National Research Ethics Committee

NREC-CT Meeting

9th April 2025

Attendance

Name	Role
Prof David Brayden	Chairperson, NREC-CT D
Prof David Smith	Deputy Chairperson, NREC-CT D
Prof Andrew Green	Committee Member, NREC-CT D
Prof Cathal Walsh	Committee Member, NREC-CT D
Dr Geraldine O'Dea	Committee Member, NREC-CT D
Mr Gerry Daly	Committee Member, NREC-CT D
Ms Deirdre McLoughlin	Committee Member, NREC-CT D
Dr Mary McDonnell Naughton	Committee Member, NREC-CT D
Prof Geraldine O'Sullivan Coyne	Committee Member, NREC-CT D
Ms Chita Murray	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: Deirdre Murray, Christina Skourou, Jeff Moore, Chanel Watson, Lina Zgaga

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-504323-25-01
- 2024-517780-24-00
- 2024-517423-40-00
- 2023-506669-70-00 SM-6
- 2023-504962-52-00 SM-9
- 2023-507881-19-00 SM-5
- 2023-504923-20-00 SM-3
- 2023-510351-31-00 SM-2
- 2023-506924-94-00 SM-2
- AOB

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

Applications

2023-504323-25-01

Institutions: St Vincent's University Hospital

Study title: A Randomized, Multicenter, Placebo-controlled, Phase 3 study to Evaluate the Efficacy and Safety of HER2/neu Peptide GLSI-100 (GP2 + GM-CSF) in HER2/neu Positive Subjects with Residual Disease or High-Risk PCR after both Neoadjuvant and Postoperative Adjuvant Trastuzumab-based Therapy (FLAMINGO-01)

Dossiers Submitted: Part I & II

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

- **Additional Information Required**

Part II Considerations
1. Compliance with national requirements on data protection
• No considerations raised by NREC
2. Compliance with use of biological samples
• No considerations raised by NREC
3. Financial arrangements
• No considerations raised by NREC
4. Proof of insurance
• No considerations raised by NREC
5. Recruitment arrangements
• No considerations raised by NREC
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 Main ICF pg 15 and Pre-Screening ICF pg 8 be updated with a placeholder for the qualification of the person performing the consent interview
• It was unclear to the NREC-CT if legally designated representatives would be required in this trial in Ireland as the Recruitment arrangements document Section 2.1 says incapacitated subjects will not be recruited but sections 2.2 to 2.4 go on to describe the process of how they determine if someone has capacity and how they will be informed about the trial. Please clarify. The Committee requests the the

Main ICF be updated to include a space for a legally designated representative to sign if necessary.

