Trade-offs between benefits and harms of drugs: a stated preference study with adult patients with cancer in Europe (Patient preferences)

First published: 03/06/2021

Last updated: 12/06/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44575

EU PAS number

EUPAS41433

Study ID

44575

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Poland
- [ ] Spain

Study description

This is a cross-sectional study where data is collected using a patient preference (PP) survey aiming to assess the patient and disease characteristics that influence cancer treatment preferences towards key endpoints in European patients with cancer. This study will include two phases: A Qualitative Evidence Generation phase with approximately 30 patients with cancer and a Quantitative Evidence Generation phase with approximately 900 patients with cancer. A pilot/feasibility phase with approximately 20 patients with cancer will be included as part of the Quantitative Evidence Generation phase.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA NL, Real-World-Evidence

- [ ] Netherlands

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Institution | Other | ENCePP partner

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2020

Actual: 01/11/2020

Study start date

Planned: 04/10/2021

Actual: 01/09/2022

Date of final study report

Planned: 04/03/2022

Actual: 28/04/2023

Sources of funding

- EMA

Study protocol

EMA patient preferences on benefits and harms of cancer drugs_Protocol_v3.0_Clean.pdf(1.09 MB)

EMA patient preferences on benefits and harms of cancer drugs_Protocol 6 December 2021.pdf(1.11 MB)

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 type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

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

Patient preferences

Data collection methods:

Primary data collection

Main study objective:

1)To identify and describe PP relating to benefits and harms of cancer drugs in patients with both common and rare cancer types 2. To identify and describe the PP towards key endpoints used traditionally to assess the efficacy and safety of oncology drugs in patients with both common and rare cancer types

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Neoplasm

Additional medical condition(s)

Common and rare cancer types

Population studied

Short description of the study population

A survey of patients with cancer in Europe to determine the heterogeneity in treatment preferences.

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)

Special population of interest

Other

Special population of interest, other

Patients with cancer

Estimated number of subjects

900

Study design details

Outcomes

To assess attribute-levels of stated preferences. To determine the extent to which patients’ heterogeneous characteristics are associated with stated preferences.

Data analysis plan

The primary objective is aimed at identifying and describing the cancer PP about benefits and harms of cancer drugs and to understand the trade-offs

between factors leading to PP with the main method, DCE. For this objective, we propose using Bayesian multinomial logistic regression (MNL) models reporting odds ratio’s and 95% confidence intervals. Attribute-levels will be estimated relative to a reference level for each attribute. The reference level will be selected based on the attribute-level having the lowest parameter estimate. The analysis of preferences of patients towa

Documents

Study results

EMA patient preferences on benefits and harms of cancer drugs - Final Report v1.0 03May.pdf(1.72 MB)

Data management

Data sources

Data sources (types)

Other

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

No