Sponsor : Centre Léon Bérard
Department of Translational Medicine
28 Rue Laennec, 69008 Lyon, FRANCE
Chief Investigator: Pr. Pierre Saintigny
Local Investigator: [Please Insert text]

PARTICIPANT INFORMATION SHEET

ISEBIO: Immune-based Stratification and Evolutionary Biomarkers In Oral potentially malignant disorders

Dear Patient,

We are inviting you to participate in the ISEBIO study. You can decide not to take part to this research. Before you take a decision, it is important that you understand why this study is being done and what it is all about.

This document has been designed to provide you with detailed information regarding this study. Take your time to read it. You can ask any questions you want to your doctor. Before making a decision, feel free to take a period of reflection, if needed.

Whether you decide to participate or not in this study, it will not change the quality of therapeutic care that is offered to you.

What is the purpose of the study?

Oral squamous cell carcinomas (OSCC) represent the most common site (44%) of all head & neck squamous cell carcinomas (HNSCC), itself the 8th most common cancer occurrence worldwide (over 600,000 cases reported per year).

The diagnosis of OSCC is often made at late stage. OSCC may be preceded by an oral potentially malignant disorder (OPMD), most frequently presenting as white or red patches called "oral leukoplakia", visible upon inspection of the oral cavity. These lesions confer an increased risk of developing OSCC, as 7.7% to 22.0% of lesions progress to OSCC.

Except for high-grade dysplasia (abnormal growth or development of cells) that is associated with a high risk of OSCC, the predictive value of clinical and pathological features are however poor and pathological grading of dysplasia is poorly reproducible.

This research aims to improve risk prediction in patients with oral (erythro)leukoplakia. By improving risk prediction, we aim at making diagnosis of OSCC at an earlier stage and improve its overall prognosis.

About 246 patients will participate in this study from several countries in Europe (e.g. UK, France, Italy, Portugal, Norway…).

Why have I been invited?

You have been in the past diagnosed with oral (erythro)leukoplakia and you fit the criteria for taking part in the study.

Do I have to take part?

Taking part in this research is voluntary and entirely up to you. You may choose either to take part or not to take part in the study. If you agree to take part, we will then ask you to sign a consent form.

Commenté [SP1]: To adapt to each country regulation

You should not feel any pressure to participate if you do not want to and you may withdraw without giving any reason, at any time. If you choose to not participate or withdraw from the study, you will not lose any medical benefits to which you are otherwise entitled and it will not have any effect on your future medical care.

What will happen to me if I decide to take part?

The study will take place over a 36 month-period and five sites from several European countries (e.g. UK, France, Italy, Portugal, Norway…) will be involved. If you agree to participate, a portion of the lesion that was removed previously from you will be used for analysis in a research laboratory.

Personal and clinical data will be collected from your medical file. This data will be analyzed in accordance with the General Data Protection Regulation (EU) 2016/679. These data relate

to your disease and associated treatments: clinical characteristics (sex, month and year of birth, smoking and alcohol status), characteristics of your oral (erythro)leukoplakia (date of initial diagnosis, location, histological grade) and treatment types.

These health data correspond and are limited to the sole scientific purposes of the **ISEBIO** study. The site staff and the investigator dedicated to this project will collect these data from your medical file. No additional medical visit nor examination will be required for the collection of these data.

Are there any possible disadvantages or risks from taking part?

This study does not test any new treatment. Your care will not be modified with no additional visit or examination to be carried out as part of this study compared to the usual medical care. You will not have an additional visit to the hospital to make as part of this study.

What are the possible benefits of taking part?

There is no direct benefit for the patients to participate in this study. In the future, the data from this work may help to ameliorate the management of patients with oral (erythro)leukoplakia by improving risk prediction. This will benefit high-risk patients, through better follow-up and early detection or OSCC, but also low-risk patients by avoiding to overburden them, thereby also lowering the associated financial pressure on healthcare systems.

Will my General Practitioner/family doctor (GP) be informed of my participation?

Do not hesitate to ask your doctor, for more information or details on points that do not seem clear to you. You can also discuss your participation with your General Practitioner or relatives before making a decision.

Will my taking part in the study be kept confidential? And what will happen to my data?

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

This information will include:

- Name
- Age at the initial diagnosis of (erythro)leukoplakia

People will use this information to do the research or to check your records to make sure that the research is being done properly.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it AND/OR for future research.

We will make sure no-one can work out who you are from the reports we write. Some of your information will be sent to France. They must follow our rules about keeping your information safe.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from medical records and your GP. If you do not want this to happen, tell us and we will stop.

Your data will be treated confidentially. All documents delivered to the Sponsor will contain only:

- your trial number
- initials
- year of birth

Your name will not appear in these documents. The study Doctor will keep the consent form that you have signed safely and securely stored in the study team's office.

