# Predicting Long-Term Outcome Risk with Tirzepatide: A Post-Hoc Analysis of SURMOUNT-1

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# Administrative details

**Study description** 

<b>EU PAS number</b> EUPAS49988	
<b>Study ID</b> 49989	
DARWIN EU® study	
Study countries  United States	

This study will evaluate the change in predicted risk for cardiovascular disease and type 2 diabetes between tirzepatide and placebo-treated participants using the SURMOUNT-1 trial data at baseline and 72 weeks. SURMOUNT-1 was a phase 3 trial in adults with overweight or obesity evaluating the impact of tirzepatide versus placebo on weight loss and associated endpoints. The predicted risk will be calculated using validated risk engines.

#### **Study status**

**Planned** 

#### Research institutions and networks

#### Institutions

# Eli Lilly and Company

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Institution

## Contact details

#### Study institution contact

Lilly Value Evidence and Outcomes emily.hankosky@lilly.com

 $\Big( \mathsf{Study} \ \mathsf{contact} \Big)$ 

emily.hankosky@lilly.com

#### **Primary lead investigator**

# Lilly Value Evidence and Outcomes

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 16/07/2022

Actual: 27/06/2022

#### Study start date

Planned: 09/12/2022

#### Data analysis start date

Planned: 09/12/2022

#### Date of final study report

Planned: 31/01/2024

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Eli Lilly and Company

# Study protocol

2022-11193\_S-1 Risk Prediction\_Protocol\_EXPERT response\_v2\_clean\_amended (1).pdf (687.35 KB)

2022-11193\_S-1 Risk Prediction\_Protocol\_EXPERT response\_v3\_clean.pdf (767.53 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

Pangaea ID 2022-11193

# Methodological aspects

Study type

Study type list

**Study type:** 

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

#### Main study objective:

To describe and compare the change from baseline predicted risk of long-term outcomes (listed below) between tirzepatide and placebo at 72 weeks among people with overweight or obesity using SURMOUNT-1 trial data. -

Atherosclerotic Cardiovascular Disease -Type 2 diabetes

# Study drug and medical condition

#### Medical condition to be studied

Obesity

Type 2 diabetes mellitus

# Population studied

#### 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**

2500

# Study design details

#### **Outcomes**

Predicted risk for cardiovascular disease and predicted risk for type 2 diabetes

#### Data analysis plan

The primary analysis will use the American College of Cardiology/American Heart Association (ACC/AHA) risk engine to calculate CVD risk scores and the Cardiometabolic Disease Staging (CMDS) engine to calculate T2D risk scores. Risk scores will be calculated at baseline and Week 24 and Week 72 as well as the change of risk score from baseline.

#### **Documents**

#### **Study publications**

Jastreboff AM, Aronne LJ, Ahmad NN et al. Tirzepatide Once Weekly for the Treat...

# 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

SURMOUNT-1 trial Unit	ed States	
Data sources (types		
Other		
Data sources (types	, other	
Prospective patient-bas	sed data collection	
Use of a Comr	non Data Model (CDM	)
CDM mapping		
No		
Data quality s	pecifications	
Check conformance		
Unknown		

Unknown

# **Check stability**

Unknown

# **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No