association for innovation and biomedical research on light and image

INTEGRATED MANAGEMENT SYSTEM MANUAL

NP EN ISO 9001:2015 – "Quality Management Systems-Requirements"

ISO/IEC 27001:2022 – "Information security, cybersecurity and privacy protection - Information security management systems – Requirements" – being implemented

Good Clinical Practices

ECRIN Requirements for Data Centre Certification

General Data Protection Regulation (EU) 2016/679

Ver. 46

INDEX

Note: Correlation with ISO 27001: 2022 is documented in the "Statement of Applicability" (SoA) classified as restricted and confidential information.

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I – PROMULGATION

This Integrated Management System Manual describes the Integrated Management System (SGI/IMS) of AIBILI in accordance with the requirements of ISO 9001, ISO/IEC 27001 currently being implemented, Principles of Good Clinical Practices whenever a clinical study is performed, requirements for Certification of ECRIN Data Centre when performing IT and Data Management services within clinical studies and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 and national Law when processing personal data and on the free movement of such data.

As part of its commitment to quality, information protection, and the continual improvement of its processes, the organization is currently implementing an Information Security Management System (ISMS) in accordance with the requirements of ISO/IEC 27001.

At this stage, the implementation places particular emphasis on the IT/Data Centre of AIBILI, which is considered critical in the context of information management and protection. Nevertheless, the principles, practices, and requirements related to information security are promoted and applied across the organization, with impact and influence extending throughout AIBILI.

AIBILI Board of Directors and Management Committee demonstrates its commitment to protecting AIBILI's information assets by ensuring the confidentiality, integrity, and availability of information, as well as the systematic management of information security risks and compliance with legal and regulatory requirements. For this purpose, a structured process for the identification, analysis, and evaluation of information security risks has been conducted, based on which a Statement of Applicability (SoA) has been established. The SoA identifies the applicable security controls, their justification, and their implementation status, as well, as the scope of the Information Security Management system classified as restricted and confidential information.

The organization is committed to implementing, maintaining, and continually improving the Integrated Management System, while ensuring compliance with applicable legal, regulatory, and contractual requirements related to quality and information security

The AIBILI Board of Directors demonstrates leadership and commitment with respect to the Integrated Management System (SGI/IMS), including the Quality and Information Security

I – PROMULGATION

Management System. The Board ensures that the necessary resources and governance are in place for the effective implementation and continual improvement of the system.

The Board of Directors delegates authority to the President and to the Management Committee, of which the President is a member, for the formal approval and oversight of the Quality and Information Security Policy, as well as the Integrated Quality and Information Security Manual.

AIBILI Staff are responsible for supporting the implementation, maintenance, and continual improvement of the Integrated Management System (SGI/IMS), in accordance with their roles and responsibilities within the organization.

II – QUALITY AND INFORMATION SECURITY POLICY

- Ensure to the client and other interested parties, a high quality service that meets their needs and expectations in compliance with the standard ISO 9001, ISO/IEC 27001, Principles of Good Clinical Practices whenever a clinical study is performed, requirements for Certification of ECRIN Data Centres when performing Data Centre activities, Legislation applicable to the protection of personal data, in particular Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 and Portuguese Law No. 58/2019 and Law No. 59/2019 of 8th August when processing personal data and on the free movement of such data, as well as regulatory requirements, statutory and legal, applicable to AIBILI activities.
- Ensure the transfer of basic science to clinical practice and the health market through translational research, thus contributing to the development of the country;
- Maintain adequate and updated technical resources, infrastructure and work environment that allow an effective and efficient response to the needs and expectations of Client as well as to ensure compliance with Client requirements;
- Ensure adequate and continual training of personnel to maintain and improve their competence to carry out the activities for which they are responsible;
- Raise awareness among all personnel of the Integrated Management System (including but not limited to Quality and Information Security), ensuring the application of the process approach and risk-based thinking, maintaining the confidentiality, integrity, and availability of information, and promoting the fulfilment of client and interested parties' requirements, as well as continual process improvement.
- Promote partnership with other interested parties relevant to the Integrated Management System to achieve mutual benefits and continuity.
- Regularly review the performance of the processes and the impact on Client and interested parties, particularly their satisfaction, to implement actions to achieve the continual improvement of services and the efficiency and effectiveness of the Integrated Management System.

THE MANAGEMENT COMMITTEE

III – GENERAL INFORMATION OF AIBILI

AIBILI - Association for Innovation and Biomedical Research on Light and Image is a Research Technology Organisation in the health area dedicated to the development and clinical research, of new products for medical therapy and diagnostic imaging.

It is a private non-profit organisation, founded in 1989. By providing the infrastructure and regulatory expertise needed for clinical trials, it supports pharmaceutical and medical device companies bring new treatments to market faster and more safely. Our focus area is clinical research, and we coordinate and perform multinational clinical trials (Phases I–IV) for both industry and investigators. We are also involved on transforming medical imaging into predictive tools for personalized medicine through artificial intelligence and deep learning models. While it supports various medical fields, AIBILI is internationally renowned for its expertise in ophthalmology.

