS and ICF Section 15 Consent form be updated to include separate and explicit consent item for this follow-up. This should be on a separate page with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research.
- The NREC-CT requested that the SIS and ICF be updated to provide information about the availability of the clinical trial results at the end of the trial and location of same.

- The NREC-CT notes page 25 of Protocol Visit and Assessment Schedule refers to optional blood samples and page 41 of protocol refers to optional additional PET-CTs however these are not referred to in the SIS and ICF. Please clarify and update SIS and ICF as appropriate.
- The NREC-CT notes that the SIS and ICF has used a bundled approach to consent in the Informed Consent Section of the PISCF and requested that a layered approach to consent is used (in that each consent item is listed and a box for participants to provide their initials is included alongside each consent item) in line with HSE policy Please see HSE National Policy for Consent in Health and Social Care Research (V2.1, 2025). Dublin: Health Service Executive https://www2.healthservice.hse.ie/organisation/national-pppages/hse-national-policy-for-consent-in-health-and-social-care-research/
- The NREC-CT requests that page numbering of the SIS and ICF be corrected as every page currently reads "Page 1 of 11".
- The NREC-CT notes from the Compensation for trial participants document that travel expenses are to be reimbursed for participants, carers and legal representatives. The Committee requests that the SIS and ICF page 10 be updated to detail this.
- The NREC-CT requests that SIS and ICF be updated to provide lay language explanation for:
    - Page 1 brain metastases
    - Page 2 PARP inhibitor
    - Page 4 Obstipation
    - Page 6 pruritis
    - Page 7 *"with the exception of damage due to changes in the genetic material in germline cells"*
- The NREC-CT requests that SIS and ICF be updated to clarify the following:
    - Page 7 provide an explanation why "*damage due to changes in the genetic material in germline cells"* is not covered by insurance
    - Page 8 *"Information for women of childbearing potential…":* The last point in this paragraph *("provide safe contraception…newly produced sperm cells")* is confusing and difficult to follow. Please rephrase in a clearer lay language manner..
    - Page 9 Data processing the statement: *"In addition, the right to data portability is suspended in the case of a clinical trial under the Medicinal Products Law."* It is unclear what this statement actually means; please rephrase for clarity.
- The NREC-CT requests that page 1 SIS and ICF be updated to include reference to and explanation of TUXEDO-2.
- The NREC-CT requests that page 9 SIS and ICF be updated to explicitly state for participants that refusal to take part in or withdrawal from the trial won't affect their care.
- The NREC-CT requests that pages 2 and 3 of the SIS and ICF be updated to detail the duration of each visit
- The NREC-CT notes on page 3 of the SIS and ICF it states that CT and MRI scans will be performed every 9 weeks and that *"these examinations would also be performed if you do not participate in the study",* however the Site Suitability Form

section 5 states “They will receive some additional radiation burden, which is above that anticipated in routine clinical care”. The Committee requests clarification on the level of excess radiation exposure associated with participation in the study is and how this compares to standard of care. Additionally, the Committee requests that SIS and ICF be updated to include this information such that the participant is fully informed.

- The NREC-CT request that page 5 of the SIS and ICF be updated to give a more detailed explanation of what lung disease is, given it is a major and potentially fatal risk.
- The NREC-CT requested that the details provided on L2_information sheet (guidance on oral health) is also incorporated into the SIS and ICF.

5. Suitability of the investigator

- The NREC-CT requests clarification is provided in relation to [redacted] CV, specifically the section on Relevant Clinical Trial/Study Experience. All 13 studies listed, where [redacted] is a Sub-Investigator or Principal Investigator, appear to have commenced in year 2000. Please confirm if this is correct or amend accordingly.

2025-523530-30-00

Institutions: University Hospital Galway

Study title: Single-centre, open-labelled, randomised, and placebo-controlled phase 1 clinical trial investigating the safety and tolerability of ascending multiple doses of nebulised SS0331 in healthy participants

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**
- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. Proof of insurance

- The NREC-CT requests that a study specific insurance certificate be provided prior to granting study approval.

2. Recruitment arrangements

- The NREC-CT notes that the healthy volunteers for this trial will be recruited via university and hospital groups via email. The Committee requests the Recruitment arrangements document be updated to include clarification on the safeguards in place to ensure that recruitment does not result in undue accrual or enrolment and that unequal power dynamics are mitigated against given that the Principal Investigator, and possibility other research team members, work at both Galway University Hospital and University of Galway where recruitment will take place.

