National Research Ethics Committee

NREC-CT Meeting

6th March 2024

Attendance

Name	Role
Prof David Brayden	Chairperson, NREC-CT D
Prof David Smith	Deputy Chairperson, NREC-CT D
Dr Christina Skourou	Chaired meeting Deputy Chairperson, 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
Ms Deirdre McLoughlin	Committee Member, NREC-CT D
Prof Tina Hickey	Committee Member, NREC-CT D
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Ms Patricia Kenny*	Project Officer, National Office for RECs

Apologies:

Enda Dooley, Andrew Green, Mary McDonnell Naughton and Geraldine O'Sullivan Coyne

Quorum for decisions: Yes

Agenda

- Welcome & Apologies

- 2022-501105-12-00
- 2023-506696-10-00
- 2023-505242-25-00
- 2022-501707-27-01
- 2022-502669-14-00 SM-6
- 23-NREC-CT-030_Mod-2
- 23-NREC-CT-033_Mod-2
- AOB

- The Chair welcomed the NREC-CT D.
  - The minutes from the previous NREC-CT D meeting on 31st January 2024 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2022-501105-12-00

Principal Investigators & Institutions: Tallaght University Hospital (Prof. Ray McDermott), Cork University Hospital (Dr Richard Bambury)

Study title: An Open-label, Randomized, Controlled Phase 3 Study of Disitamab Vedotin in Combination with Pembrolizumab Versus Chemotherapy in Subjects with Previously Untreated Locally Advanced or Metastatic Urothelial Carcinoma that Expresses HER2 (IHC 1+ and Greater)

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required RFI**

Part II Considerations
1. Compliance with national requirements on data protection
• No Considerations raised by the NREC
2. Compliance with use of biological samples
• No Considerations raised by the NREC
3. Financial arrangements
• No Considerations raised by the NREC
4. Proof of insurance
• No Considerations raised by the NREC
5. Recruitment arrangements
• The NREC-CT were unclear if the Patient Recruitment Brochure and Patient Flyer that were submitted would be used as advertisements for the trial in Ireland as the Recruitment Arrangement document advised that patients will be identified during standard hospital visits or through patient lists. The Committee requested that the Recruitment Agreement document be updated to clarify use of the brochure and flyer at Irish sites.
• The NREC-CT noted that the recruitment brochures only pictured men, but that the trial is targeted at both male and females over 18. The Committee advised that all images in recruitment materials should be relevant and diverse.
6. Subject information and informed consent form
• The NREC-CT noted the collection of data on race in SIS and ICF Main pg 40 and pg 46 and SIS and ICF Pre-Screening pg 7 and pg 13. In line with GDPR special category data requirements, the NREC-CT requested justification regarding collection of race and ethnicity data. The Committee also requested that the SIS and ICF Main be updated to include this justification in line with GDPR requirements.
• The NREC-CT noted that SIS and ICF Main pg 42, the SIS and ICF Pre-Screening pg 9 and the SIS and ICF Pregnant Partner pg 5, state that anonymised results from the study may be shared with other researchers. The Committee requested that the SIS and ICF Main pg 46 be updated to include a specific statement for the

participant to explicitly consent to the processing of their personal data from coded to anonymised data it as per Article 4 (2) and (6) General Data Protection Regulation (GDPR).

