# Sildenafil orodispersible film patient-centred experience in the treatment of erectile dysfunction: an observational, prospective, multicentre cohort study (18I-SDF01)

**First published:** 13/09/2018

**Last updated:** 31/01/2022

Study Finalised

## Administrative details

**EU PAS number**

EUPAS25496

**Study ID**

45458

**DARWIN EU® study**

No

**Study countries**

Italy

**Study status**

Finalised

# Research institutions and networks

## Institutions

Multiple centres: 17 centres are involved in the study

## Contact details


**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Vincenzo Mirone

**Primary lead investigator**


## Study timelines

**Date when funding contract was signed**

Planned: 17/09/2018

Actual: 12/10/2018

**Study start date**
Planned: 28/06/2019

Actual: 16/09/2019

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**Date of final study report**
Planned: 30/12/2021

Actual: 13/01/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

IBSA Institut Biochimique

## 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

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If ‘other’, further details on the scope of the study**

Prospective observational cohort study

**Data collection methods:**

Primary data collection

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**Main study objective:**

To gather information on a patient-centred experience with the new formulation of Sildenafil IBSA ODF, and on the new, intermediate 75 mg dose, in the treatment of ED of different origins.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

SILDENAFIL CITRATE

**Medical condition to be studied**

Erectile dysfunction

# Population studied

**Short description of the study population**

Erectile dysfunction patients.

**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)

**Estimated number of subjects**

525

# Study design details

**Outcomes**

Change from Visit 1 to Visit 3 in the Erectile Function Domain of the 15-item International Index of Erectile Function (IIEF-EF score), effectiveness, patient’s preference, and satisfaction, time to onset of pharmacological effects, treatment safety, patient's evaluation of the ease-of-use

**Data analysis plan**

Safety Set (SS):data analysis for the safety outcome measures will be performed using data of all enrolled patients for whom evidence of treatment can be documented. Full Analysis Set (FAS): primary and secondary outcome measures will be analysed using data of all enrolled patients. Per Protocol set (PP): a sensitivity analysis using all of the subjects who completed the study.

# 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

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**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**

No