National Research Ethics Committee

NREC-CT Meeting

17th December 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
Prof Lina Zgaga	Committee Member, NREC-CT D
Mr Gerry Daly	Committee Member, NREC-CT D
Ms Deirdre McLoughlin	Committee Member, NREC-CT D
Dr Mary McDonnell Naughton	Committee Member, NREC-CT D
Prof Geraldine O'Sullivan Coyne	Committee Member, NREC-CT D
Ms Chanel Watson	Committee Member, NREC-CT D
Dr Jeff Moore	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

*Drafted minutes

Apologies: Dr Geraldine O'Dea

Quorum for decisions: yes

Agenda

- Welcome & Apologies
- 2025-522145-21-00
- 2025-522512-16-00
- 2024-512733-32-00 SM-2
- 2022-502122-41-00 SM-6
- 2024-513682-40-01 SM-3
- 2022-502503-30-00 SM-16
- 2024-512536-29-00 SM-4
- 2024-517614-14-00 SM-14
- 2024-513009-30-00 SM-13
- 2023-507881-19-00 SM-7
- AOB

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

Applications

2025-522145-21-00

Institutions: St Vincent's University Hospital, Cork University Hospital, Saint Luke's Radiation Oncology Network, UPMC Hillman Cancer Centre, UPMC Whitfield Hospital Mater Misericordiae University Hospital, Beaumont Hospital, Tallaght University Hospital

Study title: Studying Treatments in patients receiving androgen deprivation therapy (ADT) for Metastatic Prostate Cancer: Evaluation of Drug and radiation Efficacy: A 2nd multi-arm multi-stage randomised controlled trial (STAMPEDE2)

Dossiers Submitted: Part I and 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 section 4 of the S1_STPD2_Compliance on the collection use and storage of biological samples_Ireland is updated to align with requested changes to the PISCF documents.

2. **Financial arrangements**

- The NREC-CT requested that the P1_STPD2_Compensation trial participants_Ireland document is updated to align with changes requested in the PISCF documents regarding reimbursement of participants for out-of-pocket expenses.

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

- The NREC-CT noted that the Participant Information Sheets and Informed Consent Forms are presented as two separate documents. The committee requested that each Participant Information Sheets and its corresponding Informed Consent Form are integrated into one single document. Please include the EU CT number on each updated PISCF document.
- The NREC-CT requested that it is explained to participants on pg. 2 of the L1_STPD2_PIS_Reg_IRE why they are being randomised.
- The NREC-CT noted that pgs. 4 & 7 of the L1_STPD2_PIS_Reg_IRE states that participants may have to share their personal contact details with UCL so they can be sent Quality of Life questionnaires. The Committee requested justification for this and clarification as to why these questionnaires cannot be administered by the local study team / PI.
- The NREC-CT requested that participants are informed in the PISCF documents if they are required to attend a hospital / site different to their study site, to access study procedures, including radiotherapy.

