



ANNUAL REPORT

2025





ANNUAL REPORT 2025

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Message from the President

In an era defined by rapid scientific and technological transformation, AIBILI continues to strength its position as an institution committed to sustained growth and increasing scientific impact. Through a strategic focus on clinical research, AIBILI has broadened its national and international partnerships and demonstrated a strong capacity to address emerging scientific challenges and adapting to market demands. Its recognition as Technology and Innovation Centre (CTI) by the Ministry of Economy emphasizes AIBILI's key role in advancing innovation by facilitating collaboration between scientific institutions, business and industry, to deliver innovative solutions to the healthcare market.

Since the creation of the Clinical Trial Centre (CEC) and the Centre for New Technologies in Medicine (CNTM), originally focused on Ophthalmology, the institution has progressively expanded its activities into additional medical fields. New Units have also been created, including the Coimbra Clinical Research Coordination Centre (4C), which plays a vital role in supporting investigator initiated and industry-sponsored clinical studies and trials. Another important unit is the Coimbra Ophthalmology Reading Centre (CORC), that provides centralized grading services for multicenter studies worldwide, with international recognition for its excellence. In recent years, CNTM significantly broadened its scope, increasingly focusing on innovative areas, such as the development and validation of AI models for early detection of retinal diseases and related systemic complications, such as cardiovascular or neurodegenerative conditions. Another unit that has become increasingly essential for guaranteeing the security and integrity of data collected for clinical research is the Data Centre (DC), which plays a fundamental role in improving information security, cybersecurity, and privacy protection at AIBILI, in accordance with national and international standards.

AIBILI also recognizes the importance of the Quality Management Unit (QMU), essential for continuous improvement and quality assurance, as well as the Translational Research and Technology Transfer Unit (UTT), which supports research to reach the market and fosters collaborations, and the Information Technology Unit (IT), responsible for managing IT networks and information systems.

Since 2010, AIBILI coordinates the EVICR.net, a European network that brings together 90 clinical research centres in ophthalmology, distributed across 16

countries, with more than 800 researchers. This network plays a crucial role in strengthening the EU's capacity to conduct multinational clinical research in line with the highest standards. More recently, EVICR.net has developed the EVICR.net Eye Platform, designed to gather high-quality ophthalmology data generated in Europe, enabling the secondary use of data for large-scale analyses and fostering clinical research.

With a strong focus on key research areas – including diabetic retinopathy, age-related macular degeneration, imaging biomarkers, drug evaluation, and translational vision science – AIBILI has remained committed to fulfilling its Strategic Scientific Research Plan 2020 to 2025, believing that by transforming our knowledge into innovative solutions, it will be possible to improve the health and well-being of humanity in the future. In 2025, AIBILI was evaluated as “Excellent” by the External Scientific Council confirmed that our scientific work and strategic direction are aligned with national and international research standards, further reinforcing our commitment to continue innovating with quality and maintaining a strong focus on the future.



Conceição Lobo
President

AIBILI

associação para
investigação biomédica e
inovação em luz e imagem





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Introduction

AIBILI, founded in 1989, is a non-profit Research Technology Organisation dedicated to clinical research and contributing to the development of new products for medical therapy and diagnostic imaging. It has been recognized by the Ministry of Economy as a Technology and Innovation Centre in the health field, to support technology transfer and translational research.

AIBILI is located in the Coimbra University Health Campus since 1994 and has its own building with 1.454 m² and state-of-the-art equipment.

AIBILI main areas of activity are:

- Performance of Clinical Studies
- Planning, Coordination, Monitoring of Clinical Research Studies
- Pharmacovigilance, Pharmacoepidemiology and Pharmacoconomics
- Grading of Eye Exams
- Research and Development in New Technologies for Medicine in the areas of Imaging, Optics and Photobiology
- Data Centre

AIBILI is ISO 9001:2015 certified for all its activities. Clinical research is performed in accordance with ICH-GCP Good Clinical Practice Guidelines and national and European regulatory requirements, as well as personal data protection legislation. AIBILI Data Centre is certified by ECRIN – European Clinical Research Infrastructures Network since 2016.

Regarding human resources it has a permanent staff of 59 people including medical doctors, researchers, engineers, pharmacists, technicians, project managers, statisticians, data managers, quality manager, study coordinators and administrative personnel. Another 42 professionals collaborate regularly in research activities.

In order to promote science and technology advancement and to bring potential new treatments and diagnostic tools to the market, AIBILI has assumed an integrated Strategic Scientific Research Plan 2020-2025 with five main Research Programs: Diabetic Retinopathy; Age-Related Macular Degeneration; Imaging Biomarkers; Drug Evaluation; and Translational Vision. The outcome of this Strategic Scientific Research Plan will be a key element to enable AIBILI to maintain its excellence in health innovation. We aim to increase the number and quality of research projects, as well as their funding; to promote AIBILI as an added-value to clinical development and innovation; to promote technology transfer and translational research, and to stimulate novel national and international collaborations, focusing on the improvement of health research and life quality.

AIBILI closely follows current technological developments, particularly information technologies, artificial intelligence, and open science, opening new doors for AI research collaborations. These efforts aim to promote more inclusive and effective partnerships, while reinforcing its dedication to scientific progress and knowledge sharing.

AIBILI is dedicated to advancing translational research and innovation, with a clear focus on improving human health and enhancing overall wellbeing.

2025 Highlights

- Participation in the workshop **Fostering Investigator-Initiated Clinical Trials in Portugal: A Multidisciplinary Dedicated Workshop Across Scientific Societies**, in Coimbra on 24/01/2025. The workshop, organized by PtCRIN with the support of ECRIN, brought together representatives from scientific societies, clinical researchers, healthcare professionals, and other key stakeholders involved in Investigator-Initiated Clinical Trials (IICTs) to discuss and collaborate on advancing clinical trial initiatives in Portugal.
- Approval of 3 research projects in the 2023 edition of the **Scientific Research and Technological Development Projects (IC&DT) call**, promoted by the Foundation for Science and Technology (FCT), reflecting the excellence and impact of the research carried out at AIBILI.
- Prof. José Cunha-Vaz was awarded the **Prémio Carreira – Diário As Beiras**, a distinction that recognizes the outstanding contributions of Professor José Cunha-Vaz to vision science and the lasting impact of his work at both national and international levels.
- Participation in two **international benchmarking missions in technology transfer**, in the scope of the INOVC+ Project - one to Leuven and Ghent and another to Barcelona - to learn about international best practices, reinforce knowledge and technology transfer, and strengthen cooperation networks.
- CEC Director, Inês Marques, was awarded the **Award for Best Oral Presentation in Clinical Research** at the Portuguese Congress of Diabetes, for the work entitled *Progression of Diabetic Retinopathy in Patients with Moderate to Severe Non-Proliferative Diabetic Retinopathy: One-Year Analysis from the CHART Study*.
- CNTM Director, Luís Mendes, was a guest speaker at the **AI in Healthcare** event, on 26/05/2025 in Stockholm, Sweden, where experts gathered to discuss the growing impact of artificial intelligence in healthcare, with special emphasis on its benefits, challenges, and ethical implications.
- Participation in the **EATRIS-CONNECT Annual Consortium Meeting**, May 27-28, Stockholm, Sweden.
- Organization of the **AIBILI Research Groups Annual Meeting**, on 02/07/2025, which provided a privileged forum for in-depth discussion and the exchange of ideas in the field of ophthalmology.
- Strengthened the collaboration with **Champalimaud Foundation** for the provision of CRO services for investigator-initiated studies. This agreement will promote closer collaboration in the coordination of clinical research services delivered by 4C and AIBILI Data Centre.
- AIBILI, in collaboration with CIBIT and IPN, co-organized two events under the **EATRIS Spotlight Program**: Medical Devices Roadmap on 24/06/2025 and Digital and Imaging Biomarkers: Identification, Validation, and Clinical Application on 12/09/2025.
- The **10th Meeting of AIBILI's External Scientific Council**, on 08/09/2025, brought together distinguished national and international experts to evaluate AIBILI's activities and advise on future strategic directions. The evaluation was rated Excellent.
- Patrícia Barreto, Clinical Trial Centre Sub-Director, was awarded the **PhD in Health Sciences by the University of Coimbra**, on 17/09/2025, with the thesis "Age-Related Macular Degeneration: Genetic Susceptibility, Nutrition and Lifestyle", based on research developed at AIBILI.
- Participation in the **12th Research Data Management Forum**, held on 27–28 November 2025 in Bragança, where Pier Basile, Data Manager Coordinator, presented a poster on the AIBILI Dataverse Repository, contributing to the dissemination of Open Science.
- The **José Cunha Vaz SPO /ROCHE Award** for the best presentation in the retina field at the 68th Portuguese Congress of Ophthalmology, was awarded to Inês Figueiredo for the work titled *Prevalence, Incidence, and Risk Factors of AMD in Portugal: Eleven-Year Multimodal Follow-up From the AMD_LifeGene Study*, sponsored by AIBILI.
- AIBILI together with the University of Coimbra and the Coimbra Nursing School, co-organized the 2nd edition of the **Innovation in Health** showcase, on 10/12/2025, with Prof. Conceição Lobo and Luís Mendes among the featured speakers.

- AIBILI actively participated in **national annual meetings**, including the Portuguese Congress of Ophthalmology, Portuguese Congress of Diabetes, Ophthalmology Colloquia 2025, Coimbra International Ophthalmology Conference, National Congress of Orthoptists, Congress of the Portuguese Statistical Society, National Congress of Neurology, 12th Forum of Research Data Management, Iberian Pharmacovigilance Meeting, and the National Pharmacovigilance Day.
- During 2025, AIBILI members participated actively **through presentations and posters in the following international congresses**: The Macula Society 48th annual meeting, February 12-15, Charlotte Harbor, Florida; 9th San Raffaele OCT & Retina Forum, March 13-14, Milan, Italy; ARVO 2025 Annual Meeting, May 4-8, Salt Lake City, USA; 35th EAsDEC Meeting, June 5-7, Liverpool, UK; EATRIS Sweden Spotlight Symposium: AI in healthcare – opportunities, challenges and ethical considerations, June 25, Stockholm, Sweden; MACULART, June 29-30, 1st July, Paris, France; E3 Consortium Meeting, August 26-28, Dijon, France; 61st EASD Annual Meeting, 15-19 September, Vienna, Austria; 25th Euretina Congress, September 4-7, Paris, France; 43rd Congress of the ESCRS, September 12-16, Copenhagen; AAO 2025, October 18-20, Orlando, USA; ISoP Annual Meeting 2025, October 24-27, Cairo, Egypt; OftaCafé Retina Symposium 2025, 18 October, Lugano, Switzerland; ISPOR Europe 2025, November 9-12, Glasgow, Scotland; FLORetina ICOOR Congress 2025, December 4-7, Florence, Italy.



Technology and Innovation Centre (CTI)

AIBILI is a Technology and Innovation Centre (CTI) in the Health Sector of the National Technology Network of the Economy Ministry. This recognition identifies AIBILI as a key partner facilitating collaboration between scientific institutions, businesses, and industry to deliver innovative solutions to the healthcare market.



To promote research of excellence and scientific innovation, AIBILI has established the following priorities:

- To maintain a position of excellence in clinical and translational research, allowing the creation of new knowledge in collaboration with other reference institutions and participation in international consortia;
- To promote the integration of the different research programs through the application of different concepts under study and which make up the scientific strategy;
- To develop new imaging biomarkers in ophthalmology that support the diagnosis and identification of disease stages and facilitate the analysis for risk of development and progression of disease;
- To diversify the research carried out into the areas of diabetes, cardiology and neurology, benefiting from the link with primary health care units, and taking advantage of the skills and knowledge existing in the institution and their possible use in the study of the retina-brain relationship;
- To increase AIBILI's technological intensity by hiring qualified human resources, reinforcing and updating the knowledge/continuous training of its employees and acquiring state-of-the-art equipment.