- The NREC-CT requests that the Main ICF pg 14 Informed Consent Form be updated to ensure each consent statement has a box for participant to initial or tick to show explicit consent for each statement.
- The NREC-CT notes that the consent items on pg. 14 of the Main ICF are bundled and requested that a tiered / unbundled approach to consent is used in all PISCF forms, in that each consent item is listed (it is not sufficient to say '' By signing this subject information and informed consent form, I confirm that:,' consent must be specific with each item listed). A box for participants to provide their initials or Yes/No tick box must be included alongside each consent item. Please see: HSE National Policy for Consent in Health and Social Care Research (V2.0, 2024) https://hseresearch.ie/consent/
- The NREC-CT requests that the Main ICF pg 14 be updated to include specific statement that the participant confirms that they have both read and understand the information.
- The NREC-CT requests that the Main ICF pg 15 be updated to include the following information under the witness signature *"Under certain circumstances (see Good Clinical Practice) a witness* to informed consent is required. By signing the consent form, the witness attests that the consent information was accurately explained to and apparently understood by the participant or the participant's legally acceptable representative and that informed consent was freely given by the participant or the participant's legally acceptable representative"*
- The NREC-CT requests that Main ICF pg 3 screening period be updated to provide more details on the testing of the blood sample, whether this is optional and participants informed if this testing is requested to be carried out even if they do not pass screening.
- The NREC-CT noted that the future use of data / samples (including genetic research) is not described in line with regulations / best practice on pg. 4 of the Pre-screening ICF *"Data or specimens collected in this research-pre-screening will be de-identified and used for future research or distributed to another investigator for future research without your consent"* and pg 5 Main ICF "*Your blood samples will be stored for an indefinite amount of time for research that might include: DNA sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code) related to your cancer and HLA type for the purpose of screening, diagnostics, or biomarker research. Immune cell response to GLSI-100 and looking at markers in your blood to investigate how the study drug works in the body."* and pg 10 of Main ICF "Sponsor *may share your coded personal data with these business partners for research purposes.".* 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 be updated to 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 notes Pre-screening ICF pg 4 "Data or specimens collected in this research-pre-screening will be de-identified and used for future research or distributed to another investigator for future research without your consent."
  If some or all of the data is anonymised the Committee requests that the ICFs be updated to explain this to participants and to include a consent statement on consent form for the participant to explicitly consent to the processing of their personal data from pseudanonymised /coded to anonymised data it as per Article 4 (2) and (6) General Data Protection Regulation (GDPR).
- The NREC-CT notes Main ICF pg 8 if you become pregnant "With your consent, the Sponsor will collect information about the health of your pregnancy and your pregnancy outcome". The Committee notes no Pregnancy ICF was submitted for review and advises that the Pregnancy ICF will need to be submitted for review before information can be collected on a pregnancy.
- The NREC-CT requests that the Main ICF pg 12 be updated to remove reference to contact the NREC for the listed situations.
- The NREC-CT requests that the Main ICF pg 13 and Pre-screening ICF pg 3 be updated to provide more detail on what the participant can get reimbursed for and how the process works.
- The NREC-Ct requests that Main ICF consent page be updated to include a specific consent statement for the collection of race and ethnicity as these are considered special data under data protection law.
- The NREC-CT requests that the Main ICF pg 9 be updated to provide more detail why it is necessary to determine race and ethnicity and how this data will be used.
- The NREC-CT notes Main ICF pg 13 *"You can withdraw from study participation at any time without penalty or loss of benefits that are otherwise entitled to you. If you decide to leave this study, contact the study team so that the study doctor can withdraw you from the study. The study doctor may ask you to come in for a final visit. Any data collected prior to your withdrawal may not be removed from the study database."* The Committee requests that every effort be made to respect the wishes of the research participant to withdraw from further processing of their biological material or personal data and that the Main ICF be updated to clarify for participants why they not be able to withdraw their data. Please refer to HSE National Policy for Consent in Health and Social Care Research for more information. https://assets.hse.ie/media/documents/ncr/20250107_HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-V2.0.pdf

- The NREC-CT requests that the Main ICF pg 13 *"Will I be paid for taking part in this study?"*, which states "some of your expenses will be reimbursed. "be updated to include more specific information around what expenses will be paid, and ensure participants are reimbursed for all reasonable out of pocket expenses.
- The NREC-CT noted contradiction between the information in section 4.1 Protocol and pg 3 of Main ICF in relation to the inclusion/exclusion of HLA-A*02 negative patients.

7. Suitability of the clinical trial sites facilities

- No considerations raised by NREC

8. Suitability of the investigator

- No considerations raised by NREC

2024-517780-24-00

Institutions: National University of Ireland Galway, St James's Hospital, Mater Private Hospital, St Vincent's University Hospital, Beaumont Hospital, Cork University Hospital

Study title: A Phase III, Randomized, Double-blind, Multicenter, Global Study of Rilvegostomig or Pembrolizumab Monotherapy for the First-line Treatment of Patients with PD-L1-high Metastatic Non-small Cell Lung Cancer (ARTEMIDE-Lung04)

Dossiers Submitted: Part I & II

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

- **Additional Information Required**

Part I Considerations (RFI) for addition to CTIS

1. The Sponsor is requested to provide clarification whether the scientific advice regarding study design/methodology and dual primary endpoint approach, as suggested by the EMA has been implemented.
2. It was noted that the eligibility criteria 7 is a minimum life expectancy of 12 weeks. It is noted that this may be difficult to estimate when starting a first line therapy, and also that participants with brain metastases are permissible which impacts life expectancy. Please clarify.
3. Clarity is requested on exclusion criteria 4 which states: 'persistent toxicities from prior anticancer therapy': The exclusion criteria should specify if it is relating to prior neoadjuvant or adjuvant therapy.

Part II Considerations

1. Compliance with national requirements on data protection

- No considerations raised by NREC

2. Compliance with use of biological samples

- The NREC-CT requests that the Compliance with use of biological samples document section 4.8 be updated to make it clear that subsequent research ethics review will be sought for all future use of samples once the research is clearly defined. The NREC-CT ethics opinion is limited to the clinical trial protocol and application dossier that has been assessed. Any future research conducted beyond the protocol and application dossier will require a separate ethics approval from a recognised research ethics committee once that future research question is defined
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3. Financial arrangements

- The NREC-CT noted that participants may require the assistant of care giver to attend appointments and stated the caregivers should be reimbursed for out-of-pocket expenses should they accompany the participant to study visits. The Compensation for participant documents and the ICF's should be updated to confirm this.