- The NREC-CT noted that pg. 9 of the L1_STPD2_ICF_Reg_IRE states that the study has been authorised by "…by each participating hospital" and requested that this is amended as clinical trials submitted to CTIS under the CTR cannot be authorised by hospitals in Ireland, as per Regulation (EU) No. 536/2014 Clinical Trials on Medicinal Products for Human Use (Clinical Trial Regulation or CTR).
- 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. 8 of the L1_STPD2_ICF_Reg_IRE PISCF ("When you agree to take part in a research study, the information about your health, care, biological samples and scans (stored in the imaging repository) may be provided to researchers running other research studies, including genetic studies, and stored for use in ethically and scientifically approved research in the UK and Europe."). 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,
- The NREC-CT noted that the frequency of visits and duration of treatment as described on pg. 5 of the L1_STPD2_PIS_CompP_IRE may be difficult for participants to follow and requested that this information is also presented in a graphic format, to aid accessibility.
- The NREC-CT requested that it is clarified in the PISCF documents how many additional PET/CT scans participants are required to undergo in comparison to standard of care treatment, on pg. 9 of the L1_STPD2_PIS_CompP_IRE.
- The NREC-CT requested that participants are informed in the main body of the FBR: L1_STPD2_opt PIS_CompP_IRE & L1_STPD2_opt PIS_CompS_IRE PISCFs 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. 63 of the D1_STAMPEDE2 Master Protocol NOT FOR PUBLICATION_2025-522145-21-00 states that participants may undergo whole genome sequencing and requested that participants are advised of this is in the relevant PISCF documents, including relevant PISCFs relating to optional future research. Please include the following:
    - Genomic sequencing should be confined to genes involved in the disease being treated or related diseases and /or genes involved in the metabolism of the medicines being used in the trial and this is 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 (V2.1, 2025). Dublin: Health Service. https://www2.healthservice.hse.ie/files/157/
- The NREC-CT noted that the GP letters do not include sufficient relevant information and requested the following is added to the GP letters; details of the treatment that participants may be randomised to, including the radioactive dose /half-life of radiation administered (SABR / 177Lu), toxicity, details of the IMP and possible side effects.
- The NREC-CT requested that explicit consent is sought from participants for permission to contact their GP in the informed consent section of the relevant PISCF documents.
- The NREC-CT requested that details of the half life of 177 Lu is detailed on the patient card, as this information may be required by clinical staff should participants require emergency care.
- The NREC-CT noted that the sections on data protection in the PISCF documents are vague and do not provide sufficient information for participants to make an informed decision about participating in the trial. The Committee requested that the sections on data protection in each of the PISCF documents are revised to be more concise, precise, and informative. It should be clear to participants in the PISCFs that their samples / data will be protected in compliance with the relevant EU / Irish regulations and these regulations should be listed. Details as to the data protection / data processing, data sharing, data storage / retention (including maximum length of time data / samples will be stored) and data destruction arrangements in place should be clear to participants.
- The NREC-CT noted that pg. 6 of the L1_STPD2_PIS_CompP_IRE states that “as it may be possible to reimburse reasonable travel costs for additional study visits outside your standard care”. The NREC-CT requested that to ensure equity in accessing clinical trials across all socioeconomic groups, all trial participants are reimbursed for reasonable out of pocket expenses and this is clearly stated in the PISCF documents, including the L1_STPD2_ICF_Reg_IRE. The process for reimbursement should also be detailed in the PISCF documents.
- The NREC-CT noted that there are conflicting statements in the L1-STPD2_PIS_Pregn_IRE PISCF (pg. 3 states that information collected from the mother and child will be anonymised, whereas a later statement refers to data being pseudonymised). The committee requested that it is made clear to pregnant partners whether their data and their baby’s data will be anonymised or pseudonymised and requested the following:
    - clarification in the PISCF as to whether the pregnant partner and their baby’s data is to be anonymised or pseudonymised
    - an explanation is included in the PISCF of the terms ‘anonymised’ and ‘pseudonymised, as applicable, using plain English suitable for a lay audience.

    - if data is to be anonymised, then an explicit consent item regarding the processing of anonymised data should be added to the informed consent section of the PISCF.
    - If data is to be pseudonymised then then this needs to be in line with regulations and best practice. Regulations should be listed.
- The NREC-CT requested that it is clarified for participants in all relevant PISCF documents whether their data will be anonymised or pseudonymised and requested the following:
    - clarification in the PISCF as to whether the pregnant partner and their baby's data is to be anonymised or pseudonymised
    - an explanation is included in the PISCF of the terms 'anonymised' and 'pseudonymised, as applicable, using plain English suitable for a lay audience.
    - if data is to be anonymised, then an explicit consent item regarding the processing of anonymised data should be added to the informed consent section of the PISCF.
    - If data is to be pseudonymised, then then this needs to be in line with regulations and best practice. Regulations should be listed.
- The NREC-CT noted that section 5.2 of the L1-STPD2_PIS_Pregn_IRE PISCF states that the study team will collect "details about your pregnancy and the health of your baby." from the pregnant partner and their baby, which is not sufficient for informed consent. The Committee requested that pregnant partners are fully informed as to the following:
    - what data will be collected from them and their baby,
    - why this data will be collected
    - who will have access to this data
    - what it will be used for.
- The NREC-CT noted that the statement on pg. 3 & 4 of the L1-STPD2_PIS_Pregn_IRE PISCF "UCL will be responsible for looking after your information and using it properly and will keep information about you for 25 years after the study has finished" is not sufficiently robust to reassure participants that their data will be safeguarded. The committee requested that it is made clear to participants in the PISCF that their data will be protected in compliance with the relevant EU / Irish regulations and these regulations should be listed. Details as to data protection/data processing, data storage/retention and data destruction arrangements should be clear to participants.
- The NREC-CT noted that pregnant partners are advised on pg. 4 of the L1-STPD2_PIS_Pregn_IRE PISCF that "Full details of how data about you will be collected and stored is available in Part 2, sections 3 and 6 of the Registration PIS1" which is not sufficient for informed consent. The Committee requested that all the necessary information for pregnant partners to make an informed decision about participating in the trial is included in the L1-STPD2_PIS_Pregn_IRE PISCF.
- The NREC-CT noted that the future use of data is not described in line with regulations/best practice on pg. 4 L1-STPD2_PIS_Pregn_IRE ("The information will only be used for the purpose of health and care research"). The NREC-CT requested that future use of samples/personal data is sufficiently explained to