With these priorities, participation in international reference networks, following the Strategic Scientific Research Plan and the quality management system, AIBILI is positioned to achieve excellence in research and innovation contributing to improvements in clinical practice and bringing benefits to society.



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 e Universitário de Coimbra
- SUCH – Serviço de Utilização Comum dos Hospitais

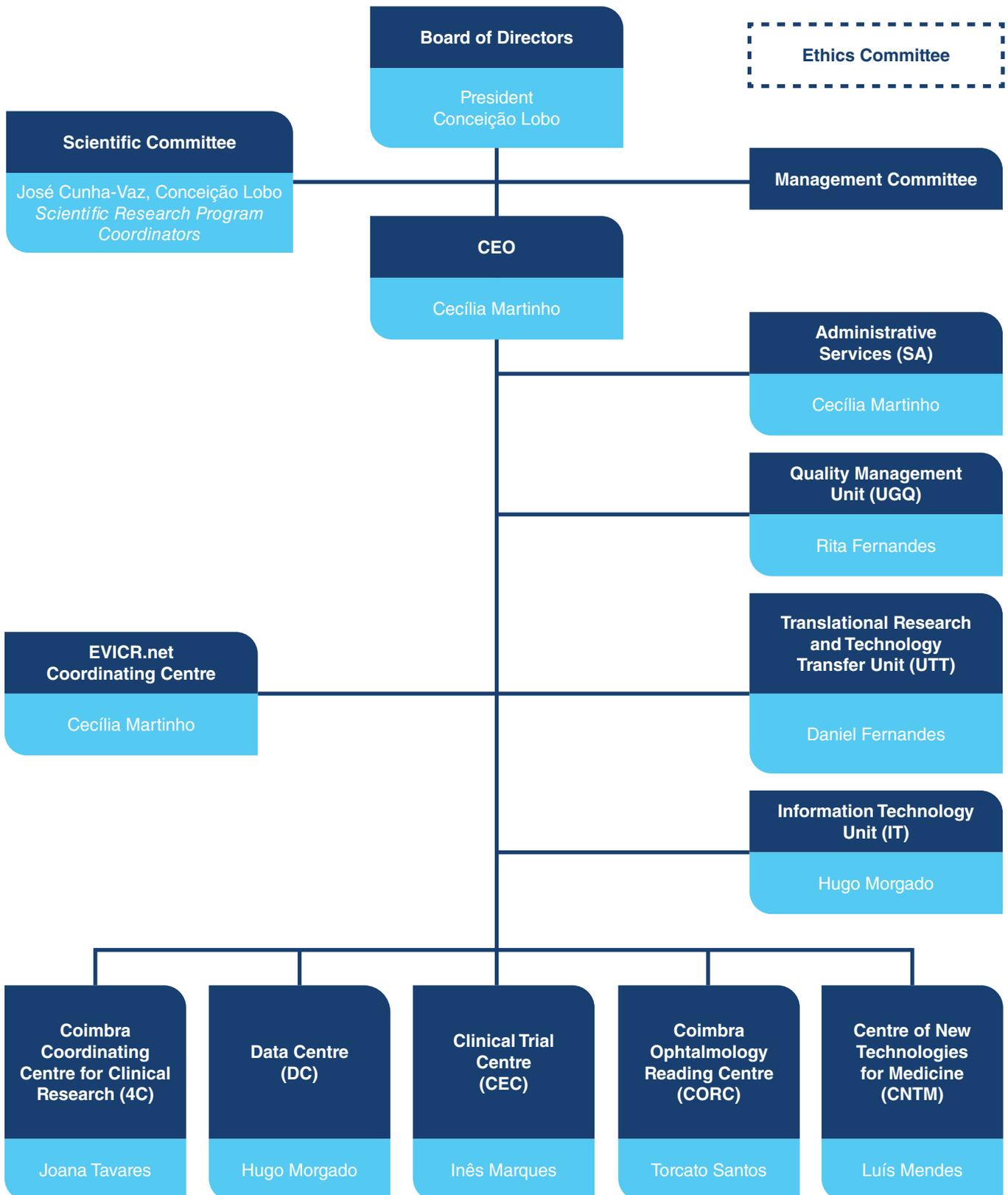
Other Associates

- Universidade de Coimbra (Honorary Associate)
- Fundação Champalimaud (Honorary Associate)
- Alcon Portugal - Prod. e Equip. Oftalmológicos, Lda.
- BIAL - Portela & C^a, SA
- Cecília Martinho
- Centro de Oftalmologia da Universidade de Coimbra
- Conceição Lobo
- Escola Superior de Saúde do Politécnico do Porto
- Francisco Batel Marques
- Hospital CUF Coimbra / José de Mello Saúde
- Laboratórios Pfizer, Lda.
- Novartis Farma, SA

Board of Directors (2023-2026)

- Conceição Lobo, President
- António Parreira (Rep. Fundação Champalimaud), Vice-President
- Nuno Pires (Rep. BIAL - Portela & C^a, SA)
- Ana Matos (Rep. Laboratórios EDOL - Produtos Farmacêuticos, S.A.)
- Margarida Gonçalo (Rep. Serviço de Dermatologia do Centro Hospitalar e Universitário de Coimbra)
- António Cotta (Rep. José Cotta - EMS, Lda)
- Cecília Martinho, CEO
- José Cunha-Vaz, Honorary President

Organigram



AIBILI in Numbers

1989

AIBILI Foundation

1991

Public Utility
Recognition

2010

European C-TRACER Member



2009

Expansion of AIBILI 4C
Retmarker® – Official market launch



2016

Data Centre Certification



2017

Establishment of DruSER.net



Recognition as an Interface Center
by Ministry of Economy



Fulltime Staff	59
N° of PhD	21
N° of Consultants	42
N° of Ongoing studies, services, projects, contracts	144

N° Patents	3 (USA) + 1 (Europe)
N° of European Union funded projects (ongoing)	3
N° of Publications (2024-2025)	41

1994

1st Building in the Coimbra University Health Campus

1999

Good Laboratory Practices Certification

2008

Expansion of AIBILI Units CORC and CHAD

2004

ISO 9001 Certification



EVICR.net Coordinating Centre



2022

Recognition as a Technology and Innovation Center by Ministry of Economy



2023

Recognition of 4C as an EATRIS Expert Centre



2025

10th External Scientific Council Evaluation
Data Centre Recertification



2024

Celebration of 35 years



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Research Centres and Organisational Units

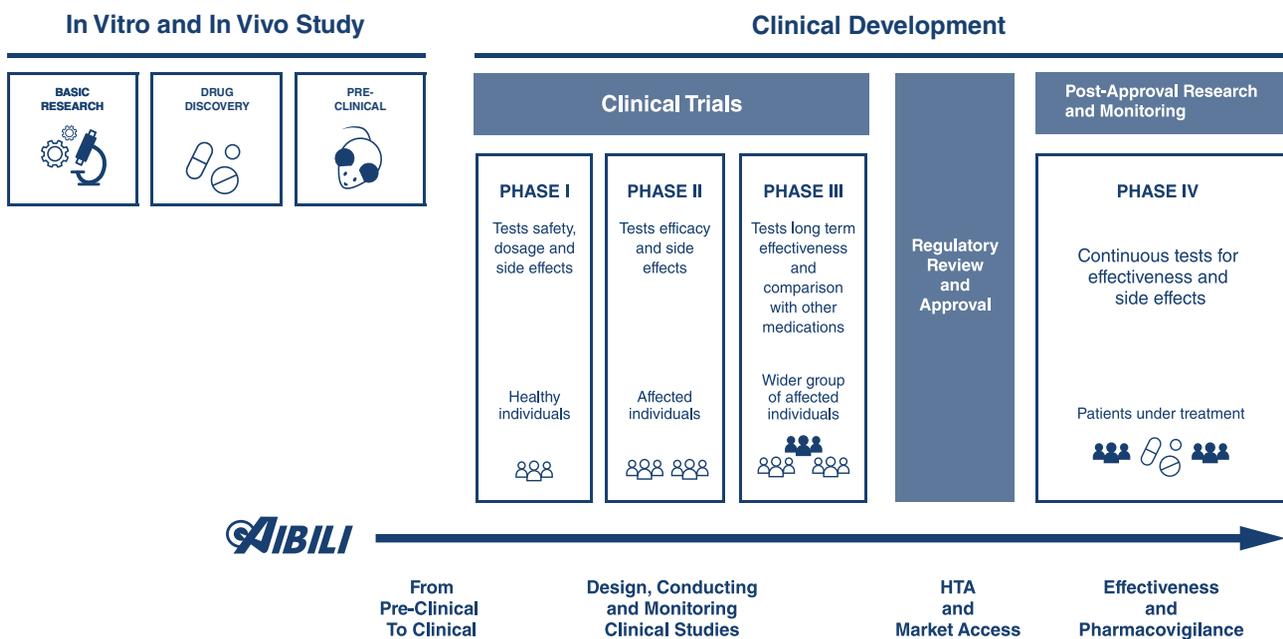
AIBILI is organised in Research Centres and Organisational Units.

Research Centres

- Coimbra Coordinating Centre for Clinical Research (4C)
- Clinical Trial Centre (CEC)
- Coimbra Ophthalmology Reading Centre (CORC)
- Centre for New Technologies in Medicine (CNTM)
- Data Centre (DC)

Organisational Units

- Administrative Services (SA)
- Quality Management Unit (QMU)
- Translational Research and Technology Transfer Unit (UTT)
- Information Technology Unit (IT)



4C – Coimbra Coordinating Centre for Clinical Research

Director: Joana Tavares, PhD

Staff: Alexandre Sousa, Alina Humenyuk, Ana Silva, Cândida Dias, Carolina Fernandes, Carolina Ramalho, Cecília Martinho, Conceição Lobo, Daniela Cravo, Daniel Fernandes, Daniel Figueiredo, Débora Ferreira, Inês Aires, Inês Tavares, José Cunha-Vaz, Laura Seco, Liliana Carvalho, Liseta Lemos, Mário Ribeiro, Marta Pais, Raquel Gomes, Rita Coimbra, Rita Fernandes, Rita Ribeiro

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



Contacts

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PRE-STUDY

- Study Design
- Statistical Plan
- Protocol and Informed Consent development
- Clinical Centre selection
- Master File and Site File development
- SOPs development
- Regulatory Affairs
- Contracts and Insurance
- Monitoring Plan

IN-STUDY

- Study Coordination
- Investigational Medicinal Product/Medical Device Management
- Monitoring
- Pharmacovigilance and Risk Management

POST-STUDY

- Biostatistics
- Final Report
- Medical Writing
- Publication

4C uses the Clinical Management System (CMS), developed in house, for planning, management and monitoring of clinical studies. 4C has all the capacities to plan and implement/manage/coordinate multinational clinical studies, as well as medical devices clinical investigations.

4C is compliant with ICH GCP - Good Clinical Practice Guidelines (R3) and European regulations, namely Clinical Trials Regulation (Regulation (EU) No 536/2014), Medical Devices Regulation (Regulation (EU) No 2017/745) and ISO 14155 as well as national legislation.

4C is a useful resource to work closely with Pharmaceutical Industry and medical device sector, through all stages of drug development and medical device clinical investigations. It performs pharmacovigilance services necessary in clinical studies. It has a pharmacovigilance system 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 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 AIBILI has been responsible for a Pharmacovigilance Unit (Unidade de Farmacovigilância de Coimbra, UFC) of the National Pharmacovigilance System which is contracted with the National Authority of Medicines and Health Products (INFARMED, IP).

