National Research Ethics Committee

NREC-CT A Meeting

8th January 2025

Attendance

Name	Role
Prof. Alistair Nichol	Chairperson, NREC-CT A
Ms Caoimhe Gleeson	Deputy Chairperson, NREC-CT A
Prof. Gene Dempsey	Deputy Chairperson, NREC-CT A
Dr Brian Bird	Committee Member, NREC-CT A
Dr Maeve Kelleher	Committee Member, NREC-CT A
Dr Dawn Swan	Committee Member, NREC-CT A
Dr Darren Dahly	Committee Member, NREC-CT A
Prof. Aisling McMahon	Committee Member, NREC-CT A
Mrs Erica Bennett	Committee Member, NREC-CT A
Dr David Byrne	Committee Member, NREC-CT A
Ms Margaret Cooney	Committee Member, NREC-CT A
Dr Sean Lacey	Committee Member, NREC-CT A
Ms Mandy Daly	Committee Member, NREC-CT A
Ms Muireann O'Briain	Committee Member, NREC-CT A
Ms Dympna Devenney	Committee Member, NREC-CT A
Dr Emily Vereker	Head of Office, National Office for RECs
Dr Jane Bryant	Programme Officer, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Peadar Rooney*	Project Officer, National Office for RECs

Dr Susan Quinn	Programme Manager, National Office for RECs
Dr Emma Heffernan	Project Officer, National Office for RECs
Ms Deirdre Ní Fhloinn	Project Officer, National Office for RECs
Ms Rachel Mc Dermott	Project Administrator, National Office for RECs
Ms Patricia Kenny	Project Officer, National Office for RECs

*Drafted minutes

Apologies:

Dr Dawn Swan

Dr Sean Lacey

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2023-503895-25-00
- 2024-518007-22-00
- 2023-504816-14-00 SM-19
- 2022-501980-42-00 SM-13
- 2023-508852-21-00 SM-1
- 2023-507536-21-00 SM-2
- 2022-501895-25-00 SM-21
- 2024-514082-19-00 SM-1
- 2022-501709-11-00 SM-10
- 2024-513087-26-00 SM-6
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 20th November 2024 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2023-503895-25-00

Institutions: Beaumont Hospital, Tallaght University Hospital, University Hospital Galway, Mater Misericordiae University Hospital

Study title: Preventing caRdiovascular collapsE with VasoprEssors duriNg Tracheal IntubatiON: The PREVENTION Randomized Controlled Trial

Dossiers Submitted: Part II

- NREC-CT Decision: Request for Further Information

Additional Information Required

Part II Considerations:

Recruitment Arrangements

- The NREC-CT noted that in the recruitment arrangements documentation, in answer to 1.1 the statement “All critically ill patients, admitted to the emergency department or in the intensive care unit, requiring intubation will be screened for eligibility by the critical care staff and a notification sent to the local investigator or to his/her delegates.” The NREC-CT requests more information on how this procedure will be conducted, specifically:
  Will the emergency staff be screening the potential participants? Will the emergency staff be given clinical trial training; are they part of the clinical trial team? Given the emergency nature of the situation, how much time is given for the local investigator to be notified? The NREC-CT requests that this section be expanded to provide details regarding how this will be implemented and if this will affect emergency room workload, given that is applicable for all sites.
- The NREC-CT notes the statement provided in answer to question 2.3 of the recruitment arrangements document: “when they will fully and permanently recover from their condition of impaired capacity”. The NREC-CT requested further information is provided regarding the process followed in the event that a participant becomes incapacitated as a result of the medical emergency and does not regain capacity.
- The NREC-CT notes in section 4 that no minors will be recruited to the study. The NREC-CT notes in answer 1.5 “Informed consent for intubation and for study participation may be impracticable before the procedure and trial inclusion, given both the high urgency of the procedure and patient’s severe condition.” Given the urgency of the situation, and the difficulty of identifying the age of people with any given certainty, the NREC-CT requested clarity on the process to determine identification of those of appropriate age to be inducted into the trial.
- The NREC-CT notes the following statement in the recruitment materials “Given this premises and the emergency nature of the intervention, it is unlikely that a patient has expressed any previous objection to participate to the clinical trial. Any objection will be then assessed at the moment of informed consent or at any

following time." The NREC-CT notes that some potential participants might not want to be part of a clinical trial. The NREC-CT requests that the recruitment arrangements be detailed and expanded to include how any assessment will be done to assess potential participants' unwillingness to be part of a clinical trial.

