National Research Ethics Committee

NREC-CT Meeting

30th July 2025

Attendance

Name	Role
Prof David Brayden	Chairperson, NREC-CT D
Prof David Smith	Deputy Chairperson, NREC-CT D
Dr Christina Skourou	Deputy Chairperson, NREC-CT D
Prof Andrew Green	Committee Member, NREC-CT D
Prof Cathal Walsh	Committee Member, NREC-CT D
Prof Deirdre Murray	Committee Member, NREC-CT D
Dr Geraldine O'Dea	Committee Member, NREC-CT D
Prof Lina Zgaga	Committee Member, NREC-CT D
Mr Gerry Daly	Committee Member, NREC-CT D
Ms Deirdre McLoughlin	Committee Member, NREC-CT D
Prof Geraldine O'Sullivan Coyne	Committee Member, NREC-CT D
Ms Chanel Watson	Committee Member, NREC-CT D
Ms Chita Murray	Programme Manager, 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
Mr Peadar Rooney	Project Officer, National Office for RECs

Apologies: Jeff Moore, Mary McDonnell Naughton

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2025-520554-11-00
- 2024-519188-17-00
- 2025-522774-36-00
- 2023-510333-28-00
- 2024-514180-25-00 SM-2
- 2023-504231-41-01 SM-11
- 2024-515914-41-00 SM-3
- 2023-507024-24-00 SM-8
- AOB

- The Chair welcomed the NREC-CT D.
  - The minutes from the previous NREC-CT D meeting on 18th June 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2025-520554-11-00

Institutions: Mater Private, Tallaght University Hospital, St Vincent's University Hospital, University Hospital Galway, St James's Hospital

Study title: A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing Olpasiran Use to Prevent First Major Cardiovascular Events in Participants with Elevated Lipoprotein(a)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Recruitment arrangements

- The NREC-CT notes section 1.1 of Recruitment Arrangements document states "Potential participants will be identified through existing patient lists, site records and new patient visits to the sites". The Committee also notes that the Principal Investigators (PIs) for Tallaght University Hospital, St Vincent's University Hospital and University Hospital Galway are chemical pathologists and may not routinely see patients in practice. It was not clear to the Committee how participants will be recruited if the PIs do not have patient lists. Please update Section 1.1 Recruitment Arrangement document to clarify.

2. 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 SIS and ICF Main Study pg 22 and SIS and ICF Lpa Test pg 12 be updated to include specific statement that the participant confirms that a copy of the signed and dated Informed Consent Form will be provided to them and that a copy will be retained by the study doctor.
- The NREC-CT notes SIS and ICF Main Study pg 19 and SIS and ICF Lpa Test pg 10 state *"Your information will be anonymised".* The Committee requests that the SIS and ICF Main Study and SIS and ICF Lpa Test be updated to include a consent statement for the participant to explicitly consent to the processing of their

personal data from pseudonymised /coded data to anonymised data as per Article 4 (2) and 6 General Data Protection Regulation (GDPR).

- The NREC-CT notes SIS and ICF Main Study pg 19 and SIS and ICF Lpa Test pg 10 state "*Where there is a risk that you can be directly identified your data will only be used in studies that have been independently reviewed by an ethics committee."* The Committee requests that this sentence be updated as the ethics opinion given for this study will be limited to the clinical trial protocol and application dossier that has been assessed. Any future research conducted beyond this specific protocol and application dossier regardless if the data used is identifiable or not will require a separate ethics approval from a recognised research ethics committee once that future research question is defined. The Committee also requests that both SIS and ICFs be updated to state that identifiable participant data will not be shared outside of the study site/team unless participant has given explicit consent to be contacted about future research studies.
- The NREC-CT notes SIS and ICF Main Study pg 16 *"You will be asked to provide information on the pregnancy or breastfeeding outcome for you and the baby."* The Committee request that Pregnancy ICF be provided for review, if available.
- The NREC-CT notes references to personal information being shared with *"independent third-party company"* in several parts of p 4 of the SIS and ICF Main. The Committee requests that the ICF be updated to clarify the identity of this/these third-party company/companies and in what circumstances would this/these independent third-party company/companies be given participants personal information.
- The NREC-CT notes reference to personal information being shared with *"third-party web-based video technologies"* on pg 11 of the SIS and ICF Main. The Committee requests that the ICF be updated to clarify the identity of this third-party company.
- The NREC-CT requests the SIS and ICF Main pg 12-15 Risk section be updated to provide detail on the frequency of occurrence for side effects.
- The NREC-CT notes that the GP Letter states that GP should not tell their patient about any lipid test results obtained in the course of normal medical care. The Committee requests that the relevant SIS and ICF Main be updated to inform participants that the results of lipid tests carried out by GP will not be given to them.

3. Suitability of the clinical trial sites facilities

- The NREC-CT notes the Principal Investigators (PIs) for Tallaght University Hospital, St Vincent's University Hospital and University Hospital Galway are chemical pathologists and may not routinely see patients in practice. It was not clear to the Committee:
    - how participants will be recruited at each site by PIs
    - who is clinically responsible at each site,
    - who will be directly seeing participants at each site
    - who will review safety events and be responsible for safety reporting at each site

The Committee requests the Site Suitability Forms for Tallaght University Hospital, St Vincent's University Hospital and University Hospital Galway be updated to clarify.

4. Suitability of the investigator

- The NREC-CT notes that [redacted] CV shows they have not had previous experience as a Principal Investigator on a clinical trial. The Committee requests detail of supports in place from other suitably qualified clinicians if required

2024-519188-17-00

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

Study title: A Phase 1/1b Study of IAM1363 in Participants with Advanced Cancers Harboring HER2 Alterations

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Compliance with use of biological samples

- The NREC-CT requests that the Compliance on Biological Samples document Section 4.1 "What is the purpose of the future use and SIS and ICF Main Part 2 pg 16 "What Will Happen to My Blood and Biopsy Samples Used for Research? " be updated to provide examples of 'other similar diseases' that may be investigated in the future using data and samples collected in this study. Please note Health Research Regulations Reg 3(1)(e)) "specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof."

2. 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 SIS and ICF Main Part 2 pg 16 "What will happen to my blood and biopsy samples used for research?" be updated to confirm what

are the ‘other similar disease ‘that may be investigated in the future using data and samples collected in this study. Please note Health Research Regulations Reg 3(1)(e)) “specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof. “The NREC-CT requested that the SIS and ICF Main Part 2 pg 18 “Where Can I get More Information?” be updated to provide information on European website which the clinical trial results will be published at the end of the trial.

- The NREC-CT requests that statements SIS and ICF Main Part 2 pg 17 “*Your coded study data may also be re-used in the future for additional research by Iambic Therapeutics or its collaborators, to better understand how IAM1363 works, to learn more about HER2 tumours, or other similar diseases“* and SIS and ICF Main Part 2 pg 17 “*“For future uses not limited to the above (i.e., future uses for purposes beyond the drug development program or for unrelated diseases/areas), an additional consent and favourable ethics committee opinion will be obtained prior to processing where required by law.”* be updated to confirm that ethics approval will be sought of all future research studies. The NREC-CT advises that the ethics opinion given for this submission 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.
- The NREC-CT notes SIS and ICF Main Part 2 pg 15 ““the data will be destroyed or anonymised.” The Committee requests that the SIS and ICF Main Study be updated to include a consent statement for the participant to explicitly consent to the processing of their personal data from pseudonymised /coded data to anonymised data as per Article 4 (2) and 6 General Data Protection Regulation (GDPR).
- The NREC-CT requests that the SIS and ICF Main Part 2 pg 13. “Financial support may be available for reasonable travel expenses for being part of this study” be updated to include more detail on how this will be managed for participants including reference to accommodation expenses and meal expenses being reimbursed to align with the Compensation for trial participants’ document. The Committee requests that the Sponsor consider providing reimbursement to carers/companions who accompany participants to study visits. The Committee also notes that loss of earnings has been ticked in Compensation for trial participants document, the Committee requests that this be updated to align with the ICF which states that loss of earnings will not be reimbursed.
- The NREC-CT notes the Main ICF pg 13 states “If you are injured as a direct result of following a research test/procedure or from taking IAM1363 (a “Study-related Injury”), the Sponsor will pay the reasonable and necessary costs of medical treatment to treat your Study-related Injury that are not already covered by your government-provided or private health insurance provided that you have followed the instructions of the study doctor.” The Committee requested clarification as to whether this statement is applicable for the Irish context and to amend/remove if not.
- It is unclear to the NREC-CT if the consent statements on pg 20 with “I agree/ I do not agree” tick boxes are optional consent statements as the other consent

statements on this page are not tick boxes. If these are optional consent statements then please move all optional components onto a separate page with separate signatures section, so it is distinct from the main consent to participate in the research. The Committee requests that if ticking yes to these statements is mandatory, then please make it clear to participants if they tick "I do not agree" they cannot take part in the research study.