Our Vision – Advance health through clinical and translational research, supporting the development, evaluation and implementation of innovative diagnostic and therapeutic solutions.

Our Mission – Be an international reference partner in health technology innovation, transforming research into solutions that improve patient outcomes and healthcare practice.

Our Values - Quality and rigor, foster innovation, work collaboratively, act with ethics and social responsibility, and invest in continuous development of people, methods and technologies.

AIBILI is ISO 9001 certified for the following activities:

- 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.

AIBILI Data Centre is certified by ECRIN Data Centre requirements

AIBILI is currently implementing ISO/IEC 27001:2022. While the implementation of the Information Security Management System currently prioritizes the IT/Data Centre of AIBILI, due to its key role in information handling and protection, the organization promotes a broader adoption of information security principles so that their application and benefits extend across all areas of AIBILI. Clinical

III – GENERAL INFORMATION OF AIBILI

Research is performed in accordance with ICH Guidelines for Good Clinical Practice (GCP), European and national applicable legislations and regulations. AIBILI follows Regulation (EU) No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, as implemented in Portugal by Law No. 9/2026. It also complies with Portuguese Law No. 21/2014 on clinical research, as amended by Law No. 73/2015, Law No. 49/2018, and Law No. 9/2026.

AIBILI also follows Regulation (EU) No. 2017/745, Portuguese Law No. 71/2025 and Law-Decree No. 29/2024, as well as ISO 14155 - Clinical investigation of medical devices for human subjects - Good clinical practice, when performing clinical investigation of medical devices for human subjects.

The processing of personal data and the free movement of such data is performed in accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 and other legislation applicable to the protection of personal data, namely, the Portuguese Law No. 58/2019, of 8 August.

AIBILI is located in the Health Campus of Coimbra University since 1994 and has its own building with 1.454 m2 and state-of-the-art equipment. Regarding human resources it has a permanent multidisciplinary staff and some part-time individual collaborations mainly for research activities.

AIBILI is organized in research centres:

- 4C - Coimbra Coordinating Centre for Clinical Research – academic Clinical Trial Unit / CRO
- CEC - Clinical Trial Centre – Clinical Research Centre / Clinical Site
- CORC - Coimbra Ophthalmology Reading Centre
- CNTM - Centre for New Technologies in Medicine
- DC - Data Centre

The Integrated Management System Unit (USGI) is responsible for the management, maintenance, and continuous improvement of AIBILI's Integrated Management System (SGI/IMS), ensuring compliance with quality, regulatory, and ethical requirements as well as information security. ISO/IEC 27001 has been under implementation, strengthening information security, cybersecurity, and privacy.

USGI has 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).

AIBILI has a Personal Data Privacy Committee which 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. Any question regarding personal data protection should be addressed to privacy@aibili.pt.

AIBILI has also a Compliance Committee responsible for compliance with the Portuguese General Regime for the Prevention of Corruption (RGPC), which comprises managing and processing whistleblower breach reports submitted through the internal channel available at www.aibili.pt, as well as for the Gender Equality Plan (GEP). The Compliance Committee together with the IT Unit, the Personal Data Privacy Committee (in case of personal data) and applicable information asset responsible is also responsible to ensure the assessment of an Information Security Incident.

AIBILI has a Scientific Committee, responsible for defining and implementing a Strategic Scientific Research Plan, and overseeing its follow-up, across five main research areas: Diabetic Retinopathy and Imaging Biomarkers; Age-Related Macular Degeneration; Artificial Intelligence and Biomarkers; Drug Evaluation and Translational Vision.

AIBILI has also an independent Ethics Committee for Clinical Research (CE) to assess the clinical studies as applicable by Law 21/2014 of 16 of April amended by the Law No. 73/2015, of 27 of July, Law No. 49/2018, of 14th of August, and Law No. 9/2026, of 6 March, the latter on clinical trials on medicinal products for human use.

AIBILI Board of Directors delegates their functions on the Management Committee that ensure the development and implementation of the management system and continual improvement of its effectiveness.

AIBILI has partnerships with national and international institutions, namely with: CF - Champalimaud Foundation; ESS.PP – Escola Superior de Saúde do Politécnico do Porto; FMUC - Faculty of Medicine of the University of Coimbra; i3S – Institute for Research and Innovation in Health of the University of Porto; iCBR - Coimbra Institute for Clinical and Biomedical Research; INFARMED - National Authority of Medicines and Health Products, I.P.; INFOCUS Clinical Research, USA; IPN - Instituto Pedro Nunes; , Massachusetts Eye and Ear – Harvard Medical Scholl, USA; MIA Portugal – Multidisciplinary Institute of Ageing; Moorfields Eye Hospital, UK; SANO - Centre for Computational Personalised Medicine; SPO – Sociedade Portuguesa de Oftalmologia; UA – Universidade de Aveiro; ULS Coimbra -Local Health Unit of Coimbra; and others.

