

A Phase 1/2, Open-label, Dose-Escalation and Dose-Expansion Cohort Study of SNDX-5613 in Patients with Relapsed/Refractory Leukemias, Including Those Harboring an MLL/KMT2A Gene Rearrangement or Nucleophosmin 1 (NPM1) Mutation

Published: 22-09-2021

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This study has been transitioned to CTIS with ID 2024-513759-34-00 check the CTIS register for the current data. Primary ObjectivesPhase 2The primary objectives of Phase 2 are:• To evaluate short- and long-term safety and tolerability of SNDX 5613...

| | |
|------------------------------|----------------|
| Ethical review | Approved WMO |
| Status | Recruiting |
| Health condition type | Leukaemias |
| Study type | Interventional |

Summary

ID

NL-OMON56180

Source

ToetsingOnline

Brief title

SNDX-5613-0700 (ICON 2636/0009): Phase 2 Study in Patients with Leukemias

Condition

- Leukaemias

Synonym

Relapsed/Refractory Leukemias / Acute Leukemias

Research involving

Human

Sponsors and support

Primary sponsor: Syndax Pharmaceuticals, Inc

Source(s) of monetary or material Support: Industry

Intervention

Keyword: Open-label Study, Patients with Relapsed/Refractory Leukemias, SNDX 5613

Outcome measures

Primary outcome

Phase 2

Primary endpoints in Phase 2 are:

- CR+CRh rate.
- Frequency, duration, and severity of TEAEs, TRAEs, and SAEs.
- Incidence and shifts of clinically significant clinical laboratory abnormalities.
- Change from baseline in other observations related to safety, including ECGs, vital signs, ophthalmologic examination findings, and performance status.

Secondary outcome

Phase 2

Secondary endpoints in Phase 2 are:

- Transfusion independence, defined as any transfusion-free period lasting for at least 56 consecutive days, during which the patient is either on SNDX-5613 therapy or after cessation of SNDX-5613 therapy but prior to the start of new therapy.
- CRc rate (ie, CR+CRh+CRi+CRp).

- ORR (CRc+MLFS+PR).
- TTR.
- DOR.
- EFS.
- OS.
- PK parameters: Cmax, Tmax, AUC0-t, AUC0-24, CL/F, Vz/F, and t1/2.

Exploratory Endpoints

Phase 2

The exploratory endpoint in Phase 2 is:

- Response relationship with correlative biomarkers in blood and bone marrow.
- PK parameters: Cmax, Tmax, AUC0-t, AUC0-24, CL/F, Vz/F, t1/2.

Study description

Background summary

Acute leukemias generally result from acquired mutations in hematopoietic progenitor cells. Chromosomal abnormalities are often discrete mutational features in leukemia. Many of these chromosomal abnormalities are due to specific rearrangements that lead to the formation of fusion genes, which become drivers for tumorigenesis and tumor development (Wang 2017). A specific example involves the KMT2A gene (Wang 2017). Rearrangements at the KMT2A locus (11q23) can lead to the formation of oncogenic gene fusions that characterize KMT2Ar acute leukemias.

The KMT2A protein is a key regulator of development and is the mammalian homologue of *Drosophila trithorax*. It is an important epigenetic regulator of HOX gene expression (Del Rizzo 2011). Rearrangements at the KMT2A locus create chimeric proteins that fuse the N-terminus of KMT2A to variable C-terminal domains derived from different rearrangement partners. Currently, more than 90 different fusion partners are known (Meyer 2018). Expression of these fusions enables an aberrant transcription program characterized by overexpression of HOX and other developmental genes. This transcription program suppresses

differentiation and enhances proliferation, leading to the KMT2Ar acute leukemias.

Rearrangements involving the KMT2A locus (11q23) are routinely diagnosed using fluorescence in situ hybridization (FISH). Depending on the progenitor cell of origin, KMT2Ar can phenotypically appear as acute lymphoblastic leukemia (ALL), AML, or mixed phenotype acute leukemia (MPAL). These rearrangements are rare and KMT2Ar has a combined annual incidence of ~4000 cases per year in the United States (US), Europe and Japan. Approximately 10% of all leukemias harbor KMT2A rearrangements (Winters 2017).

