National Research Ethics Committee

NREC-CT Meeting

26th February 2025

Attendance

Name	Role
Prof Mary Donnelly	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
Prof Andrew Smyth	Committee Member, NREC-CT C
Dr Steve Meaney	Committee Member, NREC-CT C
Dr Dervla Kelly	Committee Member, NREC-CT C
Dr Deborah Wallace	Committee Member, NREC-CT C
Mr Philip Berman	Committee Member, NREC-CT C
Prof Anne Mathews	Committee Member, NREC-CT C
Dr Christina Skourou	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
Dr Emma Heffernan*	Project Officer, National Office for RECs
Dr Peadar Rooney	Project Officer, National Office for RECs
Mr Ciaran Horan	Administrative Assistant, National Office for RECs
Ms Deirdre Ní Fhloinn	Project Officer, National Office for RECs
Ms Rachel Mc Dermott	Project Administrator, National Office for RECs

Apologies: Ms Paula Prendeville, Mr Gerry Eastwood, Susan Finnerty, Susan Kelly & John Faul

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-507482-26-00
- 2024-517422-25-00
- 2023-508773-82-00
- 2023-506918-45-00 SM-3
- 2024-514135-17-00 SM-1
- 2024-511378-60-00 SM-2
- 2024-517528-20-00 SM-1
- 2022-502276-23-00 SM-2
- 2023-508890-10-00 SM-4
- AOB

- The Chair welcomed the NREC-CT C.
  - The minutes from the previous NREC-CT C meeting on 22nd January 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-507482-26-00

Institutions: Mater Private Hospital, Tallaght University Hospital, Bon Secours Hospital Cork

Study title: Combination of darolutamide and stereotactic body radiation therapy in patients with castration resistant prostate cancer and oligometastases on functional imaging (PEACE-8)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

Request for Further Information

- **Additional Information Required**

Part I Considerations (RFI) for addition to CTIS

1. It is stated in the protocol that gross tumour volume for arm B will be based on MR/CT visible disease (protocol section 5.1.3.1 Delineation - GTV). However, the premise of this trial is to treat disease discernible on functional PET (as per inclusion criteria 6). Please provide clarification whether gross tumour volume (or microscopic tumour volume CTV) for arm B will be based on disease discernible by MR/CT, or functional PET.

Part II Considerations

1. Subject information and informed consent form

- The NREC-CT noted that description of 'oligometastases' on pg. 4 of the L1_SIS and ICF_Main PISCF may be confusing for participants, as it could be interpreted that only metastases visible with PET imaging are being included in the trial, which is not the case, as up to 80% of participants will have CT- or bone-scan detectable metastases. The committee requested that the term 'oligometastases' is described to participants using plain English suitable for a lay audience. This explanation should include detail of the mechanism for detection of oligometastases.
- The NREC-CT noted that the flow chart on pg. 6 of the L1_SIS and ICF_Main PISCF has a number of formatting errors, in that text boxes appear superimposed on other text boxes and requested that this is corrected.
- The NREC-CT noted that pg. 6 of the L1_SIS and ICF_Main PISCF states that participants are to undergo 3 sessions of radiation therapy spread over *'+/- 10 days'* and requested that the text is changed to state that the 3 sessions of radiation therapy are spread over *'a maximum of 10 days'*, so it is clearer for participants.
- The NREC-CT noted contradictory statements on pg. 12 of the L1_SIS and ICF_Main PISCF' regarding the potential risks associated with stereotactic radiation (under the heading 'Risks associated with stereotactic radiation therapy (only if you are randomized to Arm B)). The first 2 sentences state 'The stereotactic radiation therapy you receive is likely to cause adverse reactions' whereas the subsequent sentence states 'In the literature, adverse reactions are rare and mild'. As this may be confusing for participants, the Committee requested

that this paragraph is revised so potential risks associated with stereotactic radiation are clearly described to participants using plain English suitable for a lay audience.

