

National Research Ethics Committee

NREC-CT Meeting

10th September 2025

Attendance

Name	Role
Prof David Smith	Deputy Chairperson, NREC-CT D
Dr Christina Skourou	Deputy Chairperson, NREC-CT D
Prof Andrew Green	Committee Member, NREC-CT D
Prof Cathal Walsh	Committee Member, NREC-CT D
Prof Deirdre Murray	Committee Member, NREC-CT D
Dr Geraldine O'Dea	Committee Member, NREC-CT D
Prof Lina Zgaga	Committee Member, NREC-CT D
Dr Mary McDonnell Naughton	Committee Member, NREC-CT D
Prof Geraldine O'Sullivan Coyne	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
Ms Patricia Kenny*	Project Officer, National Office for RECs

*Drafted minutes

Apologies: David Brayden, Deirdre MacLoughlin, Jeff Moore, Chanel Watson, Gerry Daly

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2025-521293-34-00
- 2024-513676-18-00
- 2024-517136-21-00
- 2024-511458-32-00 SM-4
- 2023-504957-11-00 SM-12
- 2023-503765-37-00 SM-8
- 2022-501254-10-00 SM-36
- 2023-508636-61-00 SM-27
- 2023-505650-17-00 SM-3
- AOB

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- The Chair welcomed the NREC-CT D.
 - The minutes from the previous NREC-CT D meeting on 30th July 2025 were approved.
 - The NREC Business Report was discussed and noted.
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Applications

2025-521293-34-00

Institutions: Our Lady of Lourdes Hospital, St Vincent's University Hospital

Study title: A Seamless Phase 2a/2b, Randomized, Double-Blind, Placebo- and Active-Controlled, Multiple-Arm, Multiple-Stage, Adaptive Study Evaluating the Efficacy and Safety of LAD191 in Adults With Moderate-to-Severe Hidradenitis Suppurativa

Dossiers Submitted: Part I & II

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

- **Additional Information Required RFI**

Part II Considerations

1. Financial arrangements

- The NREC-CT requests that Section 2 of the Compensation for trial participants be updated to provide clear and detailed information on how compensation to participations will be managed and if there are requirements such as submitting receipts. Additionally, the Committee requests that the sponsor consider providing monetary compensation to participants to help offset additional expenses they may incur as a result of taking part in the clinical trial - such as childcare costs of loss of income due to time taken off work.

2. Recruitment arrangements

- The NREC-CT notes that references on pg. 3 and 4 of the Study Brochure and pg. 5 of the Flip chart regarding removing one of the LAD arms and introducing adalimumab, is confusing. The Committee requests that these sections be simplified or explained more clearly.

3. Subject information and informed consent form

- Standard Consideration: 1. 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. 2. All documentation provided in response to RFI should be 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 SIS and ICF Main pg 2, pg 3, pg 6 be updated/rewritten to clarify that home visits are allowed in Ireland.
- The NREC-CT requests that SIS and ICF Main pg 5 last bullet point re. photographs be updated to detail of the three options participants have i.e. none to be taken, taken for research, taken with option to be shared in publications/conferences.