The relapse risk for KMT2Ar patients is high after conventional chemotherapy and stem cell transplantation, with an overall 5-year survival rate of only approximately 35% (Muntean 2012). No therapies are currently available that specifically target KMT2Ar leukemia. SNDX 5613 may provide a novel, targeted treatment for KMT2Ar acute leukemias.

Study objective

This study has been transitioned to CTIS with ID 2024-513759-34-00 check the CTIS register for the current data.

Primary Objectives

Phase 2

The primary objectives of Phase 2 are:

- To evaluate short- and long-term safety and tolerability of SNDX 5613.
- To assess the CR+CRh rate.

Secondary Objectives

Phase 2

Secondary objectives of Phase 2 are:

- To assess postbaseline transfusion independence.
- To assess the CRc rate (CR+CRh+CRI+CRp).
- To assess the overall response rate (ORR) (CRc+MLFS+partial remission [PR]).
- To assess the time to response (TTR), duration of response (DOR), and event free survival (EFS).
- To assess overall survival (OS).
- To characterize PK parameters of SNDX 5613 and relevant metabolites.

Exploratory Objectives

Phase 2

The exploratory objective of Phase 2 is:

- To evaluate SNDX 5613 pharmacodynamic, safety, and efficacy relationship with correlative biomarkers, which may include immunophenotyping of circulating PBMC and/or bone marrow, gene expression, mutational analysis, and MRD.

Study design

Study SNDX 5613-0700 is a Phase 1/2, open-label, dose-escalation, and expansion study of SNDX 5613. Patients aged ≥ 6 months (or ≥ 12 years in Germany only), and weighing ≥ 35 kg if intended to receive SNDX-5613 in combination with cobicistat, with R/R acute leukemia are planned to be enrolled. This Phase 1/2 study was opened in September 2019 and at the time of this amendment, Phase 1 Arms A-F are closed to enrollment. The Phase 2 portion initiated with the identification of a recommended Phase 2 dose (RP2D) for patients receiving a strong cytochrome P450 (CYP)3A4 inhibitor azole. At the time of this amendment, Phase 2 Cohorts 2A and 2B are closed to enrollment. Phase 2 Cohort 2C is currently enrolling.

The RBA assessment has also been completed, and the PK between the capsule and tablet formulations are comparable with no change in the safety profile observed in patients receiving tablet formulation, indicating that the formulation switch should not result in a clinically meaningful difference. All US patients who are able to swallow tablets have been switched to the tablet formulation. In addition, the low fat meal food effect evaluation has been completed; the effect of a low fat meal on PK was minimal. A description of the Phase 1 Arms A-F elements of the protocol remains in place for reference.

Phase 1

SNDX 5613 will be investigated on an every-12-hour (q12h) schedule and a 3-times-a-day (TID) schedule; alternative dose schedules may be explored as guided by emerging data. SNDX 5613 will be administered orally (PO) in 28-day cycles, with the first study drug dose administered on Cycle 1, Day 1 (C1D1). Reasons for discontinuation of Study Intervention are listed in Section 7.1.1.

Upon enrollment, patients will be assigned to one of 6 dose-escalation arms as described below:

- Arm A: Patients must not be receiving any strong CYP3A4 inhibitor/inducers or fluconazole. Patients who were receiving a strong CYP3A4 inhibitor/inducer or fluconazole must have discontinued the medication at least 7 days prior to enrollment. Patients will receive SNDX-5613 q12h.
- Arm B: Patients must be receiving above (strong CYP3A4 inhibitors) for antifungal prophylaxis for at least 7 days prior to enrollment and while on SNDX-5613 treatment. Patients must not be receiving any other strong CYP3A4 inhibitors/inducers.
- Arm C: Patients must receive a daily dose of cobicistat from C1D2 on. Patients must not be receiving any other strong or moderate CYP3A4 inhibitors/inducers. Patients who were receiving a moderate/strong CYP3A4 inhibitor/inducer must have discontinued the medication at least 7 days prior to enrollment. Patients will receive SNDX-5613 q12h.
- Arm D: Patients must be receiving fluconazole (moderate CYP3A4 inhibitor) for antifungal prophylaxis for at least 7 days prior to enrollment and while on SNDX-5613 treatment. Patients must not be receiving any other strong or moderate CYP3A4 inhibitors/inducers. Patients will receive SNDX-5613 q12h.
- Arm E: Patients must not be receiving any weak, moderate, or strong CYP3A4 inhibitors/inducers. Patients who were receiving a CYP3A4 inhibitor/inducer

must have discontinued the medication at least 7 days prior to enrollment.