- The NREC- CT requested that the risks associated with SABR should be given greater emphasis in the risk section of the L1_SIS and ICF_Main PISCF as there are known/quantified risks for SABR and spine/liver/lung.
- The NREC-CT requested that if the evidence for the safety of Darolutamide combined with radiation is not conclusive, participants should be informed of this in the risk section of the L1_SIS and ICF_Main PISCF. The risk section should include known risks from SABR and state if these can be affected by the addition of Darolutamide.
- The NREC-CT notes that pg. 22 of the L1_SIS and ICF_Main PISCF states that 'I certify that I am affiliated with a social security scheme' which may not be relevant in an Irish context. The committee requested that the meaning of this is either clarified for participants or removed if not relevant to participants in Ireland.
- The NREC-CT requested that it is made clear to participants in the L1_SIS and ICF_Main that participants randomised to arm B will be required to attend a radiotherapy centre for radiation therapy i.e. participants recruited to Tallaght Hospital will be required to undergo radiation therapy at St Lukes's Hospital in Dublin 6.
- The NREC-CT noted that the L1_SIS and ICF_Main PISCF has used a bundled approach to consent in the Informed Consent Section of the PISCF and requested that a layered approach to consent is used (in that each consent item is listed and a box for participants to provide their initials is included alongside each consent item) in line with HSE policy Please see HSE National Policy for Consent in Health and Social Care Research (V2, 2024). Dublin: Health Service Executive https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf.
- The NREC- CT noted that pg. 23 of the L1_SIS and ICF_Main PISCF refers to 'coded data' and requested that it is clarified in the PISCF whether this refers to future use of 'pseudonymised' or 'anonymised' data.
    - If 'coded data' refers to anonymised data, then please:
    - Explain this to participants in the PISCF using plain English suitable for a lay audience. This should include an explanation of the term 'anonymised'.
    - Include processing of anonymised data as an explicit consent item in the informed consent section on pg. 23 of the PISCF
- If 'coded data' refers to future use of pseudonymised data, then this needs to be described to participants in the PISCF in line with regulations and best practice. Future use of data should be 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 made optional
    - 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/ 23 of the 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: HSE National Policy for Consent in Health and Social Care Research (V2.0, 2024) https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf

- The NREC-CT noted that an impartial witness is included for both literacy and language issues on pg. 24 of the L1_SIS and ICF_Main PISCF. The Committee requested that this should include a statement to clarify that the impartial witness is not consenting on the participant's behalf, and that participant consent is still required.
- The NREC-CT noted that participants are to complete a patient diary (D4_Patient Diary_EN) as described on pg. 8 of the PISCF. It was noted that this diary includes a number of asterisks without accompanying explanatory foot notes (in the schedule of visits and tests section on pg. 7 of the diary). The NREC-CT requested that this is amended, so all asterisks are accompanied by relevant explanatory footnotes.
- 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.

2. Suitability of the clinical trial sites facilities

- The NREC-CT requested clarification as to where participants recruited to the Bons Secours in Cork will undergo radiation therapy (R/T). If participants recruited to the Bons Secours in Cork are required to attend a different site for R/T, they should be informed of this in the L1_SIS and ICF_Main PISCF.

3. Suitability of the investigator

- The NREC-CT noted that Bons Secours and the Mater Private do not have medical oncology PIs listed and requested clarification as to how participants at these sites will be managed in terms of input from medical oncologists.

2024-517422-25-00

Institutions: Beaumont Hospital, Tallaght University Hospital, Cork University Hospital

Study title: A Phase 3, Two-part, Randomized, Open-label, Adaptive Study Comparing BMS-986365 versus Investigator's Choice of Therapy Comprising Either Docetaxel or Second Androgen Receptor Pathway Inhibitor (ARPI), in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) - rechARge

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

Request for Further Information

- **Additional Information Required**

Part II Considerations

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

- The NREC-CT requested that the S1_Compliance on the collection_use and storage of biological_IE_ENG is updated to align with relevant changes to the PISCF documents.

2. **Proof of insurance**

- The NREC-CT requested confirmation that insurance is in place for the duration of the trial.

