# Modified Prescription-Event Monitoring Study to Monitor the Introduction of Atrovent Inhaler CFC-Free® MDI in the United Kingdom (Atrovent CFC-free M-PEM)

**First published:** 16/04/2014

**Last updated:** 16/02/2024

Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/6353

**EU PAS number**

EUPAS6352

**Study ID**

6353

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

This was a modified prescription event monitoring (M-PEM) study to monitor the safety of Atrovent® CFC-free MDI following a switch from CFC-containing propellants. M-PEM is a non-interventional prospective observational study methodology. The exposure data comprise information from prescriptions collected by the NHS Business Services Authority (NHSBSA) in England. The outcome data are event reports during three month pre- and post-exposure periods, obtained by sending questionnaires to the general practitioners (GPs) who issued prescriptions for Atrovent® CFC-free MDI.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Drug Safety Research Unit (DSRU)

United Kingdom

**First published:** 10/11/2021

**Last updated:** 16/02/2024

Institution | Not-for-profit | ENCePP partner

## Contact details

**Study institution contact**

Saad Shakir

**Study contact**

saad.shakir@dsru.org

**Primary lead investigator**

Saad Shakir

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 05/05/2004

**Study start date**

Actual: 06/05/2004

**Date of final study report**

Actual: 06/07/2010

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim

## Regulatory

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

Yes

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

**Main study objective:**

To actively monitor the safety of the introduction of Atrovent® CFC-free MDI into general practice in England, for both adults and children.

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Prescription event monitoring

## Study drug and medical condition

**Name of medicine, other**

Atrovent CFC-free MDI

## Population studied

**Short description of the study population**

General practitioners (GPs) who issued prescriptions for Atrovent® CFC-free MDI.

---

**Age groups**

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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)

---

**Estimated number of subjects**

13211

## Study design details

**Data analysis plan**

Incidence densities for events occurring three months prior to and in the first three months of exposure to Atrovent® CFC-Free MDI were calculated, together with incidence density ratios to compare event rates before and during exposure. A matched analysis of specific events occurring in the three-month before and three-month after exposure period was performed to produce risk ratios.

# Data management

## Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Prescription event monitoring

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No