NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-CT A

16th June 2021

Attendance

Name	Role
Prof Alistair Nichol	Chairperson, NREC CT-A
Prof Orla Sheils	Deputy Chairperson, NREC-CT A
Dr Heike Felzmann	Deputy Chairperson, NREC-CT A
Prof Catherine Hayes	Committee Member, NREC-CT A
Prof Tina Hickey	Committee Member, NREC-CT A
Prof David Brayden	Committee Member, NREC-CT A
Dr Dervla Kelly	Committee Member, NREC-CT A
Dr Darren Dahly	Committee Member, NREC-CT A
Ms Muireann O'Briain	Committee Member, NREC-CT A
Dr John O'Loughlin	Committee Member, NREC-CT A
Dr Jimmy Devins	Committee Member, NREC-CT A
Ms Ann Twomey	Committee Member, NREC-CT A
Prof. John Wells	Committee Member, NREC-CT A
Prof Patrick Dillon	Committee Member, NREC-CT A
Ms Aileen Sheehy*	Programme Manager, National Office for RECs
Dr Jane Bryant*	Project Officer, National Office for RECs
Dr Jennifer Ralph James	Head, National Office for RECs

*Drafted minutes

Apologies: Dr Geraldine Foley, Mr Gerry Daly, Prof Mary Donnelly, Prof Mark Sherlock

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- Application 21-NREC-CT-004
- Application 21-NREC-CT-005
- Application 21-NREC-CT-006_AMEND-1
- Application 21-NREC-CT-007
- AOB

- The Chair welcomed the NREC-CT A.
  - No declarations of interest were made related to the applications under review.
  - The minutes from the previous NREC-CT A meeting were approved.

Applications

21-NREC-CT-004

Principal Investigator: Prof. Gerard O'Sullivan

Study title: DEXTERITY-AFP: Perivenous Dexamethasone Therapy: Examining Reduction of Inflammation after Thrombus Removal to Yield Benefit in Acute Femorpopliteal DVT (CIP0217)

Lead institution: University Hospital Galway

  - NREC-CT comments:
- The NREC-CT A noted that the clinical trial application represents a Phase II study, combining Dexamethasone treatment with a medical device to prevent recurrence of acute Femorpopliteal DVT post-removal.
- The NREC-CT A noted that this is trial in two parts; with a lead-in phase followed by a double-blind study, and that the PIL, while comprehensive, would benefit from clarity on the differences between the two phases.

- The NREC-CT A noted that while this is a well prepared application, there remains areas requiring clarity on the numbers to be recruited for each part of the trial, and information concerning female participants.
- The NREC-CT A is not in a position to return a final ethics opinion based on the information and documentation received thus far. In this regard, the Committee requires additional information to inform its deliberations.

  - NREC-CT Decision:

- Request for Further Information

  - Further Information Requested:

- The NREC-CT A noted that as this study consists of two distinct phases, the Committee requested agreement from the Principal Investigator that a preliminary report is shared with the NREC-CT A on completion of Phase 1 and before Phase 2 commences.
- The NREC-CT A noted that high doses of the medicinal product could have an impact on blood sugars, and requested further information on how this will be assessed.
- The NREC-CT A requested clarity on patient recruitment.
- The NREC-CT A requested further information and clarity on the Patient Information leaflet (PIL). Further information was requested regarding the presence of an executive summary, that separate PILs be prepared for the two trial phases and adapted to an Irish audience, information on exposure to ionising radiation, the retention of biological samples and GDPR- related rights. Clarity was requested on the randomisation process, the length of time participants will have to consider the information, the length of time female participants are required to take contraception, and who will present the PIL to potential participants.
- The NREC-CT A recommended that results in plain English from the study are shared with participants once the study is completed.
- The NREC-CT A requested further information on how participants will be reimbursed for travel and refreshments, and whether a maximum amount will be set for expenses.
- The NREC-CT A requested detail on what jurisdictions data from the study will be transferred to.
- The NREC-CT A requested confirmation on whether the Principal Investigator has experience in using the device associated with the procedure. The NREC-CT A also requested clarity on which healthcare professional will undertake the procedure in participants.

21-NREC-CT-005

Principal Investigator: Prof. Gerard O’Sullivan

Study title: DEXTERITY-SCI: Perivenous Dexamethasone Therapy: Examining Reduction of Inflammation after Thrombus Removal to Yield Benefit in Subacute and Chronic Iliofemoral DVT (CIP0218)

Lead institution: University Hospital Galway

- NREC-CT comments:

- The NREC-CT A noted that the clinical trial application represents a Phase II study, combining Dexamethasone treatment with a medical device to prevent recurrence of subacute and chronic iliofemoral DVT post-removal.
- The NREC-CT A noted that this is trial in two parts; with a lead-in phase followed by a double-blind study, and that the PIL, while comprehensive, would benefit from clarity on the differences between the two phases.
- The NREC-CT A noted that while this is a well prepared application, there remains areas requiring clarity on the numbers to be recruited for each part of the trial, and information concerning female participants.
- The NREC-CT A is not in a position to return a final ethics opinion based on the information and documentation received thus far. In this regard, the Committee requires additional information to inform its deliberations.

