# Prospective Clinical Utility Study for the NaPi2b (67) Assay in Serous Ovarian Cancer

Published: 05-06-2023
Last updated: 07-04-2024

To evaluate the clinical utility of the NaPi2b (67) Assay for use in the detection of NaPi2b in formalin-fixed, paraffin-embedded (FFPE) serous ovarian carcinoma tissue to determine patient eligibility for treatment with XMT-1536.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Reproductive neoplasms female benign |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53260

**Source**
ToetsingOnline

**Brief title**
TSUNAMI UP-NEXT Clinical Utility Study Protocol

### Condition

- Reproductive neoplasms female benign

**Synonym**
ovarian cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leica Biosystems Newcastle
**Source(s) of monetary or material Support:** industry sponsored trial by Mersana Therapeutics Inc.,Mersana Therapeutics Inc.

## Intervention

**Keyword:** NaPi2b (67), Ovarian Cancer, Tsunami, UP-NEXT

## Outcome measures

### Primary outcome

Acceptance criteria are established by Mersana and analysis will be conducted

by Mersana.

### Secondary outcome

N/A

# Study description

### Background summary

The purpose of this study is to prospectively screen formalin-fixed, paraffin-embedded (FFPE) serous ovarian carcinoma tissue samples collected from the Mersana Therapeutics study MER-XMT-1536-3 (UP-NEXT) with the NaPi2b (67) Assay. This assay is being used to determine the NaPi2b status, a requirement for determining patient eligibility in MER-XMT-1536-3 (UP-NEXT).

### Study objective

To evaluate the clinical utility of the NaPi2b (67) Assay for use in the detection of NaPi2b in formalin-fixed, paraffin-embedded (FFPE) serous ovarian carcinoma tissue to determine patient eligibility for treatment with XMT-1536.

### Study design

In this clinical utility study, the anonymized serous ovarian cancer samples will be assessed for NaPi2b status, a requirement for determining patient eligibility in Mersana UP-NEXT Study MER-XMT-1536-3.

### Intervention

N/A

### Study burden and risks

N/A

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

• FFPE tissue block or at least 3 FFPE tissue slides (1 for detecting NaPi2b status, 1 for negative rabbit control, and 1 slide for H&E assessment) of 4-5 µm section thickness received from Mersana collection sites, collected according to Mersana study MER-XMT-1536-3 (UP-NEXT).
• Surgical resections or core needle biopsies (FFPE)
Tissue preparation must meet all slide/sectioning requirements as detailed within the NaPi2b (67) Assay IFU and BOND User Manual:
• Section Thickness (if slides): 4-5 µm
• Slides: Positively Charged, Leica BOND-III Compatible

• Fixative: Formalin Fixed

### Exclusion criteria

• Fine Needle Aspirate (FNA) and ascites samples prepared as FFPE cell blocks
• Cytology specimens (FNA, ascites, cell block)
• The specimen is collected at a site which is not covered under Mersana study MER-XMT-1536-3 IRB/IEC review.
• The specimen is a repeat specimen from a patient whose sample has already been included in the study.
• FFPE section thickness is not 4-5 µm
• Slides are not positively charged or are incompatible with BOND-III
• Tissue is not formalin-fixed

## Study design

### Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 10-04-2023 |
| Enrollment: | 12 |
| Type: | Anticipated |

### Medical products/devices used

| | |
|---|---|
| Generic name: | Leica Biosystems BOND Ready-to-Use Primary Antibody NaPi2b (67) |
| Registration: | No |

# Ethics review

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|---|---|
| Approved WMO Date: | 05-06-2023 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# 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 |
|---|---|
| CCMO | NL83931.000.23 |