

# NN8640-4787 A Non-interventional, Observational, Registry-based Study to Investigate Long-term Safety and Clinical Parameters of Somapacitan Treatment in Paediatric Patients With Growth Hormone Deficiency During Routine Clinical Practice

**First published:** 24/06/2025

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000602

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### Study ID

1000000602

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### DARWIN EU® study

No

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### Study countries

 Germany

 Saudi Arabia

 Slovenia

 United States

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## Study description

The aim of this study is to look at the long-term safety and clinical parameters of somapacitan in paediatric participants with growth hormone deficiency under routine clinical practice conditions. The study population will include at least 400 paediatric growth hormone deficient participants from the Global Registry for Novel Therapies in Rare Bone and Endocrine Conditions (GloBE-Reg) treated with once-weekly somapacitan and fulfilling the eligibility criteria of the study. The total duration of the study is planned to 10 years consisting of a 5-year recruitment period in the GLoBE-Reg followed by a 5-year follow-up period.

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## Study status

Ongoing

# Research institutions and networks

## Institutions

**Novo Nordisk**

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

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**Institution**

## Contact details

**Study institution contact**

Clinical Transparency (dept. 2834) Novo Nordisk A/S  
pactadmin@novonordisk.com

Study contact

[pactadmin@novonordisk.com](mailto:pactadmin@novonordisk.com)

**Primary lead investigator**

Clinical Transparency (dept. 2834) Novo Nordisk A/S

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 13/09/2023

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**Study start date**

Planned: 13/12/2024

Actual: 13/12/2024

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**Date of final study report**

Planned: 20/09/2035

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novo Nordisk A/S

## Study protocol

[4787 protocol hma-ema redacted.pdf](#) (1.01 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:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To investigate long-term safety of somapacitan treatment in paediatric patients with growth hormone deficiency (GHD) in the setting of routine clinical practice with special focus on neoplasms and type 2 diabetes mellitus (T2DM).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

SOGROYA

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

SOMAPACITAN

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**Anatomical Therapeutic Chemical (ATC) code**

(H01AC07) somapacitan

somapacitan

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**Medical condition to be studied**

Growth hormone deficiency

Neoplasm

Type 2 diabetes mellitus

## Population studied

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

Paediatric participants with growth hormone deficiency.

Inclusion Criteria:

- Treated with commercially available somapacitan according to local practice at the discretion of the physician.
- Primary confirmed diagnosis of growth hormone deficiency as per local practice.
- Male or female below 18 years of age at the time of signing informed consent in the GLoBE-Reg.

Exclusion Criteria:

- Participants with active malignancy or in treatment for active pre-existing malignancy.
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### **Age groups**

- **Paediatric Population (< 18 years)**

- Neonate
    - Preterm newborn infants (0 - 27 days)
    - Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
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### **Estimated number of subjects**

400

## Study design details

## **Outcomes**

Number of adverse drug reactions, Number of medication errors (incorrect dose administration), Number of participants with incident neoplasm, Number of participants with incident diabetes mellitus type 2, Height velocity, Change in height velocity standard deviation score (HVSDS), Change in height standard deviation score (HSDS), Change in insulin-like growth factor I (IGF-I) standard deviation score (SDS), Change in bone age (measured as years), Change in bone age (measured as months), Participants reaching near adult height, Change in height SDS in participants reaching near adult height.

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## **Data analysis plan**

No statistical comparison is planned due to limitations in the observational nature of the data collection.

## 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), other**

**Data sources (types)**

[Disease registry](#)

[Drug prescriptions](#)

## 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**

No