National Research Ethics Committee

NREC-CT Meeting

04 September 2024

Attendance

Name	Role
Prof Mary Donnelly	Chairperson, NREC-CT C
Prof John Faul	Deputy Chairperson, NREC-CT C
Dr Jean Saunders	Deputy Chairperson, NREC-CT C
Prof Austin Duffy	Committee Member, NREC-CT C
Prof Fionnuala Breathnach	Committee Member, NREC-CT C
Dr Susan Finnerty	Committee Member, NREC-CT C
Prof Andrew Smyth	Committee Member, NREC-CT C
Dr Steve Meaney	Committee Member, NREC-CT C
Dr Dervla Kelly	Committee Member, NREC-CT C
Ms Susan Kelly	Committee Member, NREC-CT C
Dr Deborah Wallace	Committee Member, NREC-CT C
Ms Paula Prendeville	Committee Member, NREC-CT C
Mr Philip Berman	Committee Member, NREC-CT C
Prof Anne Mathews	Committee Member, NREC-CT C
Ms Aileen Sheehy	Programme Manager, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Dr Emma Heffernan*	Project Officer, National Office for RECs
Dr Emily Vereker	Head of Office, National Office for RECs
Mr Ciaran Horan	Administrative Assistant, National Office for RECs

Ms Rachel McDermott	Project Administrator, National Office for RECs

Apologies: Dr Deborah Wallace, Ms Susan Kelly, Mr Gerry Eastwood

Quorum for decisions: Yes

Conflict of Interest: 2024-514135-17-00 Andrew Smyth – not present for discussion of trial at meeting

Agenda

- Welcome & Apologies
- 2022-501866-22-00
- 2022-501867-42-01
- 2024-514135-17-00
- 2023-506327-29-00
- 22-NREC-CT-095_Mod-4
- 22-NREC-CT-125_Mod-4
- 2023-505850-16-00 SM1
- 2023-507684-19-00 SM1
- 2023-504655-27-00 SM1
- 2023-505989-29-00 SM1
- 2023-503614-80-00 SM6
- 2022-502684-37-00 SM3
- AOB

- The Chair welcomed the NREC-CT C.
  - The minutes from the previous NREC-CT C meeting on 17/07/2024 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2022-501866-22-00

Institutions: N/A

Study title: International proof of concept therapeutic Stratification trial of Molecular Anomalies in Relapsed or Refractory HEMatological malignancies in children – sub protocol B

Dossiers Submitted: Part I

- **NREC-CT Decision:**

- Favourable

2022-501867-42-01

Institutions: N/A

Study title: International proof of concept therapeutic Stratification trial of Molecular Anomalies in Relapsed or Refractory HEMatological malignancies in children - Sub-protocol C

Dossiers Submitted: Part I

- **NREC-CT Decision:**

- Favourable

2024-514135-17-00

Institutions: Cork University Hospital, University Hospital Galway, St. Vincent's University Hospital, University Hospital Waterford

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Povetacicept in Adults with Immunoglobulin A Nephropathy (RAINIER)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for more information

  - Additional Information Required

Part II Considerations

Proof of insurance

- The NREC-CT noted that the insurance policy expires on 28 February 2025 and requested confirmation that insurance is in place for the duration of the trial.

Recruitment arrangements

- The NREC-CT noted that participants are advised in the recruitment materials that they have a 2:1 chance of being randomised to the IMP, but this is not the case for

participants taking part in the exploratory study where they will be randomised 1:1. The committee requested that the recruitment materials are updated to reflect this.

