Quantitative structure Activity Relationships (QSAR) for nitrosamine risk assessment. EMA/2020/46/TDA/01(Lot 1) SC01 under FWC EMA/2020/46/TDA/L1.02 (QSAR for Nitrosamines)

First published: 02/03/2022

Last updated: 29/08/2022

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48784

EU PAS number

EUPAS46057

Study ID

48784

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Netherlands
- [ ] United Kingdom
- [ ] United States

Study description

Development of a structure activity relationship for N-Nitrosamines. A special focus will be given to the evaluation of DNA adduct formation and DNA repair processes by experimental testing. With these data, groups of highly potent carcinogens will be distinguished form less potent Nitrosamines. This knowledge will allow to set different thresholds for Nitrosamines.

Study status

Ongoing

Research institutions and networks

Institutions

Fraunhofer-Gesellschaft

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sylvia Escher

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/12/2021

Actual: 08/12/2021

Study start date

Planned: 01/01/2022

Actual: 03/01/2022

Date of interim report, if expected

Planned: 28/02/2022

Actual: 28/02/2022

Date of final study report

Planned: 31/12/2023

Sources of funding

- Other

More details on funding

EMA

Study protocol

01_QSAR_Study_Design_Protocols.pdf(2.37 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Distinguish classes of Nitrosamines, which differ with regard to their carcinogenic potential.

Population studied

Age groups

Adolescents (12 to < 18 years)

Estimated number of subjects

0

Study design details

Outcomes

Structural rules which defines properties that lead to high or low carcinogenic potency.

Data analysis plan

Derivation of acceptable daily intake values for classes of Nitrosamines

Data management

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No