4. Proof of insurance

- No considerations raised by NREC

5. Recruitment arrangements

- The NREC-CT notes Recruitment and Informed Consent Procedure: pg.1 refers to "Advertisement materials (paper and online) will be used as well" however none have been supplied for review. Please confirm that any advertising materials will be submitted for review by NREC before they are used.

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 Main ICF pg 31, Optional Genomics ICF pg 7 and Pregnant Partner ICF pg 7 be updated with a placeholder for the qualification of the person performing the consent interview. The NREC-CT requests that the Main ICF pg 24 and Pregnant Partner ICF pg 5 be updated to provide information about the availability of the clinical trial results on EU database at the end of the trial and the website address of same.
- The NREC-CT notes that the future use of optional data / samples (including genetic research) is not described in line with regulations / best practice on
    - pg. 26 of the Main PISCF *"This means that we may use the data to advance our understanding of how to make new medicines, medical devices, diagnostic products, tools (including machine learning and artificial intelligence technologies) and/or other therapies, to treat diseases. We may also use this data to improve the design and execution of future clinical studies, services and treatments, for outcome research activities and to aid in pricing and reimbursement activities"* and *"Your coded data, images and*

leftover biosamples may only be used for scientific health-related research."

- Pg 17 Main ICF *"AstraZeneca may share your coded data and biosamples with research partners (including those from universities, research hospitals, and companies) or deposit them in scientific databases. Your personal data listed above (see Part 1 Section 10a "Which data and biosamples are collected?) may also be shared with service providers or third parties including IT providers for the purposes of developing new technologies, system development and technical support."*
- Pg 19 Main ICF *"Perform additional biomarker and diagnostic test research using your biosamples or images of your tumour sample(s) to learn more about your disease …… advance science and public health".*
- Pg 3 Optional Genomics ICF *"The sponsor may share your coded data and biosamples with research partners and/ or deposit them in scientific databases as described in the main study information and informed consent form in "Part 4: Additional Information for Participants". This may include researchers from as well as universities, research hospitals, and drug- or health-related companies. In addition, the sponsor and its designated organisations may conduct further research where they will share summary data (not your individual data) with other researchers, from other companies or universities, for example."*
- Pg 3 Optional Genomics ICF "*"Part 4: Additional Information for Participants" and will only be used for the purpose of scientific health-related research to find new ways to detect, treat, prevent or cure health problems."*
- Pg 7 Pregnant Partner ICF *""I agree that my coded data can be used for other medical, healthcare or scientific related research purposes"*

The NREC-CT requests 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 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 be updated 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 notes that some of the data will be anonymised. The Committee requests that the Main ICF, Genomic ICF and Pregnant Partner ICF be updated to include a consent statement for the participant to explicitly consent to the processing of their personal data from pseudanonymised /coded to anonymised data it as per Article 4 (2) and (6) General Data Protection Regulation (GDPR).

- The NREC-CT noted reference to Unify App in the Main ICF and requested further detail on the App. The Committee also requested that the Main ICF be updated to provide more detail for participants around Unify app including who owns/operates it, what country they are based in etc.
- The NREC-CT noted that pg. 9 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 or related diseases 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 notes on pg 31 of Main ICF consent for "My registration to "Optional Services" (which may include transfer of my contact details to service providers) to: Ask your opinion on the provided Clinical Trial Transparency materials. - Home nursing visits" however there is no information in the ICF about these services. The NREC-CT requests that the information section of Main ICF be updated with information around what these optional services are so participants are fully informed before they consent or not to these optional components.
- The NREC-CT notes on page 32 of the Main ICF, pg 7 of Optional Genomics ICF and pg 8 of Pregnant Partner ICF includes a witness signature line. The NREC-CT requests information be added explaining who the impartial witness can be and the context where an impartial witness signature would be needed.
- The NREC-CT requests that the Pregnant Partner ICF be updated or a new ICF be submitted for pregnant participants to consent to the collection of their and their baby's data if she becomes pregnant.
- The NREC-CT requests that the sentence on Main ICF pg 24 section 13 *"It is not mandatory but would be helpful for the study if you explain to the study doctor why you wish to stop*" be updated to *"There is no requirement but may be helpful for the study if you explain to the study doctor why you wish to stop"*
- The NREC-CT notes contradiction in Main_ICF in relation to reimbursement pg.22 states "reimburse you for your time, effort and certain expenses related to your participation "however Pg.23 states " …will reimburse travel, accommodation and food expenses". The Committee requests that the wording be updated to align.
- The NREC-CT notes pg 19/20 Main ICF "you have the choice to refuse any

further testing on your biosamples if you do not go on to participate in the study. In this case, please inform your study doctor and your remaining biosamples will be destroyed or (if requested) sent back to your study doctor as soon as possible." The Committee requests that the consent form pg 30 be updated to include an additional statement giving the participant options to consent to or not for what they want to happen to their data and samples if they fail screening.

