National Research Ethics Committee

NREC-CT Meeting

14th January 2026

Attendance

Name	Role
Dr Cliona McGovern	Chairperson, NREC-CT B
Prof Colm O'Donnell	Deputy Chairperson, NREC-CT B
Ms Serena Bennett	Committee Member, NREC-CT B
Dr Karina Halley	Committee Member, NREC-CT B
Ms Jasmine Joseph	Committee Member, NREC-CT B
Dr Ciaran Lee	Committee Member, NREC-CT B
Dr Andrew Lindsay	Committee Member, NREC-CT B
Dr Niall McGuinness	Committee Member, NREC-CT B
Prof. Seamus O'Reilly	Committee Member, NREC-CT B
Mr Edward McDonald	Committee Member, NREC-CT B
Ms Evelyn O'Shea	Committee Member, NREC-CT B
Dr Peadar Rooney	Project Officer, National Office for RECs
Dr Jane Bryant	Project Officer, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Ms Rachel McDermott	Project Administrator, National Office for REC's
Ms Chita Murray	Programme Manager, National Office for RECs
Ms Deirdre Ni Fhloinn*	Project Officer, National Office for RECs

Drafted minutes

Apologies: Dr John Hayden, Dr Áine de Róiste, Dr John Wells, Ms Ann Twomey

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2025-523877-40-00
- 2025-522580-15-00
- 2025-524111-37-00
- 2024-516315-24-00 SM-3
- 2023-510292-65-00 SM-5
- 2023-504957-11-00 SM-13
- 2025-520488-42-00 SM-1
- 2024-515451-38-00 SM-16
- 2024-513958-29-00 SM-2
- AOB

- The Chair welcomed the NREC-CT B.
  - The minutes from the previous NREC-CT B meeting on 26th November 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2025-523877-40-00

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

Study title: TREAT-EC (Tirzepatide in the treatment of endometrial cancer) - a clinical trial

Dossiers Submitted: Part I & II

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

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS

- It was noted that participants are eligible for the clinical trial if they are unsuitable for or refuse surgical intervention (Standard of Care) due to the increased risk of surgical complications associated with their BMI and other comorbidities. Please justify why progression to surgery due to weight loss is not an outcome of the trial.
- It was noted that the inclusion criteria describes '*Females with a BMI > 27 kg/m2 at high risk of surgical complications due to co-morbidities or BMI > 30 kg/m2 with no comorbidities and have decided not to opt for immediate surgical intervention (having been advised that this is the standard of care)* (Protocol pg. 8) . Please clarify whether a participant who has significant weight loss during the trial and becomes eligible for surgery will be referred for a surgical opinion during the trial, or if referral for surgery will be delayed until the 1-year treatment is completed.
- It was noted that '*Previous treatment with GLP-1 receptor agonists within the last 3 months*' is listed in the exclusion criteria (Protocol pg.19), however it is not explicitly stated in the Protocol that treatment with GLP-1 receptor agonists or other weight loss medication during the study period are prohibited. Please confirm whether the use of GLP-1 receptor agonists and other weight loss medications during the study period are prohibited in the Protocol and in the Main PISCF.
- It was noted that the study design prohibits treatment for obesity for participants in the control arm (Protocol pg.11). Please justify the study design in light of ethical concerns relating to the inaccessibility of obesity treatment for this patient cohort.

Part II Considerations

1. Financial arrangements

- The NREC-CT noted that neither participant nor carer will be reimbursed for expenses despite the high medical and time burden (e.g. completion of questionnaires) associated with both arms of the clinical trial (pg.1 Compensation Form). The Committee requested that participants and carers are reimbursed for all reasonable out of pocket expenses to ensure equity in access to clinical trials across all socioeconomic groups and, if included, that it is elucidated in the Compensation Form and Main PISCF.

2. Subject information and informed consent form

Standard Consideration:

1. Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
2. All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents,

including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.

