

Clinical validation study of a CAD system with artificial intelligence algorithms for early non-invasive detection of in vivo cutaneous melanoma.

(LEGIT\_MC\_EVCDAO\_2019)

**First published:** 03/01/2024

**Last updated:** 01/07/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS108254

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### Study ID

108436

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### DARWIN EU® study

No

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### Study countries

Spain

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## **Study description**

The SARS-CoV-2 pandemic poses challenges to global healthcare systems, impacting the care of COVID-19 patients and causing disruptions in various medical disciplines, including dermatology.

Urgent measures, initiated almost two years ago, aimed to prioritize COVID-19 cases, resulting in a backlog of non-urgent consultations.

Dermatology practices were considered potential vectors of COVID-19 transmission, leading to the suspension of non-urgent consultations.

The ongoing threat from evolving virus variants has hindered the restoration of normal healthcare flows. In response, an alternative system is imperative for efficient and timely diagnosis and remote patient monitoring. The imbalance in dermatologist-to-patient ratios, especially in Spain and other European countries, accentuates the need for such a system.

Delayed diagnosis of skin conditions, including potentially life-threatening melanoma, and exacerbation of chronic diseases during the pandemic underscore the urgency.

Currently, no reliable tools exist for remote pathology diagnosis, emphasizing the importance of implementing an innovative solution. Human limitations in quantifying parameters and inherent biases in patient-reported measurement scales further impede accurate assessments.

The inadequacy of existing methods, coupled with the reluctance of patients to seek in-person consultations during the pandemic, highlights the necessity for advanced diagnostic tools. The study advocates for the clinical validation of an artificial intelligence tool, Legit.Health, designed to grade disease activity in dermatological patients.

Artificial intelligence, particularly Computer Aided Diagnosis (CAD) systems, offers a promising avenue. These systems, leveraging artificial intelligence and image processing, enhance the interpretation of medical images, demonstrating competence comparable to medical experts.

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## **Study status**

Finalised

## Research institutions and networks

### Institutions

#### AI Labs Group S.L. (Legit.Health)

Spain

**First published:** 08/03/2024

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**Institution**

**Non-Pharmaceutical company**

**Other**

### Contact details

#### Study institution contact

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#### Primary lead investigator

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**Primary lead investigator**

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# Study timelines

## **Date when funding contract was signed**

Planned: 04/11/2019

Actual: 04/11/2019

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## **Study start date**

Planned: 17/09/2020

Actual: 17/09/2020

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## **Date of interim report, if expected**

Planned: 17/10/2023

Actual: 23/10/2023

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## **Date of final study report**

Planned: 17/10/2023

Actual: 23/10/2023

# Sources of funding

- National competent authority (NCAs)

# More details on funding

Government institutional research programme

# Study protocol

[LEGIT\\_MC\\_EVCD AO\\_2019 Protocol v3.0 28102021\\_Melanoma\\_EN.docx-2d034302d0d9ac7f987c4ec35eb9b990.pdf](#) (2.43 MB)

# Regulatory

## Was the study required by a regulatory body?

No

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## Is the study required by a Risk Management Plan (RMP)?

Not applicable

## Other study registration identification numbers and links

NCT06221397

<https://register.clinicaltrials.gov/prs/beta/studies/S000E2DU00000030/recordSum...>

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Study design:**

The goal of this Cross-sectional analytical observational study of clinical case series is to validate a Computer-aided diagnosis software developed by AI Labs Group for the identification of cutaneous melanoma in images of lesions taken with a dermatoscopic camera.

#### **Main study objective:**

This study aims to validate our CAD system's capability, utilizing machine vision, for the early and non-invasive in-vivo diagnosis of cutaneous melanoma. The primary objective is to confirm that the AI algorithm developed for identifying cutaneous melanoma in dermatoscopic images achieves: AUC > 0.8 Sensitivity  $\geq$  80% Specificity  $\geq$  70%

## Study Design

### **Non-interventional study design**

Cohort

Cross-sectional

## Study drug and medical condition

### **Additional medical condition(s)**

Any kind of melanoma

## Population studied

### **Short description of the study population**

Patients with skin lesions with suspected malignancy seen at the Dermatology Department of the Hospital Universitario Cruces and Hospital Universitario Basurto.

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### **Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

- Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Estimated number of subjects**

200

## Study design details

### **Outcomes**

Skin Lesion Recognition:

Top-1 Image-Level Accuracy: 52.86% (initial) / 48.25% (initial + extension).

Top-3 Image-Level Accuracy: 81.20% (initial) / 74.74% (initial + extension).

Top-5 Image-Level Accuracy: 88.83% (initial) / 83.16% (initial + extension).

Malignancy Prediction: AUC for Malignancy: 87.28% (initial) / 88.26% (initial + extension).

Adverse Events and Adverse Reactions to the Product: No adverse events or reactions related to the investigated device were observed.

Product Deficiencies: No deficiencies in the device were observed, it demonstrated consistent performance. Subgroup Analysis for Special

Populations: No special population subgroups were identified in the context of the analyzed pathologies.

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### **Data analysis plan**

For the purpose of estimating the device's performance, we use different metrics depending on the task: Melanoma detection: Top-K precision Top-K sensitivity, Top-K specificity, AUC Malignancy prediction: AUC Skin lesion recognition: Top-K accuracy For this study, we set the value of K to 1, 3, and 5.

## Documents

## Study results

[Study results\\_EUPAS108254.pdf](#) (136.06 KB)

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## Study, other information

[CEIM\\_LEGIT\\_MC\\_EVCD AO\\_2019 Modificacion Favorable PIB-5737d3c2e56f73d97a641783577c20ac.pdf](#) (286.15 KB)

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

[Spontaneous reports of suspected adverse drug reactions](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Yes

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**Check completeness**

Yes

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**Check stability**

Yes

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown