National Research Ethics Committee

NREC-CT Meeting

28th January 2026

Attendance

Name	Role
Prof David Brayden	Chairperson, NREC-CT D
Prof David Smith	Deputy Chairperson, NREC-CT D
Dr Christina Skourou	Deputy Chairperson, NREC-CT D
Prof Andrew Green	Committee Member, NREC-CT D
Prof Cathal Walsh	Committee Member, NREC-CT D
Prof Deirdre Murray	Committee Member, NREC-CT D
Dr Geraldine O'Dea	Committee Member, NREC-CT D
Prof Lina Zgaga	Committee Member, NREC-CT D
Mr Gerry Daly	Committee Member, NREC-CT D
Prof Geraldine O'Sullivan Coyne	Committee Member, NREC-CT D
Ms Chanel Watson	Committee Member, NREC-CT D
Dr Jeff Moore	Committee Member, NREC-CT D
Ms Chita Murray	Programme Manager, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Jane Bryant	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Ms Patricia Kenny*	Project Officer, National Office for RECs
Ms Rachel McDermott	Project Administrator, National Office for RECs
Emily Vereker	Head of Office, National Office for RECs

*Drafted minutes

Apologies: Deirdre MacLoughlin, Mary McDonnell Naughton

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2025-521777-13-00
- 2025-523793-16-00
- 2024-512998-27-00 SM-9
- 2023-508372-10-00 SM-6
- 2024-515237-15-00 SM-1
- 2024-520407-27-00 SM-2
- 2023-506987-15-00 SM-6
- 2023-504993-40-00 SM-4
- 2024-517136-21-00 SM-1
- 2024-517131-52-00 SM-2
- AOB

- The Chair welcomed the NREC-CT D.
  - The minutes from the previous NREC-CT D meeting on 17th December 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2025-521777-13-00

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

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Oral Inhalation of Seralutinib for the Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease (PH-ILD) Followed by a Long-Term Extension Evaluating Safety and Efficacy

Dossiers Submitted: Part I & II

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

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS

1. It was noted that the study proposes to evaluate two doses of seralutinib (90 mg bd and 120 mg bd) against placebo. It was further noted that the 120 mg dose has not been previously evaluated, and only a limited justification for its inclusion has been provided in the protocol. A more comprehensive justification for the use of the 120 mg bd dose should be provided by the Sponsor.

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 requested that the Main ICF be updated to include information on the availability of the clinical trial results at the end of the study and where these results can be accessed. The details provided to participants must, at a minimum, include the EU website (https://euclinicaltrials.eu) where the clinical trial results will be published, to ensure participants are clearly informed about where they can obtain the overall study findings.

- The NREC-CT requested that Main ICF *"Will I be paid for taking part in this study?"* section (page 23/24) and Compensation for trial participants document (Section 3) be updated to state that participants will be required to provide receipts in order to obtain reimbursement to ensure participants fully understand the reimbursement process and the documentation required to receive payment.
- The NREC-CT noted that the current wording in Main ICF (page 24) which states *"You will receive a stipend up to (127 EUR) after each study visit for time spent completing the visit. Your caregiver will receive a stipend up to (64 EUR) after each study visit for time spent completing the visit"* and therelated wording in the Compensation for Trial Participants document (Section 2), does not make it clear whether the stipend amounts may be reduced and, if so, what factors determine the final amount participants and caregivers will receive after each study visit. The Committee requested that both Main ICF and Compensation for trial participants document be updated to avoid ambiguity and ensure participants clearly understand the basis on which the full stipend amount is granted.
- The NREC-CT requested the Main ICF (page 24) be updated to remove refence to "National ID number" to avoid confusion as this identifier is not used in Ireland.
- The NREC-CT requested that the first reference to placebo in the Main ICF (page 2) *"seralutinib versus placebo in treating your PH-ILD"* be updated to include the definition of placebo as provided on page 4, namely: *"an inactive substance that looks like the study drug and is given the same way but has no effect on the body"* to ensure that participants understand the meaning of "placebo" from the outset of the document and are not required to read ahead for essential information relevant to the study design.
- The NREC-CT noted that the Main ICF (page 3) states: *"You may also need additional tests during screening depending on whether or not these tests have been performed recently and there have been changes to your PH treatment."* However, according to the protocol, any participant who has not had a high-resolution CT (HRCT) scan performed within the previous 24 weeks would be required to undergo a repeat HRCT during screening, and similarly, right heart catheterisation would be repeated if not performed within the previous 12 weeks. As the wording in the Main ICF could lead participants to believe these investigations would only be repeated if there have been changes to their PH treatment, the Committee requested that the Main ICF (page 3) be updated to clearly specify the specific circumstances under which repeat HRCT and right heart catheterisation would be required during the screening period, ensuring full transparency and alignment with the protocol.
- The NREC-CT requested that the Main ICF be updated to include details of the expected duration of each study visit during the trial to ensure participants have a full understanding of the time commitment involved at each stage of the study, allowing them to make an informed decision about participation
- The NREC-CT requested that the statement in the Main ICF (page 8) *"State/Provincial law requires positive test results for certain communicable diseases, including HIV or hepatitis, be reported to a local health agency"* be updated to make this information specific to Ireland and ensure participants are not misled by references to laws that do not apply in the Irish context.