- The NREC-CT notes several exclusion criteria listed in the part I documentation. The NREC-CT requests that details on how these exclusion criteria will be screened in the emergency situation be detailed in the recruitment arrangements documentation, for example how will the clinical trial team assess if the participant is part of another clinical trial?

Subject information and informed consent form

- The Sponsor is requested to submit any Part II documentation that require updates as a result of the Part I Assessment, if applicable. If required, please include detail of the Part I consideration that triggered the update to the Part II 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 had significant concerns regarding the presentation of information to the participant in the L1_SIS and ICF Adult and considered this document needs to be re-written. A selection of the issues are highlighted in the considerations in this section but this is not an exhaustive list.
- The NREC-CT noted formatting and legibility issues throughout the document L1_SIS and ICF (PISCF) Adult, for example there is no page numbers, some of the passages seem to have been written for the carer/guardian of the participant in places and some seem to be written for the participant in others for example on page 1 contains the sentence "Please read this section as your friend or relative (person responsible) may have been enrolled into the study under emergency circumstances." Page 1 also contains the sentence **"**We are inviting you to take part in this research project". The NREC-CT also noted grammar and spelling mistakes throughout, for example on page 1, the sentence "If you don't wish to take part, you doesn't have to" and on page 9 the word "Wishe". The NREC-CT requests that a thorough revision of the PISCF be conducted.
- The NREC-CT noted errors and missing information throughout the documentation, regarding the risks, complications of procedures and standards of care. The NREC-CT requests that these should be laid out for the participant with detail and care about how a potentially vulnerable participant who has experienced a traumatic event would perceive the documentation given to them.
- The NREC-CT advised that a PISCF should be specific to who is it addressing, that it should either be for a participant for consent/assent or for a person who is giving consent on behalf of the participant. The NREC-CT advises that separate PISCFs should be created to be clear who is being informed and advised of the risks, and who is giving consent/assent. The NREC-CT suggests that a PISCF

should be created for participants, for legal representatives, and any other potential groups identified by the sponsor.

- The NREC-CT has noted that there is a lack of detail regarding how the clinical trial team will inform the participant's legal representative if the participant does not survive and requested that clarity is provided.
- The NREC-CT requests that documentation is provided with specific detail as to how all emergency consent procedures undertaken comply with each part of Article 35 of S.I. No. 40/2022 – European Union (Clinical Trials on Medicinal Products for Human Use) Regulations 2022.
- The NREC-CT noted that the risk section of the L1_SIS and ICF Adults contains no details about the procedures, or the drugs used as part of the procedures. The NREC-CT notes that while the study states that these are standard of care for some sites, the NREC-CT noted that vasopressors such as "noradrenaline" has a known risk profile and known risks such as "tissue necrosis" should be identified. The risks of these products should be explicitly listed in the PISCF.
- The NREC-CT noted that the use of the term vasopressors to refer to the study drug. The specific vasopressors included in the trial should be identified and listed along with their risks.
- The NREC-CT has concerns that the use of vasopressors is not standard of care across all the sites listed in the application. The NREC-CT requested that the PISCF be updated with a section detailing what standard of care is for a participant in that emergency situation along with how the care they receive compares to the standard of care.
- The NREC-CT noted that there is no explanation provided regarding why a participant was included in the trial, the NREC-CT requests the inclusion criteria and the exclusion criteria be listed for the understanding of the participant.
- The NREC-CT noted that there is not a sufficient explanation for the participant for the sequence of events that occurs in the clinical trial, such as when randomisation occurs, what the arms of the study they are being allocated to are, when data is collected, any follow up and when data collection occurs. The study diagram provided in the protocol Section 5 would be helpful to the participant and is recommended by NREC-CT to be included in the PISCF.
- The NREC-CT notes the sentence "No money has been set aside to pay for things like lost wages, time or pain" the NREC-CT requests the removal of this sentence.
- The NREC-CT noted the sentence in the PISCF "No additional contact with you is required for this study. Information about you will be collected from the data that is routinely recorded in the clinical information system of the hospital." However, it is stated in the protocol that there will be follow-up with participants after 28 days, which is not detailed in the PISCF. The NREC-CT requests clarity on the follow-up with patients.
- The NREC-CT noted that the relevant GDPR legislation is not identified in the PISCF. The NREC-CT requests that GDPR be identified as legislation that applies to the participant's data in the relevant section of the PISCF.