Subject information and informed consent form

- The NREC-CT requested that more information is provided for participants in the Main PISCF on how trial participation impacts their clinical care in the event of disease progression. The NREC-CT requested the following:
    - Participants are advised that standard of care treatment would not deviate from accepted standards in the case of disease progression.
    - Participants should be advised that other established treatments, including immunosuppressive agents, dialysis or transplant, would not be withheld from them in the event of disease progression, rather that the IMP would be withheld, but study visits would continue to completion of trial participation, in the event that a prohibited concomitant medication or treatment is considered necessary by the investigator.
- The NREC-CT noted that pg. 13, section 11: 'What are my alternatives to participating in the study?' in the Main PISCF states that for patients at high risk of disease progression, immunosuppressive therapies can be used, but it is not made clear to the participant that use of a range of immunosuppressive treatments would require for the study drug to be discontinued. The NREC-CT requested that this is explained to participants.
- The NREC-CT noted that the exploratory cohort is not well explained to participants in the PISCF. The committee requested that this is amended and the distinction between main study and 'exploratory study' is explained to participants including the implications of being randomized 1:1.
- The NREC-CT requested that the lack of safety / efficacy data relating to the IMP in cohorts with advanced disease (eGFR <30), and therefore at enhanced risk for potential adverse effects, should be added to the PISCF, so participants are fully informed.
- The NREC-CT noted that the L1_SIS and ICF_Other ICF_Alpine PISCF does not adequately describe procedure-related risks associated with a renal biopsy. It is not sufficient to list swelling/ bleeding/ infection/ scar as potential risks, and then defer to the participant's practitioner. The NREC-CT requested that all procedure-related risks associated with a renal biopsy are explained to participants on pg. 3 the L1_SIS and ICF_Other ICF_Alpine PISCF using plain English suitable for a lay audience.
    - It should also be explained to participants that the optional biopsy is being performed solely for research purposes and not to guide treatment.
- The NREC-CT requested that the term 'demyelination' on pg.10 of the PISCF is explained to participants using plain English suitable for a lay audience.
- The NREC-CT requested that the exact figure for inconvenience is removed from the PISCF documents, as it may constitute an inducement to participate.
- 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.

2023-506327-29-00

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

Study title: A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab With or Without V940 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy (INTerpath-009)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for more information

- Additional Information Required

Part II Considerations

Proof of insurance

- The NREC-CT noted that insurance is in place until 29/07/2026 and requested confirmation that insurance is in place for the duration of the trial.

Recruitment arrangements

- The NREC-CT requested clarity whether the recruitment materials detailed in section 1.2 of the K1_Recruitment Arrangements and IC Procedure_IRL_EN_for pub will be used in Ireland. If so, the Sponsor is requested to submit these for review.

Subject information and informed consent form

- The NREC-CT noted that all PET scans will be carried out in the Beacon Hospital in Dublin and queried whether participants based in Cork could be provided with PET scans closer to their base hospital.
- The NREC-CT noted that legitimate use is stated as the legal basis for processing personal data on pg. 18 of the PISCF and requested that participants are also informed that explicit consent is also required as an additional safeguard for the processing personal data as per the Health Research Regulations 2018.
- The NREC-CT requested clarification as to whether participants samples / data will be retained for optional future use. If so, the Committee requested that future use of 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 the disease 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.
    - is made into a separate and explicit consent item on pg. 22 of the L1_ICF_Main consent_IRL_EN_for pub PISCF, with separate signatures

section, so it is distinct from the main consent to participate in the research

The PISCF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. For further guidance, please see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/

- The NREC-CT noted that pg. 10 of the L1_ICF_Main consent_IRL_EN_for pub PISCF states that participants may undergo whole genome / whole exome sequencing and requested the following:
    - Genomic sequencing is confined to genes involved in the disease being treated 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 (V1.1, 2023) https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf
- The Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part I Assessment. Please include details of the Part 1 Consideration responsible for triggering update to Part 2 documents in your submission.
- 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.

22-NREC-CT-095_Mod-4

Institutions: Sheaf House, Tallaght Adult Mental Health Services

Study title: Efficacy and safety of COMP360 psilocybin therapy in anorexia nervosa: a proof-of-concept study

Dossiers Submitted: N/A

- **NREC-CT Decision:**

- Request for more information

- Additional Information Required

- The NREC-CT noted that the section on future research as detailed on pg. 8 (If you agree, we may also use the information collected about you to support other research in the future) and pg. 28 (Please let us know if you agree or not, for your information collected during treatment from the video and/or audio recordings to be used in the future, to support further research) of the Compass_COMP401_Participant ICF_IRE_V5.1.1_17May2024_TC is not described in line with regulations and best practice. The Committee requested that future use of personal data (including video or audio recordings) 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 the disease 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: HSE National Policy for Consent in Health and Social Care Research (V1.1, 2023) https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf

- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment. Please include details of the Part 1 Consideration responsible for triggering update to Part 2 documents in your submission.
- 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

22-NREC-CT-125_Mod-4

Institutions: St Luke's Hospital

Study title: Phase III randomised controlled trial Comparing Alternative Regimens for escalating treatment of intermediate and high-risk oropharyngeal cancer

Dossiers Submitted: N/A

- **NREC-CT Decision:**

- Request for more information
    - Additional Information Required
    - The NREC-CT noted that pg. of the PISCF states 'I understand that the COMPARE Trial office may obtain information about me from my GP or other hospital records to

follow up on my health status' and requested that this is reworded to 'I give consent for the COMPARE Trial office may obtain information about me from my GP…'

