# National Research Ethics Committee

## NREC-CT Meeting

**17 July 2024**

### 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 |
| Dr Susan Finnerty | Committee Member, NREC-CT C |
| Prof Andrew Smyth | Committee Member, NREC-CT C |
| Dr Steve Meaney | Committee Member, NREC-CT C |
| Dr Dervla Kelly | Committee Member, NREC-CT C |
| Ms Susan Kelly | Committee Member, NREC-CT C |
| Dr Deborah Wallace | Committee Member, NREC-CT C |
| Ms Paula Prendeville | Committee Member, NREC-CT C |
| Mr Gerry Eastwood | Committee Member, NREC-CT C |
| Prof Anne Mathews | Committee Member, NREC-CT C |
| Ms Aileen Sheehy | Programme Manager, National Office for RECs |
| Dr Laura Mackey | Programme Officer, National Office for RECs |
| Dr Susan Quinn | Programme Manager, National Office for RECs |
| Dr Emma Heffernan* | Project Officer, National Office for RECs |
| Ms Rachel McDermott | Project Administrator, National Office for RECs |
| Dr Emily Vereker | Head of Office, National Office for RECs |

**Apologies:** Mr Philip Berman, Prof Austin Duffy, Prof Fionnuala Breathnach

**Quorum for decisions:** Yes

## Agenda

- Welcome & Apologies
- 2023-508137-14-00
- 2023-510289-28-00
- 2023-503772-24-00
- 2023-505035-12-00 SM1
- 2024-510620-39-00 SM2
- 2023-508084-76-00 SM1
- 22-NREC-CT-177_Mod-4
- 21-NREC-CT-182_Mod-3
- 2022-500537-84-01 SM-22
- AOB

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- The Chair welcomed the NREC-CT C.
  - The minutes from the previous NREC-CT C meeting on 05 June 2024 were approved.
  - The NREC Business Report was discussed and noted.

## Applications

**2023-508137-14-00**

Institutions: Beaumont Hospital

Study title: A Phase 2, Single-Arm, Open-Label Extension Study, Evaluating the Long-Term Safety and Clinical Efficacy of INBRX-101 in Adults with Alpha-1 Antitrypsin Deficiency (AATD) Emphysema

Dossiers Submitted: Part 1&2

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required**

**Part II Considerations**

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

- The NREC-CT requested that section 2 of the S1_INBRX101-01-202_Use-of-Biological-Samples-Declaration_IE is fully completed (there is conflicting information as to whether existing archived samples will be used).

2. **Recruitment arrangements**

- The NREC-CT noted that section 1.4 of the Recruitment and informed consent procedure template lacked a detailed description of the consent process and requested that this is amended.
- The NREC-CT noted that section 4.1 of the Recruitment and informed consent procedure template document states that an impartial witness might 'be applicable for older patients'. The NREC-CT recommends that this is applied to all eligible participants who are unable to provide a written signature and not just 'older patients'.

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

- The NREC-CT requested that details of the parent study are provided on pg. 2 of the Main PISCF so that Cohort 1 participants, who did not participate in the INBRX101-01-201 study, are fully informed.
- The NREC-CT requested that the following terms are explained to participants in the Main PISCF using plain English suitable for a lay audience
    - Pg.2 'A1P1 genotype'
    - Pg. 10 Nasal brushing / swab for biomarkers taken for RNA analysis
    - Pg 11 'sputum sample'
- The NREC-CT requested that the potential consequences of 'a risk of an increase in plasma volume' is explained to participants on pg. 2 of the Main PISCF using plain English suitable for a lay audience.
- The NREC-CT requested that more detail is provided for participants regarding what biomarkers are to be measured by blood tests and blood spot cards, on pgs. 10 /11 of the Main PISCF.
- The NREC-CT noted that it is not clear to participants on pg. 10 of the Main PISCF when blood spot cards should be collected and requested it is made clear to

participants in the Main PISCF when and under what circumstances blood spot cards are to be collected.