- The NREC-CT notes that SIS and ICF Main Part 2 pg 10 states "At the end of this document, you will be asked to provide consent for this information about you and your child to be collected from your medical records in the rare case that you become pregnant during your participation in this study.", however there is no consent statement at the end of the ICF for the participant to sign. The Committee requests that a separate Pregnant Participant SIS and ICF be provided for review.
- The NREC-CT requests that the SIS and ICF Main Part 2 be updated as follows:
    - Pg 3 the term Sponsor should be defined in lay language for participants
    - Pg 2 *"What happens before the start of study treatment"* be updated to provide examples of vital signs to be assessed e.g. pulse, BP etc.
    - Pg 9 MRI scans update typo in 5th line *"anxious in small p (claustrophobic)."*
- The NREC-CT requests SIS and ICF Main Part 2 pg 5 be updated to provide information on the expected duration of the D 1 visit in C3 and subsequent visits.
- The NREC-CT requests that SIS and ICF Main Part 2 pg 8 Possible risks of taking IAM1363 be updated to provide information on the number of people exposed to the study drug to date along with data on side effects and their frequencies in this population.
- The NREC-CT notes SIS and ICF Main Part 2 pg 10 if the participant becomes pregnant "You may be asked questions about the outcome of your pregnancy". The Committee requests Pregnant Participant ICF be provided for review for female participants to sign to consent for sharing of data on pregnancy and its outcome in the case of a participant who becomes pregnant whilst in the trial.
- The NREC-CT requests that SIS and ICF Main Part 2 pg 10 "What are the possible risks of having a baby while on this study" be updated to define what highly effective contraceptives mean and provide examples of same.
- The NREC-CT notes that SIS and ICF Main Part 2 pg 15 states" A Data Safety Monitoring Board and a Safety Review Committee per the Protocol" however the study protocol does not refer to a DSMB. The Committee requests clarification on this.

3. Suitability of the clinical trial sites facilities

- The NREC-CT notes that Mater Misericordiae University Hospital SSF advises that the exposure to ionising radiation is not above what is required for standard care however, St Vincent's University Hospital and Cork University Hospital advise there will be an increase in ionising radiation. Please confirm whether the information in the Site Suitability Forms for St Vincent's University Hospital and Cork University Hospital in relation to exposure to ionising radiation is not above what is required for standard care is correct or update the SSF as necessary. Please justify why the exposure to ionising radiation in St Vincent's University Hospital and Cork University Hospital would be above that in the Mater Misericordiae University Hospital. The Committee also request that the SIS and

ICF Main Part 2 be updated to detail if the exposure to ionising radiation is above standard of care at specific sites.

2025-522774-36-00

Institutions: Mater Misericordiae University Hospital

Study title: A Phase 1 Open-label, Multi-center Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Antitumor Activity of NDI-219216 as a Single Agent in Patients with Advanced Solid Tumors with and without Microsatellite Instability and/or Deficient Mismatch Repair

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS

1. The Sponsor is requested to update the GP letter to provide explanation for the acronyms used, for example MAD and MTD.
2. It is noted that the GP letter states that the investigator will only treat the patient in the context of the clinical trial, and other medical concerns will be directed to the GP. However, as the investigator is also likely to be the patient's oncologist, other oncology concerns should be addressed by the oncologist, not the GP. The Sponsor is requested to rephrase this sentence.

Part II Considerations

1. **Proof of insurance**

- The NREC-CT notes the duration of the clinical trial is 80 months and the insurance certificate provide is valid until 30-07-2030. The Committee requests clarification that insurance will be in place for the full duration of the trial.

2. **Recruitment arrangements**

- The NREC-CT notes that Recruitment Procedure document states that persons lacking capacity to consent will not be included in the trial. The Committee requests justification for not including this group in the trial.
- The NREC-CT requests that Recruitment Procedure document section 1.8 be updated to clarify that for any document translated into another language it is only the translation certificate, and not the translated document, that will be submitted to the REC as a Non SM for acknowledgment.

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

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT notes that SIS and ICF Main pg 14 (Tumour samples) Section 8.2.2.2 'samples will be stored for up to 10 years for possible future research not connected to the study', Pg 20 "With your consent, your PK, PD, and exploratory biomarker research samples will be stored for up to 10 years for possible future research not connected to the study" and pg 26 refers to "future research not connected to the study" is not described in line with regulations / best practice. 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. 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.

