CERTIFICATION AND COMPLIANCE

since 1989

since 2004

Data Centre Certification

since 2016

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.

4C - Coimbra Coordinating Centre for Clinical Research
AIBILI, Edifício Prof. Doutor José Cunha-Vaz
Azinhaga Sta. Comba, Celas, 3000-548 Coimbra . Portugal
Telephone: +351 239 480 137
E-mail: 4c@aibili.pt Website: www.aibili.pt

FOLLOW US

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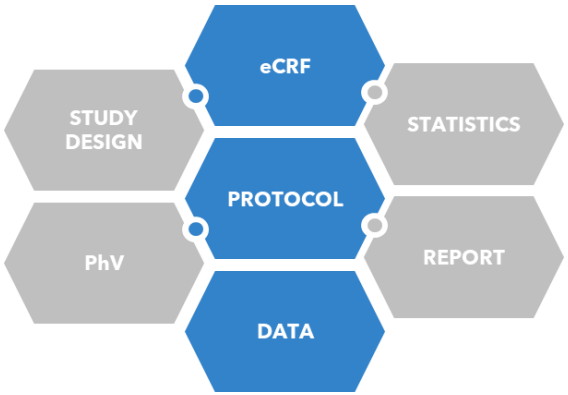
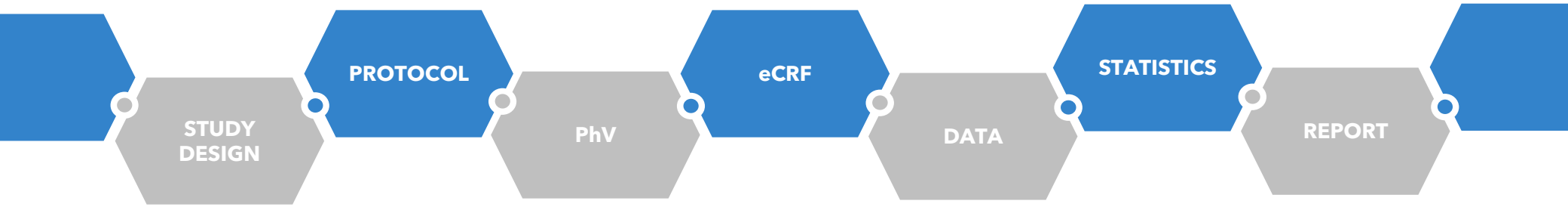
association for innovation and biomedical research on light and image



SUPPORTING YOUR CLINICAL RESEARCH

MARCH 2023



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
- Recording in Clinical Research Platforms

IN-STUDY

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

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).

SERVICES

- CDMS (Clinical Data Management System) validation, implementation and support
- eCRF (Electronic Case Report Form) development and support
- eCRF users helpdesk
- Data export and biostatistics support
- Long Term Storage
- Software development


ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

ECRIN Data Centre Certification program

The ECRIN Independent Certification Board certifies that:

Association for Innovation and Biomedical Research on light and Image (AIBILI)

Located at : Edifício Prof. Doutor José Cunha-Vaz , Azinhaga Sta. Comba, Celas, 3000-548 Coimbra , Portugal

meets the ECRIN requirements for IT and Data Management within Clinical Trials, as per the conclusions of an independent risk based remote audit.

Reference : ECRIN Data Management Standards
Version 4.0, Dated April 2018
Date of certification: February 8 th, 2021

Jacques Demotes-Mainard
ECRIN-ERIC Director Genera

Christian Ohmann
ECRIN Independent Certification Board, Chair

Data Centre Certification since 2016

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