- The NREC-CT noted that the section on future research as detailed on pg. 106 ('Samples and clinical data collected may be useful in other studies that have received ethical approval…') and pg. 194 ('Data and images will be collected and transferred to UoB for storage and may be used for future research') of the protocol and pg. 24 ('Clinical data (without any personal identifiers) collected during your participation in the trial may be used in future research to allow researchers to analyse your scans') of the CompARE PIS E & ICF_IRL v2.0 08-Jul-2024_TCs.pdf is not described in line with regulations and best practice. The Committee requested that future use of samples 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 the disease 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/
- The NREC-CT requested that the text related to future research on pg. 28 of the Main PISCF is made into a separate and explicit consent item, with separate signatures section, so it is distinct from the main consent to participate in the research
    - It should also be clearly stated on pg. 28 that future research is optional.
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment. Please include details of the Part 1 Consideration responsible for triggering update to Part 2 documents in your submission.
- 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

2023-505850-16-00 SM1

Institutions: St James's Hospital

Study title: A Phase 3 Randomized Study Comparing Bortezomib, Lenalidomide and Dexamethasone (VRd) followed by Ciltacabtagene Autoleucel, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA versus Bortezomib, Lenalidomide, and Dexamethasone (VRd) followed by Lenalidomide and Dexamethasone (Rd) Therapy in Participants with Newly Diagnosed Multiple Myeloma for Whom Hematopoietic Stem Cell Transplant is Not Planned as Initial Therapy

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for more information

- Additional Information Required

Part II Considerations

Subject information and informed consent form

- The NREC-CT requested that it is made clear to participants on pg. 43 of the L1_TC_ICF Main _IE_en_2023-505850-16-00 PISCF that future research is optional and the reference to future research being 'opt out' is removed.
- The NREC-CT requested that the text related to future research on pg. 51 of the Main PISCF is made into a separate and explicit consent item, with separate signatures section, so it is distinct from the main consent to participate in the research
    - It should also be clearly stated on pg. 51 that future research is optional.
- The NREC-CT The NREC-CT requested clarification as to whether existing participants will be re-consented with updated PISCF documents.
- The NREC-CT requested that the statement 'Up to about a third of patients experienced blood cell effects for more than 1 month after receiving cilta-cel' on pg. 30 of the L1_TC_ICF Main _IE_en_2023-505850-16-00 PISCF is reworded to 1 in X number of patients…, so it is easier for participants to understand and is consistent with the rest of the document.
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment. Please include details of the Part 1 Consideration responsible for triggering update to Part 2 documents in your submission.
- 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

2023-507684-19-00 SM1

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

Study title: Phase 3, Randomized Study Evaluating the Efficacy and Safety of TAR-210 Erdafitinib Intravesical Delivery System Versus Single Agent Intravesical Chemotherapy in Participants With Intermediate-risk Non-muscle Invasive Bladder Cancer (IR-NMIBC) and Susceptible FGFR Alterations

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for more information

- Additional Information Required

Part II Considerations

Subject information and informed consent form

- The NREC-CT noted that the section on future research on pg. 23 of the TC_L1_SIS and ICF Main_IE_eng_42756493BLC3004 and pg. 10 of the TC_L1_SIS and ICF Molecular Eligibility_IE_eng_42756493BLC3004 (… and associated health problems' and 'to apply learnings from past studies to new ones or improve scientific analysis methods') is not described in line with regulations and best practice. The Committee requested that future use of samples is sufficiently explained 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 the disease 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: HSE National Policy for Consent in Health and Social Care Research (V1.1, 2023) https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf
- Once finalized, the NREC-CT requested that the updated ICF Molecular Eligibility_IE_eng_42756493BLC3004 PISCF as a result of this assessment are submitted to NREC-MD as a non-substantial modification. This approach has been agreed with the secretariat of the NREC-MD.
- The NREC-CT noted that Pg. 11 of the TC_L1_SIS and ICF Main_IE_eng_42756493BLC3004 states that participants 'may experience some discomfort when the cystoscope or urinary placement catheter is passed into your bladder for the cystoscopic examination, during insertion/removal of TAR-210, and possibly during the time between TAR-210 insertion and removal while TAR-210 remains in your bladder. Perforation of the bladder could also occur, which could require urgent surgery'. The NREC-CT requested the following information is added to the PISCF:
    - All potential risks associated with these procedures are detailed in the PISCF, so participants are fully informed (it is not sufficient to state that the study doctor or nurse will discuss any possible risks of the procedure prior to your decision to take part in the trial)
    - That detail regarding the likelihood that participants may experience bladder perforation is outlined i.e. 1 in XX number of participants are likely to experience this.
- The NREC-CT The NREC-CT requested clarification as to whether existing participants will be re-consented with updated PISCF documents.
- The Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part I Assessment. Please include details of the Part 1 consideration responsible for triggering update to Part 2 documents in your submission.

