# National Research Ethics Committee

## NREC-CT A Meeting

**20th September 2023**

### Attendance

| Name | Role |
|---|---|
| Prof. Alistair Nichol | Chairperson, NREC-CT A |
| Dr Heike Felzmann | Deputy Chairperson, NREC-CT A |
| Prof. Mary Donnelly | Deputy Chairperson, NREC-CT A |
| Ms Muireann O'Briain | Committee Member, NREC-CT A |
| Prof. David Brayden | Committee Member, NREC-CT A |
| Dr Darren Dahly | Committee Member, NREC-CT A |
| Prof. Gene Dempsey | Committee Member, NREC-CT A |
| Prof. Austin Duffy | Committee Member, NREC-CT A |
| Mr Gerard Eastwood | Committee Member, NREC-CT A |
| Dr Emily Vereker | Head of Office, National Office for RECs |
| Ms Aileen Sheehy | Programme Manager 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 |

*Drafted minutes

**Apologies:** Ms. Erica Bennett, Prof. Tina Hickey, Dr Dervla Kelly, Prof. John Wells, Mr Gerard Daly, Prof. Catherine Hayes, Dr Geraldine Foley, Ms Evelyn O'Shea, Ms Ann Twomey

**Quorum for decisions:** Yes

## Agenda

- Welcome & Apologies
- 2023-505616-38-00
- 2022-503013-32-00
- 22-NREC-CT-181_Mod-2
- 21-NREC-CT-001_Mod-8
- 21-NREC-CT-144_Mod-4
- 22-NREC-CT-081_Mod-3
- 22-NREC-CT-025_Mod-4
- 21-NREC-CT-038_NCP_Mod-4
- 22-NREC-CT-024_Mod-4
- 22-NREC-CT-131_Mod-1
- 22-NREC-CT-069_Mod-3
- 21-NREC-CT-012_Mod-5
- AOB

---

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 16th August 2023 were approved.
  - The NREC Business Report was discussed and noted.

---

## Applications

**2023-505616-38-00**

Principal Investigators & Institutions: Mater Private Hospital (Prof Catherine Kelly), Beaumont Hospital (Prof. Patrick Morris), St Vincent's University Hospital (Prof. Janice Walshe), Mater Misericordiae University Hospital (Dr Geraldine Coyne)

Study title: A Phase 3b, Multicenter, Global, Interventional, Open-label Study of Trastuzumab Deruxtecan (T-DXd), an Anti-HER2-Antibody Drug Conjugate (ADC), in Subjects who Have Unresectable and/or Metastatic HER2-low or HER2 Immunohistochemistry (IHC) 0 Breast Cancer (BC) (DESTINY-Breast15)

EudraCT: 2023-505616-38-00

Dossiers: Part I and II

- NREC-CT comments:

- The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.

- NREC-CT Decision:

- Request for Further Information

- The NREC-CT noted that information regarding consent for future use of biological samples is not consistent across all three ICF documents. Blanket consent is not permitted, and if broad consent is requested, additional safeguards should be included in line with the HSE National Consent Policy for Health and Social Care Research (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 that the information is clarified and consistent across all ICF documents. (Biosample Tumour Tissue Screening ICF, page 4; Main ICF, page 28)
- The NREC-CT noted that genomic analysis may be performed as part of future biological research, and requests clarification on whether participants will be informed of any incidental findings. This should be clarified in the ICF documents.
- The NREC-CT requested that the risk of Left Ventricular Dysfunction as detailed in the Investigator Brochure, be added to the PIL, in addition to detail on how common it is in participants.
- The NREC-CT requested that the following sentence in relation to data storage is rephrased to make it clear to participants what ICH means; 'last approval of marketing authorisation in ICH region'. (Biosample Tumour Tissues ICF, page 6; Main ICF, page 25, Pregnant Partner ICF, page 3)
- The NREC-CT noted the inclusion of an independent advisor, and requests further detail on who this individual will be and their role in the trial. (Biosample Tumour Tissues ICF, page 10; Main ICF, page 31, Pregnant Partner ICF, page 5). Furthermore, additional information on the independent committee detailed in the Main ICF was also requested. (Main PIL, Page 25)
- The NREC-CT requested further details on the procedure for participant reimbursement of out-of-pocket expenses in all ICF documents.
- The NREC-CT noted that the ICF states that the NREC will be notified of pregnancies during the trial and requests this be removed, as the NREC will not request or have access to this information. (Main ICF, page 21)
- The NREC-CT noted that a GP letter is mentioned in the ICF forms, and requests that this is submitted for review.
- The NREC-CT noted that there is no separate consent for the tumour screening procedure (Biosample Tumour Tissue ICF, page 13), and requested that this is added. Furthermore, additional information was requested on the procedure of the tumour sample, for example who will perform it and where it will be taken (Biosample Tumour Tissue ICF, pages 4 and 5).

**2022-503013-32-00**

Principal Investigators & Institutions: N/A

Study title: A Window-of-Opportunity trial of giredestrant +/- triptorelin vs. anastrozole + triptorelin in premenopausal patients with ER-positive/HER2-negative early breast cancer.

EudraCT: 2022-503013-32-00

Dossiers: Part I

- NREC-CT comments:

- The NREC-CT A agreed that no additional information was required following review of the Part I Dossier, and that review of the Part II Ireland-specific Dossier would occur when submitted.

**22-NREC-CT-181_Mod-2**

Principal Investigator & Institution: Dr Eugene Ng, UPMC Whitfield Hospital

Study title: ORACLE: A long-term follow-up study to evaluate the safety and durability of GT005 in participants with geographic atrophy, secondary to age-related macular degeneration treated in a Gyroscope-sponsored antecedent study.

