

# Assessment of physician behaviour regarding metabolic monitoring of patients treated with SEROQUEL® (quetiapine fumarate) Tablets and SEROQUEL® (quetiapine fumarate) Extended Release Tablets in selected countries in the European Union (EU)

**First published:** 01/02/2013

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS3287

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### Study ID

20622

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### DARWIN EU® study

No


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## Study countries

 Germany

 Hungary

 Italy

 Romania

 Spain

 Sweden

 United Kingdom

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## Study description

This is a study which will assess the effectiveness of an update to health care provider education materials in scope of the EU Risk Management Plan and Summary of Product Characteristics for SEROQUEL® (quetiapine fumarate) Tablets and SEROQUEL XR® (quetiapine fumarate) Extended Release Tablets with respect to evaluation and monitoring for hyperglycaemia and other metabolic parameters. There are 2 components to the assessment of effectiveness proposed in this study: process indicators (receipt and understanding of materials) and outcome indicators (healthcare provider behaviour and effect on patients). To realize these 2 indicators for the evaluation of the effectiveness of the metabolic education: an objective, easy to understand and complete healthcare provider survey is described by this study and the use of an Electronic Medical Records approach, as a potential means to assess the monitoring of patients is described in a separate study. This study involves the evaluation of the effectiveness of the distribution of metabolic educational materials sent to healthcare providers in the EU. It will be conducted via an evaluation survey that uses a questionnaire to assess the receipt of the educational material, whether the material was read, and to assess healthcare provider behaviour regarding the conduct of monitoring of metabolic parameters for patients treated with SEROQUEL and SEROQUEL XR. The survey will be conducted among healthcare providers who were targeted to

receive the educational materials following local guidance and directives.

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## Study status

Finalised

## Research institutions and networks

### Institutions

**AstraZeneca**

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**Institution**

## Contact details

### Study institution contact

Robert Brody [bob.brody@astrazeneca.com](mailto:bob.brody@astrazeneca.com)

**Study contact**

[bob.brody@astrazeneca.com](mailto:bob.brody@astrazeneca.com)

### Primary lead investigator

Robert Brody

**Primary lead investigator**

## Study timelines

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

Planned: 31/01/2013

Actual: 31/01/2013

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### **Study start date**

Planned: 01/03/2013

Actual: 01/03/2013

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

Planned: 20/12/2013

Actual: 10/12/2013

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca

## Study protocol

[D1443C00127 Risk Minimization Physician Survey Protocol1.pdf](#) (1.17 MB)

## 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:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The main objective of this study is evaluation of the effectiveness of the distribution of metabolic educational materials sent to healthcare providers in the EU.

## Study Design

## **Non-interventional study design**

Cross-sectional

Other

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## **Non-interventional study design, other**

Survey of healthcare providers

# Study drug and medical condition

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

QUETIAPINE FUMARATE

# Population studied

## **Short description of the study population**

Health Care Professionals who were targeted to receive the metabolic educational materials and either currently prescribe or have the potential to prescribe SEROQUEL or SEROQUEL XR.

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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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## **Estimated number of subjects**

800

# Study design details

## Outcomes

An objective assessment is based upon survey responses related to healthcare provider behavior regarding the monitoring of patients (measures of outcome) and having received and read the educational materials (measures of process).

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## Data analysis plan

Information obtained from responses to each question of the survey will be reported as descriptive statistics. The survey questionnaire contains questions about the specialty of the physician sample completing the survey, questions specific to whether referrals are made to other healthcare providers for metabolic monitoring, whether the healthcare provider conducts monitoring of patients, general questions regarding receipt of the educational materials, and behavior about reading the materials. Each risk minimization behavior included in this study (monitoring of weight, hyperglycaemia, lipids, metabolic risk) will be evaluated individually. The following will be reported, as appropriate, as part of this analysis:- Percent of respondents selecting desired response to each question relating to each risk minimization activity and 95% confidence interval- Percent of respondents demonstrating success of composite risk minimization activities and 95% confidence interval.

## Documents

### Study results

[D1443C00127 Clinical Study Report.pdf](#) (404.57 KB)

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### Study publications

[Brody R.S., Liss C.L., Wray H., Iovin R., Michaylira C., Muthutantri, A., Damst...](#)

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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

A healthcare provider survey will document the receipt of educational materials and assess the behaviour of healthcare providers around the key metabolic monitoring messages communicated through the educational materials.

## 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**

Unknown