- The NREC-CT noted that SIS and ICF Main pg 40 and 41 is seeking blanket consent for future use of samples/data for unspecified purposes without further consent "possibly develop new tests, procedures, commercial products, or services" and "keep studying cancer". 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 a statement that future research will be restricted to research in the area of cancer of the urinary system and/or the study drug and this is clearly stated in the main body and informed consent sections of the SIS and ICF.
- The NREC-CT noted contradiction in information in SIS and ICF Pre-Screening in relation to genetic testing: pg 3 states that tests could include genetic testing however pg 10 advises there will be no genetic testing undertaken. The Committee requested that the SIS and ICF Pre-Screening be amended to clarify this.
- The NREC-CT considered that the SIS and ICF Main (p.7), reference to genetic testing on the tumour cells, is written in language which may be confusing for participants. The Committee requested that this section be amended to use lay language and provide clarity to participants.
- The NREC-CT requested that the SIS and ICF Main be updated to provide more information regarding where data and samples will be sent.
- The NREC-CT noted the SIS and ICF Main pg 4 provides information on the total sample size. The Committee requested that the ICF Main pg 4 be updated to provide information about the projected Irish sample size.
- The NREC-CT noted that participants will have to answer questionnaires on mental health including EORTC QLQ-C30, EQ-5D-5L and Brief Pain Inventory. The Committee requested that the SIS and ICF Main be updated to provide a brief explanation about what these measures ask about, an estimate of how long completion takes, and clarify where/how often the participant will complete them.
- The NREC-CT noted that SIS and ICF Main pg 37 states that "you may be able to have some of your costs for taking part in the study, like travel costs or accommodation paid back to you. Please ask someone from the study for more information". The Committee requested that the SIS and ICF Main pg 37 be amended to clarify that participants will be reimbursed for reasonable costs associated with travel to the study site (specifying e.g. travel, accommodation, parking and food expenses),and to explain the role of Scout Clinical in repayments.
- It was unclear to the NREC-CT if these participants are likely to require a carer/companion to accompany them on site visits. The Committee requested clarification on this and advised that if participants are accompanied by a carer, that the carer's reasonable expenses should also be covered and that this should be detailed in the SIS and ICF Main.
- The NREC-CT noted that while participants in Group B (control) on standard treatment are told that they may be able to get other standard medications at the end of the Group B chemotherapy, they are not explicitly informed that they cannot

access the study drug at end of their study treatment. The Committee requested that the SIS and ICF Main be amended to clarify this.

- The NREC-CT noted the large number of MUGA scans Group A undergoes, however the additional risk of developing cancer as a consequence of taking part in this study is not detailed in the ICF. While the Committee noted the comment in the Site Suitablity Form that the risk of this is minimal due to the poor prognosis of this study group, they requested that the additional risk should be detailed in the SIS and ICF Main.
- For the purposes of ensuring participants are fully and unambiguously informed of their rights, the Committee requests that the the SIS and ICF Main pg 11 paragraph 2 last sentence be updated as follows *"If you choose to withdraw from the study and you don't want to take part in the follow-up visits or phone calls you don't have to. However we may still ask the study staff to review your medical records to find out about your future treatments and general health"*
- The NREC-CT noted that the SIS and ICF Main advise that the participants' GP will be informed of their participation in the study. The Committee noted the GP letter had not been submitted for review and requested clarification on same.

7. Suitability of the clinical trial sites facilities

- The NREC-CT noted the Site Suitability Form submitted for Tallaght Hospital was signed by the Principal Investigator which is not appropriate under the Clinical Trial Regulations. The Committee requested that an updated Site Suitability Template be provided which is signed by the CEO, Head of Clinic / institution, Director of Research, Clinical Director, or delegate of the hospital.
- The NREC-CT noted that despite the poor prognosis for many of these participants the Site Suitability Forms do not mention availability of Palliative Care services where appropriate at each site. The Committee requested that the Site Suitability Forms be updated to provide information on Palliative Care services.

8. Suitability of the investigator

- No Considerations raised by the NREC

2023-506696-10-00

Principal Investigators & Institutions: Mater Misericordiae University Hospital (Dr Deirdre Kelly), Tallaght University Hospital (Dr Sebastian Trainor), St James's Hospital (Dr Sinead Cuffe), Beaumont Hospital (Prof. Jarushka Naidoo), St Vincent's University Hospital (Dr Emer Hanrahan)

Study title: A Phase III, Randomized, Double-Blind Study of Tiragolumab Plus Atezolizumab Compared with Placebo Plus Atezolizumab in Participants with Completely Resected Stage IIB, IIIA, or Select IIIB, PD-L1 Positive, Non-Small Cell Lung Cancer who have received Adjuvant Platinum-Based Chemotherapy

- **NREC-CT Decision:**

- Request for more information

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Part 17

It is noted that the previous Phase 2 study showed the addition of tiragolumab does not improve PFS in the low PD-L1 group. The rationale for addition of this patient group to the study should be provided by the sponsor.

