# A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of HUMIRA (adalimumab) in Pediatric Patients with Moderately to Severely Active Crohn's Disease (CD) - CAPE

**First published:** 30/04/2014

**Last updated:** 14/03/2024

Study  Ongoing

## Administrative details

**EU PAS number**

EUPAS6213

**Study ID**

48820

**DARWIN EU® study**

No

**Study countries**

☐ Bosnia and Herzegovina

☐ Bulgaria

- [ ] Canada
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Lithuania
- [ ] Netherlands
- [ ] Portugal
- [ ] Puerto Rico
- [ ] Romania
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United States

## Study description

This is a registry study to evaluate the long-term safety and effectiveness of adalimumab in pediatric patients with moderately to severely active CD who are treated as recommended in the product label.

## Study status

Ongoing

# Contact details

## Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

## Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 01/01/2012

Actual: 01/01/2012

**Study start date**

Planned: 28/07/2014

Actual: 28/08/2014

**Date of final study report**

Planned: 31/10/2028

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

AbbVie

# Study protocol

[p11292-protocol-pmos-abstract-eupas register.pdf](157.15 KB)

[p11292-protocol-pmos-amendment1-abstract.pdf](191.65 KB)

# Regulatory

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

No

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

P11-292

# Methodological aspects

# Study type

# Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Main study objective:**

This is a registry study to evaluate the long-term safety and effectiveness of adalimumab in pediatric patients with moderately to severely active CD who are treated as recommended in the product label.

# Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

**Name of medicine**

HUMIRA

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**Medical condition to be studied**

Crohn's disease

# Population studied

## Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

## Estimated number of subjects

1434

# Study design details

## Outcomes

-Number (No.) and percentage of subjects with SAEs-No. and percentage of subjects with AESI of infections, malignancies, and pregnancies-No. and percentage of subjects with other AESI-No. of treatment-emergent SAEs per 100 patient years (PYs)-No. of treatment-emergent AESI per 100 PYs of infections, malignancies-No. of treatment-emergent other AESI per 100 PYs, -Short Pediatric Crohn's Disease Activity Index (sh-PCDAI)-Physician's Global Assessment of Disease Activity (PGA)-IMPACT III-Short Quality of Life in Inflammatory Bowel Disease Questionnaire (SIBDQ)-Work Productivity and Activity Impairment (WPAI) Questionnaire

## Data analysis plan

For effectiveness data, continuous variables will be summarized using descriptive statistics by the number of non-missing observations, mean, 95% CI for mean, standard deviation, 1st quartile, median, 3rd quartile, minimum, and maximum. Categorical variables will be summarized using frequencies and percentages.For safety data, treatment-emergent adverse events (AEs) will be coded using the most current version of the Medical Dictionary for Regulatory Activities (MedDRA). The number and percent of patients experiencing serious AEs and AEs of interest will be tabulated by system organ class (SOC) and

MedDRA preferred term (PT). Events per 100 patient-years, i.e. the number of treatment-emergent serious adverse events (SAEs) and adverse events of special interest (AESI) per 100 patient-years, will be tabulated. Complete, specific details of the statistical analysis will be described and fully documented in the Statistical Analysis Plan (SAP).

# Data management

## Data sources

**Data sources (types)**

Disease 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