# TED-R13-002: A Prospective, Multi-center Registry for Patients with Short Bowel Syndrome (TED-R13-002: SBS Registry)

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# Administrative details

EU PAS number	
EUPAS7973	
Study ID	
49834	
DARWIN EU® study	
No	
Study countries  Argentina  Australia  Canada  Croatia	

Czechia	
Denmark	
Finland	
France	
Germany	
Italy	
Norway	
Slovenia	
Spain	
Sweden	
United Kingdom	
United States	

#### Study description

This is a single-group, prospective, observational, multi-center (ie, world-wide) registry designed to collect data on long-term safety and clinical outcomes in Short Bowel Syndrome (SBS) patients.

This registry permits interested SBS patients and SBS-treating health care providers to participate. Patients exposed and not exposed to teduglutide will be recruited. A select set of data will be collected at baseline, and as available, every 6 months (i.e., 2 times a year).

This study is planned for 5 years of enrollment with at least 10 years of followup for each SBS patient.

The primary objective of this registry is to evaluate the long-term safety profile for patients with SBS who are treated with teduglutide in a routine clinical setting.

The primary safety outcome is the occurrence of colorectal cancer in SBS patients with any remnant colon currently being treated with or ever having been treated with teduglutide.

The overall observed incidence of colorectal cancer for teduglutide-treated

patients with any remnant colon will be compared with the incidence of colorectal cancer in the latest available US and global cancer data sources (for example, population-based registries, healthcare claims databases, or federated electronic health record networks with validated oncology outcomes). The secondary objective of this registry is to evaluate long-term outcomes in patients with SBS.

#### **Study status**

Ongoing

## Research institutions and networks

#### **Institutions**

#### Takeda

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Institution

# Contact details

#### **Study institution contact**

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

TrialDisclosures@takeda.com

#### **Primary lead investigator**

# Study Contact Takeda

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Actual: 22/10/2013

#### Study start date

Actual: 23/06/2014

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

Planned: 30/04/2033

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Takeda

# Study protocol

TED-R13-002 Protocol V2 0 11March2014 redacted.pdf (2.14 MB)

# Regulatory

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

Yes

#### Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

# Other study registration identification numbers and links

NCT01990040

https://clinicaltrials.gov/ct2/show/NCT01990040?term=NCT01990040&rank=1

# Methodological aspects

# Study type

# Study type list

#### **Study topic:**

Disease /health condition

#### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

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

Primary data collection

#### Main study objective:

To evaluate the long-term safety profile for patients with SBS who are treated with teduglutide in a routine clinical setting.

The primary safety outcome is the occurrence of colorectal cancer in SBS patients with any remnant colon currently being treated or ever having been treated with teduglutide.

# Study Design

#### Non-interventional study design

Cohort

Other

#### Non-interventional study design, other

**Observational Registry** 

# Study drug and medical condition

#### **Anatomical Therapeutic Chemical (ATC) code**

(A16AX08) teduglutide

teduglutide

#### Medical condition to be studied

Short-bowel syndrome

# Population studied

#### 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**

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

#### **Estimated number of subjects**

1806

# Study design details

#### **Outcomes**

Occurrence of colorectal cancer in patients with SBS with any remnant colon currently being treated with or ever having been treated with teduglutide.

Occurrence of: Other malignancy, Benign neoplasia of GI tract, hepatobiliary system, and pancreas, Colorectal polyps, Intestinal obstruction, Pancreatic and biliary disease, Heart failure/other manifestations of volume overload,

Allergic/hypersensitivity reaction to teduglutide, Other adverse events potentially related to treatment with teduglutide, Change in parenteral support.

#### Data analysis plan

Detailed statistical analysis methods will be conducted as described in the SAP for this study.

Data will be summarized with tabulated descriptive statistics: number of observations, minimum, maximum, mean, median, standard deviation, and range for continuous variables and counts and percentages for categorical variables.

In addition, graphical data displays will be used to summarize selected data. Person-years of follow-up and incidence rates of selected prospective events will be calculated.

# 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 sources (types)**

Disease registry

Other

#### Data sources (types), other

Prospective patient-based data collection. US and global cancer data sources (for example, population-based registries, healthcare claims databases, or federated electronic health record networks with validated oncology outcomes).

# 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