- **Additional Information Required RFI**

Part II Considerations

1. Compliance with national requirements on data protection

- No considerations raised by the NREC

2. Compliance with use of biological samples

- No considerations raised by the NREC

3. Financial arrangements

- The NREC-CT requested a brief description of financing in place for the Clinical Trial be provided. Please note, although the NREC-CT may review budgets and contracts to support their assessment, they do not approve them on behalf of the site.

4. Proof of insurance

- No considerations raised by the NREC

5. Recruitment arrangements

- No considerations raised by the NREC

6. Subject information and informed consent form

- The NREC-CT requested that the ICF Main be updated to include details around any samples and data transferred to third parties and where they are based.
- The NREC-CT noted that the Main ISC page 20 used a bundled approach to consent 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): 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 Committee also advised that specific consent statements relating to the following also be included
    - Transfer of data and/or samples (coded) to any third parties.
    - Option to change mind and withdraw at a later stage.
    - GP being informed.
- The NREC-CT requested the addition of a space/placeholder in the ICF (pg 24) for the qualification of the person performing the interview to be provided ie. Study doctor.
- The NREC-CT noted that the ICF Main pg 17 refers to blood being tested for hepatitis and HIV infections. The Committee requested that ICF Main be updated to add a statement informing participants that the study team are required to report any positive HIV, Hep A or Hep C test result and certain personal details about the participant to the relevant authority. This is because they are mandatory notifiable diseases. (Infectious Diseases (Amendment) Regulations 2022 (S.I. No. 258 of 2022) May 2022).

- The NREC-CT requested that the ICF Main pg 17 Genome Testing section be updated to clarify that is an optional component of the study and not mandatory.
- The NREC-CT noted ICF Main pg 19 “your study doctor may contact you in the future to see if you would like to learn more about taking part in a new research study. “ The Committee requested that this optional consent be provided on a separate page at the end of the consent documents to enable participants to explicitly consent to be contacted in the future about other research studies.
- The NREC-CT noted the ICF Main pg 27 and the ICF Pre-screening pg 6 secondary purposes of data advises that “If this is not the case, your data must be either anonymized in accordance with applicable law or labelled with a participant ID “.The Committee requested that the Main ICF consent form/s be updated to include a specific statement for the participant to explicitly consent to the processing of their personal data from coded to anonymised data it as per Article 4 (2) and (6) General Data Protection Regulation (GDPR) if data will be used for secondary purposes.
- The NREC-CT noted that ICF Main pg 21 is seeking blanket consent for future use of samples/data for unspecified purposes without further consent. 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 research in the disease area and/or the study drug and this is clearly stated in the ICF and consent page. The Committee also requests that any future use of biological samples is reviewed by an ethics committee and requested that this is captured in the PISCFs.
- The NREC-CT noted ICF Pre-screening pg 25 “your study doctor may contact you in the future to see if you would like to learn more about taking part in a new research study“. The Committee requested that this optional consent be provided on a separate page at the end of the consent document to enable participants to explicitly consent to be contacted in the future about other research studies.
- The NREC-CT recommended that the ICF Pre-screening pg 8 consent page would benefit from each statement having an initial or tick box to confirm understanding and explicit consent for each statement rather than just listed in a paragraph.
- The NREC-CT recommended that the ICF Pregnant Partner pg 2/3 consent page would benefit from each statement having an initial or tick box to confirm understanding and explicit consent for each statement.
- The NREC-CT recommended that the ICF Infant Authorisation Form pg 3 consent page would benefit from each statement having an initial or tick box to confirm understanding and explicit consent for each statement.
- The NREC-CT requested that the ICF Main pg 3 be updated to state that atezolizumab is only licenced for patients with high PD-L1 in Europe.
- The NREC-CT requested that the ICF Main pg 6 Section 1.7 be updated to clarify that participants will be re-imbursed for reasonable costs associated with travel to the study site including travel, accommodation, parking and food expenses. The Committee also requested the expenses for carers who accompany participants to site visits also be included and that this be stated in the ICF Main and ‘Compensation for trial participants’ document.

