Real-world evidence of first-line Osimertinib effectiveness in Bulgarian patients: a retrospective analysis

First published: 29/07/2025

Last updated: 29/07/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000686

Study ID

1000000686

DARWIN EU® study

No

Study countries

Bulgaria

Study description

Real-World Data Analysis of First-Line Osimertinib Compared to Clinical Trials Using Danny Platform

Study status

Finalised

Research institutions and networks

Institutions

National Council on Prices and Reimbursement of Medicinal Products (NCPRMP), Bulgaria

Contact details

Study institution contact

Daniel Penchev info@sqilline.com

Study contact

info@sqilline.com

Primary lead investigator

Alexandra Savova

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 02/09/2024

Actual: 02/09/2024

Study start date
Planned: 16/09/2024

Actual: 01/10/2024

Date of final study report
Planned: 25/03/2025

Actual: 20/07/2025

Sources of funding

- No external funding

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Other study registration identification numbers and links

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Methodological aspects

Study type

Study type:

Non-interventional study

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TAGRISSO

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

OSIMERTINIB

Documents

Study report

Real-world evidence of first-line osimertinib effectiveness in Bulgarian patients a retrospective analysis.pdf (1.57 MB)

Study publications

Real-world evidence of first-line osimertinib effectiveness in Bulgarian patien...

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction