# PATIENT INFORMATION SHEET

**STUDY TITLE: "Usefulness of Oscillometry in Assessing the Effectiveness of Inhaled Corticosteroides in Patients With COPD Exacerbator Phenotype".**

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## INTRODUCTION

We are writing to inform you about a research study in which you are invited to participate. The study has been approved by the relevant Clinical Research Ethics Committee.

The document you are given describes the study with sufficient and accurate information so you can decide whether or not to participate in it. To do so, please read this information sheet carefully, and we will answer any questions you may have after the explanation. You may also consult with anyone you deem appropriate.

## VOLUNTARY PARTICIPATION

You should be aware that your participation in this study is **voluntary**, and that you may decide not to participate or change your mind and withdraw consent at any time, without this affecting or impairing your quality of healthcare.

## BACKGROUND

Chronic obstructive pulmonary disease (COPD) is a highly prevalent disease due to high tobacco consumption in our society. This condition is defined as a chronic, irreversible airflow restriction, which is progressive and associated with a permanent abnormal inflammatory response at both the pulmonary and systemic levels. Currently, spirometry is the most widely used test for the diagnosis, control, and monitoring of COPD. However, new tools such as oscillometry testing are becoming available to better define the characteristics of the disease. This is a noninvasive, easy, and quick test that assesses bronchial obstruction and emphysema using sound wave vibrations. Its use could help us optimize treatment choices for COPD patients and provide better follow-up.

## INVESTIGATION

This study is designed to evaluate, using oscillometry, the effectiveness of inhaled corticosteroids in the treatment of patients with COPD exacerbations. We seek the participation of patients with highly complex COPD. Our goal is to include 63 stable COPD patients from different hospitals in Catalonia.

## PROCEDURE

If you agree to participate, simple information about you will be collected as part of the study during the four visits conducted during the 12-week follow-up period, such as your sociodemographic and clinical characteristics. Results of previous imaging tests and laboratory tests will be recorded, as well as any treatments received based on medical criteria. Respiratory function tests will be performed (spirometry at the beginning and end of the study, and oscillometry at each visit). Questionnaires on COPD quality of life and inhaler adherence will also be administered at each visit. The collection of biological samples is not part of the study.

## BENEFITS AND RISKS OF PARTICIPATION IN THE STUDY

The results of this study could help us assess a paradigm shift in healthcare, with a beneficial impact on adjusting patient treatment, through a test that is easier to perform than spirometry. It will allow us to better identify the patient. and improve care options. Participating in this study poses no risk to you, nor does it provide any direct benefit.

## WITHDRAWAL OF CONSENT AND CONFIDENTIALITY

All personal information and its results will be processed in compliance with Regulation 2016/679 of the European Parliament (EU) and of the Council of April 27, 2017, regarding data protection (GDPR). In accordance with Organic Law 3/2018, the following confidentiality measures will be taken to protect your data: Your name, medical record number, or any other information that may identify you will be protected by a code. This code will be assigned to you when you agree to be included in the study and will be used to identify your samples with your medical information, without having to use your real information. Only one or more people responsible for the study may reveal these codes if necessary. Under no circumstances will third parties have access to this data.

This research will provide us with information directly applicable to you about your condition, stored in our databases for a period of at least two years, and you will be informed of all the results obtained. Furthermore, the general results of the study may be published in a meeting or medical journal; however, you will not be identified in these publications. As a study participant, you have the following legal rights regarding your data: rights to access, rectification, objection, deletion, restriction of data processing, the right to request a copy or transfer to a third party (portability) of the data you have provided for the study. You can address your request to the principal investigator of the study or to the CST Data Protection Officer (in writing to dpd@ticsalutsocial.cat and protecciodades@cst.cat , or by calling +34 93 700 36 17).

You may discontinue your participation in this study at any time and withdraw your consent to participate. You must inform the research team, the medical team, or the nursing team. They will contact the study leaders. This will not affect follow-up care or the quality of care. The Institute Catala de Salut (Hospital Universitari de Bellvitge) will act as the data controller. You also have the right to contact the Data Control Authority if you are not satisfied.

**Questions/Information:** If you have any questions or concerns related to this study, you should contact the research team.