National Research Ethics Committee

NREC-CT A Meeting

16th April 2025

Attendance

Name	Role
Ms Caoimhe Gleeson	Deputy Chairperson, NREC-CT A
Prof. Gene Dempsey	Chairperson, 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
Mrs Erica Bennett	Committee Member, NREC-CT A
Dr David Byrne	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
Peadar Rooney*	Project Officer, National Office for RECs
Dr Emily Vereker	Head of Office, National Office for RECs
Dr Jane Bryant	Programme Officer, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs

*Drafted minutes

Apologies: Alistair Nichol, Brian Bird, Aisling McMahon, Sean Lacey, Margaret Cooney, David Byrne

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2024-518973-32-00
- 2024-519331-42-00
- 2024-518154-16-00
- 2024-512279-10-00 SM-5
- 2022-501453-36-00 SM-11
- 2024-516440-25-00 SM-1
- 2023-505678-14-00 SM-18
- 2023-506842-22-00 SM-5
- 2023-506962-30-00 SM-4
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 12th March 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2024-518973-32-00

Institutions: St. James's Hospital

Study title: A Phase 3, Randomized, Open-Label Study of Axatilimab Versus Best Available Therapy in Participants With Chronic Graft-Versus-Host Disease After at Least 2 Prior Lines of Systemic Therapy

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

Part II Considerations
1. Compliance with national requirements on data protection
• No considerations raised by the NREC-CT
2. Compliance with use of biological samples
• No considerations raised by the NREC-CT
3. Financial arrangements
• No considerations raised by the NREC-CT
4. Proof of insurance
• No considerations raised by the NREC-CT
5. Recruitment arrangements
• No considerations raised by the NREC-CT
6. 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 requested that the Main PIS-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 noted on page 24 of the Main PIS-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 requests that the Main PIS-ICF be updated with a placeholder for the qualification of the person performing the consent interview.
• The NREC-CT noted that the Pregnancy PIS-ICF references the HSC-NI on page 2 and page 7. The NREC-CT assumed that this was a reference to the Health and Social Care of Northern Ireland. The NREC-CT requests that this reference be

removed and that reference be made to the Republic of Ireland applicable guidelines, regulations and healthcare institutions.

- The NREC-CT noted on page 5 of the Main PIS-ICF that the phrase “Benefit on you” should be replaced with the phrase “Benefit for you”.
- The NREC-CT requested that “Spirometry, more details on page 21”, be added to page 8 beside “Lung Test”
- The NREC-CT noted on page 12 in the main PIS-ICF a typo under the ‘risks of pregnancy’ section, the NREC-CT requests that ‘srug’ be corrected.
- The NREC-CT noted on page 6 of the Main PIS-ICF that the length of time for monthly visits and then subsequently visits every 3 months is unclear. The NREC-CT requests that this be rewritten to provide clarity to the participant for the context of these visits including information about if they will be on the study drug, and if the number of visits are similar to standard of care.
- The NCRE-CT requested that the type of acceptable birth control methods are listed and the duration for which the participants are expected to use birth control is clearly stated in the Main PIS-ICF on page 12.
- The NREC-CT noted on page 13 of the Main PIS-ICF it states that if the participant makes someone pregnant during that time, the study doctor will “Ask your partner to sign a separate consent form for permission for the Sponsor and Study Doctor to follow the pregnancy to see what happen.” The NREC-CT requests that context for why this permission is being sought by the Sponsor and Study Doctor is explained to the participant, and a brief explanation of the information which may be requested it provided.
- The NREC-CT noted on page 14 of the Main PIS-ICF “During the Study, you can stop being in the Study at any time and for any reason. If you decide to leave the Study, please tell your Study Doctor.” The NREC-CT requests that it be made clear that the participant has the right to withdrawn from the study at any time and that this will not affect their rights, they do not have to report their reason for withdrawal, and any requests from the study team are optional.
- The NREC-CT noted on page 15 of the Main PIS-ICF “you will be provided the option of being reimbursed through a service provider working with the sponsor and the study doctor to reimburse you” The NREC-CT requests that the vendor details, if available, be identified in the PIS-ICF. If the vendor details are not currently available, when vendor details are available that the PIS-ICF amended with the information and the participants informed of this change.
- The NREC-CT noted on page 16 of the Main PIS-ICF it states: “National ID number or passport details may be collected to facilitate international travel if necessary” The NREC-CT requests clarification if international travel is planned, and that this information is removed if not relevant.
- The NREC-CT noted that Pregnancy PIS-ICF contains acronyms that are not explained in first use. For example, BAT and HSC-NI. Please note that the pregnancy PIS-ICF is also for a partner of a study participant who might not have read the Main ICF. Please ensure that acronyms are explained in first use throughout the patient facing documentation.
- The NREC-CT noted that the Main PIS-ICF page 1 contains several acronyms. For example, BAT instead of Best Available Treatment, and other medical terminology

