# Assessing the profile of CHF patients with redUced ejection fraction being managed in the pRimary care sectOr across GeRmany as well as the phArmacologic treatment these HF patients receive (AURORA-HF)

**First published:** 22/03/2016

**Last updated:** 02/07/2024

Study | Finalised

## Administrative details

**EU PAS number**

EUPAS12912

**Study ID**

39319

**DARWIN EU® study**

No

**Study countries**

Germany

**Study description**

The non-interventional AURORA-HF study is conducted in cooperation with General Practitioners (GPs) who are treating chronic heart failure (CHF) patients in Germany. Amendment 01 of the protocol resulted in a strong reduction in the patient number and study sites. As the objectives do not address safety topics, Novartis does not expect that the trial will add knowledge on the safety of the medicinal product. Hence the trial category assessment changed from PASS to Non-PASS.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### Novartis Pharmaceuticals

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

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

**Institution**

### Multiple centres: 999 centres are involved in the study

## Contact details

**Study institution contact**

Novartis Clinical Disclosure Office

Trialandresults.registries@novartis.com

Study contact

Trialandresults.registries@novartis.com

**Primary lead investigator**

Novartis Clinical Disclosure Office

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 01/02/2016

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**Study start date**

Planned: 23/03/2016

Actual: 29/03/2016

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**Data analysis start date**

Planned: 01/08/2019

Actual: 20/12/2019

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**Date of final study report**

Planned: 15/07/2019

Actual: 17/09/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis Pharma GmbH

## Regulatory

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

No

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

Not applicable

## Other study registration identification numbers and links

CLCZ696BDE02

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Disease epidemiology

Drug utilisation

**Data collection methods:**

Primary data collection

**Main study objective:**

AURORA-HF will provide a picture of HFrEF patients being managed in the primary care sector across Germany. It will describe the pharmacologic treatment HFrEF patients receive, the demographic and clinical features of patients who will be started on Sacubitril/Valsartan and the demographic and clinical features of patients, who will receive Sacubitril/Valsartan as long-term therapy.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

SACUBITRIL

VALSARTAN

**Medical condition to be studied**

Cardiac failure chronic

# Population studied

**Short description of the study population**

Chronic heart failure (CHF) patients in Germany.

**Age groups**

- 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)

**Special population of interest**

Hepatic impaired

Immunocompromised

Renal impaired

**Estimated number of subjects**

13.056

# Study design details

**Outcomes**

– To describe the profile of patients initiated on Sacubitril/Valsartan as compared to conventionally treated patients – To describe the profile of Sacubitril/Valsartan patients who remain on Sacubitril/Valsartan therapy until the final visit (approx. 12 months) as compared to those who permanently stop Sacubitril/Valsartan therapy

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**Data analysis plan**

The data will be analyzed by Novartis and/or by the designated CRO. All data will be analyzed descriptively. Probability of remaining on treatment until month 12 will be modelled using logistic regression. The following baseline characteristics will be fitted in the model as factors in order to determine the baseline characteristics which best describe the profile of patients who will remain on treatment:– SBP (<110 mmHg, 110 – 120 mmHg, >120 mmHg)– Age (<75 years, ≥75 years)– Renal function (eGFR < 60, eGFR >= 60)– Concomitant medications– Beta-blocker (yes/no)– MRA (yes/no)– Diuretics (yes/no)– NYHA class (II, III/IV)– Hospitalization for HF within the year prior to enrollment

# 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

## 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