National Research Ethics Committee

NREC-CT Meeting

14th May 2025

Attendance

Name	Role
Prof David Brayden	Chairperson, NREC-CT D
Prof Andrew Green	Committee Member, NREC-CT D
Prof Cathal Walsh	Committee Member, NREC-CT D
Prof Deirdre Murray	Committee Member, NREC-CT D
Dr Geraldine O'Dea	Committee Member, NREC-CT D
Prof Lina Zgaga	Committee Member, NREC-CT D
Ms Deirdre McLoughlin	Committee Member, NREC-CT D
Dr Mary McDonnell Naughton	Committee Member, NREC-CT D
Ms Chanel Watson	Committee Member, NREC-CT D
Dr Jeff Moore	Committee Member, NREC-CT D
Ms Aileen Sheehy	Programme Manager, National Office for RECs
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

*Drafted minutes

Apologies: Geraldine O'Sullivan Coyne, Christina Skourou, Gerry Daly and David Smith

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-504661-23-00
- 2024-512733-32-00
- 2024-519746-70-01
- 2023-504655-27-00 SM -2
- 2023-505242-25-00 SM-4
- 2023-508832-68-00 SM-4
- 2023-505617-24-00 SM-3
- 2024-515198-91-00 SM-2
- 2022-502705-15-00 SM-17
- 2023-504198-19-00 SM-6
- 2024-513429-21-00 SM-3
- AOB

- The Chair welcomed the NREC-CT D.
  - The minutes from the previous NREC-CT D meeting on 9th April 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-504661-23-00

Institutions: Rotunda Hospital

Study title: HYPATIA: A prospective randomised controlled trial of HYdroxychloroquine to improve Pregnancy outcome in women with AnTIphospholipid Antibodies

Dossiers Submitted: Add MSC Part I and II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

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

- The NREC-CT requests that the Compliance with national requirements on data protection document point 15 be updated to provide information on what safeguards will be put in place to protect participants data that is transferred outside of EU.

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

- The NREC-CT requests that the Compliance with use of biological samples document be updated with the correct EU CT number.

3. **Proof of insurance**

- The NREC-CT requests clarification on the details on the insurance certificate provided, namely the Insured [redacted] and Address (the Mater Hospital) as these do not correspond with the SSA provided for review. If Mater Hospital has a role in the study, then clarification should be provided and an SSA for the Mater Hospital be provided for review.

4. **Recruitment arrangements**

- The NREC-CT requests that the Recruitment Arrangements section 1.9 be updated to include detail that participants will be asked if the study team can collect data from their hospital notes when they withdraw. It should be clear that this is optional for participants.

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

- The Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation.
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.

- The NREC-CT requests the PIL be updated to include detail on how participants will be monitored and risk mitigation measures in place for suicidal behaviour.
- The NREC-CT notes the PIL pg 6 states that “For babies born to mothers who take part in the HYPATIA no extra tests beyond the routine newborn examination provided as part of the HSE routine care are needed.” The Committee requests that if any test above standard of care will take place these should to be detailed in the PIL.
- The NREC-CT requests that the PIL be updated to include details of pregnancy testing carried out during the trial.
- The NREC-CT requestions clarification on the inclusion of “Declaration by the person providing the information” on Consent Form pg 2 as it is not clear who is signing this section and the purpose of same.
- The NREC-CT requests that the Consent Form pg 2 be updated to include specific statement that the participant confirms that a copy of the signed and dated Consent Form will be provided to them and that a copy will be retained by the study doctor.
- The NREC-CT requested that the PIL pg 15 be updated to provide information about the availability of the clinical trial results at the end of the trial and details of website where results will be published. (ie EU Database)
- The NREC-CT requests that the PIL be updated to provide more detail in relation to the screening process.
- The NREC-CT requested that it is made clear to participants if any study activities or visits will be above that of standard maternity care.
- The NREC-CT requests that the PIL, Consent Form and Consent Form 2 be combined into one document.
- The NREC-CT requests that the PIL Pg 6 “what will happen to my baby if I take part” should be written in a more balanced manner including any potential risks to the baby. The NREC-CT requests that the 2nd sentence be updated to improve grammar.
- The NREC-CT requests that the PIL pg.10 What happens if I don’t want to carry on the study be updated to include detail that participants who wish to withdraw will be asked to sign a consent form to agree to allow for the study team to collect data from hospital notes, without the participant being contacted. It should be clear that this is optional for participants.
- The NREC-CT requests that the PIL pg. 13 be updated to remove reference to the NREC having access to personal data.
- The NREC-CT requested that page 4 of the Main ICF is updated to clarify that participants in the trial will receive hydroxychloroquine/placebo in addition to the standard of care treatment for aPL/APS, rather than referring to “usual medications” which is ambiguous.
- The NREC-CT requests that the Main ICF be updated to include detail of the dose of hydroxychloroquine that is proposed to use in the study, in order to ensure the participant is informed
- The NREC-CT notes refences to RCSI throughout the Main ICF however the site listed in the SSA is Rotunda Hospital. The Committee requests clarification on the role of RCSI and Rotunda in the trial and update to the Main ICF to clarify their roles.