Patients will receive SNDX-5613 TID.

- Arm F: Patients must be receiving isavuconazole (moderate CYP3A4 inhibitor) for antifungal prophylaxis for at least 7 days prior to enrollment and while on SNDX-5613 treatment. Patients must not be receiving any other weak, moderate, or strong CYP3A4 inhibitors/inducers. Patients will receive SNDX-5613 q12h.

Exclusion criteria addressing the use of moderate and strong CYP3A4 inhibitors in each arm can be found in Section 5.2 Exclusion Criterion 15.

Throughout the study, the Safety Review Committee (SRC) will monitor safety and efficacy parameters as specified in the SRC Charter.

An Independent Data Monitoring Committee (IDMC) has been established for the phase 2 study and specific guidelines on the operation and purpose of the IDMC is documented in a Charter.

Intervention

SNDX 5613 capsules (25 and 113 mg free base equivalents), SNDX-5613 tablets (25, 110, and 160 mg), or oral solution will be taken orally or administered through NG/G- or duodenal tube q12h or TID at the designated dose according to patients* cohort assignments (further information is available in the Pharmacy Manual). For patients receiving SNDX-5613 in a q12h regimen, study drug is to be administered on an empty stomach, at least 2 hours after a meal and 1 hour before the next meal.

In Phase 2, all patients will receive SNDX-5613 at the RP2D, as determined based on data from Phase 1.

Patients will receive SNDX 5613 PO either q12h or TID in 28-day cycles, with the first study drug dose administered on C1D1. More dosing schedules may be explored based on emerging data. Reasons for discontinuation of Study Intervention are listed in Section 7.1.1.

Study burden and risks

Overall Phase I Safety Summary:

- Grade 3 TRAE observed: anemia, diarrhea, generalized weakness, hypokalemia, increased fatigue, platelet count decreased, QTc prolongation
- Related SAE observed: QTc prolongation, differentiation syndrome

Conclusion:

- The intermediate dose levels of 276 mg in Arm A and 163 mg in Arm B are both safe and tolerable.
- The currently available safety data suggests a clinical QTc signal (which was predicted based on in vitro and toxicology studies). Otherwise SNDX-5613 has been well tolerated.

Contacts

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Scientific

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US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

Babies and toddlers (28 days-23 months)

Inclusion criteria

Diagnosis

1. Patients in phase 1 Arm A and Arm B must have active acute leukemia harboring KMT2A rearrangement or NPM1 mutation (bone marrow blasts $\geq 5\%$ or reappearance of blasts in peripheral blood) as defined by the National Comprehensive Cancer Network (NCCN) guidelines in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia (Version 1.2020) and Acute Myeloid Leukemia (Version 3.2020) (National Comprehensive Cancer Network 2020; National Comprehensive Cancer Network 2020).

Patients in phase 1 Arm C, Arm D, Arm E and Arm F must meet one of the following 2 criteria:

- active acute leukemia (bone marrow blasts $\geq 5\%$ or reappearance of blasts in peripheral blood) as defined by the National Comprehensive Cancer Network (NCCN) in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia (Version 1.2020) and Acute Myeloid Leukemia (Version 3.2020) (National Comprehensive Cancer Network 2020; National Comprehensive Cancer Network 2020).
- acute leukemia harboring an KMT2A rearrangement, NUP98 rearrangement, or NPM1 mutation that have detectable disease in the bone marrow not meeting criterion for active leukemia as described above.

2. Phase 1: see more details in the protocol.

- Note that phase 1 is not applicable for the Netherlands.

3. 3. Phase 2: Documented R/R active acute leukemia (bone marrow blasts $\geq 5\%$ or reappearance of blasts in peripheral blood) as defined by the NCCN Guidelines® for Acute Lymphoblastic Leukemia (Version 1.2020) and Acute Myeloid Leukemia (Version 3.2020) (National Comprehensive Cancer Network 2020; National Comprehensive Cancer Network 2020).

Cohort 2A: Documented R/R ALL/MPAL with a KMT2A rearrangement.

Cohort 2B: Documented R/R AML with a KMT2A rearrangement.

Cohort 2C: Documented R/R AML with NPM1m.

Mutational status is to be reviewed locally to determine patient eligibility in Phase 2 and confirmed centrally. Central confirmation of KMT2Ar status will be obtained by fluorescence in situ hybridization (11q23 MLL-Break Apart FISH testing Flagship Biosciences, Morrisville, NC). NPM1 mutational status confirmation will be obtained by PCR based amplification and sequencing (Focus Myeloid panel, Flagship Biosciences, Morrisville, NC). All assays will be conducted in a CLIA certified laboratory. Patients whose mutational status cannot be confirmed centrally, or whose final pathology or flow reports do not confirm the presence of $\geq 5\%$ bone marrow blasts, will be replaced to ensure a sufficient number of patients for the primary efficacy analyses.

Disease Status

4. Recurrent or refractory AML/ALL or MPAL, as defined by standardized criteria (for example, European LeukemiaNet criteria [Döhner 2017]; International Working Group criteria [Cheson 2003]) after standard of care therapy, including but not limited to one or two cycles of intensive chemotherapy, or venetoclax combinations.. Patients with persistent leukemia after initial therapy or with recurrence of leukemia at any time after achieving a response during or after the course of treatment (including allogeneic [HSCT] are eligible. Refractory or relapsed leukemia is defined by presence of $\geq 5\%$ blasts in the bone marrow and/or persistence or reappearance of peripheral blasts. Patients who have $< 5\%$ blasts in the bone marrow at baseline may be replaced to ensure a sufficient number of patients for the efficacy analyses.

In addition, all patients must have:

- White blood cell (WBC) count below 25,000/ μ L at time of enrollment. Patients may receive cytoreduction prior to enrollment per Inclusion Criterion 11 and 14.

Age/Weight

5. Male or female patient aged ≥ 6 months. Patients intend to receive SNDX-5613 in combination with cobicistat must weigh ≥ 35 kg.

Performance Level

6. Eastern Cooperative Oncology Group (ECOG) performance status score 0-2 (if aged ≥ 18 years); Karnofsky Performance Scale of ≥ 50 (if aged ≥ 16 years and < 18 years); Lansky Performance Score of ≥ 50 (if aged ≥ 12 years and < 16 years).

Prior Therapy:

7. Any prior treatment-related toxicities resolved to \leq Grade 1 prior to enrollment, with the exception of \leq Grade 2 neuropathy or alopecia.
8. Radiation Therapy: At least 60 days from prior total body irradiation (TBI), craniospinal radiation and/or $\geq 50\%$ radiation of the pelvis, or at least 14 days from local palliative radiation therapy (small port).
9. Stem Cell Infusion: At least 60 days must have elapsed from HSCT and at least 4 weeks must have elapsed from donor lymphocyte infusion (DLI).
10. Immunotherapy: At least 42 days since prior immunotherapy, including tumor vaccines, and at least 21 days since receipt of chimeric antigen receptor therapy or other modified T or NK cell therapy.

11. Antileukemia Therapy: At least 14 days, or 5 half-lives, whichever is shorter, since the completion of antileukemic therapy (for example, but not limited to, small molecule or cytotoxic/myelosuppressive therapy), with the following exceptions:

- Hydroxyurea for cytoreduction can be initiated and continued concomitantly with SNDX-5613.
- Phase 1 patients may receive intrathecal chemotherapy at the time of diagnostic lumbar puncture at least 24 hours prior to the start of SNDX-5613 and may continue prophylactic intrathecal chemotherapy beginning in Cycle 2, at the treating physician's discretion.
- Phase 2 and Phase 1 backfill patients may continue to receive prophylactic intrathecal chemotherapy at any time at the treating physician's discretion.

12. Hematopoietic Growth Factors: At least 7 days since the completion of therapy with short-acting hematopoietic growth factors and 14 days with long-acting growth factors.

