# I8F-MC-B015: Observational Study of Pregnancy and Infant Outcomes Among Women Exposed to Tirzepatide During Pregnancy in US-based Administrative Claims Data

**First published:** 25/11/2026

**Last updated:** 25/11/2026

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000518

**Study ID**

1000000518

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

Secondary data use study of women exposed to TZP during pregnancy and their offspring compared to those not exposed to TZP during pregnancy

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Eli Lilly and Company

**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**

Sangmi Kim

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**
Planned: 11/03/2024

Actual: 11/03/2024

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**Study start date**
Planned: 31/03/2026

Actual: 03/06/2026

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**Date of interim report, if expected**
Planned: 30/09/2026

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**Date of final study report**
Planned: 30/09/2032

# Sources of funding

- Pharmaceutical company and other private sector

# Study protocol

LY3298176 B015_Redacted_Noninterventional PASS Protocol - Version 3_HMA_EMA_Catalogue_Redacted.pdf (1.75 MB)

# Regulatory

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

Yes

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**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

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## Study drug and medical condition

**Medicinal product name, other**

Zepbound

# Data management

## 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