PATIENT / POTENTIAL PARTICIPANT INFORMATION SHEET

STUDY TITLE: Clinical validation of an artificial intelligence platform to improve the adequacy of referrals to dermatology

STUDY CODE: LEGIT.HEALTH_DAO_Derivación_PH_2022

SPONSOR: Instituto de Investigación Sanitaria Puerta de Hierro

PRINCIPAL INVESTIGATOR*:*

Name: Dr. Gastón Roustan Gullón

Department: Servicio de Dermatología

CENTRE: Hospital Universitario Puerta de Hierro Majadahonda

DOCUMENT VERSION: 1.0 - 29/06/2022

INTRODUCTION

We are providing you with this information to invite you to participate in a research study. The study has been approved by the relevant Clinical Research Ethics Committee.

Our aim is solely to provide you with the correct and sufficient information so that you can evaluate and decide whether or not you wish to participate in this study. Please read this information sheet carefully, and we will clarify any doubts you may have after our explanation. You may also consult anyone you deem appropriate.

VOLUNTARY PARTICIPATION

Please be aware that your participation in this study is entirely voluntary. You may choose not to participate or withdraw your consent at any time without affecting your relationship with your doctor or any aspect of your medical treatment.

GENERAL DESCRIPTION OF THE STUDY

The primary objective of this study is to validate the clinical usefulness of the Legit.Health platform, developed by AI LABS GROUP SL, in the management of patients with dermatological conditions by both primary care physicians and dermatologists at Hospital Universitario Puerta de Hierro Majadahonda involved in the project.

A study involving 100 participants is planned, to be conducted by the Dermatology Department of Hospital Universitario Puerta de Hierro Majadahonda over a period of four months.

The study will focus on adult participants with tumoral, inflammatory, or infectious skin conditions. Legit.Health is a digital medical device designed to assist primary care physicians in improving diagnostic accuracy and decision-making, as well as ensuring more appropriate referrals to dermatology. This is achieved through automatic image analysis and the auto-filling of measurement scales.

Who can participate?

The study will involve volunteers of any gender who have signed the informed consent form, have a proficient level of written and spoken Spanish or English, and are suspected of having one of the following conditions in primary care: tumoral, inflammatory, or infectious skin diseases.

BENEFITS AND RISKS OF PARTICIPATION IN THE STUDY

Although you may not directly benefit from participating in this study, your involvement will contribute to improving the quality of clinical care, enhancing knowledge of the condition under investigation, and developing new strategies and treatments for future patients.

Your participation in this study will not pose any risk to your safety.

CONFIDENTIALITY

The processing, communication, and transfer of personal data for all study participants will comply with Regulation (EU) No. 2016/679 and Organic Law 3/2018, of 5 December, on Personal Data Protection and the Guarantee of Digital Rights.

Both the study centre and the sponsor are responsible for data processing and commit to complying with current data protection regulations. The data collected for the study will be identified using a code, and only the study doctor and collaborators will be able to link this data to you and your medical records. Your identity will not be disclosed to anyone, except in cases of medical emergencies or legal requirements.

Access to your personal information will be restricted to the study doctor, collaborators, health authorities, the Research Ethics Committee, and authorised sponsor personnel (study monitors, auditors), when necessary to verify the study data and procedures. However, confidentiality will always be maintained in accordance with current legislation.

Under data protection laws, you have the right to access, modify, oppose, or request the deletion of your data. Additionally, you may limit the processing of incorrect data, request a copy, or transfer the data you have provided for the study to a third party (data portability). To exercise your rights, you may contact the study's principal investigator. Alternatively, you can submit a written request to the following address: c/Sant Quintí 77-79, 08041 Barcelona. You also have the right to file a complaint with the Data Protection Agency if you are not satisfied with the handling of your data.

If you decide to withdraw your consent to participate in this study, no new data will be added to the database. However, please note that previously collected data cannot be erased, as it is necessary to ensure the validity of the research and comply with legal obligations.

The investigator and sponsor are required to retain study data for at least five years after the study concludes. After this period, your personal information will only be kept for healthcare purposes or for other scientific research purposes if you have provided explicit consent or if permitted by law and applicable ethical standards.

If we transfer your coded data outside the EU to entities within our group, service providers, or collaborating researchers, appropriate safeguards such as contracts or other mechanisms approved by data protection authorities will be implemented to ensure data security. If you wish to obtain further details, you may contact the study’s Principal Investigator or the sponsor's Data Protection Officer via email.

FINANCIAL COMPENSATION

Your participation in the study will not incur any expenses, nor will you receive financial compensation. You will not be required to pay for any study-related procedures.

OTHER RELEVANT INFORMATION

If you decide to withdraw your consent to participate in this study, no new data will be added to the database. You may also request the destruction of any previously collected identifiable samples to prevent further analysis.

By signing the attached consent form, you agree to comply with the study procedures as explained to you.

If you have any questions or require further information, please contact the study’s principal investigator.

Thank you for your cooperation.

CONSENTIMIENTO INFORMADO

Título del estudio:

Yo (nombre y apellidos).....

He leído la hoja de información que se me ha entregado.

He podido hacer preguntas sobre el estudio.

He recibido suficiente información sobre el estudio.

He hablado con:

.....

(nombre y apellidos del investigador)

Comprendo que mi participación es voluntaria.

Comprendo que puedo retirarme del estudio:

1º Cuando quiera

2º Sin tener que dar explicaciones.

3º Sin que esto repercuta en mis cuidados médicos.

- Presto libremente mi conformidad para participar en el estudio y doy mi consentimiento para el acceso y utilización de mis datos en las condiciones detalladas en la hoja de información.

.....	**.....**
Firma del paciente	**Firma del investigador**
Fecha:	**Fecha**:

Este documento se firmará por duplicado quedándose una copia el investigador y otra el paciente

INFORMED CONSENT

Study Title:

I, …… (name and surname of the witness), declare under my responsibility that …… (name and surname of the participant):

Has read (or has had read to them, in cases where the patient is unable to read) the information sheet provided.
Has had the opportunity to ask questions about the study.
Has received sufficient information about the study.
Has spoken with:
.....
(name and surname of the investigator)
Understands that their participation is voluntary.
Understands that they may withdraw from the study:

1. At any time.
2. Without providing an explanation.
3. Without any impact on their medical care.

Has freely expressed their agreement to participate in this study and gives their consent for the access and use of data under the conditions detailed in the information sheet.

.....	**.....**
Witness Signature	**Investigator Signature**
Date:	**Date**:

This document will be signed in duplicate, with one copy retained by the investigator and the other by the participant.

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