  The Committee also request that the Compliance with use of biological samples document sections on future research be updated to align.

  For further guidance on sections be updated please see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/

- The NREC-CT requests that Main ICF pg 15 "will I be paid to take part in this study" be updated to include reference to meals, and also carer expenses.
- The NREC-CT notes the length of the SIS and ICF Main and requests that a Summary ICF be provided in addition to highlight the main points of the study.
- The NREC-CT requests that the SIS and ICF Main be updated to:

    - refer to European Union perspective and remove references to US perspective such as FDA and DHSS pg 2.
    - provide lay language explanation for Pharmacodynamics and Pharmacokinetics pg 11.
    - provide lay language explanation of what is meant by ‘Changes in other lab values’ pg 5
    - insert the word study before doctor in two references ‘please ask your doctor any questions you may have’ pg 6
    - replace the word “must” in ‘The study doctor must follow up and keep a record of during outcome of all pregnancies’ with “would like to” as this could be interpreted by the male participant that their own treatment could be compromised if the pregnant partner did not allow for such follow up by the study doctor pg 6/7
- The NREC-CT requests that the SIS and ICF Pregnant Partner be updated to refer to European Union perspective and remove references to US perspective such as FDA and DHSS pg 2.
- The NREC-CT notes SIS and ICF Main pg.17 Section 15 (what health information will be used and disclosed) states that the ‘Sponsor and Study doctor may use the following personal data \ protected information …….. Past, Present and Future Medical Reports’ . The Committee noted that there is no consent requested or detail provided for the use of ‘Future Medical Reports’. The Committee requests that the SIS and ICF Main be updated ensure it is clear to the participant what is required.
- The Committee noted the SIS and ICF Main pg 18 refers to ‘Authorized recipients of your personal data …… (includes) your Insurance Company’. The Committee requested rationale is provided for sharing of persona data with the participants’ Insurance Company, or removal of this text if not relevant in an Irish context.
- The NREC-CT notes SIS and ICF Main pg.15 refers to reimbursement of ‘e.g. actual costs for lodging and transportation incurred with travel that is more than 80.5Km from the study site’. It was unclear to the Committee if this meant that only travel expenses for those living more than 80.5 km away will be paid or is that lodging will only be paid if you live more than 80.5 km away. The Committee requests that the SIS and ICF Main pg 15 be updated to clarify this. The Committee also requests that the Compensation Trial Participants document, pg.2 be updated to align, as it currently states that there are no conditions attached to payment of compensation.
- The NREC-CT requests that a Pregnant Participant SIS & ICF be submitted for review.
- The NREC-CT noted the statement “It is anticipated that the amount of NDI-219216 that may be circulating in the blood of participants who receive the highest dose being tested in this study will be less than the amount of NDI-219216 that was seen in the blood of animals who experienced any of these side effects” in the SIS & ICF Main page 5. The Committee requests that this be updated in lay language to ensure it is clear and understandable to participants what this comparison means.

- The NREC-CT requests that the SIS and ICF Pregnant Partner be updated to replace pg 1 "'This form may contain words that you do not understand" with "This Form may contain words that you are unfamiliar with".
- The NREC-CT requests that the SIS and ICF Pregnant Partner pg 1 'discuss the form with family or friends' be updated to "discuss the form with family, friends, GP or Obstetrician.