III – GENERAL INFORMATION OF AIBILI

AIBILI is the Coordinating Centre of the European Vision Institute Clinical Research Network – EVICR.net, an independent European Economic Interest Grouping (EEIG), established in 2010 in accordance with the Council Regulation (EEC) No. 2137/85 of 25 July.

EVICR.net is a disease-oriented network of European Ophthalmological Clinical Research Sites, dedicated to perform multinational clinical research in ophthalmology with the highest standards of quality, following the European, International Directives for Clinical Research and ICH-GCP Guidelines. It is mainly dedicated to support multinational Investigator Initiated Research (IIR). Scientifically it is organized by ophthalmology subspecialty Expert Committees. For detailed information consult website: www.evicr.net.

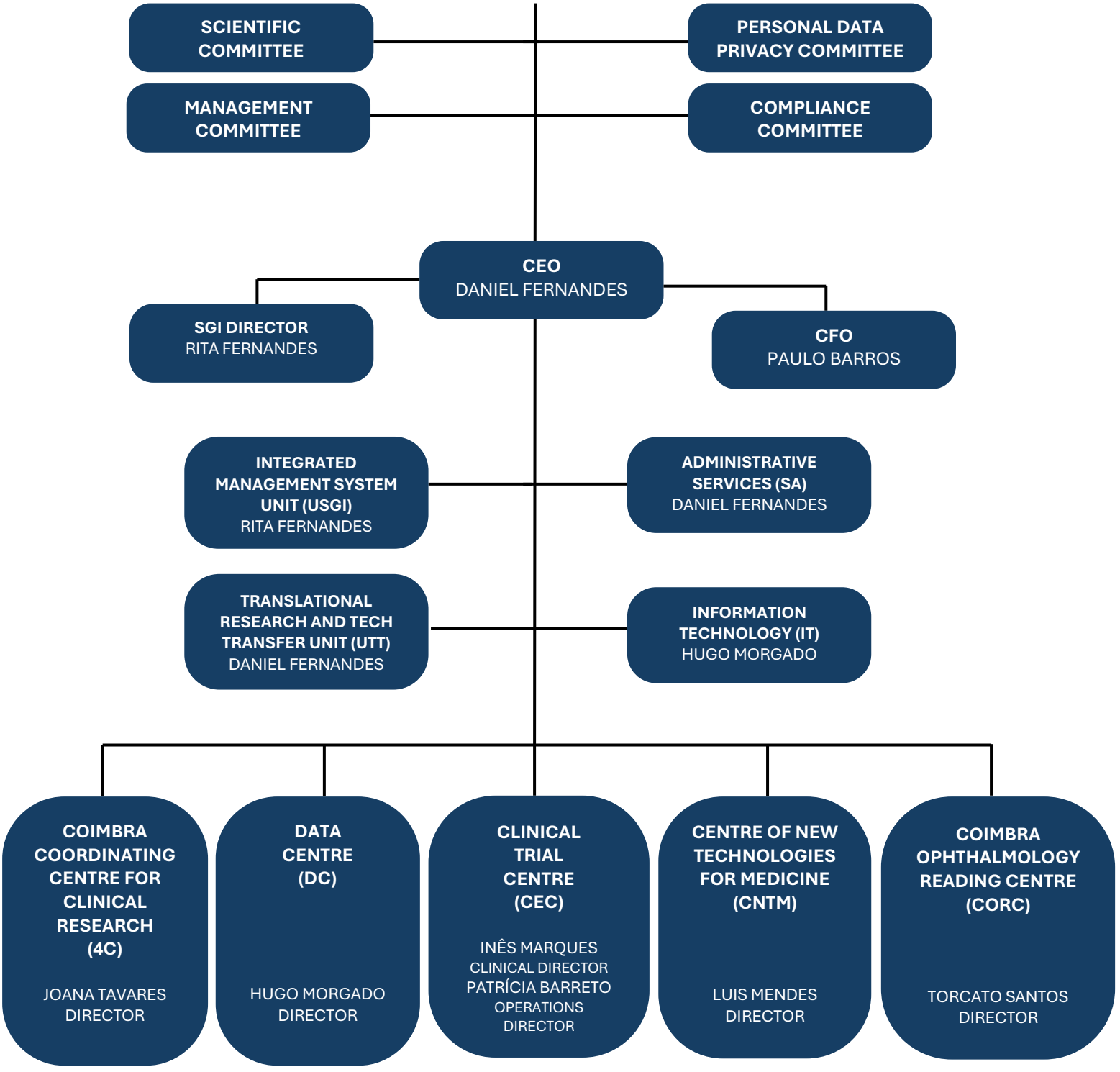
EVICR.net is as a fundamental resource for the development of translational research in the European Union in the area of Ophthalmology and Vision Sciences.

The main goals of AIBILI are **translational research and innovation** contributing to the conversion of basic research knowledge into practical applications in order to improve human health and wellbeing. For detailed information, consult website: www.aibili.pt.

