# Machine learning prediction of anemia events before and after talazoparib dose modification using TALAPRO-2 phase 3 trial data

**First published:** 19/11/2024

**Last updated:** 21/08/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000344

**Study ID**

1000000344

**DARWIN EU® study**

No

**Study countries**

☐ United States

**Study description**

The risk of anemia due to talazoparib is common and may be a barrier in its utilization and/or lead to premature treatment discontinuation. Successful prediction of this adverse event in patients receiving talazoparib is an important step in understanding and reducing the risk of such toxicities while maintaining patients on treatment through individualized patient-centered approaches such as more vigilant monitoring and early dose management. The primary goal of this study is to assess how well machine learning models predict anemia events before and after talazoparib dose modification.
The objectives are:
1. Describe patient characteristics, dosing patterns and hemoglobin trajectories with respect to anemia events in talazoparib-treated metastatic castrate-resistant prostate cancer (mCRPC) patients from the TALAPRO-2 trial data; 2. Develop and evaluate machine learning prediction models of anemia risk after treatment initiation and preceding dose modification;
3. Develop and evaluate machine learning prediction models of anemia recovery after dose modification. This is a non-interventional (NI), observational, retrospective study with secondary data analysis of already existing clinical trial data.
This study will use the existing TALAPRO-2 trial data of mCRPC patients allocated to the talazoparib + enzalutamide treatment arm and included in the safety analysis.
A variety of machine learning models including LASSO Cox regression, extreme gradient boosting, survival support vector machine, and deep cox proportional hazards model will be applied to identify the best performing model for predicting anemia risk and recovery based on performance metrics such as concordance index (test c-index) and dynamic area under the curves (AUCs).

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**Study status**

Ongoing

## Research institutions and networks

## Institutions

### Pfizer

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

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

Institution

## Contact details

**Study institution contact**

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Study contact

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Primary lead investigator

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## Study timelines

**Date when funding contract was signed**

Planned: 30/09/2024

**Study start date**
Planned: 11/11/2024

Actual: 02/12/2024

**Data analysis start date**
Actual: 22/08/2024

**Date of final study report**
Planned: 30/06/2026

## Study protocol

C3441068 NI study protocol anemia ML prediction 20241025_clean.pdf (639.72 KB)

C3441068_Protocol_V2_12 June 2025_Redacted.pdf (267.14 KB)

## Regulatory

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

No

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

Non-EU RMP only

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

**Data collection methods:**

Secondary use of data

## Study drug and medical condition

**Medicinal product name**

TALZENNA

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

TALAZOPARIB

**Anatomical Therapeutic Chemical (ATC) code**

(L01XK04) talazoparib

talazoparib

# 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)**

Clinical trial

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No