Clinical Validation of a Computer-Aided Diagnosis (CAD) System Utilizing Artificial Intelligence Algorithms for Continuous and Remote Monitoring of Patient Condition Severity in an Objective and Stable Manner. (LEGIT\_COVIDX\_EVCDAO\_2022.)

First published: 03/01/2024 Last updated: 01/07/2025



# Administrative details

#### **EU PAS number**

EUPAS108260

#### Study ID

108261

#### DARWIN EU® study

No

Spain

#### Study description

This clinical investigation examines the Legit.Health software medical device, utilizing advanced machine vision and deep learning for dermatological diagnostics.

With 160 patients, the study prioritizes ethical standards and regulatory compliance, potentially transforming dermatological diagnostics.

The primary objective is to validate the device's effectiveness in tracking chronic dermatological conditions, aiming for a Clinical Utility Questionnaire score of 8 or higher.

Secondary objectives include confirming high patient satisfaction with remote device application, assessing the device's impact on reducing face-to-face consultations, and validating its reliability in consistently monitoring conditions. The study encompasses patients with chronic dermatological conditions meeting inclusion criteria at the Dermatology Department of Hospital Universitario de Torrejón.

The design involves a six-month recruitment period, informed consent, and initial supervised device use. Patients autonomously complete questionnaires, use the Dermatology Life Quality Index, and submit pathology photographs through Legit.Health.

With 160 patients recruited, the study initiated on March 03, 2022, and completed on October 23, 2023, spanning a total duration of 19 months. The results indicate positive outcomes, with specialists perceiving ease of use and effectiveness in optimizing consultation time.

The Data Utility questionnaire affirms the device's usefulness, and high user satisfaction and ease of navigation are reflected in System Usability Scale results. Positive patient satisfaction scores were observed, and no adverse events were noted, indicating a favorable safety profile. In conclusion, the Legit.Health device proves highly effective, safe, and userfriendly for managing chronic dermatologic conditions. Positive feedback from specialists and patients highlights its potential as a valuable clinical tool, offering objective follow-up in skin evaluation.

# Finalised Research institutions and networks Institutions

# Al Labs Group S.L. (Legit.Health) Spain First published: 08/03/2024 Last updated: 08/03/2024 Institution Non-Pharmaceutical company Other

# Contact details

#### Study institution contact

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Study contact

**Study status** 

mandreu@torrejonsalud.com

Primary lead investigator

Marta Andreu-Barasoain

Primary lead investigator

# Study timelines

**Date when funding contract was signed** Planned: 01/03/2022 Actual: 01/03/2022

**Study start date** Planned: 03/03/2022 Actual: 03/03/2022

**Date of final study report** Planned: 23/10/2023 Actual: 23/10/2023

# Sources of funding

- EU institutional research programme
- Other

### More details on funding

COVID X Initiative, as can be seen in the following page: https://www.covidx.eu/game-changers/

# Study protocol

LEGIT\_COVIDX\_EVCDAO\_2022 Protocol Multipathology\_v\_2\_0\_EN.docx-5e3dc4ebfabd52f146d349d035e59f5c (1).pdf(3.81 MB)

# Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

# Other study registration identification numbers and links

https://www.biocrucesbizkaia.org/servicios/medtech Website where our study is registered as a beneficiary of the MEDTECH funding programme. NCT06237036

https://register.clinicaltrials.gov/prs/beta/studies/S000E3L800000026/recordSum...

Methodological aspects

Study type

Study type list

Study type:

#### Data collection methods:

Combined primary data collection and secondary use of data

#### Main study objective:

This study aims to: Evaluate the effectiveness of the device in remotely monitoring the severity of chronic dermatologic pathologies. Assess patient satisfaction with the device for remote monitoring.

# Study Design

#### Non-interventional study design

Cohort

# Population studied

#### Short description of the study population

Patients diagnosed with any of the specified chronic dermatological conditions that meet the inclusion criteria.

These patients are attended at the Dermatology Department of the Hospital Universitario de Torrejón.

It encompassed a diverse patient cohort with a range of chronic dermatologic pathologies, providing a comprehensive representation of the population affected by these conditions.

#### 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)

#### Estimated number of subjects

160

# Study design details

#### Outcomes

Primary Analyses - Clinical Utility Questionnaire Specialists found the device easy to use, optimized consultation time, and enhanced data collection. General satisfaction was high, with an overall mean score of 71.39.

Statistical Analysis A one-sample Student's t-test suggested no substantial evidence to reject the hypothesis, aligning the observed sample mean with a population mean of 80, Data Utility Questionnaire: Specialists unanimously agreed on app usefulness. Mean scores revealed strong preferences for app functionalities, with some variations.

System Usability Scale Questionnaire: Specialists found the device easy to use, with positive feedback on integration. Discrepancies encountered indicated areas for improvement.

#### Data analysis plan

For the purpose of estimating mean responses and their variability, we calculated the mean and standard deviation for all questions. Additionally, to evaluate the hypothesis concerning the CUS value, we conducted a one-sample Student's t-test to determine the statistical significance and either accept or reject the hypothesis based on the test results.

# Documents

#### Study, other information

CEIm\_LEGIT\_COVIDX\_EVCDAO\_2022\_TRJON-8abc0f12d828135f5b5e7bf93985ee24.pdf(317.94 KB)

#### **Study publications**

Clinical Validation of a Computer-Aided Diagnosis (CAD) System Utilizing Artifi...

## 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)

Administrative healthcare records (e.g., claims) 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**

Unknown

#### **Check completeness**

Unknown

#### **Check stability**

Unknown

#### Check logical consistency

Unknown

# Data characterisation

#### Data characterisation conducted

No