

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

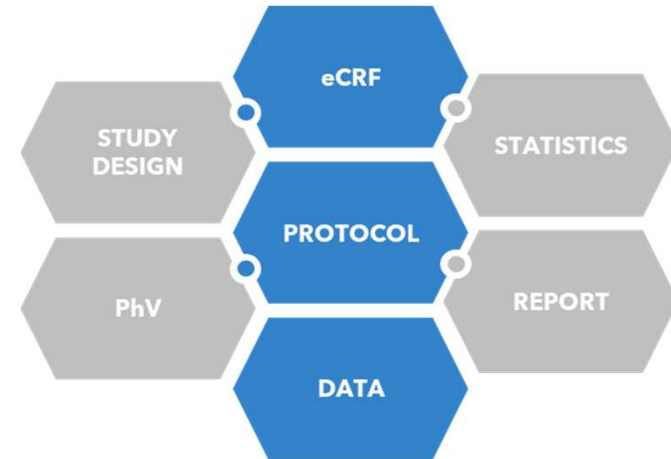


Centro Interface

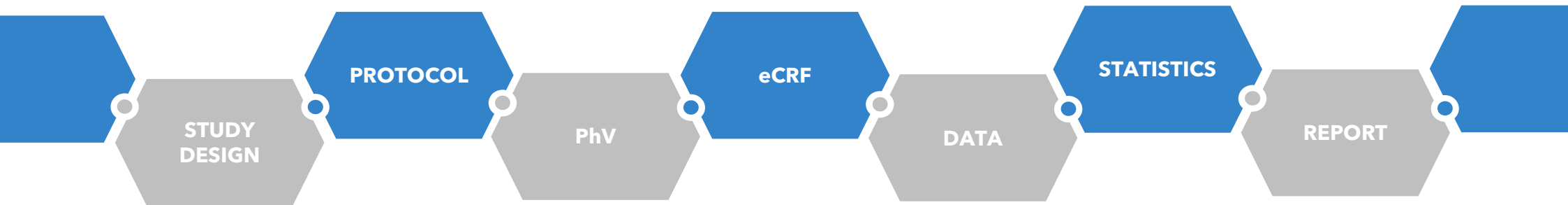


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# SUPPORTING YOUR CLINICAL RESEARCH



## 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