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

- The NREC-CT noted that L1_SIS and ICF Main_IE_ENG PISCF refers to Part 1 of the trial only (i.e. the 1:1:1 randomisation) and requested clarification as to the status of the Part 2 (i.e. 1:1 randomisation) aspect of the trial.
- The NREC-CT noted that the language to describe precautions participants need to take in relation to pregnant or breastfeeding partners ('drugs may be dangerous if you get someone pregnant') on pg. 3 of the L1_SIS and ICF Main_IE_ENG PISCF is not phrased appropriately and requested that this is revised.
- The NREC-CT noted that the potential risks associated with BMS-986365, and pregnant and breastfeeding women is not well explained on pg.3 of the L1_SIS and ICF Main_IE_ENG PISCF. The NREC-CT requested that the detail regarding the potential risks and the necessary precautions (as detailed on pg. 11) required when handling BMS-986365 are also explained on pg. 3.
- The NREC-CT noted that the text 'end of the first part' on pg. 6 of the L1_SIS and ICF Main_IE_ENG PISCF may be confusing for participants and requested that this is reworded so the meaning is clear.
- The NREC-CT noted that use of the comparator in the description of the two-part nature of the study on pg. 6 of the L1_SIS and ICF Main_IE_ENG PISCF is not described using a patient friendly / accessible approach and requested that the description of the comparator is described using plain English suitable for a lay audience.
- The NREC-CT noted that the second sentence 'Unless you are receiving docetaxel plus prednisone/prednisolone, if so this part of the study will last about 30 weeks' on pg. 9 of the L1_SIS and ICF Main_IE_ENG PISCF is not clear and requested it is revised for clarity.
- The NREC-CT requested that the flow of the information regarding the duration of the trial on pg.9 of the L1_SIS and ICF Main_IE_ENG PISCF is revised for clarity.
- The NREC-CT noted that the description of optional sampling for PK studies on pg. 10 of the L1_SIS and ICF Main_IE_ENG PISCF lacks clarity and precision, in

that it implies that samples will be collected and that participants 'may be asked to sign a separate consent form'. The Committee requested the following:
    - clarification so participants are aware that this is an optional component of the study and if they decide to take part then they will need to sign a separate consent form.
    - that it is clarified for participants how it is decided who takes part in the PK study.
- The NREC-CT requested that the account of how the drug works on pg.11 of the L1_SIS and ICF Main_IE_ENG PISCF should be presented much earlier in the participant information sheet (suggest in the general information section on pgs. 1 & 2), as it is essential information for participants when deciding if they want to participate in the trial.
- The NREC-CT noted that the S1_Compliance on the collection_use and storage of biological_IE_ENG PISCF states that archival samples may be used for testing and that this is not well explained to participants on pg. 11 of the L1_SIS and ICF Main_IE_ENG PISCF. The committee requested that this explained to participants using plain English suitable for a lay audience. Furthermore,
    - If the entire archival sample is to be used for this trial, participants should be informed in the PISCF that their archival sample will not be available for any other research studies.
    - Explicit consent should be sought for the use of archival samples in the informed consent section on pg. 34 of the L1_SIS and ICF Main_IE_ENG (in line with what is detailed in the S1_Compliance on the collection_use and storage of biological_IE_ENG)
- The NREC-CT noted that the two columns detailing appropriate types of birth control on pg. 24 of the L1_SIS and ICF Main_IE_ENG may be confusing for participants in that they distinguish between birth control for 'people that can get pregnant' and 'male (as assigned at birth)' participants. As this is a prostate cancer trial and only those with a prostate will be taking part in the trial, the Committee requested that birth control advice should pertain to trial participants only.
- The NREC-CT noted that pg. 25 of the L1_SIS and ICF Main_IE_ENG states that participants will be reimbursed for meals during study visits, whereas the P1_Compensation trial participants_investigator_funding and other arrangements document states that reimbursement for meals is provided for visits greater than 3 hours. The NREC-CT requested that participants are reimbursed for all reasonable out-of-pocket expenses.
- The NREC-CT noted that pg. 26 of the L1_SIS and ICF Main_IE_ENG states that if participants withdraw from the study (with no follow up) information pertaining to them may still be collected from their GP, which appears to conflict with the participants' decision to withdraw from the study. The Committee requested that this text is amended so that if participants withdraw from the study, then no further data will be collected from them.
    - The NREC-CT requested that explicit consent is sought from participants who wish to withdraw from the study, but continue with follow up, for their GP to be contacted regarding their health status on pg. 34 of the L1_SIS and ICF Main_IE_ENG PISCF.
- The NREC-CT noted that section 11.2 on pg. 29 of the L1_SIS and ICF Main_IE_ENG PISCF states that 'biomarker testing is required for the study'

whereas the inclusion of the L1_SIS and ICF Optional PK Sampling IC_IE_ENG PISCF in the submission implies that biomarker tests are optional. The NREC-CT requested that it is made clear to participants whether the biomarker component of the study is optional or mandatory in the L1_SIS and ICF Main_IE_ENG.