- The NREC-CT noted that Main ICF 6MWT with Dyspnoea Scale section (page 9) states: *"Some visits will require two 6MWTs, in which case they will be performed at least 4 hours apart, at approximately the same time of day (Day 1, End of PCP, Early Discontinuation visit if applicable, and Early Withdrawal visit if applicable "* is unclear, as performing the second test *"at approximately the same time of day"* as the first would suggest a 24-hour interval rather than a 4-hour interval. The Committee requested Main ICF be updated to clarify the intended timing of the first and second 6MWT and ensure the description accurately reflects the study procedures.
- The NREC-CT requested that Main ICF (page 17) be updated to include a clear statement that there is no experience with the use of the 120 mg seralutinib bd dose in humans, to ensure that participants are fully informed about the level of existing knowledge with this dose before deciding whether to participate.
- The NREC-CT requested that Main ICF Risks section (page 18) be updated to provide an explanation for the symbol ≥ to ensure that all participants clearly understand the terminology used when describing risk levels and do not misinterpret important safety information.
- The NREC-CT noted the phrase *"not abstinent"* on Main ICF (page 20); and requested that it be deleted as this terminology is not commonly used in Ireland and does not add clarity for participants.
- The NREC-CT requested that Main ICF (page 20) be updated to replace *"(lack of menses)"* with *"(lack of menstrual periods)"* to ensure the terminology is clear and easily understood by all participants.

2025-523793-16-00

Institutions: Connolly Hospital, Beaumont Hospital, Cork University Hospital

Study title: A Phase 2, Multicenter, Randomized, Placebo-controlled, Double-blind Study of the Efficacy and Safety of Vamifeport in Adult Subjects with HFE-related Hereditary Hemochromatosis (FERROCLEAR Study)

Dossiers Submitted: Part I & II

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

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS
- The protocol proposes that participants with HFE haemochromatosis and confirmed iron overload receive either Vamifeport or placebo for 12 months, during which standard of care therapeutic phlebotomy will be withheld. Phlebotomy is an established, effective and safe treatment known to produce significant clinical improvement within a 12-month period. The sponsor is requested to update the study

protocol to provide clear ethical justification for withholding an evidence-based standard treatment for a prolonged period in individuals whom it is clinically indicated. This should include:

  - An explanation of why it is appropriate to expose participants to a 12-month period without standard of care in favour of experimental drug for which benefit cannot be guaranteed.
  - An account of how the risks associated with delaying standard of care have been assessed
  - Details on how participants best interests will be protected throughout the study.