BOARD OF DIRECTORS
CONCEIÇÃO LOBO
PRESIDENT

ETHICS COMMITTE

III – GENERAL INFORMATION OF AIBILI



4C - Coimbra Coordinating Centre for Clinical Research

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

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

Since 2008 AIBILI has been responsible for a Regional Pharmacovigilance Unit of the National Pharmacovigilance System which is contracted with the National Authority of Medicines and Health Products (INFARMED, IP).

DC - Data Centre

AIBILI Data Centre was built specifically to support AIBILI's information systems. However, the existing space and environment conditions allow for expansion to store clients/partners data and information. AIBILI Data Centre services are provided by the Information Technology / Data Centre (IT/DC) Unit.

AIBILI Data Centre is certified by ISO 9001:2015 for Data Centre Activities and by ECRIN Data Centre requirements since 2016, meeting the ECRIN requirements for IT and Data Management within Clinical Studies, complies with Good Clinical Practices, Good Practice for Computerised Systems, as well as regulatory requirements, statutory and legal, applicable to AIBILI activities.

AIBILI Data Centre is currently implementing ISO/IEC 27001:2022.

The services provided by AIBILI Data Centre are:

- 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
- Long Term Storage

CEC - Clinical Trial Centre

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.

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

CNTM - Centre of New Technologies for Medicine

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. Its mission is to develop and validate advanced AI models, imaging biomarkers, and trial endpoints that improve disease characterization and risk stratification, enable earlier detection of eye disease and associated complications including cardiovascular and neurodegenerative conditions, and objectively monitor disease progression and treatment response.

Artificial intelligence is tightly integrated with imaging and medical records across CNTM's work, supporting the development of interpretable AI 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.

Building on more than three decades of contribution to ophthalmic imaging science, CNTM is particularly interested in developing non-invasive methodologies that allow repeated observations and measurements to identify early alterations amenable to timely therapeutic intervention, supporting precision medicine. CNTM contributed to the concept of Multimodal Macula Mapping, the integration of information from multiple imaging techniques to establish spatial and temporal correlations among retinal parameters and pioneered automated monitoring of diabetic retinal disease progression through co-registration of sequential fundus images and automatic lesion detection. This work led to the creation of Retmarker SA, initially a company of the Critical Software group and now part of METEDA S.r.l. (Rome, Italy). Another innovative solution, OCT-Leakage, enables non-invasive analysis of Blood-Retinal Barrier permeability and has been granted both European and United States

patents. The process of technology transfer is initiated by innovation at the laboratory level well before the development of applications that can later be tested in clinical studies, and this approach has led to R&D contracts with industry.

AIBILI is a member of EATRIS, the European infrastructure for translational medicine, reinforcing its capacity to bring innovative diagnostic and biomarker-based solutions from bench to bedside within a pan-European framework. Currently, CNTM is also engaged with EVICR.net in the creation of the Eye Platform, a cloud-based infrastructure for gathering and reusing high-quality ophthalmological data across European clinical sites. In the field of oculomics, CNTM is building a computational framework that integrates open-source and in-house AI tools for metric extraction into unified, reproducible processing pipelines applicable to multiple retinal imaging modalities (CFP, OCT, OCTA, ultra-wide-field). A major effort is also underway in the validation of Optical Coherence Tomography Angiography for diagnosing and monitoring progression of diabetic retinopathy and in the development of interpretable AI models incorporating explainability techniques such as SHAP analysis for NPDR staging and progression prediction. CNTM is also exploring new concepts for intelligent clinical trial monitoring that combine risk-based quality management, automated imaging quality assurance, and AI-assisted oversight to improve the efficiency and reliability of ophthalmic clinical research.

As the result of the work developed in CNTM the following international patents were granted:

- Ocular Fluorometer for Clinical Use, US Patent n.º 6,013,034. 05/11/1997.
- Method and Apparatus for Measuring Quantity of a Fluorochrome in a Biological Environment, WO/2008/067525. 20/11/2008.
- System for Analysing Ocular Fundus Images, US Patent n.º 7,856,135. 02/12/2009.
- Method and device for the non-invasive indirect identification of sites of alterations of the Blood-Retinal Barrier, EPO Patent 3 289 565 B1 and US 11,234,591 B2.

CORC – Coimbra Ophthalmology Reading Centre

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.

By grading several features using different imaging modalities, CORC aims to contribute to the characterization and quantification of ophthalmic diseases, mainly in the areas of posterior segment/retinal diseases as Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME), Age-related Macular Degeneration (AMD), Inherited Retinal Diseases (IRD) like Retinitis Pigmentosa (RP) and Stargardt Disease (STGD), Retinal Vein Occlusion (RVO) and anterior segment diseases as Neurotrophic Keratitis. The variety of imaging modalities of CORC expertise include retinal fundus images (FP, FA, UWF imaging, ICG, FAF, OCT and OCTA), anterior segment images (Cornea or anterior surface photography) as well as some functional examinations like visual fields, microperimetry and ERG.

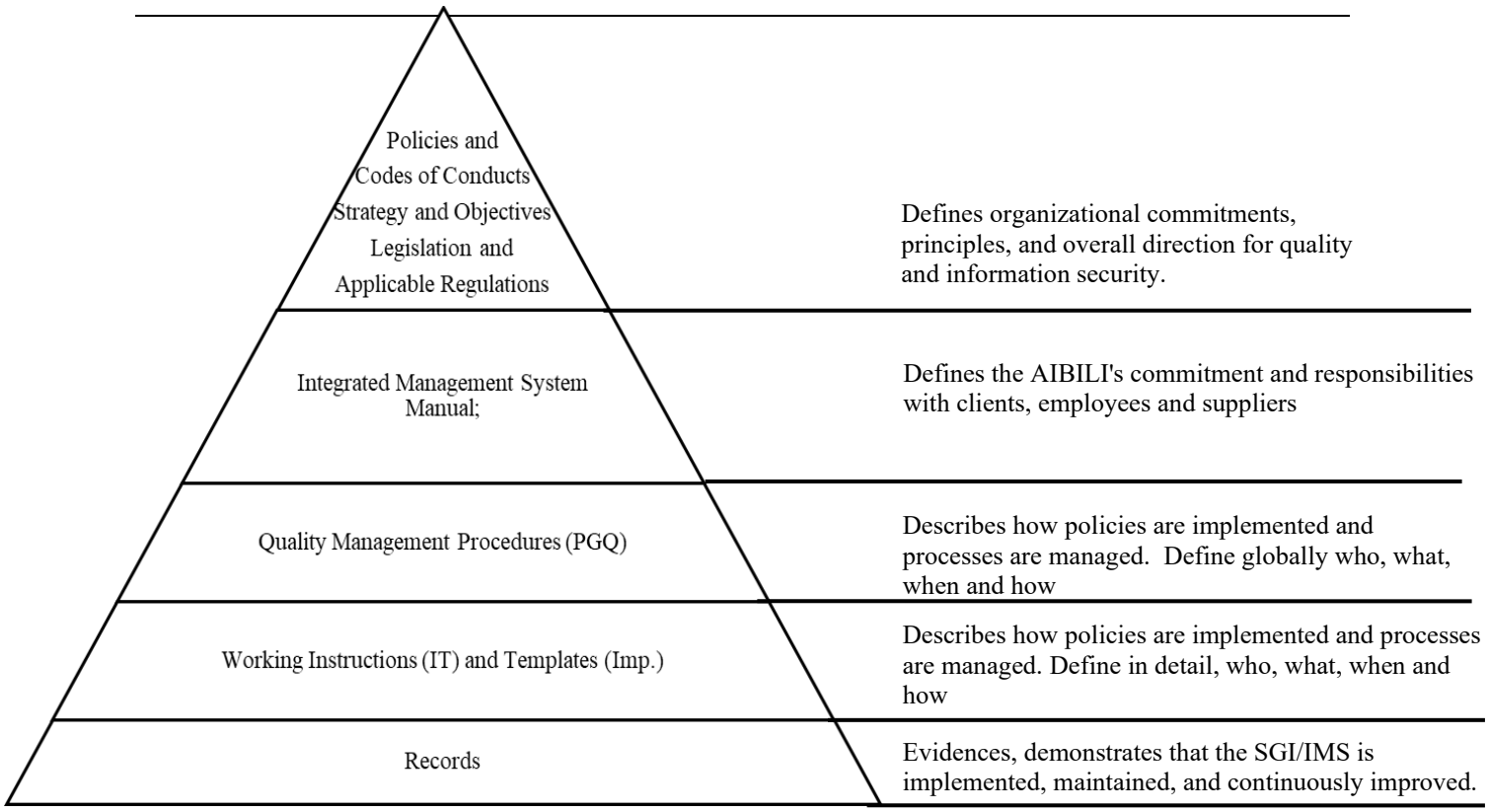
CORC uses IT systems hosted on AIBILI's Data Centre certified by ECRIN such as the CORC imaging Platform (www.studies.corc.pt), a secure custom-designed web-based tool for the transmission of images between Clinical Sites and CORC; and the REDCap software used as CORC Digital Grading Forms Platform to record grading results (Digital Grading Forms).

III – GENERAL INFORMATION OF AIBILI

- The AIBILI Integrated Management System Unit (USGI) is responsible for the management, maintenance, and continuous improvement of AIBILI's Integrated Management System (SGI/IMS) of several standards, guidelines and regulations, as ISO 9001, ISO/IEC 27001, ECRIN Data Centre requirements, Principles of Good Clinical Practices, GDPR, as well as other regulatory requirements, statutory and legal, applicable to AIBILI activities.
- Top Management ensures that the Integrated Management System (such as Quality Management System (QMS), Information Security Management System (ISMS)) are established, implemented, maintained, and continually improved. Relevant policies, objectives, and documented information are communicated within the organization and made available through the internal document management system. Awareness and training activities are conducted to ensure that personnel understand their roles and responsibilities, and relevant information is communicated to interested parties where appropriate.

