

# Incidence of Pancreatic Malignancy and Thyroid Neoplasm in Type 2 Diabetes Mellitus Patients who Initiate Exenatide Compared to Other Antihyperglycemic Drugs - Phase 2 (Extended Accrual and Follow-Up)

**First published:** 06/07/2016

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS13956

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### Study ID

24671

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### DARWIN EU® study

No

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### Study countries

## **Study description**

This is a retrospective cohort study that compares incidence rates of pancreatic cancer and thyroid neoplasm between initiators of exenatide and initiators of other antidiabetic drugs using 2 administrative databases from commercial health plans in the US. The study cohorts will be created to include patients accrued from 01 June 2005 through 30 June 2015 in Optum Research Database and 31 March 2015 in Impact National Benchmark Database. Initiators will be matched 1:1 or 1:2 (exenatide:Others) on propensity scores within 6-month calendar blocks. The matched cohorts, when aggregated, will form the analytic population. The analyses of outcomes will account for the source databases and matching ratios through statistical conditioning. Data from the 2 databases will be combined to increase statistical precision. Pancreatic cancer and thyroid neoplasm will be identified via patterns of claims using algorithms applied in the previous study. A validation of the algorithms will be conducted within a sample of medical records of patients in the Optum Research Database. Clinical characteristics that are captured poorly in the claims data will be abstracted from the medical records. Estimation of effects will involve time-fixed and time-dependent, cumulative classifications of exposure. A nested case-control analysis will also be performed to account for potential confounders that are captured poorly in the claims data, if sample size allows.

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## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

# Optum

 Germany

**First published:** 03/01/2012

**Last updated:** 07/02/2014

Institution

Outdated

Other

ENCePP partner

## Contact details

### Study institution contact

Caihua Liang [ClinicalTrialTransparency@astrazeneca.com](mailto:ClinicalTrialTransparency@astrazeneca.com)

Study contact

[ClinicalTrialTransparency@astrazeneca.com](mailto:ClinicalTrialTransparency@astrazeneca.com)

### Primary lead investigator

Caihua Liang

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 24/10/2014

Actual: 24/10/2014

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### Study start date

Planned: 03/03/2016

Actual: 03/03/2016

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### **Data analysis start date**

Planned: 03/03/2016

Actual: 03/03/2016

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

Planned: 01/11/2017

Actual: 17/04/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca

## Study protocol

[Redacted protocol BO15.pdf](#) (746.88 KB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

D5550R00003

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objectives are to estimate the absolute and relative incidence of pancreatic cancer and thyroid cancer that occurs at least one year after initiation of exenatide twice daily or once weekly or initiation of other antidiabetic drugs—overall and by duration of follow-up and duration of

exposure.

## Study Design

### **Non-interventional study design**

Case-control

Other

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### **Non-interventional study design, other**

Retrospective cohort study

## Study drug and medical condition

### **Medicinal product name**

BYDUREON

BYETTA

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

EXENATIDE

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### **Medical condition to be studied**

Type 2 diabetes mellitus

## Population studied

### **Short description of the study population**

Patients with Type 2 Diabetes Mellitus who had at least 9 months of continuous enrollment in their health plan between 01 September 2004 and 31 December 2015.

Eligible patients will have:

- Complete medical and pharmacy benefits and at least 9 months of continuous enrollment in the health plan prior to the cohort entry date
  - A diagnosis of T2D (ICD-9-CM 250.x0, 250.x2) during the 9-month baseline period, inclusive of the cohort entry date
  - A dispensing of at least one antidiabetic drug other than the initiating drug during the 9- month baseline period, inclusive of the cohort entry date
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### **Age groups**

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Diabetes mellitus patients

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### **Estimated number of subjects**

523741

## **Study design details**

## Outcomes

The primary outcomes are newly diagnosed pancreatic cancer and thyroid cancer occurring at least one year following cohort entry. The secondary outcomes are newly diagnosed benign thyroid neoplasm, medullary thyroid carcinoma, and non-medullary thyroid carcinoma occurring at least one year following cohort entry.

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## Data analysis plan

An “intent-to-treat” analysis will be conducted that holds the original exposure assignment constant from the date of accrual through the end of follow-up. At-risk person-time will be accrued from one year post drug initiation until the earliest occurrence of an outcome, health plan disenrollment, or end of study period. Hazard ratios and 95% confidence intervals of newly diagnosed pancreatic cancer or thyroid cancer will be estimated. To estimate the cumulative effect of exenatide exposure on the outcomes Analysis of Cumulative Exposure will also be conducted. A nested case-control study design will be applied to account for potential confounders that are poorly captured in the claims data. The cases will consist of all chart-confirmed cases of pancreatic or thyroid cancers in the propensity-matched exenatide and comparison cohorts from the Optum Research Database. Controls without cancers will be selected from the same source cohorts that gave rise to the cases.

## Documents

### Study results

[D5550R00003 \(EUPAS13956\) Revised Final Report](#)

[17APR2018\\_AZ\\_Redacted.pdf](#) (4.07 MB)

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## 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)

[Administrative healthcare records \(e.g., claims\)](#)

## 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