

# Incretin-based therapies and Pancreatic Cancer risk in Medicare enrollees – new user protocol

**First published:** 21/12/2012

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS3255

### Study ID

8912

### DARWIN EU® study

No

### Study countries

United States

### Study description

This will be a retrospective cohort study using a new-user active comparator design on Medicare Part A, B and D claims data from 2006-2010. The study population consists of Medicare enrollees initiating Incretin-based drugs (IBRx) or other antidiabetic drugs (CompRx). Newusers of IBRx and CompRx will be compared with respect to incidence of pancreatic cancer (primary outcome) and incidence of mortality due to pancreatic cancer (secondary outcome) adjusted for baseline information collected prior to drug initiation. Given the FDA signal about increased pancreatic cancer reporting with IBRx, it is possible that IBRx new-users are subjected to increased screening and there is increased/earlier detection of pancreatic cancer in the IBRx group compared to the CompRx group. We will therefore evaluate and quantify the use of diagnostic procedures that may lead to a preclinical diagnosis of pancreatic cancer among new users of IBRx and CompRx in the 6 month period before and after the start of drug therapy.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

[University of North Carolina at Chapel Hill](#)

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[Institution](#)

# Department of Epidemiology

## Contact details

### **Study institution contact**

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### **Primary lead investigator**

Til Stürmer

[Primary lead investigator](#)

## Study timelines

### **Date when funding contract was signed**

Actual: 10/08/2012

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### **Study start date**

Planned: 24/12/2012

Actual: 24/12/2012

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### **Data analysis start date**

Planned: 24/12/2012

Actual: 24/12/2012

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

Planned: 20/12/2013

Actual: 10/09/2014

## Sources of funding

- Other

## More details on funding

University of North Carolina Chapel Hill Clinical and Translational Science Awards (UNC-CTSA)

## Study protocol

[Incretin\\_PC\\_protocol 20DEC2012.pdf](#) (246.52 KB)

## Regulatory

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

No

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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  
Other

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**Study topic, other:**

Diagnostic procedures

**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 objective of this study is to examine the effect of initiation of incretin-based therapies (IBRx) relative to other anti-diabetic therapies (CompRx) on the incidence of pancreatic cancer based on a new-user active comparator design. A secondary aim is to evaluate the use of diagnostic procedures that may lead to a preclinical diagnosis of pancreatic cancer prior to and after initiation

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

BYDUREON

BYETTA

JANUVIA

ONGLYZA

VICTOZA

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**Medical condition to be studied**

Diabetes mellitus

## Population studied

**Short description of the study population**

Medicare enrollees > 65 years of age initiating Incretin-based drugs (IBRx) or other antidiabetic drugs (CompRx)

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**Age groups**

- 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**

75000

## Study design details

## Outcomes

Incident pancreatic cancer, pancreatic cancer mortality, incidence of diagnostic work-up

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## Data analysis plan

IBRx new-users will be compared with new users of CompRx with respect to incidence of pancreatic cancer diagnosis, pancreatic cancer mortality and incidence of diagnostic work-up. We will use propensity scores to balance measured risk factors for cancer/diagnostic work-up between these cohorts. Hazard rates for each of the outcomes will be estimated using a Cox proportional hazards model controlling for age and sex as well as any covariates remaining imbalanced after implementation of the propensity score. In addition, cumulative incidence of diagnostic work-up in the IBRx and CompRx groups across time before and after drug initiation will be examined. Please see full protocol for additional details and description of secondary and sensitivity analyses.

## Documents

### Study results

[Summary of results\\_incretin manuscript.pdf](#) (304.27 KB)

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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**

No