- The NREC-CT were unclear in relation to the wording on Main ICF pg. 12 paragraph 3 where it mentions initials and DoB will be sought from KCL clinical trials unit as the study site should have the initials and DoB for their participants. Please clarify and update the ICF as necessary.
- The NREC-CT requests that the Main ICF pg 15 be updated to provide information on what safeguards will be put in place to protect participants data that is transferred outside of EU.
- The NREC-CT notes that the Main ICF pg 4 states “current national and international medical guidelines state that hydroxychloroquine is safe in pregnancy” however this statement contradicts the information in the SmPC for hydroxychloroquine, which states that hydroxychloroquine shouldn’t be used in pregnancy. The Committee requests that the Main ICF pg. 4 be updated to provide more balanced information in relation to the risk/benefit ratio based on the SmPC for hydroxychloroquine, for participants to be able to make an objective and informed decision about the risks.
- The NREC-CT requests that Main ICF pg 4 reference to “congenital malformations” be updated to include a lay language explanation of what a congenital malformation is.

6. Suitability of the clinical trial sites facilities

- The NREC-CT requests the SSA for Rotunda hospital be updated to clarify the role of RCSI and Rotunda in the trial

2024-512733-32-00

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

Study title: HOVON 177: Randomized study to assess revumenib in combination with azacitidine + venetoclax in adult patients with newly diagnosed NPM1 mutated or KMT2A rearranged AML ineligible for intensive chemotherapy

Dossiers Submitted: Add MSC Part I and II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Financial arrangements

- The NREC-CT notes that participants will not be offered a reimbursement of expenses associated with their study specific hospital visits. Given the additional burden on participants for greater number of bone marrow examinations and completion of diaries and questionnaires above standard of care, the Committee

requests that the sponsor consider some compensation for this. At a minimum, participants should be compensated for out-of-pocket expenses as a result in taking part in a clinical trial. The Main ICF should be updated to align.

2. Recruitment arrangements

- The NREC-CT noted that participants 'not able to understand the information in English' are excluded from the study. The Committee requested justification for the exclusion of this cohort.

3. Subject information and informed consent form

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT requests that the Main ICF pg 27, Pregnancy pg 8, Screening ICF pg 9 and Biobank ICF pg 10 be updated with a placeholder for the qualification of the person performing the consent interview
- The NREC-CT requests that the Main ICF pg 26, Pregnancy ICF pg 8, Screening ICF pg 9 and Biobank ICF pg 10 be updated to include 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 requests that the Main ICF pg 25 be updated to include specific statement that the participant confirms that they have read and understand the information.
- The NREC-CT notes pg 27 of Main ICF, pg 10 Biobank ICF and pg 9 Screening ICF includes a witness signature line. The NREC-CT request information be added explaining the context where a witness signature would be needed under ICH GCP Guidelines. The NREC-CT noted it was unclear for participants as to whether the collection of data/samples as described in the Main ICF (page 18, page 20, page 26) and Pregnancy ICF (page 4, page 8) described optional future use of data/samples, beyond the study objectives. 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 requests that the Biobank ICF be updated to include detail in the Information section of the ICF around the fact that the study team may contact the participant for consent for the use of their data or samples if it is to be used outside the field of (the treatment of) AML.
- The NREC-CT noted the participant information leaflet appears to have been translated, resulting in some loss of meaning and requests a full review is carried out. The NREC-CT requests that the following updates be made at a minimum:
    - Screening ICF pg 2 Section 1 first sentence delete 'the' that precedes Ireland.
    - Screening ICF pg 2 Second sentence change 'review' to 'reviewed'.
    - Screening ICF pg 2 Section 4 'What discomforts might you get' consider changing this heading to 'What discomforts might you experience'
    - Main ICF pg 2 Page 2 'What the participation will involve' consider changing to 'What will participation in the study involve'
    - Main ICF pg 2 How long participation will last?' consider changing to 'How long will I participate in the clinical trial?'
    - Replace the word pseudonymised with pseudonymisation throughout all the ICF's
    - Replace the words bodily materials with biological samples throughout all the ICFs
- The NREC-CT requests that the Screening ICF pg 2 section 3 first mention of 'bodily materials' be updated to specify in brackets which bodily materials will be collected.
- The NREC-CT requests the Screening ICF pg. 8 be updated to make it clear that the reason for determining the specific characteristics of the red blood cells is to identify whether the person being screened, rather than their blood cells, would be suitable to participate in a HOVAn study for the treatment of AML.
- The NREC-CT requests that the Screening ICF pg 8 statement of consent 2 be updated to specify that the participant is participating in a screening study. The Committee also request that the text "after all" at the end of the 1st sentence be removed as it is unnecessary.
- The NREC-CT requests that the Main ICF pg. 6 be updated to specify the number of questionnaires to be completed and the approximate time it will take to complete the questionnaires.
- The NREC-CT requests that the Main ICF side effects section be updated to list the side effects of the IMP Revumenib before the side effects for venetoclax and azacitidine.
- The NREC-CT notes that the side effects listed for revumenib in Main ICF are those identified in ongoing clinical studies as of 24 July 2023. The Committee

