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

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# Administrative details

#### 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.

#### **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Institution Outdated Not-for-profit ENCePP partner



## **Novartis Pharmaceuticals**

First published: 01/02/2024

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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**

David Lewis david-1.lewis@novartis.com

Study contact

david-1.lewis@novartis.com

#### **Primary lead investigator**

**David Lewis** 

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Planned: 01/04/2019

Actual: 01/04/2019

## **Study start date**

Planned: 01/03/2022

## Data analysis start date

Planned: 01/06/2022

## 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

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

Not applicable

# Methodological aspects

Study type

Study type list

**Study type:** 

Non-interventional study

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 selfreported pregnancy pharmacovigilance data with corresponding data supplied by healthcare professionals (HCPs) in a variety of different contexts.

# Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

Data validation study

# Population studied

#### **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

## Special population of interest

Pregnant women

#### **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

#### 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