# A Retrospective and prospective, obsErvational (non-interventional), post-authorization Safety cohort sTudy to evaluate the incidence of the breAkages and insertion/Removal complications of buprenorphine implants in rouTine clinical care (RE-START)

**First published:** 19/04/2024

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Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000092

**Study ID**

1000000092

**DARWIN EU® study**

No

**Study countries**

Italy

**Study description**

RE-START study, under real world conditions, aims to describe the rate of breakage of Sixmo® implants occurring during the observation period. The study population consists of adult patients with a diagnosis of opioid dependence and treated with Sixmo® as part of their routine clinical care, according to the approved Summary of Product Characteristics (SmPC).

**Study status**

Ongoing

## Research institutions and networks

### Institutions

L. Molteni & C. dei Fratelli Alitti Società di Esercizio S.p.A.

## Contact details

**Study institution contact**

RE-START study Team RE-START@moltenifarma.it

**Study contact**

RE-START@moltenifarma.it

**Primary lead investigator**

Claudio Leonardi

Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Actual: 03/05/2024

**Study start date**
Actual: 24/10/2022

**Date of final study report**
Planned: 31/12/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

The Sponsor of RE-START study is L. Molteni & C. dei Fratelli Alitti Società di Esercizio S.p.A.
(Address: Strada Statale 67 - Loc. Granatieri 50018 Scandicci (Fi), Italy)

## Regulatory

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

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

**Regulatory procedure number**

EMEA/H/C/PSA/S/0097

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

**Study design:**

Multi-centre, retrospective and prospective cohort, observational (non-interventional) PASS

**Main study objective:**

The primary objective is:

- To describe the rate of breakage of Sixmo® implants (endpoint: all implant breakages reported as occurring during the treatment period, whether or not associated with adverse events linked to Sixmo® implant).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

SIXMO

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

BUPRENORPHINE

**Anatomical Therapeutic Chemical (ATC) code**

(N07BC01) buprenorphine

buprenorphine

**Additional medical condition(s)**

Opioid dependence

## Population studied

**Short description of the study population**

Study population will consist of alive male and female patients aged 18 years or over, with a diagnosis of opioid dependence and treated with Sixmo® as part of their routine clinical care, according to the approved Summary of Product Characteristics (SmPC).

**Age groups**

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)

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**Estimated number of subjects**

120

# Data management

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

Unknown