# Demonstration study 2.5.5 of the ConcePTION project; Validation of primary source pregnancy exposure and outcomes (pharmacovigilance data)

**First published:** 01/12/2021

**Last updated:** 03/03/2022

Study Planned

## Administrative details

**EU PAS number**

EUPAS44505

**Study ID**

44506

**DARWIN EU® study**

No

**Study countries**

Netherlands

United Kingdom

**Study description**

The overarching aim of this demonstration project is to ascertain whether self-reporting methods of data collection in pregnancy exposure and outcomes can be considered reliable for pharmacovigilance purposes. The main objective of demonstration study 2.5.5 is to compare the completeness and accuracy of self-reported pregnancy pharmacovigilance data with corresponding data supplied by healthcare professionals (HCPs) in a variety of different contexts. The validation exercises undertaken in this demonstration project will be split into two main sub-studies.

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**Study status**

Planned

# Research institutions and networks

## Institutions

### Novartis Pharmaceuticals

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

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

Institution

### Netherlands Pharmacovigilance Centre Lareb

Netherlands

**First published:** 05/02/2010

**Last updated:** 19/07/2016

Institution | Outdated | Not-for-profit | ENCePP partner

## University of Manchester

United Kingdom

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

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

Institution | Educational Institution

## Novartis Pharmaceuticals

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

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

Institution

## University of Manchester Manchester, United Kingdom, Novartis Pharma AG Basel, Switzerland, UK Teratology Information Serrvice Newcastle upon Tyne, United Kingdom, University of KwaZulu-Natal Durban, South Africa

# Contact details

**Study institution contact**

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**Primary lead investigator**

David Lewis

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Planned: 01/04/2019

Actual: 01/04/2019

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**Study start date**

Planned: 01/03/2022

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**Data analysis start date**

Planned: 01/06/2022

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**Date of final study report**

Planned: 30/09/2023

# Sources of funding

- Pharmaceutical company and other private sector
- EU institutional research programme

## More details on funding

EFPIA, IMI

## Regulatory

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

No

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If ‘other’, further details on the scope of the study**

Data validation study

**Main study objective:**

The main objective is to compare the completeness and accuracy of self-reported pregnancy pharmacovigilance data with corresponding data supplied by healthcare professionals (HCPs) in a variety of different contexts.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Data validation study

## Population studied

**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

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**Special population of interest**

Pregnant women

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**Estimated number of subjects**

1000

## Study design details

**Data analysis plan**

Sub-study 1 (validation of SADR reports) - Descriptive statistics (absolute numbers, percentages) will be used to describe the total number of reports available, the stratified numbers per report source (e.g. SRS, literature), and the stratified numbers for self-reported and HCP-validated ICSRs. Comparative statistics such as Cohen’s Kappa can be calculated to show agreement between the reports. Sub-study 2 (validation of neurodevelopmental assessment tools) - Agreement between parental reports and clinical assessment results will be quantified using a range of statistical approaches, including (where appropriate) Cohen’s Kappa statistic, correlation coefficients, receiver operating characteristic (ROC) and area under the curve (AUC) plots, and calculations of sensitivity/specificity. Descriptive statistics and qualitative methods may also be utilised where required.

# 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.

## Data sources

**Data sources (types)**

Spontaneous reports of suspected adverse drug reactions

Other

**Data sources (types), other**

Sub-study 2 will undertake child health and neurodevelopmental assessments conducted during clinical reviews to validate data provided by parents through remotely completed questionnaires. The study will recruit women with Fetal Valproate Spectrum Disorder, and in utero exposure to other antiepileptic drugs.

## 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