National Research Ethics Committee

NREC-CT A Meeting

4th February 2026

Attendance

Name	Role
Prof. Alistair Nichol	Chairperson, NREC-CT A
Ms Caoimhe Gleeson	Deputy 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 Dawn Swan	Committee Member, NREC-CT A
Dr Darren Dahly	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 Margaret Cooney	Committee Member, NREC-CT A
Dr Sean Lacey	Committee Member, NREC-CT A
Ms Mandy Daly	Committee Member, NREC-CT A
Ms Muireann O'Briain	Committee Member, NREC-CT A
Ms Dympna Devenney	Committee Member, NREC-CT A
Ms Shaunagh Galgey	Committee Member, NREC-CT A
Dr Isobel Cunningham	Committee Member, NREC-CT A
Ms Carol Ann OShea	Committee Member, NREC-CT A
Dr Mary Fitzgerald	Committee Member, NREC-CT A
Dr Jane Bryant	Programme Officer, National Office for RECs

Dr Laura Mackey	Programme Officer, National Office for NRECs
Dr Susan Quinn	Programme Manager, National Office for NRECs
Dr Peadar Rooney*	Project Officer, National Office for NRECs
Ms Deirdre Ní Fhloinn	Project Officer, National Office for NRECs
Ms Rachel McDermott	Project Administrator, National Office for NRECs

*Drafted minutes

Apologies: Dr Maeve Kelleher, Dr David Byrne, Dawn Swan, Mrs Erica Bennett, Dr Caitriona Ryan

Quorum for decisions: Yes

Conflict of Interest: None

Agenda

- Welcome & Apologies
- 2023-508047-40-00
- 2025-522748-42-00
- 2025-524002-16-00
- 2022-501254-10-00 SM-37
- 2024-515092-36-00 SM-3
- 2023-505616-38-00 SM-7
- 2023-508852-21-00 SM-3
- 2024-516009-22-00 SM-6
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 7th January 2026 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-508047-40-00

Institutions: St James's Hospital, Cork University Hospital, St Vincent's University Hospital

Study title: A Phase 3, Randomized, Open-label, Multicenter Study of Sacituzumab Tirumotecan (sac-TMT, MK-2870) Maintenance Treatment With or Without Bevacizumab Versus Standard of Care in Participants With Newly Diagnosed Advanced HRD-Negative Ovarian Cancer Following First-line Platinum-based Chemotherapy (TroFuse-021/ENGOTov85/ GOG-3102)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. **Financial arrangements**

- The NREC-CT noted that in the P1_compensation for trial participants, section 3 states "Where applicable, the participant's carer/companion may also be reimbursed for the above expenses, if accompanying the participant for the duration of the trial visit". The NREC-CT noted in section 2 that the carers are not included in the tick box options for who will be offered compensation. The NREC-CT requested that section 2 and section 3 are aligned.

2. **Recruitment arrangements**

- The NREC-CT noted on page 5, section 5 of the document "K2_Recruitment Doc Summary PIS", the statement "you will be offered monetary payments for clinical trial visits". The NREC-CT requests that this is removed from this recruitment document.
- The NREC-CT noted that in the P1_compensaiton for trial participants, section 3 states "Where applicable, the participant's carer/companion may also be reimbursed for the above expenses, if accompanying the participant for the duration of the trial visit". The NREC-CT requests that the information that carers are being offered compensation for trial visits is included in the "Expenses and payments" section on page 5 of the summary participant information sheet.
- The NREC-CT requests that text relating to the voluntary nature of the clinical trial is added to the summary participant information sheet. The NREC-CT requests the bullet points below from the Main PISCF are added to page 1 of the summary participant information sheet.
  - "Taking part in this trial is voluntary. It is up to you to decide whether or not to take part"
  - "If you decide to join the trial, you can leave at any time without providing a reason, by telling the trial doctor your decision."

