

# An Observational Study of Cardiac Events in Patients With HER2 Positive Early Breast Cancer Treated With Herceptin® (OHERA)

**First published:** 10/06/2015

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS9914

---

### Study ID

23949

---

### DARWIN EU® study

No

---

### Study countries

- ☐ Austria
- ☐ Belgium
- ☐ Germany
- ☐ Hungary

- ☐ Italy
  - ☐ Poland
  - ☐ Spain
  - ☐ Sweden
  - ☐ United Kingdom
- 

### Study description

This observational, single-arm cohort safety study has been designed to observe the occurrence of cardiac events in participants with HER2-positive early breast cancer treated with trastuzumab (Herceptin®) in daily clinical practice. All participants will be treated and monitored according to the local clinical practice. No additional procedures or visits in comparison with the usual clinical practice are planned for the study. Data will be collected from medical records for up to 5 years or until death, loss to follow-up, or withdrawal of informed consent.

---

### Study status

Finalised

## Research institutions and networks

### Institutions

**F. Hoffmann-La Roche**

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

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

**Institution**

Multiple centres: 199 centres are involved in the study

## Contact details

### Study institution contact

Mona Shing [global.clinical\\_trial\\_registry@roche.com](mailto:global.clinical_trial_registry@roche.com)

Study contact

[global.clinical\\_trial\\_registry@roche.com](mailto:global.clinical_trial_registry@roche.com)

### Primary lead investigator

Mona Shing

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 01/05/2006

---

### Study start date

Actual: 31/08/2007

---

### Data analysis start date

Actual: 30/09/2008

---

### Date of final study report

Planned: 31/05/2017

Actual: 23/06/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Hoffmann-La Roche

## Regulatory

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

Yes

---

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

BO20652

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

The main objective will be to observe, in the routine clinical practice setting, the incidence of symptomatic congestive heart failure (CHF, New York Heart Association NYHA class II to IV) and cardiac death of participants diagnosed with HER2-positive early breast cancer who receive Herceptin® as per the approved Summary of Product Characteristics (SmPC).

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Observational post-authorization safety study (PASS)

## Study drug and medical condition

**Name of medicine**

HERCEPTIN

---

**Medical condition to be studied**

HER2 positive breast cancer

## Population studied

**Short description of the study population**

Patients with HER2-positive early breast cancer treated with trastuzumab (Herceptin®) in daily clinical practice.

---

**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**

HER-2 positive breast cancer patients

---

**Estimated number of subjects**

3800

## Study design details

## **Outcomes**

- Incidence of NYHA class II, III, and IV symptomatic CHF- Incidence of cardiac death, - Association between demographic characteristics and incidence of symptomatic CHF and cardiac death - Time to onset of symptomatic CHF and other significant cardiac conditions - Time to recovery of symptomatic CHF and other significant cardiac conditions - Incidence of asymptomatic left ventricular dysfunction

---

## **Data analysis plan**

This is an observational study designed to observe the incidence of symptomatic CHF and other significant cardiac events in participants treated with Herceptin for early breast cancer. There is no predefined hypothesis testing. All analyses will be regarded as exploratory and performed annually, available interim data will be reported. Analysis for Primary Objective: The incidence of CHF and of cardiac deaths will be summarized for all participants treated with Herceptin, with 95% Pearson Clopper confidence interval (CI) calculated for the individual rates. The onset of CHF in relation to Herceptin administration will be displayed. Analysis for Secondary Objective: If data permit, characteristics like age, history of disease, and other known risk factors will be evaluated for their prognostic influence on the occurrence of CHF and cardiac death. Time to onset of CHF will be described and estimated using Kaplan-Meier procedures. Duration and time to recovery will be also described.

## **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, Participant medical records

## 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