N° OF CLINICAL STUDIES / PROJECTS AT 4C (2023-2025)

Coordination of Clinical Studies (N°)

Year	Investigator Initiated	Industry Sponsored	Drug Safety	Market Access	Other	Total
2023	16	3	10	2	7	38
2024	15	2	10	0	6	33
2025	19	3	14	0	6	42



CEC - Clinical Trial Centre

Director: Inês Marques, MD, PhD

Sub-Director: Patrícia Barreto, PharmD, PhD

Staff: Aida Vitorino, Ana Almeida, André Coutinho, Catarina Eloy, Cláudia Farinha, Conceição Lobo, Cristina Fonseca, Cristina Januário, Daniela Guelho, Filipe Martins, Filipe Mira, Gina Maria Alves, Guilherme Castela, Inês Laíns, Inês Pinto, Isabel Pires, Joana Providência, João Figueira, João Gil, João Pedro Marques, José Cunha-Vaz, Luísa Ribeiro, Margarida Gonçalves, Marcela Pascoal, Maria Filipa Ponces, Maria da Luz Cachulo, Marta Lopes, Paulo Marques, Rufino Silva, Sandra Pardal, Tânia Mesquita, Telma Alves



Contacts

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The Clinical Trials Centre (CEC) is dedicated to advancing eye care through innovative clinical trials and studies, with a strong emphasis on ophthalmology, particularly diabetic retinopathy and age-related macular degeneration. Its expertise extends to a broad range of ophthalmic conditions, also including glaucoma, dry eye disease, and refractive disorders. CEC has a strong research record, with numerous scientific publications, and has been a certified Clinical Site of Excellence by EVICR.net since 2006.

With experienced investigators, supported by certified research team and state-of-the-art diagnostic equipment, CEC ensures high-quality data collection and patient safety throughout every study. The Centre emphasizes patient comfort and education, providing clear guidance and compassionate care during the clinical trial process. By participating in CEC studies, patients gain access to cutting-edge treatments while contributing to the development of therapies that shape the future of eye health.

CEC collaborates with leading pharmaceutical companies and research organizations to evaluate new treatments, devices, and therapies aimed at improving vision and managing ocular diseases.

Clinical Research: Diabetic Retinopathy; Age-Related Macular Degeneration; Glaucoma; Neurology; Diabetes

Nº OF CLINICAL STUDIES AT CEC (2023-2025)

Clinical Studies (Nº)

Year	Investigator Initiated	Industry Sponsored	Total
2023	12	10	22
2024	10	9	19
2025	11	10	21

INVESTIGATOR-INITIATED STUDIES

Diabetic Retinopathy

RECOGNISED - Retinal and Cognitive Dysfunction in Type 2 Diabetes: Unraveling the Common Pathways and Identification of Patients at Risk of Dementia

ClinicalTrials.gov ID: NCT04281186
Financial Support: European Union - H2020-SC1-BHC-01-2019-847749

CHART - Characterization of Retinal disease progression in eyes with NPDR in diabetes Type 2 using non-invasive procedures

ClinicalTrials.gov ID: NCT04636307
Financial Support: IIR Grant from Bayer

RICHARD - Retinal Ischemia characterization in diabetes

ClinicalTrials.gov ID: NCT05112445
Financial Support: IIR Grant from Boehringer Ingelheim

PREDICTION - Prediction of Retinal Ischemia in Diabetes

ClinicalTrials.gov ID: NCT05581225
Financial Support: AIBILI

CLARUS DR - Diabetic Retinopathy Classification: ETDRS 7-fields vs Widefield Imaging

ClinicalTrials.gov ID: NCT05746975
Financial Support: IIR Grant from Carl Zeiss Meditec AG

ALERT - Analysis of DR progression to identify risks and need for treatment

Financial support: COMPETE 2030 / FEDER and Portuguese Foundation for Science and Technology - COMPETE2030-FEDER-00921900)

IMPORTANT - IMaging pre-PrOlifeRative sTAge of diabetic retiNopaThy to guarantee timely treatment

Sponsor: AIBILI
Financial support: COMPETE 2030 / FEDER - COMPETE2030-FEDER-00851200

Age-related macular degeneration

AMD_LifeGene - Diet, medication, and lifestyle in Age-related Macular Degeneration: can the genetic expression be modulated?

ClinicalTrials.gov ID: NCT05735730
Financial Support: EURETINA Clinical Research Award 2022

MACUSTAR - Intermediate AMD: Development of novel clinical endpoints for clinical trials in patients with a regulatory and patient access intention

ClinicalTrials.gov ID: NCT03349801
Financial Support: European Union and EFPIA – IMI 2 Joint Undertaking - Grant Agreement n° 116076

Retinal Degenerative Diseases

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

Financial Support: AIBILI

EYEMARKER - Characterization of potential biomarkers of Eye Disease and Vision Loss

ClinicalTrials.gov ID: NCT02500862
Financial Support: AIBILI

INDUSTRY-SPONSORED CLINICAL TRIALS

Diabetic Macular Edema

BRUNELLO - A Randomized, Double-Masked, Multi-Center, 3-Arm Pivotal Phase 2/3 Study To Evaluate The Efficacy And Safety Of Intravitreal Eye103 Compared with Intravitreal Ranibizumab (0.5mg) In Participants With Diabetic Macular Edema

ClinicalTrials.gov ID: NCT06571045

BAROLO - A Randomized, Double-Masked, Multi-Center, 3-Arm Pivotal Phase 2/3 Study To Evaluate The Efficacy And Safety Of Intravitreal Eye103 Compared with Intravitreal Ranibizumab (0.5mg) In Participants With Diabetic Macular Edema

EUCT Number: 2025-520809-12-00

Diabetic Retinopathy

SAONA - A Multicenter, Prospective, Observational, Low-Interventional, Nondrug Study on the Progression of Ischemia in Diabetic Retinopathy

4FRONT-2 - A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of 4D-150 in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration

EUCT Number: 2025-521349-25-00

Uveitic Macular Edema

MEERKAT - A phase III, multicenter, randomized, double masked, sham controlled study to investigate the efficacy, safety, pharmacokinetics, and pharmacodynamics of RO7200220 administered intravitreally in patients with uveitic macular edema

EudraCT Number: 2022-501793-19-00

SANDCAT - A phase III, multicenter, randomized, double-masked, sham-controlled study to investigate the efficacy, safety, pharmacokinetics, and pharmacodynamics of RO7200220 administered intravitreally in patients with uveitic macular edema

EudraCT Number: 2022-501794-39-00

Thyroid Eye Disease

SatraGO-2 - A Phase Iii, Randomized, Double-Masked, Placebo-Controlled, Multicenter Study To Evaluate The Efficacy, Safety, Pharmacokinetics, And Pharmacodynamics Of Satralizumab In Participants With Moderate-To-Severe Thyroid Eye Disease

EudraCT Number: 2023-503669-50-00

Macular Edema Secondary to Retinal Vein Occlusion

QUASAR - Randomized, Double-Masked, Active-Controlled, Phase 3 Study of the Efficacy and Safety of Aflibercept 8 mg in Macular Edema Secondary to Retinal Vein Occlusion
 EudraCT Number: 2022-502174-16-00

Neurological Disorders

PALOMA - A Multicenter Longitudinal Study to Evaluate the Correlation between Oculometric Measures and Clinical Assessment in Patients with Idiopathic Parkinson's Disease
 ClinicalTrials.gov ID: NCT05862649

Breast Cancer

EvoPAR-Breast01 - A Randomised, Open-Label, Phase III Study of Saruparib (AZD5305) Plus Camizestrant compared with Physician's Choice CDK4/6 Inhibitor Plus Endocrine Therapy or Plus Camizestrant for the First-Line Treatment of Patients with BRCA1, BRCA2, or PALB2 Mutations and Hormone Receptor-Positive, HER2-Negative (IHC 0, 1+, 2+/ ISH non-amplified) Advanced Breast Cancer
 ClinicalTrials.gov ID: NCT06380751



CORC – Coimbra Ophthalmology Reading Centre

Director: Torcato Santos, BSc

Scientific Coordinator: Conceição Lobo, MD, PhD

Staff: Alda Baltar, Ana Catarina Almeida, Ana Cláudia Rocha, Ana Raquel Branco, André Rocha, António Martinho Beatriz Pereira, Cátia Sousa, Carla Sofia Gomes, Carolina Ramalho, Catarina Neves, Christian Schwartz, Cláudia Farinha, Cláudio Ferreira, Daniel Figueiredo, Diana Ramos, Francisco Pereira, Inês Marques, Inês Pinto, Isa Sobral, Isabel Pires, Joana Providência, João Gil, João Pedro Marques, José Cunha-Vaz, José Filipe Costa, Lia Correia, Luisa Cardoso, Luisa Ribeiro, Márcia Ferreira, Maria Filipa Ponces, Maria da Luz Cachulo, Marta Fernandes, Marta Lopes, Matheus Matos, Miguel Raimundo, Nuno Gouveia, Pedro Pereira, Petra Gouveia, Telma Machado, Thomas Almeida, Tiago Baptista, Rúben Magalhães

The Coimbra Ophthalmology Reading Centre (CORC) is a qualified provider for central reading and grading of ophthalmology exams for multinational and multicentric clinical studies, as well as for the Diabetic Retinopathy Screening Programmes of the Central and South Regions of Portugal. It receives and grades exams from all over the world, contributing to standardized results and high quality data to ophthalmic research, by grading several features in different imaging modalities, focusing its activities in the characterization and quantification of ophthalmic diseases.



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CORC AREAS OF EXPERTISE

Posterior segment / Retinal Diseases

- Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME)
- Age-related Macular Degeneration (AMD)
- Inherited Retinal Diseases (IRD): Retinitis Pigmentosa (RP), Stargardt Disease (STGD)
- Retinal Vein Occlusion (RVO)

Anterior Segment Diseases

- Neurotrophic Keratitis (NK)

OPHTHALMIC EXAMS GRADED BY CORC

Ophthalmic Exams

- Retinal fundus images
 - Fundus Photography (FP)
 - Fluorescein Angiography (FA)
 - Ultrawide field (UWF) imaging (UWF FP and UWF FA)
 - Indocyanine-green Angiography (ICG)
 - Fundus Autofluorescence (FAF)
- Optical Coherence Tomography (OCT)
- Optical Coherence Tomography Angiography (OCTA)
- Anterior Segment Photography
- Functional examinations: Perimetry, Microperimetry, Electrophysiology

CORC SERVICES

Study Development

- Consultancy support for study design (before study start-up activities)
- Project set-up and management
- Scientific and technical support before and during the service
- Study-specific Acquisition Protocols development
- Providing Web-based platform for exams' submission
- Study-specific Grading Forms database development and validation
- Study-specific Grading Protocols development
- Study-Specific Reading Centre Manual development
- Participation in Investigators meeting(s)

Training and Certification

- Equipment
- Technicians
- Support and management of Sites' difficulties
- Training sessions for Sites

In-study Services

- Grading of ophthalmic exams
- Eligibility criteria review and confirmation
- Quality check of functional objective examinations
- Management and monitoring of exams received and results
- Data management for data quality monitoring, data validation and data transfers
- Exploratory analysis
- Data backup procedures and a Disaster Recovery Plan
- Secure long-term archiving of study materials, both digital and hardcopy

CORC IT SYSTEMS*

*hosted on AIBILI's Data Centre certified by ECRIN.

