National Research Ethics Committee

NREC-CT Meeting

3rd September 2025

Attendance

Name	Role
Prof Mary Donnelly	Chairperson, NREC-CT C
Prof John Faul	Deputy Chairperson, NREC-CT C
Dr Jean Saunders	Deputy Chairperson, NREC-CT C
Prof Fionnuala Breathnach	Committee Member, NREC-CT C
Dr Susan Finnerty	Committee Member, NREC-CT C
Prof Andrew Smyth	Committee Member, NREC-CT C
Dr Steve Meaney	Committee Member, NREC-CT C
Ms Susan Kelly	Committee Member, NREC-CT C
Dr Deborah Wallace	Committee Member, NREC-CT C
Mr Gerry Eastwood	Committee Member, NREC-CT C
Prof Anne Mathews	Committee Member, NREC-CT C
Dr Juan Trujillo	Committee Member, NREC-CT C
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 Emma Heffernan*	Project Officer, National Office for RECs
Dr Peadar Rooney	Project Officer, National Office for RECs
Dr Emily Vereker	Head of Office, National Office for RECs

*Drafted minutes

Apologies: Mr Philip Berman, Dr. Dervla Kelly, Prof. Patrick Forde, Dr Paula Prendeville

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2025-520896-13-00
- 2024-517614-14-00
- 2023-508015-23-00
- 2022-502122-41-00 SM-5
- 2023-507353-15-00 SM-3
- 2022-502282-24-00 SM-19
- 2024-512536-29-00 SM-3
- 2024-515526-89-00 SM-1
- 2024-517500-11-00 SM-4
- AOB

- The Chair welcomed the NREC-CT C.
  - The minutes from the previous NREC-CT C meeting on 16th July 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2025-520896-13-00

Institutions: Children's Health Ireland

Study title: A Phase 3, 2-Part, Randomized, Double-Blind, Placebo-Controlled Study (Part 1) and Open-Label Extension (Part 2) to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Omaveloxolone (BIIB141) in Participants With Friedreich's Ataxia Aged 2 to < 16 Years

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**
- Request for Further Information
- **Additional Information Required**

Part II Considerations

1. **Compliance with national requirements on data protection**
   - No Considerations raised by NREC
2. **Compliance with use of biological samples**
   - No Considerations raised by NREC
3. **Financial arrangements**
   - No Considerations raised by NREC
4. **Proof of insurance**
   - No Considerations raised by NREC
5. **Recruitment arrangements**
   - The NREC-CT requested that the procedure describing how responses to advertisements will be managed is detailed in section 1.2 of the K1_296FA301_Recruitment-Consent-Procedure_IE_English_Public.
   - The NREC-CT noted that the GP letter states "I would like to inform you that your patient, …has given his/her freely consent to participate in a clinical study" and requested that this is amended to also include minors participating in the study, as they will have provided assent and their parents/guardians will have provided consent to participate in the study.
   - The NREC-CT noted that section 4 of the K1_296FA301_Recruitment-Consent-Procedure_IE_English_Public states that an impartial witness will not be required during the trial. Please provide justification as to why an impartial witness will not be required.
6. **Subject information and informed consent form**
   - The NREC-CT noted that the submitted PISCFs and Assent forms have used a bundled approach to consent in the Informed Consent Section of the PISCF/ Assent forms 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