- The protocol indicates that rescue therapy, anticipated to be therapeutic phlebotomy or iron chelators, may be initiated at the Principal Investigator's discretion, if a participant's serum ferritin increases by 100% over baseline and this rise is attributable to haemochromatosis. For participants who already present with markedly elevated ferritin, such an increase would represent a clinically significant concern. Although the sponsor cites Coutinho (2022) and Adams (2017) as evidence for expected rates of ferritin re-accumulation, it is noted that both studies describe ferritin re-accumulation after completion of phlebotomy to achieve normal ferritin levels. This scenario is not comparable to the population proposed for this trial, in which participants may not have undergone first line phlebotomy treatment. To ensure participant safety and appropriate risk justification the sponsor is requested to update the protocol to:
  - Clarify the rescue therapy procedures in full detail, including criteria for intervention and timelines for monitoring
  - Provide a clear rationale for selecting such a high threshold for intervention and explain how this aligns with clinical best practice
  - Present iron-accumulation data relevant to this specific cohort, including individuals with untreated iron overload, rather than data derived from post-treatment populations
- It is noted that the Sponsor has elected not to implement the additional study dose of 180mg recommended during EMA Scientific Advice. While acknowledging the response provided to the advice, further clarification is requested regarding the rationale for not adopting the additional recommended dose.

Part II Considerations

1. Proof of insurance

- The NREC-CT noted the insurance certificate submitted expires 30 June 2026 and requests confirmation that insurance will be in place for the full duration of the trial.

2. Recruitment arrangements

- The NREC-CT noted that a large number of advertisements, flyers and study descriptions of the study have been provided. Although the Recruitment and informed consent procedure document describes the recruitment in Ireland and England as being by the PI's – either by identifying patients from their existing lists, or through referrals from other doctors - the purpose of these additional recruitment

materials for Irish participants is not clear. The following updates and clarifications are therefore requested to to ensure 1) transparency regarding the recruitment pathways being used in Ireland, 2) compliance with data protection requirements and transparency for potential participants.

- The Committee requested clarification regarding the document "K1_CSL624_2001_Doctor Letter_IRL_ENG_Public" and whether doctors will be contacted by the PIs using this letter in Ireland. If so, it is requested that the Recruitment and informed consent procedure document be updated to include this detail.
- The Committee requested clarification regarding the document "K1_CSL624_2001_Patient Letter_IRL_ENG_Public" and whether doctors will be writing directly to their patients using this template in Ireland. Please also clarify whether this letter will be used to mailshot the PIs patients. If so, the letter should state how the PI got their personal details, and that the patient is attending the PIs clinic.
- The Committee requested clarification regarding the document "K1_CSL624_2001_DIRECT MAIL_IRL_ENG_Public" and whether direct mailing to advertise the study will be used in Ireland. If this is the case, it is requested that the Recruitment and informed consent procedure document be updated to include this detail. The Committee also noted the statement "For participants anywhere contacted from the Synexus database" in the document. The Committee noted, Synexus does not have a presence in Ireland and requested that Recruitment and informed consent procedure document be updated to clarify whether Irish participants will be sourced from this database and if so, how this would occur.
- The Committee also noted the statement that enrolment is only for a limited time, in the following study documents: K1_CSL624_2001_DIRECT MAIL_IRL_ENG_Public, K1_CSL624_2001_LONG LIVE DIAL SCRIPT_IRL_ENG_Public.and considered this to be potentially coercive wording which may mislead or pressure potential participants. The Committee requested that such elements be removed from the script to ensure ethical recruitment practices.
- The Committee requested clarification regarding the document "K1_CSL624_2001_Email_IRL_ENG_Public" and whether people in Ireland will receive direct marketing emails as part of recruitment and if so, how their contact details will be obtained. The Committee requested that the Recruitment and informed consent procedure document be updated to include this detail.
- The Committee requested clarification regarding the document K1_CSL624_2001_AUTOCALL OUTBOUND_IRL_ENG_Public and who will be conducting these follow up calls in Ireland. The Committee requested that the Recruitment and informed consent procedure document be updated to include this detail.
- The Committee requested clarification regarding the documents K1_CSL624_2001_Social Media Ads_IRL_ENG_Public, K1_CSL624_2001_Social_1080x1080_IRL_ENG_Public and K1_CSL624_2001_Social_1200x628_IRL_ENG_Public and whether social-media-based recruitment will be used for Irish participants and, if so,

requested that the Recruitment and informed consent procedure document be updated to describe the recruitment process to ensure the Committee fully understands the recruitment approach being proposed have been included.

- The Committee requested clarification on K1_CSL624_2001_LandingPage_IRL_ENG_Public and K1_CSL624_2001_Landing Page_IRL_ENG_Public and what happens once a participant goes to the landing page and chooses to proceed. The Committee requested that the Recruitment and informed consent procedure document be updated to clarify the next steps for participants, so the Committee understands how participants progress through the recruitment process.
- The Committee requested clarification regarding the document K1_CSL624_2001_Primary_Screener_Consent_MASTER_IRL_ENG_Public including who will be completing this form in Ireland and at what stage in the recruitment process. The Committee requested that the Recruitment and informed consent procedure document be updated with this detail. The Committee also requested that the Primary_Screener_Consent be updated to comply with GDPR , including stating the legal basis for data processing and how long CSL Behring will retain data to ensure compliance with EU data protection law and to provide clear information to potential participants.
- The Committee requested clarification regarding the document K1_CSL624_2001_Primary_Screener_MASTER_IRL_ENG_Public and who will be conducting the interviews in Ireland and confirmation on their qualifications and experience, particularly given that sensitive topics such as drug and alcohol use and abuse are included. The Committee requested that the Recruitment and informed consent procedure document be updated with this detail. The Committee also noted that the interview schedule appears to provide the facility to book an appointment for the participant with a clinic where the trial is running however this is not permissible in Ireland as hospitals do not allow third-party companies to book appointments. The Committee requested Recruitment and informed consent procedure document be updated to clarify this to ensure the process accurately reflects what will occur in Ireland.
- The Committee requested clarification regarding the document K1_CSL624_2001_SMS_IRL_ENG_Public and who will be responsible for sending the text messages in Ireland and how the sender will obtain the participants' contact details. The Committee requested Recruitment and informed consent procedure document be updated to ensure that recruitment communications comply with data protection requirements.
- The NREC-CT noted that participants will be provided with comfort blanket with the study logo, and requested that the logo be omitted from these items to avoid the participants' condition being shown publicly.

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 requested that the Main ICF(page 5) be updated to include more specific information on expenses and reimbursement amounts as participants should not have to consult the study team to obtain this essential information.
- The NREC-CT noted the Main ICF (page 43) " Your coded personal data will be sent to groups in countries where data protection measures like the EU cannot be applied, ….". The Committee requests that the Main ICF (page 43) be revised to include clear information on the safeguards and protective measures in place for transferring participants' personal data outside the EU as per Article 46 (1) GDPR.
- The NREC-CT requested that the Main ICF be updated to clearly inform participants that they will be required to travel to Hermitage Clinic for MRI scans during the trial to provide clarity to participants of the commitments required, during the consent process.
- The NREC-CT requested that a short summary version of the Main ICF be provided to ensure participants can access the key information in a clear and easily understandable format.
- The NREC-CT noted that the Main ICF does not currently state that participants who choose to take part will forego the standard of care (phlebotomy) for HFE haemochromatosis and will be randomised to either experimental treatment or placebo. The Committee emphasised that participants need to be explicitly informed of the risks associated with forgoing the standard of care and requested that Main ICF and all patient-facing materials, including those intended for social media, should be revised to explicitly communicate that participants will be forgoing standard of care for 12 months and also detail the risks associated with this.
- The NREC-CT requests that the Main ICF (page 2) be updated to remove the phrase "*you will receive one of the study drugs – either IMP or a placebo"*, as this may be misleading to participants. The wording should be revised to distinguish clearly between the active study drug vamifeport and the placebo
- The NREC-CT noted that Main ICF (page 28) states "You will be asked to avoid some medical treatments, medications, foods, and supplements during the study". The Committee requested that Main ICF (page 28) be updated to specify the exact foods and drinks to be avoided, so that participants are fully informed of any restrictions in advance and can clearly understand how to comply with the study requirements.

2023-508372-10-00 SM-6

Institutions: Beaumont Hospital, St Vincent's University Hospital

Study title: A Phase 2 Randomized Study of Relatlimab plus Nivolumab in Combination with Chemotherapy vs. Nivolumab in Combination with Chemotherapy as First Line Treatment for Participants with Stage IV or Recurrent Non-small Cell Lung Cancer (NSCLC)

Dossiers Submitted: Part I & II

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

2024-515237-15-00 SM-1

Institutions: St Luke's Radiation Oncology Network, University Hospital Galway

Study title: NRG-HN009: RANDOMIZED PHASE II/III TRIAL OF RADIATION WITH CISPLATIN AT 100 MG/M2 EVERY THREE WEEKS VERSUS RADIATION WITH WEEKLY CISPLATIN AT 40 MG/M2 FOR PATIENTS WITH LOCOREGIONALLY ADVANCED SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK (SCCHN)

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 both the SIS and ICF Master (page 13-15) and SIS and ICF Addendum (page 2-3) include two separate lists of potential risks/side effects, While the content broadly overlaps, several side effects appear under different frequencies or likelihoods across the two lists. This could cause confusion for participants and reduce the clarity of the consent process. The Committee

requested that these lists be combined or an explanation provided to the participant regarding the reason for two lists.

2024-520407-27-00 SM-2

Institutions: Children's Health Ireland Crumlin

Study title: APOLLO: A Randomized, Double-Blind, Placebo-Controlled Study of Bitopertin to Evaluate the Efficacy, Safety, and Tolerability in Participants with Erythropoietic Protoporphyria (EPP) or X-Linked Protoporphyria (XLP)

Dossiers Submitted: Part I & II

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

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS

1. The Sponsor should provide a clear justification for limiting the optional post-trial interview process to English-speaking participants, including an explanation as to why the interviews cannot be made accessible to non-English-speaking participants (e.g., through interpreters or translated materials), and why such an exclusion is necessary, proportionate, and does not introduce unnecessary barriers to participation or bias into data collection

Part II Considerations raised

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

- The NREC-CT noted that the protocol requires mandatory genotyping of all participants to determine eligibility, even when previous genotyping results are available. The Committee requested that Main Participant ICF (page 7), Parent Legal Guardian ICF (page 7) and Assent form (page 5) be updated to inform participants that repeat genotyping will be required, even if they have undergone genotyping in the past, and to advise them that the new genotyping results may differ from previous results.

2023-506987-15-00 SM-6

Institutions: Tallaght University Hospital

Study title: Phase Ib/II Trial of Pembrolizumab (MK-3475) Combination Therapies in Metastatic Castration-Resistant Prostate Cancer (mCRPC) (KEYNOTE-365)

Dossiers Submitted: Part I & II

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

2023-504993-40-00 SM-4

Institutions: Beaumont Hospital, Mater Misericordiae University Hospital

Study title: Phase 3b, multi-center, randomized, parallel-group, open-label, non-inferiority study evaluating the efficacy, safety, and tolerability of oral dolutegravir/lamivudine once-daily as a first-line regimen compared to oral bictegravir/emtricitabine/tenofovir alafenamide once daily for virologic suppression and maintenance in antiretroviral therapy naive adults living with HIV

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 requested that the Main ICF (page 39) be updated to include a consent statement for the participant to explicitly consent to the processing of their personal data from pseudonymised /coded data to anonymised data as per Article 4 (2) and 6 General Data Protection Regulation (GDPR).

2024-517136-21-00 SM-1

Institutions: St Vincent's University Hospital, Tallaght University 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:**
- Favourable

2024-517131-52-00 SM-2

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

Study title: A Study to Investigate Progression-Free Survival With Sonrotoclax Plus Obinutuzumab Or Sonrotoclax Plus Rituximab Compared With Venetoclax Plus Rituximab Treatment In Patients With Relapsed and/or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

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 requested that SIS and ICF Main (page 17) be updated to re-insert the guidance on what participants should do in the event of vomiting. Although this instruction is also provided in the patient diaries, it is essential that it also appears in the SIS and ICF to ensure participants receive this information at all key

decision points in the consent and study process. In addition the committee requested that the timeframe referenced in Patient facing diary_Arm D (page 3), Patient facing diary_Arm A and C (page 37) & Patient facing diary_Arm B (page 4) regarding what to do if vomiting occurs be reverted back to the original 15 mins as after 15 minutes, there is a higher likelihood that some portion of the medication has dissolved or been absorbed, even if vomiting occurs and could potentially, lead to overdosing.

- **AOB:**
- Reminder that new members will be joining as observers at next meeting.