- The NREC-CT noted that pg. 14 of the Main PISCF describes an optional home care service that 'may' be available for participants and requested that it is clarified in the Main PISCF whether this service is available or not.
- The NREC-CT noted that pg. 22 of the Main PISCF states that year of birth and age may also be recorded to help identify study records and requested that it is clarified why this information is needed, if that data is coded.
- The NREC-CT noted that pg. 21 of the Main PISCF and pg. 3 of the Pregnant Partner and Pregnant Participant PISCFs states that 'Other employees or students of Inhibrx Inc or its authorised agents, will have access to data and requested detail of these 'authorised agents' are added to the PISCF documents.
- The NREC-CT requested that the terms 'authorised representatives' and 'individuals from the sponsor' referred to in the informed consent sections of the Main, Pregnant Partner, Pregnant Participant and Bronchoscopy Sub-Study PISCF documents are explained to participants so they are fully informed with whom their data will be shared.
- The NREC-CT requested it is clarified on pg. 11 of the Main PISCF how it is determined which participants take part in the Bronchoscopy Sub-Study.
- The NREC-CT noted that pgs. 4 & 6 of the Bronchoscopy Sub-Study PISCF refers participants back to the Main PISCF for details of what happens to samples and data collected from participants. The Committee requested that this information is added to the Bronchoscopy Sub-Study PISCF, so that signed informed consent is obtained for the bronchoscopy sub-study.
- The NREC-CT noted that pg. 1 of the K2_INBRX101-01-202_Phone-and-Email-Script_IE_English document states that 'compensation *may* be offered' and requested that this is changed to 'compensation *will* be offered' so that participants are reassured that they will be reimbursed for trial related out-of-pocket expenses.
- The NREC-CT noted that pg. 1 of the K2_INBRX101-01-202_Phone-and-Email-Script_IE_English document states that 'The option to perform certain visits at your home with a qualified study nurse may be offered' and requested it is clearly stated whether home visits with a qualified nurse will be offered.
- The NREC-CT noted that the study is also referred to as the 'ElevATTe OLE Study' in the K2_INBRX101-01-202_Phone-and-Email-Script_IE_English document and clinical leaflets, but not across all of the other patient facing documents, which may be confusing for participants. The NREC-CT requested that the name of the study is aligned across all communications with potential participants and in the patient facing materials.
- The NREC-CT suggested that the Clinical Leaflets provided for participants would benefit from being written using pain English suitable for a lay audience.
- The NREC-CT requested clarification as to why participants would require the L2_INBRX101-01-202_Scout-Taxable-Payments-Letter_IE_English when they are not being paid to participate in the study, but only being reimbursed for trial related out-of-pocket expenses.
- The NREC-CT noted that pg. 13 of the Main PISCF states that 'If you withdraw from the study, any sample collected prior to your withdrawal may still be analyzed as described in this Participant Information Sheet and Informed Consent Form,

unless you specifically ask for your samples to be destroyed'. The Committee requested that it is explained to participants the process for withdrawing consent for sample use.

- The NREC-CT noted that the statement 'NREC will watch over this study while you're in it' on pg. 4 of the Main PISCF is potentially misleading and requested that it is removed.
- The NREC-CT noted that participants will not have access to the study drug after completion of the trial and recommends that this is reconsidered, so that all participants benefiting from the study drug continue to have access.
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment. Please include details of the Part 1 Consideration responsible for triggering update to Part 2 documents in your submission.
- 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.

**4. Suitability of the investigator**

- Please fully complete the relevant clinical trial experience section in the CV for [redacted]

**2023-510289-28-00**

Institutions: St James's Hospital

Study title: A Phase 2, Open-label, Multicenter Study of Mitapivat in Subjects With Sickle Cell Disease and Nephropathy

Dossiers Submitted: Part 1&2

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required**

## Part II Considerations

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

- The NREC-CT requested that any updates to the PISCF are aligned in the compliance with biological samples document.

**2. Recruitment arrangements**

- The NREC-CT noted conflicting statements in section 1.8 of the K1_AG348-C-026_Recruitment-Arrangements_IE document regarding recruitment of participants who do not speak English or Irish. The first sentence states that 'It is not expected that participants do not speak the national language of the country that study is open in' which seems to contradict the subsequent statement 'In the case of identified patients who do not speak the national language, the sponsor will arrange for the translation of the Patient Information Sheet and Informed Consent Forms'. The NREC-CT requested confirmation that 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.

