A Prospective non-interventional study (NIS) of trastuzumab deRuxtecan (T-DXd) for adult patients with advanced HER2-pOsitive gaStric or gastroesoPhageal junction (GEJ) adEnocarcinoma who have Received a prIor Trastuzumab-based regimen, accompanied by a disease registrY of patients treated with conventional therapies in a real-world setting in Europe (PROSPERITY).

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Study Planned

Administrative details

EU PAS number

EUPAS1000000340

Study ID

1000000340

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Germany
- [ ] Italy
- [ ] Portugal

Study status

Planned

Research institutions and networks

Institutions

Clinical, Regulatory and Safety, Cerner Enviza

- [ ] Germany

First published: 15/03/2022

Last updated: 05/02/2025

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Daiichi-Sankyo Europe GmbH

- [ ] Germany

First published: 23/07/2024

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Institution | Pharmaceutical company

Contact details

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Study contact

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Primary lead investigator

Petra Laeis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/06/2023

Actual: 06/06/2023

Study start date

Planned: 31/03/2024

Date of final study report

Planned: 30/09/2027

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Data collection methods:

Primary data collection

Study design:

Multinational, multicenter, prospective observational, non-interventional study with trastuzumab deruxtecan in adult patients with advanced HER2-positive gastric or GEJ adenocarcinoma who have received a prior trastuzumab-based regimen in a real-world setting in Europe

Main study objective:

The primary objective is to describe the effectiveness of T-DXd based on real-world Time to Next Treatment (rwTTNT1) in adult patients with advanced HER2-positive gastric or GEJ adenocarcinoma who have received a prior trastuzumab-based regimen in a real-world setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ENHERTU

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

TRASTUZUMAB DERUXTECAN

Medical condition to be studied

Gastric cancer

Population studied

Short description of the study population

Adult patients planned to be treated with T-DXd or conventional therapies for advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen

Data management

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.

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