# Disease Registry for Patients with Digital Ulcers associated with Systemic Sclerosis (DUO Registry)

**First published:** 29/08/2013

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

Study Finalised

## Administrative details

**EU PAS number**

EUPAS4619

**Study ID**

28356

**DARWIN EU® study**

No

**Study countries**

- ☐ Austria
- ☐ Czechia
- ☐ Denmark
- ☐ Finland

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Slovakia
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

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**Study description**

The registry is a multi-center, prospective, observational, non-interventional program and was designed to document adherence to the Summary of Product Characteristics (SmPC) requirements for liver function tests, pregnancy testing and the use of adequate contraception in DU/ SSC patients exposed to Tracleer, to collect Safety relevant information from patients treated with Tracleer and to obtain data on DU disease history, baseline characteristics (collected at the time of enrolment into the registry), and disease course irrespective of treatment regimen, in patients with DU/ SSC.Inclusion criteria: At time of enrolment the patient must present with Systemic sclerosis and ongoing digital ulcer disease.Exclusion criteria: Patients refused to sign the patient informed consent.

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**Study status**

Finalised

## Research institutions and networks

## Institutions

### Actelion Pharmaceuticals

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

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

**Institution**

### Multiple centres: 428 centres are involved in the study

## Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Eric Schoenamsgruber

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Actual: 10/03/2008

**Study start date**
Actual: 14/04/2008

**Date of final study report**
Actual: 02/03/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Actelion

## Regulatory

**Was the study required by a regulatory body?**

Yes

**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:**

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

For Tracleer treated patients only: to document adherence to the Summary of Product Characteristics (SmPC) requirements (liver enzymes monitoring, pregnancy testing and contraception methods) and to describe the occurrence of specific safety (e.g. pregnancy and discontinuation reasons).For ALL patients: to describe DU disease history, baseline status and disease course.

# Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

**Medical condition to be studied**

Scleroderma associated digital ulcer

# Population studied

**Short description of the study population**

Patient with Systemic sclerosis and ongoing digital ulcer disease at time of enrolment.

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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)

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**Estimated number of subjects**

6108

# Study design details

**Outcomes**

Proportion compliance to SmPC, occurrence of new DUs, and complications and interventions associated with DUs.

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**Data analysis plan**

Safety of Tracleer: cumulative event rates, Adherence to Tracleer SmPC requirements: Proportion of patients with contraception, pregnancy testing and LFT monitoring, DU disease history, patient entry characteristics and disease course: descriptive statistics by treatment group, time to event estimate.

# Data management

## Data sources

**Data sources (types)**

Disease registry

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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown