# Long-term investigation following exposure to individual medicines in utero: The LIFETIME system

**First published:** 04/10/2021
**Last updated:** 23/04/2024

Study | Ongoing

## Administrative details

**PURI**
https://redirect.ema.europa.eu/resource/47521

**EU PAS number**
EUPAS43300

**Study ID**
47521

**DARWIN EU® study**
No

**Study countries**
Ireland
Netherlands
United Kingdom

**Study description**
This project is one of design and feasibility testing. Initially this project will focus on the development of the LIFETIME System: a set of questionnaires which will be the primary source of standardised data collection and the development of infrastructure to collect the data. Following this, three observational studies will be completed which will investigate validity and feasibility of the proposed system through the collection of primary data.

**Study status**
Ongoing

# Research institution and networks

## Institutions

### University of Manchester
United Kingdom
**First published:** 01/02/2024
Last updated
01/02/2024
**Institution**
**Educational Institution**

### Netherlands Pharmacovigilance Centre Lareb
Netherlands
**First published:** 05/02/2010
Last updated
19/07/2016
**Institution**
**ENCePP partner**
**Not-for-profit**

### University of Kwa-Zulu Natal South Africa, UK Teratology Information Service UK, UK & Ireland Epilepsy Pregnancy Register UK & Ireland, Medicines and Health Regulatory Authority UK

## Networks

### ConcepTION
**First published:** 01/02/2024
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01/02/2024
**Network**

# Contact details

**Study institution contact**
Rebecca Bromley
Study contact

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**Primary lead investigator**
Rebecca Bromley
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:
11/02/2022
Actual:
18/02/2022

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**Data analysis start date**
Planned:
01/06/2022
Actual:
01/09/2022

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**Date of interim report, if expected**
Planned:
30/09/2022

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**Date of final study report**
Planned:
30/09/2023

# Sources of funding

- EU institutional research programme

## More details on funding

Innovative Medicine Initiative (IMI)

## Study protocol

EUPAS43300-43376.pdf(774.81 KB)

## 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:**
Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**
The investigation into methods of routine surveillance for longer-term child health and neurodevelopmental outcomes in children exposed to medications in utero.

## Study Design

**Non-interventional study design**
Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**
(N03AG01) valproic acid
(N03AF01) carbamazepine
(N03AX09) lamotrigine
(N03AX14) levetiracetam
(N03AX15) zonisamide
(N03AX18) lacosamide
(N03AX11) topiramate

**Medical condition to be studied**
Epilepsy
Foetal anticonvulsant syndrome

## Population studied

**Age groups**
Infants and toddlers (28 days – 23 months)
Children (2 to < 12 years)
Adolescents (12 to < 18 years)
Adults (18 to < 46 years)

**Special population of interest**
Pregnant women

**Estimated number of subjects**
660

## Study design details

**Outcomes**
The feasibility of undertaking routine follow up for longer term outcomes. This will be measured by the ability to recruit and retain women during their pregnancy and past their child's 2nd birthday.

**Data analysis plan**
Data will be analyzed investigating the feasibility and the acceptability of the LIFETIME System. Frequency information will be provided with regards to number of women recruited in specific time periods by specific groups and as a total by medication type. Rates of completion of the Ages and Stages Questionnaires at each age point, stratified by key demographic variables will be calculated. Rates of questionnaire completion and missing data will also be calculated.

# Data management

## ENCePP Seal

**This study has been awarded the ENCePP seal**


**Conflicts of interest of investigators**
EUPAS43300-43377.pdf(164.98 KB)

**Composition of steering group and observers**
EUPAS43300-45478.pdf(58.15 KB)

## Data sources

**Data sources (types)**
Disease registry
Other

**Data sources (types), other**
Prospective patient-based data collection, Exposure registry

## 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