

Quantitative Testing of Patient and Prescriber Knowledge, About GATTEX (Teduglutide) for Injection Safety and Use Information

First published: 28/09/2022

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Study

Ongoing

Administrative details

EU PAS number

EUPAS48716

Study ID

49716

DARWIN EU® study

No

Study countries

 United States

Study description

The study is about learning and documenting how well participants and physicians understand how to use GATTEX and about potential risks by using a survey (called Knowledge Assessment Survey). This survey, which is conducted every two years, is part of the Gattex Risk Evaluation and Mitigation Strategy (REMS). REMS is a safety program required by the US health authority (FDA) for certain medicines that have serious risks. REMS intends to help reduce these risks while still allowing treatment. The goal is to make sure these medicines are used in the safest way possible. The main aim of this survey is to find out how well participants and physicians understand the checkups and tests (so called monitoring) participants should have while taking GATTEX, and the possible risks or of using GATTEX to treat Short Bowel Syndrome.

The knowledge assessment survey will be done via internet, telephone, or paper and both physicians and participants will be able to choose the method that is preferred.

No study medicines will be provided to participants in this study.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda medinfoUS@takeda.com

Study contact

medinfoUS@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/08/2013

Study start date

Actual: 01/08/2013

Date of final study report

Planned: 31/12/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

NCT05561647 (<https://clinicaltrials.gov/ct2/show/NCT05561647>), TAK-633-4008 (<https://clinicaltrials.takeda.com/study-detail/43674fa3720540ed?idFilter=%5B%22TAK-633-4008%22%5D>)

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Assessment of healthcare provider and patient knowledge, attitudes, and behaviors regarding Gattex risks and safe use

Study type:

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Other

If 'other', further details on the scope of the study

Knowledge Assessment Survey

Data collection methods:

Primary data collection

Main study objective:

The study is about learning and documenting how well participants and physicians understand how to use GATTEX and about potential risks by using a survey (called Knowledge Assessment Survey). This survey, which is conducted every two years, is part of the Gattex Risk Evaluation and Mitigation Strategy (REMS). REMS is a safety program required by the US health authority (FDA) for certain medicines that have serious risks. REMS intends to help reduce these risks while still allowing treatment. The goal is to make sure these medicines are used in the safest way possible. The main aim of this survey is to find out how well participants and physicians understand the checkups and tests (so called monitoring) participants should have while taking GATTEX, and the possible risks or of using GATTEX to treat Short Bowel Syndrome.

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Study Design

Non-interventional study design

Other

Non-interventional study design, other

Survey

Study drug and medical condition

Medicinal product name, other

GATTEX

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

TEDUGLUTIDE

Anatomical Therapeutic Chemical (ATC) code

(A16AX08) teduglutide

teduglutide

Medical condition to be studied

Short-bowel syndrome

Population studied

Short description of the study population

The population of prescribers and potential participants identified from the GATTEX REMS database at a given point in time who met the inclusion criteria and none of the exclusion criteria would be invited to participate in the Wave 8 of the Gattex Knowledge Assessment Survey.

Age groups

- 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)
-

Estimated number of subjects

600

Study design details

Outcomes

Number of Participants and Prescribers Providing Correct Responses to Questions.

Number of Participants and Prescribers Providing Correct Responses (80%) to and

Demonstrated Understanding of Survey Knowledge Domains.

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.

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)

[Other](#)

[Patient surveys](#)

Data sources (types), other

The primary source for this study is the Knowledge, Attitudes and Behavioral (KAB) and Risk Evaluation and Mitigation Strategy (REMS) surveys. Survey will be administered via internet, phone, or paper.

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