

# Diabetes, Insulin and Malignancies Study New User Protocol (DIMSum)

**First published:** 24/01/2012

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS2333

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### Study ID

25978

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### DARWIN EU® study

No

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### Study countries

United States

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### Study description

This study utilizes a retrospective cohort design in which subjects with diabetes enter the cohort at the time of first use of insulin (glargine or NPH), and baseline information is obtained from a fixed period of time prior to first insulin

use. New users of glargine will be compared with new users of NPH insulin with respect to incidence of breast, colon and prostate cancer (individually) and all cancers combined (excluding non-melanoma skin cancer). Data will be obtained from electronic medical record systems and administrative databases in the US.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Collaborative Studies Coordinating Center, Gillings School of Public Health, University of North Carolina at Chapel Hill

Ochsner Health System Louisiana, Partners HealthCare System Massachusetts, MedAssurant Maryland, Solucia Connecticut

## Contact details

### **Study institution contact**

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**Study contact**

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**Primary lead investigator**

Haibo Zhou

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 09/04/2010

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**Study start date**

Actual: 13/09/2010

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**Data analysis start date**

Actual: 01/09/2011

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**Date of final study report**

Planned: 30/06/2012

Actual: 22/07/2013

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi-aventis

# Study protocol

[DIMSum New User Protocol 23Jan2012.pdf](#) (446.62 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

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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 objective of the study is to investigate whether use of the long-acting insulin glargine is associated with an increased cancer risk compared with use of human NPH insulin.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(A10AC01) insulin (human)

insulin (human)

(A10AE04) insulin glargine

insulin glargine

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**Medical condition to be studied**

Diabetes mellitus

## Population studied

**Short description of the study population**

Patients with diabetes aged 18 years and older at the time of first use of insulin (glargine or NPH).

For the analysis of data from Partners HealthCare System and Ochsner, individuals from their diabetes registries will be eligible to enter the new user cohort on January 1, 2005 (approximately) or later at the time of their first eligible prescription of either insulin glargine or NPH insulin. The earliest date when individuals in the MedAssurant database will enter the new user cohort is July 1, 2004. Individuals must have at least 19 months of continuous membership and pharmacy benefits prior to new user cohort entry; if membership is not well defined, a prescription is required in each of four 6-month periods prior to the first eligible prescription.

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### **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)
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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**

61000

## Study design details

## Outcomes

The three primary outcomes include breast, prostate and colon cancer individually. The secondary outcome will be all cancers combined excluding non-melanoma skin cancers.

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## Data analysis plan

New users of glargine insulin will be compared with new users of NPH insulin with respect to cancer outcomes. We will use propensity scores to balance measured risk factors for cancer between these cohorts. To address the potential for confounding by BMI not measured in the claims database, we will assess the independent contribution of BMI towards the propensity score in 2 external validation studies using electronic medical records data. Hazard rates for each of the cancer endpoints 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. See full protocol for additional details and description of secondary and sensitivity analyses.

## Documents

### Study results

[PMC3816915.pdf](#) (147.61 KB)

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### Study publications

[Stürmer T, Marquis MA, Zhou H, Meigs JB, Lim S, Blonde L, MacDonald E, Wang R, ...](#)

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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.

## **Conflicts of interest of investigators**

[Disclosure Buse long.pdf](#) (81.75 KB)

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## Data sources

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

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

[Electronic healthcare records \(EHR\)](#)

## 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