YEARS OF EXCELLENCE
YEARS OF EXCELLENCE
AIBILI - Association for Innovation and Biomedical Research on Light and Image, was founded thirty years ago. Its main goals were to contribute with innovative solutions to our knowledge in the areas of ophthalmology, neurosciences, imaging and pharmacology and to develop tools to improve health care delivery. The scientific work performed at AIBILI has been published regularly in the best international scientific journals and has led to the development of new products.

AIBILI is recognised internationally and has now a leading role in European eye research by coordinating a network of more than 100 clinical research centres (EVICR.net). AIBILI is a sought after research partner that has contributed extensively to translational research, developing new biomarkers of disease progression and treatment response. It is now in the process of coordinating a European network of translational research centres.

AIBILI has achieved during these thirty years a reputation of scientific excellence, adherence to highest and most exigent quality standards and is now an active partner in joint projects with reference centres, such as Harvard Medical School (USA), University of Paris and Institut de La Vision (France), Moorfields Eye Hospital (London, UK), University of Bonn (Germany), University of Milano (Italy), University of Antwerp (Belgium) and Vall d’Hebron Institute of Research (Spain).

AIBILI has been recognized as an Interface Centre by the Portuguese Ministry of Economy, and is the only one in the health sector.

I can say that the main objectives set thirty years ago have been generally fulfilled and I am convinced that in the next thirty years AIBILI will continue to pursue its path on research and innovation in the Health Sector, contributing to the development of scientific knowledge, international collaboration and the economy of Portugal.

José Cunha-Vaz
President
AIBILI - Association for Innovation and Biomedical Research on Light and Image 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 an Interface Centre of the Portuguese Network of the Economy Ministry. It is a private not-for-profit organisation, founded in 1989, established to support technology transfer and translational research in the health area.

AIBILI main areas of activity are:
- Coordination of clinical trials at both national and multinational levels
- Performance of clinical studies
- Centralized grading of eye examinations
- Research and development of new technologies for medicine in the area of imaging
- Health technology assessment
- Data Centre

AIBILI is ISO 9001:2015 certified for all its activities. Clinical research is performed in accordance with ICH - Good Clinical Practice (GCP) Guidelines and national and European regulatory requirements.

AIBILI is located in the area of the Health Campus of Coimbra University since 1994 and has its own building with 1.454 m² and state-of-the-art equipment funded by European Union funds. Regarding human resources it has a permanent staff of 57 including medical doctors, researchers, engineers, pharmacologists, technicians, project managers, statisticians data managers, study coordinators and administrative personnel. Another 54 professionals collaborate regularly in research activities.

The main goals of AIBILI are translational research and innovation contributing to the conversion of basic research knowledge into practical applications in order to improve human health and well-being.
AIBILI is an Interface Centre in the Health Sector of the National Technology Network of the Economy Ministry. This recognition identifies AIBILI as the technology transfer centre acting as the facilitating partner between scientific institutions, enterprises and industry in order to bring novel products to the market.

AIBILI strategy for the period 2019-2021 focuses on its role as Centre for Technological Interface of Portugal in the Health Sector. The innovation and technological objectives focus on:

• Maintaining its position as a Reference Centre for coordination and logistical support of clinical research activities in Europe
• Development of imaging biomarkers of disease progression and response to treatment
• Research on diseases related to ageing of the eye and brain
• Assessment of economic viability in the process of development of new products

In the area of clinical research coordination and logistical support activities it is crucial to maintain its present status of international recognition. The internationalization already achieved with EVICR.net and C-TRACERs Networks create unique opportunities for Portuguese SMEs and research centres to participate in new studies. AIBILI will continue to expand its partnerships with Portuguese companies and universities in order to foster the development of new products.

Innovation is focused in the development of imaging biomarkers of progression and response to treatment of retinal and brain diseases. Ageing of the eye and brain is a research focus of AIBILI. AIBILI will continue contributing to the development of screening programmes using tele-ophthalmology particularly in primary health care centres, promoting clinical research and reaching out to different population of patients. Another focus of AIBILI research is the area of artificial intelligence applications to image analysis of eye images. A main goal of AIBILI is the development and validation of new imaging biomarkers thus creating opportunities for companies of the health sector to develop and market new products.

In the course of the development of new products it is intended by AIBILI to evaluate the economic viability of medicines, design of the value strategy, regulation and translation of technology that will allow greater knowledge of the chain value and transfer of knowledge to SMEs, market access, as well as follow-up and effectiveness after commercialization.
AIBILI Associates

Founding Associates
• FLAD - Fundação Luso-Americana para o Desenvolvimento (Honorary Associate)
• IAPMEI - Instituto de Apoio às Pequenas e Médias Empresas e à Inovação
• José Cotta - EMS, S.A.
• José Cunha-Vaz
• Laboratório EDOL - Produtos Farmacêuticos, S.A.
• Biofísica da Faculdade de Medicina da Universidade de Coimbra
• Farmacologia da Faculdade de Medicina da Universidade de Coimbra
• Serviço de Dermatologia do Centro Hospitalar Universitário de Coimbra
• SUCH - Serviço de Utilização Comum dos Hospitais

Other Associates
• Alcon Portugal - Prod. e Equip. Oftalmológicos, Lda.
• BIAL - Portela & Cª, SA
• Centro de Oftalmologia da Universidade de Coimbra
• Conceição Lobo
• Francisco Batel Marques
• Fundação Champalimaud (Honorary Associate)
• Hospital CUF Coimbra / José de Mello Saúde
• Laboratórios Pfizer, Lda.
• Novartis Farma, SA
• Universidade de Coimbra (Honorary Associate)

AIBILI Board of Directors
(2017-2020)

• José Cunha-Vaz, President
• José Cotta - EMS, SA, Vice-President (Conceição Lobo)
• BIAL - Portela & Cª, SA (Tice Macedo)
• Fundação Champalimaud (António Parreira)
• Laboratórios Edol, Produtos Farmacêuticos, SA (Gonçalo Pimpão)
• Serviço de Dermatologia do Centro Hospitalar Universitário de Coimbra (Américo Figueiredo)
• Francisco Batel Marques
ORGANIGRAM

Boards of Directors
President
José Cunha-Vaz

CEO
Cecília Martinho

Administrative Services (SA)
Cecília Martinho

Quality Management (QMU)
Rita Fernandes

Translational Research and Technology Transfer (UTT)
Daniel Fernandes

Information Technology (IT)
Data Centre (DC)
Carlos Domingues

Coordinating Centre
Cecília Martinho

Coimbra Coordinating Centre for Clinical Research 4C
Sandrina Nunes

Clinical Trial Centre
CEC
Inês Marques

Coimbra Ophthalmology Reading Centre
CORC
Conceição Lobo

Centre for New Technologies in Medicine
CNTM
José Cunha-Vaz

Centre for Health Technology Assessment and Drug Research
CHAD
Francisco Batel-Marques

AIBILI 2019 REPORT
30 YEARS AT A GLANCE

- 1989: AIBILI Foundation
- 1991: Public Utility recognition
- 1994: 1st Building in the Coimbra University Health Campus
- 1999: Good Laboratory Practices certification
- 2004: ISO 9001 certification
- 2008: Expansion of AIBILI, CORC and CHAD