3. **Subject information and informed consent form**

Standard Consideration:

1. 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.
2. 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 in the P1_compensaiton for trial participants, section 3 states “Where applicable, the participant’s carer/companion may also be reimbursed for the above expenses, if accompanying the participant for the duration of the trial visit”. The NREC-CT requests that the information that carers are being offered compensation for trial visits is included in the “Expenses and payments” section on page 18 of the Main PISCF
- The NREC-CT noted that optional Greenphire PISCF. The NREC-CT requests that the process if a participant declines to use the Greenphire services is detailed in the Greenphire PISCF on page 1 and in the “Expenses and payments” section on page 18 of the Main PISCF.
- The NREC-CT noted that in S1_Compliance with use of biological samples, section 5.2.8, it is explicitly stated that there will be no future research and that samples will be destroyed. However, in the Main PISCF it is stated that samples will be used for biomarker research and genome will be used for “research purposes only.” The NREC-CT requests that clarity is provided in the PISCF regarding whether this sample collection is mandatory as part of the study, and the S1_compliance with use of biological samples and relevant PISCFs are revised to align if required. If optional future research is taking place, this must be clearly optional with separate consent, and must be confined to a specified disease, related disease or drug under study.
- The NREC-CT noted that page 11 of the Main PISCF states that participants may undergo whole genome / whole exome sequencing “This research may include whole exome or whole genome sequencing.” And “The whole exome and whole genome sequencing results are for research purposes only.” and requested the following:
    - Genomic sequencing is confined to genes involved in the disease being treated or related diseases and /or genes involved in the metabolism of the medicines being used in the trial and this is elucidated in the PISCF.
    - Explicit consent, including outlining the risks entailed in such analysis being performed, is added to the PISCF.
    - The possible ownership of such data by private or commercial interests and that this elucidated in the PISCF.
    - The right to withdraw genetic data, and clear information on how to do so, must also be provided in the PISCF.
    - Clarification is provided in the PISCF on the mechanism for anonymisation, storage and security and transfer of genetic material and its associated data.
    - For guidance, please see HSE National Policy for Consent in Health and Social Care Research (V2.0, 2024). Dublin: Health Service Executive https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-national-policy-for-consent-in-health-and-social-care-research
- The NREC-CT noted that page 26 of the Main PISCF, page 12 of the optional limited screening PISCF and page 6 of the Greenphire PISCF includes a witness

signature line. The NREC-CT requests information be added to all relevant PISCF's explaining the context where a witness signature would be needed (as per CTR: Annex I,L 62(b)).

4. Suitability of the investigator

- In alignment with the training expectations outlined by the Health Products Regulatory Authority (HPRA), the NREC-CTs request that Principal Investigators [redacted] have completed training on the current revision (R3) of ICH E6 (Good Clinical Practice) in order to ensure the rights, safety and well-being of trial participants, as well as the integrity of trial data.
- The NREC-CT noted the submission of the GCP-ICH R3 certificate of [redacted]. The NREC-CT noted that the CV of Dr Collins states the GCP ICH was last updated in 2022. The NREC-CT requested that [redacted] CV is revised to include the completed ICH E6 (R3) Good Clinical Practice completed in Aug 2025.

2025-522748-42-00

Institutions: None

Study title: A Phase 3, Randomized, Open-Label Study of INCB123667 Versus Investigator's Choice of Chemotherapy in Participants With Platinum Resistant Ovarian Cancer With Cyclin E1 Overexpression (MAESTRA 2)

Dossiers Submitted: Part I

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part I Considerations

- It was noted that the EMA scientific advice on page 6 states "The dual primary endpoints are not supported, and the primary endpoint should preferably be overall survival (OS) in this setting". It is requested that the sponsor clarifies if the sponsor is using dual primary or overall survival endpoints.
- It was noted that the EMA scientific advice on page 6 states: "Additionally, based on the recommendations, bevacizumab should be recommended in combination with weekly paclitaxel, PLD or topotecan in patients without contraindications to bevacizumab and not previously exposed to bevacizumab". It is requested that the sponsor clarity if bevacizumab will be allowed as part of treatment options for the investigator.
- It was noted on page 39 of the protocol it states: "Treatment-emergent adverse events were reported in 97.8% of participants (n = 219), with 85.7% (n = 192) having TEAEs deemed related to INCB123667 by the investigator (TRAEs). The most frequently (> 15% of participants) reported hematological TEAEs included." It subsequently states on page 40 of the protocol "Serious TEAEs were reported in

16.1% of participants (n = 36).” It is requested that clarity is provided regarding the details of these serious TEAEs.

- It was noted on pages 40, 41 and 42 of the protocol that INCB123667 has an “Acceptable safety profile” It is requested that the sponsor clarifies the parameters of an acceptable safety profile.

