# The Mycophenolate Pregnancy Registry

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# Administrative details

EU PAS number	
EUPAS10541	
Study ID	
27036	
DARWIN EU® study	
No	
Study countries United States	

### **Study description**

The Mycophenolate Pregnancy Registry is designed as a prospective, observational registry collecting data regarding mycophenolate exposure during pregnancy, and pregnancy, fetal and infant outcomes after exposure. Early and later term pregnancy outcomes will be solicited at selected

gestational time points and at the estimated date of delivery. Structural and functional birth defects identified in the perinatal period through one year of life will be collected and classified.

### **Study status**

Ongoing

### Research institutions and networks

# Institutions

# Campbell Alliance

First published: 01/02/2024

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Institution

United BioSource Corporation (UBC)	
Switzerland	
First published: 25/04/2013	
<b>Last updated:</b> 06/03/2024	
Institution Non-Pharmaceutical company ENCePP partner	

### Contact details

### **Study institution contact**

Trial Information Support Line TISL global.clinical\_trial\_registry@roche.com

Study contact

global.clinical trial registry@roche.com

### **Primary lead investigator**

Annette Stemhagen

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Actual: 06/02/2009

### Study start date

Actual: 20/11/2012

### Date of final study report

Planned: 31/12/2021

# Sources of funding

Pharmaceutical company and other private sector

# More details on funding

Genentech, Inc. Novartis Pharma. Corp. Accord Healthcare, Inc. Alkem Lab. Ltd. Alkem Lab.Ltd. U.S. REMS Agent Apotex Corp. Mylan Pharma., Inc. Pfizer, Inc. Roxane Lab., Inc. Sandoz Incorporated Teva Pharma. USA, Inc. Vintage Pharma., LLC

# Study protocol

MPR-ML22679 Protocol version 6.pdf (1.18 MB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

ML22679

# 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

Voluntary reporting by HCPs and/or patients of any mycophenolate-exposed pregnancy in the US.

### Main study objective:

• Document maternal and fetal outcomes of each exposed pregnancy to further characterize the risk of mycophenolate fetal exposure. • Determine mycophenolate exposure status for each reported pregnancy. • Root cause analysis of circumstances that led to fetal exposure. • Identify factors that affect the risk of adverse outcomes such as dose, timing of exposure, or maternal characteristics.

# Study Design

### Non-interventional study design

Other

### Non-interventional study design, other

A prospective, observational registry

# Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

#### Medical condition to be studied

Pregnancy

# 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)

### Special population of interest

Pregnant women

### **Estimated number of subjects**

500

# Study design details

#### **Outcomes**

Maternal outcomes: Incidence of pregnancy complications • Fetal outcomes:
 Incidence of congenital disorders • Time/duration of mycophenolate exposure •
 Mycophenolate dose/regimen • Indications for mycophenolate use • Maternal medical/demographic characteristics, • Occurrence of educational counseling

#### Data analysis plan

All statistical analyses will be coordinated by Outcome Sciences, Inc. Analyses and reporting will be performed semi-annually, for regulatory update or other purposes, and possibly more often according to the needs of and at the discretion of the Registry sponsor(s) and the Mycophenolate Pregnancy. Based on the prospective case data, 95% confidence intervals will be constructed around the observed defect rate. For pregnancies with known outcome, line listings and descriptive summaries will be included.

### 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)

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