Risk Evaluation and Mitigation Strategy (REMS) Assessment Protocol - Zydelig (idelalisib) tablets (Zydelig REMS KAB)

First published: 10/11/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11551

Study ID

20922

DARWIN EU® study

No

Study countries

United States

Study description

Knowledge attitude and behavior (KAB) survey of Zydelig REMS safety messages in the US.

Study status

Finalised

Research institutions and networks

Institutions

BioTrak Research Inc.

Contact details

Study institution contact

David Magnuson david.magnuson@gilead.com

Study contact

david.magnuson@gilead.com

Primary lead investigator

Risen Larry

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/01/2015

Study start date
Actual: 21/07/2015

Data analysis start date
Actual: 06/11/2015

Date of final study report
Planned: 15/12/2015

Actual: 04/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences, Inc.

Study protocol

Zydelig_REMS HCP Protocol.pdf (662.46 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Other

If ‘other’, further details on the scope of the study

KAB survey of risk minimization messages

Data collection methods:

Primary data collection

Main study objective:

The objective of this healthcare provider (HCP) assessment is to evaluate the effectiveness of the Zydelig REMS as determined by HCP knowledge and understanding of the risks of Zydelig, specifically that Zydelig can cause fatal and/or serious hepatotoxicity, fatal and/or serious and severe diarrhea or colitis, fatal and serious pneumonitis, and fatal and serious intestinal perforations.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Survey of prescribers

Study drug and medical condition

Medicinal product name

ZYDELIG

Population studied

Short description of the study population

Healthcare professionals in the U.S. who could potentially prescribe or have prescribed Zydelig (“intended users”). Intended users were identified using Zydelig targeted prescriber information or prescribing data provided by the Sponsor. Only intended users who have not participated in the survey pretesting or a prior assessment survey for Zydelig were invited to participate.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

200

Study design details

Data analysis plan

Responses to questions for all completed surveys will be tabulated, and summary tables will include simple descriptive statistics (e.g. mean, median,

and standard deviations for continuous variables, and frequencies with percentages for categorical variables as appropriate). All results will be reported in aggregate and, where applicable, subanalyses of practice specialty, Zydelig prescription volume, and receipt of REMS materials will be included.

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

Data sources (types), other

Survey of prescribers.

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