Transmission of images from Clinical Sites to CORC

- CORC Online Platform (<https://www.studies.corc.pt>), a secure custom-designed web-based tool for both certification activities and study exams submission

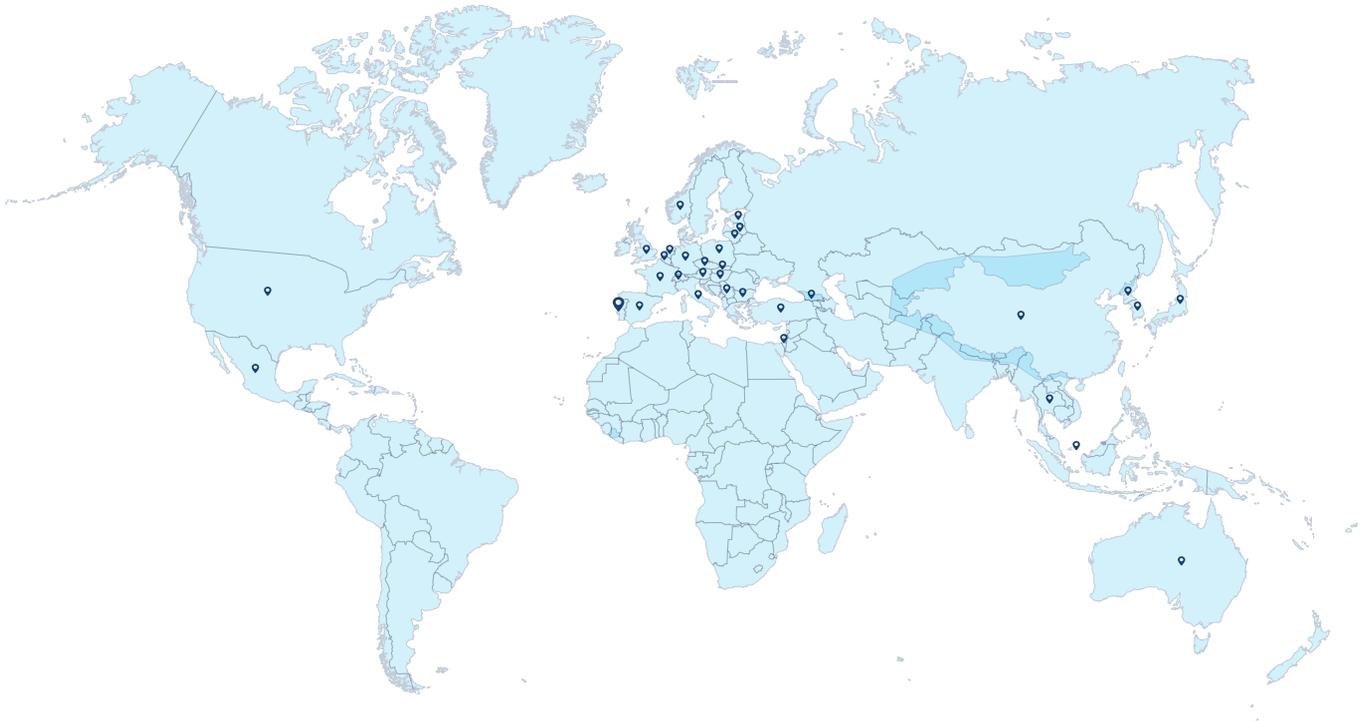
Grading

- REDCap software, used as CORC Digital Grading Forms Platform to record grading results (Digital Grading Forms)
- Licensed software from the equipment suppliers (e.g., Cirrus (Carl Zeiss Meditec), EyeSuite (Octopus, Haag-Streit), Heidelberg Eye Explorer (Heidelberg Engineering), Topcon (Topcon Corporation), ReVue/iVue software (Optovue), Navis-EX (Nidek CO), Optopol OCT (Optopol), OptosAdvance (Optos), Zeiss CLARUS Review (Carl Zeiss Meditec), etc)
- Common applications for imaging edition and analysis (e.g., GIMP, XnViewer, ImageJ, etc)

Management

- CORC Management System (CORCMS), an internal custom-designed web-based tool to support managing CORC activities and CORC studies/services.

CORC RECEIVES AND GRADES EXAMS FROM ALL OVER THE WORLD:



- | | | | |
|------------------|-----------|---------------|---------------|
| 📍 AUSTRALIA | 📍 GERMANY | 📍 LITHUANIA | 📍 SLOVAKIA |
| 📍 AUSTRIA | 📍 GEORGIA | 📍 MALAYSIA | 📍 SPAIN |
| 📍 BELGIUM | 📍 HUNGARY | 📍 MEXICO | 📍 SWITZERLAND |
| 📍 BULGARIA | 📍 ISRAEL | 📍 NETHERLANDS | 📍 THAILAND |
| 📍 CZECH REPUBLIC | 📍 ITALY | 📍 NORWAY | 📍 TURKEY |
| 📍 CHINA | 📍 JAPAN | 📍 POLAND | 📍 UK |
| 📍 ESTONIA | 📍 KOREA | 📍 PORTUGAL | 📍 USA |
| 📍 FRANCE | 📍 LATVIA | 📍 SERBIA | |

N° OF PROJECTS PER SCIENTIFIC AREA AT CORC (2023-2025)

Year	N° of Projects			Total
	DR & DME	AMD	Others (RVO, RP, STGD, NK)	
2023	12	3	8	23
2024	14	3	10	27
2025	17	2	6	25



CNTM - Centre for New Technologies in Medicine

Director: Luís Mendes, PhD

Scientific Coordinator: José Cunha-Vaz, MD, PhD

Staff: António Martinho, Celine Canguero, Francisco Ambrósio, Gonçalo Ferreira, Nicole Duarte, Raquel Santiago, Rufino Silva, Telmo Miranda



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The Centre for New Technologies in Medicine (CNTM) drives innovation at the intersection of artificial intelligence, image processing, and healthcare. Focused mainly on ophthalmology, it bridges research and clinical practice by extracting actionable insights from multimodal imaging data and medical records. It aims to develop and validate advanced AI models, imaging biomarkers, and trial endpoints to improve disease characterization and risk stratification, enable earlier detection of eye disease and associated complications such as cardiovascular or neurodegenerative conditions, and objectively monitor disease progression and treatment response.

CNTM's main research areas include diabetic retinopathy (DR) and age-related macular degeneration (AMD), two major causes of blindness. The centre has contributed extensively to the current knowledge of these conditions through active participation in large European multi-centric studies such as EUROCONDOR, RECOGNISED, and MACUSTAR.

Artificial intelligence is tightly integrated with imaging and medical records in CNTM's work, supporting models that identify eyes at higher risk of diabetic retinopathy progression and those most likely to benefit from specific treatments. These AI-driven approaches also deepen understanding of DR pathophysiology and its complications, while enabling scalable screening and decision-support systems for diabetic retinopathy programs and primary care settings.

Recognizing the eye as a “window to the body,” CNTM develops non-invasive imaging methodologies that enable repeated, quantitative assessment of retinal structure and function. CNTM is actively involved in innovative projects such as the ALERT and IMPORTANT projects, which leverages AI and advanced analytics to enhance risk detection, longitudinal monitoring, and data-driven decision-making in ophthalmology and related systemic diseases. CNTM also participates in EATRIS-CONNECT European project, which aims to strengthen digital readiness and AI-enabled translational solutions across European research infrastructures in personalized medicine. In parallel, CNTM is contributing to global efforts such as the Global RETFound initiative, which uses large-scale retinal image datasets to build Foundations AI models that can be used for ocular and systemic disease detection, including cardiovascular and neurodegenerative conditions.

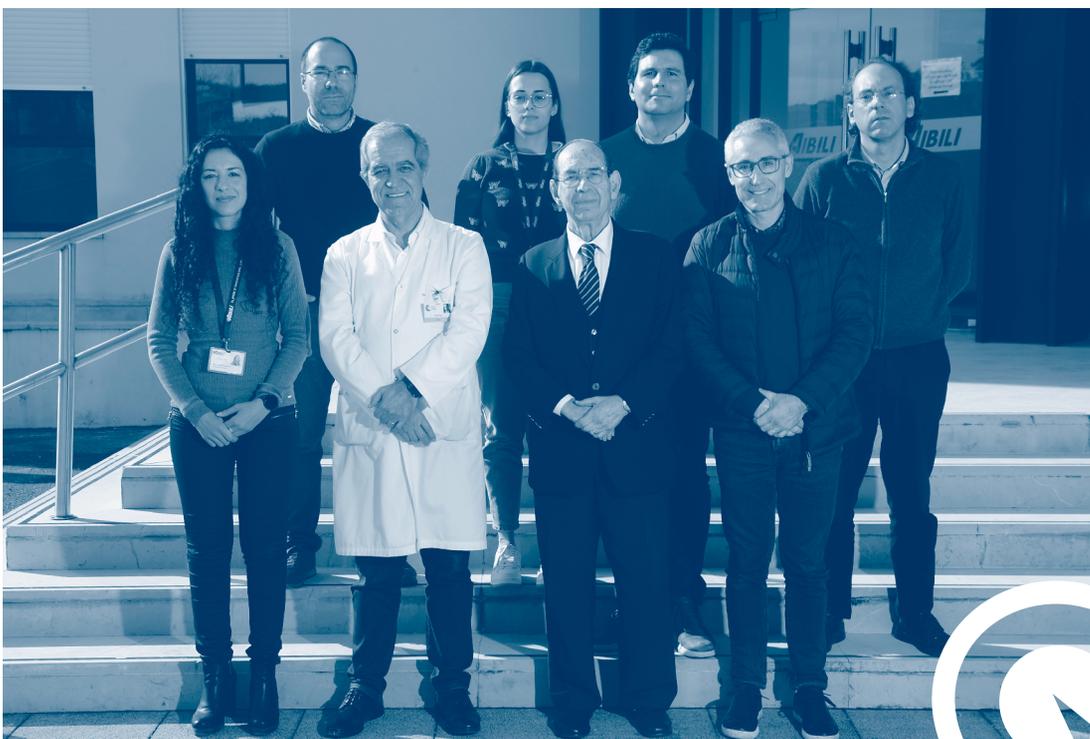
CNTM is deeply involved with development of the EVICR.net Eye Platform, a cloud-based infrastructure designed to aggregate high-quality ophthalmology data across Europe. This platform enables secondary use of clinical data for large-scale analyses, supporting clinical research and the development and validation of data-driven technologies such as artificial intelligence.

RESEARCH FOCUS

- Multimodal imaging of retinal disease, integrating structural, functional, and vascular information for comprehensive disease characterization.
- Oculomics-based detection of systemic disease risk, leveraging retinal imaging and AI to identify early biomarkers of cardiovascular and neurodegenerative conditions in diabetes.
- Development of interpretable artificial intelligence models for disease staging and identification of eyes at higher risk of progression and treatment response
- Identification and validation of prognostic imaging and clinical biomarkers of retinal disease progression.
- Development of automated biomarker measurement algorithms using artificial intelligence/image processing for objective quantification across multimodal imaging datasets.
- Evaluation of microaneurysm and intraretinal microvascular abnormality (IRMA) dynamics as quantitative tools for characterizing diabetic retinopathy progression.
- Development and validation of imaging biomarkers and trial endpoints for accelerating clinical studies and drug development in ophthalmology.

N° OF PROJECTS AT CNTM (2023-2025)

N° of Projects			
Year	Imaging / Artificial Intelligence	Diabetic Retinopathy	Total
2023	12	8	20
2024	9	9	18
2025	10	5	15



DC – Data Centre

Director: Hugo Morgado, MSc

Staff: Celine Canguero, Daniel Figueiredo, Fábio Mesquita, José Monteiro, Pedro Silva, Pier Basile, Rafael Santos, Telmo Miranda, Tiago Baptista

Consultant: Torcato Santos



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The AIBILI Data Centre was specifically built to support AIBILI's information systems, as well as to store clients and partners data. Inside the Data Centre, the server racks are connected to two separate power circuits, protected by redundant Uninterruptible Power Supplies (UPS). These redundant power supply units ensure that a failure of one power supply unit does not cause any problems, ensuring continuous power to all equipment, including servers, switches and storage. The UPS also ensures that the power 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 cooling, the Data Centre has implemented a cold air container solution with redundant air conditioning units. Cold air is directed to the container through the floor and flows through the racks, effectively dissipating the heat produced by servers and maintaining optimal temperature and humidity for electronic equipment. Water detection sensors on the floor and an automatic fire extinguisher (based on gas-based suppression system FM200) complement the Data Centre asset protection.