Coordinating Centre
<table>
<thead>
<tr>
<th>Year</th>
<th>Event/Recognition</th>
</tr>
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<tr>
<td>2009</td>
<td>Expansion of AIBILI 4C</td>
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<tr>
<td>2010</td>
<td>Official market launch</td>
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<tr>
<td>2016</td>
<td>Establishment of Data Centre certification</td>
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<tr>
<td>2017</td>
<td>Establishment of DruSERoNet</td>
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<tr>
<td>2019</td>
<td>Recognition by Ministry of Economy</td>
</tr>
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</table>

**Key Statistics (2018-2019):**

- **Fulltime Staff:** 57
- **Nº of PhD:** 19
- **Nº of Consultants:** 37
- **Nº of Ongoing studies, services, projects, contracts:** 106
- **Nº of Patents:** 4 (USA) + 1 (Europe)
- **Nº of European Union funded projects (ongoing):** 2
- **Nº of Publications (2018-2019):** 89
- **Nº of Publications / PhD (2018-2019):** 4.7
AIBILI is organized in Research Centres and Organizational Units.

The Research Centres are:
• Coimbra Coordinating Centre for Clinical Research (4C)
• Clinical Trial Centre (CEC)
• Coimbra Ophthalmology Reading Centre (CORC)
• Centre for New Technologies in Medicine (CNTM)
• Centre for Health Technology Assessment and Drug Research (CHAD)
• Data Centre (DC)

Organizational Units are:
• Administration (SA)
• Quality Management Unit (UGQ)
• Translational Research and Technology Transfer Unit (UTT)
• Information Technology Unit (IT)

**AIBILI RESEARCH CENTRES AND UNITS**

**In Vitro and In Vivo Study**

**Clinical Development**

**Pre-Clinical**

**Clinical Trials**

**PHASE I**
Tests safety, dosage and side effects
Healthy individuals

**PHASE II**
Tests efficacy and side effects
Affected individuals

**PHASE III**
Tests long term effectiveness and comparison with other medications
Wider group of affected individuals

**Regulatory Review and Approval**

**PHASE IV**
Continuous tests for effectiveness and side effects
Patients under treatment

**Post-Approval Research and Monitoring**

**AIBILI**

From Pre-Clinical To Clinical
CHAD and 4C

Design, Conducting and Monitoring Clinical Studies
CEC, 4C and CHAD

HTA and Market Access
CHAD

Effectiveness and Pharmacovigilance
CEC, 4C and CHAD

**AIBILI 2019 REPORT**
4C - COIMBRA COORDINATING CENTRE FOR CLINICAL RESEARCH

Director: Sandrina Nunes, PhD

Staff: Beatriz Melício, Cecília Martinho, Conceição Lobo, Daniel Fernandes, Daniel Silva, Joana Tavares, Laura Seco, Liliana Carvalho, José Cunha-Vaz, Maria Viegas Nascimento, Mónica Fernandes, Pier Basile, Rita Coimbra, Rita Fernandes, Sónia Simões, Vanessa Santos

The Coimbra Coordinating Centre for Clinical Research (4C) is a structure to support the development and coordination of Investigator Initiated and Industry Sponsored Clinical Research by providing the following services:

**PRE-STUDY**
- Study Design
- Statistical Planning
- Development of Protocol and Informed Consent
- eCRF Development
- Database Validations and Implementation
- MF and Site File development
- Clinical Centre Selection
- SOPs Development
- Submission to RAs
- Insurance and Contracts
- Monitoring Planning

**IN-STUDY**
- Study Coordination
- IMP Management
- eCRF Management and Support
- Data Management
- Monitoring
- Pharmacovigilance

**POST-STUDY**
- Data Base Lock
- Biostatistics
- Final Report
- Regulatory Affairs
- Publication

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**Nº of Projects Coordinated by 4C (2017-2019)**

<table>
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<th>Year</th>
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</tbody>
</table>

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Contacts
Sandrina Nunes, PhD
Phone: +351 239 480 137
E-mail: sandrina@aibil.pt
Representative Publications


The Clinical Trial Centre (CEC) performs randomized clinical trials with special emphasis on ophthalmology. CEC has dedicated facilities and updated ophthalmological equipment. Clinical patient-oriented research involves characterizing disease progression and testing new discoveries by carrying out controlled research studies in patients, i.e., clinical trials. This includes testing not only new drugs, but also new methods, devices, imaging and surgical procedures as well as well-designed prospective, non-interventional, longitudinal studies.

Our research is focused in age-related eye diseases with special emphasis on diabetic retinopathy and age-related macular degeneration. The CEC has proven expertise and scientific publications in these areas and is a certified Clinical Site of Excellence by the EVICR.net - European Vision Institute Clinical Research Network since 2006. The CEC has experienced and qualified staff and the necessary equipment to perform clinical research according to ICH GCP Guidelines and uses an Electronic Medical Record in its daily routine.

Nº of Investigator Initiated and Industry Sponsored Studies performed at CEC (2017-2019)

<table>
<thead>
<tr>
<th>Year</th>
<th>Investigator Initiated</th>
<th>Industry Sponsored</th>
<th>Total</th>
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<tr>
<td>2019</td>
<td>5</td>
<td>13</td>
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</table>
**Investigator Initiated Studies**

**Diabetic Retinopathy**

1. **PROGRESS** - Progression of Diabetic Retinopathy. Identification of Signs and Surrogate outcomes
   ClinicalTrials.gov nº NCT 03010397

2. **CORDIS** - Characterization of retinal vascular disease in eyes with mild to moderate Nonproliferative diabetic retinopathy in Diabetes type 2, using novel non-invasive imaging methods, in a longitudinal and prospective clinical study with 2 years of duration
   ClinicalTrials.gov nº NCT03696810
   Financial support: Portugal 2020 - 02/SAICT/2017 - Project nº 030375

**Age-Related Macular Degeneration**

3. **MACUSTAR** - Intermediate AMD: Development of novel clinical endpoints for clinical trials in patients with a regulatory and patient access intention
   ClinicalTrials.gov nº NCT03494801
   Financial Support: European Union and EFPIA - Innovative Medicines Initiative 2 Joint Undertaking - Grant Agreement nº 116076

**Retinal Degenerative Diseases**

4. **STAR** - Development of a Model for Advanced Screening for Timely Treatment of Age-Related Eye Diseases

5. **EYEMARKER** - Characterization of potential biomarkers of Eye Disease and Vision Loss
   ClinicalTrials.gov nº NCT02500862

**Industry Sponsored Clinical Trials**

**Diabetic Macular Edema**

1. An Open Label, Registry Study of the Safety of ILLUVIEN® 190 Micrograms Intravitreal Implant in Applicator (IRISS)
   ClinicalTrials.gov nº NCT01998412

2. An open-label, randomized, active-controlled, parallel-group, Phase-3b study of the efficacy, safety, and tolerability of three different treatment regimens of 2 mg aflibercept administered by intravitreal injections to subjects with diabetic macular edema (DME) (VIOLET - BAY 86-5321/17613)
   EudraCT nº 2014-004938-25