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

- The NREC-CT requested that the EU trial number is added to the PISCF documents.
- The NREC-CT noted that Pg. 1 of the PISCF states that 'Participants aged 16 or over can provide consent to take part in this study but your parents or guardian will need to consent to the use of your data until you are 18'. The NREC-CT requested that this sentence is removed as 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 the PISCF is seeking blanket consent for future use of biomarkers, for unspecified purposes, without further consent on pg. 7 of the PISCF. This type of consent is not in line with best practice, the Declaration of Taipei 2016 and not in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), where informed participant consent is a mandatory safeguard. The NREC-CT requested that future research is restricted to 'specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof' (i.e. sickle cell disease and nephropathy) and this is clearly stated in the main body and informed consent section of the PISCF. The NREC-CT requested
    - i) that consent for future use of biomarkers is provided on a separate consent form and not bundled
    - ii) is made optional, and
    - iii) consent can only be obtained where future use of biomarkers and data is defined such that participants are fully informed,
    - and/or iv) that an option is provided to enable participants to consent to be contacted is provided in a separate consent form.
    - The NREC request confirmation that subsequent research ethics review will be sought for specific research once clearly defined.
- The NREC-CT noted that pg. 2 of the PISCF states that participants will have 3 research DXA scans 'if available at your site' and requested confirmation that all participants will be able to access DXA scans as per protocol (pg. 38), even if they are not provided at the study site and this is explained in the PISCF.
- The NREC-CT requested clarification on pg. 6 of the PISCF as to whether participants are to undergo whole genome sequencing. If participants are to undergo whole genome sequencing the NREC request 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 (V1.1, 2023) https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf
- The NREC-CT noted that the Main PISCF and Pregnancy Participant ICF and the state of transfer of participant / mother / child data of the outside of the EU. Please provide detail in the PISCF how this transfer of data outside the EU complies with regulations.
- The NREC-CT requested that the reference to NREC having access to participant's personal data is amended on pg. 17 of the PISCF to make clear to participants that the NRECs will not have access to identifiable data.
- The Sponsor is requested to submit any participant-facing documentation that require updates as a result of the Part I Assessment. Please include details of the Part 1 Consideration responsible for triggering any updates to Part 2 documents in your submission.
- 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.

**2023-503772-24-00**

Institutions: Cork University Hospital, St Vincent's University Hospital, University Hospital Galway, University Hospital Waterford

Study title: A Phase 2b/3, Multi-part, Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Atacicept in Subjects with IgA Nephropathy (IgAN)

Dossiers Submitted: Part 1&2

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required**

## Part II Considerations

### 1. Subject information and informed consent form

- The NREC-CT noted that pg. 13 of the PISCF, in the section 'Atacicept Risks' there are a number of very common side effects (such as UTI, URTI) listed, but it is also stated that 'serious infections' are no more common with the trial drug than

a placebo. The NREC-CT requested that this is clarified, as it may be confusing for participants. Please also provide clarification as to whether participants are likely to experience multiple infections that are not classified as 'serious'.

- The NREC-CT noted that pg. 14 of the PISCF references potential rare side effects and requested that these potential rare side effects are explained in more detail in the PISCF, so participants are fully informed.
- The NREC-CT requested that the mechanism of action of the study drug should be explained to participants in the PISCF using plain English suitable for a lay audience.
- The NREC-CT requested that the global nature of the study should be flagged earlier in the PISCF, so that the participants can understand the scale/scope of the study.
- The NREC-CT requested it is clarified on pg. 4 of the PISCF if participants are to undergo PCR testing for COVID -19. If so, this should be listed in Table 1. Study Procedures.
- The NREC-CT requested that the quality of life / fatigue questionnaires are explained to participants in the main body of the PISCF (separate from what is listed in the schedule).
- The NREC-CT requested that specific details of the laboratory tests (i.e. hormone tests) are explained to participants in the main body of the PISCF (separate from what is listed in the schedule).
- The NREC-CT requested that the working 'get treatment' is replaced with 'be treated' on pg. 2 of the PISCF
- The NREC-CT requested that the term 'qualify to participate' is replaced with 'meeting eligibility criteria' on pg. of the PISCF.
- The NREC-CT noted that pg. 2 of the PISCF states that 'alternative treatments' may be available for participants which suggests that there are other efficacious treatments available and requested that this is rephrased.
- The NREC-CT requested that the term 'Your study doctor may remove you' on pg. 6 of the PISCF is replaced with 'You will no longer be able to participate if…
- The NREC-CT requested that the details of the remote visits etc. are presented separately in the PISCF to improve clarity.
- The PICSF requested that there is consistency in the use of language when referring to the trial (reference to 'phase 3', 'Origin 3' and 'the study') in the participant facing documentation and requested that these are aligned. The NREC-CT suggested that the term 'Origin 3' is used on most of the participant facing documentation so may be clearer to use this.
- The PICSF requested that there is consistency in the use of language when referring to the study drug (reference to 'atacicept' 'VT-001' 'study drug') in the participant facing documentation and requested that these are aligned. and abbreviation introduced before it is defined.
- The NREC-CT requested that the reference to 'tumour tissue' in the informed consent section (pg. 20) of the PISCF is revised and amended.
- The NREC-CT requested that the rationale for Early Termination and the follow up visits on pg. 5 of the PISCF is made clearer for participants (e.g. why they need you back from a participant health / safety perspective, rather than a study data collection aspect.
- The NREC-CT noted that details of how the TrialPACE app will be used in the trial is not described to participants in the PISCF and requested that this is explained to participants
    - Please also provide details with regards to alerts and push notifications (to ensure this will not 'pester' a participant).

