

CERTIFICATION AND COMPLIANCE



since 1989



since 2004



Data Centre Certification

since 2016



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 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

Development of new medical diagnostic techniques

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 is, in fact, a window to the body.