request that the Sponsor confirms whether there is any more recent data on side effects from this population. If this data is available the side effect section for revumenib should be updated in line with this data.

- The NREC-CT requests the Main ICF side effects from revumenib be updated to include information for side effects identified in the relapsed refractory AML population to give an overall view of the risks.
- The NREC-CT requests that the Sponsor consider placing the paragraph on differentiation syndrome pg. 14 at the beginning of the Very Common section (Revumenib) given the seriousness of it.
- The NREC-CT requests that the Main ICF consent form page 26, Pregnancy ICF pg 8 and Biobank ICF pg 9 statement regarding data transfer outside of EU/EEA be updated to include a sentence specifying that the data transferred will be pseudonymised/coded.

4. Suitability of the clinical trial sites facilities

- The NREC-CT notes that all the Irish sites apart from Cork University Hospital advise that the exposure to ionising radiation is not above what is required for standard care. Please confirm that the information in the Site Suitability Forms for the remaining sites in relation to exposure to ionising radiation is not above what is required for standard care is correct or update the SSF as necessary. Please justify why the exposure to ionising radiation in Cork University Hospital would be above that for standard of care in the other trial sites.
- The NREC-CT notes a discrepancy between the number of participants in Ireland on CTIS structured data (1 participant) versus the numbers of participants listed on SSA forms for 7 Irish sites (1-3 per site). Please clarify and update CTIS structured data or SSA forms as appropriate.

5. Suitability of the investigator

- The NREC-CT requests confirmation of the name of the PI at University Hospital Galway. [redacted] is named on CTIS system however no CV was provided for [redacted], however a CV was provided for [redacted]. Please clarify the inclusion of this CV. If [redacted] is actually the PI at University Hospital Galway then please update CTIS and provide an updated CV for [redacted] showing when she took up a consultant post at University Hospital Galway as her CV shows she was a consultant at the Royal Free Hospital, London until April 2025.
- The NREC-CT requests updated CVs for [redacted] (if a PI on the study) providing more detail of relevant clinical trial/study experience.

2024-519746-70-01

Institutions: St James's Hospital

Study title: A Phase 2, Double-blind, Randomized, Placebo-Controlled, Multicenter, Dose-Finding, Efficacy, and Safety Study of Tebapivat in Participants With Sickle Cell Disease

Dossiers Submitted: MSC Part I and II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS

1. The Sponsor is requested to clarify how participants on placebo will be monitored during the 12 weeks.

Part II Considerations

1. Compliance with use of biological samples

- The NREC-CT notes Compliance with Use of Biological Samples Section 3.7 “Who will have access to the sample code list” states Sponsor testing laboratories and Section 4.6 “Sponsor and testing laboratories”. The Committee requests clarification be provided in what circumstances the sponsor and testing laboratories would have access to the sample code list with identifiable patient data on it.

2. Recruitment arrangements

- The NREC-CT requests that the Recruitment arrangements document Section 1.2 be updated to provide more information in relation to how recruitment resources will be presented to potential participants. E.g.via the post, in the clinic, through social media or on the radio.
- The NREC-CT requests that the Recruitment arrangement document Section 1.11 be updated as the question has been answered incorrectly. Please provide information on how participants will be recruited. .

