DARWIN EU® - Characterisation of systemic treatments for the management of ovarian cancer

First published: 10/11/2025

Last updated: 10/03/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000815

Study ID

1000000815

DARWIN EU® study

Yes

Study countries

- [ ] Denmark
- [ ] France
- [ ] Netherlands
- [ ] Norway

Study description

Ovarian cancer remains a significant health concern in Europe, resulting in more deaths than any other gynaecological cancer. Treatment strategies for ovarian cancer include surgery, chemotherapy, and targeted therapies that are selected based on patient characteristics, as well as type and stage of cancer. Chemotherapy drugs include alkylating agents, anthracyclines, antimetabolites, platinum-based drugs, taxanes, and other targeted therapies, such as poly (ADP-ribose) polymera (PARP) inhibitors, hormonal agents, and anti-angiogenesis drugs (Bevacizumab).
The aim of this study is to inform which authorised systemic treatments are actively being used as a treatment for epithelial ovarian cancer.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution **Educational Institution** **ENCePP partner**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anum Zahra

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/06/2025

Actual: 02/06/2025

Study start date

Planned: 30/10/2025

Actual: 30/10/2025

Date of final study report

Planned: 17/04/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-012_DUS Ovarian Cancer mgt_V4.0.pdf (1.48 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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:

Secondary use of data

Study design:

A cohort study, describing characteristics of females with newly diagnosed ovarian cancer (objective 1), assessing the number of individuals treated by ingredient and treatment class (objective 2), as well to analyse treatment sequences and combinations (objective 3).

Main study objective:

1. To describe demographic and pre-specified characteristics of patients newly diagnosed with epithelial ovarian cancer, overall and by age.
2. To describe the number of patients treated with systemic treatments, by ingredient and treatment class (i.e., alkylating agents, anthracyclines, antimetabolites, DNA agents, platinum-based chemotherapy, taxanes, topoisomerase inhibitors, vinca alkaloid, PARP inhibitors, monoclonal antibodies, hormonal agents), overall and by age and calendar year, and where possible, cancer stage.
3. To describe sequences of treatments and treatment combinations for ovarian cancer, overall and stratified by age, and where possible, cancer stage.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Ovarian epithelial cancer

Population studied

Short description of the study population

For all study objectives, the inclusion criteria include:

• Individuals with a first diagnosis of ovarian cancer during the study period, up to one year prior to end of data availability.

• Females aged ≥18 years at the date of diagnosis.

No prior history requirement has been established for this study, in accordance with how patient's observability is defined in the included data sources (see Section 8.4). We will include cases up to one year prior to the end of data availability to ensure some follow-up time for capturing treatments (e.g., if data are available through December 2024, cases will be included up to December 2023).

EOC will be defined using a range of EOC types, consisting of several histological subtypes (such as, high-grade and low-grade serous cancers and (aetiologically and genetically distant) endometrioid, clear-cell and mucinous cancers) and stages.

This also includes cancers that arise in the fallopian tube as well as the histologically similar primary peritoneal cancers. Systematised Nomenclature of Medicine (SNOMED) and International Classification of Diseases for Oncology, Third Edition (ICD-O-3) codes will be used to identify ovarian cancer cases.

A preliminary concept set for the identification of ovarian cancer specific to ovaries is described in Annex IV.

These codes will be refined during the study execution following the DARWIN EU® phenotyping standard processes, which involve the review of code lists by clinical experts, and the review of phenotypes after their execution in the participating data sources.

Age groups

- **Adult and elderly population (≥18 years)**
    - Adults (18 to < 65 years)

        - Adults (18 to < 46 years)
        - Adults (46 to < 65 years)
    - Elderly (≥ 65 years)
        - Adults (65 to < 75 years)
        - Adults (75 to < 85 years)
        - Adults (85 years and over)

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 source(s)

Danish Health Data Registries

Clinical Data Warehouse of the Bordeaux University Hospital

Netherlands Cancer Registry

The Cancer Registry of Norway

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No