# Breast Cancer Treatment with Afinitor® (Everolimus) and Exemestane for HR+ Women (BRAWO)

**First published:** 16/04/2015

**Last updated:** 02/07/2024





# Administrative details

**Study description** 

EU PAS number  EUPAS9462	
EUPA59402	
Study ID	
27127	
DARWIN EU® study	
No	
Study countries	
Germany	

BRAWO is a German, non-interventional study with a planned enrollment of 3,000 patients with HR+ advanced breast cancer receiving

Everolimus+Exemestane according to the approved label. Main objectives of the BRAWO study are to extend knowledge in the following areas• Efficacy and the impact of physical activity on efficacy and quality of life in routine clinical care• Prophylaxis and management of stomatitis• Sequence of therapy and drug utilization when EVE+EXE is used in routine clinical care

#### **Study status**

Finalised

#### Research institutions and networks

#### **Institutions**

#### **Novartis Pharmaceuticals**

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Institution

Multiple centres: 400 centres are involved in the study

#### Contact details

#### **Study institution contact**

Novaratis Clinical Disclosure Office trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

#### **Primary lead investigator**

Novaratis Clinical Disclosure Office

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 20/06/2012

Actual: 20/06/2012

#### Study start date

Planned: 01/10/2012

Actual: 12/10/2012

#### Data analysis start date

Planned: 08/06/2017

Actual: 29/12/2017

#### Date of interim report, if expected

Planned: 08/06/2015

#### Date of final study report

Planned: 31/12/2018

Actual: 16/11/2018

# Sources of funding

Pharmaceutical company and other private sector

# More details on funding

**Novartis** 

# Study protocol

Protocol\_final\_BRAWO\_CRAD001JDE53\_Amendment 6 20151011\_Redacted.pdf (421.26 KB)

# Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

# Other study registration identification numbers and links

CRAD001JDE53

# Methodological aspects

# Study type

#### **Study topic:**

Disease /health condition

Human medicinal product

#### Study type:

Non-interventional study

#### Scope of the study:

Effectiveness study (incl. comparative)

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

Primary data collection

#### Main study objective:

The aim of this NIS is to acquire information from routine care• on the impact of physical activity on efficacy and quality of life, • on prophylaxis and management of stomatitis in routine clinical practice• on the sequence of treatmentin the treatment of patients with advanced or metastatic HR+ breast cancer who are treated on-label with Afinitor® und exemestane. AEs will be documented.

# Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

**Observational Study** 

# Study drug and medical condition

#### Name of medicine

**AFINITOR** 

#### Medical condition to be studied

Breast cancer metastatic

# Population studied

#### Short description of the study population

Postmenopausal women with advanced breast cancer previously treated with a nonsteroidal aromatase inhibitor and currently being treated with Afinitor® in accordance with routine practice and the Summary of Product Characteristics.

#### Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

#### **Special population of interest**

Other

#### Special population of interest, other

Breast Cancer metastatic patients

#### **Estimated number of subjects**

3000

# Study design details

#### **Outcomes**

Primary Observation Parameters: Efficacy of combination of Afinitor® and exemestane in routine use and in relation to intensity of physical activity. Quality of life and physical activityDrug use and treatment sequenceStomatitis managementDocumentation of adverse events

#### Data analysis plan

Variables measured to be analysed using epidemiology methods with primary use of descriptive statistical methods. If inferential statistical methods are used their results are considered to be purely descriptive. In this exploratory context, no alpha adjustments in multiple statistical comparisons are made. Variables reaching at least interval level will be presented in tabular form including their sample values (no of valid and missing values, min, max, 5th and 95% percentile, first and third quartile, median, mean, standard deviation). For variables at nominal and ordinal level, distribution of the absolute and relative frequencies will be indicated. For adverse events, incidences will be reported based on the patient population included and incidence density (number of events/sum of person times in years) according to the MedDRA system organ class and preferred term for adverse events. Times of events and survival time analyses will be analysed using the Kaplan-Meier methodology.

#### **Documents**

#### **Study results**

2018-11-16\_CSR\_BRAWO Final Report Redacted.pdf (1.09 MB)

# 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)**

Other

#### Data sources (types), other

Prospective patient-based data collection

# 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**

Unknown