

# Swiss Soliris® and Ultomiris® Reimbursement Registry SSURR: An observational registry for capturing data of patients suffering from paroxysmal nocturnal hemoglobinuria (PNH) who are treated with Soliris® (eculizumab) or Ultomiris® (ravulizumab)

**First published:** 22/09/2020

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Study

Ongoing

## Administrative details

### **EU PAS number**

EUPAS37218

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### **Study ID**

37332

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### **DARWIN EU® study**

No

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## Study countries

 Switzerland

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## Study description

Swiss Soliris® and Ultomiris® Reimbursement Registry SSURR: An observational registry for capturing data of patients suffering from paroxysmal nocturnal hemoglobinuria (PNH) who are treated with Soliris® (eculizumab) or Ultomiris® (ravulizumab). The participating centres are determined by FOPH/BAG and per requirements a study report is submitted every year, usually at the last quarter.

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## Study status

Ongoing

# Research institutions and networks

## Institutions

### Hôpitaux Universitaires de Genève (HUG)

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

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

**Institution**

### Inselspital

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

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

Institution

## University Hospital of Basel

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

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

Institution

Hôpitaux Universitaires de Genève Switzerland,  
Centre Hospitalier Universitaire Vaudois  
Switzerland, Inselspital Bern Switzerland,  
Kantonsspital Luzern Switzerland,  
Universitätsspital Basel Switzerland, Kantonsspital  
Aarau Switzerland, Universitätsspital Zürich  
Switzerland, Kantonsspital Chur (for Ultomiris  
only) Switzerland, Ente Ospedaliero Cantonale  
Bellinzona Switzerland, Kantonsspital St. Gallen  
Switzerland

Contact details

### **Study institution contact**

Jan Bolten [jan.bolten@alexion.com](mailto:jan.bolten@alexion.com)

Study contact

[jan.bolten@alexion.com](mailto:jan.bolten@alexion.com)

### **Primary lead investigator**

Jan Bolten

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 29/11/2011

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### **Study start date**

Actual: 19/01/2012

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### **Data analysis start date**

Actual: 28/12/2012

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### **Date of final study report**

Planned: 20/12/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Alexion Pharma GmbH

## Regulatory

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

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Main study objective:**

Collection of medical information related to initiation and continuation of therapy for patients diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) and treated with Soliris® or Ultomiris® in Switzerland.

## Study Design

## **Non-interventional study design**

Other

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## **Non-interventional study design, other**

Observational registry

## Study drug and medical condition

### **Anatomical Therapeutic Chemical (ATC) code**

(L04AA25) eculizumab

eculizumab

(L04AA43) ravulizumab

ravulizumab

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### **Medical condition to be studied**

Paroxysmal nocturnal haemoglobinuria

## Population studied

### **Age groups**

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Estimated number of subjects**

## Study design details

### Outcomes

hematological parameters, LDH value, PNH symptoms such as abdominal pain, chest pain, dyspnoea and pain requiring medical intervention, performance on a "quality of life" scale, need for transfusions, thrombotic events, occurrence of renal failure and pulmonary arterial hypertension

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### Data analysis plan

The statistical evaluation of will be laid out according to the reporting requirements for the FOPH/BAG. Mainly descriptive statistics will be applied.

## 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](#)

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## **Data sources (types), other**

Observational registry and retrospective collection of patient data

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No