

# Nationwide analysis of the breast cancer guidelines adherence in Bulgaria

**First published:** 15/05/2025

**Last updated:** 15/05/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000571

### Study ID

1000000571

### DARWIN EU® study

No

### Study countries

☐ Bulgaria

### Study description

Real-World Data Analysis of Breast Cancer Guidelines Adherence Using Danny Platform

### Study status

Finalised

## Research institutions and networks

### Institutions

#### Sqilline Health

☐ Bulgaria

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

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

Institution

Non-Pharmaceutical company

Medical University - Pleven, Bulgaria

### Contact details

#### Study institution contact

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Study contact

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#### Primary lead investigator

Dobromir Dimitrov

Primary lead investigator

# Study timelines

## **Date when funding contract was signed**

Planned: 18/09/2023

Actual: 18/09/2023

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## **Study start date**

Planned: 01/01/2019

Actual: 01/01/2019

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## **Date of final study report**

Planned: 16/04/2024

Actual: 24/04/2024

# Sources of funding

- No external funding

# 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

[Nationwide Analysis of Breast Cancer Guidelines Adherence in Bulgaria](#)

# Methodological aspects

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Nationwide analyses of breast cancer

**Data collection methods:**

Secondary use of data

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**Study design:**

Assess adherence to breast cancer diagnostic and treatment guidelines in Bulgaria using RWD processed and analyzed by Danny Platform.

**Main study objective:**

Evaluate the utilization rates of core-needle biopsy, frozen section, breast-conserving surgery, and sentinel lymph node biopsy.

Identify challenges and opportunities for improving adherence to international guidelines in Bulgaria.

## Study Design

**Non-interventional study design**

Cohort

## Population studied

## Short description of the study population

Data from January 2019 to August 2023 nationwide was analyzed using the platform with access to anonymized medical information from Bulgaria's leading territorial oncology hospitals. A total of 13,790 patients met the inclusion criteria.

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### Age groups

All

In utero

Paediatric Population (< 18 years)

Neonate

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population ( $\geq 18$  years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly ( $\geq 65$  years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

## Study design details

### Summary results

The analysis revealed suboptimal adherence to breast cancer diagnostic and treatment guidelines in Bulgaria.

Low utilization of core-needle biopsy (CNB), high reliance on frozen sections, and below-average rates of breast-conserving surgery and sentinel lymph node biopsy were observed.

The gold standard diagnostic tool, CNB, was done in 5,427 patients (39.35%), an intraoperative frozen section was performed as a method for confirmation of breast cancer in 6,257 patients (45.37%) and the standard technique for lymph node evaluation, sentinel lymph node biopsy, was done in 357 patients (2.99%). These findings highlight the need for targeted interventions to improve guideline adherence and patient outcomes in Bulgaria.

## Documents

### Study report

[Nationwide analysis of the breast cancer guidelines adherence in Bulgaria\\_ScienceDirect\\_1.pdf](#) (477.65 KB)

### Study publications

[Nationwide Analysis of Breast Cancer Guidelines Adherence in Bulgaria](#)

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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 source(s)**

Danny Platform

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Yes

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**Check completeness**

Yes

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**Check stability**

Yes

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**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Not applicable