

# Studies on tissue specific carcinogenicity and on metabolism of N-nitrosamines (SC05 to FWC EMA/2020/46/TDA/L1.02 – ROC38))

**First published:** 11/11/2025

**Last updated:** 08/12/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000819

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### Study ID

1000000819

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### DARWIN EU® study

No

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### Study countries

Germany

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### Study description

The MUTAMIND SC05 project investigates the major metabolic sites of the NDSRIs, which are presumed to impact the metabolic activations of these compounds. For this purpose, the MUTAMIND SC05 project will explore the (de)activation of NDSRIs using the in vitro human liver models. This aim to identify the major sites of the metabolic activation to study e.g. the hydroxylation sites.

Furthermore, the impact of the potential conjugation reactions, which may influence the reactivity of the NDSRIs and the general detoxification process will be addressed in in vitro studies. Additionally, in silico tools will be employed to predict the metabolites generated during this process. This will facilitate the evaluation of their applicability and predictivity for the upcoming projects related to NDSRIs.

This deliverable provides an overview of the approaches that will be employed throughout the course of the project. The project is categorized into two main objectives:

- Objective 1: Review of quantitative organ-specific carcinogenicity for N-nitrosamines.
- Objective 2: Mechanistic study on the metabolism of N-nitrosamines.

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### **Study status**

Planned

## Research institutions and networks

### Institutions

Fraunhofer Institute for Toxicology and Experimental  
Medicine (ITEM)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

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**Study contact**

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### Primary lead investigator

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**Primary lead investigator**

### ORCID number:

0000-0001-9616-5270

## Study timelines

### Date when funding contract was signed

Planned: 05/08/2025

Actual: 05/08/2025

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### Study start date

Planned: 05/08/2025

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**Data analysis start date**

Planned: 01/01/2026

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**Date of interim report, if expected**

Planned: 06/08/2026

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**Date of final study report**

Planned: 06/09/2026

## Sources of funding

- EMA

## More details on funding

SC05 to FWC EMA/2020/46/TDA/L1.02 – ROC38

## Study protocol

[202510\\_EMA\\_SC05\\_D2\\_study\\_protocol\\_final.pdf](#) (849.34 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Other

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**Study topic, other:**

Evaluate tissue specific carcinogenicity and on metabolism of N-nitrosamines

**Study type:**

Not applicable

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**Scope of the study:**

Method development or testing

**If 'other', further details on the scope of the study**

Research project to better define threshold for nitrosamine impurities

## Study drug and medical condition

**Medicinal product name, other**

Several model compounds with nitrosamine substructure

## Population studied

**Short description of the study population**

none

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**Special population of interest**

Other

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**Special population of interest, other**

no patients involved

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### **Estimated number of subjects**

0

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No