# Training requirements to master inhaler devices available in real-life clinical practice (TMID)

**First published:** 09/03/2016

**Last updated:** 22/02/2024

Study Planned

## Administrative details

**EU PAS number**

EUPAS12321

**Study ID**

18084

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

A prospective evaluation of time required and patient preferences when training patients with asthma and COPD to use inhaler devices as part of their routine care in the UK.

**Study status**

Planned

## Research institutions and networks

### Institutions

#### Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

**First published:** 06/10/2015

**Last updated:** 20/08/2026

Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

## Contact details

**Study institution contact**

David Price dprice@rirl.org

Study contact

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**Primary lead investigator**

Lucy Wood

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 01/10/2015

Actual: 01/10/2015

**Study start date**

Planned: 06/04/2016

**Data analysis start date**

Planned: 08/06/2016

**Date of interim report, if expected**

Planned: 19/09/2016

**Date of final study report**

Planned: 19/12/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Teva Pharmaceutical Industries

## Study protocol

R02615_TEVA_Training Requirements _Protocol_151217_V1.4.pdf (1.82 MB)

R02615_TEVA_Training Requirements _Protocol_170303_V1.5.pdf (1.87 MB)

## 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 type:**

Non-interventional study

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**Main study objective:**

To measure the time needed and number of attempts for patients with asthma and COPD to master the required inhaler technique for a specific delivery device available as part of their normal care.

## Study Design

**Non-interventional study design**

Cohort

Cross-sectional

## Study drug and medical condition

**Medical condition to be studied**

Asthma

Chronic obstructive pulmonary disease

## 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**

204

## Study design details

**Outcomes**

Time taken to achieve device mastery (as recorded in seconds from the beginning of training) and number of attempts to reach device mastery (please

see full protocol for details). After training and assessment on the devices, the patient will complete an inhaler device preference questionnaire developed by OPC and administered by the HCPs and/or service coordinator on the day of the iHARP asthma/COPD review clinic (please see full protocol for details).

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**Data analysis plan**

Statistically significant results will be defined as $p<0.05$ and trends as $0.05 \leq p<0.10$. Summary statistics will be produced for all baseline and outcome variables, as a complete dataset and by inhaler device. The mean/median time required to achieve device mastery will be compared by using Cox regression analysis. Log-rank tests will be carried out and p-values reported. The mean/median number of attempts required to achieve device mastery will be compared by using a paired t-test (means) or Wilcoxon signed rank test (medians), dependent on the data distribution. Results from the patient preference questionnaire will be compared using a paired t-test or wilcoxon signed rank test depending on the data distribution. The 5% level of significance will be used (two-tailed test).

# 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)**

Optimum Patient Care Research Database

**Data sources (types)**

Electronic healthcare records (EHR)

Other

**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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

## Data characterisation conducted

No