# Vumerity (Diroximel Fumarate) Prospective MS Pregnancy Exposure Registry

**First published:** 31/08/2023

**Last updated:** 15/03/2024

Study Planned

## Administrative details

**EU PAS number**

EUPAS106453

**Study ID**

106454

**DARWIN EU® study**

No

**Study countries**

- [ ] Australia
- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Spain
- [ ] Switzerland

☐ United Kingdom (Northern Ireland)

☐ United States

**Study description**

Pregnancy Exposure Registry for Vumerity (Diroximel Fumarate)

**Study status**

Planned

# Research institutions and networks

## Institutions

### Biogen

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

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

**Institution**

## Contact details

**Study institution contact**

Study Director Biogen ctrr@biogen.com

**Study contact**

ctrr@biogen.com

**Primary lead investigator**

Study Director Biogen

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Actual: 21/01/2021

**Study start date**
Planned: 31/08/2023

**Date of final study report**
Planned: 18/05/2034

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Biogen

# Regulatory

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

No

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

NCT05658497: https://classic.clinicaltrials.gov/ct2/show/NCT05658497

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

The purpose of this Pregnancy Registry is to better characterize how diroximel fumarate (DRF) may affect pregnancy and infant outcomes.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

VUMERITY

**Medical condition to be studied**

Multiple sclerosis

# Population studied

**Age groups**

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

**Estimated number of subjects**

908

# Study design details

**Outcomes**

Number of Major Congenital Malformations (MCMs), Number of: Elective/Therapeutic Terminations, Spontaneous Abortions, Fetal Deaths Including Still Birth, Live Births, Ectopic Pregnancies, Molar Pregnancies, Maternal Deaths, Neonatal Deaths, Perinatal Deaths, Infant Deaths, Serious or Opportunistic Infections in Liveborn Children, Infants with Abnormal Postnatal Growth and Development, Subjects with Pregnancy Complications

**Data analysis plan**

All analyses will be conducted on an overall basis, as well as stratified by earliest trimester exposure. For MCMs, analyses will be conducted for participants who only have exposure in the first trimester in the exposed cohort. Participants who had earliest DRF exposure after the first trimester will be excluded from the analysis for MCMs. The prevalence and 95% confidence interval (CIs) of MCMs and spontaneous abortion will be calculated. Other negative pregnancy outcomes will be similarly examined as the sample size permits. Infants with minor malformations, chromosomal abnormalities, genetic syndromes, positional defects, and prematurity-related defects will be excluded from the primary outcome analyses related to MCM prevalence.

# 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)**

Disease 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