pregnant partners in the PISCF 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,
  - optional future research should be made into a separate and explicit consent item in the L1_STPD2_ICF_Pregn_IRE_public, with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research.
  - The PISCF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. For further guidance, please see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/

- The NREC-CT noted that the statement on pg. 4 of the L1 STPD2_PIS_Pregn_IRE PISCF "The MRC CTU at UCL, who organise this study, will oversee who accesses the samples." is not sufficiently robust to reassure participants that their data will be safeguarded and requested this is amended to reassure participants that their data will be protected in compliance with the relevant EU Irish regulations and these regulations should be listed.
- The NREC-CT noted that the statement on pg. 12 of the L1_STPD2_PIS_Reg_IRE "We promise to respect the confidentiality of the personal information that you, as a participant in our research, provide to us; that we get from other organisations; and that we share with other collaborating organisations, such as other universities or our research funders" is not sufficiently robust to reassure participants that their data will be safeguarded. The Committee requested that it is made clear to participants in the PISCF that their samples / data will be protected in compliance with the relevant EU / Irish regulations and these regulations should be listed. Furthermore, the sections on data protection should be revised to be more concise and include details as to the data protection / data processing, data sharing, data storage / retention including maximum length of time data / samples will be stored) and data destruction arrangements in place.
- The NREC-CT requested that the PISCF documents are updated to provide information about the availability of the clinical trial results at the end of the trial on European clinical trials database/website and details of how to access same.

Standard Consideration:

1. Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.

2. All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.

4. Suitability of the clinical trial sites facilities

- The NREC-CT noted that the SSA documents do not provide sufficient detail on the nuclear medicine / radiation oncology infrastructure at individual hospitals / sites. The committee requested that the following information is clarified in the SSA for each site:
    - Details of the nuclear medicine / radiation oncology infrastructure at each individual site.
    - Clarification as to what study related procedures will be carried out at each site (hospital) – it should be clear which hospitals are providing radiotherapy, and which are not.
    - Clarification as to whether participants will be required to undergo radiotherapy at a site different to their study site, e.g. will participants at Beaumont Hospital access all study treatment at Beaumont, or will they be referred to SLRON (or another site / hospital) for radiotherapy.
- It should be clear in each SSA if any study related procedures need to be outsourced to another site / including detail as to oversight by a PI.

2025-522512-16-00

Institutions: Mater Misericordiae University Hospita

Study title: A Phase 1, Multicenter Trial Evaluating the Safety, Tolerability, and Efficacy of Valemetostat (DS-3201) in Combination with Darolutamide in Metastatic Castration Resistant Prostate Cancer (mCRPC)

Dossiers Submitted: Part I and II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

1. Compliance with use of biological samples

- The NREC CT noted that section 4 of the S1_Statement on biological sample handling document, detailing the future use of samples is is not described in line with regulations/best practice (“The stored samples may be analysed to design or improve methods for analyzing the development of diagnostic tests, for better

understanding of the characteristics of cancer, and for possible research related to other diseases that may lead to new treatments and/or the development of a diagnostic test that could be commercialized in the future to benefit patients".) The NREC-CT requested that section 4 of the S1_Statement on biological sample handling document is updated to align with changes to the PISCF documents, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).

2. Recruitment arrangements

- The NREC-CT noted the section 1.8 of the K1_Recruitment arrangements document states that documents will be translated if required. The NREC-CT request confirmation that a translator will be available to answer questions, if required by potential participants.