3. Subject information and informed consent form

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT requests that the Main ICF pg 22 be updated with a placeholder for the qualification of the person performing the consent interview
- The NREC-CT requests that the sentence on Main ICF pg 7 “Leftover samples may be used to understand SCD disease, why study participants do or don’t respond to tebapivat treatment, and to understand how tebapivat works” be updated to “Any leftover samples will only be used to understand SCD disease, why study participants do or don’t respond to tebapivat treatment, and to understand how tebapivat works”.
- The NREC-CT requests that the Main ICF pg 18 *“For samples retained for research purposes, your Coded Information and remaining samples will be used to conduct additional studies with the data collected in this study to advance scientific research and public health”* be updated to be clear that coded information and samples will only be used for future research involving SCD disease or tebapiva.

Anonymised data and anonymised samples may be used for other research purposes.

- The NREC-CT requests that Main ICF pg 21 be updated to move optional components on to a separate page of the PISCF, with separate signatures section, so it is distinct from the main consent to participate in the research
- The NREC-CT requests that the Main ICF pg. 7 *"the NREC must conduct a review of the new project"* be updated to *"an ethics committee must conduct a review of a new project*" as, depending on the type of research being conducted, it may not require NREC approval.
- The NREC-CT requests that Main ICF pg 11 be updated to remove reference to social security number.
- The NREC-CT requests that the Main ICF pg 13 "The Sponsor will pay for reasonable travel expenses you and your caregiver (if applicable) incur" be updated to include accommodation and meals as described in the compensation for clinical trial document.
- The NREC-CT requests that the Main ICF pg 21 be updated to include a consent statement for the participant to explicitly consent to the processing of their personal data from pseudanonymised /coded data to anonymised data as per Article 4 (2) and (6) General Data Protection Regulation (GDPR).
- The NREC-CT notes that the future use of data / samples (including genetic research) is not described in line with regulations / best practice on pg. 6 of Pregnancy ICF. 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 Pregnancy 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 requests that the Main ICF pg 2 be updated to provide more information for participants about what open label extension is and to make it clear for participants if tebapivat will be provided free of change for this period. The Main ICF should also be updated to clarify what will happen for participants who are in open label extension period and the drug comes to market i.e. who would pay for tebapivat beyond the extension period.

- The NREC-CT notes the reference on Main ICF pg. 6 Genetic testing and requests clarification on what consideration is given to incidental findings. The ICF should be updated to clarify if participants will be informed of any incidental findings.
- The NREC-CT requests that the Main ICF pg 20 be updated to include an explicit consent statement for processing of data.
- The NREC-CT notes that participants will be offered a reimbursement of expenses associated with their study specific hospital visits. Given the rising cost of living and the substantial commitment to study activities by participants, the Committee requests that further consideration is given as to whether the participants should be offered a payment towards earnings lost. The Main ICF should be updated to align.
- The NREC-CT requests that the Main ICF pg 2 be updated to provide a lay language explanation of "platelets".
- The NREC-CT requests that the Main ICF pg. 11. Section on risk of knowing genetic information section be updated to clear explanation of what the risk is and to improve clarity.
- The NREC-CT requests that the Main ICF be updated to include detail on the expected duration of study visits.
- The NREC-CT notes that the Pregnancy ICF pg 6 refers to the study doctor informing the participants if any new information becomes available in relation to the effects of the study drug on 'quality of sperm'. The Committee requests clarification on why updates of the effects of the study drug on females eggs are not referred to.
- The NREC requests that the Pregnancy ICF be updated to clarify how long child's data will be held for. If the data will be held after the child turns 16 the committee requests clarification whether the child will be consented when they turn 16 years to allow the data to continue to stored.
- The NREC-CT requests that the GP letter- pg 1 be updated to include an explanation of the acronym "SCD".

4. Suitability of the clinical trial sites facilities

- The NREC-CT notes a discrepancy between the number of participants in Ireland on CTIS structured data (2 participants) versus the numbers of participants listed on SSA form (3-5 participants). Please clarify and update CTIS structured data or SSA form as appropriate.

2023-504655-27-00 SM-2

Institutions: Royal Victoria Eye and Ear Hospital

Study title: A Phase 3 Randomized, Masked, Controlled Trial to Evaluate Efficacy and Safety of Belzupacap Sarotalocan (AU-011) Treatment Compared to Sham Control in Subjects with Primary Indeterminate Lesions or Small Choroidal Melanoma

Dossiers Submitted: MSC Part I and II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

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

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT requests that the Main Adult ICF pg. 2 “given as a suprachoroidal injection (as described below)” be updated to “(as described above)”.
- The NREC-CT requests that the Main Adult ICF pg. 22 and Pregnant Partner or Pregnant Participant ICF pg. 13 be updated to include a consent statement for the participant to explicitly consent to the processing of their personal data from pseudanonymised /coded data to anonymised data as per Article 4 (2) and (6) General Data Protection Regulation (GDPR).
- The NREC-CT requests clarification on who the authorised individual conducting informed consent discussion is.
- The NREC-CT requests that the Main Adult ICF pg. 22 Consent form be updated to reinstate the 4 data privacy consent statements for participants to be able to give implicit informed consent.

2023-505242-25-00 SM-4

Institutions: University Hospital Galway, Cork University Hospital, Mater Misericordiae University Hospital

Study title: PHASE 2 DOSE-RANGING AND INTERCEPTION STUDY OF LINVOSELTAMAB IN PATIENTS WITH HIGH-RISK MONOCLONAL GAMMOPATHY OF UNDETERMINED SIGNIFICANCE OR NON-HIGH-RISK SMOLDERING MULTIPLE MYELOMA

Dossiers Submitted: MSC Part I and II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

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

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT considers the updates to the Treatment-Emergent Adverse Events in Investigator Brochure, page 104 have not been adequately addressed in the Main ICF pg 15-18 where the 'very common' side effects are defined as >10%, however, the updated TEAEs cite up to 50% risk of some of these side effects. The Committee considered that given the high probability of side effects including serious TEAEs and that these participants have a condition which may or may not progress to myeloma these risks need to be clearly stated in the ICF. The Committee also request that the sponsor consider addition of a consent statement to the Main ICF pg 25 consent form which states "I am aware that I may never develop multiple myeloma'.
- The NREC-CT notes the addition of new text 'relapsed/refractory'. In SIS and ICF Main pg.12. The Committee requests a lay language explanation be provided for refractory.
- The NREC-CT believes the RFI-CT-2023-505242-25-00-SM04-004-04 has not been adequately addressed. The Committee requests that the side effects section (page 15-16) be updated to include detail that there is up to 50% risk of potentially serious side effects (as are reported in the updated linvoseltamab Investigator Brochure) and to also insert in the same section that the potential participant may not develop active myeloma.

2023-508832-68-00 SM-4

Institutions: Cork University Hospital, Mater Misericordiae University Hospital, University Hospital Waterford

Study title: A Phase 1b/2 Open-Label Trial of Tisotumab Vedotin (HuMax® -TF-ADC) Monotherapy and in Combination with Other Agents in Subjects with Recurrent or Stage IVB Cervical Cancer

Dossiers Submitted: MSC Part I and II

- **NREC-CT Decision:**
- Favourable

2023-505617-24-00 SM-3

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

Study title: A Randomized Phase 2 Study of Ocular Toxicity Evaluation and Mitigation During Treatment with Mirvetuximab Soravtansine in Patients with Recurrent Ovarian Cancer with High Folate Receptor-Alpha Expression

Dossiers Submitted: MSC Part I and II

- **NREC-CT Decision:**
- Favourable

2024-515198-91-00 SM-2

Institutions: St Vincent's University Hospita

Study title: A Phase II/III Multicenter Randomized, Double-Blind, Placebo-Controlled Platform Trial of Potential Disease Modifying Therapies Utilizing Biomarker, Cognitive, and Clinical Endpoints in Dominantly Inherited Alzheimer's Disease

Dossiers Submitted: MSC Part I and II

- **NREC-CT Decision:**
- Favourable

2022-502705-15-00 SM-17

Institutions: Cork University Hospital, Tallaght University Hospital

Study title: A PHASE III, DOUBLE-BLIND, MULTICENTER, RANDOMIZED STUDY OF ATEZOLIZUMAB (ANTI-PD-L1 ANTIBODY) VERSUS PLACEBO AS ADJUVANT THERAPY IN PATIENTS WITH HIGH-RISK MUSCLE INVASIVE BLADDER CANCER WHO ARE CTDNA-POSITIVE FOLLOWING CYSTECTOMY

Dossiers Submitted: RMS Part II only

- **NREC-CT Decision:**
- Favourable

2023-504198-19-00 SM-6

Institutions: Beaumont Hospital

Study title: A Randomized, Double-blind, Placebo-Controlled, Phase 3 Study to Evaluate the Safety and Efficacy of Fazirsiran in the Treatment of Alpha-1 Antitrypsin Deficiency–Associated Liver Disease With METAVIR Stage F1 Fibrosis

Dossiers Submitted: RMS Part II Only

- **NREC-CT Decision:**
- Favourable

2024-513429-21-00 SM-3

Institutions: St Vincent's University Hospital, Mater Misericordiae University Hospital

Study title: PaTcH Trial: A phase 2 study to explore primary and emerging resistance mechanisms in patients with metastatic refractory Pancreatic cancer treated with Trametinib and Hydrochloroquine

Dossiers Submitted: RMS Part I and II

- **NREC-CT Decision:**
- Favourable

- AOB:
  - None