- The NREC-CT requested clarification if e-consent is being undertaken in Ireland. If e-consent is being undertaken in Ireland, please confirm that e-consent procedures with be compliant with GDPR and HRR.
- The NREC-CT noted that pg. 5 of the L1_296FA301_Adult-and-Parental-Pregnant-Partner-Consent_IE_English_NotPublic includes the statement “Applicable for pregnant partners aged 16 and 17 years only - I agree to processing of my child’s personal data as described in this Patient Information Sheet” and requested that this sentence is removed. Due to a recent national policy change in Ireland, participants aged 16yrs+ may consent to both participation in a regulated study and associated data processing. Therefore, the consent for participation in the study and use of personal data for the study, should not be treated separately and there is no requirement to seek consent from a parent/guardian for data processing for participants aged 16 and 17. Please see our website for guidance https://www.nrecoffice.ie/guidance-on-age-of-consent-for-regulated-research-in-ireland/
- The NREC-CT noted that assent forms were not provided for minors under 6 years of age and requested justification for this e.g. the “Assent / Informed Consent Guidance for Paediatric Clinical Trials with Medicinal Products in Europe” developed by the Enpr-EMA’s Working Group on Ethics provides guidance on the development of Assent forms for specific age groups https://www.ema.europa.eu/system/files/documents/other/informed_consent_assent_content_recommendations_for_paediatric_clinical_trials_in_europe_en.pdf
- The NREC-CT noted that a pregnant partner assent form was included in the submission and requested that a pregnant partner consent form should also be provided, should the pregnant partner be aged 16 years plus.
- The NREC-CT requested clarification on whether participants will be reconsented once they reach 16 years old, in line with the age of consent as detailed in the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
- The NREC-CT noted that the future use of data/samples (including genetic research) is not described in line with regulations/best practice in the L1_296FA301_PGx-Assent_All-Ages_IE_English_Public, the L1_296FA301_Adult-and-Parental-PGx-ICF_IE_English_Public (pg. 2: “The study sponsor cannot predict all of the genetic research that may be done with the DNA sample. The optional genetic research may look at your/your child’s disease or condition or may look at other diseases or conditions”), the L1_296FA301_FSR-Assent_All-Ages_IE_English_Public, and the L1_296FA301_Parental-ICF_IE_Engish_NotPublic and L1_296FA301_Main-Adult-ICF_IE_English_NotPublic (pg. 8: "The study sponsor may use your coded data for research on other diseases and to develop other drugs, diagnostic tests, or medical aids") PISCFs. The NREC-CT requested that future use of samples/personal data is sufficiently explained to participants in the PISCF documents so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,

- it should be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed,
- and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,

The 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 pgs. 1 of the L1_296FA301_Main-Adult-ICF_IE_English_NotPublic and L1_296FA301_Parental-ICF_IE_Engish_NotPublic state that participants are to undergo genetic testing and requested the following is explained to participants using plain English suitable for a lay audience:
  - 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. For guidance, please see HSE National Policy for Consent in Health and Social Care Research (V1.1, 2023) https://hseresearch.ie/wp-content/uploads/2023/02/HSENational-Policy-for-Consent-in-Health-and-Social-Care-Researchcompressed.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.

7. Suitability of the clinical trial sites facilities

- No Considerations raised by NREC

8. Suitability of the investigator

- No Considerations raised by NREC

2024-517614-14-00

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 I & II

- **NREC-CT Decision:**
- Request for Further Information
- **Additional Information Required**

Part II Considerations

1. Compliance with national requirements on data protection

- No Considerations raised by NREC

2. Compliance with use of biological samples

- Please update section 4 of the S1_Compliance on biological samples_IE if future / secondary use of samples is being undertaken so it aligns with updates to the PISCF.

3. Financial arrangements

- No Considerations raised by NREC

4. Proof of insurance

- The NREC-CT noted that the insurance certificate expires in June 2026 and requested confirmation that insurance will be kept in place for the duration of the trial.

5. Recruitment arrangements

- The NREC-CT noted that section 1.8 of the K1_Recruitment Arrangements_IE document states that it is not planned to recruit participants who do not speak the national language. The NREC-CT requested that, on inclusionary grounds, where possible, reasonable efforts to accommodate/support participants who do not speak the 'national language' to take part in the trial will be taken and provided with translation services as required. The NREC-CT requires that any translations of participant materials are completed by a certified translator/translation service. This should be detailed in the K1_Recruitment Arrangements_IE document.
- The NREC-CT noted that the K2_Recruitment material_Brochure_IE states, 'it is also possible that your CIDP may get worse" and requested that a statement of intention to discontinue the investigational medicinal product (IMP) and revert to standard of care treatment in the event of relapse during Period 1 is added to this document, to reassure potential participants.
- The NREC-CT requested that the procedure describing how responses to advertisements will be managed is detailed in section 1.2 of the K1_Recruitment Arrangements_IE document.