- The NREC-CT noted the sentence in the PISCF, Section: Processing of Personal Data: "*Note: These parties will either be acting as Processors of your information as part of this research study e.g. CROs, non-GUH employees supporting research process or Controllers in their own right." The NREC-CT requests clarity on who is acting as data processors, data controllers and what the asterisk(*) is referring to, such that it is clear to the participant.
- The NREC-CT noted the abbreviation PMH used in the table in the PISCF, Section: Processing of Personal Data. There is no explanation provided regarding what a PMH is. The NREC-CT recommends that all abbreviations be fully explained in the PISCF.
- The NREC-CT notes the "Joint Commission Internation" is listed in the PISCF, Section: Processing of Personal Data. The NREC-CT requests that more information is provided for the participant regarding who the third parties are such as the Joint commission are, the reason data is being shared with them and for what purposes. If consent is needed for the data to be shared, how and where will this consent be collected?
- The NREC-CT noted that this is an international trial. However, there is no mention in the PISCF of sharing data with relevant clinical trial partners in different countries. The NREC-CT requests that clarification on the sharing of data, its annoymised status, and the personal nature of the data be clarified in the PISCF.
- The NREC-CT noted the sentence "If a study has been published that included data linked to you, it may not be possible to alter this result". When this occurs and how this affects the inability of the patients to withdraw their data from the trial needs to be expanded and clarified for the participant.
- The NREC-CT notes the statement "I agree to allow other researcher use my information if they have permission from an ethical review board to conduct studies" be removed from the consent section of PISCF, this is covered by other consent options.
- The NREC-CT noted the text "The ethics and medical research committee of Galway University Hospitals has reviewed and approved this study" this should be revised to include details of the NREC-CT.
- The NREC-CT notes that the section on "Withdrawal from the Study" does not provide information on how a participant withdraws from the study. The NREC-CT requests that this section be updated and expanded.
- The NREC-CT noted that on the last page of the PISCF, there is no space for the qualification of the person who is conducting the consent process. This should be amended to include space for the qualification of the person conducting the consent process.
- The NREC-CT noted as consent will be recorded post emergency procedure, information and clarity is requested regarding how a non-English speaking participant will be consented.

- The NREC-CT noted that the PISCF contains only an option for “yes” in the informed consent section. The NREC-CT requests that this be updated for options for both “Yes/No” or the participant’s initials to indicate consent.
- The NREC-CT requested that the Main ICF be updated to include specific statement that the participant/legally designated representative 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 that this trial will recruit incapacitated adults, the NREC-CT requested that the SIS and ICF Adult be updated to include a specific statement that the participant/legally designated representative confirms that they have read and understand the information.
- The NREC-CT requested that the PISCF page 1 be updated to include the EU trial number for participants.
- The NREC-CT requested that the PISCF be updated to provide information about the availability of the clinical trial results at the end of the trial and location of same.

Suitability of the clinical trial sites facilities

- The NREC-CT noted the PI listed on page one and throughout the PISCF has not provided CV, DOI or GCP information.

Suitability of the investigator

- The NREC-CT noted the PI listed on page one and throughout the PISCF has not provided a site suitability form.

2024-518007-22-00

Institutions: St Vincent's University Hospital, Dublin

Study title: A Phase 2 Randomised, Open Label Trial of an Intradermal or Subcutaneous booster dose of MVA-BN Vaccine to Investigate MPXV Immunogenicity and Safety for Protection Against Mpox in Intradermally or Subcutaneously Primary Vaccinated and a Non-Randomised Trial of a Subcutaneous Booster Dose for Subcutaneously Primary Vaccinated

Dossiers Submitted: Part I & II

- NREC-CT Decision: Request for Further Information

Part I Considerations

- There is inconsistency between the protocol and CTIS regarding participating sites and investigators from Ireland, as well as the submitted CVs, DOIs and GCP certificate. The sponsor is requested to ensure the protocol and CTIS are aligned for consistency and additional sites listed as a substantial modification if needed.
- Section 3.4 Risk and Hazards states that the STI-clinic staff is open during the week and the infectious disease clinic adjacent is open 24/7 which seems to be a remnant from when the protocol was mono-national. It needs to be clarified in the protocol for current

and future sites how unexpected reactions/AEs and unplanned visits will be handled outside of office hours.

- • The protocol section 5.1.4 states “In Ireland…..sites affiliated to the Infectious Diseases Clinical Trial Network of Ireland”. The sponsor is requested to provide clarification on the Infectious Diseases Clinical Trial Network of Ireland roles in recruitment, screening, data sharing, data processing or data analysis and any clinical trial activities.

