

# UK – A DISEASE REGISTRY STUDY TO PROSPECTIVELY OBSERVE TREATMENT PATTERNS AND OUTCOMES IN PATIENTS WITH HER2-POSITIVE UNRESECTABLE LOCALLY ADVANCED OR METASTATIC BREAST CANCER (ESTHER)

**First published:** 26/03/2018

**Last updated:** 02/07/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS23334

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### Study ID

26411

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### DARWIN EU® study

No

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### Study countries

## Study description

This disease registry is a prospective, multicentre, non-interventional study designed to observe anti-cancer treatment regimens and clinical outcomes with these regimens in patients with human epidermal growth factor receptor 2 (HER2)-positive unresectable LA/mBC.

Patients can be enrolled in the study irrespective of the anti-cancer treatment they are prescribed. Once a patient is enrolled in the study, she/he will be followed until death, withdrawal of consent or study termination, whichever occurs first.

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## Study status

Finalised

## Research institutions and networks

### Institutions

**F. Hoffmann-La Roche**

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

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

**Institution**

The study will be performed at approximately 28 sites.

## Contact details

### Study institution contact

Trial Information Support Line (TISL)  
global.clinical\_trial\_registry@roche.com

Study contact

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

### Primary lead investigator

Alistair Ring

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 13/11/2014

Actual: 13/11/2014

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### Study start date

Planned: 23/02/2015

Actual: 23/02/2015

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### Data analysis start date

Planned: 16/03/2023

Actual: 19/04/2023

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### Date of final study report

Planned: 31/12/2024

Actual: 15/02/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Roche Products Limited

## Study protocol

[ML29659\\_PROTOCOL\\_Redacted.pdf](#) (1.27 MB)

[ML29659 - Protocol v5\\_03-Mar-2022\\_Redacted.pdf](#) (806.25 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)?**

Not applicable

## Other study registration identification numbers and links

ML29659, ESTHER

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness  
Disease epidemiology  
Drug utilisation  
Effectiveness study (incl. comparative)  
Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

In patients with unresectable locally advanced (LA) or metastatic breast cancer (mBC), to observe the different anti-cancer treatment regimens and their sequencing throughout the course of the disease and to describe clinical outcome for each anti-cancer treatment regimen measured as progression-free survival (PFS).

## Study drug and medical condition

**Medicinal product name**

HERCEPTIN

KADCYLA

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

PERTUZUMAB

TRASTUZUMAB

TRASTUZUMAB EMTANSINE

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**Anatomical Therapeutic Chemical (ATC) code**

(L01FD01) trastuzumab

trastuzumab

(L01FD02) pertuzumab

pertuzumab

(L01FD03) trastuzumab emtansine

trastuzumab emtansine

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**Medical condition to be studied**

Breast cancer

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**Additional medical condition(s)**

HER2-Positive Unresectable Locally Advanced or Metastatic Breast Cancer

## Population studied

**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)
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## **Estimated number of subjects**

300

## **Study design details**

### **Setting**

All eligible subjects were invited to participate in the study and enrolled sequentially. No other pre-selection criteria were applied.

Subjects met the following inclusion criteria for study entry:

- Males or females
- Initially diagnosed with HER2-positive unresectable LA/mBC no more than 6 months prior to enrolment, although they could have received anti-cancer treatment during that time
- Age  $\geq 18$  years
- Able and willing to provide written informed consent and to comply with the study protocol

No exclusion criteria were applied.

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### **Outcomes**

In patients with unresectable LA/mBC, to observe the different anti-cancer treatment regimens and their sequencing throughout the course of the disease and to describe clinical outcome for each anti-cancer treatment regimen measured as progression-free survival (PFS).

To observe safety profiles of different anti-cancer treatment regimens through reporting of serious adverse events (SAEs), specific adverse events relevant to HER2-targeted therapies and AEs leading to discontinuation or dose modification of an anti-cancer therapy, to describe incidence of and reasons for anti-cancer treatment modifications and treatment of populations of special interest.

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## Data analysis plan

All enrolled patients who received at least one dose of an anti-cancer medication for HER2-positive unresectable LA/mBC will be included in the full analysis set, which will be the primary analysis population for safety and efficacy parameters.

Other analysis populations may be defined based on more restrictive criteria. The analysis of the present study will be exploratory and primarily make use of descriptive statistical methods. In addition, exploratory statistical testing and modelling will be used to highlight interesting aspects of the data. Any test performed will be two-sided and carried out with a 5%  $\alpha$  error rate without correction for multiplicity. A descriptive analysis of safety will be performed. The main safety parameter is the incidence of SAEs.

The proportion of patients experiencing at least one event within each line of treatment will be estimated with 95% Clopper–Pearson CIs.

## Documents

### Study report

[ML29659-Clinical\\_Study\\_Report\\_Synopsis\\_Redacted.pdf](#) (532.61 KB)

### Study publications

[A disease registry study to prospectively observe treatment patterns and outcom...](#)

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## 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)

[Disease registry](#)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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### 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

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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**

Unknown