such as allogenic. The NREC-CT requests that this be rewritten in lay language and without the use of acronyms.

- The NREC-CT noted that Main PIS-ICF page 14, the sponsor, will provide reasonable payment for medical expenses. The NREC-CT requests clarification on any limits to this compensation, and if limits exist for this information to be provided to the participants.
- The NREC-CT noted on page 3 of the Pregnancy PIS-ICF "*The care you will receive during pregnancy and birth will be in line with HSC-NI standards.* ***What if I have private healthcare insurance or use private healthcare arrangements for your pregnancy care:*** *The regular medical care costs related to your pregnancy and the birth and care of your baby will be billed to you and/or your health insurance in the usual way. The study Sponsor will not pay for your regular medical care costs*." The NREC-CT requests that this section be rewritten to make it applicable to Ireland, and to make it clear that the Sponsor of the clinical trial has no role to play in that person's maternity care.

7. Suitability of the clinical trial sites facilities

- No considerations raised by the NREC-CT

8. Suitability of the investigator

- No considerations raised by the NREC-CT

2024-519331-42-00

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

Study title: A Phase 3, Randomized, Open-label, Multicenter Study to Compare the Efficacy and Safety of Sacituzumab Tirumotecan in Combination with Pembrolizumab Versus Pembrolizumab Alone as First-line Maintenance Treatment in Participants with Mismatch Repair Proficient Endometrial Cancer (TroFuse-033/GOG-3119/ENGOT-en29)

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

Part II Considerations

1. Compliance with national requirements on data protection

- No considerations raised by NREC-CT

2. Compliance with use of biological samples

- No considerations raised by NREC-CT

3. Financial arrangements

No considerations raised by NREC-CT

4. Proof of insurance

No considerations raised by NREC-CT

5. Recruitment arrangements

- The NREC-CT requests that the Master Tissue Brochure include information about how long samples will be stored for and what happens to the samples after this time.

- The NREC-CT noted that there is no statement in the Recruitment Clinical Trial Brochure, regarding the right of the participant to withdraw. The NREC-CT requested that the right of the participant to withdraw without any fault, notice or effect on their ability to access medical treatment or affect their rights is explained clearly in the Recruitment Clinical Trial Brochure.