2025-524002-16-00

Institutions: Beaumont Hospital

Study title: A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Pridopidine in Participants with Amyotrophic Lateral Sclerosis

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part I Considerations

- It was noted in the EMA scientific advice it was strongly recommended that the trial length should be greater than 48 weeks. It is requested that the sponsor clarifies the decision not to increase the double-blind period, and its implications for participant involvement and the results of the trial.
- It was noted that page 39 and page 44 of the protocol has provisions for the transition to PEG feeding tube during the course of the study, i.e., “For delivery via enteral feeding such as PEG, the capsule can be opened and the contents diluted in 20-30 mL of water and mixed”. It is requested that the sponsor clarifies that opening the IMP capsule for PEG administration does not affect the integrity of blinding, and that appropriate measures are in place to prevent unintentional unblinding.
- It was noted on page 39 of the Protocol, inclusion criteria no. 11 states that in countries with regulatory approval, participants can continue with edaravone. However, it is also noted on page 40 of the protocol that the exclusion criteria state participants may continue treatment with Neudexta in countries with regulatory approval. It is requested that the inclusion and exclusion criteria be aligned.
- It was noted on page 50 of the Protocol that “If a clinic visit is replaced by a virtual visit, a limited number of assessments shall be performed”. It is requested for the sponsor to clarify if participants are unable to attend visits: 1) how will ECG data be obtained and 2) how will the absence of this data affect the study endpoints and data quality.
- It was noted that the study drug will be provided in high-density polyethylene bottle with a child-resistant cap. It is requested that specific considerations are provided in the protocol for participants who may require support with opening the IMP bottle. This may include 1) caregivers training for IMP administration 2) any

requirement for recording the IMP administrator in the case report form, 3) alternative administration of the capsule, if required.

Part II Considerations

1. Recruitment arrangements

- The NREC-CT noted in section 1.6 of the recruitment and informed consent document. "There is no limit to the time a potential participant may consider the information provided, before they decide to participate and provide consent." The NREC-CT requests clarification if the potential participants are allowed to leave with the consent resources given to them and read the information and return, so that participants are given sufficient time to read and understand the PISCF, and requests that this is detailed in the recruitment and informed consent document.
- The NREC-CT noted section 2 of the recruitment and informed consent document regarding recruitment of adults lacking decision making capacity, is marked N/A. The NREC-CT noted that ALS is a neurodegenerative disease with cognitive impairment, language dysfunction and executive dysfunction as symptoms of this disease. The NREC-CT requests that this section is answered by the sponsor, including details of how those with cognitive impairment are not excluded or inappropriately excluded from the trial.
- The NREC-CT noted section 4.0 of the recruitment and informed consent document is marked N/A. The NREC-CT noted that ALS is a neurodegenerative disease with cognitive impairment, language dysfunction and executive dysfunction as symptoms of this disease, along with muscle degeneration limiting dexterity and potentially their ability to sign the consent form and that therefore an impartial witness may be needed. The NREC-CT requests that section 4.0 of the recruitment and informed consent document is answered by the sponsor..

2. 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 caregiver is mentioned in three locations in the protocol. The NREC-CT noted that ALS is a neurodegenerative disease with cognitive impairment, language dysfunction and executive dysfunction as symptoms of this disease, along with muscle degeneration that can lead to limited dexterity. The NREC-CT requests that the PIL is rewritten to include the role of the caregiver in the trial. Including but not limited to their role in appointments, administration of the IMP, site visits, telephone calls, speech recordings and completion of questionnaires over the course of the trial.

