National Research Ethics Committee

NREC-CT B

8th of December 2021

Attendance

Name	Role
Dr Cliona McGovern	Chairperson, NREC-CT B
Dr Jean Saunders	Deputy Chairperson, NREC CT-B
Prof. John Faul	Deputy Chairperson, NREC-CT B
Ms Serena Bennett	Committee Member, NREC-CT B
Mr Philip Berman	Committee Member, NREC-CT B
Ms Mandy Daly	Committee Member, NREC-CT B
Dr Enda Dooley	Committee Member, NREC-CT B
Dr Lorna Fanning	Committee Member, NREC-CT B
Dr John Hayden	Committee Member, NREC-CT B
Dr Mary McDonnell Naughton	Committee Member, NREC-CT B
Dr Eimear McGlinchey	Committee Member, NREC-CT B
Prof. Abhay Pandit	Committee Member, NREC-CT B
Mr Gavin Lawler,	Committee Member, NREC-CT B
Dr Mark Robinson	Committee Member, NREC-CT B
Prof. David Smith	Committee Member, NREC-CT B
Ms Paula Prendeville	Committee Member, NREC-CT B
Ms Caoimhe Gleeson	Committee Member, NREC-CT B
Prof. Colm O'Donnell	Committee Member, NREC-CT B
Dr Jennifer Ralph James	Head, National Office for RECs
Ms Aileen Sheehy*	Programme Manager, National Office for RECs

Dr Laura Mackey*	Project Officer, National Office for RECs

*Drafted minutes

Apologies:

None

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- Application 21-NREC-CT-146
- Application 21-NREC-CT-147
- Application 21-NREC-CT-156
- AOB

- The Chair welcomed the NREC-CT B.
  - The Minutes from the NREC-CT B meeting on the 3rd of November were approved.

Applications

21-NREC-CT-146

Principal Investigator: Prof. Sean Raymond McDermott

Study title: A Randomized Open-Label Phase III Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice in Subjects with Metastatic or Locally Advanced Unresectable Urothelial Cancer

Lead institution: Tallaght University Hospital

  - NREC-CT comments:
- The NREC-CT B noted this clinical trial application represents a Randomized Open-Label Phase III Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice in Subjects with Metastatic or Locally Advanced Unresectable Urothelial Cancer.
- The NREC-CT B noted that the quality of this application was impressive overall.
- The NREC-CT B agreed that additional information was required to inform its deliberations and therefore, was not yet in a position to return a final ethics decision.

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required:

- The NREC-CT B noted that the ionising radiation aspect of the application is described in a UK context and requested that this is adapted to an Irish setting.
- The NREC-CT B requested clarification around the period of time participants will remain on treatment when there is clinical benefit, specifically, does clinical treatment continue until the study has concluded or beyond the end of the study.
- The NREC-CT B noted that the PIL is necessarily long but suggested that the addition of visuals may improve the overall readability of the document.
- The NREC-CT B noted that although the adverse effects of each drug are described in the PIL, it may not be clear to participants that they will not be receiving each of these medications and requests that this is clarified.
- The NREC-CT B commended the efforts made to ensure accessibility but requested that information regarding British sign-language interpreters is adapted to an Irish context in the participant materials.
- The NREC-CT B spoke favourably about the Biomarker Future Genetic participant information leaflet and considered it to be very informative. The Committee suggested that some of the information in the PIL, where included in the Biomarker Future Genetic PIL, could be removed to reduce the length of the main PIL.
- The NREC-CT B noted a number of typos in the Addendum and requests that the document is proof-read to avoid typographical errors.
- The NREC-CT B requested further detailed information on the financial arrangements in place.
- The NREC-CT B requested further information on the process for consent in the event of pregnancy during participation in the study and an overview of supports available to the participant.
- The NREC-CT B queried if the Sponsor would seek to obtain access to the participant's full medical history or would the information be limited to medical information related to the pregnancy, which should also be clarified in the Pregnancy PIL.
- The NREC-CT B noted that the insurance certificate does not cover the duration of the trial and requested confirmation that adequate insurance cover is in place for the full duration of the trial.

21-NREC-CT-147

Principal Investigator: Prof. Afif El Khuffash

Study title: The use of Sildenafil in Neonates with Down's Syndrome to Reduce Pulmonary Vascular Resistance

Lead institution: Rotunda Hospital

- NREC-CT Comments:

- The NREC-CT B noted this clinical trial application represents the use of Sildenafil in Neonates with Down's Syndrome to Reduce Pulmonary Vascular Resistance.
- The NREC-CT B commented that this application was clearly presented in general.
- The NREC-CT B agreed that additional clarifications were required and requested further information to inform its deliberations before a final ethics opinion could be returned.