3. Subject information and informed consent form

- The NREC-CT noted that the section "what is this trial about" on pg. 2 of the L1_ SIS and ICF_Main Participant is not written in patient friendly manner and uses overly technical language. The committee requested that this section is revised to be more patient friendly using plain English suitable for a lay audience. It should be clear to participants what the trial is about and why the research is being undertaken. Further detail is also required to explain what ARPIs are and why androgen receptors should be blocked.
- The NREC-CT noted that pg. 4 of the L1_ SIS and ICF_Main Participant states that "Blood and urine samples during the Screening Period will be collected after you have signed and dated the consent form. These samples will be used for laboratory assessments, including studying how the combination of Valemetostat with darolutamide behaves, as well as evaluating baseline values". The Committee requested that this statement is amended in the PISCF to make it clear that participants will not be exposed to the IMP at screening.
- The NREC-CT noted that the pg. 5 of the L1_ SIS and ICF_Main Participant states "…a special period called the Dose Limiting Toxicity (DLT) Evaluation Period, which lasts for 28 days. During this time, we closely monitor for any serious side effects that might occur as a result of the treatment… ". The NREC-CT requested that participants are advised to refer to section 5 of the PISCF for detail of the potential serious side effects that will be monitored during dose escalation.
- The NREC-CT noted that pg. 6 of the L1_ SIS and ICF_Main Participant in the section on dose expansion states "In the future, we might enrol other groups of participants or test different medication combinations as part of this trial", which may be confusing for participants. The Committee requested that this text is amended or removed.
- The NREC-CT requested that the text "trial interventions" is replaced with "study drugs" in the first sentence on pg. 12 of the L1_ SIS and ICF_Main Participant.
- The NREC-CT noted that section 5.1 on pg. 12 of the L1_ SIS and ICF_Main Participant states that "Valemetostat has been given to a limited number of participants" and requested that detail as to the number of people exposed to Valemetostat is added.
- The NREC-CT noted that participants are advised on pg. 14 of the L1_ SIS and ICF_Main Participant that one of the potential side effects of Valemetostat is the risk of developing a secondary malignancy. The Committee requested that participants are provided with more detail as to the potential risk of developing a

secondary malignancy, including the incidence of secondary malignancies in patients taking Valemetostat to date.

- The NREC-CT noted that pg. 18 of the L1_ SIS and ICF_Main Participant states that participants may be required to undergo a gastrointestinal endoscopy. This does not appear to be detailed in the protocol or included in the list of trial procedures on pgs.7 and 8 of the PISCF. It is unclear why participants in this trial would require a gastrointestinal endoscopy. If participants are to undergo a gastrointestinal endoscopy, then a rational for this should be provided in the PISCF and it should also be listed in the trial procedures.
- The NREC-CT requested that the text "If your partner becomes pregnant…" on pg. 18 of the L1_ SIS and ICF_Main Participant is amended to state "if your partner becomes pregnant *or is already pregnant…*" to align with advice in section 4.6 of the E2_SmPC_Darolutamide which states that "If the patient is engaged in sexual activity with a pregnant woman, a condom should be used during and for 1 week after completion of treatment with NUBEQA."
- The NREC-CT requested that specific frequencies for common and very common side effects are detailed on pg. 13 of the L1_ SIS and ICF_Main Participant.
- The NREC-CT noted that participants are advised on pg. 27 of the L1_ SIS and ICF_Main Participant that their pseudonymised data may be transferred outside the EU. The NREC-CT requested that participants are advised that data transferred outside the EU may be subject to lower data protection standards.
- The NREC-CT noted that participants are advised on pgs. 23 & 27 of the L1_ SIS and ICF_Main Participant that they may withdraw from the trial at any time. The committee requested that participants are also advised that they do not have to give a reason for withdrawing from the trial and should only provide a reason if they wish to do so.
- 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. 24 ("If you agree, your coded data and left over biosamples (collected before you start the trial interventions and during the trial) may be used to further study in other related diseases, and to design or improve the way diagnostic tests are developed.") and pg. 25 ("Genomic testing, such as Whole Genome Sequencing or Whole Exome Sequencing (scientific techniques for sequencing some or all your genes), may be performed on your leftover samples") of the L1_ SIS and ICF_Main Participant PISCF. The NREC-CT requested that future use of samples/personal data is sufficiently explained to participants in the PISCF documents so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,
    - it should be made optional
    - it should be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed,
    - and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,
    - optional future research should be made into a separate and explicit consent item in the Informed Consent section of the Main PISCF, with

separate participant information section and signatures section, so it is distinct from the main consent to participate in the research