13. Biologics (eg, monoclonal antibody therapy): At least 90 days or 5 half-lives, whichever is shorter, since the completion of therapy with an antineoplastic biologic agent.

14. Steroids: At least 7 days since systemic glucocorticoid therapy, unless receiving physiologic dosing (equivalent to ≤ 10 mg prednisone daily for patients ≥ 18 years or ≤ 10 mg/m²/day for patients < 18 years) or cytoreductive therapy.

Adequate Organ Function Requirements within 10 Days of Treatment Initiation

15. Estimated glomerular filtration (GFR) based on local institutional practice for age-appropriate determination (eg, Schwartz formula for pediatric patients or Cockcroft Gault formula for adults): $GFR \geq 60 \text{ mL/min/1.73m}^2$.

16. Adequate liver function defined as:

- Total bilirubin $< 1.5 \times$ the upper limit of normal (ULN) for age or normal conjugated bilirubin.
- Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) $< 3 \times$ ULN (unless attributed to leukemic involvement).

Reference tables for normal liver function criteria by age and sex are provided in Section 10.9.

Other Adequate Organ Function Requirements.

17. Adequate cardiac function defined as ejection fraction (EF) of $> 50\%$ by echocardiogram or multigated acquisition (MUGA) scan.

Contraception

18. If a female of childbearing potential, willing to use a highly effective method of contraception or double barrier method from the time of enrollment through 120 days following the last study drug dose. (See Section 10.4 for details regarding contraception.)

19. If male who can father a child, agrees to use barrier contraception from the time of enrollment through 120 days following the last study drug dose. See Section 10.4 for details regarding contraception.)

Exclusion criteria

Diagnosis

1. Diagnosis of active acute promyelocytic leukemia.
2. Isolated extramedullary relapse (Phase 2 only).
3. Active CNS disease (cytologic, such as any blasts on cytospin, or radiographic). Patients who have cleared CNS disease by at least one negative tap prior to dosing may be enrolled, and prophylactic intrathecal chemotherapy may be continued while on trial.

The following patients are required to have a lumbar puncture or Ommaya reservoir tap during the screening period:

- Signs and symptoms of CNS disease
-
- AML with monocytic phenotype.
- $WBC \geq 50,000 /\mu\text{L}$ at presentation.
- History of CNS or any extramedullary disease.
- ALL or MPAL.

Infection

4. Detectable human immunodeficiency virus (HIV) viral load within the previous

6 months. Patients with a known history of HIV 1/2 antibodies must have viral load testing prior to study enrollment.

5. Hepatitis B (defined as hepatitis B virus [HBV] surface antigen positive and HBV core antibody positive or positive HBV deoxyribonucleic acid [DNA],

6. Hepatitis C (defined as positive hepatitis C [HCV] antibody with reflex to positive HCV ribonucleic acid [RNA]).

Pregnancy and Breast-Feeding

7. Pregnant or nursing women. Negative serum pregnancy tests are required during Screening and a negative serum or urine pregnancy test is required within 72 hours prior to receiving the first study drug administration, in females of childbearing potential. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required.

Concurrent Conditions

8. Cardiac Disease:

- Any of the following within the 6 months prior to study entry: myocardial infarction, uncontrolled/unstable angina, congestive heart failure (New York Heart Association Classification Class \geq II), life-threatening, uncontrolled arrhythmia, cerebrovascular accident, or transient ischemic attack.
- QTc using Fridericia's correction (QTcF) >450 msec (Section 8.2.7).

9. Gastrointestinal Disease:

- Any gastrointestinal issue of the upper GI tract likely to affect oral drug absorption or ingestion (gastric bypass, gastroparesis, etc).
- Cirrhosis with a Child-Pugh score of B or C.

10. Graft-Versus-Host Disease (GVHD): Signs or symptoms of acute or chronic GVHD $>$ Grade 0 within 4 weeks of enrollment. All transplant patients must have been off all systemic immunosuppressive therapy and calcineurin inhibitors for at least 4 weeks prior to enrollment. Patients may be on physiological doses of steroids.

11. Concurrent malignancy in the previous 2 years with the exception of basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or carcinoma in situ (eg, breast carcinoma, cervical cancer in situ, melanoma in situ) treated with potentially curative therapy, or concurrent low-grade lymphoma, that is asymptomatic and lacks bulky disease and shows no evidence of progression, and for which the patient is not receiving any systemic therapy or radiation.

12. Concurrent malignancy must be in complete remission (CR) or no evidence of disease (NED) during this timeframe.

13. History of or any concurrent condition, therapy, laboratory abnormality, or allergy to excipients (see formulation details in Investigator Brochure) that in the Investigator's opinion might confound the results of the study, interfere with the patient's participation for the full duration of the study, or is not in the best interest of the patient to participate.

Concomitant Medications and Interventions

14. Any commercially available or investigational antileukemic therapy other

than SNDX-5613, with the following exceptions:

- Short-term administration of corticosteroid and/or hydroxyurea for cytoreduction.
- In the Phase 2 portion and Phase 1 backfill, intrathecal chemotherapy for CNS prophylaxis is permitted, at the treating physician's discretion. In the Phase 1 DLT evaluable cohort, CNS prophylaxis may continue starting in C2D1.

15. In Phase 1 some Exclusions apply. see more details in the protocol.

- Note that phase I is not applicable for the Netherlands.

In Phase 2: Patients who will not receive SNDX 5613 with co administration of a strong CYP3A4 inhibitor must discontinue all strong CYP3A4 inhibitors at least 7 days prior to first dose of SNDX 5613. They will receive the SNDX 5613 RP2D for patients who are not on a strong CYP3A4 inhibitor, and they may continue to receive moderate or weak CYP3A4 inhibitors, including fluconazole and isavuconazole.

Patients who will receive SNDX 5613 with co administration of a strong CYP3A4 inhibitor azole antifungal (itraconazole, ketoconazole, posaconazole, or voriconazole) must have started the azole antifungal treatment at least 24 hours prior to enrollment. They will receive the SNDX 5613 RP2D for patients who are on a strong CYP3A4 inhibitor.

Note that the RP2D for SNDX 5613 for patients on a strong CYP3A4 inhibitor versus patients who are not on a strong CYP3A4 inhibitor is outlined in Table 9. Refer to Appendix 10.6 for examples of strong CYP3A4 inhibitors/inducers.

16. Participation in Phase 1 and Phase 2: Patients requiring the concurrent use of medications known or suspected to prolong the QT/QTc interval, with the exception of drugs with low risk of QT/QTc prolongation that are used as standard supportive therapies (eg, diphenhydramine, famotidine, ondansetron, Bactrim) and the azoles permitted in the relevant arms of Phase 1 and in phase 2. Please see Appendix 10.7 for examples of medications that may be appropriate substitutes for such medications.

17. Receipt of an investigational agent within 30 days of starting SNDX-5613 unless Inclusion Criteria 8, 9, 10, and 13 apply, then the longer period must be applied. Patients may continue with noninterventional follow-up from previous clinical studies.

18. Patients who have had prior exposure to a menin inhibitor.

19. Any concurrent systemic treatment to prevent GVHD.

Study design

Design

| | |
|------------------|-------------------------|
| Study phase: | 2 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

Recruitment

| | |
|---------------------------|------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 23-12-2022 |
| Enrollment: | 6 |
| Type: | Actual |

Medical products/devices used

| | |
|---------------|-----------|
| Registration: | No |
| Product type: | Medicine |
| Brand name: | SNDX-5613 |
| Generic name: | n/a |

Ethics review

| | |
|--------------------|------------------|
| Approved WMO | |
| Date: | 22-09-2021 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO | |
| Date: | 20-04-2022 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO | |
| Date: | 02-09-2022 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO | |

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|--------------------|---|
| Date: | 14-10-2022 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO | |
| Date: | 21-07-2023 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO | |
| Date: | 18-09-2023 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO | |
| Date: | 04-04-2024 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO | |
| Date: | 25-04-2024 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|------------------------|
| EU-CTR | CTIS2024-513759-34-00 |
| EudraCT | EUCTR2020-004104-34-NL |

Register

CCMO

ID

NL77798.041.21