A multi-center prospective non-interventional study to understand the use of next generation sequencing (NGS) in patients with metastatic non-small cell lung cancer and metastatic colorectal cancer in Belgium.

First published: 07/12/2023

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Study | Discontinued

Administrative details

EU PAS number

EUPAS107702

Study ID

107703

DARWIN EU® study

No

Study countries

Belgium

Study description

There is a lack of real-world data relating to how next generation sequencing (NGS) is being implemented and adopted in real-world clinical practice and associated clinical outcomes.

Belgium has recently implemented a national policy to make NGS use available to all cancer patients, thus representing an ideal population to examine the use of NGS in standard clinical practice and associated treatment patterns and outcomes.

The primary objectives of this study are to describe the real-world time from diagnosis of metastatic colorectal cancer (mCRC) or metastatic non-small cell lung cancer (mNSCLC) to NGS test result and the real-world time from NGS test result to treatment in the overall cohort and across selected patient, clinical, disease, treatment and healthcare resource utilization (HCRU) characteristics for patients who undergo NGS testing within routine clinical practice in Belgium and the HRUC and overall survival of patients.

The secondary objectives of this study are to describe the current practices for implementing NGS testing in clinical settings, the baseline characteristics, and clinical and disease characteristics in patients with mNSCLC or mCRC who undergo NGS testing within routine clinical practice in Belgium.

Study status

Discontinued

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Institution | Pharmaceutical company

OPEN Health

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Institution

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Actual: 02/06/2022

Study start date
Planned: 26/02/2024

Actual: 26/09/2024

Date of final study report
Planned: 15/12/2025

Actual: 19/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp &amp, Dohme LLC

Regulatory

Was the study required by a regulatory body?

No

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

Main study objective:

The primary objectives of this study are to describe the real-world time from diagnosis of mCRC or mNSCLC to NGS test result and the real-world time from NGS test result to treatment in the overall cohort and across selected patient, clinical, disease, treatment and HCRU characteristics for patients who undergo NGS testing within routine clinical practice in Belgium.

Study Design

Non-interventional study design

Cohort

Population studied

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

Study design details

Outcomes

Real-world time from diagnosis to NGS test result, real-word time from NGS test result to treatment, number and reasons for resource use (per patient) post-index, and overall survival from index.

Sample characteristics, NGS testing practices, age (years) at index date, sex at birth, relevant comorbidities, CCI score (if documented), time since diagnosis (at index), state of disease at primary diagnosis, tumor grade at primary diagnosis, BMI, smoking history, ECOG performance status (if documented), prior treatments, number and location of metastases, and histologic subtype.

Data analysis plan

For the primary and secondary outcomes, statistical analysis will be descriptive with summary statistics calculated for quantitative variables (including the mean with standard deviation, median with interquartile range, and range) and frequencies and percentages for categorical variables. Estimated proportions (based on the Clopper-Pearson intervals) or 95% confidence intervals of the mean (based on the normal distribution and derived means and standard errors) may also be calculated.

Time-to-event analyses will be conducted using Kaplan–Meier methodology. For the primary objective, the association of this time-to-event analysis with selected patient, clinical, treatment and HCRU outcomes will also be assessed. The specific outcomes to be used for the association analysis will be dependent on subgroup sample size and will be selected as pre-specified and will employ appropriate association statistics (e.g. hazard ratios from Cox regression), where applicable.

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

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