#### CERTIFICATION AND COMPLIANCE







since 1989

since 2004

Data Centre Certification since 2016

# **GIBILI** association for innovation and biomedical research on light and image

#### **MEDICAL DEVICES**

AIBILI follows ISO 14155 and Regulation (EU) 2017/745 when performing clinical investigation of medical devices for human subjects.

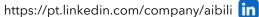
#### PROCESSING OF PERSONAL DATA

AIBILI complies with Regulation (EU) 2016/679 and Portuguese Law n° 58/2019 applicable to the protection of personal data.





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# YOUR PARTNER IN **CLINICAL RESEARCH**

## **Research Technology Organisation**

dedicated to clinical research and health technologies development

## **Private non-profit organization** established in 1989

with Public Utility recognition

## Interface Centre of the **Portuguese Network**

unique with focus on Human Health

#### 4C - COIMBRA COORDINATING CENTRE FOR CLINICAL RESEARCH

## **Overall management of clinical research studies**

Supports the development and coordination of Investigator Initiated and Industry Sponsored Clinical Studies by providing the following services:



#### **PRE-STUDY**

- Study Design
- Statistical Plan
- Protocol and Informed Consent development
- Clinical Centre selection
- eCRF development
- Database validations and implementation
- MF and Site File development
- SOPs development
- Regulatory Affairs
- Contracts and Insurance
- Monitoring

#### **IN-STUDY**

- Study Coordination
- IMP Management
- eCRF Management and Support
- Data Management
- Monitoring
- Pharmacovigilance

#### **POST-STUDY**

- Data Base Lock
- Biostatistics
- Final Report
- Medical Writing
- Publication
- Archiving



## **DC - DATA CENTRE**

## **Guarantee clinical data safety and integrity**

Responsible to guarantee the safety and integrity of the data and images collected for clinical research.

AIBILI Data Centre follows SOPs compliant with GCP Guidelines, US FDA 21 CFR part 11 (Guidance for Electronic Records) and ISO 27001 (Information Security Management).

#### **CEC - CLINICAL TRIAL CENTRE**

## **Dedicated area to perform clinical research studies**



Performs clinical trials and studies with special emphasis on ophthalmology as well as in diabetes, neurology and oncology. CEC has dedicated facilities and the most updated ophthalmological equipment.

Clinical patient-oriented research involves characterizing disease progression and testing new discoveries.

## **CORC - COIMBRA OPHTHALMOLOGY READING CENTRE**



**Central grading of eye exams** 

is, in fact, a window to the body.

Is a Central Reading Centre for multinational and multicentric clinical studies.

CORC focus its activities on grading of ophthalmic exams for characterization and quantification of ophthalmic disease, mainly of the posterior segment/retinal diseases.

## **CNTM - CENTRE FOR NEW TECHNOLOGIES IN MEDICINE**



Develops new medical diagnostic techniques with special emphasis on the

area of eye fundus imaging. The eye offers unique opportunities to obtain in a non-invasive manner information on the body in general and of the retina and brain in particular. It