- The NREC-CT noted that the ICF Main does not include detail around the dose of study treatments. The Committee requested that the ICF Main be updated to provide this information.

7. Suitability of the clinical trial sites facilities

- No considerations raised by the NREC

8. Suitability of the investigator

- The NREC-CT requested that an updated CV for Dr Deirdre Kelly be provided with greater detail on clinical trial experience including types of trials.

2023-505242-25-00

Principal Investigators & Institutions: Cork University Hospital (Dr Vitaliy Mykytiv), Mater Misericordiae University Hospital (Dr Peter O'Gorman)

Study title: Phase 2 dose-ranging and interception study of linvoseltamab in patients with high-risk monoclonal gammopathy of undetermined significance or low-risk smoldering multiple myeloma

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required RFI**

Part II Considerations

1. Compliance with national requirements on data protection

- No considerations raised by NREC

2. Compliance with use of biological samples

- No considerations raised by NREC

3. Financial arrangements

- The NREC-CT requested a brief description of financing in place for the Clinical Trial be provided. Please note, although the NREC-CT may review budgets and contracts to support their assessment, they do not approve them on behalf of the site.

4. Proof of insurance

- No considerations raised by NREC

5. Recruitment arrangements

- The NREC-CT noted that the Recruit and ICF Process document is not accessible and/or searchable. The NREC-CT requested that a fully accessible (such as word or original pdf version) Recruit and ICF Process document is provided for review.
- The NREC-CT noted that Recruit and ICF Process document pg 3 states that *"Only potential participants that can understand trial information in national language are subject to participation in the trial…"* The Committee requested rationale is provided regarding the absence of translation and other supports for non-native English speakers as necessary.

6. Subject information and informed consent form

- The NREC-CT noted the collection of data on race and/or ethnicity in SIS and ICF Main pg 6. In line with GDPR special category data requirements, the NREC-CT requested justification regarding collection of race and ethnicity data. The Committee also requested that the Main Consent Form be updated to include this justification in line with GDPR requirements.
- The NREC-CT noted that the SIS and ICF FBR are seeking blanket consent for future use of samples/data for unspecified purposes and diseases without further consent. 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 research in the disease area and/or the study drug and this is clearly stated in the main body and informed consent sections of the SIS and ICF FBR and Compliance for use of Biological Samples document. The Committee advised that alternatively an option could be provided to enable participants to consent to be contacted in the future about new research studies once the future research is clearly defined. The Committee also requests that any future use of samples or data is reviewed by an ethics committee and requested that this is captured in the PISCFs.
- The NREC-CT noted this is a phase 2 trial in participants who are clinically well and have a moderate risk of progression to multiple myeloma and that even without treatment and without enrolling in the trial, a significant number of those eligible will never develop myeloma. The Committee stated that the risk/benefit analysis for this population is therefore harder to balance. In addition, from the limited existing studies, side effects, including cytokine release symptoms are a risk. The Committee requested that the participants' risk of progression to multiple myeloma must be stated in the PIL, such that the participant can compare this to the risks of participation and make a fully informed decision. The Committee determined that the SIS-ICF Main does not address this risk/benefit issue sufficiently. The Committee requested that the SIS-ICF Main should be rewritten to adequately reflect the benefits and risks of participation.
- The NREC-CT noted that the SIS-ICF Main does not explain how many of the investigations such as bone marrow aspirate, CT, MRI, PET scans would be part of standard follow up of MGUS monitoring, and how many would be part of the trial. The Committee requested that the SIS-ICF Main be updated to provide this information.
- It was unclear to the NREC from the SIS-ICF Pregnant Partner how the study doctor will collect information on the pregnancy. The Committee requested that the SIS-ICF Pregnant Partner be updated to clarify if the pregnant partners' doctor/midwife will be contacted for information and to add a consent statement on pg 6 for the pregnant partner to explicitly consent to this.
- The NREC-CT requested that the SIS-ICF Main pg 24 be updated to provide an explanation of when an impartial witness will be required.
- The NREC-CT requested that the SIS-ICF Main be updated to provide detail around the number of Irish participants taking part.

- The NREC-CT noted the SIS and ICF Main pg 12 and SIS and ICF FBR pg 2 Privacy risks paragraph, states *"The databases and storage facilities that contain your personal data will generally not contain identifying information…".* The Committee requested the SIS and ICFs be updated to clarify what is meant by "generally" and in what instances personal data would be included. If the inclusion of the word "generally" is an error, then please remove from the SIS and ICFs.

7. Suitability of the clinical trial sites facilities

- No considerations raised by NREC

8. Suitability of the investigator

- The NREC-CT requested that an updated CV is provided for Peter O'Gorman and Vitaliy Mykytiv to provide the date of their most recent GCP training. Please note GCP training should be renewed every 2-3 years depending on the course provider.

2022-501707-27-01

Principal Investigators & Institutions: Crescent Medical Centre, Galway (Dr Sinead Feeney); Heights Medical Centre, Galway (Dr Virag Feher); Main Street Clinic, Loughrea (Dr Cathal Nugent); Moyview Family Practice, Ballina (Dr Scott Walkin); Tramore Medical Centre, Tramore (Dr Dermot Nolan); Moycullen Medical Centre, Moycullen (Dr Eva Flynn)

Study title: European Clinical Research Alliance on Infectious Diseases – primary care adaptive platform trial for pandemics and epidemics (ECRAID-Prime)

- **NREC-CT Decision:**

- Request for more information
- **Part I**
- It was noted that there is a lack of clarity in ISA B around the inclusion/exclusion of women of childbearing potential (WOCBP) and the requirement for use of contraception for 30 days prior to recruitment. ISA B pg 2 states that one of the inclusion criteria is *"For women of child-bearing potential*: prepared to use a highly effective method of contraception* or abstinence* for 30 days before and after terminating study medication"* however pg12 states *"Pregnant/breastfeeding women and women of childbearing potential will be excluded"* The Sponsor should update the ISA B to clarify if WOCBP are excluded or not.

- **Additional Information Required RFI**

Part II Considerations

1. Compliance with national requirements on data protection

- No considerations raised by NREC

2. Compliance with use of biological samples

- The NREC-CT noted that the 'Compliance on the collection, storage and future used of biological samples' documents states that "Only respiratory pathogens will

be detected retrospectively without direct feedback of results for patient management: no unsolicited findings". The Committee requested that this be updated to provide a rationale for this.

3. Financial arrangements

- The NREC-CT noted that the Compensation site document notes reimbursement of €120 per patient, for which a portion refers to reimbursement for travel/time. Rationale and further details of what is covered by this per patient reimbursement has not been provided. The Committee requested that Compensation site document and SIS and ICF be updated to clarify this.

4. Proof of insurance

- No considerations raised by NREC

5. Recruitment arrangements

- The NREC-CT noted that study treatment must be started within 7 days of the onset of symptoms. The Committee requested clarification regarding:
    - how long participants will have to consider their participation in the trial
    - given the potential delays in getting an immediate GP appointment for non-urgent medical issues, how participants will be triaged to ensure they are seen within the 7 days to facilitate recruitment.

6. Subject information and informed consent form

- The NREC-CT noted the collection of data on ethnicity in SIS and ICF version A pg 3. In line with GDPR special category data requirements, the NREC-CT requested justification regarding collection of race and ethnicity data. The Committee also requested that the SIS and ICF version A be updated to include this justification in line with GDPR requirements.
- The NREC-CT requested that the SIS and ICF version A pg 11 contains an optional consent to be contacted for interview. The NREC requested this optional aspect be moved to a separate section from the Main informed consent section, with a separate signature box to show explicit consent.
- The NREC-CT requested that the SIS and ICFs version A, Patient Interviews, Clinician Interviews and Researchers Interviews, be updated to include specific statement for the participant to confirm a copy of the signed participant information sheet will be given to them.
- The NREC-CT noted that SIS and ICF version A pg 6 and 11 refers to "anonymised data". The Committee requested that the SIS and ICF version A pg 11 be updated to include a specific statement for the participant to explicitly consent to the processing of their personal data from coded to anonymised data as per Article 4 (2) and (6) General Data Protection Regulation (GDPR).
- The NREC-CT requested that the ICF be updated to align with compensation documents, and provide further details regarding reimbursement for travel, and to be clear to the participant that the €15 is provided as a voucher. The NREC-CT suggested that a lay language explanation of what a platform trial is be provided in all the information sheets.
- The NREC-CT noted that SIS and ICF version A pg 4 advises whom who become pregnant to "contact GP or coordinating team". The Committee were unclear if data on the woman's pregnancy and baby would be collected, if so, please supply Pregnant Participant ICF for review.

