

# A Post-Authorization Safety Study (PASS) to characterize the risk of secondary primary malignancy including MDS/AML among metastatic prostate cancer patients exposed to AKEEGA (niraparib/abiraterone acetate fixed-dose combination tablet) plus Prednisone/Prednisolone

**First published:** 24/02/2025

**Last updated:** 24/02/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000323

### Study ID

1000000323

### DARWIN EU® study

No

## Study countries

☐ Sweden

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## Study description

The primary objective is to estimate the incidence of myelodysplastic syndrome / acute myeloid leukemia and other second primary malignancies among patients exposed to AKEEGA and other BRCA1/2 mutated patients exposed to AAP or other neoadjuvant hormonal therapies (NHTs) indicated for metastatic castrate resistant prostate cancer (mCRPC).

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## Study status

Planned

# Research institutions and networks

## Institutions

**Johnson & Johnson**

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

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

**Institution**

## Contact details

### Study institution contact

Dina Gifkins DGifkins@its.jnj.com

**Study contact**

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**Primary lead investigator**

Dina Gifkins

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 17/07/2024

Actual: 17/07/2024

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**Study start date**

Planned: 24/04/2025

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**Date of final study report**

Planned: 31/12/2029

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Johnson and Johnson

## Study protocol

## Regulatory

### **Was the study required by a regulatory body?**

No

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

#### Study type list

##### **Study topic:**

Disease /health condition  
Human medicinal product

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##### **Study type:**

Non-interventional study

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##### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

##### **Data collection methods:**

## Study drug and medical condition

### **Name of medicine**

AKEEGA

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

NIRAPARIB

ABIRATERONE ACETATE

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### **Anatomical Therapeutic Chemical (ATC) code**

(L01XK52) niraparib and abiraterone

niraparib and abiraterone

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### **Medical condition to be studied**

Prostate cancer metastatic

## 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), other**

Swedish Medical Registries, Optum Clinformatics DOD database

## 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**

Yes