

# Real-world data of treatment patterns, outcomes and genomic profiling in early breast cancer in Greece (SONATA study)

**First published:** 04/01/2025

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000428

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### Study ID

1000000428

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### DARWIN EU® study

No

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### Study countries

Greece

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### Study description

SONATA is a research collaboration between the Oncology Department at Iatriko Diavalkaniko Thessalonikis Hospital in Greece and Novartis, focusing on early breast cancer (eBC) patients.

Research Collaboration Details: The collaboration is represented by Iatriko Athinon (Iatriko Diavalkaniko Thessalonikis Hospital) and Dr. Konstantinos Papazisis (Primary Investigator) and involves Novartis Hellas contributing scientifically to the research.

Study Overview: The study, titled "Real-world data of treatment patterns, Outcomes and genomic profiling in early breast cancer in Greece" (SONATA study), aims to describe patient demographics, clinical characteristics, and treatment patterns in early breast cancer (eBC) in Greece.

Study Design: This non-interventional, observational study will include data analysis of approximately 2000 eBC patients and genomic profile analysis of 300 HR+/HER2- patients using the PRIME-Dx platform.

Study Objectives: The primary objective is to describe patient demographics and clinical characteristics, while the exploratory objective is to test the hypothesis that endocrine resistance molecular subtypes predict early recurrence in HR+/HER2- eBC patients.

Statistical Analysis: The study will use descriptive statistics to present continuous and categorical variables, and time-to-event analyses for recurrence-free survival (RFS) and breast cancer-free interval (BCFi).

Pharmacovigilance Requirements: The collaboration partner, as the regulatory sponsor, is responsible for meeting safety reporting requirements to Novartis and health authorities.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### European Interbalkan Medical Center (EIMC)

Greece

**First published:** 16/12/2024

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**Institution**

**Hospital/Clinic/Other health care facility**

## Contact details

### Study institution contact

Ilias Christopoulos [i.christopoulos@iatriko.gr](mailto:i.christopoulos@iatriko.gr)

**Study contact**

[i.christopoulos@iatriko.gr](mailto:i.christopoulos@iatriko.gr)

### Primary lead investigator

Konstantinos Papazisis

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 24/09/2024

Actual: 10/10/2024

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**Study start date**

Actual: 16/10/2024

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**Data analysis start date**

Planned: 21/10/2024

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**Date of interim report, if expected**

Planned: 21/10/2025

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**Date of final study report**

Planned: 30/09/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis Hellas SACI, Research Collaboration in Breast Cancer

## Study protocol

[NIS\\_PDC\\_Breast Cancer\\_SONATA RC\\_Protocol synopsis.pdf \(374.02 KB\)](#)

## 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

**Methodological aspects**

**Study type**

**Study type list**

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Study design:**

This non-interventional, observational study will include data analysis of approximately 2000 eBC patients and genomic profile analysis of 300 HR+/HER2- patients using the PRIME-Dx platform.

**Main study objective:**

The study aims to describe patient demographics, clinical characteristics, and treatment patterns in early breast cancer (eBC) in Greece.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

This is a non-interventional, observational, single-center, primary data collection study, which will include a representative sample of outpatients diagnosed with early Breast Cancer (eBC) in Northern Greece. The collaborator holds a database of eBC patients (~2000 patients up to date) and of good quality. The collaborator is also performing genomic profile analysis for various mutations as part of his clinical practice. Data will be retrieved from the electronic patient database owned by the collaborator.

## Study drug and medical condition

**Medical condition to be studied**

Breast cancer

## Population studied

**Age groups**

- **Adult and elderly population ( $\geq 18$  years)**
  - Adults (18 to < 65 years)

- Elderly ( $\geq 65$  years)

## Study design details

### Data analysis plan

The study will use descriptive statistics to present continuous and categorical variables, and time-to-event analyses for recurrence-free survival (RFS) and breast cancer-free interval (BCFi).

## 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)

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

## 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**

No