# A Post-Marketing Observational Study of Implanon® Radiopaque among Chinese Women Aged 18 and Older Requesting Contraception (MK-8415-038)

**First published:** 27/01/2016

**Last updated:** 11/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS11131

**Study ID**

47862

**DARWIN EU® study**

No

**Study countries**

☐ China

**Study description**

This is a post-marketing observational study intended to evaluate participant and physician satisfaction, serious adverse events (SAEs), drug related adverse events (AEs) including topical AEs as well as overall contraceptive effectiveness in routine clinical practice. The primary objective is to evaluate the overall safety profile of Implanon® Radiopaque.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Merck Sharp & Dohme LLC

United States

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

**Last updated:** 08/07/2025

**Institution** **Pharmaceutical company**

### Merck Sharp & Dohme (China) Ltd. Level 7,Tower E3, The Towers, Oriental, Beijing,100738 China

## Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Actual: 20/11/2014

**Study start date**
Planned: 18/03/2016

Actual: 24/03/2016

**Data analysis start date**
Planned: 15/07/2021

Actual: 27/07/2021

**Date of interim report, if expected**
Planned: 09/03/2018

**Date of final study report**
Planned: 28/04/2022

Actual: 06/06/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme Corp.

## Regulatory

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

Yes

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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:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The main objective is to evaluate the overall safety profile of Implanon® Radiopaque.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Postmarketing observational study

## Study drug and medical condition

**Medical condition to be studied**

Pregnancy

## Population studied

**Short description of the study population**

Women ≥ 18 years of age at the time of screening requesting contraception at approximately 50 sites throughout China. The identification of eligible subjects was to be based on standard clinical practice and the product labeling. All

investigators were to be trained to insert Implanon® Radiopaque. Subjects who were willing to join this survey and sign the ICF were to be enrolled and followed, and the decision of the subject to use the Implanon® Radiopaque would have been made prior to the decision to be involved in the observational study.

Inclusion Criteria
All inclusion criteria were reviewed by the investigator or qualified designee to ensure that the subject qualifies for the study.
• Women ≥18 years of age at the time of screening requesting contraception;
• Capable to answer the questionnaire;
• Decided to use Implanon® Radiopaque for contraception;
• Willing to participate in the survey and give informed consent in writing.

**Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

**Special population of interest**

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

**Estimated number of subjects**

1900

## Study design details

**Outcomes**

The participant proportion of (1) drug related AEs, (2) SAEs, (3) discontinuation due to drug-related AE or SAE. (1) To evaluate the topical safety profile of IMPLANON, (2) to assess participant and physician satisfaction with IMPLANON, (3) to estimate the overall contraceptive effectiveness of IMPLANON.

**Data analysis plan**

Summary statistics of socio-demographic and clinical characteristics of participants on Implanon® Radiopaque treatment will be tabulated. Safety endpoints will be summarized by count, point estimate and corresponding 95% confidence interval (CI).

## Documents

**Study results**

MK-8415-038-02-CSR_final redaction.pdf (1.54 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**

No