National Research Ethics Committee

NREC-CT A Meeting

19th November 2025

Attendance

Name	Role
Prof. Gene Dempsey	Deputy Chairperson, NREC-CT A
Dr Brian Bird	Committee Member, NREC-CT A
Dr Maeve Kelleher	Committee Member, NREC-CT A
Dr Dawn Swan	Committee Member, NREC-CT A
Dr Darren Dahly	Committee Member, NREC-CT A
Prof. Aisling McMahon	Committee Member, NREC-CT A
Mrs Erica Bennett	Committee Member, NREC-CT A
Dr David Byrne	Committee Member, NREC-CT A
Dr Sean Lacey	Committee Member, NREC-CT A
Ms Mandy Daly	Committee Member, NREC-CT A
Ms Muireann O'Briain	Committee Member, NREC-CT A
Ms Dympna Devenney	Committee Member, NREC-CT A
Dr Emily Vereker	Head of Office, National Office for RECs
Dr Jane Bryant	Programme Officer, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Ms Deirdre Ní Fhloinn*	Project Officer, National Office for RECs

*Drafted minutes

Apologies: Prof Alistair Nichol, Caoimhe Gleeson, Margaret Cooney

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2025-522792-29-00
- 2025-523275-27-00
- 2023-508265-33-00 SM-8
- 2023-504918-29-00 SM-12
- 2022-502785-25-00 SM-12
- 2023-510128-66-00 SM-6
- 2023-508522-95-00 SM-5
- 2023-506924-94-00 SM-4
- 2025-521188-11-00 SM-15
- 2023-503711-15-00 SM-9
- 2024-512279-10-00 SM-9
- AOB

- The Chair welcomed the NREC-CT A.
  - The minutes from the previous NREC-CT A meeting on 15th October 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2025-522792-29-00

Institutions: Beaumont Hospital

Study title: An Open-label, Multicenter, Randomized, Non-Inferiority Pharmacokinetic and Safety/Tolerability Study of Two Different Weekly Doses of Alpha1-Proteinase Inhibitor Subcutaneous (Human) 15% in Patients with Alpha1-Antitrypsin Deficiency Compared to Corresponding Standard 60 mg/kg/week and 120 mg/kg/week Doses of Intravenous Alpha1-Proteinase Inhibitor (5%)

Dossiers Submitted: Part I & II

- NREC-CT Decision:

  Request for Further Information

Part I Considerations (RFI) for addition to CTIS

1. It is noted that safety analysis will be performed on a 'safety population'. However, given that the IMP is unlicensed and that only two small prior studies have been conducted in humans, it is requested that additional detail on safety monitoring is provided. In particular, please justify why there is no data safety monitoring board established for this study or why no early or interim analysis is planned.

Part II Considerations

1. Compliance with national requirements on data protection

- No considerations raised

2. Compliance with use of biological samples

- No considerations raised

3. Financial arrangements

- No considerations raised

4. Proof of insurance

- No considerations raised

5. Recruitment arrangements

- No considerations raised

6. Subject information and informed consent form

Standard Consideration:

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
- All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft

Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.

- The NREC-CT requested that the consent section on page 18 of the Main ICF be updated to include a specific statement that the participant/legally designated representative confirms that they have read and understood the information provided.
- The NREC-CT noted reference to a home healthcare service in the Main ICF (pg. 7, 12, 19). The Committee requested information on this process (including but not limited to; the specific procedures included, logistics, details of the home service vendor and data protection information) be more clearly elucidated in the Main PISCF to facilitate informed consent.
- The NREC-CT noted that the Main PISCF has used a bundled approach to consent 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 (V2.1, 2025). Dublin: Health Service Executive www2.healthservice.hse.ie/files/157/
- The NREC-CT noted that the study description in the Main ICF (pg. 3) is too complex, and that the definition of randomisation is embedded and unclear to a lay person. The Committee requested that the sentences in this section be simplified and that a definition of randomisation be independently outlined to ensure informed consent.
- The NREC-CT noted that the frequency of blood samples for Alpha1-PI levels at weeks 8 and 16 is not sufficiently highlighted in the Main ICF (pg. 7). The Committee requested that the burden of PK blood testing, including frequency and duration of study visits, be made explicit in the Main ICF such that participants are adequately informed.
- The NREC-CT noted that the participant will choose whether their GP (family doctor) is informed (Main ICF pg.10). The Committee requested that a sentence is added to the Main ICF to note the rationale and potential importance of informing the participant's GP about their study participation, including its relevance to participant safety.
- The NREC-CT noted that participants will be requested to provide additional blood samples for up to 1 year following a positive immune response to the study drug and that samples will be kept for up to 5 years after the end of the study for possible future analysis (Main ICF, pg.11). The Committee requested that the Main ICF is updated to clarify whether the provision of further samples is optional or mandatory, and that the purpose of further sampling is clearly elucidated. As the S1_Compliance with use of human biological samples states that no future research will be conducted, please align all relevant documentation accordingly.
- The NREC-CT noted that if a participant becomes pregnant the study will follow progress and outcome "to ensure that the study procedures have no bad effects on your health or of the baby's health" (Main ICF, pg.14). The Committee requested that this sentence is rephrased to include the possibility of adverse effects such that the participant is sufficiently informed.
- The NREC-CT noted that a section on general study risks (including the sentence "In addition…you should use caution and not drive") appears to be included in the "pregnancy risks" section of the Main ICF (pg.14) . The Committee requested that this paragraph be relocated from the "pregnancy risks" category to a new section entitled "other possible risks" or equivalent, to ensure readability and informed consent.