- The NREC-CT requests that the consent sections for optional components of the study including photographs and left over blood samples should be moved to a separate page of the SIS and ICF Main with separate participant information section and signatures section, so they are distinct from the main consent to participate in the research and it is clear to the participant that these aspects are optional. The Committee also requests that Yes/No option also be provided for participants to give explicit consent or not to photographs being “distributed, published, or otherwise used by the Sponsor and its ePartner(s)/Collaborator(s), for treatment awareness and other related purposes ...”
- The NREC-CT notes the Recruitment arrangements document section 4.1 states *“In the event that a participant is unable to write/read, consent may be provided and recorded using alternative appropriate tools, with the presence of an impartial witness (the number of witness will be determined based on Country regulation). Impartial witness will be asked to participate in the informed consent discussion and sign and date the informed consent document”* however the SIS and ICF Main doesn't have a witness signature section. The Committee requests that the SIS and ICF Main be updated to include a space for witness signature and a note explaining in which instances this may be used.
- The NREC-CT requests that the SIS and ICF Main pg. 14 Section 1.7 be updated to provide clear detail in relation to reimbursement including if receipts are required and how reimbursement it will be paid.
- The NREC-CT notes that SIS and ICF Main pg. 1 states “Fortrea is contracted by the Sponsor to manage the research study for them”. The Committee requests that the SIS and ICF Main be updated to specify the exact role and responsibilities.
- The NREC-CT advises that reference on SIS and ICF Main pg. 3 to removal of one of the LAD arms and introduction of adalimumab is unclear and confusing. The Committee requests that a figure or diagram be added to help clarify.
- It was unclear to the NREC-CT from SIS and ICF Main pg. 3 if they have understood correctly that some participants will change therapy three times, at different times throughout the trial. Please clarify if this is correct. The Committee requests that the SIS and ICF Main be updated to clearly explain this aspect of the study.
- The NREC-CT notes that the information in the Study Brochure pg. 2 and Flipchart pg. 5 in relation to the dosing per arm is different to that presented in SIS and ICF Main pg 2 for example “LAD191 600 mg every week for the first 4 weeks then 600 mg every 2 weeks” whereas the Study Brochure and Flipchart only refers to every 2 weeks dose. The Committee requests that the Study Brochure and Flipchart be updated to be align. The Committee also requests that the SIS and ICF Main pg 2 be updated to clearly state the number of injections administered at each visit, as it is understood that some visits will involve four injections while other will involve two.
- The NREC-CT notes SIS and ICF Main pg. 3 *“If you were receiving LAD191 during the first treatment period (Weeks 0 to 16), you will continue on the same dose for the second treatment period (Weeks 16 to 32) unless the dose you were receiving was dropped after the early analysis. In this case, if you have not started the second treatment period, as well as for those participants that received placebo or adalimumab during the first treatment period, you will receive the highest dose*

available of LAD191 during the second treatment period” and “If you are receiving a dose of LAD191 that is dropped after the early analysis due to safety concerns, you will be withdrawn from this treatment. You will not be able to restart study drug, even if you did not directly experience any health issues”. The Committee found these statements unclear and noted that both refer to the discontinuation of a specific dose of LAD191 following early analysis. The Committee requested that SIS and ICF Main pg 3 paragraph 4 be revised to clarify the rationale for withdrawing participants from treatment and prevent re-initiation of the study drug, while also explaining why participants listed in paragraph 3 may receive the highest available dose of LAD191.

- The NREC-CT, while noting reference to it being reimbursed on pg 14 SIS and ICF Main, requests that SIS and ICF Main pg 3 last paragraph be updated to be clear to participants, from the outset, that they will be reimbursed for topical antiseptic required for use during the study.
- The NREC-CT, requests that the SIS and ICF Main pg. 5 be updated to indicate how long the daily skin pain questionnaire will take to complete.
- The NREC-CT requests that SIS and ICF Main pg. 13 wording regarding data collection in the event of pregnancy be revised to emphasise that this data collection is optional. It should also be clearly stated that participants and female partners of male participants will be asked to provide separate consent for this data collection by signing an additional informed consent form.
- The NREC-CT requests that SIS and ICF Main consent section pg 21 reference to HIV testing be updated to include testing for Hep, B, C and TB also.

2024-513676-18-00

Institutions: Tallaght University Hospital, Mater Misericordiae University Hospital

Study title: A Phase 3, Open-Label, Multicenter, Extension Study of Acoramidis in Patients with Newly Diagnosed Variant Transthyretin Amyloid Cardiomyopathy (ACT-EARLY OLE)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Financial arrangements

- The NREC-CT notes that the SIS and ICF Main Section 8 pg. 12 description of the reimbursement processes is unclear and could give rise to confusion. The Committee requests that the SIS and ICF Main be updated to clarify
 - how compensation for all expenses will be paid to the participant.

- if the debit card for travel expenses is only for travel expenses and not for any other expenses such as food or accommodation
- how this debit card could be used by the Participant.

The Committee also requests that the sponsor consider reimbursing carers/companions who attend hospital visits with the participant.

