

# Proton therapy for head and neck cancer therapy: A real-world data case study from Bulgaria

**First published:** 06/05/2025

**Last updated:** 24/07/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000569

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### Study ID

1000000569


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### DARWIN EU® study

No

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### Study countries

 Bulgaria

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### Study description

## Study status

Finalised

## Research institutions and networks

### Institutions

Faculty of Pharmacy, Medical University - Sofia,  
Bulgaria

## Contact details

### Study institution contact

Daniel Penchev [info@sqilline.com](mailto:info@sqilline.com)

Study contact

[info@sqilline.com](mailto:info@sqilline.com)

### Primary lead investigator

Maria Dimitrova

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 17/05/2023

Actual: 17/05/2023

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**Study start date**

Planned: 01/01/2020

Actual: 01/01/2020

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**Date of final study report**

Planned: 02/07/2024

Actual: 02/07/2024

## 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

[Proton therapy for head and neck cancer therapy: A real-world data case study f...](#)

## Methodological aspects

### Study type

**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:**

Secondary use of data

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**Study design:**

To assess the access to proton therapy for head and neck cancer (HNC) patients using RWD analyzed by Sqilline's Danny Platform.

**Main study objective:**

To evaluate the feasibility of establishing a national proton therapy center in Bulgaria.

To analyse strategic policy documents to understand the level of support and potential challenges for implementing proton therapy in Bulgaria.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

## Population studied

### Age groups

- **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 (≥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)

## Study design details

### Outcomes

From 2020 to 2022, only ten children with head and neck cancer were referred abroad for proton therapy, underscoring the lack of local facilities. These patients, with an average age of 9.8 years, received treatment in Germany, Italy, Austria, and Russia.

## Documents

## Study publications

[Proton therapy for head and neck cancer therapy: A real-world data case study](#)  
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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

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### Data sources (types)

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

## 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