- AIBILI structured its Integrated Management System (SGI/IMS) and supports it through a hierarchical set of documents that are described below.

III – GENERAL INFORMATION OF AIBILI



AIBILI Operational Manual is organized by PGQs, ITs and Imp. and structured as stated in Appendix 1.The correlations of AIBILI IMS with ISO 9001:2015 are listed in Appendix 2, Principles of Good Clinical Practices in Appendix 3, AIBILI IMS correlation with ECRIN Data Centre requirements is in Appendix 4, GDPR Correlation in Appendix 5. ISO/IEC 27001:2022 is currently being implemented, the correlation with ISO 27001: 2022 is documented in the "Statement of Applicability" (SoA) classified as restricted and confidential information.

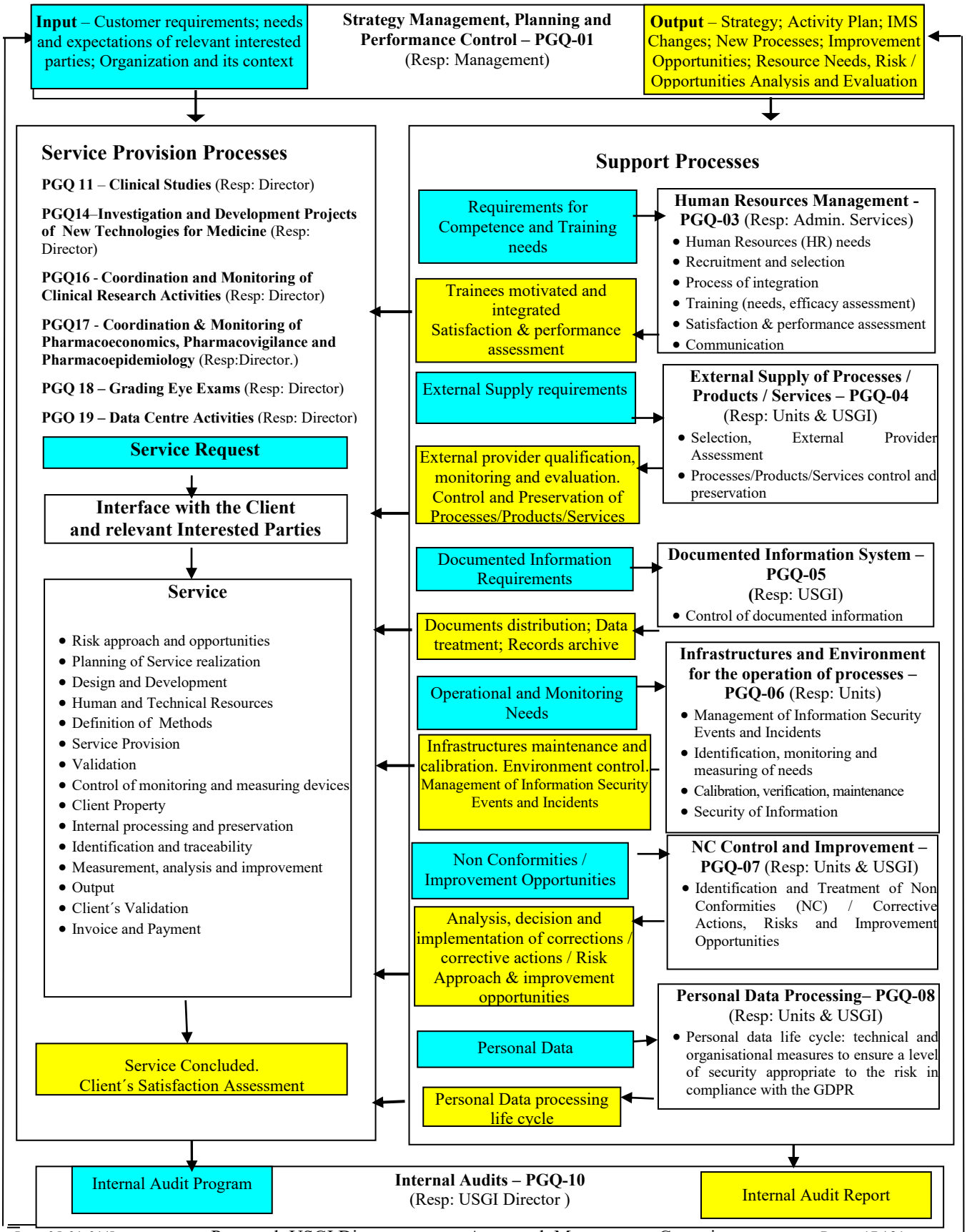
All this documentation is communicated, including subsequent versions, to whom may be concerned.

