# Assessment of Real Life cAre – Describing European Heart FailurE Management (ARIADNE)

First published: 21/06/2016

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





# Administrative details

<b>EU PAS number</b> EUPAS13835	
Study ID	
36264	
DARWIN EU® study	
No	
Study countries  Austria Belgium Bulgaria Cyprus	

Estonia			
France			
Germany			
Greece			
Ireland			
<pre>Israel</pre>			
Italy			
Malta			
Norway			
Poland			
Portugal			
Romania			
Russian Fed	eration		
Slovakia			
Spain			
Switzerland			
United Kingo	dom		

### Study description

This is an observational, European NIS with prospective collection of primary data. Data will be collected for two groups of HFrEF patients: symptomatic patients who receive the current individualized standard of care (SoC) for the treatment of CHF and patients for whom the physician has decided to prescribe sacubitril/valsartan. Switching between different CHF treatments (e.g. between SoC and sacubitril/valsartan) is allowed at any time as per decision of the investigator. Enrollment will start in each country when sacubitril/valsartan is available for clinical use. Overall the present NIS will enroll 6000 patients on SoC and 6000 patients on sacubitril/valsartan across Europe.

### **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 Officer trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

# Primary lead investigator

Novartis Clinical Disclosure Officer

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Actual: 28/07/2015

### Study start date

Planned: 30/07/2016 Actual: 25/07/2016

## **Date of final study report**

Planned: 31/12/2019 Actual: 27/01/2020

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

**Novartis** 

# Study protocol

LCZ696B3401-redacted protocol final.pdf (679.81 KB)

# 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

CLCZ696B3401

# Methodological aspects

# Study type

# Study type list

# **Study topic:**

Disease /health condition

Human medicinal product

### Study type:

Non-interventional study

### Scope of the study:

Other

# If 'other', further details on the scope of the study

Patient characterization in terms of demographics, medical history, HF status, comorbidity burden

### **Data collection methods:**

Primary data collection

### Main study objective:

To describe the demographic and clinical features of HFrEF patients managed in the outpatient sector and the diagnostic and pharmacological interventions they receive and the demographic and clinical features of patients for whom treating physician decided to start sacubitril/valsartan, the pattern of administration of this drug, the diagnostic and therapeutic interventions these patients receive

# 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

Chronic left ventricular failure

# Population studied

### Short description of the study population

The present study wil include consecutive HFrEF patients treated by office based cardiologists or selected primary care physicians across Europe. Inclusion criteria:

- 1. Written informed consent provided by the patient or legal representative for participting in the study
- 2. Age 18 years or older
- 3. Patient with symptomatic CHF with a documented reduce left ventricular ejection fraction (LVEF) as assessed by clinical examination and any imaging technique performed anytime in the past

### 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**

Other

# Special population of interest, other

Chronic left ventricular failure patients

### **Estimated number of subjects**

12000

# Study design details

### **Outcomes**

- Descriptive analysis of baseline characteristics of patients initiated on sacubitril/valsartan and patients continued on SoC in outpatient sector -Descriptive analysis of profile of sacubitril/valsartan patients not reaching and maintaining target dose of 200mg twice daily in terms of demographics, medical history, HF status, comorbidity burden as compared with patients reaching target dose, - describe the overall HFrEF population managed in the outpatient sector in Europe- describe HF-treatment in the outpatient sector in Europe- describe the starting dose, titration and maintenance dose of sacubitril/valsartan in patients with different anamnestic and demographic characteristics- describe safety and tolerability features of sacubitril/valsartan in real-world HF patients

### **Data analysis plan**

Only descriptive data analyses will be carried out, supported by calculation of confidence intervals. No statistical testing will be performed. Analyses will be performed for the total sample and stratified by demographic, anamnestic and medical factors (e.g. sex, duration of HF, severity of HF, previous HF-treatment), using an adequate grouping. As appropriate, analysis of all endpoints will also be carried out after stratification according to CHF treatment during the observation period.

# **Documents**

### Study results

lcz696b3401p01--legacy-clinical-study-report Redacted.pdf (534.29 KB)

# 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**

# Data characterisation

# **Data characterisation conducted**

No