- The NREC-CT requests that the Flyer be updated to include information in relation to whom to contact if interested in participating.

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 requested that the Participant Information Leaflet page 24 be updated to include a specific statement that the participant confirms that a copy of the signed and dated Informed Consent Form will be provided to them and that a copy will be retained by the study doctor.
- The NREC-CT requested that the Participant Information Leaflet page 1 be updated to include the EU trial number for participants.
- The NREC-CT requested that the Participant information Leaflet page 18 be updated to provide information about the availability of the clinical trial results at the end of the trial on European clinical trials database/website and details of how to access same.
- The NREC-CT requests that Participant Information Leaflet page 1 and footer throughout be updated to include the date.
- The NREC-CT notes page 3 Participant Information Leaflet – *"in the event of an emergency contact the hospital at 091 524222 and request Professor Melissa McDonnell".* The Committee requests that participants be provided with further information on what to do in the event of an emergency, including contacting emergency services, details as to when the number provided will be available to contact etc.
- The NREC-CT note page 10 Participant Information Leaflet states that participants will receive two doses of IMP *"3-15 hours apart".* The Committee requested that greater clarity on the timing of the dosing be provided to the participants.
- The NREC-CT requests that Page 19 Participant Information Leaflet be updated to provide a lay language explanation for the term*" sentinel participants"*
- The NREC-CT requests that page 17 Participant Information Leaflet be updated to fully inform participants about compensation arrangements, including the amount, process and options for reimbursement and if there is a requirement to provide receipts.
- The NREC-CT note reference that data may be *"transferred to associated researchers within/outside the European Union (EU)"* on page 24 Participant Information Leaflet. The Committee requested that Participant Information Leaflet page 19 be updated as follows:

- list of persons whom data may be shared with be updated to include detail about these associated researchers
- sharing your data section be updated to include detail that data may be shared both inside and outside of the EU.

2024-518895-30-00

Institutions: Children's Health Ireland Crumlin

Study title: A Phase 2 Study of Mutant-selective PI3Kα Inhibitor, RLY-2608, in Adults and Children with PIK3CA Related Overgrowth Spectrum and Malformations Driven by PIK3CA Mutation

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**
- Request for Further Information

- **Additional Information Required**

Part II Considerations
1. Proof of insurance
• The NREC-CT notes the insurance certificate provided indicates 10 participants will be recruited in Ireland however the Site Suitability From states 1-2 participants. The Committee requests clarification on the actual number of participants to be recruited in Ireland and asks that all relevant documentation be updated accordingly.
2. Recruitment arrangements
• The NREC-CT acknowledges that adults lacking decision making capacity are not included in this trial. The Committee notes that certain PIK3CA disorders (e.g. MCAP) may result in mental incapacity and expressed concern that these patients could be excluded. The Committee requests clear justification for the decision not to recruit participants from this group.
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.
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- The NREC-CT notes Participant/Parent/Guardian ICFs (Part 1-2 and Part 3) page 3 *states "The study may then open enrolment to an additional group of patients ages 2 to less than 6 to also receive increasing doses of the study drug until side effects are seen that mean the dose shouldn't be increased further"* . If this age group are to be recruited in Ireland, the NREC-CT requests that an assent form be provided for this additional group of participants.
- The NREC-CT notes that combined Participant/Parent/Guardian ICF Parts 1-2 and Participant/Parent/Guardian ICF Part 3 has been provided, however, the Committee is concerned that merging participant and parent forms may cause confusion for parents. The Committee therefore requests that separate ICFs be submitted for review (1) one for participants and (2) one for parent/guardians for both Parts 1-2 and Part 3. Please ensure the parent/guardian consent forms includes a section for the participating child's name to be recorded.
- The NREC-CT requests that the Assent ICF Ages 6-11 be updated to include clear information about the child's diagnosis and to explain that their parents are being asked to consent for their participation in the trial.
- The NREC-CT notes that the Assent ICF Ages 12-15 (Parts 1-2 and Part 3) are lengthy and detailed. The Committee requests that these documents be condensed into a more concise summary appropriate for this age group.
- The NREC-CT notes that page. 3 of Participant/Parent/Guardian ICF (Part 1-2 and Part 3) states that the purpose of Part 1 of the study is *"to determine the dose (s) of RLY-2608 that provides the most benefit".* The Committee requests that this be corrected to align with the stated purpose of the study ("learn about the safety and effectiveness"), as it may lead participants to believe they will personally benefit from participation in a dose safety study.
- The NREC-CT requests that page 26 Participant/Parent/Guardian ICF Parts 1-2 and Participant/Parent/Guardian ICF Part 3 be updated to include a consent statement for participants to consent to the processing of their data processing collected in the course of this clinical trial as described in the Privacy of Health Information section of the ICF. "