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

- The NREC-CT noted that pg. 10 of 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 or related diseases and /or genes involved in the metabolism of the medicines being used in the trial and this is 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 (V2.1, 2025). Dublin: Health Service https://www2.healthservice.hse.ie/files/157/
- The NREC-CT requested that it is clarified in the PISCF documents whether the results of genetic testing will be made available to participants. If so, then participants should be advised of the process in place, including the potential supports available. If results will not be made available to participants, then this should be clearly stated.
- The NREC-CT requested that the Informed Consent Section of the is updated to include an explicit statement to say they are willing to take part in the study for example “I agree to take part in this research”.
- The NREC-CT noted that pg. 2 of the L1_SIS and ICF_Pregnant Partner states that “If there is no connection between the time you became pregnant and your partner’s exposure to the trial intervention, the trial doctor will inform your doctor that no follow-up of your pregnancy will be necessary”. The Committee requested that this should be amended, as the effect of the IMP (via semen) on the foetus is unknown.
- The NREC-CT noted that pg.2 of the L1_SIS and ICF_Pregnant Partner states that “the test and scan may be done by your current doctor, and the results will be sent to the trial doctor” The Committee requested clarification in the PISCF as to the whether the pregnant partner will be reimbursed for out of pocket expense (for instance GP visits and /or scans) related to any additional doctor visits / scans required as a result of their partner being a participant in the trial.

Standard Consideration:

3. Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of

the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.

4. All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.

2024-512733-32-00 SM-2

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

Study title: HOVON 177: Randomized study to assess revumenib in combination with azacitidine + venetoclax in adult patients with newly diagnosed NPM1 mutated or KMT2A rearranged AML ineligible for intensive chemotherapy

Dossiers Submitted: Part I and II

- **NREC-CT Decision:**

- Favourable

2022-502122-41-00 SM-6

Institutions: Beaumont Hospital, Adelaide and Meath Hospital

Study title: An Open-label, Randomized Phase 3 Study to Evaluate Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Belzutifan (MK-6482) and Lenvatinib (MK-7902), or MK-1308A in Combination with Lenvatinib, versus Pembrolizumab and Lenvatinib, as First-line Treatment in Participants with Advanced Clear Cell Renal Cell Carcinoma (ccRCC)

Dossiers Submitted: Part I and II

- **NREC-CT Decision:**

- Favourable

2024-513682-40-01 SM-3

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

Study title: A Phase 3, Randomized, open-label Study of Nivolumab + Relatlimab Fixed-dose Combination with Chemotherapy Versus Pembrolizumab with Chemotherapy as First-line Treatment for Participants with Non-squamous (NSQ), Stage IV or Recurrent Non-small Cell Lung Cancer and with Tumor Cell PD-L1 expression ≥1%

Dossiers Submitted: Part I and II

- **NREC-CT Decision:**

- Favourable

2022-502503-30-00 SM-16

Institutions: Children's Health Ireland Crumlin

Study title: Interfant-21: International collaborative treatment protocol for infants under one year with KMT2A-rearranged acute lymphoblastic leukemia or mixed phenotype acute leukemia

Dossiers Submitted: Part I and II

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

2024-512536-29-00 SM-4

Institutions: Beaumont Hospital

Study title: A phase 2, randomized, double-blind, placebo-controlled parallel group study of VHB937 in Amyotrophic Lateral Sclerosis (ALS) over 40 weeks followed by an Open-label Extension (ASTRALS)

Dossiers Submitted: Part I and II

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

2024-517614-14-00 SM-14

Institutions: University Hospital Waterford

Study title: A Phase 2b, Multi-center, Randomized, Double-blind, Placebo controlled Study of IMVT-1402 Treatment in Adult Participants with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Dossiers Submitted: Part II only

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

2024-513009-30-00 SM-13

Institutions: Letterkenny University Hospital, Connolly Hospital, Portiuncula University Hospital, Our Lady Of Lourdes Hospital, Regional Hospital Mullingar, St Vincent's University Hospital, Beaumont Hospital

Study title: A Phase 2a Multicenter, Randomized, Platform Study of Targeted Therapies for the Treatment of Adult Subjects with Moderate to Severe Crohn's Disease

Dossiers Submitted: Part I and II

- **NREC-CT Decision:**

- Favourable

2023-507881-19-00 SM-7

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

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

Dossiers Submitted: Part I and II

- **NREC-CT Decision:**

- Favourable

- AOB:
  - None