- The NREC-CT noted a lengthy appendix related to Data Protection which is presented after the participant signature section in the Main ICF. The Committee requested that a summary paragraph in lay language pertaining to the most relevant data protection issues (e.g. movement of data/samples outside of the EEA, standard contractual clauses, pseudonymisation) be included in the Personal Data Protection, Confidentiality, and Release of Medical Records Section on page 15 of the Main ICF. In addition, the inclusion of consent items requiring signatures for the most relevant data protection issues could be considered in the main consent section.
- The NREC-CT noted reference to the use of a travel vendor. The Committee requested that further information regarding the process for the utilisation of the travel vendor service be provided in the Main ICF to facilitate informed consent.
- The NREC-CT noted that while the Recruitment Form (pg.2) states that adults lacking capacity will not be recruited, the term “Legally acceptable representative” permeates the Main ICF. The Committee requested that both documents are aligned and that the term “Legally acceptable representative” be removed from throughout the Main ICF if applicable.
- The NREC-CT noted reference to the reporting of positive HIV/Hepatitis results in the Main ICF (pg.11). The Committee requested the insertion of the relevant Irish regulations regarding the reporting of positive HIV/Hepatitis results in the main ICF.
- The NREC-CT noted that the Main ICF is comprehensive but lengthy and text heavy. The Committee requested that a Plain English and/ or graphical summary of the salient points of the study be included in the Main ICF to facilitate informed consent.
- The NREC-CT noted the sentence ‘Financial compensation for such things as lost wages, disability, or discomfort due to any research- related injury is not available’ in the Main ICF (pg. 15). The Committee requested confirmation that no financial burden will be placed on the participant as a result of participation in this clinical trial and this is elucidated in the Main ICF.

7. Suitability of the clinical trial sites facilities

- No considerations raised

8. Suitability of the investigator

- No considerations raised

2025-523275-27-00

Institutions: Children's Health Ireland Crumlin

Study title: HELIOS: An Open-Label, Long-Term Study to Investigate the Safety, Tolerability, and Efficacy of DISC-1459 (Bitopertin) in Participants with Erythropoietic Protoporphyria (EPP) or X-Linked Protoporphyria (XLP)

Dossiers Submitted: Part I & II

- NREC-CT Decision:

Request for Further Information

Part II Considerations
1. Compliance with national requirements on data protection
• No considerations raised
2. Compliance with use of biological samples
• No considerations raised
3. Financial arrangements
• No considerations raised
4. Proof of insurance
• No considerations raised
5. Recruitment arrangements
• No considerations raised
6. Subject information and informed consent form

Standard Consideration:

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
- All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.
- The NREC-CT noted that the PISCF for Adolescents is lengthy and text heavy document. The Committee requested that the PISCF for Adolescents is shortened and simplified (to broadly align with the readability of the PISCF for Adolescents approved for the original study, EU CT 2024-520407-27-00, which was 10 pages in length).
- The NREC-CT noted that the term 'personal data' is used indiscriminately throughout section 16 'Collection and processing of personal data for the research study' in both the Adult PISCF (pg.19) and Parent PISCF (pg. 19). Please clarify who will have access to pseudonymised vs personal data throughout all relevant

PISCF's, specifically including the term pseudonymised and a lay definition where applicable.