- The NREC-CT requests that the sentence on Pregnant Partner ICF pg 2 "you do not have to explain your reasons for stopping but it would be helpful for us to know" be removed.
- The NREC-CT requests that Optional Genomics Consent form pg 6 Item 6 "*If I decide not to participate in the optional multi-omics research, or to stop my participation during the study, this will not affect my standard medical care"* be updated to include the following text *"I further understand that my coded data and biosamples will not be used for further research and will be destroyed as soon as possible"*
- The NREC-CT requests that the Main ICF pg. 30 be updated to include a specific consent statement for participant to consent for research team members to access their healthcare records.
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7. Suitability of the clinical trial sites facilities

- Please submit an original version (word or original PDF) of the Site Suitability Assessment Form for St James's Hospital and Beaumont Hospital. 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 notes a discrepancy between the sites taking part in this study as [redacted] her CV and Site Suitability Form states the site as University Hospital Galway however her DOI and DPIA states she is working in Galway Clinic, Doughiska. The Committee notes no SSF has been submitted or Galway Clinic Doughiska. Please note that all sites taking part in the study in Ireland must have a Site Suitability Form submitted.
- The NREC-CT notes that all the Irish sites apart from University Hospital Galway advises that the exposure to ionising radiation is above what is required for standard care. Please confirm that the information in Site Suitability Form for University Hospital Galway in relation to exposure to ionising radiation as not above what is required for standard care is correct or update the SSF as necessary.
- The NREC-CT notes the Site Suitability Form for Mater Private pg .5 states re [redacted] "any unused portion must be discarded" however the Protocol pg.64 states that "dose reduction is not permitted". The Committee requests that the Site Suitability Form for Mater Private be updated to remove this wording or clarify in what instance an unused portion would arise.

8. Suitability of the investigator

- The NREC-CT notes a discrepancy between the information in [redacted] CV, Declaration of Interest and Site Suitability Form, her CV and Site Suitability Form states that she is employed at University Hospital Galway however her DOI and DPIA states she is working in Galway Clinic, Doughiska. The Committee

requests these documents be reviewed and updated to align and show her current place of employment.

2024-517423-40-00

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

Study title: A Phase 3, Open-label Study of Ifinatamab Deruxtecan Versus Docetaxel in Participants with Metastatic Castration-Resistant Prostate Cancer (mCRPC) (IDeate Prostate01)

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

- Additional Information Required

Part I Considerations (RFI) for addition to CTIS	
1.	The Sponsor is requested to confirm that the terms relating to the colour of medication in the Analgesic diary are relevant to participants in all countries, including Ireland.
2.	The Sponsor is requested to provide details of provisions in place to support participants should the FACT-P and EQ-5D questionnaire indicate a mental health issue.
3.	It was noted that in the protocol, initial tumour scans take place up to 42-days prior to randomization. RECIST 1.1 assessment criteria require that the baseline scan should be done within 4 weeks before treatment starts, and that slice thickness ⩽ 5 mm and i.v. contrast are mandatory. The Sponsor is requested to confirm if this criterion has been taken into consideration.

Part II Considerations

1. Compliance with national requirements on data protection

- No considerations raised by NREC

2. Compliance with use of biological samples

- No considerations raised by NREC

3. Financial arrangements

- No considerations raised by NREC

4. Proof of insurance

- No considerations raised by NREC

5. Recruitment arrangements

- No considerations raised by NREC

Commented [PK1]: To come back to this to put up considerations

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 Main ICF pg 22 and Greenphire ICF pg 6 be updated with a placeholder for the qualification of the person performing the consent interview
- The NREC-CT notes that the future use of data / samples (including genetic research) is not described in line with regulations / best practice on Main ICF pg 23 *"the goal of this research is to help develop better treatments and to learn more about human disease and health."* and "*The Sponsor may use information from this additional research together with any other information collected about you for scientific research.".* 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 be updated to 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 pg. 9 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 or related diseases 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 notes that the study will collect a high volume of imaging scans. It is unclear to the Committee if the scans will be shared with the sponsors or if they will only be used locally to identify progression / response and only the metadata will be shared with the sponsors. The Committee requests that the Main ICF be updated to clarify.
- The NREC-CT requests that the Main ICF be updated in lay language to make it clear to participants the number of scans above standard of care, a lay explanation of the approx. dose of radiation and the risk of same.
- The NREC-CT requests that Main ICF be updated to include an acknowledgement that completion of FACT-P and EQ-5D questionnaires may cause distress, and clarification as to the pathway of care and referral offered to participants displaying a mental health issue.
- The NREC-CT notes that pg. 21 of the Main ICF states that participants may have photographs taken. The NREC-CT requested the following is explained to participants in the PISCF:
    - What exactly is being photographed.
    - Why these photos need to be taken and what they will be used for
    - Details of the data protection measures related to the use, access and storage of these photographs.