Institutional Communication between AIBILI and employees and other interested Parties

To make sure that ISMS and related Policies are well known and communicated within the organization, they are available in the Filedoc (*Digital Documental System*) and internal training is regularly performed, as well as communicated to other interested parties, when applicable.

APPENDIX 1 – INTEGRATED MANAGEMENT SYSTEM – PROCESSES INTERRELATION

The Integrated Management System (SGI/IMS) is supported by processes with the following interrelation:



APPENDIX 2 - CORRELATION WITH NP EN ISO 9001:2015

Integrated Management System Manual and Procedures	Requirements of NP EN ISO 9001:2015																							
	4	5.1	5.2	5.3	6.1	6.2	6.3	7.1	7.2	7.3	7.4	7.5	8.1	8.2	8.3	8.4	8.5	8.6	8.7	9.1	9.2	9.3	10.2	10.3
I - Promulgation	■																							
II - Quality and Information Security Policy			■																					
III- General Information	■																							
PGQ 01- Strategy Management, Planning and Performance Control	■	■	■		■	■	■			■	■		■							■		■		
PGQ 03-Human Resources Management		■		■				■	■	■														
PGQ 04-External Supply of Processes / Products / Services					■		■	■					■			■	■	■	■					
PGQ 05- Documented Information System												■					■							
PGQ 06- Infrastructures and Environment for the operation of processes								■									■							
PGQ 07- - NC Control & Improvement Management																	■		■				■	■
PGQ 08- Personal Data Processing	■	■			■		■			■	■	■	■	■	■	■	■	■	■	■				
PGQ 10-Internal Audits																					■			
PGQ 11- Clinical Studies	■	■			■	■	■			■	■	■	■	■	■	■	■	■	■	■				
PGQ 14- Investigation and Development Projects of New Technologies for Medicine	■	■			■	■	■			■	■	■	■	■	■	■	■	■	■	■				
PGQ 16 –Coordination & Monitoring of Clinical Research Activities	■	■			■	■	■			■	■	■	■	■	■	■	■	■	■	■				
PGQ 17 – Coordination & Monitoring of Pharmacoeconomics, Pharmacovigilance and Pharmacoepidemiology	■	■			■	■	■			■	■	■	■	■	■	■	■	■	■	■				
PGQ 18 – Grading Eye Exams	■	■			■	■	■			■	■	■	■	■	■	■	■	■	■	■				
PGQ 19 – Data Centre Activities	■	■			■	■	■			■	■	■	■	■	■	■	■	■	■	■				

Legend: ■ applicable; not applicable

APPENDIX 3 - CORRELATION WITH PRINCIPLES OF GOOD CLINICAL PRACTICES and – National Law No. 21/2014, of 16 April, changed by Law No. 73/2015, of 27 July; Law No. 49/2018, of 14 August and Law No. 9/2026, of 6 March

Integrated Management System Manual and Procedures	GCP Requirements applicable to AIBILI - Articles of Law No. 21/2014, changed by Law No. 73/2015, Law No. 49/2018 and Law No. 9/2026***																																
	Art.1º	Art.2º	Art. 3º	Art. 4º	Art. 5º	Art. 6º	Art. 7º	Art. 8º	Art. 9º	Art. 10º	Art. 11º	Art. 11º-A	Art. 12º	Art. 13º	Art. 14º	Art. 15º	Art. 16º	Art. 17º	Art. 18º	Art.19º	Art 20, Art 22º	Art. 23º	Art. 25º	Art. 26º	Art. 27º a 31º	Art32	Art33 e 34º	Art. 36º e 37º	Art.38º	Art.39º	Art.40	Art.42	Art.51º	& Art.5º,16,17,21, 24a28,33a39, 43a46,51,52a56
I - Promulgation	■																																
II - Quality and Information Security Policy			■	■																													
III- General Information			■	■																								■					
PGQ 01- Strategy Management, Planning and Performance Control														■																			
PGQ 03-Human Resources Management									■	■																							
PGQ 04-External Supply of Processes / Products / Services									■	■					■	■																	
PGQ 05- Documented Information System																	■		■	■	■			■									
PGQ 06- Infrastructures and Environment for the operation of processes																																	
PGQ 07- NC Control & Improvement Management									■	■																							
PGQ 08- Personal Data Processing	■		■			■	■	■	■	■	■	■				■				■	■	■	■	■					■				
IT 06-6 – Management of Information Security Events and Incidents	■		■			■	■	■	■	■	■	■				■				■	■	■	■	■					■				
PGQ 10-Internal Audits																																	
PGQ 11- Clinical Studies*	■	■	■	■	■	■	■	■		■			■			■	■			■	■	■	■			■				■	■	■	■	
PGQ 14- Investigation and Development Projects of New Technologies for Medicine *	■	■	■	■						■										■			■							■	■	■	■	
PGQ 16 –Coordination & Monitoring of Clinical Research Activities**	■	■	■	■	■	■	■	■	■		■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■			■	■	■	■	
PGQ 17 – Coordination & Monitoring of Pharmacoeconomics, Pharmacovigilance and Pharmacoepidemiology	■	■	■	■						■							■			■	■									■	■	■	■	
PGQ 18 –Grading Eye Exams	■	■	■	■						■							■			■	■									■	■	■	■	
PGQ 19 – Data Centre Activities	■	■	■	■						■							■			■													■	