2023-510333-28-00

Institutions: St Vincent's University Hospital

Study title: EORTC 2022-MG: Adjuvant tebentafusp (IMCgp100) versus observation in HLA-A*02:01 positive patients following definitive treatment of high-risk uveal melanoma: an EORTC randomized phase III study (ATOM Trial)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations
1. Compliance with use of biological samples
• The NREC-CT requests that the Compliance with use of biological samples document section 3.3 and ICF Enrolment pg 26 be updated to clarify exactly where the biobank will be located rather stating "somewhere in Europe"
2. Financial arrangements
• The NREC-CT noted that participants are not reimbursed for out of expenses and requested that trial participants are reimbursed for all reasonable out-of-pocket expenses incurred as a result of participating in the trial, including meals / refreshments and travel. The Committee requests that the Sponsor consider this in order to ensure equitable access to clinical trials across all socio-economic groups.
3. Recruitment arrangements
• The NREC-CT notes that Recruitment Arrangements document section 1.8 – states for participants who do not speak English a translator will be present which is welcome. The Committee also advises that the SIS and ICF's must also be translated into the required language. The Committee requests that the Recruitment Arrangements document section 1.8 be updated to confirm this
4. 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 the future use of data / samples (including genetic research) is not described in line with regulations / best practice on pg 22, 23 and 26, 30 of the SIS and ICF Enrolment. And pg 7 and 8 SIS and ICF Pre-Screening 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 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 NREC-CT nots SIS and ICF Enrolment pg 8 *"In case the collected material cannot be used, the material will be destroyed or fully anonymized for further research."* The Committee requests that the SIS and ICF Enrolment pg 29 be updated to include a consent statement for the participant to explicitly consent to the processing of their personal data from pseudonymised /coded data to anonymised data as per Article 4 (2) and 6 General Data Protection Regulation (GDPR).
- The NREC-CT requests that ICF Enrolment pg 22 be updated to clarify where the pseudonymised (coded) data will be held while the trial is ongoing.
- The NREC-CT notes that the SIS and ICF Enrolment states that the treatment phase of the study is 26 weeks. The Committee requests that SIS and Enrolment be updated to clearly state the duration of the trial including the length of follow up for participants also.
- The NREC-CT requests that SIS and ICF Enrolment be updated to detail the expected length of time each study visit will take.
- It was unclear to the NREC-CT if the treatment group will be observed in the same way as observation group. Please update the SIS and ICF Enrolment to clarify.
- The NREC-CT requests that the SIS and ICF Enrolment be updated as follows:
    - be updated to provide a lay language definition of what constitutes "high risk" uveal melanoma
    - pg 4 study design figure be updated to replace "R" with the word "Randomisation" for clearness
    - Pg 7 replace "collected in addition to the routine samples"" with "collected at the same time as routine samples "
    - pg 8 – "mandatory translational research" (middle of the page) be rephrased in lay language to clarify what this means
    - pg 8 collected material that cannot be used, please update to clarify in what instances would this material not be able to be used.
    - pg 19 be updated to provide a lay language explanation of "Alopecia".

5. **Suitability of the clinical trial sites facilities**

- The NREC-CT notes that Site Suitability Form for St Vincent's University Hospital Section 5 states that the additional radiation exposure is justified as "The risk of harm from the additional radiation burden is outweighed by the potential benefits the participants may derive from the research study" however it is not known whether there will be any benefit. The Committee comments that CT scans every 12 weeks is cumulatively not negligible and requests that Site Suitability Form for St Vincent's University Hospital Section 5 be rephrased so that it is objectively presented.

2024-514180-25-00 SM-2

Institutions: Bon Secours Hospital Cork, Mater Misericordiae University Hospital, Mater Private Hospital, University Hospital Waterford, St Vincent's University Hospital, Beaumont Hospital, Cork University Hospital

Study title: An Open-label Randomized Phase 3 Study of Tucatinib in Combination with Trastuzumab and mFOLFOX6 versus mFOLFOX6 given with or without either Cetuximab or Bevacizumab as First-line Treatment for Subjects with HER2+ Metastatic Colorectal Cancer

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

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 notes on pg 76 of ICF Main the list of people/organisations who are authorised recipients of personal data. The NREC-CT requests clarification of why each named organisation needs personal data and not coded data. The NREC-CT requests that the list be divided into who will receive participants' personal information as defined under GDPR and who will receive coded information.

2023-504231-41-01 SM-11

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

Study title: A Randomized Open-Label Phase 2/3 Study of BT8009 as Monotherapy or in Combination in Participants with Locally Advanced or Metastatic Urothelial Cancer (Duravelo-2)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Subject information and informed consent form

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT notes the updates made to SIS and ICF Main Cohort 1 pg 3 and SIS and ICF Main Cohort 2 pg 3 "What Medication will you have during the study" sections. The Committee commented that the updated wording it is very complicated and difficult to understand. The Committee requests that this wording be reviewed and updated to make it simpler and clearer for participants to understand.

2024-515914-41-00 SM-3

Institutions: Cork University Maternity Hospital

Study title: A Phase 2b, Multicenter, Randomized, Open-label, Two-Arm Study to Evaluate the Clinical Efficacy and Safety of OHB-607 Compared to Standard Neonatal Care for the Prevention of Bronchopulmonary Dysplasia, the Most Common Cause of Chronic Lung Disease of Prematurity

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-507024-24-00 SM-8

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

Study title: A Phase 3, Randomized, Double-blind Trial of Pembrolizumab (MK-3475) Plus Enzalutamide Plus ADT Versus Placebo Plus Enzalutamide Plus ADT in Participants With Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) (KEYNOTE-991)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

  Favourable

- **AOB:**
  - None