2. Subject information and informed consent form

- Standard Consideration: 1. 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. 2. All documentation provided in response to RFI should be presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software
- The NREC-CT noted that information provided in the SIS and ICF Main did not clearly indicate to participants whether future research was optional or part of the current study. The Committee requested that SIS and ICF Main be reviewed and reviewed to explicitly clarify this distinction.
- The NREC-CT notes reference to *“A separate consent will be requested at that time for any additional research outside the scope of this study”* pg 21 SIS and ICF Main. The Committee advises that it should be optional for participants to consent to be contacted in the future about additional research outside of scope of this study, so an optional consent statement for this should be added to the consent form.
- The NREC-CT requests that sentence on pg. 12 SIS and ICF Main *“You will be asked to indicate your consent for use PCS at the end of this document”* be updated to specify that the participant will be asked to consent to the use of their data by PCS for the purpose of reimbursement.
- The NREC-CT requests that SIS and ICF Main pg 17 *“Encoded personal data about you that is collected during the study may be kept securely to be used in future scientific research activities that are unanticipated but will be consistent with the general research purposes for which the personal data were originally collected and subject to appropriate safeguards and may also be shared with other researchers”* be updated to include reference to samples being retained for future use as well.
- The NREC-CT requests that SIS and ICF Main Section 5 pg. 10 be updated to provide more detail on contraception including listing of acceptable types of combined oral contraceptive pills and progestogen only pills.
- The NREC-CT requests that the SIS and ICF Main pg. 10/11 be updated to provide more clarity around the importance of contraception in this trial and more information around the actual contraception requirements. The Committee also requests that a Pregnancy Follow up ICF be provided for review for the participant or female partner of male participant to be provided with relevant information and consent to the collection of data in the event of pregnancy.
- The NREC-CT notes the SIS and ICF Main Section 12 pg. 14 *“The Sponsor has no plans to compensate you if you are hurt or become ill because of this study, or pay for any lost wages, disability or discomfort you may have from participating in*

this study. Neither the Sponsor nor the Study Doctor has a program in place to provide other compensation in the event of an injury.”. The Committee stated that this wording is not acceptable as the Sponsor is required to take out an insurance policy to cover compensation. The Committee requests that the SIS and ICF Main be updated to remove the wording above and replaced with “Any compensation paid for any injury caused by taking part in this Study will be in accordance with local guidelines and legal requirements. For further guidance Clinical Trial Compensation Guidelines please see SIG-10-03-Indemnity-and-Insurance-Arrangements-for-Clinical-Trials-Health-Research-Interactive.pdf and <https://www.ipha.ie/clinical-trials-and-regulatory-affairs/clinical-trials/>

3. Suitability of the clinical trial sites facilities

- The NREC-CT notes that Tallaght University Hospital SSF Section 6 states that the pharmacy services for this study will be provided by McGreal’s Pharmacy Blessington. However, it is unclear to the Committee whether this implies that participants from Tallaght University Hospital will need to attend McGreal’s Pharmacy to receive the study drug. The Committee requests that Tallaght University Hospital SSF be updated to clarify this point. If drug dispensation will occur at McGreal’s Pharmacy, the Committee also requests that the SIS and ICF main be updated to inform participants that they may need to travel to a separate location to collect the study drug.
- The NREC-CT notes that the study population will have been participants in the prevention study AG10-501 who have developed cardiomyopathy or a combination of cardiomyopathy and polyneuropathy. The Committee noted the PI in Tallaght is a neurologist and that all participants will have cardiomyopathy. The Committee requested clarity as to whether there will be involvement of a cardiologist in the follow up of these participants during the up to five years of this study. Please update the Tallaght University Hospital SSF to clarify what arrangements will be made for the appropriate cardiological follow up of participants at the Tallaght site as these participants may deteriorate and require more intensive treatment and follow up.