  • The protocol section 10.3 Sample Size Calculations notes six sites in Ireland. If these are not all submitted and approved, the protocol may require amendment. This section should be amended to reflect the sites currently part of the application and future sites that will be added, and their effect on the power calculations.

- • The protocol section 11.3 Source Data details how medical records will be kept in accordance with the Patient Data Act which is not relevant in Ireland and France. The sponsor is requested to provide a section relevant to European wide specific law, and country specific laws and legislations. A section on GDPR as detailed in 12.4 could be referred to but this section should cover all countries participating. There also should be additional language added to ensure that source data includes written and electronic medical records (and more).

- • The protocol section 11.5 Audits and Inspections should include a statement that National Research Ethics Committees or country specific equivalent can access records.

Part II Considerations
Compliance with use of biological samples

- The NREC-CT noted in the ‘Human and biological samples document’, for “Residual/remnant samples” there is mention of destruction “once the analysis has been completed”. In section 3.4 it is stated that “samples being held for 10 years following trial completion”. The NREC-CT requests clarification on exactly what will happen to samples collected in Ireland.
- The NREC-CT noted a discrepancy between statements regarding bio-banking which needs clarity. In part 1 Dossier: Future use: “No bio-banking of biological materials will take place”. The NREC-CT noted the Human and biological samples document section 4 indicates that bio-banking will take place and that the purpose of future research is vague. The NREC-CT requests clarification on bio-banking of samples and more specificity on future research on these samples and how consent will be sought for this future research.

Financial arrangements

- THE NREC-CT noted in the “Compensation for trial participants” document that participants are not being compensated for travel expenses. The NREC-CT noted in the PICSF on page 10 “You will not be paid for your participation in this study however you may receive reimbursement for costs related to attending the study visit”. The NREC-CT requests clarification will the participants be offered reimbursement for travel and alignment between the documentation.

Subject information and informed consent form

- 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 (if applicable).
- 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 PICSF be reviewed on a country specific level. In parts, it seems specific for Sweden, in others for Ireland. These need to be either made to refer to all three countries together or be specific to one country. Ensure regulations and state/EU laws are referred to as appropriate and explained where required. For example, is “Health Declaration” relevant for all countries.
- The NREC-CT requests the documentation to be reviewed and revised for the use of abbreviations and terminology that could hinder understanding. For example, the use of SC in place of subcutaneous, the use of the term “Day 0”, instead of first visit. The NREC requests an explanation of “mpox serology” in lay terms be included in the PICSF.
- The NREC-CT requests that in the section “Participation is voluntary”, the PICSF needs to more explicitly point out that there may be no benefits to the participant.
- The NREC-CT notes that there is no mention of the risks of scarring for participants who are in the intradermal injection group in the PICSF. This has been a barrier to vaccination previously and has been included in US and UK information on Jynneos. As per NIAC, ID administration is not recommended for those with a history of keloid scar formation. The NREC-CT requests that this information be included in the PICSF or to receive clarification on this information not being included.
- The NREC-CT requests more information needs to be supplied to the patient regarding the sub study and use of their samples for primary and secondary objectives (any explanation of proteomics should be in lay terms), for example information should include what will happen to the participant in the sub-study, benefit and risks to the participant. The NREC-CT requests that this information be included as either a separate PICSF or as separate sections of the main ICF.
- The NREC-CT requests that it be clarified in the PICSF regarding biobanks and an explanation of what a biobank (in lay terms) be included in the PICSF.
- The NREC-CT noted in the section Data protection: The sentence “This explicit consent acts as a safeguard under the Irish Health Research Regulation”. The NREC-CT requests details on what the regulation is and how it affects this consent and the NREC-CT requests that information on how to find the regulation be included in PICSF.
- The NREC-CT requests that the section on personal data being processed should include information about data relating to HIV status and how positive HIV tests are reported to the Health Authorities in Ireland. The NREC-CT also requests that

a reference to HIV results should be inserted into the PISCF Table about Personal Data that will be processed, along with a reference to the section explaining how positive HIV results are reported.

- The NREC-CT requests information about the laboratories involved in this study and their processes and security measures taken to ensure patient data confidentiality, for example if the laboratories are GDPR compliant.
- The NREC requests that a place for time be inserted beside the date on Signature Page, along with a space for the qualification of the investigator obtaining consent.
- The NREC-CT requests that greater clarity be included in the PICSF about the vaccines in this trial. For example, that Jynneos will only be administered in Sweden, that Imvanex is being administered in Ireland and Sweden, that Jynneos is approved in the US but not approved in Sweden except by exception.

Suitability of the clinical trial sites facilities

- The NREC-CT noted that there is no mention of accreditation for the laboratory site used for analysis of samples and requested that this information is provided in the site suitability form.

2023-504816-14-00 SM-19

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

Study title: A Phase 3, Randomized, Active-controlled, Open-label, Multicenter Study to Compare the Efficacy and Safety of MK-2870 Monotherapy Versus Treatment of Physician's Choice in Participants With Endometrial Cancer Who Have Received Prior Platinum-based Chemotherapy and Immunotherapy (MK-2870-005/ENGOT-en23/GOG-3095)

Dossiers Submitted: Part I & II

NREC-CT Decision: Request for Further Information

Additional Information Required

Subject information and informed consent form

- The NREC-CT notes that on page 11 of the Main ICF, the text switches from using the MK-2870 to refer to the study drug to using the name sac-TMT. The NREC-CT advises that the sponsor use one name consistently throughout the ICF and all patient facing documentation to avoid confusion.
- The NREC-CT requests that a section be added to the Greenphire ICF. This section should explain to the participant what will happen if the participant declines to use Greenphire services and how the offer of reimbursement, travel arrangements, local transportation and trial related reminders will be arranged.
- The NREC-CT notes on the Greenphire PICSF on page 2 states that "operates in compliance with privacy and data protection laws in the UK". This language should be localised to Irish laws and regulations.

- The NREC-CT notes that the tracked changes versions of Recruitment brochure and Recruitment brochure for tissue were not submitted. Please submit for review as part of the RFI.

2022-501980-42-00 SM-13

Institutions: Children's Health Ireland

Study title: A Phase 3, Open-label, Uncontrolled Study to Evaluate the Activity, Safety, Pharmacokinetics and Pharmacodynamics of Roxadustat for the Treatment of Anemia in Pediatric Participants with Chronic Kidney Disease

Dossiers Submitted: Part I & II

NREC-CT Decision: Request for Further Information

Additional Information Required

Subject information and informed consent form

The NREC-CT noted that the Main PIS/ICF had not been updated to include the higher risk of cerebrovascular events (CVAs). The Committee requested that this document be updated to include this additional information in the section 'Risks and Benefits' (which starts on Page 11 of 24).

2023-508852-21-00 SM-1

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

Study title: A Phase II, Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer (NeoCOAST-2)

Dossiers Submitted: Part I & II

NREC-CT Decision: Request for Further Information

Additional Information Required

Subject information and informed consent form

- The NREC-CT noted on the main ICF on page 4 the addition of text: "As part of the main study, you are also asked to provide a mandatory blood sample for genetic testing." The NREC-CT suggests that participants should be referred to pages and sections further down where information can be found about the genetic testing and data from the genetic testing be added to this section. The NREC-CT requests that additional detail are to be provided and this should be a separate section, similar to mandatory tumour tissue sample on page 6.
- The NREC-CT noted on the main ICF Page 25: addition of text: "*Your biosamples collected during the study will be <<returned to your study doctor/destroyed>> as*

soon as possible after the tests described above are completed. your biosamples will be kept for a maximum of 15 years." The NREC-CT advised that this text should be clarified for which scenario applies to the samples in this study.

- The NREC-CT noted on the factsheet the sentence "*you will be provided with extensive information about your health through regular examinations and tests, which may help to uncover undiagnosed medical conditions*." The NREC-CT requests that the words "which may help to uncover undiagnosed medical conditions" be removed from the factsheet.
- The NREC-CT noted that on Flipchart on page 4, it contains the sentence. "*Studio to redraw & ensure Legibility*". Can the sponsor confirm whether or not this is the final version of the graphics that the participants will see?
- The NREC-CT notes that the ICF Pregnant partner on page 3 is "*The following sentence needs to be added for studies conducted in EEA and registered on euclinicaltrials.eu (transition clinical studies and any new clinical study): Trial Result Summaries will also be posted on http://euclinicaltrials.eu.*" The NREC-CT notes that this sentence is duplicated in the paragraph below and asks for this to be revised.
- The NREC-CT notes that the pregnant partner information does not provide the information on potential harm to an unborn child, nor makes clear that pregnancy was counter-indicated, the NREC-CT advises the sponsor to consider that not all pregnant partners might have access to the main ICF. The NREC-CT requests to copy the section in the main ICF titled "Harm to the unborn section" and place into the pregnant partner ICF.