- The NREC-CT noted that the Main PISCF lacks information regarding the potential role of GLP-1 agonists in reproductive function and cancer suppression as outlined in the protocol (pg. 10). The Committee requested that the Main PISCF is updated to include the rationale for the use of the study drug for endometrial cancer (EC), including the potential roles in both reproductive function and cancer suppression, as well as investigational effects that weight loss may have on EC.
- The NREC-CT noted that the investigator must record information on pregnancy, that the participant must be followed to pregnancy outcome and that it may be necessary to monitor the development of the newborn for an appropriate period post-delivery (Protocol pg. 39). The Committee requested that this information is also provided in the Main PISCF, to ensure that the participant is fully informed.
- The NREC-CT noted that patients will be monitored at Week 12, 24 and 36 for progression of their endometrial cancer and that if there is progression from stage 1A , that they will be seen urgently and advised regarding surgical management (Protocol pg. 32). The Committee requested that this assurance is also provided in the Main PISCF such that the participant is fully informed.
- The NREC-CT noted that the Mirena Coil has not been studied in women over 65 years of age (Mirena SmPC, pg.3). The Committee requested that this information is provided in the PISCF such that the participant is informed.
- The NREC-CT noted that the risk of expulsion of the Mirena Coil is increased in women with a higher BMI (Mirena SmPC pg.6). The Committee requested that further information regarding the risk of expulsion and associated information as per the SmPC be communicated in the Main PISCF (e.g. signs of expulsion, checking threads, need for alternative contraception).
- The NREC-CT noted that while low mood and depression are listed as common side effects of the Mirena Coil in the Main PISCF(pg. 12), participants are not advised to contact their general practitioner (GP) in case of mood changes and depressive symptoms as outlined in the Mirena SmPC (pg.7). The Committee requested that the Main PISCF is updated to encourage participants to contact their GP in case of mood changes and depressive symptoms.
- The NREC-CT noted the absence of a GP Letter in the application submission. While not a mandatory document for application submission, the Committee requested that a GP letter be submitted for review.
- The NREC-CT noted that the Main PISCF lacks information regarding the role of Mirena Coil in both reproductive function (e.g. contraceptive effects) and cancer suppression as outlined in the Protocol (pg. 10). The Committee requested that the Main PISCF is updated to include the rationale for the use of Mirena Coil for endometrial cancer (EC) in plain English suitable for a lay audience, including its potential dual role in both reproductive function and cancer suppression.
- The NREC-CT noted that participants are eligible for the clinical trial if they are unsuitable for or refuse surgical intervention (Standard of Care) due to the increased risk of surgical complications associated with their BMI and other

comorbidities (Protocol pg. 8). The Committee requested that this information is included in the PISCF such that the participant is fully informed.

- The NREC-CT noted a lack of information regarding alternative treatment options (e.g. External Beam Radiation Therapy or Brachytherapy) in the Main PISCF. The Committee requested that information be provided to the participant on alternative treatment options available to them, if applicable.
- The NREC-CT noted that participants are required to fast on specific visits but that the rationale for same is not explained (Main PISCF pg. 3-7). The Committee requested that the rationale for fasting be included in the Main PISCF such that the participant is fully informed.
- The NREC-CT noted that the Main PISCF (pg.9) states that the collection of tissue samples will involve removal and reinsertion of the Mirena Coil, but that this contradicts the Protocol (pg. 20) which states that the procedure method is at the discretion of the Principal Investigator (PI), and that removal of the Mirena Coil may not be required for tissue sample collection. The Committee requested that the Main PISCF is updated to clarify that the removal / reinsertion of the Mirena Coil for tissue sampling is at the discretion of the PI and will be decided on a case by case basis, if applicable. Furthermore, the Committee suggest that any risks associated with the removal / reinsertion of the Mirena Coil be communicated in the Main PISCF if applicable.
- The NREC-CT noted that the requirement for the additional tissue biopsies is not well explained in the Main PISCF (pg.9: 'These samples will be tested to see how quickly the cells in the sample are multiplying'). The Committee requested that this section is reworded to clearly elucidate the rationale for additional tissue biopsies (i.e. to monitor disease progression).
- The NREC-CT noted that 'Previous treatment with GLP-1 receptor agonists within the last 3 months' is listed in the exclusion criteria (Protocol pg.19). However, it is not explicitly stated in the Protocol whether treatment with GLP-1 receptor agonists or other weight loss medication during the study period is prohibited. Please confirm in the PISCF whether the use of GLP-1 receptor agonists and other weight loss medications during the study period are prohibited.
- The NREC-CT noted that two consent options for the future use of data in the Main PISCF (pg. 22), whereby one option is limited to 'the field of endometrial cancer and/or the effect of GLP type medication' while the other option is for 'future research related to the current clinical trial'. The Committee requests that the latter consent option (relating to both UCD and the Ludwig Institute) is removed such that future research is confined to a specified disease, related diseases or drug under study in this trial, thus constituting broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
- The NREC-CT noted that page 23 of the Main PISCF includes a witness/ translator signature line. The NREC-CT requests that information be added to the PISCF explaining the context when a witness signature would be needed (as per CTR: Annex I,L 62(b)). Furthermore, the Committee require confirmation that a translator will not be utilised without the provision of approved translated documents to the participant.

- The NREC-CT noted that page 23 of the Main PISCF includes a legal representative/guardian signature. The NREC-CT requests this section be removed as neither individuals lacking capacity nor minors are listed for recruitment (Recruitment Arrangement Form pg.4/5)

2025-522580-15-00

Institutions: Beaumont Hospital

Study title: A phase 2b, randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of Usnoflast administered to adult subjects with Amyotrophic Lateral Sclerosis (ALS)

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:

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

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

- The NREC-CT noted that the future use of data / samples is not described in line with regulations / best practice in the Main PISCF (pg 11, 22 and 23), OLE PISCF (pg 11, 19) and Biological Samples Form (pg. 6). The NREC-CT requested that all documents are aligned and 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,
- it should be optional
- 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 while the Recruitment Form (pg.2) states that adults lacking capacity will not be recruited, there is a consent section for both an Impartial Witness and a Legally Acceptable Representative (LAR) in all PISCF's. The Committee requested clarification on the circumstances in which a LAR would be required or that the consent sections for "Legally Acceptable Representatives" be removed from all relevant PISCF's if applicable.
- The NREC-CT requested that all PISCF's be updated to provide information about the availability of the clinical trial results at the end of the trial and location of same.

2025-524111-37-00

Institutions: Mater Misericordiae University Hospital

Study title: Phase 1/2A Study of OTP-01, a Dual Paratopic PD-1/VEGFR2 Antibody, in Patients with Advanced Solid Tumors

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

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

- The NREC-CT noted that the Compliance for with Use of Biological Samples Form (pg. 4) states that newly collected samples will not be stored for future use, which contradicts both the PISCF and Protocol. The Committee requested that the Compliance for with Use of Biological Samples Form is updated to align with all other relevant documentation.

2. Financial arrangements

- The NREC- CT noted that carers of participants have not been included for travel, accommodation and meal expense reimbursement in the Compensation Form (p1). The Committee requested that reimbursement of travel, accommodation and meal expenses are considered for carers of participants and, if included, that it is elucidated in the Compensation Form and PISCF's.

3. Subject information and informed consent form

Standard Consideration:

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

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

- The NREC-CT noted that the risk section related to the IMP is insufficiently detailed (Main PISCF pg14). The Committee requested that the risk section is updated to explicitly convey to prospective participants, in plain English suitable for a lay audience, that this dual-paratopic IMP carries a cumulative or synergistic risk that is unknown in comparison to monotherapy or combination therapy targeting the same PD-1 and/or VEGFR2 pathways.
- The NREC-CT noted that the 'Background and Purpose' Section of the Main PISCF lacked a clear scientific rationale for the use of an IMP simultaneously targeting both the PD-1 and VEGFR2 pathways. The Committee requested that a clear rationale for the use of the paratopic IMP is included in the Main PISCF, using simple lay language, such that the prospective participant is fully informed
- The NREC-CT noted the Sponsor will only cover 'medical costs not covered by participant insurance or other programs', and that all costs related to standard of care and adverse effects will be charged to the participants insurance. (Main PISCF pg. 18) The Committee requested confirmation that all study costs associated with participation in the clinical trial will be paid by the Sponsor and the PISCF is updated to reflect that no costs to the participant or their insurance will be incurred, to ensure equity in access to clinical trials across all socioeconomic groups. Furthermore, please ensure that all insurance policies which are required under national law in the Republic of Ireland will be in place.

- The NREC-CT noted that the information regarding the compulsory biopsy (if archival tissue is not available) and optional matched tumour biopsies is unclear in the PISCF (Main PISCF pg.4). The Committee requested that the PISCF is updated to clearly outline the circumstances in which a tumour biopsy is mandatory and to explicitly differentiate this from the option to provide matched tumour biopsies.
- The NREC-CT noted that the future use of data / samples (including genetic research) is not described in line with regulations / best practice on pg. 13 of the Main PISCF. The NREC-CT requested that future use of samples / personal data is sufficiently explained to participants in the PISCF documents so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,
    - it should be 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/

2024-516315-24-00 SM-3

Institutions: Centre for Eye Research Ireland

Study title: A phase III, randomized, double-masked, placebo controlled, parallel-group, multicenter study of the safety and efficacy of OT-101 (Atropine Sulfate 0.01%) in treating the progression of myopia in pediatric subjects

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-510292-65-00 SM-5

Institutions: St James's Hospital

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Axatilimab (INCA034176) and Corticosteroids as Initial Treatment for Chronic Graft-Versus Host Disease

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

1. Subject information and informed consent form

Standard Consideration:

Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
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- The NREC-CT noted that several of the side effects for Axatilimab listed in Main ICF (pg. 14) have been reclassified (e.g. side effects that were once listed as 'very common' have been transferred to the 'common' section, and that several side effects that were once listed as 'rare' have been removed) but that the explanation for same is incomplete when referenced against changes to the Investigator Brochure. The Committee requested an explanation regarding the reclassification of risks.
- The NREC-CT noted that page 25 of the Main PISCF includes a witness signature line. The NREC-CT requests information be added to all relevant PISCF's explaining the context where a witness signature would be needed (as per CTR: Annex I,L 62(b)).
- The NREC-CT noted that information regarding dosing has been removed from the GP Letter (pg. 1). The Committee requested a justification for removal of this detail.
- The NREC-CT noted that the future use of data / samples (including genetic research) is not described in line with regulations / best practice on pg. 13 of the Main PISCF. The NREC-CT requested that future use of samples / personal data is sufficiently explained to participants in the PISCF documents so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,
  - it should be made optional

- 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/

2023-504957-11-00 SM-13

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

Study title: MK-5684-004: A Phase 3, Randomized, Open-label Study of Opevesostat Versus Alternative Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) That Progressed On or After Prior Treatment With One Next-generation Hormonal Agent (NHA) (OMAHA-004)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2025-520488-42-00 SM-1

Institutions: Connolly Hospital, Our Lady of Lourdes Hospital, St Vincent's University Hospital, Tallaght University Hospital, Cork University Hospital, University Hospital Galway

Study title: A Phase 2b Randomized, Double-blind, Placebo-controlled, Parallel-Group Study to Assess Efficacy and Safety of Verekitug (UPB-101) in Participants with Moderate-to-Severe Chronic Obstructive Pulmonary Disease (COPD)

Dossiers Submitted: Part I & II

- NREC-CT Decision:

- Favourable

2024-515451-38-00 SM-16

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

Study title: A Phase 3, Multicenter, Randomized, Double-Blinded, Placebo-Controlled, Parallel-Arm Study Followed by an Open-Label Arm to Evaluate the Efficacy and Safety of Efgartigimod IV in Adult Participants With Primary Immune Thrombocytopenia