3. A phase III, multicentre, randomized, double-masked, active comparator-controlled study to evaluate the efficacy and safety of RO6867461 in patients with diabetic macular edema (Rhine)
   EudraCT nº 2017-005105-12

4. A two-year, three-arm, randomized, double-masked, multicentre, phase III study assessing the efficacy and safety of brovilucumab versus aflibercept in adult patients with visual impairment due to diabetic macular edema (KESTREL)
   EudraCT nº 2017-004742-23

5. A randomized, double-masked, placebo-controlled exploratory study to evaluate safety, tolerability, pharmacodynamics and pharmacokinetics of orally administered BI 1467335 for 12 weeks with a 12 week follow up period in patients with non-proliferative diabetic retinopathy without center-involved diabetic macular edema (ROBIN Study)
   EudraCT nº 2016-002971-91

**Age-Related Macular Degeneration**

6. An open-label, randomized, active-controlled, parallel-group, Phase-3b study of the efficacy, safety, and tolerability of 2 mg aflibercept administered by intravitreal injections using two different treatment regimens to subjects with neovascular age-related macular degeneration (nAMD) (AZURE)
   EudraCT nº 2012-003763-22

7. A Multicenter, Double Masked, Randomized, Dose-Ranging Trial to Evaluate the Efficacy and Safety of Conbercept Intravitreal Injection in Subjects with Neovascular Age-Related Macular Degeneration (PANDA)
   EudraCT nº 2017-004825-34

**Glaucoma**

8. Long-Term Surveillance Study of Latanoprost to Monitor Hyperpigmentation changes in the eye in Pediatric Populations (A6111144)

**Neurological Disorders**

   EudraCT nº 2012-003056-36

10. A multi-site, open-label extension Trial of Oral RPC1063 in relapsing Multiple Sclerosis (RPC01-3001)
    EudraCT nº 2015-002500-91

11. Multicenter, randomised, double-blind, parallel-group, active-controlled, superiority study to compare the efficacy and safety of ponseimod to teriflunomide in subjects with relapsing multiple sclerosis (AC-058301 - OPTIMUM)
    EudraCT nº 2012-000540-10

12. Multicenter, non-comparative extension to study AC-058301, to investigate the long-term safety, tolerability, and control of disease of ponesimod 20 mg in subjects with relapsing multiple sclerosis
    EudraCT nº 2016-004719-10

**Cancer**

13. A randomized, open label, multicenter Phase 2/3 study to evaluate the efficacy and safety of rogaratinib (BAY 1163877) compared to chemotherapy in patients with FGFR-positive locally advanced or metastatic urachal carcinoma who have received prior platinum-containing chemotherapy
    EudraCT nº 2016-004340-11
Representative Publications


CORC – COIMBRA OPHTHALMOLOGY READING CENTRE

Director: Conceição Lobo, MD, PhD

Staff: Adozinda Simão, Alda Baltar, Amélia Martins, Ana Paula Pascoal, Ana Raquel Branco, Ana Rita Santos, Carla Sofia Gomes, Catarina Neves, Christian Schwartz, Cláudia Farinha, Inês Marques, Isa Sobral, Isabel Pires, João Gil, João Pedro Marques, José Cunha-Vaz, José Filipe Costa, Marco Marques, Mariana Costa, Maria Luísa Ribeiro, Maria da Luz Cachulo, Marta Lopes, Patricia Ferro, Renata Castanheira, Rui Alberto Pita, Silvia Simão, Telmo Miranda

The Coimbra Ophthalmology Reading Centre (CORC) focus its activities in grading retinal diseases on fundus images and OCT images of the retina, as well as functional evaluations of the retina using mfERG and visual fields. It serves as central Reading Centre for a series of multinational-multicentric clinical studies, mainly in Diabetic Retinopathy (DR) and Age-related Macular Degeneration (AMD). CORC is also the central Reading Centre for the Diabetic Retinopathy Screening Programme of the Central Region of Portugal since 2011.

CORC has a secure custom-designed web based tool to transmit images between Clinical Sites and CORC (https://studies.corc.pt/). This system is hosted in the AIBILI’s Data Centre.

For grading purposes CORC uses licensed software from the equipment suppliers, such as Cirrus HD-OCT (Carl Zeiss Meditec), Heidelberg Eye Explorer (Heidelberg Engineering), RETIsystem (Roland Consultant), Topcon OCT (Topcon Corporation), etc.

For research, CORC has novel in-house developed software to assess microaneurysm turnover in DR (RetmarkerDR®), classify and quantify AMD lesions (RetmarkerAMD) and perform segmentation of the retinal layers on OCT.
Receive and Grade Exams from

AUSTRIA  BELGIUM  BULGARIA  CANADA  CZECH REPUBLIC  ESTONIA  FRANCE  GERMANY  HUNGARY  INDIA  ISRAEL  ITALY  LATVIA  LITHUANIA  POLAND  ROMANIA  RUSSIA  SLOVAKIA  SPAIN  SWITZERLAND  UK  UKRAINE  USA

Nº of Projects at CORC (2017-2019)

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<td>2019</td>
<td>8</td>
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</table>
Representative Publications


The Centre for New Technologies in Medicine (CNTM) develops new medical diagnostic techniques with special emphasis on the area of eye fundus imaging.

The eye offers unique opportunities to obtain in a non-invasive manner information on the body, in general and of the retina and brain in particular. It is, in fact, a window to the body. We are particularly interested in methodologies that allow repeated observations and measurements in order to identify early alterations that may allow timely therapeutic interventions, e.g., precision medicine.

Our group has been able to identify novel biomarkers of disease progression, such as microaneurysm turnover in diabetic retinopathy identified automatically by software developed in-house, the Retmarker®, and fluid quantification in the retinal diseases by identifying noninvasively changes in the Blood-Retinal Barrier in the retina, using a novel patented algorithm, the OCT-Leakage.

### Research Focus

- Multimodal imaging of retinal disease
- Characterization of capillary closure as the main alteration that identifies diabetic retinopathy progression
- OCT-Leakage. Layer by layer fluid analysis of the retina
- Characterization of prognostic biomarkers of retinal disease progression using artificial intelligence
- Characterization of response to anti-VEGF treatment in Diabetic Macular Edema

### Nº of Projects at CNTM (2017-2019)

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<th>Year</th>
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<td>2019</td>
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</tbody>
</table>
Representative Publications


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.

Since 2008 CHAD has been responsible for a Pharmacovigilance Unit of the National Pharmacovigilance System which is contracted with the National Authority of Medicines and Health Products (INFARMED, IP).
### Nº of Projects at CHAD (2017-2019)

<table>
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<tr>
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</table>

### Representative Publications


DC – DATA CENTRE

Director: Carlos Domingues, BSc

Staff: Celina Cangueiro, Hugo Morgado, José Monteiro, Patrícia Silva, Telmo Miranda, Torcato Santos

AIBILI Data Centre was built specifically to support AIBILI’s information systems but the existing space and environment conditions allow to grow up to store clients/partners data and information. Inside the Data Centre, the server racks are connected to two separate power circuits, protected by two redundant Uninterruptable Power Supplies (UPS). These redundant power supply units ensure that a failure of one power supply unit does not cause any problems and that power is always supplied to servers. The UPS also ensures that the quality remains constant. It compensates for voltage and frequency fluctuations and thereby effectively protects sensitive computer electronic components and systems. Block batteries ensure that all operating applications can run for almost three hours. For Data Centre cooling AIBILI has implemented a cold air container solution with redundant air conditioning units. The air is directed to the container through the floor and flows through the racks, dissipating the heat produced by servers and providing adequate temperature and humidity for electronic equipment’s. Water detection sensors on the floor and automatic fire extinguisher (based on gas-based suppression system FM200) complements the Data Centre asset-protection.