All information collected about you for this trial will be subject to the Data Protection Act 1998 and will be kept strictly confidential.

The ISEBIO clinical study meets the EU General Data Protection Regulation (GDPR) criteria which replaced the Data Protection Directive 95/46/EC and is designed to harmonize data privacy laws across Europe and to protect all EU citizens' data privacy. Your personal medical data will be transferred by your study doctor to the Sponsor of the study or its delegates who act on behalf of the Sponsor in the respect of the confidentiality, security, integrity and the availability of your personal data.

With your permission, your GP will be notified that you intend to participate in the trial. A copy of your consent form will be sent in the post to the Trial Office and to your GP.

By taking part in the trial, you will be agreeing to allow research staff from the Trial Office to look at the trial records, including your medical records.

As per regulation for research studies, it is important that information relating to this study is checked to make sure it is accurate and that the study is being conducted properly. This is to ensure that the study is being conducted to the highest possible standards. It is therefore necessary for representatives of the Sponsor to carry out regular checks on some of the information in hospital records. This means that they must be able to look at your medical notes. It may also be necessary for other people (such as authorised personnel from government regulatory agencies to be able to look at your medical data. Taking part in the study also implies that you give consent to this access. All individuals who have access to your

information have a duty of confidentiality. Under no circumstance will you be identified in any way, in any report, presentation or publication arising from this trial.

In addition, anonymised data from the study may be provided to other 3rd parties (e.g., other academic institutions) for research only.

In addition, the initials, partial date of birth and pathology number of patients who donate tissue for the study may also be passed on to personnel at external research laboratories/institutions or tissue banks in Europe to help them identify the samples.

We would also like to obtain information about your progress through your doctor and the national health registries.

All individuals who have access to your information have a duty of confidentiality.

Will I be reimbursed for taking part?

Your participation in this study will not result in any personal costs and will not result in any financial compensation.

What will happen to the samples I give?

Routine biological samples will be disposed of once the required standard tests have been completed by the Hospital laboratory in France (Lyon). (Erythro)leukoplakia samples taken from you for the purpose of the study could be safely transferred outside UK for secure storage and analysis in specialised and approved Sponsor's laboratory in Centre Léon Bérard, Lyon, France. Your samples will be given the same code number as your study information. This code makes sure that no-one handling your samples will be able to identify you.

After the samples have been used for research associated with this trial, there may be spare material left over. With your consent, this may be stored and used for other medical research on (erythro)leukoplakia. Storage and use of these samples will be done in the respect of the confidentiality policy according to Good Clinical Practice and Good Laboratory Practices.

If you agree to your samples being used in future research, your consent form will be held until the samples have been depleted or destroyed. You are free to decide whether or not to allow further investigations. You will just need to indicate your choice at the end of this informed consent form.

What will happen if I don't want to carry on with the study?

If you choose to withdraw from the study, we would still like to collect relevant information about your health, as this will be invaluable to our research. If you have any objection to this, please let your study doctor know.

You can withdraw your consent to our processing of your data at any time. Under the provisions of the Data Protection Act 1998 you have the right to know what information the Trial Office have recorded about you. If you wish to view this information, please contact Legal Services at the address below.

Who can I contact if I have a complaint?

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer.

[Insert Data Protection Officer Information]

Name:

Email:

What happens at the end of the study?

When the study is completed, the results will be published in a medical journal but under no circumstances you will be identified in any way in any report, presentation or publication arising from this trial. If you would like to obtain a copy of the published results, please ask the doctor.

During the study, you can ask your study doctor the information he/she has regarding your health. Your study doctor will let you know any information that could affect your health or could question your participation to the study

Once study completed, your data will be securely retained for at least 25 years after the end of the study.

What if we find something unexpected?

Some of these analyses will use genetic material (DNA/RNA) extracted from your biological samples for the presence of abnormalities or special characteristics. These analyses will not allow your identification and do not relate to the study of hereditary genetic characteristics. However, in rare special situations, it is possible that your doctor may consider that some results of these tests could be useful for your therapeutic management. He will then discuss it with you if he considers that these results could involve the implementation of preventive measures, including: genetic counseling or care, for yourself or your family members.

Commenté [BM2]: A garder ?

Who is organising and funding the study?

The study is being sponsored by the Centre Léon Bérard which undertake all responsibilities related to the study conduct. The study is financially supported by the French National Cancer Institute (INCa) through Centre Léon Bérard.

Who has reviewed the study?

Any proposed research is reviewed and approved by your country's National health authority and by an independent group of peoples, called a Research Ethics Committee, who protect your safety, rights, wellbeing and dignity. This study has been reviewed and has received approval from xxxx.

Further information and contact details:

Please contact < > by < >(telephone, e-mail, in writing)

Thank you for reading this information.