The Information Technology Unit (IT) maintains more than 70 servers, either virtual or physical, supported by various operating systems and technologies. There are specific Standard Operating Procedures (SOPs) in place, developed according to IT best practices, such as Information Technology Infrastructure Library (ITIL), and project management standards, as recommended by the Project Management Institute (PMI). All changes in the production environment are preceded by testing and validation processes, following the GAMP5 V-model methodology. The Data Centre Unit is responsible for guaranteeing the safety and integrity of data and images collected in compliance with GCP Guidelines and applicable national legislation.

In recognition of the critical importance of information security in today's digital landscape, AIBILI has been implementing the best practices, server management and information system security, aligned with ISO 27001 (Information Security Management Systems). Regular internal audits and penetration tests are performed to ensure the safety and integrity of data. Furthermore, AIBILI Data Centre has a Security Operation Center (SOC) that was implemented and is managed by Visionware, a specialized company in cybersecurity.

All this information is categorized with specific backup policies defined according to information value. Long-term storage procedures are in place to ensure the whole information lifecycle. Information Technology Unit manages more than 90 TB of useful information/data (clinical images and databases, administrative information, project information and long-term storage) and has the capacity for further expansion.

AIBILI Data Centre is certified by ECRIN – European Clinical Research Infrastructure Network (www.ecrin.org) version 3 since April 2016, with the recertification (for version 5.0) obtained in December 2025. AIBILI Data Centre is the only one certified in the Iberian Peninsula. ECRIN certification confirms AIBILI capacity to provide compliant, effective, and efficient data management services for multinational, randomized controlled clinical trials as well as for clinical studies.

AIBILI developed and provides management, maintenance and support to two registries, one in Keratoconus and another in Endophthalmitis for the SPO – Portuguese Society of Ophthalmology.

MAIN ACTIVITIES

- CDMS (Clinical Data Management System) implementation, validation and support
- eCRF (Electronic Case Report Form) development and management
- eCRF users training and helpdesk
- Data Management, data export and biostatistics support
- Development of Digital Grading Forms and support
- Cybersecurity activities
- Long Term Storage

N° OF SERVICES AT DC (2023-2025)

Year	Design & Development of CDMA/eCRF and Data Management	Development of Grading Forms	Development of Registries	Others	Total
2023	11	12	2	7	32
2024	12	18	1	7	38
2025	17	17	2	5	41



Organisational Units

ADMINISTRATIVE SERVICES

CEO: Cecília Martinho, BSc

Staff: Laura Seco, Mara Miraldo, Marco Santos, Paulo Barros, Sandra Jesus, Tânia Melro



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The Administrative Services (SA) are responsible for the management of AIBILI and for performing all the necessary administrative tasks, including finances and accountability, human resources management, as well as maintenance of infrastructure according to the institution's needs and in compliance with national legislation and requirements. The Administrative Services establishes a direct liaison between the Board of Directors and its Research Centres and Organisational Units. They also provide secretariat support to AIBILI Ethics Committee.



QUALITY MANAGEMENT UNIT (QMU)

Quality Manager: Rita Fernandes, BSc

Staff: Marta Ventura, Margarida Santos

The Quality Management Unit (QMU) is responsible for maintaining and continuously improving the Integrated Management System (IMS), which is implemented using an integrated approach and is compliant with ISO 9001:2015- Quality Management Systems Requirements, the principles of Good Clinical Practice (GCP – ICH E6), the requirements for Certification of ECRIN Data Centres, and applicable regulatory requirements, including Regulation (EU) 2016/679 (GDPR), Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and Regulation (EU) 2017/745 on medical devices.

The QMS supports AIBILI's activities through a process-based and risk-based approach, regular internal audits, and continuous support to the operational units, ensuring continual improvement.

In addition, ISO/IEC 27001 has been under implementation since 2023, reinforcing information security and data protection within the integrated management framework.

AIBILI is currently incorporating in its AIBILI's Integrated Management System several standards to meet the current Organizational context, namely for Data Centre services the ISO/IEC 27001 — Information security management systems - Requirements to improve its information security, cybersecurity, and privacy protection, the NIS 2 Directive(EU) 2022/2555) to enhance AIBILI cybersecurity; EMA Guideline on Computerised Systems and Electronic Data in Clinical Trials and FDA CFR Part 11 Electronic Records; Electronic Signatures.

Internal auditing is a guarantee that procedures are followed and the QMS is in continual improvement to enhance Client's satisfaction by meeting Clients' requirements. Information security internal audits have been also performed by QMU to assess the employees' conduct regarding data protection and security issues and their compliance with the internal Policies, as well as to prepare them for the current implementation of stricter procedures.

The QMU assures that the Integrated Management System (QMS) is maintained effective and efficient, permitting continual improvement and has the necessary resources to provide the services and meet the needs of its Clients and interested parties. AIBILI QMS is in digital format streamlining approvals, records and archiving, as well as giving permanent access to all information.



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AIBILI is ISO 9001 certified for all its main activities, namely for: Performance of Clinical Studies, Planning, Coordination, Monitoring of Clinical Research Activities, Pharmacovigilance, Pharmacoepidemiology and Pharmacoeconomics, Grading of Eye Exams, Research and Development in New Technologies for Medicine in the areas of Imaging, Optics and Photobiology, Data Centre Activities. The ISO 9001 certification was renewed in 2025 and is valid until 2028. Compliance is ensured through annual external audits conducted by the Certified Body.

AIBILI Data Centre is certified by ECRIN – European Clinical Research Infrastructure Network (www.ecrin.org) « since April 2016 The ECRIN certification was renewed in 2025 and is valid until 2029.

The QMU provides internal and external Quality Assurance (QA) services. The QMU also performs internal and external training on quality and regulatory requirements applicable to clinical research activities.

The QMU, as Personal Data Privacy Committee, is responsible for promoting compliance and awareness of applicable personal data protection laws, advising on the implementation of data protection standards and monitoring compliance in AIBILI.

The QMU has also a Compliance Committee, which is responsible for managing and processing whistleblower breach reports in a work-related context submitted through an internal channel available at www.aibili.pt and for the Gender Equality Plan (GEP) and the Corruption Risk Prevention Plan and Related Offences elaboration and monitoring

The QMU has also a Data Access Committee (DAC) responsible for evaluating Data Access Requests to AIBILI in order to re-use data for scientific research (via DAC@aibili.pt).

During the year, the QMU actively participated in the Data Centre – Research Data Management for Open Science, managed by the AIBILI Data Centre Unit.

QMU has been actively participating with EVICR.net Coordinating Centre in the development and implementation of the EVICR.net Eye Platform, namely in compliance with regulatory requirements, as well as in the development of SOPs for its implementation.



TRANSLATIONAL RESEARCH AND TECHNOLOGY TRANSFER UNIT (UTT)

UTT Manager: Daniel Fernandes, BSc

Staff: Cecília Martinho, Isabel Ferreira



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The Translational Research and Technology Transfer Unit supports the development of research activities and promotes translational activities by establishing the connection between the different stakeholders. It identifies opportunities for generating new knowledge and transferring technology, while also facilitating contracts with industry, research collaborations, and the pursuit of funding programs.

The UTT is also responsible for promoting and disseminating AIBILI's activities and serves as the primary point of contact for partnerships and collaborative initiatives.

INFORMATION TECHNOLOGY UNIT (IT)

IT Manager: Hugo Morgado, MSc

Staff: Celine Canguero, José Monteiro, Pedro Silva, Rafael Santos, Telmo Miranda, Tiago Baptista

Consultant: Torcato Santos



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The Information Technology Unit (IT) is responsible for AIBILI IT support and maintenance, management and maintenance of AIBILI Data Centre, IT network and information systems. The Data Centre, built in 2014 for storing AIBILI's critical information, houses all AIBILI servers and systems, including: the Electronic Medical Record that is daily used to collect patient clinical information at CEC; the custom-designed web based platform used for the transmission of images from Clinical Sites to CORC (<https://studies.corc.pt/>); the Clinical Data Management System that is used in the development of eCRFs and Grading Forms for each clinical study; as well as the Clinical Management System (CMS) used for the management of multiple multinational clinical studies by 4C.

Additionally, the AIBILI Data Centre supports other business related information systems. It also hosts the EVICR.net website (www.evicr.net) and EVICR.net Eye Platform (<https://www.evicr.net/eyeplatform/>) as well as other administrative/office information systems.

IT has been implementing the best practices in accordance with ISO 27001 for Information Security Management Systems. Furthermore, IT is incorporating several standards to meet the EMA Guideline on Computerised Systems and Electronic Data in Clinical Trials and FDA CFR Part 11 Electronic Records; Electronic Signatures.

Ethics Committee

AIBILI has an Independent Ethics Committee (IEC) that is responsible for protecting the rights, safety and wellbeing of human subjects involved in clinical studies (not involving Investigational Medicinal Products (IMP) or medical devices classified as Class IIb or III) performed by AIBILI according to the Portuguese Decree Law No. 80/2018 of October 15th.

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

For more information regarding the AIBILI Ethics Committee: <https://www.aibili.pt/units-centres/ethics-committee/>.

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MEMBERS

President

André Dias Pereira, PhD

President of the Board of Directors of the Centre for Biomedical Law of the University of Coimbra

Associate Professor at the Faculty of Law of the University of Coimbra

Vice-President of the National Council of Ethics for Life Sciences

Vice-President and Secretary

Margarida Duarte Ramos Caramona, PhD

Emeritus Professor at the Faculty of Pharmacy, University of Coimbra

Members

José António Moura Pereira, MD

Ophthalmologist at the University Hospital of Coimbra

Maria Elizabete Batista Geraldês, MD

Endocrinologist at the University Hospital of Coimbra

Paulo Simões, BSc

Former Chaplain of the University of Coimbra, Master's Student in Philosophy

Filomena Maria Ferreira Ramos Mena, BSc

Nurse at the National Institute of Forensic Medicine, Coimbra

Maria Cecília Martinho, BSc

AIBILI CEO

Technology and Innovation Center

AIBILI

associação para
investigação biomédica e
inovação em luz e imagem

EDIFÍCIO

PROF. DOUTOR JOSÉ CUNHA-VAZ





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Research and Innovation

Throughout its thirty-six 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 novel imaging methodologies in the past years, and the increased complexity in medical needs, it has become crucial for 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, AIBILI has assumed an integrated **Strategic Scientific Research Plan 2020 - 2025** with five main research areas:

- Diabetic Retinopathy
- Age-Related Macular Degeneration
- Imaging Biomarkers
- Drug Evaluation
- Translational Vision

AIBILI Strategic Scientific Research Plan 2020 - 2025 aimed to achieve four main goals, to stimulate the complementarity of AIBILI's main research areas:

INTEGRATE SCIENCE AND MEDICINE DEVELOPMENT

- Support the development of precision medicine, biomarkers
- Create integrated evaluation pathways for assessment of medical devices and innovative products

IMPROVE RESEARCH QUALITY

- Foster innovation in clinical trials
- Exploit digital technology and artificial intelligence (AI)
- Expand benefit-risk assessment and communication

ADVANCE IN PATIENT-CENTRED ACCESS TO MEDICINE

- Contribute to HTA decision-making in innovative medicines
- Promote high-quality real-world data
- Deliver improved products, targeted on earlier stages and precision medicine

LEVERAGE RESEARCH AND INNOVATION

- Foster collaboration between academia and other research institutes to address critical research innovation questions in our dedicated Research Programs
- Contribute to better healthcare and personalized medicine

The new Strategic Scientific Research Plan for 2026 - 2030 will build upon and extend the previous framework and is currently under development.

