# Incidence rates of morphoea, systemic sclerosis and scleroderma

**First published:** 11/01/2023

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

Study Finalised

## Administrative details

**EU PAS number**

EUPAS50510

**Study ID**

50511

**DARWIN EU® study**

No

**Study countries**

France

Germany

Italy

Romania

**Study description**

This was a cohort study describing population- and patient-level incidence rates of morphoea (including localised and linear scleroderma), systemic sclerosis and scleroderma (including both systemic and localised/linear in a number of European databases. The study population was patients visiting general practices in Germany, France, Italy and Romania

**Study status**

Finalised

# Research institutions and networks

## Institutions

### European Medicines Agency (EMA)

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

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Institution

# Contact details


**Study institution contact**

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Study contact

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**Primary lead investigator**

Karin Hedenmalm

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Planned: 26/09/2022

Actual: 26/09/2022

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**Study start date**
Planned: 26/09/2022

Actual: 26/09/2022

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**Date of final study report**
Planned: 16/12/2022

Actual: 20/12/2022

# Sources of funding

- EMA

# Study protocol

Final analysis plan - morphoea - 20221021.pdf (1.11 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)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The objectives of the study were to describe: Incidence rates of (a) morphoea (including localised and linear scleroderma), (b) systemic sclerosis, and (c) scleroderma (including both systemic and localised/linear) in the general population and in patients with diagnosis of Hodgkin lymphoma and malignant neoplasms.

## Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

**Medical condition to be studied**

Morphoea

Systemic scleroderma

Scleroderma

# Population studied

**Short description of the study population**

The study focused on general population in the UK and patients visiting general practices in Germany, France, Spain, Italy and Romania identified from the IMRD databases to determine the incidence rates of morphoea, systemic sclerosis and scleroderma.

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**Age groups**

- 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)
- 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)

**Special population of interest**

Other

**Special population of interest, other**

Patients with morphoea, systemic sclerosis and scleroderma

**Estimated number of subjects**

1.600

## Study design details

**Outcomes**

Morphoea (localised and linear scleroderma), systemic sclerosis and scleroderma (including both systemic and localised/linear), Incidence rates in the general population were stratified by sex, age group, and year of recorded diagnosis. Incidence rates in patients with cancer diagnosis were stratified by sex and age

**Data analysis plan**

This was a cohort study describing population- and patient-level incidence rates of morphoea (including localised and linear scleroderma), systemic sclerosis and scleroderma (including both systemic and localised/linear in a number of European databases

## Documents

**Study results**

Final-REPORT-Nov 2022_Morphoea.pdf (738.59 KB)

# 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)**

IQVIA Disease Analyzer Germany

THIN® (The Health Improvement Network®)

Disease Analyzer - OMOP

IQVIA Medical Research Data - OMOP

**Data sources (types)**

Electronic healthcare records (EHR)

## 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