# Pregistry International Pregnancy Exposure Registry (PIPER)

**First published:** 20/04/2022

**Last updated:** 23/04/2024

Study Planned

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/48094

**EU PAS number**

EUPAS46841

**Study ID**

48094

**DARWIN EU® study**

No

**Study countries**

- ☐ Canada
- ☐ Nigeria
- ☐ Philippines

☐ South Africa

☐ United Kingdom

☐ United States

---

**Study description**

The aims of the Pregistry International Pregnancy Exposure Registry (PIPER) are to provide early signals of risk after prenatal exposure to medical products and to define boundaries of safety for medical products. The goal is to assist prescribers and study participants in weighing the potential risks of prenatal treatments on the wellbeing of mother and the unborn offspring. Specifically, the PIPER will estimate the risk of obstetric outcomes (spontaneous abortion, antenatal bleeding, gestational diabetes, gestational hypertension, intrauterine growth restriction, postpartum hemorrhage, fetal distress, uterine rupture, placenta previa, chorioamnionitis, Caesarean delivery, COVID-19), neonatal outcomes (major congenital malformations, low birth weight, neonatal death, neonatal encephalopathy, neonatal infections, neonatal acute kidney injury, preterm birth, respiratory distress in the newborn, small for gestational age, stillbirth, COVID-19), and infant outcomes (developmental milestones motor, cognitive, language, social-emotional, and mental health skills, height, weight, failure to thrive, medical conditions during the first 12 months of life, COVID-19) among pregnant women.

---

**Study status**

Planned

# Research institutions and networks

## Institutions

# Pregistry

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

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

Institution

## Contact details

### Study institution contact

Wyszynski Diego

Study contact

hello@pregistry.com

### Primary lead investigator

Wyszynski Diego

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 01/12/2021

### Study start date

Planned: 16/07/2022

### Data analysis start date

Planned: 15/07/2032

**Date of final study report**
Planned: 15/07/2032

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pregistry, LLC

## 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

Disease epidemiology

Drug utilisation

**Main study objective:**

The aims of the Pregistry International Pregnancy Exposure Registry (PIPER) are to provide early signals of risk after prenatal exposure to medical products and to define boundaries of safety for medical products. The goal is to assist prescribers and study participants in weighing the potential risks of prenatal treatments on the wellbeing of mother and the unborn offspring.

## Study Design

**Non-interventional study design**

Cohort

Other

---

**Non-interventional study design, other**

Pregnancy registry

## Study drug and medical condition

**Medical condition to be studied**

Pregnancy

Drug exposure before pregnancy

Stillbirth

Abortion spontaneous

Gestational hypertension

COVID-19

## Population studied

**Age groups**

Adults (18 to < 46 years)

**Special population of interest**

Pregnant women

**Estimated number of subjects**

10000

## Study design details

**Outcomes**

Risk of obstetric, neonatal, and infant outcomes.

**Data analysis plan**

There are no a priori defined primary or secondary endpoints in the PIPER. The aim is to conduct surveillance of adverse events (AEs) potentially associated with prescription medical products in the United States. As described below, the analyses will include a descriptive component, a real-time disproportional reporting evaluation, a clinical assessment of similar cases, and analyses of causal inference.

# Data management

## Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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