2023-507536-21-00 SM-2

Institutions: Mater Misericordiae University Hospital

Study title: A Phase 1/2 Open Label, Dose Escalation and Expansion Study of MDNA11, IL-2 Superkine, Administered Alone or in Combination with an Immune Checkpoint Inhibitor in Patients with Advanced Solid Tumors

Dossiers Submitted: Part I & II

NREC-CT Decision: Request for Further Information

Additional Information Required

Subject information and informed consent form

- The NREC-CT also noted that all side effects were classified as "mild or moderate in intensity" on page 11 of the PICSF. The NREC-CT noted in the updated MDNA11 investigator's brochure that in table 16, several patients withdrew due to adverse events. The NREC-CT requests consistency between the IB and PICSF in relation to the severity of adverse events, and adverse events that may have lead withdrawal from the study and this information be included in PICSF.

- NREC-CT notes that on pages 9, 10 and 11 section detailing optional and mandatory tumor tissue collection. The NREC-CT advises that clarification be inserted on page 9, in the “tumor tissue collection” section (in lay person terminology) for why a participant would be assigned to optional tumor collection or mandatory tumor collection.

2022-501895-25-00 SM-21

Institutions: St Vincent’s University Hospital, Beaumont Hospital, Connolly Hospital, Our Lady’s Hospital, Cork University Hospital, University Hospital Galway, St James’s Hospital

Study title: A randomized, parallel-group, double-blind, placebo-controlled, multicenter Phase III trial to evaluate efficacy and safety of secukinumab administered subcutaneously versus placebo, in combination with a glucocorticoid taper regimen, in patients with polymyalgia rheumatica (PMR)

Dossiers Submitted: Part I & II

NREC-CT Decision: Request for Further Information

Additional Information Required

Suitability of the clinical trial sites facilities

- The NREC-CT noted that in the cover letter, detailed the closure of sites 6701, site 6702 and 6704 in Ireland. The NREC-CT requests the names of these sites so that the approval can be issued only for the sites that are conducting the study.
- The NREC-CT also advises that the structured data on CTIS be updated to reflect those sites which are closing.

2024-514082-19-00 SM-1

Institutions: Beaumont Hospital

Study title: A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating Safety and Efficacy of CORT113176 (Dazucorilant) in Patients with Amyotrophic Lateral Sclerosis (DAZALS)

Dossiers Submitted: Part I & II

NREC-CT Decision: Favourable

2022-501709-11-00 SM-10

Institutions: Cork University Hospital, St James’s Hospital

Study title: A single arm, open-label Phase 3b study to describe the safety and tolerability of ivosidenib in combination with azacitidine in adult patients newly diagnosed with IDH1m acute myeloid leukemia (AML) ineligible for intensive induction chemotherapy ALIDHE

Dossiers Submitted: Part I & II

NREC-CT Decision: Favourable

2024-513087-26-00 SM-6

Institutions: Beaumont Hospital, St James's Hospital

Study title: A Randomized, Controlled, Multiregional Phase 3 Study of Ivonescimab Combined with Chemotherapy Versus Pembrolizumab Combined with Chemotherapy for the First-line Treatment of Metastatic Squamous Non-small Cell Lung Cancer (HARMONi-3)

Dossiers Submitted: Part I & II

NREC-CT Decision: Request for Further Information

Additional Information Required

Subject information and informed consent form

- The NREC-CT noted that several of the modifications which were made to the Main PIS/ICF appeared to utilise language intended for the healthcare professional (HCP)/study team members and not for the participant. The Committee requests that amendments be made to simplify the language throughout and in particular at sections indicated below:
- Page 6: please explain the word 'histology' in the phrase "dependent on histology type".
- Page 6: please simplify the language used in the paragraph beginning "medications may be given to you prior to your chemotherapy infusion(s)…"
- Page 7: please simplify the language used in the statement "a fresh or archival tumour tissue is needed" to clarify whether a re-biopsy is required.
- Page 9: please simplify sentence beginning "if available, a haematoxylin and eosin stained tumour tissue…"
- Page(s) 10 and 16: please provided additional clarity as to the parameters associated with the term 'women of child-bearing potential'
- Page 16: please note that some amendments have been written in the third person, and should be simplified and adapted to address the participant reading the PIS/ICF (e.g. "if you do not abstain…", "if you are a male patient…" and so on as applicable.

- AOB:

None