- The NREC-CT noted that a questionnaire related to depression and suicide will be conducted (pg. 6 Adult and Parent PISCF, pg. 5 Adolescent PISCF). The Committee requested an acknowledgement be included in all PISCF's that completion of the questionnaire may cause distress to participants, along with details of the supports and safeguards that will be place if required.
- The NREC-CT noted that relevant lay terminology is placed inside of brackets following the use of technical terminology throughout all PISCF's (including but not limited to examples in the Adult PISCF and Parent PISCF such as 'Haem production pathway' pg. 2, 'Fibrosis' and 'Steatosis' pg.3, porphyrins pg. 5, 'somnolence' pg. 14 'bilateral oophorectomy, bilateral salpingectomy, bilateral tubal ligation and fallopian inserts with confirmed blockage' pg. 16) The Committee requested that all PISCF's are updated to ensure lay terminology is presented first with the technical term in brackets alongside.
- The NREC-CT noted the phrase 'You should carry your patient card with you' on pg. 12 of the Parent ICF. The Committee requested clarification whether there is a separate patient card for parents and/or that the sentence is amended to reflect that the child is the participant.
- The NREC-CT noted that while the Reimbursement Form outlines that travel, accommodation and meal expenses will be reimbursed for both participants and carers, this is not uniformly outlined in the Adult PISCF (pg. 12), Parent PISCF (pg.12) and Adolescent PISCF (pg. 9). The Committee requested that all PISCF's be updated to clearly state that travel, accommodation and meal expenses will be reimbursed for both participants and carer.
- The NREC-CT noted that the study participant may be advised 'not to drive or operate machinery' in the Parent PISCF (pg.14) and Adolescent PISCF (pg.13). The Committee requested that the sentence is removed or amended to reflect more age-appropriate advice.
- The NREC-CT noted that participants may be required to pay for treatment of side effects (pg. 18 Parent PISCF, pg.18 Adult PISCF). The Committee requested that this is reconsidered to ensure no financial burden is placed on the participant as a result of trial participation, and that this is elucidated in all PISCF's if applicable.
- The NREC-CT noted the sentence 'Scout Clinical will collect information about you that may include… bank transfer instructions, PayPal account' in the Adolescent PISCF (pg.9). Furthermore, this information is duplicated on the same page but includes reference to obtaining caregiver details. The Committee requested that the section on reimbursement is amended to remove duplication and to clarify that reimbursement will be made via the participants care-giver rather than the adolescent participant.
- The NREC-CT noted that the section on reproductive risks and birth control in the Adolescent PISCF (pg.14) contains technical and age-inappropriate language (examples include but are not limited to: 'postmenopausal', 'hysterectomy', 'fallopian tubes tied', 'diaphragm, sponge, or spermicidal cream', 'vasectomy'). The Committee requested that this section is amended to include more age-appropriate language and to align with the readability of the PISCF for Adolescents approved for the original study, EU CT 2024-520407-27-00.

- The NREC-CT noted that the first four paragraphs of Section 9 'What are the possible risks and disadvantages of taking part' are lengthy and vague in both the Adult (pg. 13/14) and Parent PISCF (pg.13/14). The Committee requested that this section is reworded in both PISCF's to provide a more concise overview of the potential risks and disadvantages of study participation.
- The NREC-CT noted reference to the terms 'Full Reaction' and 'Early Warning Signs' in Patient Facing Document 1 (pg. 1/2), but that definitions for both terms were absent from the questionnaire. The Committee requested that definitions for both terms (with examples of mild, moderate, severe and very severe occurrences) be provided in the questionnaire to facilitate participant use and to aid standardisation of results.

