PATIENT INFORMATION SHEET AND INFORMED CONSENT

(Vers. N. 3 - 30.05.2025)

Title of the study: "Effects of Genomic Profile on Thromboembolic Risk in Patients with Locally Advanced or Metastatic Non-Small-Cell Lung Cancer "

Study code: 20223ZYAJL

Study Promoter: Department of Medicine and Surgery, University of Perugia

Trial centre: S. M. della Misericordia Hospital, Perugia; Internal Medicine, Vascular Medicine and Emergency Medicine Department

Principal Investigator: Prof. Melina Verso

Dear Sir/Madam,

This document will provide you with information about an observational study and then ask if you would like to participate.

As required by law, the study we are proposing has been reviewed and approved by the Ethical Committee of the study's Promoting Centre and will be conducted in accordance with the Declaration of Helsinki, Good Clinical Practice Guidelines and all applicable regulations governing observational studies.

We therefore ask you to read this document carefully and take the time to reflect, possibly consulting with your relatives and your family doctor, before making your decision about this research.

The doctor in charge will discuss the information provided with you, and it is important that you ask for explanations about anything that is not clear to you.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW FROM THE STUDY

Participation in the study is entirely voluntary. You are free to refuse, to participate, or to withdraw from the study at any time without having to provide any justification and without penalty. If you do not participate or withdraw from the study, you will continue to receive all the treatments prescribed for your condition, and the doctors will continue to monitor you with due care.

If you withdraw from the study, no further data will be collected or recorded, without prejudice to the use of any data already collected to determine the results of the study, without altering them.

RATIONALE AND PURPOSE OF THE STUDY

You are invited to participate because you have locally advanced or metastatic NSCLC lung cancer. This study is being conducted to evaluate the effects of the genomic profile of lung cancer on the risk of developing venous thromboembolic complications.

STUDY PROCEDURE

The study plans to enrol approximately 500 subjects and is expected to be completed by 28/02/2026. The study is observational in nature, as it involves the collection and recording of a series of clinical information and data according to the timing and methods of the treatment you are undergoing in normal clinical practice for the treatment of your condition. Your doctor will freely decide and choose the most appropriate therapy for the treatment of your condition from among the available therapies, regardless of whether you participate in the study. You will be observed and your data collected for a total period of 6 months.

No additional blood chemistry, laboratory, or neuroimaging tests will be required to conduct the study beyond those performed in standard clinical practice. Blood samples will be collected to determine plasma coagulation activation levels during other routine blood tests, which will be analysed centrally by the study's Promoting Centre.

They will be collected for the purpose of assessing the presence of coagulation activation that could expose you to an increased risk of thromboembolism. The biological samples will be used exclusively for the purposes indicated in the study and will be destroyed at the end of the study.

In particular, the following information will be collected: the patient's clinical and medical history, medical treatment, blood tests, and diagnostic tests performed, genetic characterisation of the neoplasm, and thromboembolic events.

RISKS ASSOCIATED WITH PARTICIPATION IN THE STUDY

Observational studies do not pose any risks to participants, as they will not undergo any additional treatments, examinations, or procedures beyond those required by normal clinical practice.

BENEFITS RELATED TO PARTICIPATION IN THE STUDY

As this is an observational study, no direct clinical benefits are expected from participation. However, the results of the study may be used to improve scientific knowledge of the relationship between the genomic profile of NSCLC lung cancer and the risk of developing thromboembolic complications.

HOW WILL THE DATA BE PROCESSED AND WHO WILL HAVE ACCESS TO HEALTH DATA, INCLUDING IDENTIFYING DATA, DURING THE TRIAL

Your data, in particular personal data and health data, and only to the extent that it is essential in relation to the objective of the trial and for pharmacovigilance purposes, will be processed in compliance with EU Regulation 2016/679, known as the GDPR (General Data Protection Regulation), and Legislative Decree No. 101 of 10 August 2018. In practical terms, documents relating to participants will be kept in a secure location and will not bear their names in plain text, which will only be known to researchers, but rather an identification code.

The anonymised data may be subject to scrutiny by regulatory bodies and used for scientific publications (journals, conferences).

Your clinical data collected for the purposes of the trial, as well as the results of the tests carried out, will be kept for the time required by law and then destroyed. They will not be destroyed only if a) it is no longer possible to trace them back to your identity because they have been anonymised during the trial itself; b) you have given your specific informed consent.

Further information is included in the attached data processing authorisation form.

ADDITIONAL INFORMATION

If you agree to participate in this observational study, we will ask you to sign an informed consent form, attached to this document, certifying that you understand the purpose of the study and wish to participate.

Participation in this study will not incur any additional costs for you.

If you agree, your participation in the study will be communicated to your treating physician. You also have the right to know the results of the study, to view your documentation, and to correct any errors.

CONTACTS AND LIST OF STUDY PARTICIPANTS

If you have any further questions regarding the study and/or your rights as a research subject, please contact the principal investigator or one of his/her colleagues listed below.

	Name	***Surname***	***Qualification***
First	*Melina*	*Verso*	*Associate Professor*
	Alessandra	*Vinci*	*Medical Director*
	Francesco	*Piancatelli*	*Training specialist*
	Cecilia	*Becattini*	*Full Professor*

Name and Surname of the subject (in block capitals) _____

Signature of the subject _____

Date _____

Name and Surname of the Investigator (in block capitals) _____

Signature of the subject _____

Date _____

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