- The NREC-CT noted on page 3 of the Main PISCF “The study medication will be given as a capsule.” The NREC-CT noted that ALS is a neurodegenerative disease with muscle degeneration limiting dexterity, potentially limiting their ability to open a medicine bottle, and that page 39 of the protocol has provisions for the transition to PEG feeding tube during the course of the study. The NREC-CT requests clarification on the role caregivers administrating the IMP and provisions for PEG tube feeding in the Main PISCF.
- The NREC-CT noted on page 4 of the Main PISCF that “If you are unable to come to a study visit, you will be asked to complete the study visit remotely by phone. In this case, study drug may be shipped directly to your home via a qualified courier.” The NREC-CT request clarification is provided to the participant in the Main PISCF regarding how the inability to attend the site is determined, which site visits are mandatory, and which visits can be completed by telephone. The NREC-CT also request information is provided regarding how the ECG, speech recording, breathing test and blood tests may be carried out when a study visit is instead completed by phone, and if these are not carried out, how that will impact the endpoints of the study or the participants continued participation in the study.
- The NREC-CT noted on page 3 of the Main PSICF that telephone calls and unscheduled telephone calls will occur during the study. The NREC-CT requests clarification if there is a script for telephone calls and for the script to be made available for review by the committee.
- The NREC-CT noted that the future use of data / samples (including genetic research) is not described in line with regulations / best practice on page 5, page 6, page 12 and page 17 of the Main PISCF. 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 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 page 6 of the Main PISCF states that participants may undergo whole genome / whole exome sequencing and requested the following:
    - Genomic sequencing is confined to genes involved in the disease being treated or related diseases and /or genes involved in the metabolism of the medicines being used in the trial and this is elucidated in the PISCF.
    - Explicit consent, including outlining the risks entailed in such analysis being performed, is added to the PISCF.
    - The possible ownership of such data by private or commercial interests and that this elucidated in the PISCF.
    - The right to withdraw genetic data, and clear information on how to do so, must also be provided in the PISCF.

  - Clarification is provided in the PISCF on the mechanism for anonymisation, storage and security and transfer of genetic material and its associated data.
  - For guidance, please see HSE National Policy for Consent in Health and Social Care Research (V2.0, 2024). Dublin: Health Service Executive https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-national-policy-for-consent-in-health-and-social-care-research
- The NREC-CT noted in S1_NREC_CT Collection storage and future use of human biological samples form that samples will be sent to IQVIA in the United Kingdom and PPD in the United States. To ensure that participants are fully informed, the NREC-CT requests that this is detailed in the relevant PISCFs.
- The NREC-CT noted on page 1 and 2 of the Main PISCF "It is hoped that the study drug will be of medical benefit to you, but this cannot be guaranteed. There may not be any direct benefit for you." The NREC-CT noted the first sentence "it is hoped" may imply that the treatment is anticipated to be of medical benefit. The NREC-CT request that this is rewritten in more neutral language similar to that used on page 3 of the Main PSICF ("Prior clinical studies have shown that the study drug may help to slow disease progression and improve speech and quality of life in some people living with ALS.")
- The NREC-CT noted the use of the term "Survival Assessment" on page 4,5 and 10 of the Main PSICF. The NREC-CT requests that this is rewritten to a more appropriate term, such as using the term "assessment" or "medical assessment".
- The NREC-CT noted on page 8 of the Main PSICF that Toferson (Qalsody) could be used for treatment of ALS. However, the NREC-CT noted that the protocol does not mention Toferson (Qalsody). The NREC-CT requests clarification if Toferson (Qalsody) is permitted under the protocol and that the protocol and Main PSICF are aligned.
- The NREC-CT noted in the protocol specific safety issues are noted in relation to the study drug being an inhibitor of CYP2D6 and also issues with QT prolongation. The NREC-CT requests that this information is included in the Main PISCF in lay terminology, other to ensure that participants are fully informed.
- The NREC-CT noted C-SSRS can be used to asses self-harm and suicide risk, the NREC-CT requests so that the participants are fully informed, this information should be included in the main PISCF, along with information for the participant and the caregiver if a risk of self-harm or suicide risk is identified in the questionnaire.
- The NREC-CT noted on page 9 in the Main PISCF that Greenphire will be used as an option for reimbursements. The NREC-CT requests clarification if a GDPR agreement is in place between Greenphire and the sponsor.
- The NREC-CT noted on page 9 in the Main PISCF that Greenphire will be used as an option for reimbursements. The NREC-CT requests that the alternative reimbursement process if a participant declines to use the Greenphire services is detailed on page 19 of the Main PISCF.
- The NREC-CT noted that in the P1_compensaiton for trial participants, section 2 states that carers will also be offered compensation. The NREC-CT requests that the information that carers are being offered compensation for trial visits is included on page 9 of the Main PISCF
- The NREC-CT noted on page 9 of the Main PISCF "You will be reimbursed) for travel expenses up to XX per visit, meals up to XX per visit and in case any overnight accommodation is required this will be reimbursed up to XX per visit" The NREC-CT noted that in the P1_compensaiton for trial participants section 3 states that no conditions will be attached to the payment of compensation. The NREC CT requests that participants are reimbursed for all reasonable out-of-

pocket expenses incurred as a result of participation in the trial, and that a maximum value should not be placed on this.