Presently Information Technology Unit maintains more than 30 servers, either virtual or physical supported on different operating systems and technologies. There are specific Standard Operating Procedures (SOPs) in place, developed according IT best practices such as Information Technology Infrastructure Library (ITIL), and project management standards such as recommended by the Project Management Institute (PMI). All changes in the production environment are preceded by testing and validation processes, according to GAMP5 V-model and methodology. This Unit is responsible to guarantee the safety and integrity of the data and images collected all in compliance with GCP Guidelines and applicable national legislation. AIBILI specific SOPs for Information Technology and Data Centre also comply with US FDA 21 CFR part 11 (Guidance for Electronic Records) and ISO 27001 (Information Security Management). Regular internal audits and penetration tests are performed to ensure the safety and integrity of data.

All this information is categorized and specific backup policies are defined according information value. Long term storage procedures are in place to assure all the information lifecycle. Information Technology Unit manages over than 30 TB of useful storage (clinical images and databases, administrative information, project information and long term storage).

AIBILI Data Centre is certified by ECRIN - European Clinical Research Infrastructure Network (www.ecrin.org) since April 2016. Compliance with ECRIN v3 standards confirms AIBILI capacity to provide appropriate and effective data management services for multinational, randomised controlled studies.

Contacts
Carlos Domingues, BSc
Phone: +351 239 480 150
E-mail: cdomingues@aibili.pt
Main Activities

- CDMS (Clinical Data Management System) validation, implementation and support
- eCRF (Electronic Case Report Form) development and support
- Key users helpdesk
- CORC-IT platform support
- Data export and biostatistics support
- Long Term Storage
- EVICR.net webinar platform
- Software development

Nº of Projects at DC (2017-2019)

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ORGANIZATIONAL UNITS

ADMINISTRATION

CEO: Cecília Martinho
Staff: Laura Seco, Mara Miraldo, Marco Santos, Paulo Barros, Tânia Melro

The Administrative Services are responsible for the management of AIBILI and to perform all the necessary administrative tasks, including finances and accountability, human resources management, as well as maintenance of infrastructure according to the institution’s needs. The Administrative Services establishes a direct liaison between the Board of Directors of AIBILI and its Centres and supporting Units.

QUALITY MANAGEMENT UNIT (QMU)

Staff: Cecília Martinho, Rita Fernandes, Marta Ventura

The Quality Management Unit (QMU) guarantees that AIBILI has the necessary resources to provide the services and meet the needs of its Clients and interested parties. The QMU assures that the Quality Management System (QMS) is maintained effective and efficient permitting improvement. AIBILI is ISO 9001 certified for the activities of: Research and Development in New Technologies for Medicine with particular emphasis in the Areas of Imaging, Optics and Photobiology; Performance of Clinical Studies; Planning, Coordination, Monitoring of Clinical Research Activities; Health Technology Assessment; Grading of Eye Exams; and Data Centre Activities.

It has a Standard Operating Procedure (SOP) Manual which contains general organizational SOPs and specific SOPs for each process, in compliance with ISO 9001:2015, ICH-GCP Guidelines, requirements for Certification of ECRIN Data Centres, General Data Protection Regulation (EU) 2016/679 and applicable national law, as well as other regulatory requirements, statutory and legal, applicable to AIBILI activities.

Currently the paper Document Management System (SOP Manual) is being transposed into a digital format to streamline the access to management information, approvals, records and archiving.

Internal auditing is a guarantee that procedures are followed at AIBILI and the QMS is in improvement to enhance customer satisfaction by meeting customers’ requirements.

AIBILI’s Quality Management Unit also provides consultancy services to other healthcare institutions to implement quality systems ISO 9001 and ICH-GCP compliant due to its long and vast experience in this field.
TRANSLATIONAL RESEARCH AND TECHNOLOGY TRANSFER UNIT (UTT)

Staff: Cecília Martinho, Daniel Fernandes, Maria Madeira

The Translational Research and Technology Transfer Unit is responsible to provide all the support to facilitate and promote the transfer of R&D activities and pre-clinical studies to the development of clinical studies and to enhance the adoptions of best practices in the community. It is responsible for identifying perspectives and perform analysis of technology transfer, creating the conditions for contracting with industry and other stakeholders, namely intellectual property implications.

This Unit is responsible to identify opportunities and apply for external funding, namely R&D programs in the health market. Currently it is responsible for AIBILI participation in European Union projects and supporting the other partners on administrative and legal issues.

The Translational Research and Technology Transfer Unit is responsible for promoting AIBILI and its Centres and is the main contact point for establishing partnership and collaborations with other institutions.

INFORMATION TECHNOLOGY UNIT (IT)

Staff: Celina Cangueiro, Carlos Domingues, Hugo Morgado, Patrícia Silva, Telmo Miranda, Torcato Santos, José Monteiro

The Information Technology Unit is responsible for the management and maintenance of AIBILI Data Centre, IT networks and information systems. The Data Centre, built in 2014 for storing AIBILI’s critical information, houses all AIBILI servers/systems: the Electronic Medical Record that is daily used to collect patient clinical information at CEC; the custom-designed web based platform used to exchange grading data and images by CORC (https://studies.corc.pt/); the Clinical Data Management System that is used in the development of eCRFs for each clinical study; the PhVC Manager – Extedo that is used for pharmacovigilance in clinical studies by CHAD as well as the Clinical Trial Management System (CTMS) used for the management of multiple multinational clinical studies by 4C. There are also other administrative information systems supported in AIBILI’s Data Centre. AIBILI’s Data Centre houses EVICR.net website (www.evicr.net), EVICR.net Educational Programme webinar platform (https://cloud.aibili.pt/evicrnet_webinars) and also supports other administrative/office information systems.

AIBILI Data Centre is certified by ECRIN - European Clinical Research Infrastructure Network (www.ecrin.org) and is part of the ECRIN Data Centre Network. AIBILI Data Centre can provide safe, secure, compliant and efficient management of clinical research data.
ETHICS COMMITTEE

AIBILI has an Independent Ethics Committee (IEC/IRB) that is responsible for protecting the rights, safety and wellbeing of human subjects involved in clinical studies (not involving Investigational Medicinal Products (IMP’s) or medical devices) performed at AIBILI according to the Portuguese Law nº 97/95 of 10 May.

AIBILI Ethics Committee is available to be called upon CEIC’s request, in case it is needed for the review of ophthalmology clinical trials or studies since it has expertise in this scientific area.

