

CERTIFICATION AND COMPLIANCE



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 nº 58/2019 applicable to the protection of personal data.



YOUR PARTNER IN CLINICAL RESEARCH



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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

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
- MF and Site File development
- SOPs development
- Regulatory Affairs
- Contracts and Insurance
- Monitoring Plan

In-Study

- Study Coordination
- IMP Management
- Monitoring
- Pharmacovigilance and Risk Management

Post-Study

- Biostatistics
- Final Report
- Medical Writing
- Publication
- Archiving

For eCRF development and management see Data Centre services.



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 is certified by ECRIN and follows SOPs compliant with GCP Guidelines, US FDA 21 CFR part 11 (Guidance for Electronic Records) and ISO 27001 (Information Security Management). Services provided:

- eCRF development
- Database validations and implementation
- eCRF Management and Support
- Data Management
- Data Base Lock
- Data Transfer



CEC - CLINICAL TRIAL CENTRE

Dedicated to perform clinical research studies

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



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 eye fundus imaging. The eye offers unique opportunities to obtain, in a noninvasive manner, information on the body in general and of the retina and brain in particular, allowing timely identification of early alterations and therapeutic interventions.