    - The NREC-CT requested that the Terms and Conditions of the data aspects of this app should be made clear to participants.
    - The NREC-CT requested it is clarified in the PISCF whether participants require a smart phone to be able to participate in the trial.
- The NREC-CT noted that optional future research is confined to research into the study drug and current study and requested confirmation that future research will undergo further ethics approval once defined.
- The NREC-CT noted that it is it clear to participants in the PISCF if it's possible to withdraw from optional future use after completion of the study and requested that this is clarified in the PISCF.
- The NREC-CT noted that the Main PISCF (pgs.19 /20) has used a bundled approach to consent for some for some of the items listed in the Informed Consent Section of the PISCF 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 (V1.1, 2023). Dublin: Health Service Executive https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf.
- The NREC-CT noted that participants will be provided with branded items designed with the study logo 'Origin 3' and requested that the logo is omitted from these items to avoid the participants' condition being shown publicly / to protect participant privacy and confidentiality.
- The NREC-CT noted that rare side effects are omitted from the GP letter and requested that the GP letter is updated to include rare side effects.
- 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.

**2. Suitability of the clinical trial sites facilities**

- The NREC-CT requested that the description of the trial design (section 4) is aligned across all Site Suitability Assessment documents.

**2023-505035-12-00 SM1**

Institutions: St James's Hospital

Study title: A PHASE III, RANDOMIZED, OPEN-LABEL STUDY OF PRALSETINIB VERSUS STANDARD OF CARE FOR FIRST-LINE TREATMENT OF RET FUSION POSITIVE, METASTATIC NON-SMALL CELL LUNG CANCER

Dossiers Submitted: Part 1&2

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required**

**Part II Considerations**

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

- The NREC-CT noted that those already on Pralsetinib can choose to stay in the study until completion of their treatment and requested that this is made clearer to participants in the PISCF addendum.
- The NREC-CT noted that the PISCF addendum asks participants to refer to prescribing information or talk to their study doctor in relation to the side effects of Pembrolizumab. For participants to be fully informed and that the information is readily available for participants, the NREC-CT requested that the side effects of Pembrolizumab are detailed in the addendum.
- The NREC-CT requested that it is clarified in the PISCF addendum why special precautions have been issued for men, so they are fully informed**.**
- The NREC-CT noted that participants might not have access to the study drug (Pralsetinib) after completion of the trial and requested rationale for this decision. The Committee recommends that this is reconsidered, so that all participants benefitting from the study drug continue to have access.

**2024-510620-39-00 SM2**

Institutions: Tallaght University Hospital

Study title: An Open-label, Randomized, Phase 3 Study of MK-6482 in Combination with Lenvatinib (MK-7902) vs Cabozantinib for Treatment in Participants with Advanced Renal Cell Carcinoma Who Have Progressed After Prior Anti-PD1/L1 Therapy

Dossiers Submitted: Part 1&2

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required**

**Part II Considerations**

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

- The NREC-CT requested that it is stated in the PISCF that data breaches will be reported to the Irish Data Protection Commissioner in line with GDPR, 2018.
- The NREC-CT noted that pg. 9 of the PISCF state that participants may undergo whole exome / whole genome sequencing and requested the following:
    - Whole exome /whole genome sequencing is confined to genes involved in the disease being treated (i.e. renal cell carcinoma) and /or genes involved in the metabolism of the medicines being used in the trial and this is explained 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 (V1.1,

2023) https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf

- The NREC-CT requested it is clarified on pg. 9 of the PISCF whether genetic testing is being carried out by the sponsor alone or is also being carried out by 3rd parties. If 3rd parties will be used for genetic testing, the Committee requested that additional information is provided to participants to ensure transparency of processes.

**2023-508084-76-00 SM1**

Institutions: Beaumont Hospital

Study title: A Phase 2, Double-Blind, Randomized, Active-Control, Parallel Group Study To Assess The Pharmacokinetics, Pharmacodynamics, Immunogenicity, And Safety Of Inbrx-101 Compared To Plasma Derived Alpha1-Proteinase Inhibitor (A1pi) Augmentation Therapy In Adults With Alpha-1 Antitrypsin Deficiency (AATD) Emphysema

