# An Active Surveillance Study to Monitor the Real-World Long-term Safety of Somatrogon Among Paediatric Patients in Europe

**First published:** 28/11/2023

**Last updated:** 21/07/2025

Study Planned

## Administrative details

**EU PAS number**

EUPAS107217

**Study ID**

107218

**DARWIN EU® study**

No

**Study countries**

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

**Study description**

The primary purpose of this study will be to assess the long-term safety of somatrogon, a long-acting hGH, under routine clinical care and is intended to reflect outcomes that occur in real-world clinical practice.

**Study status**

Planned

# Research institutions and networks

## Institutions

### Pfizer

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

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

Institution

### Real World Studies, LA-SER Research

☐ France

☐ United Kingdom

**First published:** 23/03/2012

**Last updated:** 23/03/2012

Institution Outdated Other ENCePP partner

### IQVIA

United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

## Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

**First published:** 24/03/2010

**Last updated:** 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

## Cegedim Health Data (CHD)

France

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

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

Institution | Other | ENCePP partner

## EPIFOCUS

Spain

United Kingdom

**First published:** 06/03/2025

**Last updated:** 02/04/2025

Institution | Other | ENCePP partner

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Kofi Asomaning

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 30/03/2022

**Study start date**

Planned: 15/06/2024

**Date of final study report**

Planned: 15/12/2032

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer Inc

## Study protocol

C0311023_SOMATROGON PROTOCOL FINAL_05AUG2022.pdf (744.81 KB)

C0311023_SOMATROGON_PROTOCOL_AMENDMENT_CLEAN_20MAR2023.pdf (472.55 KB)

C0311023_SOMATROGON_PROTOCOL_AMENDMENT_CLEAN_20MAR2023.pdf (472.55 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

**Study type:**

Non-interventional study

**Main study objective:**

Estimate the incidence rates of neoplasms, and diabetes mellitus type 2, the primary safety events of interest in paediatric patients treated with somatrogon, and paediatric patients treated with once daily somatropin, in the course of routine clinical care.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

NGENLA

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

SOMATROGON

**Anatomical Therapeutic Chemical (ATC) code**

(H01AC08) somatrogon

somatrogon

## Population studied

**Age groups**

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

**Estimated number of subjects**

1

## Study design details

**Outcomes**

diabetes and neoplasms, immunogenicity, medication errors, long-term efficacy

**Data analysis plan**

Baseline demographic and clinical characteristics will be described.
For all the safety events of interest and efficacy measurements of interest, descriptive statistics, counts and proportions, crude incidence rates (ie, number of events per person years) and age/sex standardized incidence rates with associated two-sided 95% confidence intervals will be calculated as appropriate.
Rates will be expressed as events/1,000 person-years of follow-up.

# 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)**

THIN® (The Health Improvement Network®)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

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**Data source(s), other**

SNDS France, LPD Spain, Swedish Registries Sweden

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**Data sources (types)**

Administrative healthcare records (e.g., claims)

Disease registry

Drug prescriptions

Electronic healthcare records (EHR)

# Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No