- The NREC-CT noted that pg. 29 of the L1_SIS and ICF Main_IE_ENG, pg. 4 of the L1_SIS and ICF Optional PK Sampling IC_IE_ENG and pg. 4 of the L1_SIS and ICF Optional Future Research IC_IE_ENG PISCFs state that participants may undergo whole genome / whole exome sequencing and requested the following:
    - Genomic sequencing is confined to genes involved in the disease being treated and /or genes involved in the metabolism of the medicines being used in the trial and this elucidated in the PISCF.
    - Explicit consent, including outlining the risks entailed in such analysis being performed, is added to the PISCF.
    - The possible ownership of such data by private or commercial interests and that this elucidated in the PISCF.
    - The right to withdraw genetic data, and clear information on how to do so, must also be provided in the PISCF.
    - Clarification is provided in the PISCF on the mechanism for anonymisation, storage and security and transfer of genetic material and its associated data. For guidance, please see HSE National Policy for Consent in Health and Social Care Research (V2.0, 2024). Dublin: Health Service Executive https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-national-policy-for-consent-in-health-and-social-care-research/
- The NREC-CT noted conflicting statements across the PISCF documents regarding the length of time samples will be stored (pg. 29 of the L1_SIS and ICF Main_IE_ENG & pg. 4 of the L1_SIS and ICF Optional PK Sampling IC_IE_ENG state 20 years whereas pg. 4 of the L1_SIS and ICF Optional Future Research IC_IE_ENG states up to 25 years). The NREC-CT requested that the maximum length of time samples will be retained is compliant with CTR and is clearly stated and aligned across all PISCF documents and the S1_Compliance on the collection_use and storage of biological_IE_ENG document.
- The NREC-CT requested that the typical/average amount of blood to be collected at each visit should be explained to the participants on pg. 11 of the L1_SIS and ICF Main_IE_ENG PISCF.
- The NREC-CT noted that pg. 3 of the L1_SIS and ICF Pregnant Partner IC_IE_ENG.PDF states that the sponsor may use coded information to 'Understand if the study drug is safe in pregnant individuals and their babies' and requested that this text is revised as this is a prostate cancer study and will therefore not include pregnant participants.
- The NREC-CT requested that the duration of the data collection period is detailed for pregnant partners on pg. 3 of the L1_SIS and ICF Pregnant Partner IC_IE_ENG PISCF.
- The NREC-CT noted that genetic testing is not well explained to participants in the L1_SIS and ICF Optional PK Sampling IC_IE_ENG.PDF PISCF. The NREC-CT requested the following are explained to participants using plain English suitable for a lay audience:
    - detail as to the types of genetic testing being undertaken

  - detail as to the rationale for the inclusion of the genetic testing, including details of biomarker and genetic testing (especially in the context of ADME and potential pharmacogenetic studies)
  - detail outlining the potential risks entailed in such analysis being performed.
- The NREC-CT noted that pg. 2 of the L1_SIS and ICF Optional Future Research IC_IE_ENG.PDF states that the results of future research will help researchers 'better understand your disease' and requested that the name of the disease is specified i.e. Metastatic Castration-resistant Prostate Cancer (mCRPC).
- The NREC-CT requested that it is explained to participants in the L1_SIS and ICF Optional Future Research IC_IE_ENG PISCF that subsequent research ethics review will be sought for specific research once clearly defined.
- The NREC-CT noted that the L1_SIS and ICF Main_IE_ENG, L1_SIS and ICF Optional Future Research IC_IE_ENG.PDF, L1_SIS and ICF Optional PK Sampling IC_IE_ENG.PDF & L1_SIS and ICF Treatment Beyond Progression IC_IE_ENG PISCFs have used a bundled approach to consent in the Informed Consent Section of the PISCF documents and requested that a layered approach to consent is used (in that each consent item is listed and a box for participants to provide their initials is included alongside each consent item) in line with HSE policy. Please see HSE National Policy for Consent in Health and Social Care Research (V2, 2024). Dublin: Health Service Executive https://assets.hse.ie/media/documents/ncr/20250107_HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-V2.0.pdf
- 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.