4. Suitability of the clinical trial sites facilities

- The NREC-CT notes the study is described as including adults however CHI only treats children up to 16 years of age. Given that there is no adult hospital listed as a study site, the Committee requests clarification:
    - if only children will be recruited to this trial in Ireland
    - on the arrangements for participants who reach the age of 16 during the study.
- The NREC-CT note that section 4 of Site Suitability Form states "If required, echo will be carried out at a private facility". The Committee requests that the Site Suitability Form be updated to clarify what private facility this is, when known, and , Participant/Parent/Guardian ICFs be updated in tandem to inform participants they will need to travel to another location to have ECHO.

2024-517422-25-00 SM-1

Institutions: Cork University Hospital, Tallaght University Hospital, Beaumont Hospital

Study title: A Phase 3, Two-part, Randomized, Open-label, Adaptive Study Comparing BMS-986365 versus Investigator's Choice of Therapy Comprising Either Docetaxel or Second Androgen Receptor Pathway Inhibitor (ARPI), in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) - rechARge

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.
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- The NREC-CT requests that pg. 3 SIS and ICF Treatment Beyond Progression be updated to include a specific consent statement for processing of data.

2023-504931-42-00 SM-9

Institutions: University Hospital Limerick, Beaumont Hospital

Study title: A Phase 2 Study to Evaluate the Efficacy and Safety of MK 1026 in Participants with Hematologic Malignancies

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 requested that the Summary PIS be updated to include additional information on the possible adverse effects of the drug

2023-507890-17-00 SM-11

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

Study title: A Phase 3, Double-Blind, Randomized Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) Versus Placebo in Subjects with Myeloproliferative Neoplasm-Associated Myelofibrosis on Concomitant JAK2 Inhibitor Therapy and Who Require Red Blood Cell Transfusions

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 clarify the reason for the extension of trial duration.

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 notes the changes to the ICF in relation to safety profile and requests clarification if and when participants on trial will be reconsented.
- The NREC-CT requests that page 19/20 Main ICF be updated with plain language heading throughout the paragraph including heading currently titled “MF”

2023-509877-22-00 SM-5

Institutions: Children’s Health Ireland Crumlin

Study title: A Phase 3, Prospective, Open-label, Uncontrolled, Multicenter Study on Efficacy and Safety of Prophylaxis with Vonicog Alfa (rVWF) in Children Diagnosed With Severe von Willebrand Disease

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.
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- The NREC-CT notes that pg. 5 SIS and ICF Main Parent Legal Guardian and pg. 5 SIS and ICF Turning 16 have been updated to include information on the post trial access programme. The Committee requests that both SIS and ICFs be updated to also provide further clarity on the length of the programme (two years) and how access will be determined (participants whom the Principal Investigator considers likely to benefit). The Committee also requests that the term “qualified patients” be

revised as it suggests a certain status must be achieved which could be misleading.

- The NREC-CT requests that page 25 of SIS and ICF Main Parent Legal Guardian be updated to make it explicitly clear that future use of data is optional and participants will be asked to consent to be contacted about future research studies.
- The NREC-CT notes the addition of wording on page 12 SIS and ICF Main Parent Legal Guardian *"In the event the Sponsor sells the study drug to another company conducting clinical research, your child's samples collected as part of this study may be shared with that company as part of that transaction".* The Committee requests that SIS and ICF be updated to provide detail on safeguards or reassurances to participants regarding protection of their privacy and the use of their data and/or samples is in accordance with the consent they have given for this trial.
- The NREC-CT requests that Assent guide 12-17 year old be updated to 12-16 year old.

- **AOB:**
  - None