

# PGx7612: Pharmacogenetic investigation of the association of the ADRB2 rare variant, Thr164Ile with severe asthma exacerbation (204661)

**First published:** 04/08/2015

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS10464

### Study ID

42099

### DARWIN EU® study

No

### Study countries

United States

### Study description

A recent publication (Lancet Respiratory Medicine 2014, 2:204-213) described evidence of association between a genetic variant, Thr164Ile, in the ADRB2 gene with hospitalization due to asthma exacerbations in non-Hispanic white patients treated with long-acting beta agonists (LABAs). Insufficient numbers of hospitalization events are documented among LABA-treated patients in GSK clinical studies to attempt a direct replication of this paper's findings. However, to better understand risk / benefit for our LABA-treatment regimes, we plan to explore the effect of this genetic variant (ADRB2 Thr164Ile) on the related endpoint evaluated in GSK clinical studies, clinically significant asthma exacerbations. The sample for this study will comprise genetic samples with relevant clinical data from patients enrolled in the studies HZA106837, ADA109055, and ADA109057.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

[GlaxoSmithKline \(GSK\)](#)

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

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[Institution](#)

## Contact details

### **Study institution contact**

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor 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: 04/05/2015

Actual: 04/05/2015

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### **Study start date**

Planned: 29/05/2015

Actual: 13/07/2015

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### **Data analysis start date**

Planned: 29/05/2015

Actual: 13/07/2015

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

Planned: 17/03/2016

Actual: 22/02/2016

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## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[gsk-204661-reporting-and-analysis-plan-redact.pdf](#) (368.63 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:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Pharmacogenetic study

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Determine if there is evidence for the association of ADRB2 Thr164Ile with clinically significant asthma exacerbation in non-Hispanic white subjects treated with LABA.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective, non-interventional exploratory genetic investigation study

## Study drug and medical condition

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

FLUTICASONE FUROATE

**Medical condition to be studied**

Asthma

**Population studied**

**Short description of the study population**

Non-Hispanic white (NHW) subjects from HUI 06837 , ADA109055, and ADA109057 who were actually treated with Fluticasone Furoate/Vilanterol (GW685698 GW642444) in HZAI 06837 or Fluticasone Propionate/Salmeterol (GR33343+CC118781) in ADA109055 and ADA109057 and for whom the requisite genetic and clinical data were available.

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**Age groups**

- 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)

**Special population of interest**

Other

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**Special population of interest, other**

Asthma patients

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**Estimated number of subjects**

876

**Study design details**

## Outcomes

Clinically significant asthma exacerbations are defined as the requirement of treatment with an oral or parenteral corticosteroid or an unscheduled urgent care visit (e.g. unscheduled clinic visit, physician office visit, ED visit, hospitalization) for acute asthma symptoms requiring intervention.

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## Data analysis plan

Retrospective analyses to test for an effect of the ADRB2 Thr164Ile genotype on asthma exacerbation rate in subjects treated with LABA-containing products.

## Documents

### Study results

[gsk-204661-clinical-study-result-summary.pdf \(247.7 KB\)](#)

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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 source(s), other

HZA106837, ADA109055, and ADA109057 clinical trials

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**Data sources (types)**

[Other](#)

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**Data sources (types), other**

Clinical Trial Data

## 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

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## Data characterisation

**Data characterisation conducted**

No