

## Lay Protocol Synopsis

<b>Lay language title:</b>	Understanding treatment in adults with metastatic colorectal cancer and BRAF <sup>V600E</sup> mutation - CAPSTAN CRC study
<b>Full study title:</b>	Retrospective non-interventional study on first line treatment for patients with BRAF <sup>V600E</sup> mutant metastatic colorectal cancer (mCRC) – CAPSTAN CRC study
<b>Registry Number:</b>	NCT04317599

### 1 What is the reason for the study?

Colorectal cancer is the third most common cancer in men and women worldwide with an estimated 1.4 million cases and 694,000 deaths in 2012; the majority of cases happen in the developed countries. When people are first diagnosed with colorectal cancer, about 1 in 4 already have cancer that has spread to other parts of the body: this is called metastatic disease. After the initial diagnosis, about 1 in 2 people will eventually have their cancer spread to other areas.

Around 10% of people with colorectal cancer have a change in their DNA called the BRAF mutation. When the BRAF gene is mutated, it produces an over-active BRAF protein that tells the cells to continuously grow and divide, leading to cancer. The way colorectal cancer is treated can be different depending on where you are: local practices and guidelines influence how doctors decide on the best treatment options.

There is a gap in information about how doctors currently treat people with metastatic colorectal cancer who have the BRAF<sup>V600E</sup> mutation. It is important to record how effective and safe these treatments are when used in everyday life.

This study looks at how doctors diagnose and treat people living with metastatic colorectal cancer with BRAF<sup>V600E</sup> mutation. It aims to describe the treatments commonly used and how well these treatments work.

### 2 What are the objectives of the study?

The main objective of this study was to describe how doctors usually treat adults living with metastatic colorectal cancer with the BRAF<sup>V600E</sup> mutation. In particular, the study looked at the treatments received after diagnosis of the metastasis.

The study also aimed to:

- describe the characteristics of people (such as age, sex, and medical details)
- describe how long people lived without their cancer getting worse and how long they lived after the start of the treatments
- explain how and when doctors tested for the BRAF mutation
- describe unwanted medical events (adverse events\*), that led to changing treatment, dose adaptation, stopping treatment, or death.

\* Participants can have medical problems during the study. These medical problems may or may not be caused by the treatments. They are named adverse events.

### 3 How is the study conducted?

This was an observational study. This means doctors watched what happened as part of normal care, without changing or influencing treatment choices.

The study took place in Austria, Belgium, France, Germany, Italy, Spain, and the United Kingdom.

Adults with metastatic colorectal cancer, with the BRAF<sup>V600E</sup> mutation, who started their first treatments between 2016 and 2018, were invited to participate. People followed their usual care. No extra tests or visits were required for the study.

4

**Who can take part in the study?**

The following people could participate in the study:

- Aged 18 or older when diagnosed with metastatic colorectal cancer
- With BRAF<sup>V600E</sup> mutation, confirmed by adequate testing
- Starting first treatments for advanced colorectal cancer, with the BRAF<sup>V600E</sup> mutation, between 2016 and 2018
- Agreed to participate and allow their data to be used according to local rules
- Did not have another tumor or abnormal cells
- Not participating in another study.

5

**What are the study treatments and how are they administered?**

The study did not provide, request, or require any specific or experimental treatment.

Doctors chose the treatment as part of normal medical practice.

The study simply collected information about the treatment chosen and about what happened after the treatment began.

6

**Ethical considerations**

The study was carried out in accordance with ethical guidelines and research regulations. It began only after getting official approval. People agreed voluntarily to take part in the study.

7

**What are the possible benefits and risks in taking part in the study?**

Taking part in this study was voluntary and had no impact on the treatment.

There were no additional risks or no direct benefit for participants. However, the study's findings could contribute in improving the knowledge of treatments for a colorectal cancer.