6. 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 GP letter referenced in the Part 1 documentation is made available for review.
- The NREC-CT noted on page 5 of the Main ICF that "After you complete your follow-up visits, the trial doctor or staff will contact you about every 3 months, or more frequently, to check on your health" The NREC-CT requests that the Main ICF be amended to include the maximum follow up period.
- The NREC-CT noted on page 17 of the Main ICF "If you are able to become pregnant, you must use acceptable birth control. The trial doctor or staff will discuss the birth control methods allowed during the trial. They will also tell you how long you must use birth control after your last dose of trial drugs. You must also agree not to donate or store your eggs during this time." The NREC-CT requests that the acceptable birth control methods be briefly listed in the main ICF and that the timelines for using birth control, not donating or storing eggs be listing in the appropriate section in the Main ICF.
- The NREC-CT noted that the Main ICF states that data will be retained for at least 25 years. The DPIA page 6, states that the data will be stored for 35 plus years. The NREC-CT requests that data storage duration is aligned across all documentation.
- The NREC-CT noted on page 22 of the Main ICF "coded information will be stored for at least 25 years" and "the trial site is required to keep information relating to the trial for about 25 years". The NREC-CT requests that these two phrases align (at least/about) to ensure that the participant is informed regarding data storage duration.
- The NREC-CT noted page 9 of the Main ICF includes the risks of radiation. The NREC-CT requests that context is included, to explain that the frequency of the scans is greater than that of the standard of care frequency of scans.
- The NREC-CT noted that page 10 of the Main ICF 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 and /or genes involved in the metabolism of the medicines being used in the trial and this 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 the Greenphire PIS-ICF on page 2 “Once the verification process is complete, the third party does not retain any of your data, including the photograph of your government-issued identification.” The NREC-CT would like the PIS-ICF to clarify the language to be clearer in lay terminology that the data and scans of the photo ID will be deleted.
- 2nd RFI
- The NREC-CT noted on page 10 of the Main PIL "The imaging procedures performed in the trial are standard assessments for persons receiving treatment for your condition and could be performed outside a clinical trial. However, some of these will be extra to those that you would have if you did participate in the trial." The NREC would appreciate if the second sentence was rewritten so that it read "However, some of these will be extra to those that you would have if you did not participate in the trial."

7. Suitability of the clinical trial sites facilities

- No considerations raised by NREC-CT

8. Suitability of the investigator

- No considerations raised by NREC-CT

2024-518154-16-00

Institutions: Mater Private Hospital, Beaumont Hospital, University Hospital Galway, St. Vincent’s University Hospital, University Hospital Limerick, Tallaght University Hospital, Cork University Hospital

Study title: RASolve 301: Phase 3 Multicenter, Open Label, Randomized Study of RMC-6236 versus Docetaxel in Patients with Previously Treated Locally Advanced or Metastatic RAS(MUT) NSCLC

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

Part II Considerations

1. Compliance with national requirements on data protection

- No considerations raised by NREC-CT

2. Compliance with use of biological samples

- The NREC-CT noted in section 4.9 Who will use these samples? “Future research may include sharing patient´s samples and coded data with third party researchers or other commercial sponsor contracted companies, including in other countries.”

The NREC-CT requests that the conditions for the sharing of participant samples with third party researchers are elucidated in this document and included in the Main PIS-ICF and Prescreening PIS-ICF where applicable.

3. Financial arrangements

- No considerations raised by NREC-CT

4. Proof of insurance

- No considerations raised by NREC-CT

5. Recruitment arrangements

- The NREC-CT noted in section 1.2, “Animated video to explain the trial as part of the Informed Consent process may be presented by the clinical trial team to potential participants interested in the trial in the clinic on a device specifically intended for this” The NREC-CT requests the transcript of the animated video be provided for the committee to review, if available.

