

CERTIFICATION AND COMPLIANCE



since 1989



since 2004



Data Centre Certification

since 2016



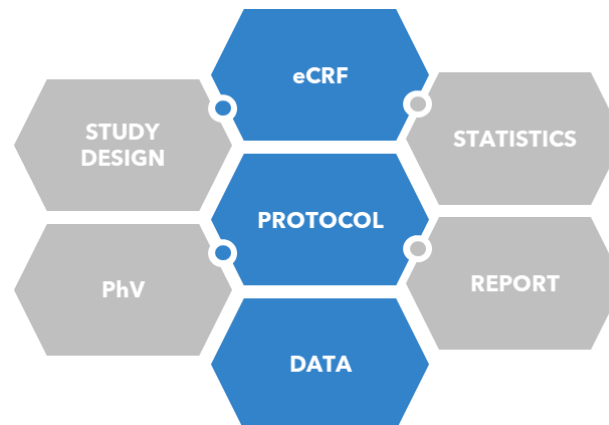
association for
innovation and biomedical
research on light and image

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

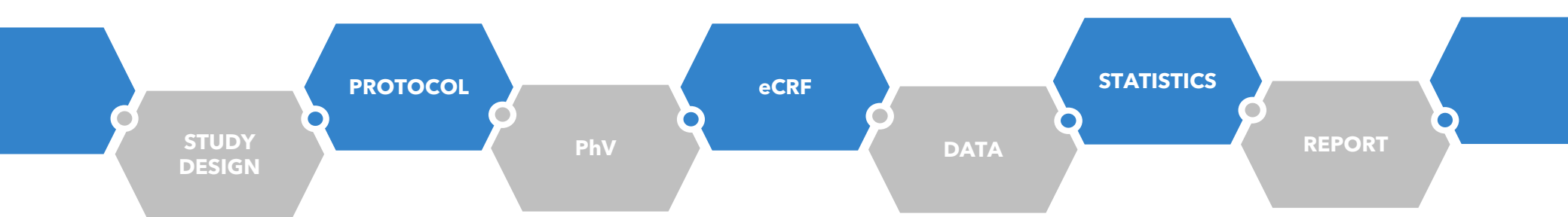
AIBILI complies with Regulation (EU) 2016/679 and Portuguese Law n° 58/2019 applicable to the protection of personal data.



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SUPPORTING YOUR CLINICAL RESEARCH



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).

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



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