7. Suitability of the clinical trial sites facilities

- No considerations raised by NREC

8. Suitability of the investigator

- No considerations raised by NREC

2023-506669-70-00 SM-6

Institutions: St James's Hospital

Study title: A Phase 3, Randomized, Double-blind, Placebo controlled, Multicenter Study to Evaluate the Efficacy and Safety of Amyloid Depleter ALXN2220 in Adult Participants with Transthyretin Amyloid Cardiomyopathy (ATTR-CM)

Dossiers Submitted: Part I & II

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

- **Additional Information Required**
- None

2023-504962-52-00 SM-9

Institutions: St Vincent's University Hospital, University Hospital Galway, Bon Secours Hospital Cork

Study title: A Phase 3, Randomized, Open-label, Study to Compare the Efficacy and Safety of Adjuvant MK-2870 in Combination with Pembrolizumab (MK-3475) Versus Treatment of Physician's Choice (TPC) in Participants With Triple-Negative Breast Cancer (TNBC) Who Received Neoadjuvant Therapy and Did Not Achieve a Pathological Complete Response (pCR) at Surgery

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Request for Further Information

- Additional Information Required

Part II Considerations raised

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

- 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 Optional Greenphire adults ICF be updated to replace reference to privacy and data protection laws in the UK with privacy and data protection laws in Ireland as the research takes place in Ireland.
- The NREC-CT notes Main ICF pg 7 that tissue may be completely used and may not be available for future testing. The Committee requests that the Main ICF be updated to provided clarification regarding the storage and potential future use of any remaining tissue, participants should be informed whether any leftover tissue will be stored, whether it may be used in future ethically approved research, and their rights regarding withdrawal of consent.

2023-507881-19-00 SM-5

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

Study title: Vaccination to prevent Mpox Infection (MPOX-VAX Study)

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

- 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 MPOX PIL pg 7 be updated to correct the two bullet points at the bottom of page as they currently do not make sense due to a typographical error.
- The NREC-CT requests that the information in MPOX PIL pg 8: 3rd paragraph and the last paragraph (headed Will My Data Be Used in Future Research?) be updated at there is duplication in the information contained in these sections.
- The NREC-CT requests MPOX PIL pg 9, 2nd paragraph regarding types of future research and Consent form pg 19 Storage and Future Use 2nd bullet point be updated to clarify whether future research relating to the immune system will be focusing on MPOX or infectious diseases in general.
- The NREC-CT requests the MPOX PIL pg 9 be updated to inform participants that pseudonymised data from the study could be shared with another study team outside the EU. This information should also be included on the consent form

2023-504923-20-00 SM-3

Institutions: Tallaght University Hospital

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

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

- **Additional Information Required**
- None

2023-510351-31-00 SM-2

Institutions: Children's Health Ireland Temple Street

Study title: A Randomized, Double-Blind, Placebo-Controlled, Multiple Ascending Dose Study Assessing Safety, Tolerability, Pharmacodynamics, Efficacy, and Pharmacokinetics of DYNE-251 Administered to Participants with Duchenne Muscular Dystrophy Amenable to Exon 51 Skipping

Dossiers Submitted: Part I & II

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

- **Additional Information Required**

Part II Considerations raised

1. **Subject information and informed consent form**
   - 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 the Main ICF pg 7 be updated to clarify how long the additional muscle biopsy will be kept.

2023-506924-94-00 SM-2

Institutions: St Vincent's University Hospital, St James's Hospital, Mater Misericordiae University Hospital, Connolly Hospital, National University of Ireland

Study title: The cardiovascular safety and efficacy of cagrilintide 2.4 mg s.c. in combination with semaglutide 2.4 mg s.c. (CagriSema 2.4 mg/2.4 mg s.c.) once-weekly in participants with established cardiovascular disease.

Dossiers Submitted: Part I & II

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

- **Additional Information Required**
- None

- AOB:
  - Overview of CTIS system