

# Non-Interventional Post-Marketing Safety Study on the Long-Term Safety of HYQVIA (Global)

**First published:** 14/11/2017

**Last updated:** 16/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS21523

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### Study ID

49332

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### DARWIN EU® study

No

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### Study countries

United States

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### Study description

The purpose of the proposed study is to acquire additional data (including the assessment of anti-rHuPH20 antibodies) on the long-term safety of HYQVIA and to assess the prescribed treatment regimens and product administration in routine clinical practice.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Shire

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

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Institution

Multiple centres: 50 centres are involved in the study

## Contact details

### **Study institution contact**

Study Contact Shire [clinicaltransparency@shire.com](mailto:clinicaltransparency@shire.com)

**Study contact**

[clinicaltransparency@shire.com](mailto:clinicaltransparency@shire.com)

**Primary lead investigator**

Study Contact Shire

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 02/03/2015

Actual: 17/09/2015

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**Study start date**

Planned: 12/11/2015

Actual: 12/11/2015

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**Data analysis start date**

Planned: 30/10/2021

Actual: 21/10/2021

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**Date of final study report**

Planned: 16/05/2022

Actual: 16/08/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Baxalta, now part of Shire

## Study protocol

[161406-protocol-amend-2-2015sep17\\_redacted.pdf](#) (1.26 MB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective is to collect and assess additional safety data, in particular the occurrence of long-term changes in incidence and severity of related adverse events in patients treated with HYQVIA

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Prospective, uncontrolled, multi-center, open-label, post-marketing surveillance study

## Study drug and medical condition

**Medicinal product name**

HYQVIA

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**Medical condition to be studied**

## Population studied

### **Short description of the study population**

The study involved adult subjects aged 16 years or older with primary immunodeficiency diseases (PIDD) who were prescribed or initiated treatment with HYQVIA to assess the safety and tolerability data under routine clinical conditions.

Inclusion criteria:

- Subject requires immunoglobulin treatment for PIDD
- Subject age is compatible with local package insert requirements (US  $\geq$  16, EU  $\geq$  18 years of age)
- Subject has been prescribed or has started treatment with HYQVIA
- Subject is willing and able to comply with the requirements of the protocol

Exclusion criteria:

- Subject has known hypersensitivity to any of the components of the medicinal product
  - Subject has participated in an interventional clinical study involving a medicinal product or device within 30 days prior to enrollment or is scheduled to participate in an interventional clinical study involving a medical product or device during the course of this study
  - Subject is a family member or employee of the investigator
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### **Age groups**

- 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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### **Special population of interest**

Immunocompromised

Pregnant women

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### **Estimated number of subjects**

250

## Study design details

### **Outcomes**

Incidence of all related serious adverse events (SAEs), Safety: - all SAEs and non-SAEs - immunologic AEs Treatment: 1. Regimen: - dose - infusion interval 2. Administration: - infusion volume - maximum infusion rate - mean infusion rate - duration of infusion - number of infusion sites Health-related quality of life and health resource use assessments

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### **Data analysis plan**

Statistical analyses and data displays will be mainly descriptive. Data from all enrolled subjects will be included in the analysis. If groups of sufficient sample size (such as: age groups, PIDD types) are available, confidence intervals may accompany the point estimates. All SAEs and non-serious AEs will be categorized according to MedDRA system organ class (SOC) and preferred term. Concomitant medications and non-drug therapies will be recorded and tabulated. Tables will be prepared to list for each SAE and non-serious AE the number of events and the number of subjects who experienced one or more

events.

## Documents

### Study results

[161406-clinical-study-report-redact.pdf](#) (716.12 KB)

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## 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)

[Drug registry](#)

## 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