Dossiers Submitted: Part II

- **NREC-CT Decision:**

- Favourable

2024-513958-29-00 SM-2

Institutions: University Hospital Galway, Turloughmore Medical Centre, Centric Health Navan Road, Griffin Daly Medical Centre, St James's Hospital

Study title: Semaglutide for people with obesity and resistant hypertension (SUPPORT): a pilot, randomized, parallel-group, integrated, multicentre clinical trial

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

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Part I Considerations

1. A lack of rationale and objectives for the extension study was noted in the Protocol. Please provide a clear rationale and outline of the objectives of the extension study in both the Protocol and Main PISCF.
2. It was noted that the procedures for unblinding are not sufficiently detailed in the Protocol. Please provide further details on the unblinding process (including but not limited to; the rationale for unblinding participants in the extension phase, when the unblinding will occur, whether the unblinding will be staggered between participants, when the database lock will occur) as per CTR ANNEX I, section D.
3. It was noted that '*Participants who received Semaglutide in the main trial will transition to usual care. Usual care may include discontinuation of Semaglutide or continuation on a self-funded basis, as determined by the participant in consultation with their treating physician'* (Protocol Pg. 76). To ensure equity in access to clinical trials across all socioeconomic groups please remove the financial burden to any prospective study participant and confirm that no costs for participation in the study will be incurred.
4. It was noted that '*Participants who received Semaglutide in the main trial will transition to usual care. Usual care may include discontinuation of Semaglutide or continuation on a self-funded basis, as determined by the participant in consultation with their treating physician*' (Protocol Pg. 76). Please include further detail in the Protocol and Main PISCF on the specific circumstances in which continuation of the IMP in the usual care arm may occur.

5. Several differences between the initial study and the extension study designs were noted which may preclude an effective statistical comparison between the initial study and extension phase outcomes. These include but are not limited to the following
    - Health Care Professional administration of the IMP vs self-administration
    - Blinded vs open-label study design
    - A variation of the IMP treatment duration at the maximum dose
    - The potential inclusion of the IMP in the 'usual care' arm of the extension phase

Please justify the proposed analysis of the specified endpoints of the extension phase (Section 13.1.5 Protocol) given the potential confounding variables outlined above.

Part II Considerations raised

1. Proof of insurance

- The NREC-CT noted that the insurance certificate provided expired on 30th November 2025, but that rolling insurance is in place (Cover Letter, pg. 3). Please confirm that an up-to-date insurance certificate will be submitted once received.

2. Subject information and informed consent form

Standard Consideration:

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- The NREC-CT noted (Main PISCF Pg. 3) that "In total, the trial will last for 64 weeks". The Committee requested that this miscalculation with regard to the duration of the trial be corrected.
- The NREC-CT noted that the IMP will be self-administered during the extension phase, but this is not stated in the main PISCF. The Committee requested that the PISCF be updated to specify that the IMP will be self-administered in the extension phase and to include details of the instructions provided to participants.
- The NREC-CT noted that an open label study design is proposed for the extension phase but that this information has not been included in the Main PISCF. The Committee requested that information on the open label design of the extension phase is provided to the participant in the Main PISCF, including the rationale for the open label design, an explanation of the unblinding process and a timeframe for same, such that the participant is fully informed.

- The NREC-CT noted that the Main PISCF outlines that participants will move from the placebo arm of the main study to the active treatment arm of the extension phase. However, there is a paucity of information regarding the cohort of participants who may be required to discontinue the IMP and enter into the 'usual care' treatment arm. The committee requested that it is clearly outlined in the Main PISCF that the IMP may be discontinued in this patient cohort but that continuation may be possible under specified circumstances.

3. Suitability of the investigator

- The Committee notes that the CV for Dr Roisin Lyons does not contain previous clinical trial supervisory experience. If Dr Lyons does not have prior supervisory experience in clinical trials, please outline the supports that will be in place from other suitably qualified clinicians to enable her to undertake the role.

- AOB:
  - None