MEMBERS

President
André Dias Pereira, PhD
(Director of the Centre for Biomedical Law of the University of Coimbra and Professor at the Faculty of Law, University of Coimbra)

Vice-President and Secretary
Margarida Duarte Ramos Caramona, PhD
(Emeritus Professor at the Faculty of Pharmacy, University of Coimbra)

José António Moura Pereira, MD
(Ophthalmologist at the University Hospital of Coimbra)

Maria Elizabete Batista Geraldes, MD
(Endocrinologist at the University Hospital of Coimbra)

Paulo Simões, BSc
(Father, Director of University Institute of Justice and Peace, Coimbra)

Filomena Maria Ferreira Ramos Mena, BSc
(Nurse at the National Institute of Forensic Medicine, Coimbra)

Maria Cecília Martinho, BSc
(AIBILI CEO)

Contacts
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Throughout its thirty years of existence, AIBILI has created an excellence track record in ophthalmology clinical research, being internationally recognized for its innovation in the area of imaging biomarkers and diagnostics. With the huge acceleration in innovation in the past years, and the increased complexity in medical needs, it has become crucial to science to escort this acceleration. Researchers must provide more insight on disease understanding and deliver more healthcare solutions to promote and protect human health. Likewise, AIBILI also needs to keep up its pace in innovation. In order to promote science and technology advancement and bring potential new treatments and diagnostic tools to the market, in 2019 AIBILI has assumed an integrated Strategic Research Plan with five main research pathways.
Diabetic Retinopathy (DR) remains a major cause of blindness as the prevalence of diabetes is expected to approximately double globally between 2000 and 2030. DR progresses over time at different rates in different individuals with only a limited number developing significant vision loss due to the two major vision-threatening complications, clinically significant macular edema and proliferative retinopathy. Good metabolic control is important to prevent and delay progression, but whereas some patients escape vision loss even with poor control, others develop vision loss despite good metabolic control. Our research group has been able to identify three different DR phenotypes characterized by different dominant retinal alterations and different risks of progression to vision-threatening complications. Microaneurysm turnover (MAT) has been validated as a prognostic biomarker of development of clinically significant macular edema, whereas subclinical macular edema identified by Optical Coherence Tomography (OCT) appear to be also a good candidate as organ-specific bio markers of DR. Haemoglobin A1c (HbA1c) remains the only confirmed systemic prognostic biomarker of DR progression.

The identification of different phenotypes of DR with different risks for development of vision-threatening complications opens new avenues for the comprehension of DR onset.

Projects

PROGRESS – Progression of Diabetic Retinopathy. Identification of Signs and Surrogate outcomes
ClinicalTrials.gov nº NCT 03010397

PROGRESS is a project dedicated to characterize the 5-year progression of mild non-proliferative DR (NPDR), in patients with diabetes type 2, to vision-threatening complications. Through this work, the predictive risk of ocular and systemic markers will be accessed to identify prediction methods for disease development and progression. Moreover, in the retinal neurodegenerative steps in different stages of DR will be explored.

CORDIS - Characterization of retinal vascular disease in diabetes type 2, using novel non-invasive imaging methods
ClinicalTrials.gov nº NCT03696810
Financial support: Portugal 2020 - 02/SAICT/2017 - Project nº 030375

The main objective of this project is to better characterize, using new methods, OCTA and OCT-Leakage, the evolution and progression of phenotypes B and C of DR identifying eyes that show worsening and disease progression to sight-threatening DR (progression phenotypes), allowing for a better characterization of the two main features of the leaky or ischemic progresor phenotypes, using non-invasive methodologies.

RECOGNISED - Retinal and cognitive dysfunction in type 2 diabetes: unravelling the common pathways and identification of patients at risk of dementia
Sponsor: VHIR, Barcelona, Spain
Financial support: Horizon2020 – SC1-BHC-2019 – Project nº 847749

RECOGNISED is a multicentre, multinational study that aims to investigate the common mechanisms involved in the pathogenesis of DR and cognitive impairment in the type 2 diabetes (T2D). At the end, a main goal is to use the retina as a tool to identifying individuals with T2D at a higher risk of developing cognitive decline or dementia.
Representative Publications


Age-related macular degeneration (AMD) is the leading cause of adult blindness in developed countries, which affects almost 30% of the older population. In fact, with the aging of population, AMD will become globally an increasingly important and prevalent disease worldwide. The hallmark of the early phases of AMD are macular drusen and pigmentary changes, and it progresses slowly from early AMD to intermediate AMD (iAMD) and ultimately late-stage AMD with severe and frequently irreversible lesions. Of note, it is probable that the early and intermediate forms of AMD do not represent a single disease, but rather a collection of subtypes, which ultimately progress to the advanced forms. Therefore, elucidating these subtypes and their underlying pathogenesis will be critical in developing effective therapies for these earlier stages of AMD.

The aetiology of AMD is complex, and although genome-wide and gene-candidate studies have been enabled to identify genetic variants associated with AMD pathogenesis, studies on gene-environment interactions have gain increased relevance on the disease onset. Hence, an healthy diet and the use of nutritional supplements created the environment for prevention in this area.

Projects

**Metabolomics, Genetics and Environment - A novel integrative approach to Age-Related Macular Degeneration**

This project purposes to characterize the metabolome of AMD progression over five years and evaluate the relationship between metabolomics and genetics in AMD and identify new candidate AMD-metabolite associations.

It will provide unique insights into the AMD pathogenesis and progression and has the potential to identify novel potential future biomarkers, which can ultimately lead to precision medicine in AMD.

**COIMBRA EYE STUDY - Epidemiological study of the prevalence and incidence of Age-Related Macular Degeneration in Portugal**

ClinicalTrials.gov nº NCT01298674 and NCT02748824

**Age-related Macular Degeneration in Portugal - Prevalence, incidence and risk factors in the era of multimodal imaging**

The main objective of this project is to take advantage of multimodal evaluation of possible risk factors and biomarkers, demographic factors, genetics and structural markers, to evaluate a possible progression biomarker and infer on an association with fast progressor AMD phenotype or another particular phenotype.
Age-Related Macular Degeneration: Genetic susceptibility, Nutrition and Lifestyle
The purpose of this project is to determine the effect modification on the risk of AMD onset and progression of high-risk patients due to nutrition and lifestyle. It will assess on what grounds food, nutrients and lifestyle protect or not patients at genetic risk for AMD.

ATLANTIC - A Randomized, Double-masked, Sham-controlled Phase 4 Study of the Efficacy, Safety, and Tolerability of Intravitreal Aflibercept Monotherapy Compared to Aflibercept With Adjunctive Photodynamic Therapy in patients with Polypoidal Choroidal Vasculopathy
EudraCT n° 2015-001368-20
ClinicalTrials.gov n° NCT02495181

Atlantic is a multicentre study dedicated to compare the efficacy and safety of intravitreal aflibercept (IVA) with sham photodynamic therapy (sPD) versus IVA with verteporfin photodynamic therapy (sPD) in a Caucasian population with treatment-naive PCV, enrolling in a treat and extend regimen.