- 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.

2023-504655-27-00 SM1

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: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-505989-29-00 SM1

Institutions: Beaumont Hospital

Study title: A Phase 3, Open-label, Multicenter, Randomized Study of Tarlatamab in Combination With Durvalumab vs Durvalumab Alone in Subjects with Extensive-Stage Small-Cell Lung Cancer Following Platinum, Etoposide and Durvalumab (DeLLphi-305)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for more information
  - Additional Information Required

Part II Considerations

Compliance with use of biological samples

- The NREC-CT requested that the S1_ Compliance on the collection use and storage of biological samples TC_Not for Publication document is updated to reflect updates to the PISCF documents.
- The NREC-CT requested that the S1_ Compliance on the collection use and storage of biological samples TC_Not for Publication document is updated to incorporate reference to saliva collection (as per protocol pg.28)

Subject information and informed consent form

- The NREC-CT requested that pg. 32 of the L1_ SIS and ICF_Main Study Tracked Changes_Not For Publication includes a specific consent item in relation to understanding the requirements for post infusion support (including the requirement for care giver support and proximity to the hospital).
- The NREC-CT requested that the L1_ SIS and ICF_Main Study Tracked Changes_Not For Publication is updated to incorporate reference to saliva collection (as per protocol pg.28).

- The NREC-CT noted that the section on future research on pg. 17 of the L1_ SIS and ICF_Pre-Screening Tracked Changes_Not For Publication and Pg. 29 of the S1_ Compliance on the collection use and storage of biological samples TC_Not for Publication ('…and may be used for research into other therapies such as scientific research purposes other than the study, including looking into if any medical product or treatment included in the study is safe or works; identification of new medical uses of any medical product or treatment included in the study; further examination of the disease(s) or condition(s) that are the subject of the study to identify new learnings; and analysis of how Amgen can improve its clinical research processes') is not described in line with regulations and best practice. The Committee requested that future use of samples is sufficiently explained 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 the disease 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/
- The Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part I Assessment. Please include details of the Part 1 Consideration responsible for triggering update to Part 2 documents in your submission.
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2023-503614-80-00 SM6

Institutions: Mater Misericordiae University Hospital

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oral Inhalation of Seralutinib for the Treatment of Pulmonary Arterial Hypertension (PAH)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for more information

- Additional Information Required

Part II Considerations

Recruitment arrangements

- The NREC-CT requested that updates to the PISCF documents regarding impartial witness are reflected in the K1_GB002-3101-Recruitment-and-Informed-Consent-Procedure-Template-_IE_TC_NotPublic

Subject information and informed consent form

- The NREC-CT noted that the option to include an impartial witness has been removed from the L1_GB002-3101_Main-ICF_IE_English_TC_NotPublic and requested that this is reinstated, so that participants who require an impartial witness are not discriminated against.
- The NREC-CT noted that pg. 1 of the L1_GB002-3101_Main-ICF_IE_English_TC_NotPublic states that '*and 2 visits may be done by telephone call with an associated lab blood sample being taken'* and requested it is explained to participants how these blood samples will be taken if the visits are taking place over the phone.
- The NREC-CT requested that the sentence that '*your do not need to provide consent for the pharmacogenetic research study'* is revised on pg. 6 of the L1_GB002-3101_Main-ICF_IE_English_TC_NotPublic PISCF as participants are required to provide consent for the optional pharmacogenetic study.
- The NREC-CT noted that pg. 21 of the L1_GB002-3101_Main-ICF_IE_English_TC_NotPublic PISCF states that the ethics committee may have access to participants identifiable information and requested that this is amended as NREC will not have access to identifiable information.
- The NREC-CT noted that pg. 1 of the L1_GB002-3101_PGx ICF_IC_English_TC_NotPublic states '*This pharmacogenetic research is funded by the Sponsor, GB002, Inc. The Sponsor will pay the Study Doctor for including you in this study.*'. The Committee requested further information whether study doctors are financially incentivised to recruit patients to the optional pharmacogenetics study.
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment. Please provide information as to which Part 1 consideration triggered the update to the Part 2 documents.
- 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.

2022-502684-37-00 SM3

Institutions: St Vincent's University Hospital

Study title: A Phase 1/2 First-in-Human Study of the Safety and Efficacy of IMC-F106C as a Single Agent and in Combination with Checkpoint Inhibitors in HLA-A*02:01-Positive Participants with Advanced PRAME-Positive Cancers

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

- AOB: N/A