2025 Publications

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Diabetic Retinopathy Research Program

Coordinators: João Figueira, Inês Marques and José Cunha-Vaz

Research Team: Conceição Lobo, Inês Laíns, Débora Ferreira, Inês Aires, Joana Tavares, Luís Mendes, Luísa Ribeiro, Pier Basile, Rita Coimbra, Torcato Santos, Marta Lopes, Marta Pais, Ana Cláudia Rocha, Ana Almeida, Inês Pinto



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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 diabetic 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. There is a critical need for improved characterization of DR progression, including functional, structural, and microvascular imaging across the entire spectrum of disease (ETDRS levels 20 to 61).

MAIN GOALS

To identify new biomarkers of DR progression and their correlation with different risks for development of vision-threatening complications, offering new perspectives for understanding DR and for its personalized management.

ONGOING PROJECTS

PROGRESS 10 - Progression of Diabetic Retinopathy. Identification of Signs and Surrogate outcomes -10-year follow-up

ClinicalTrials.gov ID: NCT04650165
Sponsor: AIBILI

PROGRESS 10 is the continuation of the PROGRESS study (NCT 03010397), a prospective non-interventional longitudinal clinical study designed to follow type 2 diabetic individuals with non-proliferative diabetic retinopathy, in a 10-year period of follow-up.

Patients have a complete annual ophthalmological examination, including standard methodologies as color fundus photography (CFP), visual acuity, optical coherence tomography, and also taking advantage of recent and innovative approaches as Spectral domain OCT-angiography (SD-OCTA) and Swept-source OCT-angiography (SS-OCTA)

RECOGNISED - Retinal and cognitive dysfunction in type 2 diabetes: unraveling the common pathways and identification of patients at risk of dementia.

ClinicalTrials.gov ID: NCT04281186
Sponsor: VHIR, Barcelona, Spain
Financial Support: European Union – H2020-SC1-BHC-01-2019-847749

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). The 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.

CHART - Characterization of Retinal disease progression in eyes with NPDR in diabetes Type 2 using non-invasive procedures

ClinicalTrials.gov ID: NCT04636307

Sponsor: AIBILI

Financial Support: IIR Grant from Bayer

CHART is a multicentric two-year observational study that aims to better characterize the retinal changes that occur during a 2-years follow-up period in patients with the initial stages of NPDR and at higher risk for sight-threatening complications (ETDRS 35, 43, 47 and 53), allowing better characterization of eyes at risk of progression (phenotypes B and C).

The main aim is to identify biomarkers, obtained using non-invasive procedures, that can predict disease progression and progression to sight-threatening stages of the disease and to characterize the retinal changes that occur in NPDR.

RICHARD - Retinal ischemia characterization in diabetes

ClinicalTrials.gov ID: NCT05112445

Sponsor: AIBILI

Financial Support: IIR Grant from Boehringer Ingelheim

RICHARD uses state-of the art imaging methodologies to perform a complete, accurate and noninvasive evaluation of retinal ischemic events associated with diabetes, aiming for a more precise characterization of Diabetic Macular Ischemia (DMI) and its microvascular mechanisms, which can have critical importance in clinical practice allowing a more precise medicine and essential for development of new drugs and treatments.

PREDICTION - Prediction of Progression of Retinal Ischemia in Diabetes

ClinicalTrials.gov ID: NCT05581225

Sponsor: AIBILI

PREDICTION is a non-interventional observational cross-sectional and prospective study that aims to better characterize disease progression in patients with moderate to severe disease (ETDRS DRSS grade 43, 47 or 53) and to investigate the progression of microvascular changes in the diabetic retina in a 4-year prospective study, using OCTA metrics as potential biomarkers of progression of NPDR to VTDR. This study was also designed to explore functional biomarkers of DR disease.

IMPORTANT - IMaging pre-PrOlifeRative sTAge of diabetic retiNopaThy to guarantee timely treatment

Sponsor: AIBILI

Financial Support: COMPETE 2030 / FEDER COMPETE2030-FEDER-00851200

IMPORTANTS is an observational, prospective, longitudinal study of 2 years follow-up in patients with moderate to severe non-proliferative diabetic retinopathy and low-risk proliferative retinopathy. Patients undergo biannual visits with clinical observation and complementary diagnostic tests incorporating vascular imaging (OCTA; FA for ischemic and peripheral nonperfusion areas), structural OCT (including retinal layer segmentation) and functional testing (microperimetry). The main aim is to identify biomarkers of disease progression in order to predict the development of complications and institute timely treatment.

REPRESENTATIVE PUBLICATIONS

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Age-Related Macular Degeneration Research Program

Coordinators: Rufino Silva

Research Team: Alina Humenyuk, Cláudia Farinha, Inês Laíns, Joana Tavares, José Cunha-Vaz, Patrícia Barreto, Rita Coimbra

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 a 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 manifestation 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 etiology of AMD is complex, and although genomewide and gene-candidate studies have been enabled to identify genetic variants associated with AMD.



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The AMD multifactorial nature is currently well-established; however, how these factors interact to promote the development and progression of this condition remains largely unknown. This leads to a current lack of treatments for dry AMD and to halt its progression to AMD late blinding forms. Identification of progression biomarkers would be a major advance that could greatly improve patient care.

MAIN GOALS

To contribute to the understanding of the pathophysiology of AMD, and to identify novel targets for future treatments of this condition and innovative diagnosis methods.

In order to achieve this, our research is focused on:

- Structure and function relation in AMD
 - Genomics and metabolomics of AMD
 - Lifestyle and genetics interplay in AMD onset and progression
 - Drug safety and effectiveness in AMD
 - Development of innovative approaches, based on AI, to facilitate AMD diagnosis and progression
 - Correlation of genetics, pathophysiology and phenotype
-

ONGOING PROJECTS

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

ClinicalTrials.gov ID: NCT01298674, NCT02748824 and NCT01715870

AMD LifeGene - Age-Related Macular Degeneration: Genetic susceptibility, Nutrition and Lifestyle

ClinicalTrials.gov ID: NCT05735730

Sponsor: AIBILI

Financial Support: EURETINA Retinal Medicine Clinical Research Award 2022

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.

MACUSTAR - Intermediate AMD: Development of Novel Clinical Endpoints for Clinical Trials in Patients with a Regulatory and Patient Access Intention

ClinicalTrials.gov ID: NCT03349801

Sponsor: UKB, Bonn, Germany

Financial Support: European Union and EFPIA – IMI 2 Joint Undertaking - Grant Agreement n° 116076

MACUSTAR is a multinational clinical study which the major objective of 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.

BANSKY - Um motor de inferência paraconsistente para suporte à investigação sobre Degenerescência Macular da Idade

Sponsor: INESC TEC, AIBILI and University of Aveiro (CIDMA, its Research Center in Maths)

Financial Support: COMPETE 2030 / FEDER - COMPETE2030-FEDER-00892000

This project innovates on AMD prediction analysis through new methods and tools for paraconsistent reasoning over complex, weak consistent data classified by often contradictory medical judgements. The team fosters synergies between INESC TEC, AIBILI and UA (CIDMA, its Research Center in Maths).

MONDEGO - Study to Investigate the Efficacy, Safety and Durability of Faricimab in Caucasian Patients With Polypoidal Choroidal Vasculopathy

ClinicalTrials.gov ID: NCT06709339

Sponsor: AIBILI

Financial Support: IIR Grant from Roche

MONDEGO is a Phase IV, Multicentre, Open-label, Single-arm Study to Investigate the Efficacy, Safety and Durability of Faricimab (RO6867461) in Caucasian Patients With Polypoidal Choroidal Vasculopathy.

Epigenetics in Age-related Macular Degeneration

Sponsor: AIBILI and Multidisciplinary Institute of Ageing (MIA)

Financial Support: MIA and AIBILI

This exploratory project, performed jointly by AIBILI and MIA, seeks to clarify whether the protective effect of the adherence to the Mediterranean diet is associated with epigenetic signatures.

Biomarkers for development and/or progression in Age-related Macular Degeneration

Sponsor: AIBILI and Sano – Centre for Computational Personalised Medicine

This exploratory project performed jointly by AIBILI and Sano, seeks to deepen the understanding of AMD development or progression by identifying lifestyle habits (smoking status, physical exercise, adherence to the Mediterranean diet), phenotypic and genotypic AMD profiles to identify new targets to prevent AMD progression to intermediate AMD/late AMD.

REPRESENTATIVE PUBLICATIONS

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Imaging Biomarkers Research Program

Coordinators: Conceição Lobo and José Cunha-Vaz

Research Team: Débora Ferreira, Inês Marques, João Figueira, Luís Mendes, Torcato Santos



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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. 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 data collected can be analysed automatically. The analysis of the data can also be tailored to specific purposes, allowing

validating imaging biomarkers of disease. Our group has been able to identify biomarkers of disease progression, such as microaneurysm (MA) turnover in diabetic retinopathy (DR) identified automatically by the Retmarker® software, and changes in the Blood Retinal barrier (BRB), detected non-invasively, using the AIBILI patented algorithm, OCT-Leakage.

MAIN GOALS

To develop new imaging techniques of the eye fundus for diagnosis and risk progression, with particular interest in non-invasive methodologies allowing repeated observations and measurements to identify early alterations and degree of activity.

ONGOING PROJECTS

Optical Coherence Tomography Angiography and Widefield Fundus Photography as tools to evaluate capillary closure and disease severity level

Sponsor: AIBILI

Financial Support: Study performed in partnership with Carl Zeiss Meditec (CA, USA)

Ultra-widefield CFPs devices are now commonly available at clinical practices as they allow to image more than 80% of the retinal surface area, providing detailed visualization of the retinal periphery. OCTA has also begun to play a relevant role in DR management, by offering non-invasive, three-dimensional mapping of the retinal microvasculature. This technology enables the quantification of capillary closure, which correlates with the progression of DR. Furthermore, understanding the regional distribution of retinal capillary changes, showing that changes in the periphery may be indicative of retinopathy progression. This insight enables our understanding of DR progression and helps to create more accurate risk progression profiles.

OCT-Leakage. Layer by layer fluid analysis of the retina

Sponsor: AIBILI

Our group is developing applications that result to advanced

imaging algorithms to enable analysis of OCT data, focusing on the segmentation of the different layers of the retina and to evaluate the alterations of permeability of the BRB. In a recent publication, our research group reported an association between abnormal retinal fluid accumulation, BCVA loss and increased perfusion in the deep capillary plexus in eyes with CI-DME.

A European Patent n° 3289565 was attributed to the "Method and device for the non-invasive indirect identification of sites of alterations of the Blood-Retinal Barrier" by the EPO - European Patent Office as well as by the USPTO – United States Patent and Trademark Office, with n° US 11,234,591 B2.

Artificial intelligence for characterization of retinal biomarkers

In recent years, the availability of huge amounts of data and the development of disruptive deep learning techniques are pushing artificial intelligence (AI) to another level. One of the main goals of this Research Group 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. Another related goal is the creation of a multimodal imaging dataset suitable for the training and validation of automatic methods.

ALERT - Analysis of DR progression to identify risks and need for treatment

Sponsor: AIBILI

Financial Support: COMPETE 2030 / FEDER and Portuguese Foundation for Science and Technology (FCT) (Project COMPETE2030-FEDER-00921900)

The ALERT project is a research project (2025-2028) that focuses on the diabetic population, particularly on patients at risk of developing or progressing diabetic retinopathy and related cardiovascular complications. It evaluates how widefield retinal imaging combined with artificial intelligence models can improve staging of diabetic retinopathy and prediction of disease progression.

The long-term objective is to enhance diabetes management by integrating these AI tools into clinical practice, enabling more accurate risk stratification and more personalised follow-up strategies.

Risk Profiles - Identification of the eyes that are at higher risk of DR progression and with the greatest potential to respond to a given treatment.

Sponsor: AIBILI

The progression of NPDR to vision-threatening stages with vision loss varies from individual to individual. It is, therefore, of major relevance to identify the presence of retinopathy and, when present, to identify the eyes that have the greatest risk of progression and greatest potential to benefit from treatment. Special attention was given to the development of interpretable AI models using multimodal features and studying the role of microaneurysms as a tool for characterizing DR progression.