Note: * Investigator´s Responsibility; ** Sponsor´s Responsibilities; & applicable to Regulatory Authorities; *** Law No. 9/2026, of 6 March, implementing Regulation (EU) No. 536/2014 at the national level, amended Article 1 of Law No. 21/2014, of 16 April. As of now, clinical trials of medicinal products for human use are governed by Law No. 9/2026, while other clinical research remains governed by Law No. 21/2014.

Legend: ■ applicable; not applicable

APPENDIX 4 - CORRELATION WITH ECRIN REQUIREMENTS FOR DATA CENTRE CERTIFICATION - VERSION Nº5

Integrated Management System Manual and Procedures	ECRIN Requirements for Data Centre Certification*																
	GE 01	IT 01	IT 02	IT 03	IT 04	IT 05	IT 07	DM 01	DM 02	DM 03	DM 04	DM 05	DM 06	DM 07	DM 08	DM 09	ST 01
PGQ19	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	
IT 19-01 - Management of Data Centre Services	■	■						■	■	■	■	■	■	■	■	■	
IT 19-02 - Server Management		■															
IT 19-03 - Security Access Management		■	■	■													
IT 19-04 - Business Continuity					■												
IT 19-05 - General System Validation						■											
IT 19-06 - Extracting and Reporting Data														■	■		
IT 19-07- Data Management				■				■	■	■	■	■	■	■			
IT 19-08 - General Standards	■		■											■	■	■	
IT 19-10 - Coding Procedure															■		
IT 19-11 - Randomisation, Treatment allocation, Blinding and Unblinding Procedure																	■
IT 16-09 - Protocol Deviation and Serious Breach Procedure																	ST 01.06
ISMS Policies: Operational Rules; Cryptographic and key management policy; Portable Storage Management and Destruction Policy; Internal Security Audit and Penetration Testing Policy	■	■	■	■	■	■	■										
PGQ03-Human Resources (HR) Management; IT3-3 - Management of HR Competences	■																
PGQ07 - Non Conformities Control and Improvement Management;	■																
PGQ 08- Personal Data Processing	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
IT 06-05 - Accessibility, Management, and Maintenance of the IT Network				■	■		■										
IT 06-06 – Management of Information Security Events and Incidents	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
PGQ10-Internal Audits; IT10-1- Quality Internal Audits	■																
IT 01-04 - Internal Whistleblowing Channel Procedure	■																

Legend: ■ applicable ; not applicable

Note: *IT06 and ST02 are not applicable to DC

APPENDIX 5 - CORRELATION WITH GENERAL DATA PROTECTION REGULATION (EU) 2016/679 OF 27th April 2016

Procedures	art.4,5,6,8,9,15,16,17,18,19,20,21,22, 24,25,26,27,28,29,30,31,32,33,34,35, 36,37*,38*,39*,44,45,46,48,49,88,89; considerandos 32,33,39,42,43,58 a 63,65 a 72,74 a 79,82,83,84,85 a 94, 96,97,101 a 115,129,132,156,157,159,169	art.5,12,15,16,17,18,19,20,21, 22,23,30,31,38*,39*,89; considerandos 32,33,39,42,43,58 a 63,65 a 72,82,129,132,156,157,159	art.31,33,34,38*,39 * considerandos 39,58, 59,60,74 a 78,83,85 a 88,97	art.7,13,88	art.8,9, 89	art.28,29,32, considerandos 81,83,95	art.33, 34	considerandos 32,33,38,39, 40 a50,61 a 63	art. 39*
IT 01-04- Procedure for Internal Whistleblower Report									
PGQ 03-Human Resources Management									
PGQ 04-External Supply of Processes / Products / Services									
PGQ 07- Improvement Management									
PGQ 08- Personal Data Processing									
IT 08-1 - Management of personal data processing life cycle									
IT 08-2 - Data Subject Exercise of Rights									
IT 08-3 - Management of Personal Data Breach									
IT 06-6 – Management of Information Security Events and Incidents									
PGQ 10-Internal Audits									
PGQ 11- Clinical Studies									
PGQ 14- Investigation and Development Projects of New Technologies for Medicine									
PGQ 16 –Coordination & Monitoring of Clinical Research Activities									
PGQ 17 – Coordination & Monitoring of Pharmacoeconomics, Pharmacovigilance and Pharmacoepidemiology									
PGQ 18 – Grading Eye Exams									
PGQ 19 – Data Centre Activities									

Legend:*DPO is not mandatory regarding our activity (artº37). AIBILI has a Personal Data Protection Committee applicable ; Not applicable;