AIBILI
http://www.aibili.pt

Bilateral Meetings

- Wednesday 10:40 h - 13:00 h
- Wednesday 14:00 h - 18:00 h

Description
AIBILI is a Research Technology Organisation in the health area dedicated to the development and clinical research of new products for medical therapy and diagnostic imaging.
It is a private non-profit organisation, founded in 1989, established to support translational research and technology transfer in the health area.
AIBILI is ISO 9001 certified for the following activities: performance of clinical research; planning, coordination, monitoring of clinical research activities; health technology assessment; grading of eye exams; research and development in new technologies for medicine in the areas of imaging, optics and photobiology; preclinical studies of new molecules with potential medical use; and data centre activities.
Organization Type
Research
Areas of Activities

Medical devices

Medical Services

Imaging proceedings

Other

Offer

Logistical support in the development, planning and implementation of multinational clinical studies

AIBILI-4C is a structure to support Investigator-Initiated and Industry-Sponsored Clinical Research complying with ICH GCP - Good Clinical Practice Guidelines and European regulations. 4C provides the necessary logistical support to perform multinational clinical research in Europe, with special emphasis on Investigator- Initiated Research (IIR).
AIBILI is certified by ISO 9001. The AIBILI Data Centre is also certified as an ECRIN-ERIC Data Centre.

Keywords: clinical research academic CRO logistical support investigator initiated research
Offer

Data Centre Services for Clinical Research

The AIBILI Data Centre is a structure to support Investigator Initiated Research providing Data Management and Electronic Data Capture Solutions compliant with ECRIN Data Centre Certification requirements.

The services performed by AIBILI Data Centre are:
• CDMS (Clinical Data Management System) validation, implementation and support
• eCRF (Electronic Case Report Form) development and support
• Key users helpdesk
• Data export and biostatistics support
• Long term storage

Keywords: data centre eCRF clinical storage
Offer

Health Technology Assessment

The Centre for Health Technology Assessment and Drug Research (CHAD) focus is on evaluation of medicines and other medicinal products for market access purposes, aiming at financing and reimbursement and pharmacovigilance.

CHAD provides scientific information to support the decision making in healthcare policy and practice. Health Technology Assessment studies are necessary to ensure equity in the access to medicines and the most favourable benefit/risk and cost/effectiveness ratios in the drug use process. It is, therefore, of capital importance in both drug reimbursement decisions at both ambulatory and hospital settings.

CHAD is also a qualified resource to work closely with Pharmaceutical Industry in all the different phases of drug development.

CHAD provides pharmacovigilance services necessary in clinical studies. It has a pharmacovigilance software fully compliant with the regulations, directives, and the general guidance related to electronic reporting of adverse events (US FDA 21 CFR part 11 and EMA's Good Pharmacovigilance Practice (GVP) Guidelines) for this purpose, as well as SOPs ICH-GCP compliant to perform pharmacovigilance clinical research. It has a license to use MedDRA, a standardised international medical terminology designed for use in safety monitoring of medicinal products through all phases of the development cycle (i.e., from clinical trials to post-marketing surveillance) that supports ICH electronic communication within the E2B Individual Case Safety Report.

AIBILI is ISO 9001 Certified.

AIBILI-CHAD uses PcVmanager, a drug safety management software solution based on the E2B and MedDRA industry

data standards, to classify, create, review, submit, and maintain pharmacovigilance data and Adverse Event reports.

Keywords: market access pharmacovigilance helath technology assessment drug safety