EVICR.net Eye Platform

Sponsor: AIBILI

Financial Support: IIR Grant from Boehringer Ingelheim

The Eye Platform is a cloud-based software solution designed to collect, organize, and share well-characterized multimodal ophthalmic data, thereby fostering and accelerating clinical research that uses AI-based tools. The project comprised the development of the platform itself, its operational deployment, and the continuous support needed to onboard and manage new clinical studies.

The first study incorporated into the Eye Platform was INTERCEPT-AMD (PI: Prof. Sobha Sivaprasad, Moorfields Eye Hospital), which uses existing data on patients with intermediate AMD, with and without early atrophy, to predict disease progression. A second study, commissioned to start in 2026, will focus on patients with more advanced stages of diabetic retinopathy who are at high risk of progressing to vision-threatening complications, using the platform to characterise progression patterns and develop predictive models.

Ultra-widefield CFP vs 7-fields at 30° for ETDRS severity level evaluation

Sponsor: AIBILI

Financial Support: In partnership with Carl Zeiss Meditec (CA, USA)

To identify and compare the ETDRS severity level of diabetic patients using 3 different images modalities: the standard 30° ETDRS 7-fields CFP and two wide-field techniques (Clarus 500TM and OptosTM). Our group published a paper showing a nearly perfect agreement between 7-Filed CFP and Ultra-widefield CFP on ETDRS grading. In addition, Ultra-widefield CFP helped with a finer evaluation of retinal lesions. Our goal is to demonstrate that ETDRS severity level can be accurately evaluated using only two ClarusTM high quality images with wider amplitude, while improving the quality and identification capability of key disease features with less artifacts than other WF systems.

REPRESENTATIVE PUBLICATIONS

Marques IP, Ribeiro ML, Santos T, Reste-Ferreira D, Mendes L, Martinho AC, Santos AR, Figueira J, Lobo C, Cunha-Vaz J. **Patterns of Progression of Nonproliferative Diabetic Retinopathy Using Non-Invasive Imaging.** *Transl Vis Sci Technol.* 2024;13(5):22. doi:10.1167/tvst.13.5.22

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Drug Evaluation Research Program

Coordinators: Joana Abrantes

Research Team: Daniel Figueiredo, Inês Tavares, Joana Tavares, Lisete Lemos



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The demand on healthcare services and the challenges of drug development, in the light of increased aging of population, changing patterns of disease and increased costs of drugs, creates the need for research on the effectiveness, safety and economics of medical research and development (R&D), as well as the complexities of

reimbursement. Our research is, through several interconnected ongoing projects, aimed at real world outcomes, safety, economics and market access of drugs.

MAIN GOALS

To strengthen the evaluation of drugs for the benefit of public health, through research and development of methodologies to assess their safety, effectiveness and efficiency as well as the corresponding costs for either the national Health agencies or the patient itself.

ONGOING PROJECTS

DruSER.Net – Drug Safety and Effectiveness Research Network

Sponsor: AIBILI

The DruSER.Net is a research network of Hospitals and Primary Healthcare Centers, 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 drugs used in routine clinical practice and therefore contributing for patient safety through the conduction of research projects using real-world data. In addition, DruSER.Net promotes collaboration among healthcare professionals and researchers to enhance evidence-based decision-making in clinical settings.

Post-Authorisation Safety Studies

Sponsor: AIBILI

Financial Support: INFARMED I.P.

Post Authorisation Safety Studies (PASS) are essential to obtain further information on a medicine's safety or to measure the effectiveness of risk-management measures. The MARVEL study, completed in 2023 and funded by INFARMED, I.P., focused on assessing the effectiveness of educational

materials for healthcare professionals and patients/caregivers for three Ophthalmology drugs. Building on this collaboration, a new study protocol, ARTEMIS (Aflibercept: Estudo de Monitorização Intensiva de Segurança), has been designed for 2024. This study aims to investigate the safety profile and potential adverse drug reactions associated with two dosages of the antiangiogenic agent aflibercept (Eylea®) in clinical practice in Portugal. The ARTEMIS study will also compare the safety data of the newly approved 8 mg dosage (114.3 mg/ml), granted marketing authorization by the European Medicines Agency in January 2024, with findings from the Bayer® PULSAR and PHOTON studies, while continuing to monitor the long-established 2 mg dosage (40 mg/ml). In 2025, a new collaborative study within the national pharmacovigilance system was designed to assess the effectiveness of risk minimisation measures for metamizole-induced agranulocytosis (META-RISK).

Probabilistic Models for Health Technologies Assessment (ProMoHTA)

Sponsor: AIBILI

ProMoHTA studies analytical and symbolic methods for the analysis of economic models, with a special focus on Markov models. For this purpose, it uses the software PRISM – Symbolic Probabilistic model checker. This tool allows the specification of a model and facilitates its symbolic study. Estimation tools using the Monte Carlo method are also

implemented in this software, allowing to compare the performance of both approaches. Finally, the specification of Markov models through the PRISM tool allows the researcher to use the temporal logic language embed in the software, along with other functionalities.

A case study was developed and published under the title "Probabilistic Model Checking in HTA: A Case Study for Ranibizumab", showcasing the practical application of these methods in health technology assessment.

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Translational Vision Research Program

Coordinators: António Francisco Ambrósio

Research Team: Ana Raquel Santiago, Celso Henrique Alves, Hélène Léger, José Cunha-Vaz, Raquel Boia, Rosa Fernandes



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AIBILI and the Faculty of Medicine - University of Coimbra (FMUC) have a long-term collaborative research partnership, particularly with the Coimbra Institute for Clinical and Biomedical Research (iCBR, former IBILI). This represents an excellent and strategic opportunity for the facilitation of Translational Research and Innovation based on knowledge gathered from fundamental research in vision science.

The Translational Vision Research Program results from the collaboration between AIBILI and the Retinal Dysfunction and Neuroinflammation Lab, a research Group from iCBR-FMUC, headed by the coordinator of this Program, Francisco Ambrósio.

MAIN GOALS

To promote innovative translational vision research, with two main focuses:

- translating important findings gathered in fundamental and pre-clinical research into potential novel therapies for retinal degenerative diseases;
- establishing novel biomarkers of disease, disease progression and response to therapy.

ONGOING PROJECTS

Novel therapeutic strategies: Dissecting the mechanisms of action of sitagliptin - potential drug repurposing

Financial Support: COMPETE 2030 / FEDER - COMPETE2030-FEDER-00742100

The therapies available for retinal degenerative diseases are scarce and are mainly targeted for the later stages of disease. Moreover, they are not effective in a high percentage of patients and can cause some adverse effects. Therefore, novel therapies are needed, particularly for the early stages of disease, with the aim of delaying their progression for sight threatening retinopathies. To tackle this, we have a main goal:

- testing the efficacy of sitagliptin, a drug that is already in the market, which exhibits pleiotropic effects beneficial for the retina.

We previously reported that sitagliptin, a drug used in the treatment of type 2 diabetes, has significant protective effects in the retina of diabetic animal models, including an animal model of type 1 diabetes. In this model, the glycemic levels are very high, despite the sitagliptin treatment, indicating that the protective effects of sitagliptin can be independent of the

glycemic control. Moreover, sitagliptin has potent anti-inflammatory effects in the retina of diabetic animals. (Neuro)inflammation has been regarded as an important player in neural and vascular dysfunction and degeneration in diabetic retinas. Microglia, the immune cells of the central nervous system, including the retina, have a key role in mediating neuroinflammation. Our preliminary data indicate that sitagliptin is able to inhibit retinal microglia reactivity, and the effects of sitagliptin can be exerted directly on microglia. Taking this into account, we are dissecting the mechanisms underlying the anti-inflammatory effects of sitagliptin on microglial cells. We are investigating whether those effects are exclusively mediated by the inhibition of the enzyme DPP-IV, the pharmacological target of sitagliptin, which is expressed in microglia, or if the inhibition of microglia reactivity can be also due to pleiotropic effects of sitagliptin.

The results of this project might open new avenues for drug repurposing of sitagliptin, which could potentially be used in the treatment of retinal and brain pathologies characterized by neuroinflammation-mediated neural and endothelial cell dysfunction and death.

hiPSCs derived endothelial cells to identify novel mechanisms of disease and drug targets in diabetic retinopathy (Project C2C)

Sponsor: AIBILI and iCBR/FMUC

Financial Support: AIBILI and Fundação para a Ciência e a Tecnologia (FCT), I.P. under CiBB Strategic Project (2025-2029) UID/04539/2025

We have collected skin biopsies from patients with proliferative diabetic retinopathy and from age and sex-matched non-diabetic individuals (3 samples from each group). With the collaboration of Center for Neuroscience and Cell Biology (CNC), we have obtained fibroblasts and iPSCs samples from the skin samples of those patients and controls (approximately 200 aliquotes). We have already implemented the protocol for the differentiation of hiPSCs into RPE cells, photoreceptor precursors, endothelial cells and retinal organoids. These cells/organoids will be used to investigate diabetic retinopathy disease mechanisms and to identify potential novel therapeutic targets.

A new therapeutic approach to leverage vision restoration in glaucoma

Financial Support: Medalhas de Honra L'Oréal para as Mulheres na Ciência 2022

Although anti-glaucoma eye drops effectively lower intraocular pressure, glaucoma may continue to progress and threaten vision in many patients. Thus, there is an urgent need to rethink the therapeutic paradigm of glaucoma to halt disease progression. A drug able to target retinal ganglion cells could be an important glaucoma management tool.

Retinal ganglion cell loss and degeneration that leads to permanent vision loss is attributed to an initial injury to optic nerve, resulting in a permanent loss of axonal connections with specific brain targets. Thus, the goal of this project is to protect sight by preserving the function of retinal ganglion cells (neuroprotection), while enabling these cells to re-extend axons and re-establish connections in appropriate target areas of the brain (neuroregeneration).

The failure of axonal regeneration in the mature central nervous system has been attributed both to an insufficient intrinsic growth capacity of its neurons and an inhibitory extrinsic environment. Thus, grounded in our previous work that A3R agonist protects retinal ganglion cell from glaucomatous, this project is evaluating the A3R activation in the promotion of long-distance regeneration of retinal ganglion cell axons and correct reintegration in retino-recipient brain targets, aiming vision restoration.

REPRESENTATIVE PUBLICATIONS

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4

International Networking

EVICR.NET - EUROPEAN VISION INSTITUTE CLINICAL RESEARCH NETWORK



The EVICR.net is a network of European Ophthalmological Clinical Research Centres, dedicated to performing multinational clinical research in ophthalmology, following the European and International Directives for Clinical Research.

At present, EVICR.net has 90 Clinical Ophthalmological Research Centres members from 16 European countries. 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.

Scientifically it is organised 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 and Reading Centres.

The present Chairman of EVICR.net is Prof. Francesco Bandello from Department of Ophthalmology, University Vita Salute – Scientific Institute of San Raffaele, Milan, Italy, Clinical Site n° 67.

AIBILI is the Coordinating Centre of EVICR.net, and is responsible for the management of the Network, coordination of multinational clinical research studies, as well as for developing training activities in ophthalmology clinical research.

Becoming a Member

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 agree to implement organisational SOPs according to ICH – GCP Guidelines.

Once a member, the Clinical Site can adopt/harmonise EVICR.net SOPs with the help of the Coordinating Centre in order to become a EVICR.net certified Clinical Site of Excellence. This certification is valid for 4 years period which can be renewed.

Clinical Studies and Registries

AIBILI, as EVICR.net Coordinating Centre, assumes the 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, 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. All information is available at www.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 2025 there were six ongoing multinational clinical research studies of which two are European Union funded.