6. Subject information and informed consent form

- The NREC-CT noted that pg. 23 of the L1_SIS and ICF_Main_IE_not for publication PISCF states, 'However, you may receive little or no benefit from study treatment, and your CIDP may get worse" and requested that a statement of the intention to discontinue the IMP and revert to standard of care treatment in the event of relapse during Period 1 is added to this document, to reassure potential participants.
- The NREC-CT noted that the description of the steroid tapering phase does not extend to an explanation of the target steroid dose to be continued throughout the study (5mg daily).The NREC-CT requested that the continuation of low-dose (5mg daily) corticosteroid therapy during the study in participants who are taking oral

corticosteroids at the point of recruitment, should also be stated in the L1_SIS and ICF_Main_IE_not for publication PISCF.

- The NREC-CT noted that pg. 5 of the L1_SIS and ICF_Main_IE_not for publication PISCF includes conflicting statements regarding the length of the screening period ("screening Period [up to 9 weeks]" and directly underneath "Screening [up to 35 days]"). The NREC-CT requested that the length of the screening period is clearly stated, so participants are fully informed.
- The NREC-CT noted that pg. 10 of the the L1_SIS and ICF_Main_IE_not for publication PISCF states that 'The study team will need to test for certain diseases such as Hepatitis, HIV and TB… if any of these tests are positive, the results may be reported to responsible local authorities if required in your country'. The NREC-CT requested that a statement is added to the PISCF to inform participants that they will also be informed if they test positive for these diseases.
- The NREC-CT noted that the Full Schedule of Assessments is not presented in a patient friendly format (e.g. it is laid out over 6 to 7 pages) and is in addition to a well-described narrative description of study procedures. The NREC-CT requested that this section is presented in a more patient-friendly format or removed from the PISCF.
- The NREC-CT noted that pg. 21 of the L1_SIS and ICF_Main_IE_not for publication PISCF advises participants that the text which outlines the risks of undergoing an ECG includes an unnecessary level of detail (e.g. that the sticky pad may be cold) and requested that this section is revised to remove superfluous detail that runs the risk of diluting critically important information.
- The NREC-CT noted that pg. 28 & 29 of the L1_SIS and ICF_Main_IE_not for publication PISCF states that both the FDA and the MHRA will have access to participants uncoded data and medical records and requested clarification in the PISCF as to why either the FDA or MHRA would have access to participants uncoded data and medical records in Ireland.
- The NREC-CT noted that pg. 29 of the L1_SIS and ICF_Main_IE_not for publication PISCF states, "the Sponsor will keep your coded Personal Data for at least 25 years after your participation ends" and requested that the maximum length of time data will be retained is stated in the PISCF.
- The NREC-CT requested that the EU CT number is added to the following PISCF documents: L1_SIS and ICF_Main_IE_not for publication, L1_SIS and ICF_Pregnant Partner_IE_not for publication and L1_SIS and ICF_Optional Genetic Research_IE_not for publication.
- The NREC-CT noted that pg. 28 L1_SIS and ICF_Main_IE_not for publication states that personal data will be used to "To learn more about CIDP and related health problems and to learn how to develop better tests or treatments. To help plan future studies" and "To develop ways of reviewing and using scientific data". The NREC-CT requested clarification as to whether the sponsor is intending to carry out research beyond that described in the protocol. If future use / secondary use of data / samples is not intended, then this should be clearly stated in the PISCF. If future use / secondary use of data / samples is to be undertaken then the NREC-CT requested that future use / secondary use of samples/personal data is sufficiently explained to participants in the PISCF documents so as to constitute broad informed consent, as required under the Health Research Regulations (Data

Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,

- it should be made optional
- it should be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed,
- and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,
- optional future research is made into a separate and explicit consent item in the Informed Consent section of the Main PISCF, with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research

The PISCF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. 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. 3 of the L1_SIS and ICF_Optional Genetic Research_IE_not for publication states that "There is a chance that people and companies other than the Sponsor or those described in the Participant Information Leaflet for the main study may get your genetic information from analysis of your samples and link this genetic information back to you", which is vague and may cause concern for participants. The NREC-CT requested that this is revised to provide a more specific, informative and patient-friendly description of how this may occur.
- The NREC-CT requested that the GP letter is submitted for review.
- 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.