Phenotypic and genotypic characterization of Polypoidal Choroidal Vasculopathy (PCV) in Caucasian populations.
A multicenter retrospective study
This study aims to characterize the genetic, anatomical and imaging features of PCV in a large Caucasian population in order to provide a better understanding of this condition in this specific ethnicity.

MACUSTAR - Intermediate AMD: Development of Novel Clinical Endpoints for Clinical Trials in Patients with a Regulatory and Patient Access Intention
Sponsor: UKB, Bonn, Germany
ClinicalTrials.gov n° NCT03349801
Financial Support: European Union and EFPIA - Innovative Medicines Initiative 2 Joint Undertaking - Grant Agreement n° 116076

The major objective of MACUSTAR is to develop novel clinical endpoints for clinical trials with a regulatory and patient access intention in the area of functional, structural, and patient-reported outcome measures in patients with intermediate age-related macular degeneration (iAMD). MACUSTAR will also characterize visual impairment in iAMD and its progression, as well as identify risk factors for progression to late-stage AMD.

Representative Publications


IMAGING BIOMARKERS RESEARCH PROGRAM

Coordinator: Conceição Lobo
Research Team: Ana Rita Santos, José Cunha-Vaz, João Figueira, Luís Mendes, Maria Madeira, Telmo Miranda, Torcato Santos

The eye offers unique opportunities to obtain in a non-invasive manner information on the body, in general and of the retina and brain. It is, in fact, a window to the body. The retinal circulation and the retina can be examined using a variety of methods. Fundus Digital Photography, Optical Coherence Tomography (OCT) and Optical Coherence Tomography Angiography (OCTA) are non-invasive examinations that offer extremely promising perspectives as the information collected can be analysed automatically. The analysis of the data can also be tailored to specific purposes, allowing validating imaging biomarkers of disease. These imaging biomarkers may give information on retinal and eye disease but also may serve as indicators of systemic disease, such as brain degenerative diseases and circulatory disorders.

Our group has been able to identify biomarkers of disease progression, such as MA turnover in diabetic retinopathy identified automatically by software developed in-house, the Retmarker®, and identify non-invasively changes in the Blood-Retinal Barrier in the retina, using also a novel AIBILI patented algorithm, the OCT-Leakage.

Development of new imaging techniques of the eye fundus without disturbing in any way the ocular and body environment. Particular interest is given to methodologies that allow repeated observations and measurements in order to identify early alterations and the degree of activity of these alterations when present over time.

Projects

Identification of Capillary Closure in using Optical Coherence Tomography Angiography
The major goal is to identify reliable methods to quantify retinal vascular alterations, which allow disease characterization and identification of the different disease progression groups. As ultimate goal, we aim on facilitate disease stage identification in clinical practice, as well as to facilitate the identification of patients with higher risk for progression.

OCT-Leakage. Layer by layer fluid analysis of the retina
Our group is developing applications that resort to advanced imaging algorithms to enable analysis of OCT data, focusing on the segmentation of the different layers of the retina and the permeability of the Blood-Retinal Barrier. A novel analysis “Method and device for the non-invasive indirect identification of sites of alterations of the Blood–Retinal Barrier” was published under the Patent Cooperation Treaty number WO2016/174637A1.

Artificial intelligence for characterization of retinal biomarkers
The purpose is the development, testing, and validation of cognitive computing methods applied to state-of-art imaging data to be used in the screening and management of eye disease.

FILTER - Framework to Develop and Validate Automated Image Analysis Systems for Early Diagnosis and Treatment of Eyes at Risk in Blinding Age-Related Diseases
Financial support: Portugal 2020 - 02/SAICT/2017 - Project nº 032412
FILTER aims to development and validation of a prototype to be used in the screening and management of blinding age-related diseases. The prototype will allow the detection, characterization, and follow-up of lesions associated with AMD and DR. Novel methods will be developed for the analysis of OCT imaging data and CFP images.

ADRIAN - Development and Validation of a Machine Learning Algorithms for Automated Prediction of Diabetic Retinopathy Progression
Partnership with Roche.
With this collaboration, ROCHE and AIBILI expects to develop and validate a machine learning (ML) algorithms that automatically predict Diabetes Mellitus patients that are at high risk for progression in Diabetic Retinopathy severity and vision-threatening conditions.
Research Contracts and Partnerships

Quantification of Retinal Microvasculature in Retinal Disease
Sponsor: Carl Zeiss Meditec, USA

ADRIAN - Development and Validation of a Machine Learning Algorithms for Automated Prediction of Diabetic Retinopathy Progression
Sponsor: Roche, Switzerland

Representative Publications


The demands on health services and the challenges of drug development, in the light of increased aging of population, changing patterns of disease and increased costs of medicines, creates the need for research on the effectiveness, the safety and the economics of drugs R&D and reimbursement.

In the Centre for Health Technology Assessment and Drug Research (CHAD) research is performed through several interconnected ongoing projects, aimed at study real world outcomes, safety, economics and market access of drugs.

Projects

**DruSER.Net – Drug Safety and Effectiveness Research Network**

The DruSER.Net is a research network of Hospitals and Primary Healthcare Centres, which is coordinated by the Pharmacovigilance Unit of Coimbra. The main objective of the DruSER.Net is to investigate and monitor safety and effectiveness of medicines used in routine clinical practice and therefore contributing for patient safety through the conduction of research projects using real-world data.

**The Portuguese survey on anticoagulated patients register (START-Portugal-Register)**
ClinicalTrials.gov n° NCT03977363

The purpose of the PT-START-Register study is to record the clinical history of patients who initiate anticoagulation prospectively and without interfering with current clinical practice to generate evidence to assess the safety and effectiveness of the various therapeutic options.

**ESSENCE - The Effectiveness, Safety and Patient Experience on Oncology Treatments: Achieving Real-World Evidence**

The main objective of ESSENCE Study is to assess whether the outcomes of patients with breast, lung and ovarian cancer treated under real-world conditions reflect the results obtained from clinical trials. This study also aims to identify the healthcare resources consumption and associated costs implicated in the treatment of cancer patients in routine clinical practice.

**Systematic review: role in drug safety and clinical effectiveness assessment**

The aim of this research is to understand the actual role of systematic reviews in drug’s safety assessment and to compare the methodologies of the two major orientations to plan and conduct systematic reviews. It will be analysed the combination of several types of studies (from experimental data to case reports) when performing a systematic review of drug safety.

**Economic evaluation of ophthalmic medicines: does the results estimated based on pre-marketing evidence correlates with clinical practice?**

The main objective of this project is to clarify the role of pharmaco-economic studies as a tool to inform policy decision making of ophthalmic drugs. The research will also identify, characterize and assess the methodological quality of pharmaco-economic studies of ophthalmic drugs, and it will evaluate if the results of economic studies reflect the findings from real-world clinical practice evidence.

**Network Meta-analysis**

The aim of this research is to assess whether it is possible to produce reliable risk estimates from a network meta-analysis including simultaneously clinical trials and observational studies in order to establish comparisons between treatments which would not be possible to compare based exclusively on data from experimental studies.