6. 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 requested that the Main PIS ICF and Addendum PIS ICF page 1 be updated to include the EU trial number for participants.
- The NREC-CT requests that the Main PIS ICF and Addendum PIS ICF be updated with a placeholder for the qualification of the person performing the consent interview.
- The NREC-CT noted that on page 24 of the Main PIS-ICF Section “Redisclosure to Third Parties “ and page 8 of the Prescreening PIS-ICF, the following text “I understand that once {Site} discloses my Authorized Health Information to the recipient(s) identified in the previous section Authorized Persons and Recipients, {Study Site} cannot guarantee that the recipient(s) will not re-disclose my Authorized Health Information to other persons who may not be bound by this informed consent form.” The NREC-CT is requesting clarification on this statement, under what conditions would the Study site or Sponsor disclose personal information on clinical trial participants who are not bound by this consent form.
- The NREC-CT noted reference to “Genetic Information Non-discrimination Act” on page 6 of the Prescreening PIS-ICF. The NREC-CT requests that clarification about the jurisdiction of this law is clearly identified in the PIS-ICF and that reference to applicable EU laws regarding genetic information and GDPR is added to this section.
- The NREC-CT noted that RMC-6236 and Docetaxel are not mentioned until page 15 of the Main PIS-ICF. The NREC-CT requests that the Main PIS-ICF and Prescreening PIS-ICF include a summary explanation of RMC-6236 and Doxetaxel earlier in the PIS-ICF.
- The NREC-CT requested that the information in the Lay protocol synopsis should be included in the Prescreening and Main PIS-ICF.
- The NREC-CT requested that it is clearly described in lay terminology that the participants who are on Docetaxel will not be able to avail of RMC-6236 and that participants who are on RMC-6236 would be able to transfer to Docetaxel under certain conditions. The NREC-CT requests that this information is provided in the section “Description of the Study” on page 4 of the Main PIS-ICF.

- The NREC-CT noted on page 3 of the Prescreening PIS-ICF it states “About 420 people may take part in this study.” The NREC-CT requests that information about how many participants will be recruited in Ireland be provided including how many will be on the different treatments.
- The NREC-CT noted on page 5 of the Prescreening PIS-ICF the use of the acronym REC. The NREC-CT requests that acronyms are not used in participant facing documents.
- The NREC-CT noted that in the Prescreening page 4 and Main PIS-ICF page 20, there is very limited details on the compensation that will be available to participants. The NREC-CT requested that participants should be reimbursed for all reasonable out-of-pocket expenses related to their participation in the study. This should be clarified and expanded in the Prescreening and Main PIS-ICF, including any limits to compensation, who to contact and what is needed for compensation to occur.
- The NREC-CT noted that on page 3 of the Main PIS-ICF “Let the study staff/study doctor know if you think you are pregnant (women) or if your partner is pregnant (men)”.The NREC-CT requests that additional information be included here, to include context that RMC-6236 may have unknown potential side effects on a foetus and reference made to finding more information on page 18 of the PIS-ICF.
- The NREC-CT noted that on page 3 of the Main PIS-ICF that certain medications are not allowed within 14 days of the study treatment. These medications should be listed in the Main PIS-ICF.
- The NREC-CT noted that from page 7 to page 12 of the Main PIS-ICF the different procedures that are done at different times are listed. The NREC-CT would consider that a table listing the different procedures done on the different days would be a benefit to the participant understanding the study visits.
- The NREC-CT noted on page 9 of the Main PIS-ICF that the participant is required to bring the medication back to the clinic for each visit. Considering the storage temperature requirements of the medication, the NREC-CT requests clarification on why the medication is needed at each visit, while the participant is recording medication taking in a study diary.
- The NREC-CT noted in the “compensation for clinical trial participants” document that “Accommodation expenses” will not be covered, and that “Travel expenses” will be covered. This distinction between accommodation expenses and travel expenses reimbursement should be made clear to participants in the Screening and Main PIS-ICF.
- The NREC-CT noted on page 4 of the Main PIS ICF the section “Optional Tumour Biopsies”, and on pg. 14 “leftover sample research”. The NREC-CT noted that page 4 contains no reference or information for why this biopsy is being performed. 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/

7. Suitability of the clinical trial sites facilities

- No considerations raised by NREC-CT

8. Suitability of the investigator

- No considerations raised by NREC-CT

2024-512279-10-00 SM-5

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

Study title: A Randomized, Open-label, Phase 3 Study of Adjuvant Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice in Patients With Triple Negative Breast Cancer Who Have Residual Invasive Disease After Surgery and Neoadjuvant Therapy