- NREC-CT Decision:

- Request for Further Information

- Further Information Requested:

- The NREC-CT A requested agreement from the Principal Investigator that a preliminary report is shared with the NREC-CT A on completion of Phase 1 and before Phase 2 commences.
- The NREC-CT A noted that high doses of the medicinal product could have an impact on blood sugars, and requested further information on how this will be assessed.
- The NREC-CT A requested clarity on patient recruitment.
- The NREC-CT A requested further information and clarity on the Patient Information leaflet (PIL). Further information was requested regarding the presence of an executive summary, that separate PILs be prepared for the two trial phases and adapted to an Irish audience, information on exposure to ionising radiation, the retention of biological samples and GDPR- related rights. Clarity was requested on the randomisation process, the length of time participants will have to consider the information, the length of time female participants are required to take contraception, and who will present the PIL to potential participants.
- The NREC-CT A recommended that results in plain English from the study are shared with participants once the study is completed.

- The NREC-CT A requested further information on how participants will be reimbursed for travel and refreshments, and whether a maximum amount will be set for expenses.
- The NREC-CT A requested detail on what jurisdictions data from the study will be transferred to.
- The NREC-CT A requested confirmation on whether the Principal Investigator has experience in using the device associated with the procedure. The NREC-CT A also requested clarity on which healthcare professional will undertake the procedure in participants.

21-NREC-CT-006_AMEND-1

Principal Investigator: Prof. Seamas Donnelly

Study title: GALACTIC-1 - A randomized, double-blind, multicentre, parallel, placebo-controlled phase 2b study in subjects with idiopathic pulmonary fibrosis (IPF) investigating the efficacy and safety of GB0139, an inhaled galectin-3 inhibitor administered via a dry powder inhaler over 52 weeks

Lead institution: Tallaght University Hospital

- NREC-CT Comments:

- The NREC-CT A noted that this substantial amendment follows an interim report of safety analysis, and proposes to discontinue the higher dose arm of the medicinal product, and to continue recruitment for the remaining study arms.
- The NREC-CT A noted the amended documentation was comprehensive with a quick response from the trial team following the interim review.
- The NREC-CT A is not in a position to return a final ethics opinion based on the information and documentation received thus far. In this regard, the Committee requires additional information to inform its deliberations.

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required:

- The NREC-CT A requested a copy of the letter from the Data & Safety Monitoring Committee to gain a full understanding of the requirements and recommendations from the interim report.
- The NREC-CT A requested further information on the feasibility of the study with the likely lower number of eligible participants.
- The NREC-CT A requested clarification on whether standard care will continue for participants of the study. The NREC-CT A also requested confirmation that future

prescriptions of nintedanib or pirfenidone will not be stalled for participants as part of participation in the clinical trial.

21-NREC-CT-007

Principal Investigator: Prof. Daniel Ian Flitcroft

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.

Lead institution: Centre for Eye Research Ireland, Technological University Dublin

- NREC-CT Comments:

- The NREC-CT A noted that the clinical trial application represents a phase III study investigating the use of the medicinal product Atropine Sulfate in treating myopia in paediatric patients.
- The NREC-CT A noted that this study is well designed and rigorous, with comprehensive patient information leaflets and consent and assent forms, however further information and clarifications are required.
- The NREC-CT A is not in a position to return a final ethics opinion based on the information and documentation received thus far. In this regard, the Committee requires additional information to inform its deliberations.

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required:

- The NREC-CT A recommended a plain English executive summary be added to the participant information leaflet (PIL), clearly outlining the transfer of data to a jurisdiction outside of the EU.
- The NREC-CT A requested that the duration for which the participants of child-bearing age will be required to take contraception be included in the participant materials.
- The NREC-CT A requested that the psychosocial descriptors are included in the participant materials.
- The NREC-CT A suggested that the assent forms are adapted in line with the varying communication needs and literacy levels across the age groups.
- The NREC-CT A requested information on the planned process of consenting participants who turn 16 years old while participating in the trial.
- The NREC-CT A requested further information around how the burden of some processes described in the protocol will be minimised, including minimising the amount of

school time lost through numerous visits, the collection of medication, the completion of daily diaries, and clarity on the frequency of psychosocial data collection.

- The NREC-CT A suggested that a digital version of the questionnaire is made available to participants as well as the paper-based version.
- The NREC-CT A suggested that guidance is offered to those with parental responsibility on administering the eye drops.
- The NREC-CT A requested further information on the planned process of informing the participant's GP of relevant outcomes from the psychosocial questionnaire.
- The NREC-CT A requested further information on how participants will be reimbursed for travel and refreshments, and whether a maximum amount will be set for expenses.
- The NREC-CT A requested clarity around the retention and transfer of data, including the length of time, the rationale for transfer of psychosocial data outside of Ireland, whether country identifiers will be used for the pseudonymised data, and explanation of the implications of consenting to the transfer of data outside of the EU.
- The NREC-CT A requested a letter from TU Dublin outlining the role of the trial centre, the facilities available, and the safety procedures in place in situ for undertaking a clinical trial.

- AOB:
  - The NREC-CT A discussed the format of Committee Meetings and welcomed suggestions for same.
  - Clarification was sought by the Committee regarding preparation of reports and decision letters.
  - Guidance on Applicant preparation of patient information materials was discussed.

- The Chair closed the meeting.