PATIENT INFORMATION SHEET

TITLE OF THE STUDY: "Evaluation of the usefulness of an electronic system to support decision making in the integral control of patients with diabetes mellitus treated in primary care. ARTERIOTARGET Project "
PROMOTER: Internal Medicine Service - Vascular Metabolic Unit.
MAIN INVESTIGATOR: Dr. Luis M Beltrán Romero, Department of Internal Medicine, Ext. 41743 or 650 44 96 09.

CENTERS: La Paz-IdiPAZ University Hospital, Dr. Castroviejo and Reina Victoria Health Centers.

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 corresponding Clinical Research Ethics Committee, according to current legislation, Royal Decree 223/2004, of February 6, regulating clinical trials.
Our intention is only that you receive the correct and sufficient information so that you can evaluate and judge whether or not you want to participate in this study. To read this fact sheet carefully and we will clarify the doubts that may arise after the explanation. In addition, you can consult with the people you consider appropriate.

VOLUNTARY PARTICIPATION
You should be aware that your participation in this study is voluntary and you may decide not to participate or change your decision and withdraw consent at any time, without altering the relationship with your doctor or causing any harm to your treatment.

GENERAL DESCRIPTION OF THE STUDY
Patients with diabetes have an increased risk of vascular problems such as heart attacks, strokes, and obstructions in the arteries of the legs. The cause of these problems is not only in high blood sugar levels but also in the sum of other factors that damage arteries such as high blood pressure, cholesterol and smoking among others. It is known that a treatment aimed at adequately controlling these factors decreases the risk of vascular problems and even the probability of death in diabetic patients. The main scientific societies propose objectives of control of these factors that damage the arteries in function of the risk of the patients to have a vascular problem in the following years. However, in practice these objectives are not always achieved.
In this study we intend to use a computer tool that will help your doctor make the decision about which sugar, blood pressure and cholesterol control goals are recommended in your case and which drugs may be the most favorable according to European scientific societies. It is only a support tool, which in no case will replace the clinical judgment of your doctor, who will be who will ultimately make the decisions that you think best for your health.
The aim of the study is to assess whether diabetic patients are better controlled when their physicians use this decision support program. To do so, if you agree to participate, we will re-visit the consultation within 3 months of this initial visit and

review your medical history data during the previous year to compare the values of cholesterol, blood pressure and sugar in every moment.

BENEFITS AND RISKS DERIVED FROM YOUR PARTICIPATION IN THE STUDY
You will have no direct benefit from participating in this study. In addition to the visits that your doctor considers appropriate, a program visit will be made within 3 months of having consented to participate in the study (baseline visit) with routine analyzes in the previous week. Your medical history (age, cholesterol values ...) will be recorded and used to analyze them later, ensuring complete confidentiality (see below). Therapeutic decisions will usually be in the hands of your doctor who will use the program only as a support to consult the recommendations proposed by scientific societies. In any case, it is possible for the program's recommendations to have your doctor decide to change, withdraw, and / or add medication to your treatment. For this reason, the possibility of the side effects most frequently associated with the medication of cholesterol, blood pressure and sugar, such as muscle aches, blood pressure drops, sugar or analytical alterations of potassium, creatinine or liver enzymes will be monitored.

ALTERNATIVE TREATMENTS
As an alternative to clinical care aided by this decision support tool for your physician, you can choose to receive regular clinical care based on clinical judgment and the opinion of your physician.

CONFIDENTIALITY
The processing, communication and transfer of the personal data of all the participating subjects will be in accordance with the provisions of Organic Law 15/1999, of December 13, on the protection of personal data. According to the aforementioned legislation, you can exercise the rights of access, modification, opposition and cancellation of data, for which you should contact your study doctor. The data collected for the study will be identified by a code and only your study doctor / collaborators will be able to relate the data with you and your medical history. Therefore, your identity will not be disclosed to any person except exceptions, in case of medical urgency or legal requirement.
Only data collected for the study will be transmitted to third parties and to other countries, which in no case will contain information that can directly identify it, such as name and surname, initials, address, social security number, etc. In the event that this assignment occurs, it will be for the same purposes of the study described and guaranteeing the confidentiality at least with the level of protection of the legislation in force in our country.
Access to your personal information will be restricted to the study doctor / collaborators, health authorities (Spanish Agency for Medication and Health Products), the Ethical Committee for Clinical Research and personnel authorized by the promoter, when necessary to verify the data and procedures of the Study, but always maintaining the confidentiality of the same in accordance with current legislation.

ECONOMIC COMPENSATION
Does not apply.

OTHER RELEVANT INFORMATION
If you decide to withdraw consent to participate in this study, no new data will be added to the database and may require the destruction of all identifiable samples previously held to avoid further testing.
You should also know that you may be excluded from the study if the sponsor or the study investigators deem it appropriate, either for safety reasons, for any adverse events occurring during the study, or because they believe that they are not complying with established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study
By signing the attached consent sheet, you agree to comply with the study procedures that have been set forth.

INFORMED CONSENT FOR PARTICIPATION IN THE PROJECT "ARTERIOTARGET Project
METABOLIC-VASCULAR UNIT. LA PAZ / IDIPAZ UNIVERSITY HOSPITAL.
HEALTH CENTER DOCTOR CASTROVIEJO.

Faculty responsible for the study: Dr. Luis M. Beltrán Romero, Dr. Juan García Puig, Dr. Victoria Castell.

PATIENT

I ..... .with DNI ..... I agree to participate in the study "Evaluation of the usefulness of an electronic Support for decision making in the integral control of patients with diabetes mellitus treated in primary care. Project ARTERIOTARGET "and to use my data for the purpose of this research.

Signature Date

RESPONSIBLE DOCTOR OF THE PATIENT

I .... with collegiate number ..... I have informed the patient of the purpose, utility and characteristics of the study.

Signature Date

REVOCATION OF CONSENT

I .... with DNI .... I withdraw my agreement to participate in the study "Evaluation of the usefulness of an electronic system to support decision-making in the integral control of patients with diabetes mellitus treated in primary care. ARTERIOTARGET Project "and I do not want my data to be used for this research.

Signature Date