- The NREC-CT noted that the PISCFs do not include a witness signature line. Considering the nature of the ALS and the muscle degeneration of participants which may occur over time it is requested that this is included. The NREC-CT requests information be added to all relevant PISCF's explaining the context where a witness signature would be needed (as per CTR: Annex I,L 62(b)).

2022-501254-10-00 SM-37

Institutions: Adelaide and Meath Hospital, St Vincent's University Hospital, St James's Hospital, Mater Misericordiae University Hospital, Beaumont Hospital

Study title: A Multicenter, Open-label, Phase 3 Study to Evaluate the Long-term Safety and Efficacy in Participants who are Currently on Treatment or in Follow-up in Studies That Include Pembrolizumab

Dossiers Submitted: Part I & II

- NREC-CT Decision:

- Favourable

2024-515092-36-00 SM-3

Institutions: Mater Misericordiae University Hospital

Study title: An Open-Label Extension and Safety Monitoring Study of Acoramidis (AG10) in Participants with Symptomatic Transthyretin Amyloid Cardiomyopathy Who Completed the Phase 3 ATTRibute-CM Trial (AG10-301)

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.

2. Suitability of the clinical trial sites facilities

- It is noted that Site Suitability Assessment has been signed by the PI. The SSA for Mater Misericordiae University Hospital must be signed by the CEO, Head of Clinic / Institution, Director of Research, Clinical Director, or delegate at each site. As a result of a Union Controls exercise led by the European Commission, it was highlighted that the PI as a site delegate signing the SSA is a potential conflict of interest. The NREC-CT requested a revised version of the SSA for the Mater Misericordiae University Hospital signed by the CEO, Head of Clinic / Institution, Director of Research, Clinical Director, or delegate.

2023-505616-38-00 SM-7

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

Study title: A Multicenter, Global, Interventional, Open label Study of Trastuzumab Deruxtecan (T-DXd), an Anti-HER2-Antibody Drug Conjugate (ADC), in Subjects who Have Unresectable and/or Metastatic HER2-low or HER2 Immunohistochemistry (IHC) 0 Breast Cancer (BC) (DESTINY-Breast15)

Dossiers Submitted: Part I & II

- NREC-CT Decision:

- Favourable

2023-508852-21-00 SM-3

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

Study title: A Phase II, Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

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 on page 29 of the tracked changes consent form “I consent to the collection, processing, reporting and transfer within and outside the Republic of Ireland of my coded data (including images) for healthcare and/or medical research purposes where the data protection may not be as good.” The NREC-CT request clarifications if any potential identifiable information will be present in the image. If there is any potentially identifable information, the NREC-CT requests that images be altered to remove/permantely hide any personal identifable information. The NREC-CT also requests that this is made clear in the Main ICF, and that page 29 of the Main ICF be rewritten to “I consent to the collection, processing, reporting and transfer within and outside the Republic of Ireland of my coded data (including non-identifiable images) for healthcare and/or medical research purposes where the data protection may not be as good.”

2024-516009-22-00 SM-6

Institutions: Tallaght University Hospital, University Hospital Limerick, Beaumont Hospital, St Vincent’s University Hospital, Mater Misericordiae University Hospital, Cork University Hospital

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Elritercept (KER-050) for the Treatment of Transfusion-Dependent Anemia in Adult Participants with Very Low-, Low-, or Intermediate-Risk Myelodysplastic Syndromes (MDS) (RENEW)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part I Considerations

- It was noted that page 121 of the revised protocol now includes the following text "During and after the trial, only the Sponsor may make trial information available to other trial investigators or to regulatory agencies, except as required by law or regulation." It was noted that clinical trial oversight may require sharing of information beyond that which is required by law or regulation. The sponsor is asked to consider adding wording similar to 'or where clearly relevant to the oversight of the trial' be added to the proposed altered text of the Protocol. Clarification is requested regarding the rationale for introducing this amendment. In particular, confirmation is requested that this change does not impact on investigators ability to report adverse events (AEs) and serious adverse events (SAEs) in a timely manner.

- AOB: N/A