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

Part II Considerations raised

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 noted that on page 5 and page 8 of the Optional Future and Genomic Research ICF and page 6, page 25, page 38 of the Main ICF, the phrase informed consent form has been shortened to ICF. The NREC-CT noted the Main ICF also includes the abbreviations HBC, HCV and BCRA without explanation or definition. The NREC-CT requests that abbreviations and acronyms to be used sparingly in participant facing materials and that all abbreviations should be defined in first use.
- The NREC-CT noted on page 48 of the Main ICF Consent, that there is a checkbox for additional research that is required for participation "Consent to use data for additional research". The NREC-CT noted that this is not described in line with regulations and best practice. The NREC-CT requests that this is removed and all consent regarding additional research/future use of samples is contained in the "Optional future and genomic Research" ICF.
- 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 3 of the

Optional Future Research and/or Genomic Research 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.
- 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/

2022-501453-36-00 SM-11

Institutions: Beacon Hospital, Mater Private Hospital, University Hospital Waterford, Mater Misericordiae University Hospital, St. James's Hospital

Study title: EORTC 2129-BCG: Elacestrant for treating ER+/HER2- breast cancer patients with ctDNA relapse (TREAT ctDNA)

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

Part II Considerations raised

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 noted the rare and very rare side effects have been deleted from page 28 to 32 of the Main ICF. The NREC-CT is requesting clarification regarding why these have been removed from the ICF.

2. **Suitability of the investigator**

- The NREC-CT noted that the CV of the investigator listed one clinical trial in their experience to date. The NREC-CT requested that the CV be updated if the investigator has further clinical trial experience, and if not, the NREC-CT is requesting confirmation that support will be in place from a suitable mentor with further clinical trial experience, to support this investigator.

2024-516440-25-00 SM-1

Institutions: Mater Misericordiae University Hospital

Study title: J5J-OX-JZZA: A Phase 1a/1b Trial of LY3962673 in Participants with KRAS G12D-Mutant Solid Tumors

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

2023-505678-14-00 SM-18

Institutions: St. Vincent's University Hospital, Beaumont Hospital

Study title: A Multicenter, Randomized Study to Evaluate the Safety and Efficacy of Lutikizumab for Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

Part II Considerations raised

9. 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 noted on page 12 of the Main ICF the risk of Neutropenia has been deleted. The NREC-CT requests clarification if this was intended on being removed, as the NREC-CT noted the risk still remains.
- The NREC-CT noted on page 30, the optional "Use of Coded data for continued Research – Select One Option" The NREC-CT requests that this be made separate to the Main Consent and presented to participant similarly to the "Future Use Research of Biological Samples" on page 32.
- The NREC-CT noted on page 14 of the Main ICF "Theoretical Risks". The NREC-CT requests that this be rephrased into lay terminology.
- The NREC-CT noted on page 30 of the Main ICF that text appears not to be finalized "If I become pregnant during the study, I understand that the study doctor

and staff will collect information about my pregnancy as described in the Patient Information Sheet and that I may be withdrawn from the study and the optional research<<delete if not applicable." This text should be finalized for review.

2023-506842-22-00 SM-5

Institutions: University Hospital Galway, Mater Misericordiae University Hospital

Study title: A Phase 1, First-in-Human, Open-Label, Dose-Escalation and Expansion Study of IMGN151 (anti-FRα antibody-drug conjugate) in Adult Patients with Recurrent Gynaecological Cancers

Dossiers Submitted: Part II

- NREC-CT Decision:
- Request for Further Information

Part II Considerations raised

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 noted the new side effects listed on page 14 and 15 of the Main ICF. The NREC-CT regards that the listed side effects are well laid out and clear for a participant to understand. The NREC-CT requests that context for the relatively low number of side effects is added to this section, explaining that there is limited information about the side effects as it is "first in human" and that as more information about side effects becomes known, the participants in the trial will be updated.

2023-506962-30-00 SM-4

Institutions: St. James's Hospital, Beaumont Hospital

Study title: The effect of semaglutide in subjects with non-cirrhotic non-alcoholic steatohepatitis

Dossiers Submitted: Part I & II

- NREC-CT Decision:

- Favourable

- AOB:
  - XXX
  - XXX