

# Medullary Thyroid Carcinoma Surveillance Study: a Case-Series Registry (H9X-MC-B001)

**First published:** 03/05/2022

**Last updated:** 03/06/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS45076

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### Study ID

45077

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

Please refer to EUPAS8759. This study is conducted in the US.

The aim of the study is to monitor the number of annual new cases of medullary thyroid carcinoma (MTC) and to establish a registry of incident cases of MTC in adults in order to characterize their medical histories and possible risk factors, including history of treatment with long-acting GLP-1 receptor agonists.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### United BioSource Corporation (UBC)

 Switzerland

**First published:** 25/04/2013

**Last updated:** 06/03/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[yuanyuan.wang@lilly.com](mailto:yuanyuan.wang@lilly.com)

### Primary lead investigator

Yuanyuan Wang

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 19/01/2015

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### Study start date

Actual: 19/01/2015

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### Date of final study report

Planned: 31/12/2030

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company, Novo-Nordisk, AstraZeneca

## Study protocol

[MTC Case Series Registry Protocol\\_v8.0 dated 03Feb2022\\_Redacted.pdf](#) (1.34 MB)

[MTC Case Series Registry Protocol\\_July 2024\\_FINAL\\_Redacted.pdf](#) (690.88 KB)

[MTC Case Series Registry Protocol February 2023\\_FINAL\\_Redacted.pdf](#) (957.98 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)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

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#### **Study type:**

Non-interventional study

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#### **Main study objective:**

Systematically monitor the annual incidence of MTC through North American Association of Central Cancer Registries (NAACCR) to identify any possible increase related to the introduction of long-acting GLP-1 RAs.

Establish a registry of incident cases of MTC in order to characterize their medical histories and possible risk factors, including history of treatment with long-acting GLP-1 RAs.

### Study drug and medical condition

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

DULAGLUTIDE

EXENATIDE

LIRAGLUTIDE

SEMAGLUTIDE

TIRZEPATIDE

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**Anatomical Therapeutic Chemical (ATC) code**

(A10BJ05) dulaglutide

dulaglutide

(A10BJ01) exenatide

exenatide

(A10BJ02) liraglutide

liraglutide

(A10BJ06) semaglutide

semaglutide

(A10BX16) tirzepatide

tirzepatide

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**Medical condition to be studied**

Medullary thyroid cancer

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

6750

## Study design details

### **Outcomes**

A record of medullary thyroid carcinoma (MTC) identified from the US state/regional population-based cancer registries

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### **Data analysis plan**

Descriptive statistics will be used to characterize potential risk factors, including drug exposures, radiation exposure, lifestyle factors, environmental exposures, and other characteristics (including family history of MEN syndromes or FMTC history).

Exposure to long-acting GLP-1 RAs will be characterized by dose and duration of exposure prior to the diagnosis of MTC.

## 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)**

Other

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### **Data sources (types), other**

Participating state cancer registries in the United States.

## 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