EudraCT: 2020-003987-22

- NREC-CT Decision: Request for Further Information:

- Clarity is required regarding Future Biological Research, as a result of deletion of information on Page 37 of the ICF document. It is now unclear whether unforeseen FBR will now not take place, or whether more explicit consent will now be required. The ICF should be updated to reflect this clarification, and should be consistent across the whole document.

- Note: This Substantial Modification was subsequently withdrawn following submission of local End of Trial notification.

**21-NREC-CT-001_Mod-8**

Principal Investigator & Institution: Prof. Sean Raymond McDermott, Tallaght University Hospital

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

EudraCT: 2016-002312-41

- NREC-CT Decision: Favourable

**21-NREC-CT-144_Mod-4**

Principal Investigator & Institution: Prof. Niamh O`Connell, St James's Hospital,

Study title: A multinational, open-label, randomised, controlled study to investigate efficacy and safety of NNC0365-3769 (Mim8) in adults and adolescents with haemophilia A with or without inhibitors.

EudraCT: 2020-001048-24

- NREC-CT Decision: Favourable

**22-NREC-CT-081_Mod-3**

Principal Investigator & Institution: Prof. Patrick Morris, Beaumont Hospital

Study title: A Randomized Phase 3 Double-Blinded Study Comparing the Efficacy and Safety of Niraparib to Placebo in Participants with Either HER2- Negative BRCA-Mutated or Triple-Negative Breast Cancer with Molecular Disease Based on Presence of Circulating Tumour DNA after Definitive Therapy (ZEST).

EudraCT: 2020-003973-23

- NREC-CT Decision: Favourable with Conditions

- Condition: The NREC-CT recommends that a sentence is added to the Thank You Letter to detail that a follow up meeting will be offered with the participant's treating doctor, to discuss what further options may be available following closure of the trial.

**22-NREC-CT-025_Mod-4**

Principal Investigator & Institution: Prof. Raymond McDermott, St Vincent's University Hospital

Study title: A Phase 2, Open-Label, Randomized Study to Assess the Efficacy and Safety of Zolbetuximab (IMAB362) in Combination with Nab-Paclitaxel and Gemcitabine (Nab-P + GEM) as First Line Treatment in Subjects with Claudin 18.2 (CLDN18.2) Positive, Metastatic Pancreatic Adenocarcinoma

- EudraCT: 2018-002551-15

- NREC-CT Decision: Favourable with Conditions

- Condition: In relation to the Optional Exit Interview, the following requests have been made by the Committee:
    - To confirm in the ICF that the participant can opt out of the audio recording but still participate in the interview;
    - To confirm the duration of retention for the audio recordings;

- That participants be assured of arrangements for the interview which ensure their privacy.

**21-NREC-CT-038_NCP_Mod-4**

Principal Investigator & Institution: Prof. Patrick Morris, Beaumont Hospital

Study title: Phase III postneoadjuvant study evaluating Sacituzumab Govitecan, an Antibody Drug Conjugate in primary HER2-negative breast cancer patients with high relapse risk after standard neoadjuvant treatment – SASCIA.

EudraCT: 2019-004100-35

- NREC-CT Decision: Favourable

**22-NREC-CT-024_Mod-4**

Principal Investigators & Institutions: Prof. Glen Doherty, St Vincent's University Hospital

Study title: A Phase 3 Multicenter, Long Term Extension Study to Evaluate the Safety and Efficacy of Upadacitinib (ABT-494) in Subjects with Ulcerative Colitis (UC)

EudraCT: 2016-000674-38

- NREC-CT Decision: Favourable with Conditions

- Condition: The Committee requests confirmation that insurance is in place for the duration of the study, including the extension.

**22-NREC-CT-131_Mod-1**

Principal Investigator & Institution: Prof. Fionnuala McAuliffe, UCD Perinatal Research Centre

Study title: Daily versus alternate day oral iron supplementation for the treatment of iron deficiency anaemia in pregnancy (IronMother)

EudraCT: 2022-001815-25

- NREC-CT Decision: Request for Further Information

- The Committee notes the inclusion of the following in the Consent Form: "I agree to be contacted in the future regarding possible future research", and requests further information be provided to the participant regarding the context of this request in the main body of the ICF.

**22-NREC-CT-069_Mod-3**

Principal Investigator & Institution: Prof. Glen Doherty, St Vincent's University Hospital

Study title: A Randomised Pilot Study of the Safety and Efficacy of Tofacitinib (Xeljanz) in Improving Endoscopic Outcomes in Subjects with Ulcerative Colitis with Active, Chronic, Antibiotic Dependent or Refractory Idiopathic Pouchitis (Healing of Antibiotic Refractory Pouchitis with Xeljanz): HARP-X

EudraCT: 2021-005694-87

- NREC-CT comments: Favourable

**21-NREC-CT-012_Mod-5**

Principal Investigator & Institution: Dr Amjad Hayat, University Hospital Galway

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tafasitamab Plus Lenalidomide in Addition to Rituximab Versus Lenalidomide in Addition to Rituximab in Patients With Relapsed/Refractory (R/R) Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma

EudraCT: 2020-004407-13

- NREC-CT Decision: Favourable

---

- AOB:
  - An update was given to the Committee regarding appointment of new members, and the ongoing Expression of Interest campaign.
  - Dr Laura Mackey updated the Committee on potential changes to internal documentation for assessment of the Part I Dossier.