ONGOING CLINICAL STUDIES AND ACTIVITIES

Age-Related Macular Degeneration

MACUSTAR - Intermediate AMD: Development of novel clinical endpoints for clinical trials in patients with a regulatory and patient access intention

ClinicalTrials.gov ID: NCT03349801

Financial Support: European Union and EFPIA - IMI2 Joint Undertaking - Grant Agreement n° 116076

INTERCEPT-AMD - A collaborative resource of Heidelberg multimodal imaging of Intermediate AMD with and without early atrophy to study prediction of disease progression

ClinicalTrials.gov ID: NCT05698316

Financial Support: Boehringer Ingelheim

MONDEGO - A phase IV, multicenter, open-label, single-arm study to investigate the efficacy and safety of faricimab (RO6867461) in caucasian patients with polypoidal choroidal vasculopathy

ClinicalTrials.gov ID: NCT06709339

Financial Support: IIR Grant from Roche

ADX-038-202 - Safety, Tolerability, PK and PD of ADX-038 in Healthy Participants and Paroxysmal Nocturnal Hemoglobinuria (PNH) Patients (PNH)

ClinicalTrials.gov ID: NCT05876312

Sponsor: ADARx Pharmaceuticals, Inc.

Diabetic Retinopathy

RECOGNISED - Retinal and Cognitive Dysfunction in Type 2 Diabetes: Unraveling the Common Pathways and Identification of Patients at Risk of Dementia

ClinicalTrials.gov ID: NCT04281186

Financial Support: European Union – H2020-SC1-BHC-01-2019-847749

CHART - Characterization of Retinal disease progression in eyes with NPDR in diabetes Type 2 using non-invasive procedures

ClinicalTrials.gov ID: NCT04636307

Financial Support: IIR Grant from Bayer

Glaucoma

NEUROPA - Retinal Ganglion Cell Neuroprotection Under Prostaglandin Analogues

ClinicalTrials.gov ID: NCT07074782

Financial support: IIR Grant from Viatrix

ORGANISATION OF MEETINGS

EVICR.net gathered in Belfast, UK, on 13–14 November 2025 for a highly productive and inspiring 20th EVICR.net Members Meeting. It was a great opportunity to connect, exchange ideas, and strengthen the collaboration that drives our work forward. Three Investigator Initiated Study Meetings took place. A keynote lecture “Rethinking Diabetic Retinopathy: The Neurovascular Unit as a Therapeutic Target” by Tim Curtis (CS 35, UK) and an update on ICH-GCP E6 (R3) were presented.

We would like to thank the meeting sponsors: Bayer, Boehringer Ingelheim, Roche and Viatrix. The 21th Members Meeting in 2026 will take place in Paris, France, on November 19-20, 2026. An EVICR.net Symposium at SOE 2025 in Lisbon dedicated to

Cataract Surgery in the Presence of Corneal Pathologies took place on June 8th 2025, and had the participation of the following speakers.

EVICR.net has organised the Symposium “EVICR.net – European Vision Clinical Research Network” on September 6, 2025, during EURETINA 2025 in Paris, France. This symposium was an opportunity to present updates on the MACUSTAR, CHART, RECOGNISED and INTERCEPT-AMD studies. The collaboration with the DRCR Retina Network from USA was also shared and will proceed with the participation of EVICR.net Members in the Protocol AR. The Eye Platform: European-wide high quality ophthalmic imaging database for large data analysis and clinical research was also presented.

INDUSTRY ADVISORY BOARD

The Industry Advisory Board advises the Steering Committee in all matters of strategic relevance, particularly pertaining collaborations with Industry. The Industry Advisory Board is composed of individuals or representatives of entities who have given support for the activities of EVICR.net, by invitation of the Steering

Committee. The Industry Advisory Board Members are: Alcon, AbbVie, Bayer, Boehringer Ingelheim, Pfizer (Viatrix), Novartis, Santen, SIFI, Théa and Roche.

We are glad to have SIFI as a new Industry Advisory Member in 2025.

EVICR.net EYE PLATFORM

The EVICR.net Eye Platform is a long-term initiative designed to collect in a common platform high-quality ophthalmology data (namely imaging data) generated in Europe and allow secondary use of data and foster clinical research in all ophthalmology subspecialties.

The analysis of imaging data enhances the understanding of disease progression, contributing to the improvement of patient care in ophthalmology.

Ophthalmology relies on imaging data, which is objective and can be automatically verified and analyzed for consistency, accuracy, completeness, auditability, validity, uniqueness, and timeliness. This makes imaging data highly suitable for efficient and secure collection.

INTERCEPT-AMD Study - A collaborative resource of Heidelberg multimodal imaging of Intermediate AMD with and without early atrophy to study prediction of disease progression.

EVICR.net Eye Platform first study was a collaborative project organised by the AMD Expert Committee.

The Coordinating Investigator is Prof. Sobha Sivaprasad, NIHR Moorfields Clinical Research Facility, Moorfields Eye Hospital, NHS Foundation Trust, London, United Kingdom (EVICR.net CS n° 10), together with Prof. Francesco Bandello, Department of Ophthalmology, University Vita Salute – Scientific Institute of San Raffaele, Milan, Italy (EVICR.net CS n° 67) as Coordinator of the AMD Expert Committee.

RECENT PUBLICATIONS

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Investigators from 26 EVICR.net Sites participated in the study, contributing with anonymised datasets from 1.000/819 patients, on multimodal imaging of intermediate and early atrophic AMD to develop a resource for secondary analysis and co-author publications.

The analysis of data from the study resulted in the publication of two peer-reviewed articles in *Eye*: “Visual acuity in various phenotypes of intermediate age-related macular degeneration (AMD) in a multicentre cohort study in Europe — INTERCEPT-AMD Report 1” and “Baseline factors associated with changes in visual acuity in intermediate AMD over two years in a multicentre cohort study in Europe — INTERCEPT-AMD Report 2.” A third manuscript entitled “Change in visual acuity and transition from intermediate to late AMD by two years in a multicentre cohort study in Europe- INTERCEPT-AMD Report 3” was submitted to *Eye* in the end of 2025.

The Eye Platform and the INTERCEPT-AMD study are funded by Boehringer Ingelheim.

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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 clinical research in ophthalmology, 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, whereas ECRIN provides support in the submission and coordination at national level. The MACUSTAR clinical study is an example of this collaboration where the overall clinical study coordination is performed by EVICR.net under the leadership of Prof. Frank Holz, University Hospital Bonn, Germany (Sponsor), and the submission and monitoring activities are performed by ECRIN.

More information
<https://www.ecrin.org/>

EATRIS - EUROPEAN INFRASTRUCTURE FOR TRANSLATIONAL MEDICINE

European infrastructure
for translational medicine

EATRIS is a client driven, non-profit organization comprising European academic centres 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; Biomarkers; Imaging & Tracing; Small Molecules; and Vaccines, Inflammation and Immune Monitoring.

AIBILI is a member of EATRIS and has capacities in the Biomarkers and Imaging and Tracing platforms.

More information
<https://eatris.eu/>

ERN-EYE - EUROPEAN REFERENCE NETWORK ON RARE EYE DISEASES



The European Reference Network on Rare Eye Diseases (ERN-EYE) is led by Prof. Hélène Dollfus (Strasbourg, France) and is composed of 52 full members and 8 affiliated partners in 24 EU countries. ERN-EYE is organised 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, 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/>





5

Partners



CHUC - Coimbra Hospital and University Centre

CHUC is the largest Hospital Center in Portugal playing a central role in the hospital structure of the Center region of Portugal. CHUC, which integrates the Local Health Unit of Coimbra, is a regional and national reference hospital center for a significant number of highly complex pathologies and has the recognition, by the competent bodies, of a large number of reference centers for complex and/or rare pathologies that require a degree of professional, technical and scientific differentiation.

AIBILI and CHUC have a Protocol in place that allows the performance of ophthalmology clinical research through clinical trials, as well as observational studies.



ESCOLA SUPERIOR DE SAÚDE



School of Health Polytechnic of Porto

The School of Health (e2s) is a well-established school with a recognised path in education and research in Technologies and Health Sciences. The TBIO - Center for Research in Translational Health and Medical Biotechnology intends to rely on AIBILI to pursue its objectives of solving problems for bioindustries and developing new diagnostic technologies and therapeutic approaches.



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 support FMUC investigators in the overall development and coordination of clinical research studies.



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 contributes as a Research Technology Organisation dedicated to developing, coordinate and perform clinical research studies needed before launching medicines or medical devices in the market.



iCBR – Coimbra Institute for Clinical and Biomedical Research

Coimbra Institute for Clinical and Biomedical Research (iCBR) 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 aims to establish the link between pre-clinical and clinical research, setting the ground for the development of innovative research 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 merges three institutes and researchers from several schools of the Porto University, thus consolidating an extensive collaboration between all institutions. 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.

AIBILI has a partnership with i3S in the field of Genetics and Diabetic Retinopathy and is currently involved in the co-supervision of a PhD student.



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 has been responsible for a Pharmacovigilance Regional Unit of the National Pharmacovigilance System contracted with INFARMED, IP.



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 together they are able to provide a global ophthalmology clinical research support to industry.



IPN - Instituto Pedro Nunes

Created in 1991 through a University of Coimbra initiative, Instituto Pedro Nunes (IPN) is a private non-profit organisation which promotes innovation and the transfer of technology, establishing the connection between the scientific and technological environment and the production sector.

AIBILI and IPN have signed a protocol to collaborate with the Laboratory for Automatics and Systems (LAS). LAS develops R&D and technology transfer activities in partnership with companies, in the field of Embedded Systems, Collaborative Robotics, Internet of Bodies, Validation, Evaluation and Certification of medical devices. The aim is to promote research, development and innovation with a focus on creating value for companies, transferring technological assets, accelerating the development of technologies and the generation of products, innovative processes and services for the market, particularly medical devices in the healthcare sector.



MIA – Multidisciplinary Institute of Ageing

MIA Portugal is the first research institute in Southern Europe focused on the molecular and biological basis of ageing and works for the health and wellbeing of an ageing population.

AIBILI and MIA have signed a protocol with the aim of accelerating the development of technologies and the generation of innovative products, processes and services for the health market in the field of ageing.



PtCRIN – Portuguese Academic Clinical Research Infrastructures Network

PtCRIN 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 is a Clinical Trial Unit as well as a Clinical Research Centre. AIBILI has the only ECRIN Certified Data Centre in the Iberian Peninsula since 2016, recertified in 2021 and 2025 by ECRIN.



SANO – Centre for Computational Personalised Medicine

Sano is a non-profit foundation advancing computational medicine to enhance global healthcare efficiency and effectiveness. This partnership with AIBILI enables collaboration on joint research and innovation (R&I) projects, as well as hosting activities such as curricular internships, professional internships, master's and doctoral theses, and capacity-building and training programs for students and professionals.



SOCIEDADE PORTUGUESA
OFTALMOLOGIA

SPO – Portuguese Ophthalmology Society

SPO was founded with the aim of promoting and contributing to the development of Ophthalmology in its different aspects: community and prophylactic, care and curative, scientific, educational and research, with respect for ethics and professional deontology professional ethics; defend the interests of its members, particularly in the exercise of the profession the exercise of the profession; to contribute to the correct conception of a health policy in the Ophthalmology, ensuring standards of quality and competence in accordance with the requirements of medical science. requirements of medical science.

A Protocol between AIBILI and SPO is in place allowing the mutual collaboration in clinical research activities, namely training, reinforcement of existing collaboration networks and support to investigator-initiated studies promoted by SPO associates.



universidade
de aveiro

UA – Aveiro University

The UA is a public foundation under private law whose mission is to contribute to and develop graduate and postgraduate education and training, research and cooperation with society. This partnership with AIBILI allows to cooperate in clinical research activities as well as to students from the Master in Medical Statistics of UA to perform internships at AIBILI.



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