**Coimbra Pharmacovigilance Regional Centre**

The main aim is to validate the post-marketing adverse drug reactions reported to the Coimbra Regional Unit of the Portuguese Pharmacovigilance System, by assessing causality, seriousness and previous knowledge. Different techniques for safety signals generation are being tested and applied.
Representative Publications


TRANSLATIONAL VISION RESEARCH PROGRAM

Coordinator: António Francisco Ambrósio

Research Team: Ana Raquel Santiago, Elisa Campos, Henrique Alves, José Cunha-Vaz, Maria Madeira, Rosa Fernandes

AIBILI and the Faculty of Medicine of the University of Coimbra have an historical relationship, particularly with the Coimbra Institute for Clinical and Biomedical Research (ICBR, former IBILI) that represents a critical opportunity in the facilitation of translational research and of innovation from the laboratory in vision research.

To (re)start a new research area at AIBILI, named ‘Basic and Translational Vision Research’ in collaboration with the Retinal Dysfunction and Neuroinflammation Lab from ICBR is one of our priorities and strategies to reinforce the field of translational research in this specific area.

To promote innovative translational vision research, not only by translating laboratory science into new therapeutic strategies, but also by using human samples to find new biomarkers of disease, disease progression and response to therapy.

Research Program Main Goals

Projects

Identification of new biomarkers of disease, disease progression and response to therapy
With a clear translational perspective, and with the aim of bridging the gap between fundamental and clinical research and find new biomarkers, we intend to analyse ocular fluids (tears, aqueous humour, vitreous humour) and blood, namely at a molecular level, to access proteins, microRNAs, mitochondrial DNA and antimicrobial peptides (AMPs).

Using the retina as a window to assess pathologies that affect the brain
Taking advantage of the communication between retina and brain, we will assess structural, functional, cellular and molecular changes in the retina and will try to establish correlations with changes occurring in the brain in the context of Alzheimer’s disease, and Attention Deficit Hyperactivity Disorder (ADHD).

Development of new potential therapeutic strategies for retinal diseases
Target the unmet need of novel potential therapeutic strategies to retinal degenerative diseases, focusing on test the efficacy of molecular entities that have been selected based on our studies focused on the mechanism of disease, and new delivery routes, such as biodegradable implants or microparticles loaded with drugs of interest.

Representative Publications


INTERNATIONAL NETWORKING

EVICR.net - EUROPEAN VISION INSTITUTE CLINICAL RESEARCH NETWORK

AIBILI is the Coordinating Centre of EVICR.net, that is responsible for the management of the Network, coordination of multinational clinical research studies as well as developing training activities. The EVICR.net is a network of European Ophthalmological Clinical Research Centres, dedicated to perform multinational clinical research in ophthalmology with the highest standards of quality, following the European and International Directives for Clinical Research according to harmonized SOPs. EVICR.net strengthens the capacity of the European Union to explore the determinants of ophthalmic diseases and to develop and optimise the use of diagnostic, prevention and treatment strategies in ophthalmology, by performing multinational clinical research. It is a platform for ophthalmology multinational clinical research in Europe and a structure to support multinational Investigator-Initiated Research (IIR). EVICR.net is also a resource for Industry in the development of new drugs and medical devices in ophthalmology.

In order to become a member of EVICR.net, each Clinical Research Centre must apply to the Network and fulfil basic requirements such as dedicated space to perform clinical studies, qualified and experienced personnel, experience of multinational clinical research and to agree to implement organizational Standard Operating Procedures (SOPs) according to ICH GCP Guidelines. Once a member, the Clinical Site adopts/harmonises EVICR.net SOPs with the help of the Coordinating Centre in order to become a certified Clinical Site of Excellence of EVICR.net.

Scientifically it is organized by ophthalmology subspecialty Expert Committees namely: Age-Related Macular Degeneration; Retinal Dystrophies; Diabetic Retinopathy and Vascular Diseases; Glaucoma; Anterior Segment; and Ocular Surface, Inflammation, Dry-Eye & Allergies. It also has Transversal Sections in Rare Diseases, Medical Devices and Reading Centres.

At present, EVICR.net has 100 Clinical Ophthalmological Research Centres members from 15 European countries.

Clinical Studies and Registries

AIBILI as EVICR.net Coordinating Centre, assumes the leadership of coordination and management of Investigator Initiated Research (IIR) in ophthalmology across Europe through the Network. EVICR.net Members have the opportunity to participate in IIR within the Network as well as to submit abstracts for IIR to the Coordinating Centre in order to be evaluated by a specific Expert Committee. When approved, they will have access to support in coordinating and implementing the IIR within EVICR.net.
EVICR.net investigator initiated research (IIR) has been growing in the last years, giving the opportunity for investigators to perform multinational clinical research of high quality in compliance with ICH-GCP Guidelines assuming that the rights, safety and wellbeing of the trial subjects are protected and that the clinical data are credible.

EVICR.net has contributed to the improvement of diagnostic, prevention and treatment strategies in ophthalmology. In 2019 there were eight ongoing multinational clinical research studies of which 3 are European Union funded projects.

**Ongoing Projects and Activities**

**Age-Related Macular Degeneration**
- ATLANTIC (IIR, Industry grant)
- MACUSTAR (IIR, EU funded – IMI2)
- MADEOS (External-sponsored)

**Retinal Dystrophies**
- IRD Survey (Industry Collaboration)

**Diabetic Retinopathy**
- RECOGNISED (IIR, EU funded – H2020)
- IRIS (Industry-sponsored)

**Anterior Segment**
- REDCAKE (IIR, Flemish grant)
- ANIRIDIA-NET (EU funded - COST)
Educational Programme

The EVICR.net has developed a continual training and educational programme with webinars on ophthalmology clinical research. The Educational Programme is organized in modules each with three webinars of one hour. Currently the following modules are available at https://www.evicr.net/webinars/webinars/:

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<tr>
<th>Module</th>
<th>WEBINAR #1</th>
<th>WEBINAR #4</th>
<th>WEBINAR #8</th>
<th>WEBINAR #11</th>
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<td>Multinational Clinical Research Organization</td>
<td>How to setup a clinical research study</td>
<td>DME definition, classification and imaging</td>
<td>Landmark clinical trials in glaucoma</td>
<td>Dry eye syndrome: signs and symptoms</td>
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<td>Clinical research organization</td>
<td>Predicting progression and treatment response</td>
<td>Risk factors in glaucoma</td>
<td>Diagnosis in dry eye syndrome</td>
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<td>WEBINAR #6</td>
<td>WEBINAR #7</td>
<td>WEBINAR #10</td>
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<tr>
<td>SOPs – quality and certification</td>
<td>Treatment of DME</td>
<td>Anti-VEGF treatment of DME</td>
<td>Glaucoma - Who to treat and when</td>
<td>Treatment of dry eye syndrome</td>
</tr>
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</table>

More information: www.evicr.net

Representative Publications


C-TRACER - CHAMPALIMAUD TRANSLATIONAL CENTRE FOR EYE RESEARCH

AIBILI is recognized as a C-TRACER - Champalimaud Translational Centre for Eye Research by the Champalimaud Foundation for its activities in translational eye research. This Network is of great relevance because it brings together under the Champalimaud Foundation three major eye research institutions in the world and creates links between three major continents: Asia, Europe and South America. The C-TRACERs Network brings together the LV Prasad Eye Institute in Hyderabad, India; AIBILI and the Institute for Vision at the Federal University of S. Paulo at S. Paulo, Brazil.