2024-517136-21-00

Institutions: St Vincent’s University Hospital, St James’s Hospital, Cork University Hospital

Study title: A Phase 3, Randomized, Open-label Study of Belzutifan + Zanzalintinib Versus Cabozantinib in Participants with Advanced RCC who Experienced Disease Recurrence During or After Prior Adjuvant Anti-PD-1/L1 Therapy (LITESPARK-033)

Dossiers Submitted: Part I & II

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

- **Additional Information Required RFI**

Part II Considerations

1. Compliance with national requirements on data protection

- The NREC-CT noted Compliance with national Data Protection pg. 4/5: *“Data at the clinical trial sites...at least 25 years. The sponsor may retain the data for longer, up to the life of associated medicinal product plus 35 years.”*. The Committee requested the Compliance with National Data Protection document be updated to provide justification for the 35 years requirement, and also the legal basis for same.
- The NREC-CT noted Compliance with national Data Protection pg. 4/5: *“It may not be possible to delete data that is associated with the clinical trial.”*. The Committee requested the Compliance with National Data Protection document be updated to clarify this statement with reasons why it may not be possible to delete data.

2. Subject information and informed consent form

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- No future research
- The NREC-CT requests that the reference on page 10, section 10 of the ICF Main Consent to *“...genetic variation in CYP2C19 and UGT2B17...”* be revised to include a plain English explanation of this paragraph. Specifically, the consent form should clarify what these gene codes refer to and explain their relevance in a way that is understandable to a layperson
- The NREC-CT were unclear why the paragraph ICF Main pg. 12, left-hand column near top is bolded. Please clarify. The Committee requests that this section is rewritten in plain English clearly explaining the meaning and relevance of the information in a way that is easily understandable to participants. The Committee also request that the heart related side effects are listed and explained
- The NREC-CT requests that ICF Main pg. 13 left-hand column which lists uncommon side-effects of zanzalintinib be updated to include more detailed information about the side effect *“sudden death”*
- The NREC-CT requests that ICF Main pg. 21 section 24, be updated to clarify why it may be necessary for the trial site to retain participant information for more than 25 years, and to outline the legal basis for this extended retention period.
- The NREC-CT requests that ICF Main consent Page 22, section 26 be updated to provide full contact details for the Irish Data Protection Commissioner.
- The NREC-CT requests that ICF Main pg. 2 *“The trial doctor may be on the committee but will not participate in the review of this trial”* be revised to clarify that any individual with a conflict of interest will be required to excuse themselves from the meeting during any discussions or decisions related to the trial.
- The NREC-CT requests that the ICF Main consent pg 2 Section 1 *“A clinical trial is a type of research designed to learn how our bodies respond to drugs, vaccines or*

other treatments” be updated to *”A clinical trial is a type of research that tests how well a medical treatment, drug or procedure works in people”*

- The NREC-CT requests that the ICF Main consent pg. 3 Section 3 description of the purpose of the trial be updated to include reference to seeking to help people live longer or slowing down the growth or spread of the cancer. The Committee would suggest using similar language to that in the recruitment brochure and plain language protocol.
- The NREC-CT requests that the ICF Main consent pg. 3 Section 4 be updated to include the number of people being recruited from Ireland.
- The NREC-CT requests that the ICF Main consent pg. 3/4 Section 6 be updated to include the approximate length of time each visit will take.
- The NREC-CT requests that the ICF Main consent pg. 5 be updated to include timelines into the diagram, where appropriate.
- The NREC-CT requests that the ICF Main consent pg. 11 and 12 be updated to include a lay language explanation of the term “monotherapy”.
- The NREC-CT requests that ICF Main consent pg. 20 be updated to include detail of EU Data Protection Representative.
- The NREC-CT requests that the ICF Optional Greenphire pg 5 be updated to remove the first two consent statements which are not relevant to this ICF.

3. Suitability of the clinical trial sites facilities

- The NREC-CT notes that St Vincent’s University Hospital SSF advises that the exposure to ionising radiation is not above what is required for standard care however, St James’s Hospital and Cork University Hospital advise there will be an increase in ionising radiation. Please confirm whether the information in the Site Suitability Forms for St James’s Hospital and Cork University Hospital in relation to exposure to ionising radiation is not above what is required for standard care is correct or update the SSF as necessary. Please justify why the exposure to ionising radiation in St James’s Hospital and Cork University Hospital would be above that in the St Vincent’s University Hospital. The Committee also request that the ICF Main be updated to detail if the exposure to ionising radiation is above standard of care at specific sites.