Dossiers Submitted: Part 2

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required**

**Part II Considerations**

**Subject information and informed consent form**

- The NREC-CT noted that the statement regarding the PK sub-study on pg.1 of the L1_INBRX101-01-201_intensive-PK-ICF_IRE_English_TC_NotPublic PISCF is not written in a patient friendly manner and may be confusing for participants ('This sub-study will enrol a smaller number of people compared to the main study. If your site is taking part in this sub-study and recruitment is not closed due to the recruitment target not yet being reached, you will be asked to take part. In this case…'). The NREC-CT requested that this statement is rephrased to be clear and concise, so participants are fully informed.
- The NREC-CT noted that the statement regarding the PK sub-study on pg. 9 of the Main PISCF is not written in a patient friendly manner and may be confusing for participants ['There is also a sub-study called the pharmacokinetics sub-study, depending on if your study site is it taking part and if recruitment for this sub study has ended, you may have to take part in this sub-study in order to take part in the main study (which is described in the rest of this PIS-ICF). There is a separate PK PIS-ICF which the study site staff will go through with you if appliable']. The NREC-CT requested that this statement is rephrased to be clear and concise, so participants are fully informed.
- The NREC-CT requested that the consequences of a rise in plasma volume after IV infusion of INBRX 101 is detailed in the 'what are the risks' section on pg. 2 of the Main PISCF.

- The NREC-CT requested that the information related to the optional bronchoscopy procedure detailed on pgs. 8/9 in the Main PISCF is copied to the Bronchoscopy PISCF, to ensure informed consent.
- The NREC-CT requested that the 2 consent items listed on the top of pg. 9 of the L1_INBRX101-01-201_Pregnancy_Participant-ICF_IRE_English_TC PISCF are integrated into the table of consent statements presented on pg. 7/8, so there is signed consent for these statements.
- The NREC-CT requested that the 2 consent items listed on the pg. 7 & 8 of the L1_INBRX101-01-201_Pregnancy_Partner-ICF_IRE_English_TC PISCF are integrated into the table of consent statements presented on pg. 6/7, so there is signed consent for these statements.
- The NREC-CT requested that the exact figure for inconvenience is removed from pg. 18 of the PISCF, as it may constitute an inducement to participate.

**22-NREC-CT-177_Mod-4**

Institutions: Beaumont Hospital

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

- **NREC-CT Decision:**

Favourable

**21-NREC-CT-182_Mod-3**

Institutions: Croom Orthopaedic Hospital

Study title: Clinical Study Protocol M15-572: A Phase 3, Randomized, Double Blind, Study Comparing Upadacitinib (ABT-494) to Placebo and to Adalimumab in Subjects with Active Psoriatic Arthritis Who Have a History of Inadequate Response to at Least One Non-Biologic Disease Modifying Anti-Rheumatic Drug (DMARD) – SELECT –PsA 1

- **NREC-CT Decision:**

Favourable

**2022-500537-84-01 SM-22**

Institutions: St Vincent's University Hospital, Portiuncla Hospital, Connolly Hospital, Regional Hospital Mullingar, Beaumont Hospital, Our Lady of Lourdes Hospital.

Study title: A randomized, double-blind, multicenter, phase III study to evaluate the long-term efficacy and safety of ABX464 25 mg or 50 mg once daily as a maintenance therapy in subjects with moderately to severely active ulcerative colitis

Dossiers Submitted: Part 1&2

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required**

## Part II Considerations

### 1. Subject information and informed consent form

- The NREC-CT noted that there is conflicting information in the ICF_Future research PISCF whether recipients of samples will have access to participant's information (pg. 1 states 'In any case, the recipients of the samples and related data will not have access to information that allows your identity to be associated with these samples and data' whereas pg. 2 states 'You may be recontacted in the future by the study doctor regarding the future research' and requested that this is clarified for participants in the ICF_Future research PISCF.
    - Furthermore section 4.6 of the S1- Collection-storage-and-future-use-of-human-biological-samples_redline states that 'Only the Sponsor and laboratories listed in section 3.1 and 4.3 will have access to the sample code list' and requested that this statement is aligned with the updated ICF_Future research PISCF.
- The NREC-CT noted conflicting statements as to whether participants would be contacted in the future regarding future research and requested that this is clarified and aligned across all relevant documents - the S1- Collection-storage-and-future-use-of-human-biological-samples_redline states 'No, patient will give their consent once when signing the ICF' and the the ICF_Future research PISCF states 'may be recontacted in the future by the study doctor regarding the future research'.
- The NREC-CT requested it states on pg. 4, section 8 of the ICF_Future research PISCF that existing ethics approval refers to the current study and that any future research will undergo further ethics approval once defined.
- The NREC-CT requested that the optional components of the study on pg. 25 of the Maintenance PISCF are presented on a separate page with separate signature section, so they are not bundled with general consent to the main study.

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- AOB:

  Discussed 2 stage consent processes