

# Drug Use Investigation of ANORO ELLIPTA inhaler (200311)

**First published:** 02/06/2015

**Last updated:** 18/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS9868

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### Study ID

48235

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### DARWIN EU® study

No

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### Study countries

Japan

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### Study description

This investigation will be conducted to collect and evaluate information regarding the safety and efficacy of ANORO ELLIPTA under the actual post-marketing use conditions of the product.

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## Study status

Finalised

## Research institutions and networks

### Institutions

[GlaxoSmithKline \(GSK\)](#)

**First published:** 01/02/2024

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Institution

[Iwamizawa Municipal General Hospital Iwamizawa,  
Japan](#)

### Contact details

#### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure  
Advisor [Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

Study contact

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

#### Primary lead investigator

# GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

## Study timelines

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

Planned: 15/03/2013

Actual: 15/03/2013

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### **Study start date**

Planned: 20/02/2015

Actual: 20/02/2015

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### **Data analysis start date**

Actual: 03/07/2019

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

Planned: 31/12/2019

Actual: 31/10/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

# Study protocol

[gsk-200311-protocol-redact.pdf](#) (205.63 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)?**

Non-EU RMP only

## Methodological aspects

### Study type

#### Study type list

#### **Study topic:**

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

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

This investigation will be conducted to collect and evaluate information regarding the safety and efficacy of ANORO ELLIPTA under the actual post-marketing use conditions of the product.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Non interventional, Observational Post Marketing Surveillance under actual drug use condition.

## Study drug and medical condition

**Medicinal product name**

ANORO ELLIPTA

## Population studied

**Short description of the study population**

This investigation will be conducted in patients who are first prescribed Anoro for the approved indication of the product, "Relief of symptoms of obstructive

airway disorder due to COPD (chronic bronchitis and emphysema) (in the case that long-acting inhaled anticholinergic and long-acting inhaled beta2-agonist combination is required)”).

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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**

Hepatic impaired

Pregnant women

Renal impaired

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### **Estimated number of subjects**

2000

## Study design details

### **Outcomes**

Information regarding the safety and efficacy of ANORO ELLIPTA under the actual post-marketing use conditions of the product.

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### **Data analysis plan**

Items related to patient disposition  
Patient demographic and baseline characteristics  
Items related to safety  
Items related to efficacy

## Documents

## Study results

[gsk-200311-clinical-study-report-redact.pdf](#) (1.74 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)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## 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