2024-511458-32-00 SM-4

Institutions: Children’s Health Ireland Crumlin

Study title: A multicenter study to evaluate the efficacy, safety, tolerability, and pharmacokinetics of filgotinib, with single arm induction and maintenance, in pediatric subjects (8 to <18 years of age) with moderately to severely active ulcerative colitis.

Dossiers Submitted: Part I & II

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

- **Additional Information Required RFI**

Part II Considerations

1. Subject information and informed consent form

- Standard Consideration: 1. 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. 2. All documentation provided in response to RFI should be 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 Assent Young Adult Readers be updated:
 - Page 3, “*if you do not pass the first tests, you may be allowed...*” be rephrased to “*The results of these tests will tell us if this study may be suitable for you*” as the current wording gives the sense that child is failing something.
 - Page 4: “*There are other medical reasons you might not be able to join*”, be rephrased to “*There are other medical reasons this study may not be suitable for you* “ as the current wording gives a sense of exclusion.
 - Page 5: “*the doctor may let you continue...*”, be rephrased to “*the doctor may ask you to continue*” as the current wording is too paternalistic,
- The NREC-CT were unclear if those participants already enrolled on the trial will have their doses adjusted and be reconsented to the trial. Please clarify and advise the timeframe for this reconsenting.

2023-504957-11-00 SM-12

Institutions: Tallaght University Hospital, St Vincent’s University Hospital

Study title: A Phase 3, Randomized, Open-label Study of MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) That Progressed On or After Prior Treatment with One Nextgeneration Hormonal Agent (NHA)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Subject information and informed consent form

- If applicable, the Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT requests that the Optional Limited Screening Consent pg 10 consent item 3 be updated to make it clear that access to medical records is specific to those recruited to the trial.

2023-503765-37-00 SM-8

Institutions: St James's Hospital

Study title: An Extension Study Assessing the Long-term Safety and Efficacy of Etranacogene Dezaparvovec (CSL222) Previously Administered to Adult Male Subjects with Hemophilia B

Dossiers Submitted: Part II

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

- **Additional Information Required RFI**

Part II Considerations

1. Subject information and informed consent form

- Standard Consideration: 1. 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. 2. All documentation provided in response to RFI should be 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 SIS and ICF Main be updated to include the name Block Clinical as the third-party company coordinating travel and reimbursement.

2022-501254-10-00 SM-36

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

Study title: A Multicenter, Open-label, Phase 3 Study to Evaluate the Long-term Safety and Efficacy in Participants who are Currently on Treatment or in Follow-up in Studies That Include Pembrolizumab

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-508636-61-00 SM-27

Institutions: St Vincent's University Hospital, Beaumont Hospital

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Program to Evaluate the Efficacy and Safety of Tulisokibart in Participants with Moderately to Severely Active Crohn's Disease

Dossiers Submitted: Part II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Subject information and informed consent form

- Standard Consideration: 1. 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. 2. All documentation provided in response to RFI should be 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 advised that due to the complexity of trial activities with the addition of Study 2 the Brochure and Patient letter would benefit from the inclusion of a Study Design Schema or Process Flow Diagram clearly marking out the life cycle of Study 1 (1.4 yeas), Study 2 (0.5 years) and the Extension period (3 years).
- The NREC-CT notes that the Recruitment Doc Brochure; pg.8 states "Those who are still minors will review and sign a similar form called an assent form instead of an ICF." The Committee requests that this sentence be removed as participants will be from 18 – 80.

2023-505650-17-00 SM-3

Institutions: Children's Health Ireland Crumlin

Study title: A Randomized, Double-blind, Placebo-controlled Clinical Study to Evaluate Mavacamten in Adolescents (age 12 years to < 18 years) with Symptomatic Obstructive Hypertrophic Cardiomyopathy

Dossiers Submitted: Part I & II

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

- **Additional Information Required RFI**

Part II Considerations

1. Financial arrangements

- The NREC-CT notes the Compensation trial participants document has been updated to advise that there will be items provided to participants to help support patient comfort. The Committee advised that these items must not contain any study branding or logos to avoid participants condition being shown publicly.

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- **AOB:**
 - None