# Incidence of Thyroid Neoplasm and Pancreatic Cancer in Type 2 Diabetes Mellitus Patients who Initiate Once Weekly Exenatide Compared with Other Antihyperglycemic Drugs

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# Administrative details

EU PAS number	
EUPAS13904	
Study ID	
19186	
DARWIN EU® study	
No	
Study countries	
United Kingdom	

#### **Study description**

The study is intended to monitor the occurrence of thyroid neoplasm and pancreatic cancers with weekly exenatide. Anonymised electronic health care records will be used to monitor the weekly exenatide users and compare them to patients using other types of medication

#### **Study status**

Ongoing

# Research institutions and networks

#### **Institutions**

Clinical Practice Research Datalink (CPRD)	
United Kingdom	
First published: 15/03/2010	
<b>Last updated:</b> 17/01/2025	
Institution	

## Contact details

#### **Study institution contact**

Tarita Murray-Thomas ClinicalTrialTransparency@astrazeneca.com

Study contact

ClinicalTrialTransparency@astrazeneca.com

#### **Primary lead investigator**

#### Tarita Murray-Thomas

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 21/10/2013

Actual: 07/11/2013

#### Study start date

Planned: 01/07/2011 Actual: 01/07/2011

#### Data analysis start date

Planned: 10/11/2013

Actual: 10/11/2013

#### **Date of final study report**

Planned: 31/12/2025

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

AstraZeneca

# Study protocol

Redacted protocol BO17.pdf (477.06 KB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

D5551N00007

# 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:

The objective of this study is to estimate and compare the incidence of thyroid neoplasm and pancreatic cancer among initiators of exenatide once weekly compared with users of other oral antidiabetic agents.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### Medicinal product name

**BYDUREON** 

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

**EXENATIDE** 

#### Medical condition to be studied

Type 2 diabetes mellitus

# Population studied

#### **Age groups**

• Adults (18 to < 46 years)

- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

#### **Estimated number of subjects**

55000

# Study design details

#### **Outcomes**

Incidence of thyroid neoplasm and pancreatic cancer. To describe the incidence of medullary thyroid cancer (MTC) among initiators of exenatide once weekly and matched control cohort of other anti-diabetic drugs. To estimate the incidence of new-onset benign thyroid neoplasm among initiators of exenatide once weekly compared to a matched control cohort of other anti-diabetic drugs.

#### **Data analysis plan**

Risk of cancers in relation to the exposure to exenatide once weekly will be estimated in terms of incidence and relative risk as compared with exposure to other anti-diabetic treatment. Patients will be matched based on their baseline characteristics. Intent-to-treat analysis will be performed using Cox regression analysis. Time-dependent analysis will be additionally conducted based on current and past exposure to the study drugs.

# 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 source(s)

Clinical Practice Research Datalink

#### **Data sources (types)**

Electronic healthcare records (EHR)

# 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