7. Suitability of the clinical trial sites facilities

- No Considerations raised by NREC

8. Suitability of the investigator

- No Considerations raised by NREC

2023-508015-23-00

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

Study title: A Phase 3, Randomized, Open-label, Multicenter Study to Evaluate the Efficacy and Safety of Sacituzumab Tirumotecan (MK-2870) Maintenance Treatment With or Without Bevacizumab Versus Standard of Care After Second-line Platinum-based Doublet Chemotherapy in Participants With Platinum-sensitive Recurrent Ovarian Cancer (TroFuse 022/ENGOT ov84/GOG-3103)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**
- Request for Further Information
- **Additional Information Required**

Part II Considerations

1. **Compliance with national requirements on data protection**

- No considerations raised by NREC

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

- Please update section 4 of the S1_Compliance with use of biological samples_IRL_EN_AM11-RFI001_not pub if future / secondary use of samples is being undertaken so it aligns with updates to the PISCF.

3. **Financial arrangements**

- No considerations raised by NREC

4. **Proof of insurance**

- No considerations raised by NREC

5. **Recruitment arrangements**

- The NREC-CT suggested that section 2 titled “who can be in this trial” on pg. 4 of the K2_Recruitment Doc Summary PIS_IRL_EN_Access_AM11_not pub is moved closer to the beginning of the PISCF document, as it contains pertinent information for participants regarding trial eligibility.

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

- The NREC-CT noted the presentation of the L1_ICF_Main adult information_IRL_EN_Access_AM11_not pub PISCF into two columns may be difficult for participants to read and suggested that this is reformatted to aid accessibility/readability.
- The NREC-CT requested that the following terms are clarified in the L1_ICF_Main adult information_IRL_EN_Access_AM11_not pub PISCF:
    - Pg. 3, section 3 please explain what the word “maintenance” refers to (i.e. does this refer to stand of care treatment?)
    - Pg. 3, section 3 please explain what “bevacizumab” is
    - Pg3, please clarify if a participant is enrolled in Part 1, do they automatically move to Part 2?
- The NREC-CT noted that pg. 4 of the PISCF advises participants that they may be asked to use a mouthwash to help tolerate sac-TMT and requested that participants are provided with more information on the need for the mouthwash (the Committee suggested that the side effects of the drugs are noted here, or that participants are referred to section 13 on pg. 11).
- The NREC-CT requested that the word “wee” to describe the word urine is removed from pg. 8 of the L1_ICF_Main adult_information_IRL_EN_Access_AM11_not pub PISCF
- The NREC-CT noted that pg. 8 of the L1_ICF_Main adult information_IRL_EN_Access_AM11_not pub PISCF states that notifiable diseases

are reported to the UK Health Security Agency (UKHSA) and requested that this is amended to the relevant entity in the Republic of Ireland.

- The NREC-CT requested that participants are informed on pg. 10 of the L1_ICF_Main adult information_IRL_EN_Access_AM11_not pub PISCF that scan exposure will be higher than standard of care, but that the potential benefit outweighs the risk.
- The NREC-CT noted that pg. 10 of the L1_ICF_Main adult information_IRL_EN_Access_AM11_not pub PISCF states that participants may undergo whole genome / whole exome sequencing and requested the following:
    - Genomic sequencing is confined to genes involved in the disease being treated and /or genes involved in the metabolism of the medicines being used in the trial and this elucidated in the PISCF.
    - Explicit consent, including outlining the risks entailed in such analysis being performed, is added to the PISCF.
    - The possible ownership of such data by private or commercial interests and that this elucidated in the PISCF.
    - The right to withdraw genetic data, and clear information on how to do so, must also be provided in the PISCF.
    - Clarification is provided in the PISCF on the mechanism for anonymisation, storage and security and transfer of genetic material and its associated data. For guidance, please see HSE National Policy for Consent in Health and Social Care Research (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. 10 of the L1_ICF_Main adult information_IRL_EN_Access_AM11_not pub PISCF states that personal data will be used “for genetic and biomarker testing. This research can help in discovering ways that trial drugs work, how the body responds to or resists them, and how they affect human health”. The NREC-CT requested clarification as to whether the sponsor is intending to carry out research beyond that described in the protocol. If future use / secondary use of data / samples is not intended, then this should be clearly stated in the PISCF. If future use / secondary use of data / samples is to be undertaken then the NREC-CT requested that future use / secondary use of samples/personal data is sufficiently explained to participants in the PISCF documents so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,
    - it should be made optional
    - it should be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed,
    - and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,
    - optional future research is made into a separate and explicit consent item in the Informed Consent section of the Main PISCF, with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research