7. Suitability of the clinical trial sites facilities

- No considerations raised

8. Suitability of the investigator

- No considerations raised

2023-508265-33-00 SM-8

Institutions: University Hospital Waterford, University Hospital Galway, St Vincent's University Hospital, Mater Misericordiae University Hospital, St James's Hospital

Study title: (21656) A double-blind, randomized, placebo-controlled multicenter study to investigate efficacy and safety of elinzanetant for the treatment of vasomotor symptoms caused by adjuvant endocrine therapy, over 52 weeks and optionally for additional up to 2.5 years in women with, or at high risk for developing hormone-receptor positive breast cancer

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

2023-504918-29-00 SM-12

Institutions: St Vincent's University Hospital, Bon Secours Hospital Cork, Mater Misericordiae University Hospital

Study title: An Open-label, Randomized Phase 3 Study of MK-2870 as a Single Agent and in Combination with Pembrolizumab Versus Treatment of Physician's Choice in Participants with HR+/HER2- Unresectable Locally Advanced or Metastatic Breast Cancer

Dossiers Submitted: Part I & II

- NREC-CT Decision:

Request for Further Information

Part II Considerations raised

1. Subject information and informed consent form

Standard Consideration:

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
- All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.
- The NREC-CT noted that page 24 of the Main ICF includes a witness signature line. The NREC-CT requests information be added to all relevant PISCF's explaining the context where a witness signature would be needed (as per CTR: Annex I,L 62(b)).
- The NREC-CT noted that the Main ICF (pg.3) has been updated to note that the study drug has not been approved in the UK. The Committee requested that approval for the study drug (or lack thereof) should include reference to the Irish context.
- The NREC-CT noted the sentence "trial doctor will collect information about your partner's pregnancy" in the Main ICF (pg.17). Whilst acknowledging safety reporting requirements, the Committee requested that clarification be provided in the ICF that the pregnant partners consent will be sought for pregnancy related data collection.

2022-502785-25-00 SM-12

Institutions: St James's Hospital, Beaumont Hospital

Study title: A Phase 3, Open label, Randomized Study Comparing the Efficacy and Safety of Odronextamab (REGN1979), an anti-CD20 × anti-CD3 bispecific antibody, in Combination with CHOP (Odro-CHOP) versus Rituximab in Combination with CHOP (R-CHOP) in Previously Untreated Participants with Diffuse Large B-cell Lymphoma (DLBCL) (OLYMPIA-3)

Dossiers Submitted: Part I & II

- NREC-CT Decision:

  Request for Further Information

Part II Considerations raised

1. Subject information and informed consent form

Standard Consideration:

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
- All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.
- The NREC-CT noted that page 30 of the Main PISCF includes a witness signature line. The NREC-CT requests information be added to all relevant PISCF's explaining the context where a witness signature would be needed (as per CTR: Annex I,L 62(b)).
- The NREC-CT noted the addition of the section 'Compatible Scientific Research' (Main PISCF, pg.14) and requested it is made clear to the participant the distinction between this and 'Exploratory Research' (Main PISCF, pg.13). Furthermore, both sections refer to future use of data / samples (including genetic research) and are not described in line with regulations / best practice. The NREC-CT requested that future use of samples / personal data is sufficiently explained to participants in the PISCF documents so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,
    - it should be made optional
    - optional future research is made into a separate and explicit consent item in the Informed Consent section of the Main PISCF, with

separate participant information section and signatures section, so it is distinct from the main consent to participate in the research.
    - The PISCF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. For further guidance, please see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/
    - As noted above, clarify the distinction between Compatible Scientific Research (Main PISCF pg 14) and Exploratory Research (Main PISCF pg 13) and remove duplication if applicable.

2023-510128-66-00 SM-6

Institutions: St James's Hospital

Study title: A Phase 3 Study of Pembrolizumab in Combination With Carboplatin/Taxane (Paclitaxel or Nab-paclitaxel) followed by Pembrolizumab With or Without Maintenance MK-2870 in the First-line Treatment of Metastatic Squamous Non-small Cell Lung Cancer

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

2023-508522-95-00 SM-5

Institutions: Children's Health Ireland

Study title: EPIK-P3: A phase II study to evaluate the long-term safety and efficacy of alpelisib in patients with PIK3CA Related-Overgrowth Spectrum (PROS) who previously participated in Study CBYL719F12002 (EPIK-P1)

Dossiers Submitted: Part I & II

- NREC-CT Decision:

Request for Further Information

Part II Considerations raised

Subject information and informed consent form

Standard Consideration:

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National

Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.

