# Remibrutinib in real-world clinical practice: a prospective, multi-country, non-interventional, effectiveness and safety study (REASSERT)

**First published:** 27/01/2026

**Last updated:** 03/02/2026

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000889

**Study ID**

1000000889

**DARWIN EU® study**

No

**Study countries**

Canada

China

Germany

Italy

Japan

Korea, Republic of

Spain

United States

**Study description**

This is a prospective, multi-country, non-interventional study in patients with CSU where the treatment decision prior enrolment has been made to either escalate current sgH1-AHs treatment or escalate/switch current treatment to remibrutinib.

The primary aim of this study is to gather real-world effectiveness and safety data for remibrutinib, covering a broader, real-world clinical practice population.

The study employs an umbrella design which brings the evidence needs from multiple countries under the REASSERT global program.

Countries will generate local protocol to be used in their country; the local study documentation will be a minimised version of the global document, modified to align with country's evidence needs, given local disparities in treatment guidelines, access, physician type and ePROs/eDiaries used.

To achieve the core objectives the observation needs to include either the Urticaria Control Test (UCT) or Urticaria Activity Score over 7 days (UAS7) and the Dermatology Life Quality Index (DLQI). Data from all countries will be pooled and analyzed globally. In certain instances, some modifications of the global protocol may be permitted. For example, in countries where prospective monitoring of off-label antihistamines is prohibited, cohort 1 will not be enrolled.

**Study status**

Ongoing

## Research institutions and networks

## Institutions

### Novartis Pharmaceuticals

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

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

Institution

## Contact details

**Study institution contact**

Novartis Clinical Disclosure Officer

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Study contact

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**Primary lead investigator**

Novartis Clinical Disclosure Officer

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 24/03/2025

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**Study start date**

Planned: 30/01/2026

Actual: 02/02/2026

**Data analysis start date**
Planned: 30/10/2031

**Date of final study report**
Planned: 30/08/2032

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis Pharma AG

## Study protocol

Protocol Amendment_-_v01_Redacted_22 Dec 2025.pdf (1.25 MB)

## Regulatory

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

No

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

Not applicable

# Other study registration identification numbers and links

CLOU064A2402

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Study design:**

Prospective, multi-country, non-interventional study in patients with CSU where the treatment decision prior enrolment has been made to either escalate current sgH1-AHs treatment or escalate/switch current treatment to remibrutinib

**Main study objective:**

Evaluate the 12-week real-world effectiveness of remibrutinib in adult patients diagnosed with CSU who remain inadequately controlled despite sgH1-AHs (including all patients who initiate remibrutinib, regardless of prior treatment).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L04AA60) remibrutinib

remibrutinib

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**Medical condition to be studied**

Chronic spontaneous urticaria

## Population studied

**Short description of the study population**

Patients with CSU where the treatment decision prior enrolment has been made to either escalate current sgH1-AHs treatment or escalate/switch current treatment to remibrutinib

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**Estimated number of subjects**

3.277

## Study design details

**Setting**

This is a prospective, multi-country, non-interventional study in patients with CSU where the treatment decision prior enrolment has been made to either escalate current sgH1-AHs treatment or escalate/switch current treatment to remibrutinib.

The primary aim of this study is to gather real-world effectiveness and safety data for remibrutinib, a new treatment option, covering a broader, real-world clinical practice population at a wider range of sites than in the Phase 2 and Phase 3 (REMIX) development trials.

The study employs an umbrella design which brings together the evidence needs from multiple countries under the REASSERT global program.

Countries will generate local study documentation (i.e. concept, protocol, SAP) to be applied in their country; the local study documentation will be a minimised version of the global document set, modified to align with country's evidence needs, given local disparities in treatment guidelines, access, physician type and ePROs/eDiaries used. To achieve the core objectives the observation needs to include either the Urticaria Control Test (UCT) or Urticaria Activity Score over 7 days (UAS7) and the Dermatology Life Quality Index (DLQI). These, and safety data must be observed across all participating countries.

Data from all countries will be pooled and analyzed globally. In certain instances, some modifications of the global protocol may be permitted. For example, in countries where prospective monitoring of off-label antihistamines is prohibited, cohort 1 will not be enrolled.

## 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)**

Non-interventional study

# Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings**

**CDM name**

CDISC SDTM

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**CDM website**

https://www.cdisc.org/standards/foundational/sdtm

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**CDM version**

SDTM v2.0 and SDTM IG v3.4

# Data quality specifications

**Check conformance**

Yes

**Check completeness**

Yes

**Check stability**

Yes

**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Yes

**Data characterisation moment**

after data extraction

after extract-transform-load to a common data model

after creation of study variables

**Data characterisation details**

The study will collect participant-level data including demographics, medical history, concomitant medications, and laboratory results along with variables required by the protocol. Data will be captured at baseline and at each scheduled follow-up visit as mentioned in schedule of assessment . Variables will include both categorical (e.g., sex, adverse event categories) and continuous measures (e.g., lab values).

For data collection and quality : The study will collect data in an EDC

applications. The forms will checks in place to ensure data quality and completeness. The applicable SOPs will be followed to ensure compliance with data collection and reporting process.