



Study title	An observational study to describe treatment patterns of patients with BRAFV600E mutant metastatic non-small cell lung cancer (OCTOPUS).
Disease	Non-small cell lung cancer (NSCLC).
Treatment(s) observed	First and second-line treatments for metastatic non-small cell lung cancer.
Participants	Adult patients diagnosed with BRAFV600E mutant metastatic NSCLC (mNSCLC) who initiated a first systemic treatment from December 2017 and before study enrolment, or after study enrolment.
Study dates	From 23 June 2022 to June 2025.
Study Locations	France, Germany, Italy, Spain, United Kingdom.

We do research to improve patient care. By participating in an observational study, one helps to answer important scientific questions for the benefit of all.



This document is a brief summary of a clinical study protocol. It is written in plain language for the general public, providing answers to the following questions:

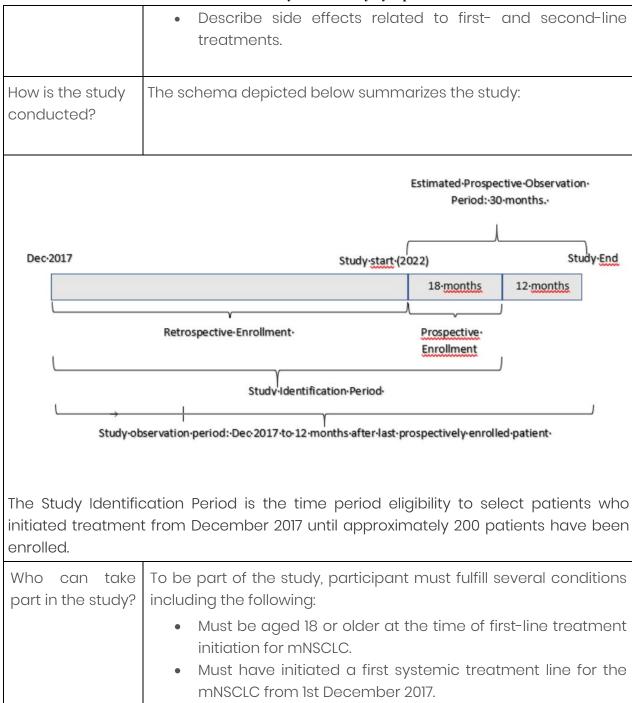
- What is the purpose of the study?
- What are the objectives of the study and how are they evaluated?
- How is the study conducted?
- Who can take part in the study?

What is the purpose of the study?	Non-small cell lung cancer (NSCLC) accounts for 80% to 85% of all lung cancer diagnoses. Approximately 1-2% of patients affected by a NSCLC have a specific genetic mutation called BRAFV600E mutation.
	In a context of a lack of information, it would be useful for the future patients to provide an overview of diagnosis and treatment processes using data of patients already affected by this cancer. Therefore, the purpose of this study is to identify treatment patterns given to patients with mutated BRAFV600E mNSCLC and to describe the efficacy of treatments and patients' quality of life in routine practice.
What are the	The primary objective of the study is to describe treatments
objectives of the	patterns for first- and second- systemic treatments lines given to adult patients with BRAFV600E mNSCLC.
study and how	addit patients with bital voods minoose.
are they evaluated?	The secondary objectives of OCTOPUS are to:
	 Describe treatment patterns for subsequent treatment lines (beyond first- and second-line). Describe demographic and clinical characteristics by collecting data such as age, gender, comorbidities, date of initial diagnosis Describe efficacy of treatments and assess the evolution of patients' quality of life through questionnaires.



NIS12500 - OCTOPUS

Clinical Study Protocol Lay Synopsis



opposition to study participation.

Must have signed Informed Consent Form or non-





Clinical Study identification

Protocol Number NIS12500

Protocol Version 2.0 dated 10 December 2021

Full study title An observational study describing diagnosis and treatment

patterns in adults with metastatic non-small cell lung cancer

with BRAF V600E mutation in clinical practice, to assess

treatment effectiveness and quality of life.

Registry ID NCT05546905

Who sponsors this study?

Name and Pierre Fabre Médicament

contact details of

Les Cauquillous

the sponsor

81500 Lavaur-France

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Additional Information

NIS12500 - OCTOPUS

Clinical Study Protocol Lay Synopsis

Glossary		
First line treatment	Initial, preferred or best treatment for a disease.	
Second line treatment	Effective treatment administrated when the first line treatment may not work, may start but then stop working or may cause serious side effects.	
Retrospective enrollment	Enrollment in the study conducted after treatment initiation.	
Prospective enrollment	Enrollment in the study conducted at or before treatment initiation.	
Informed Consent Form	A document in which patients are given important information in easy-to-understand language, including possible risks and benefits, about a medical procedure or treatment, genetic testing, or a clinical trial. This is to help them decide if they want to be treated, tested, or take part in the trial. Patients are also given any new information that might affect their decision to continue.	