- All documentation submitted in response to a Request for Information (RFI) must be provided in a format that is both accessible and searchable, such as Microsoft Word or original (non-scanned) PDF files. Please note that scanned documents, including those processed using Optical Character Recognition (OCR), are not acceptable, as they cannot be optimised for compatibility with assistive technologies.
- The NREC-CT noted the phrases “Changes in blood test results for the kidney (blood creatinine increase), which may tell us how well your kidneys are working” and ‘Changes in blood test results for the pancreas (lipase increased), which may tell us how well your pancreas is working’ (Parents ICF, pg 12) . The Committee requested that these sentences are amended to provide further clarity to participants that kidney and pancreas function may be negatively affected by study treatment, which is not inferred by the current wording.
- The NREC-CT noted the phrases “increase in your blood test results for kidneys’ and ‘increase in blood test results for your pancreas’ (Adolescent ICF, pg 14). The Committee requested that these phrases are amended to provide further clarity and to inform the participant of the potential for the kidneys to be negatively affected.
- The NREC CT noted that quantification of the side-effects associated with study drug are not provided in the Adolescent ICF. The Committee requested that the side-effects for the study drug be quantified and elucidated in common lay language in the Adolescent ICF (e.g. Uncommon - less than 1% of patients).
- The NREC-CT requested that all ICF’s be updated to include the EU clinical trial number for participants
- The NREC-CT noted that both the Parent ICF (pg. 30) and Adolescent ICF (pg. 28) include a witness signature line. The NREC-CT requests information be added to all relevant PISCF’s explaining the context where a witness signature would be needed (as per CTR: Annex I,L 62(b)).

2023-506924-94-00 SM-4

Institutions: St Vincent’s University Hospital, St James’s Hospital, Mater Misericordiae University Hospital, Connolly Hospital, National University of Ireland

Study title: The cardiovascular safety and efficacy of cagrilintide 2.4 mg s.c. in combination with semaglutide 2.4 mg s.c. (CagriSema 2.4 mg/2.4 mg s.c.) once-weekly in participants with established cardiovascular disease

Dossiers Submitted: Part I & II

- NREC-CT Decision:

Request for Further Information

Part II Considerations raised

1. Subject information and informed consent form

Standard Consideration:

- Where applicable, the Sponsor is requested to submit any Part 2 documentation requiring revision following the outcome of the Part 1 Assessment. Should an additional Request for Information (RFI) be required, please contact the National Office at clinicaltrials@nrec.ie. The request should include a concise summary of the Part 1 consideration(s) that necessitated the update to the Part 2 documentation.
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- The NREC-CT noted that text was added to the Protocol (pg.50) to clarify that the Sponsor may cover costs associated with certain concomitant medications used to treat gastro-intestinal related symptoms. The Committee requested that this information is elucidated in the PISCF Addendum to ensure the participant is informed of this potential compensation.
- The NREC-CT noted that text was added to the Protocol (pg 54) to clarify that a search agency may be used to facilitate identifying updated contact details for a missing participant. The Committee requested:
    - That the process and vendor details (if available) be clearly outlined in the PISCF Addendum. If the vendor details are not currently available, when vendor details are available, that the participant information be amended with the information and the participants informed of this change.
    - Further information be provided in the PISCF Addendum on the data sharing process with the third party vendor and the relevant data protection safeguards
    - Clarification if the sharing of personal information with the “lost to follow up” third party vendor is optional, and that this is clearly outlined in the PISCF Addendum

2025-521188-11-00 SM-15

Institutions: University Hospital Galway, Connolly Hospital, Portiuncula University Hospital

Study title: A Phase III double-blind, randomised, parallel-group superiority trial to evaluate efficacy and safety of the combined use of oral vicadrostat (BI 690517) and empagliflozin compared with placebo and empagliflozin in participants with type 2 diabetes, hypertension and established cardiovascular disease

Dossiers Submitted: Part II

- NREC-CT Decision:
- Favourable

2023-503711-15-00 SM-9

Institutions: Beaumont Hospital

Study title: A multi-site, open-label, sequential-group, multiple-dose trial to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamic effects of Lu AG13909 in participants with congenital adrenal hyperplasia

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

2024-512279-10-00 SM-9

Institutions: University Hospital Limerick, St James's Hospital, Beaumont Hospital, Mater Misericordiae University Hospital, Cork University Hospital

Study title: A Randomized, Open-label, Phase 3 Study of Adjuvant Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice in Patients With Triple Negative Breast Cancer Who Have Residual Invasive Disease After Surgery and Neoadjuvant Therapy

Dossiers Submitted: Part I & II

- NREC-CT Decision:
- Favourable

- **AOB:**
- None