The PISCF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. 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/

- 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.

7. Suitability of the clinical trial sites facilities

- No considerations raised by NREC

8. Suitability of the investigator

- No considerations raised by NREC

2022-502122-41-00 SM-5

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 & II

- **NREC-CT Decision:**

Favourable

2023-507353-15-00 SM-3

Institutions: Mater Misericordiae University Hospital, Connolly Hospital

Study title: An open-label extension trial of the long-term safety and efficacy of BI 1015550 taken orally in patients with idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF) (FIBRONEER™-ON)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

Favourable

2022-502282-24-00 SM-19

Institutions: Beaumont Hospital

Study title: A Multicenter, Open-label, Long-term, Safety, Tolerability, and Efficacy Study of XEN1101 in Subjects Diagnosed With Epilepsy (X-TOLE4)

Dossiers Submitted: Part II

- **NREC-CT Decision:**

  Favourable

2024-512536-29-00 SM-3

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 & 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 the inclusion of "an interview around your thoughts regarding ending your life" on pg. 12 of the L1-1_SIS and ICF_Novartis_CVHB937B12201_Main ICF_V01-02IRL02-00_Final_TC is not well foregrounded for participants and requested the following:
  - That a more sensitive approach is used and that a brief additional supporting narrative/explanation is added prior to the wording "an interview around your thoughts regarding ending your life".
  - The rationale for the interview should be described, with reference to the updated safety information detailing the inclusion of Columbia Suicide Severity Rating Scale on pg. 14 of the L1-1_SIS and ICF_Novartis_CVHB937B12201_Main ICF_V01-02IRL02-00_Final_TC.
- The NREC-CT noted that that the word 'photograph' is repeated on pg. 19 (section 13) of the L1-1_SIS and ICF_Novartis_CVHB937B12201_Main ICF_V01-02IRL02-00_Final_TC and requested that this is amended.
- The NREC-CT noted that section 13.2 on pg. 21 of the L1-1_SIS and ICF_Novartis_CVHB937B12201_Main ICF_V01-02IRL02-00_Final_TC describes the anonymisation of 'coded data' and requested that participants are informed that this will occur after completion of the study. Participants should also be

informed as to specific exclusions (e.g. in the case of photographs or audio recordings) so that they are aware of the limitations of the anonymisation process.
- The NREC-CT noted that the section on artificial intelligence (AI) has been deleted from pg. 20 of the L1-1_SIS and ICF_Novartis_CVHB937B12201_Main ICF_V01-02IRL02-00_Final_TC and requested clarification as to whether AI will be used during 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.

2024-515526-89-00 SM-1

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

Study title: A Randomized, Open-Label, Multicenter, Phase 2 Study Evaluating the Efficacy and Safety of Zilovertamab Vedotin (MK-2140) Plus R-CHP versus Polatuzumab Vedotin plus R-CHP in Treatment-naive Participants with GCB Subtype of Diffuse Large B Cell Lymphoma (DLBCL)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

  Favourable

2024-517500-11-00 SM-4

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

Study title: A Phase 1b/2a Dose Escalation Study of BOLD-100 in Combination with FOLFOX Chemotherapy in Patients with Advanced Solid Tumours

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

  Favourable

- **AOB:**

- None