More information:

ECRIN - EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK

ECRIN-ERIC is a network dedicated to improving the health of patients and citizens across the world through clinical research. ECRIN-ERIC supports multinational collaboration in clinical research, acting through correspondents hosted in national clinical research hubs and networks. ECRIN is based on the connection of coordinating centres for national networks of clinical research centres and clinical trials units, able to provide support and services to multinational clinical research.

AIBILI as Coordinating Centre of EVICR.net, a disease oriented network in ophthalmology for clinical research, is an Affiliate Partner of ECRIN-ERIC. Thus, EVICR.net serves as a resource to ECRIN-ERIC in the area of vision and ophthalmology multinational clinical research, particularly by providing scientific and medical expertise, access to patients and research capacity.

More information:
https://www.ecrin.org/
**EATRIS - EUROPEAN INFRASTRUCTURE FOR TRANSLATIONAL MEDICINE**

EATRIS is a client driven, non-profit organization comprising European academic centers of excellence in translational research. EATRIS partner institutes support in bringing innovative ideas for novel preventive, diagnostic or therapeutic products towards first in human application and on to clinical proof of concept. EATRIS partner institutes provide services and expertise in the following areas: Advanced therapy medicinal products and biologics, Biomarkers, Imaging and tracing, Small molecules, and Vaccines. AIBILI is a member of EATRIS and has capacities in the Biomarkers and Imaging and tracing platforms.

More information:
https://eatris.eu/

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**ERN-EYE - EUROPEAN REFERENCE NETWORK ON RARE EYE DISEASES**

The European Reference Network (ERN) on Rare Eye Diseases (ERN-EYE) is led by Prof. Hélène Dollfus (Strasbourg, France) and is composed of 29 healthcare providers from 13 European countries. ERN-EYE is organized in thematic groups: Retinal, Neuro-ophthalmology, Paediatric Ophthalmology and Anterior Segment.

EVICR.net is a member of the Scientific, Medical and Ethical Advisory Board (SMEAB). EVICR.net collaborates with ERN-EYE through the Rare Diseases Transversal Section and with its long experience in Quality Systems and certification of Clinical Sites as well as by providing overall management and logistical support needed in multinational investigator initiated studies in rare eye diseases.

More information:
https://www.ern-eye.eu/
ARSC – Health Administration of the Centre Region of Portugal
ARSC regulates the organization and functioning of healthcare institutions and services in the Centre Region of Portugal. The Protocol between AIBILI and ARSC is of great relevance as the area of primary healthcare is a major research interest of AIBILI as screening and prevention are priorities for AIBILI research particularly in imaging diagnostics. Since 2011, AIBILI-CORC is the Reading Centre for fundus images of Screening Programme for Diabetic Retinopathy in the Centre Region of Portugal.

HCP – Health Cluster Portugal
AIBILI is member of the Health Cluster Portugal (HCP) whose main objective is the promotion and implementation of initiatives and activities leading to the consolidation of a national cluster for competitiveness, innovation and technology in the health area. AIBILI is part of the Ophthalmology sub-cluster within HCP with the aim to increase Portuguese participation in international partnerships, attract national and foreign investment and make Portugal an active partner in ophthalmology healthcare and research.

More information:
www.healthportugal.com

FMUC – Faculty of Medicine of the Coimbra University
The Faculty of Medicine of the University of Coimbra (FMUC) is one of the most important schools of medicine in Portugal due to its vast research areas. The partnership between AIBILI and FMUC allows AIBILI to coordinate clinical research from FMUC investigators.

iCBR – Coimbra Institute for Clinical and Biomedical Research
Coimbra Institute for Clinical and Biomedical Research (iCBR), formerly IBILI, is a Multidisciplinary Research Unit from the Faculty of Medicine, University of Coimbra (FMUC). Research at iCBR aims to investigate molecular and cellular mechanisms underlying the pathophysiology of chronic diseases, to identify innovative therapeutic strategies and disease biomarkers, as well as to unveil and implement new approaches to promote the quality of life and wellness. The partnership between AIBILI and iCBR aim on filling the gaps between Pre-Clinical and Clinical Research, setting the ground for the development of innovative projects, translating basic science into new therapeutic strategies, but also by using human samples to find new biomarkers of disease, disease progression and response to therapy.
i3S – Institute for Research and Innovation in Health of the University of Porto

The i3S consortium, headed by the Porto University, brings together institutions and researchers from several schools of the Porto University. This wide participation of schools, research institutions and hospitals in a research institute is unique in Portugal and is a valuable asset for science and technology development, while creating an environment that feeds real breakthrough research and translation of discoveries into the clinic.

The partnership between AIBILI and i3S will increase the participation in innovation and translational projects as well as to have a more complete and robust value chain for their clients, particularly, for companies.

INFOCUS Clinical Research

INFOCUS is an ophthalmology focused full-service contract research organization (CRO) based in the USA.

AIBILI and INFOCUS are currently providers of ophthalmology clinical research development support services, respectively, in Europe and North America and are organizing themselves to be able to provide a global ophthalmology clinical research support.

INFARMED - National Authority of Medicines and Health Products, I.P.

INFARMED, IP is a Government agency accountable to the Health Ministry, that evaluates, authorises, regulates and controls human medicines as well as health products, namely, medical devices and cosmetics for the protection of Public Health.

AIBILI has a protocol with INFARMED to collaborate in the framework of the national strategy for the development of clinical research in the pharmaceutical sector.

Since 2008 that AIBILI-CHAD has been responsible for a Pharmacovigilance Unit of the National Pharmacovigilance System contracted with INFARMED, IP.

José de Mello Saúde – Hospital CUF Coimbra

The CUF Coimbra Hospital provides access to excellent health services, both inpatient and outpatient with a comprehensive and innovative offer in diverse medical-surgical areas in terms of the technology used and its processes.

The partnership between AIBILI and CUF Coimbra Hospital has as main goal the coordination and promotion of clinical research facilitating the exchange of scientific and technical knowledge.
P-BIO – Portugal’s Biotechnology Industry Organization

P-BIO is the only association that brings together the vast majority of companies linked to the biotechnology and life sciences sector. P-BIO seeks to develop an environment that is favourable to the creation and growth of start-ups, promoting their corporate development domestically and internationally.

The partnership with AIBILI allows P-BIO companies to have access to differentiated support to evaluate the economic viability of medicines, value strategy design, regulation and translation of technology, market access and effectiveness after commercialization as well as to the coordination and overall management of clinical research studies.

PtCRIN – Portuguese Academic Clinical Research Infrastructures Network

PtCRIN (www.ptcrin.pt) is the national clinical research network aiming to facilitate and improve quality in clinical research and to increase national and international research collaboration for the benefit of patients, citizens and the healthcare system. PtCRIN is the Portuguese member of ECRIN-ERIC. AIBILI is a founding member of the PtCRIN and it is a Clinical Trial Unit and a Clinical Research Centre. AIBILI has the only ECRIN Certified Data Centre since 2016 in Portugal.