Information Note:

Development of a Diagnostic and Prognostic Algorithm by Artificial Intelligence in Uterine Smooth Muscle Tumours of Uncertain Malignancy Potential (STUMP)

Research Title: Development of a Diagnostic and Prognostic Algorithm by Artificial Intelligence in Uterine Smooth Muscle Tumours with Uncertain Malignancy Potential (STUMP)

Investigator-Coordinator: Sabrina Croce, Dpt of Biopathology, Institut Bergonié, 229 Cours de l'Argonne, 33076, Bordeaux Cedex

Madam,

This information note is intended to provide you with information on a retrospective European study to better predict their clinical course of STUMPs (uterine smooth muscle tumours of uncertain malignancy potential), in order to improve their management.

Thus, personal data about your health (collected previously to this study) can be used in this research project. We will not ask you for any additional information.

It is important to note that, in the context of this study, there are no constraints or personal benefits to be expected.

1. What is the objective of this study?

The objective of this study is to develop an algorithm based on artificial intelligence to help medical doctors better predict the clinical course of uterine STUMPs.

2. How many people will participate in this study?

This study will include, approximately, 100 patients with uterine STUMPs.

The included patients were cared for in one of three European centres: the Institut Bergonié in Bordeaux, France, Radium Hospital in Oslo, Norway and the Ospedale S. Raffaele in Milan, Italy.

3. What data will be collected and used?

If you agree to participate, information from your medical file regarding your illness and your care will be compiled in a database.

Your data (date of birth, date of surgery, latest clinical news and clinical status living without disease, living with disease, death from disease, recurrence/metastasis, date of recurrence and location) will be processed and analysed. As stated above, your data will be collected from your medical records and you will not be asked for anything more. Of course, you can object to the use of medical data about your past treatment at any time (this is known as retrospective collection).

In this study, your personal data is pseudonymized, i.e. your directly identifying data (surname, first name, etc.) are replaced by indirectly identifying data at the time of registration (by a number and the initials of your first and last names), so they cannot allow you to be recognized.

Data may only be retained for up to two years after the last publication of the research results or, in the absence of publication, until the final research report is signed. They are then archived on paper or electronically for a maximum period of twenty years or for a period in accordance with the regulations in force.

4. What are your rights?

Your participation in this study is completely free and voluntary. You can, at any time, inform the doctor responsible for the research of your objection to the use of your data, without justification, without consequences for the quality of care and treatment, or for relations with your doctor or caregivers. When exercising your rights of objection, you can also exercise the right of deletion of the data already collected. In this case, however, some previously collected data may not be deleted if such deletion makes it impossible or seriously compromises the achievement of the research objectives.

You also have the right to access your personal information in order to verify its accuracy and, if necessary, to rectify, complete or update it. You also have the right to restrict processing.

You can exercise these rights by contacting the doctor who is treating you or by contacting the Data Protection Officer of the Bergonié Institute: Data Protection Officer, 229 Cours de l'Argonne, 33000 Bordeaux – donneespersonnelles@bordeaux.unicancer.fr.

If, after contacting us, you believe that your data protection rights have not been respected, you can file a complaint with the CNIL: https://www.cnil.fr/fr/webform/adresser-une-plainte.

5. What is the regulatory framework?

As the sponsor, the Institut Bergonié, Regional Centre for the Fight against Cancer of Bordeaux and the South-West located at 229, Cours de l'Argonne, 33076 Bordeaux Cedex, is responsible for the processing of the data collected as part of this research.

This research is part of one of the CNIL's "Reference Methodologies". The Bergonié Institute has signed a commitment to comply with this "Reference Methodology" (MR-004, for this study). The reference methodology MR-004 governs the processing of personal data for the **purposes of study, evaluation or research that does not involve the human person and has a purpose of public interest. More specifically, these are studies that do not meet the definition of research involving humans, in particular studies on the reuse of data.** The data controller undertakes to collect only the data that is strictly necessary and relevant to the objectives of the research.

In this regulatory framework, people accessing the data are subjected to professional secrecy. The information concerning your identity will only be known to the medical team and research professionals of the study of the centre that treated you as well as to the health or control authorities, as well as the Sponsor's Data Protection Officer, if you contact him/her.

Your pseudonymised data will be accessible to the following persons:

- The promoter and the people acting on its behalf (academic or industrial partners);
- The Data Controller;
- The Scientific Manager of the Research (Dr. S. Croce);
- Professionals involved in research and personnel acting under their responsibility or authority;
- The staff of the companies of the group to which the data controller belongs and involved in the collection and analysis of data in the context of the research;
- People responsible for data collection, quality control, processing and analysis;

- People responsible for regulatory affairs and registration of research with the competent authorities;
- The staff of health authorities and public control authorities legally authorised, in the context of a particular mission or the exercise of a right of communication;
- Authorised personnel acting under the responsibility of the insurance body guaranteeing the civil liability of the data controller;
- The independent experts in charge of re-analysing the data to verify the results of the study, with a view to their publication, under strict security conditions.

These people, subjected to professional secrecy, will have access to your coded data in the context of their function and in compliance with the regulations.

If the data were to be transferred outside France or the European Union, in all cases, Institut Bergonié ensures that any third party, having access to the data, presents sufficient and appropriate guarantees prior to the sharing of information.

The results of this research may be communicated to the scientific community during seminars, congresses or published in the scientific press. These results will be presented in a form that guarantees your anonymity.

In accordance with the regulatory framework, this project is registered in a public directory maintained by the Health Data Hub and accessible on its website (www.health-data-hub.fr).

6. What are the expected results?

It is expected that the algorithms developed will allow for better prediction of the prognosis of the disease.

Thank you for your help.