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required:

- The NREC-CT B noted that the study as described is unlikely to be randomised and noted discrepancies between the application and the protocol on the allocation of the treatment and the control. The Committee requested further clarification on how the allocation of treatments will take place.
- The NREC-CT B requested further information for the rationale for a two-week period of follow-up, which may be too short when identifying adverse events.
- The NREC-CT B requested that the technical language included in the participant materials is revised with a lay audience in mind.
- The NREC-CT B noted that the schematic on page 14 of the PIL is too complex for a lay audience and requested that it is either revised with PPI input or removed altogether.
- The NREC-CT B noted that many of the trial sites are located in urban areas with high levels of diversity across the population and requested further information on the feasibility for provision of a translator to enhance accessibility to the trial to non-native English speakers.
- The NREC-CT B requested further clarification about when parents will be first approached about participating in the study and how much time they will be given between being first approached and consenting. This should be clarified in the participant materials also.
- The NREC-CT B requested the CVs of the Principal Investigators at the various sites.
- The NREC-CT B noted that the information provided on insurance does not cover the Coombe Hospital or the National Maternity Hospital and requested confirmation of cover in place at both of these sites.

21-NREC-CT-156

Principal Investigator: Prof. Louise Gallagher

Study title: A Randomized, Double-Blind, Placebo-Controlled Multiple-Center, Efficacy and Safety Study of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome - RECONNECT

Lead institution: St James's Hospital

- NREC-CT Comments:

- The NREC-CT B noted that the clinical trial application represents a Randomized, Double-Blind, Placebo-Controlled Multiple-Center, Efficacy and Safety Study of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome.
- The NREC-CT B commended the advertising materials in particular, regarding their accessibility.
- The NREC-CT B determined that additional information was required to inform its deliberations and therefore, was not yet in a position to return a final ethics decision.

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required

- The NREC-CT B noted that the administration of dosage is based on the weight of the participant and requested further information around the rationale for this strategy.
- The NREC-CT B requested further information on the rationale and the necessity for the inclusion of potentially distressing questions regarding suicidal ideation, and whether it would be possible to remove these questions from the questionnaires.
- The NREC-CT B requested further information on the risks associated with using a Cannabis product in minors and that more comprehensive information is included in the protocol and participant materials.
- The NREC-CT B requested that the Assent Form is revised in line with easy read guidelines and incorporates some of the accessible visuals and language from the recruitment materials. The NREC-CT B also recommended that the assent forms are adapted appropriately for the various age cohorts.
- The NREC-CT B requested further information on how the applicant plans to ensure that the study participants are fully involved in the study and have the opportunity for their expression of will to be captured at every stage of the process.
- The NREC-CT B requested confirmation of the age at which the minor will be involved in the assent process.

- The NREC-CT B requested that more information is provided to participants on the risks of the treatment.
- The NREC-CT B requested that the participant materials make reference to the Health Research Regulations 2018, and if required, to the Health Research Consent Declaration Committee.
- The NREC-CT B noted that the patient cohort may require additional supports for various reasons, such as potential apprehension towards needles and aversion or suspicion towards strangers and queried whether it would be possible for the research team to implement a transition support document that is used at each participant interaction and provides participants at the end of each session with specific information on the next session. The NREC-CT B also queried the possibility of providing parents and guardians with visual or written supports to prepare minors ahead of each visit.
- The NREC-CT B requested further information on the person in the research team obtaining consent, their role and qualifications.
- The NREC-CT B requested further information on the purpose of the genetic testing described in the participant materials and whether results will be relayed to participants. This information should also be captured in the participant materials.
- The NREC-CT B requested further information on the Open Label Extension described and that more comprehensive information is provided to participants.
- The NREC-CT B requested further information on how data related to the social media campaign will be managed and confidentiality maintained, and who on the research team will moderate the social media activity.
- The NREC-CT B requested further information on where advertisement materials and posters will be used in Ireland.
- The NREC-CT B requested further information on the storage, retention and destruction of samples and the underlying data related to trial participants.
- The NREC-CT B noted that the Clinical Monitor will have access to participant data and requested further information on who this person is and their qualifications**.**
- The NREC-CT B requested further information on the process in place in the event that a participant becomes pregnant in a trial, an overview of the supports they will receive and a summary of expenses and insurance coverage they will be entitled to.

- AOB:

- None
- The Chair closed the meeting.