Study title	Encorafenib in combination with Cetuximab in BRAFV600E–Mutated Metastatic Colorectal Cancer: A European pooled analysis of observational studies
Disease 	BRAFV600E–Mutated Metastatic Colorectal Cancer
Treatment(s) observed 	Encorafenib in combination with cetuximab
Participants 	This database compiles data from 5 European observational study databases (including 4 retrospective studies: CONFIDENCE [from Spain], B-REAL [from France], CATAMARAN [from the Netherlands], Italian GONO cohort [from Italy]), and 1 ongoing prospective BERING mCRC study [from Germany, Austria and Switzerland] conducted between 2020 and 2024. The Bering mCRC study (NCT04673955) is still ongoing but only data already collected with a cutoff date defined (end of April 2024) will be included.
Study dates 	2020- 2024
Study Locations 	Confidence [from Spain], B-REAL [from France], CATAMARAN [from the Netherlands], Italian GONO cohort [from Italy]), BERING mCRC study [from Germany, Austria and Switzerland]
We do research to improve patient care. This observational study will help 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:

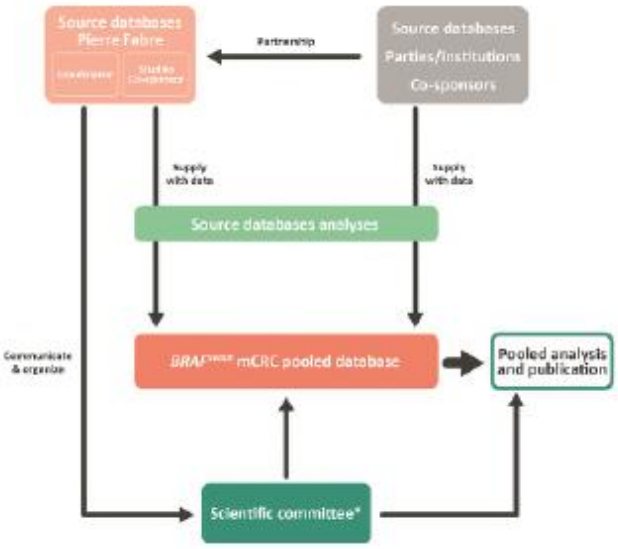
What is the purpose of the study?

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?	This real-life, retrospective, international, observational study aims to describe the clinical characteristics and clinical outcomes of BRAFV600E mutated mCRC patients across Europe treated with encorafenib in combination with cetuximab in a real-life setting after prior systemic therapy. The goal of pooling is to maximize the yield from existing datasets through large pooling efforts, thus improving scientific knowledge in this area of research and support clinical and public health solutions.
What are the objectives of the study and how are they evaluated?	The primary objective is to describe the clinical and demographic characteristics of BRAFV600E mutated mCRC patients treated with encorafenib in combination with cetuximab in a real-life setting across Europe. Secondary objectives are : To describe the treatment patterns of BRAFV600E mutant mCRC patients receiving encorafenib in combination with cetuximab. To describe the therapeutic sequence, To describe the effectiveness in BRAFV600E mutant mCRC patients receiving encorafenib in combination with cetuximab. To describe the safety profile in BRAFV600E mutated mCRC patients receiving encorafenib in combination with cetuximab through the frequency of relevant AEs overall and by subgroup of patients (e.g. with/without baseline hepatic impairment). To identify prognostic factors specific to BRAFV600E mutant mCRC patients associated with OS and PFS. To identify potential clinical and biological factors associated with encorafenib in combination with cetuximab related toxicities. To describe BRAF mutation testing procedures, timing in relation to the line of treatment and turn-around time in real-life settings.

How is the study conducted?	*The Schema summarizes the data pooling process:* 
Who can take part in the study?	To be eligible to the study*, participant must fulfill several conditions including the following • Patient aged over 18 years at encorafenib in combination with cetuximab initiation • Patient having received encorafenib in combination with cetuximab for the treatment of BRAFV600E mutant mCRC. Patients having received Encorafenib in combination with binimetinib treatment or enrolled in other trials are not part of the study. *This is a pooled database of several databases. Enrolled patients are patients enrolled in the original studies

Clinical Study identification	
Protocol Number	
Protocol Version	Final Version N°1 - 9 July 2024
Full study title	Encorafenib in combination with Cetuximab in BRAFV600E–Mutated Metastatic Colorectal Cancer: A European pooled analysis of observational studies
Registry ID	NA
Who sponsors this study?	
Name and contact details of the sponsor	Association des gastro entéroloques oncologues (AGEO) Stichting Dutch colorectal cancer group (DCCG) Gruppo Oncologico Nord-Ovest foundation (GONO) Grupo de tratamiento de los tumores digestivos Spanish cooperative group for the treatment of digestive tumours (TTD) Pierre Fabre Médicament (PFM) - Les Cauquillous - 81500 Lavaur-France
Additional Information	None

Participants	
Personal Data	Pierre Fabre Medicament, Les Cauquillous, 81500 Lavaur (France) acting as one of the Sponsors and as data controller is responsible for the processing of the personal data as part of the Study implementation in accordance with the provisions of Regulation 2016/679/EU of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of such data (GDPR), the legal basis being the legitimate interest of the data controller (art.6.1.(f) and Art. 9.1 (j) GDPR). In accordance with GDPR provisions, you may exercise your rights as listed below by contacting the data controller's Data Protection Officer (DPO) at the following address: dpofr@pierre-fabre.com.
Which are your rights and how to exercise them?	In accordance with the provisions of the GDPR, you may exercise the following rights at any time: - Access (Art. 15 GDPR) you are entitled to request access to your personal data also in the form of a free copy. - Correction (Art. 16 GDPR) you are entitled to request that any incomplete or inaccurate personal data which is hold about you is corrected. - Restriction (Art. 18 GDPR) you are entitled to ask us to suspend the processing of certain of your personal data, for example if you want us to establish their accuracy. - Opposition (Art. 21 GDPR) you can object at any time to the processing of your personal data. In this case no new data will be collected. However, already collected data can still be used if the Sponsor or the Study Centre have a compelling reason or a prevailing legitimate interest for doing so. - Erasure (Art. 17 GDPR, also known as "Right to be forgotten") you are entitled to request the erasure of the data collected by the Sponsor. However, it will not be possible to erase all the collected data if this deletion is likely to make impossible or seriously jeopardize the achievement of the research objectives. Furthermore, once the link

	between your data and your identity has been deleted, meaning that the data has become anonymous, destruction is no longer possible. You have also the right to lodge a complaint with your national supervisory authority for data protection. If you have any questions about your personal data protection rights as a participant in this Study, or a complaint about the use of your personal information you can contact the Sponsor's Data Protection Officer (DPO): dpofr@pierre-fabre.com