2023-508773-82-00

Institutions: St James's Hospital, Beaumont Hospital

Study title: An international, multicentre, open-label randomised phase III trial to evaluate the benefit of adding adjuvant durvalumab after neoadjuvant chemotherapy plus durvalumab in patients with stage IIB-IIIB (N2) resectable NSCLC (ADOPT-lung)

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

- The NREC-CT noted that pg. 13 of the L1_SIS and ICF Master_EN states that participants are to undergo genetic testing. The NREC requested that the following is clarified in the PISCF:
  - detail as to the type of genetic testing involved, including information regarding the purposes of this testing.
  - detail outlining the potential risks entailed in such analysis being performed.
  - the possible ownership of such data by private or commercial interests and that this elucidated in the PISCF.
  - the right to withdraw genetic data, the mechanism for anonymisation, storage and security and transfer of genetic material and its associated data. This should be described using plain English suitable for a lay audience.
  - Clarification as to whether genetic testing is optional or mandatory.
    - If this research is mandatory, then participants should be advised of this in the PISCF.
    - If genetic testing is optional then this should comprise 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 NREC-CT noted that pg. 13 of the L1_SIS and ICF Master_EN states that participants may undergo whole genome / whole exome sequencing and requested the following:
  - Genomic sequencing is confined to genes involved in the disease being treated and /or genes involved in the metabolism of the medicines being used in the trial and this elucidated in the PISCF.
  - Explicit consent, including outlining the risks entailed in such analysis being performed, is added to the PISCF.
  - The possible ownership of such data by private or commercial interests and that this elucidated in the PISCF.
  - The right to withdraw genetic data, and clear information on how to do so, must also be provided in the PISCF.
  - Clarification is provided in the PISCF on the mechanism for anonymisation, storage and security and transfer of genetic material and its associated data. For guidance, please see HSE National Policy for Consent in Health and Social Care Research (V2.0, 2024). Dublin: Health Service Executive https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-national-policy-for-consent-in-health-and-social-care-research/
- The NREC-CT noted that pg.16 of the L1_SIS and ICF Master_EN states that ‘We may share your coded data and biological samples with research partners at universities, hospitals, drug development companies, or research institutes in countries around the world’ and requested a full list of Sponsors ‘research partners at universities, hospitals, drug development companies, or research institutes in countries around the world’ is listed, and detail is provided as to what data will be shared, so participants are fully informed.

- The NREC-CT noted that pg. 1 of the L1_SIS_future research states the samples are to be stored for an indefinite length of time, and requested that the maximum length of time samples that will be retained is compliant with CTR and is clearly stated in the L1_SIS_future research.
- The NREC-CT requested that participants are informed in the L1_SIS_future research PISCF documents that their data will be processed in line with GDPR (EU) 2016/679 and the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
- The NREC-CT requested that participants are informed in the section titled 'How can you contribute to research' on pg. 1 of the L1_SIS_future research is restricted to lung cancer research (as noted elsewhere in the document).
- The NREC-CT noted that pg. 2 of the L1_SIS_future states that future research PISCF states 'Research projects are *generally* subject to review by the ethics committee' and requested that it is made it clear to participants that subsequent research ethics review *will* be sought for specific research once clearly defined.
- The NREC-CT noted that pg. 1 of the L1_SIS_future states that future research may involve genetic research. The NREC-CT requested that if this research involves whole genome / whole exome sequencing and requested the following:
    - Genomic sequencing is confined to genes involved in the disease being treated and /or genes involved in the metabolism of the medicines being used in the trial and this elucidated in the PISCF.
    - Explicit consent, including outlining the risks entailed in such analysis being performed, is added to the PISCF.
    - The possible ownership of such data by private or commercial interests and that this elucidated in the PISCF.
    - The right to withdraw genetic data, and clear information on how to do so, must also be provided in the PISCF.
    - Clarification is provided in the PISCF on the mechanism for anonymisation, storage and security and transfer of genetic material and its associated data. For guidance, please see HSE National Policy for Consent in Health and Social Care Research (V2.0, 2024). Dublin: Health Service Executive https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-national-policy-for-consent-in-health-and-social-care-research/

- 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.

2023-506918-45-00 SM-3

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

Study title: A randomised double-blind placebo-controlled clinical trial investigating the effect and safety of oral semaglutide in subjects with early Alzheimer´s disease (EVOKE plus)

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**

- The NREC-CT noted that pg. 6 of the protocol states that site visits 8, 10, 12, 14 & 16 can be converted to phone calls under certain conditions and requested that participants are informed of this in the PISCF.
- The NREC-CT requested that the full 14-digit U CT number is detailed on the front page of the PISCF documents

2024-514135-17-00 SM-1

Institutions: Beaumont Hospital, Cork University Hospital, University Hospital Galway, 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 Further Information

- **Additional Information Required RFI**

Part II Considerations

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

- The NREC-CT requested that updates to the protocol regarding permitted / prohibited herbal medicines, protein supplements, vaccines and other medications are communicated to participants in the PISCF, so they are fully informed.
- 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.

2024-511378-60-00 SM-2

Institutions: Beaumont Hospital

Study title: A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Global Study to Evaluate the Efficacy and Safety of Intravenous AOC 1001 for the Treatment of Myotonic Dystrophy Type 1

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**

- The NREC-CT noted that that pg. 2 of the L1_SIS and ICF_Adults_Avidity_TC PISCF states 'You will be in this study for about 60 weeks, with at least 16 study visits to the study site'. The NREC-CT requested that participants are given a clearer indication (i.e. an upper limit) of how many visits to the study site they will be required to undertake, so they are fully informed.
- The NREC-CT requested that the revised heading 'What are the possible benefits of taking part?' on the top of pg.13 in the L1_SIS and ICF_Adults_Avidity_TC PISCF is rephrased as 'what are the benefits of allowing my samples to be used in future research?'

2024-517528-20-00 SM-1

Institutions: St Vincent's University Hospital

Study title: A Randomized, Blinded, Placebo-Controlled, Phase 2 Study of INBRX-109 in Unresectable or Metastatic Conventional Chondrosarcoma

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**

- The NREC-CT noted that section 29 on pgs. 28/29 of the L1_SIS and ICF_Main ICF_Inhibrx Biosciences Inc PISCF has been deleted and requested that text related to GDPR is reinstated (in section 28 as applicable), and specific reference is made to the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018 / 2021), so participants are aware that studies conducted in the EU must be in compliance with GDPR.
- The NREC-CT noted that that pg. 9 of the L1_SIS and ICF_Main ICF_Inhibrx Biosciences Inc PISCF states that participants will be given the option to cross over to INBRX-109 and that this may extend their time in the study. The NREC-CT requested that the length of time their participation in the study will be extended by if they choose to crossover is communicated to participants in the PISCF, so they are fully informed.

2022-502276-23-00 SM-2

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

Study title: Randomized, open-label, multicenter phase 3 study to assess the efficacy and safety of GIVinostat versus hydroxyurea IN JAK2V617F-positive high-risk Polycythemia Vera patients: the GIV-IN PV TRIAL

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**

- The NREC-CT noted that the updated text '*which has the goal study to check…'* on pg. 2 of the L1_DSC08235732_Main-ICF_CTP_IE PISCF may be confusing for participants and requested that this is rephrased.
- The NREC-CT requested that the option to consent to the genetic testing on pg. 25 of the L1_DSC08235732_Main-ICF_CTP_IE PISCF is removed, as participants will consent via the L3_DSC08235732_Optional_Genetic_Testing_ICF_IE PISCF, should they wish to take part in the optional genetic testing component of the study.
- 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.

2023-508890-10-00 SM-4

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

Study title: A Phase 3, randomized, double-blind clinical study of pembrolizumab (MK-3475) plus chemotherapy versus placebo plus chemotherapy as first-line treatment in participants with HER2 negative, previously untreated, unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma (KEYNOTE-859)

Dossiers Submitted: Part I & II

- NREC-CT Decision:

- Favourable

- AOB:

N/A