- The NREC-CT requested that the SIS and ICF version A pg 6, Patient Interviews pg 3, Researcher Interviews pg 3, Future Use and Clinician Interviews pg 3 be updated to clarify that if a participant withdraws from the trial it won't be possible for their data already collected to be removed from analyses which has already been completed. The participant should be advised that samples and data already collected may be used for other ongoing and possible future studies, and the participant should be advised of their right to request withdrawal of their data and samples from future use.
- The NREC-CT noted that the interviews will be transcribed. The Committee stated that the participant should be given an opportunity to review the transcript to ensure that it reflects what was said in the interview. The Committee requested that the SIS and ICF Patient Interviews, SIS and ICF Clinician Interviews and SIS and ICF Researchers Interviews be updated to clarify this.
- It was unclear to the NREC-CT who would be conducting the Clinician Interviews. The Committee requested that the SIS and ICF Clinician be updated to clarify who will be conducting the interview.
- The NREC-CT noted the Compliance on collection use and storage of biological samples states *"What is the purpose of the future use? Possible additional analysis for respiratory pathogens. Possible validation of new assays for the detection of respiratory pathogens"* The Committee requested that the SIS and ICF Future use be updated to include this.

7. Suitability of the clinical trial sites facilities

- The NREC-CT noted the Site Suitability Forms submitted for Crescent Medical Centre, Galway, Heights Medical Centre, Galway, Main Street Clinic, Loughrea; Moyview Family Practice, Ballina, Tramore Medical Centre, Tramore and Moycullen Medical Centre, Moycullen were all signed by the Principal Investigators which is not appropriate under the Clinical Trial Regulations. The Committee requested that an updated Site Suitability Template be provided which is signed by the CEO, Head of Clinic / institution, Director of Research, Clinical Director, or delegate of the hospital.

8. Suitability of the investigator

- The NREC-CT requested that an updated CV is provided for Dr Sinead Feeney; Dr Virag Feher; Dr Cathal Nugent; Dr Scott Walkin; Dr Dermot Nolan and Dr Eva Flynn to provide more detail on their current GCP training, as this section was not completed in the form.

2022-502669-14-00 SM-6

Principal Investigators & Institutions: Beaumont Hospital (Naidoo Jarushka)

Study title: A Randomized, Open-label, Phase 3 Study of Tarlatamab Compared With Standard of Care in Subjects With Relapsed Small Cell Lung Cancer After Platinumbased First-line Chemotherapy (DeLLphi-304)

- **NREC-CT Decision:**

- Favourable

23-NREC-CT-030_Mod-2

Principal Investigator: Prof Sinead Brennan

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)

EudraCT:

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required RFI**
- The NREC-CT requested that the Master PIL-ICF pg 7 reference to ‘telehealth” be updated to include a lay language explanation of same. .
- The NREC-CT requested that the Master PIL-ICF pg 27 be updated to include a specific statement for the participant to explicitly consent to the processing of their personal data from coded to anonymised data as per Article 4 (2) and (6) General Data Protection Regulation (GDPR).
- The NREC-CT noted Master PIL-ICF pg 13 lists Ototoxicity as both very common and uncommon. The Committee requested the Master PIL-ICG be updated to clarify which section it should appear under.?

23-NREC-CT-033_Mod-2

Principal Investigator: Prof. Karen Cadoo

Study title: NRG-GY019: Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum.

EudraCT:

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required RFI**

- The NREC-CT requested that the PIL pg 39 be updated to include a specific statement for the participant to explicitly consent to the processing of their personal data from coded to anonymised data as per Article 4 (2) and (6) General Data Protection Regulation (GDPR).

- AOB:
  - None