

# An Observational Post-Authorisation Safety Specialist Cohort Monitoring Study (SCEM) to Monitor the Safety and Utilisation of Asenapine (Sycrest) in the Mental Health Trust Setting in England (OBSERVA)

**First published:** 13/11/2012

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS3136

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### Study ID

28401

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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## Study description

A study to evaluate the use and short term safety of Asenapine (Sycrest) in real-life usage in the Mental Health Trust Setting. Asenapine (Sycrest) is a new oral anti-psychotic medication and this study aims to evaluate its use and short term safety when used by patients. The study will be recruiting patients started on asenapine (Sycrest) and asking their care team to answer some simple questions about them at the time they start and again in 12 weeks time. If a participant has an adverse event during that 12 week period, we may ask the patient's care team to fill out a further follow up questionnaire. No other examinations or tests will be performed. The participant's consent will be obtained to access their medical records. Any adult patient started by their psychiatric care team on asenapine (Sycrest) during the study period will be eligible to take part. It is a national study covering the whole of England. The study will last for approximately 2 years of data collection (in order to reach a cohort of 1000 patients), although each individual patient will only be involved for a 12 week period of observation. The study is to be carried out independently by the Drug Safety Research Unit (DSRU) in Southampton, although is funded by Merck, the manufacturer of Sycrest.

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## Study status

Finalised

## Research institutions and networks

### Institutions

[Drug Safety Research Unit \(DSRU\)](#)



United Kingdom

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

**Last updated:** 09/01/2026

**Institution**

**Not-for-profit**

**ENCePP partner**

English NHS Mental Health Trusts, Multiple locations in England

## Networks

NIHR Medicines for Children Research Network

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

**Last updated:** 01/02/2024

**Network**

## Contact details

### Study institution contact

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**Study contact**

[elizabeth.lynn@dsru.org](mailto:elizabeth.lynn@dsru.org)

### Primary lead investigator

Saad Shakir

## Study timelines

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

Planned: 09/01/2012

Actual: 09/01/2012

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### **Study start date**

Planned: 01/11/2012

Actual: 01/11/2012

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

Planned: 01/11/2016

Actual: 12/01/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Inc

## Study protocol

[Asenapine SCEM protocol\\_ V 18 Final\\_18\\_09\\_2015\\_clean.pdf](#) (299.92 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)?

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:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

#### **Data collection methods:**

Primary data collection

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#### **Main study objective:**

To monitor the short-term (12 weeks) use and safety of asenapine prescribed to asenapine naïve (new user) patients for the treatment of moderate to severe

manic episodes associated with bipolar I disorder, and other psychiatric disorders by psychiatrists under normal conditions of use in the mental health care trust setting.

## Study Design

### **Non-interventional study design**

Cohort

Other

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

Intensive monitoring schemes

## Study drug and medical condition

### **Medicinal product name**

SYCREST

## Population studied

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

Patients who present to psychiatrists within the standard course of care as in- or out-patients for treatment of a clinical diagnosis of a mental health disorder which requires pharmacological treatment with an atypical antipsychotic. Patients started on asenapine (Sycrest) were included.

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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**

1000

## Study design details

### **Outcomes**

To provide timely information on:1. Accrual of psychiatrists2. Cohort accrual, the type of clinician responsible for, and the setting of initiation of treatment.3. To quantify the incidence rate of selected important identified and potential risks which are:a) Somnolence and sedation b) Weight gain c) Oral hypoaesthesia d) Swelling of the tongue and throat e) Allergic reactions, 1. To provide timely information on the baseline health profile of patients prescribed asenapine in the mental health care trust and the treatment programme they received 2. To describe the risk profile of events reported in the 12 week observation period in patient subgroups of special interest3. To describe clinical features and management of cases of suicide/ self injury

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### **Data analysis plan**

Data analysis will include• Response rates to describe recruitment• Hazard rates to explore the incidence of selected events• Descriptive analyses of baseline health profile of patients• Analysis of risk and incidence densities to describe the risk profile of events reported in patient subgroups of special interest

## Data management

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**

Unknown