CERTIFICATION AND COMPLIANCE

ICH - GOOD CLINICAL PRACTICE GUIDELINES

AIBILI follows ICH-GCP since 1989.

CLINICAL TRIALS/CLINICAL STUDIES

AIBILI follows Regulation (EU) No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, as implemented in Portugal by Law No. 9/2026. It also complies with Portuguese Law No. 21/2014 on clinical research, as amended by Law No. 73/2015, Law No. 49/2018, and Law No. 9/2026.

MEDICAL DEVICES

AIBILI follows ISO 14155 and Regulation (EU) No. 2017/745, Portuguese Law No. 71/2025 and Law-Decree No. 29/2024 when performing clinical investigation of medical devices for human subjects.

PERSONAL DATA PROCESSING

AIBILI complies with Regulation (EU) No. 2016/679, Portuguese Law No. 58/2019 and Law 59/2019 applicable to the protection of personal data.

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PRR Plano de Recuperação e Resiliência · REPÚBLICA PORTUGUESA · Financiado pela União Europeia NextGenerationEU · MI MISSÃO INTERFACE · ANI AGÊNCIA NACIONAL DE INOVAÇÃO

YOUR PARTNER IN CLINICAL RESEARCH

Research Technology Organisation
dedicated to clinical research and development of diagnostic imaging solutions

Private non-profit organization established in 1989
with Public Utility recognition

Technology and Innovation Centre
with focus on Human Health

4C - COIMBRA COORDINATING CENTRE FOR CLINICAL RESEARCH

Overall management of clinical research studies

4C 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/MD Management
- Monitoring
- Pharmacovigilance and Risk Management

Post-Study

- Biostatistics
- Final Report
- Medical Writing
- Publication

For eCRF development and management see Data Centre services.

DC - DATA CENTRE

Guarantee clinical data safety and integrity

DC is 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 aligned with GCP Guidelines, EMA Guideline on Computerised Systems and Electronic Data in Clinical Trials, US FDA 21 CFR part 11 (Electronic Records; Electronic Signatures), and ISO 27001 (Information Security Management Systems). Services provided:

- CDMS (Clinical Data Management System) validation, implementation and support
- eCRF development
- Database validations and implementation
- eCRF Management and Support
- Data Management
- Data Base Lock
- Data Transfer
- Long Term Storage

CEC - CLINICAL TRIAL CENTRE

Dedicated to perform clinical research studies

CEC conducts clinical trials and studies with special emphasis in ophthalmology, as well as diabetes, neurology, aging, and oncology. Supported by a multidisciplinary team, state of the art infrastructure, expert oversight and compliance with international research standards, CEC ensures patient safety, scientific integrity, and impactful outcomes that bring better treatments to patients.

CORC - COIMBRA OPHTHALMOLOGY READING CENTRE

Central grading of eye exams

CORC is a leading central reading center supporting multinational and multicentric clinical studies. CORC specializes in the grading and analysis of ophthalmic examinations, providing homogeneous characterization and quantification of eye diseases, particularly those affecting the posterior segment/retinal disorders.

CNTM - CENTRE FOR NEW TECHNOLOGIES IN MEDICINE

AI models + Medical Imaging + Clinical Data

CNTM drives innovation at the intersection of artificial intelligence, image processing, and healthcare. It develops and validates AI models, imaging biomarkers, and trial endpoints to enhance disease characterization, enable early detection, and improve risk stratification.