






<b>Study title</b>	An observational study to characterize patients with BRAF-mutant unresectable or metastatic melanoma using TAVIE-Skin app
<b>Disease</b> 	Melanoma.
<b>Treatment(s) observed</b> 	Combinations of BRAF/MEK inhibitors (BRAFi/MEKi).
<b>Participants</b> 	Patients diagnosed with BRAF-mutant unresectable or metastatic melanoma.
<b>Study dates</b> 	From February 2021 to December 2024 (anticipated).
<b>Study Locations</b> 	Belgium, France, Germany, Portugal, Spain.
<p>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.</p>	

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?
- How participant's data will be processed and used?

<p>What is the purpose of the study?</p>	<p>In current clinical practice, patients with a BRAF-mutant unresectable or metastatic melanoma may be treated with a combination of BRAF and MEK inhibitors (BRAFi/MEKi). Pierre Fabre has developed TAVIE-Skin, a digital application (app), to support these patients in their daily life.</p> <p>The aim of TAVIE-Skin app is (i) to deliver the necessary information and education support to the patient (for example information on the pathology, on treatments, symptoms and side effects) (ii) to keep track of the medications taken throughout the days (iii) to assist patients in identifying side effects.</p> <p>The main purpose of this study is to characterize patients with BRAF-mutant unresectable or metastatic melanoma patients in Europe using TAVIE-Skin app.</p>
<p>What are the objectives of the study and how are they evaluated?</p>	<p>The primary objective of the study is to describe demographic and clinical characteristics of patients with unresectable or metastatic BRAF-mutant melanoma treated with targeted therapy (BRAFi/MEKi) and using the TAVIE-Skin app by collecting data such as age, gender, comorbidities, date of initial diagnosis.</p> <p>The secondary objectives of TAVIE-Skin are to:</p> <ul style="list-style-type: none"> <li>• Assess patients' Quality of Life (QoL) through questionnaires completed using TAVIE-Skin app.</li> <li>• Assess use of TAVIE-Skin app.</li> </ul>

	<ul style="list-style-type: none"> <li>• Assess activity impairment during treatment.</li> <li>• Assess patient satisfaction toward TAVIE-Skin app.</li> <li>• Assess treatment adherence and satisfaction toward treatment.</li> </ul>
<p>How is the study conducted?</p>	<p>The schema summarizes the study process:</p>
<p>The diagram illustrates the study process flow:</p> <ul style="list-style-type: none"> <li><b>Start:</b> Patient with unresectable or metastatic BRAF-mutant melanoma initiating any BRAFi/MEKi combination.</li> <li><b>Step 1:</b> Health Care Provider recommends TavieSkin and provides a user specific activation code.</li> <li><b>Step 2:</b> Patient downloads and activates TavieSkin app with the code.</li> <li><b>Step 3:</b> Patient accepts the E-survey and signs the E-consent.</li> <li><b>Start of study (baseline):</b> Indicated by a green arrow pointing to the start of the data collection period.</li> <li><b>Data Collection:</b> Regular data collection by the patient him/herself via the app (Health status, QoL, Satisfaction data) ONLY during BRAFi/MEKi treatment.</li> <li><b>End of follow-up period:</b> (definitive end of treatment or patient decision), indicated by a red arrow.</li> <li><b>Timeline:</b> <ul style="list-style-type: none"> <li>Access to the TAVIE Skin application and consent: Indicated by an orange double-headed arrow.</li> <li>Total study period (≈12 months of FU): Indicated by a purple double-headed arrow.</li> </ul> </li> </ul>	
<p>TAVIE-Skin is a prospective, longitudinal, observational study, conducted in Europe. At least, 400 adult patients with metastatic unresectable melanoma will be included in the study.</p>	
<p>No specific medical procedures or in-person clinical visits beyond routine care will be required for this study.</p>	
<p>Who can take part in the study?</p>	<p>To be part of the study, participant must fulfill several conditions including the following:</p> <ul style="list-style-type: none"> <li>• Male or female patient, age <math>\geq 18</math> years at diagnosis of unresectable or metastatic melanoma. Diagnosis of histologically or cytologically confirmed BRAF-mutant melanoma.</li> <li>• Patient having an ongoing prescription of one of the three commercially available BRAFi/MEKi combination therapy, at any line of treatment (encorafenib/binimetinib or dabrafenib/trametinib or vemurafenib/cobimetinib).</li> </ul>

	<ul style="list-style-type: none"> <li>Patients who signed the e-consent and accepted to use TAVIE-Skin app</li> </ul>
How participant's data will be processed and used?	<p>All data collected during the study will be confidential. No information bearing the participant's name will be supplied to any person. Participant's data will be retained and used for the only purpose of the study objectives,</p> <p>As well, all data collected through Tavie-skin Apps are confidential. Each user will be assigned to a unique identifier code preserving his identify.</p>

### Clinical Study identification

Protocol Number NIS-PFO-2020-3501

Protocol Version 8.0 dated 11 June 2020

Full study title **A prospective non interventional study on targeted therapy for patients with unresectable or metastatic BRAFV600E mutant melanoma (TAVIE-Skin)**

Registry ID [NCT04911998](https://clinicaltrials.gov/ct2/show/study/NCT04911998)

### Who sponsors this study?

Name and contact details of the sponsor Pierre Fabre Médicament  
 Les Cauquillous  
 81500 Lavaur-France

### Additional Information

[Tavie Skin \(tavie-skin.com\)](http://tavie-skin.com)

Glossary	
<b>Unresectable</b>	That cannot be removed by surgery
<b>BRAF/MEK inhibitors</b>	<p>BRAF and MEK are genes that makes proteins which help control cell growth.</p> <p>In some patients with cancer, BRAF gene mutates and makes the tumor grow faster.</p> <p>Inhibitors are drugs designed to target these proteins (targeted therapy).</p>
<b>Metastatic</b>	Metastatic means that cancer has spread to a different part of the body than where it started
<b>Prospective study</b>	Type of study, where participants are enrolled into the study before they develop the disease or outcome in question.
<b>Longitudinal study</b>	A longitudinal study is a study that involves patients' monitoring over an extended period of time.