AIBILI association for innovation and biomedical research on light and image

QUALITY MANUAL

NP EN ISO 9001:2015
ISO/IEC 27001:2022 – being implemented.
Good Clinical Practices
ECRIN Requirements for Data Centre Certification
General Data Protection Regulation (EU) 2016/679

Ver. 43

INDEX

Note: ISMS – Information Security Management System Manual (ISO/IEC 27001:2022) is available for consultation in AIBILI website https://www.aibili.pt/downloads/

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Approved by the Management Committee:
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I – PROMULGATION

This Quality Manual describes the Quality Management System of AIBILI in accordance with the requirements of ISO 9001, ISO/IEC 27001, 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 when processing personal data and on the free movement of such data.

AIBILI Board of Directors demonstrates the leadership and commitment with respect to AIBILI´s Information Security Management System (ISMS) and delegates in the President and in the Management Committee the formal approval of the Quality and Information Security Policy and Quality Manual.

AIBILI staff is responsible for the implementation, maintenance, and improvement of AIBILI´s QMS.

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 nº58/2019 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;
- Promote awareness to all personnel of the Integrated Quality Management System with the Information Security System, standards, regulatory requirements, statutory and legal, applicable the activity , the use of the process approach and risk-based thinking, ensure the confidentiality, integrity and availability of information stored, processed and transmitted, through the application of administrative, management, legal and technological controls, so that, in its daily activities, they meet Client and other interested parties requirements and participate in the processes of continual improvement;
- Promote partnership with other interested parties relevant to the quality 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 improvement of services and the efficiency and effectiveness of the Integrated Quality 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, established to support technology transfer and translational research in the health area.

AIBILI is a Technology and Innovation Centre (CTI) in the health area of the National Network of the Economy Ministry. This recognition identifies AIBILI as the facilitating partner between scientific institutions, enterprises, and industry in order to bring novel solutions to the health market.

Our Mission – to be a reference partner with the best resources and quality systems in the field of health technology innovation.

Our Vision – to improve human health and wellbeing by converting basic research knowledge into innovative applications.

Our Values - to perform quality services, in an innovative and collaborative manner, to be internationally renowned.

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 Data Centre is currently implementing ISO/IEC 27001:2022

Clinical Studies are performed in accordance with ICH Guidelines for Good Clinical Practice (GCP), European and national applicable legislations and regulations.

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 nº58/2019 of 8th August.

AIBILI is located in the Health Campus of Coimbra University since 1994 and has its own building with 1.454 m^2 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 organizational Units are: Administrative Services (SA), the Translational Research and Technology Transfer Unit (UTT), the Information Technology Unit (IT) and the Quality Management Unit (UGQ).

The Quality Management Unit (UGQ) 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.

The Quality Management Unit (UGQ) has also a Compliance Committee 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) elaboration and monitoring.

The Compliance Committee together with the IT Unit, 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.

UGQ 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).

III – GENERAL INFORMATION OF AIBILI

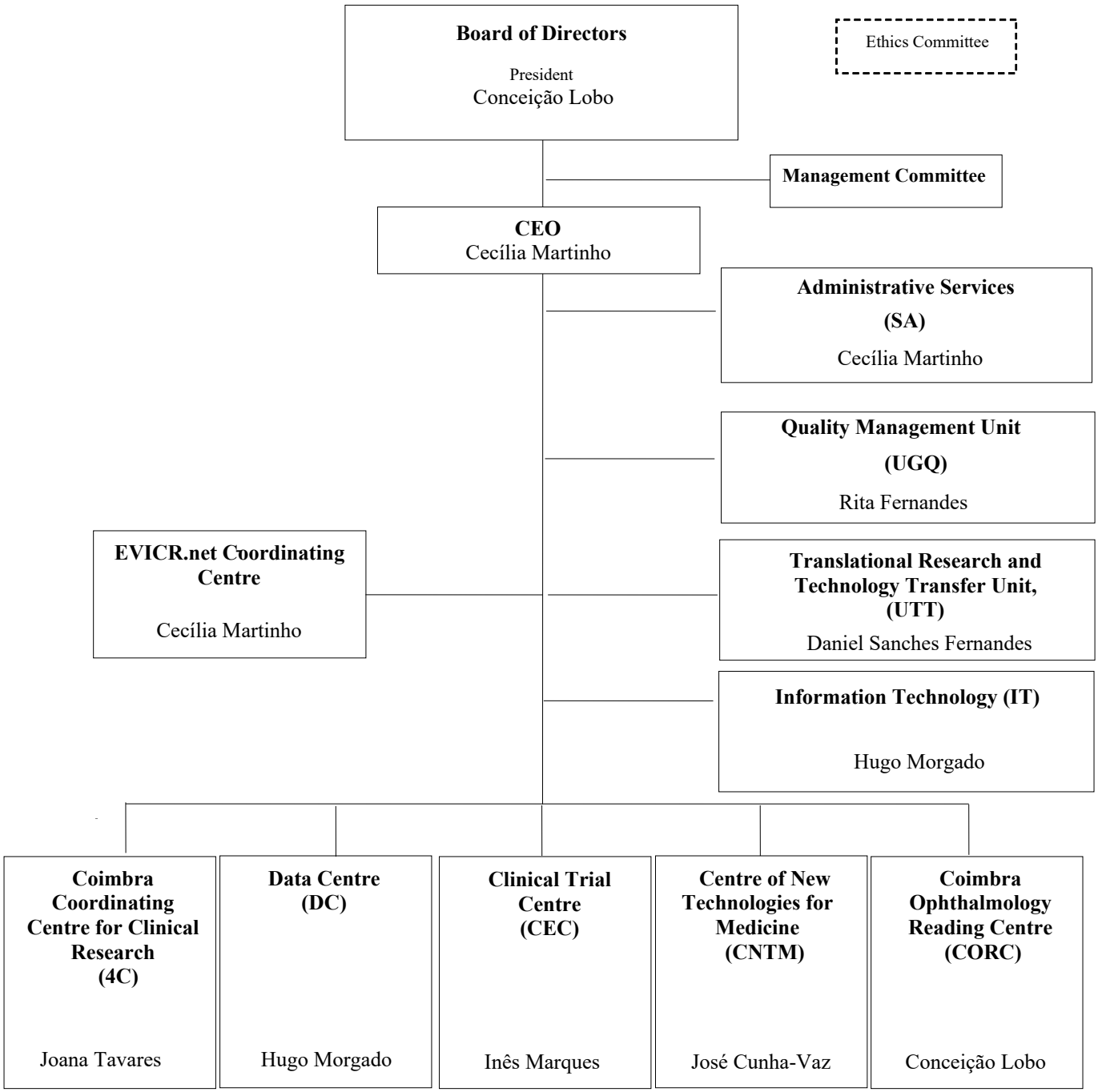
AIBILI has also an independent Ethics Committee for Clinical Research (CE) to assess the clinical studies as applicable by Law 21/2014 of 16 of April amended by the Law n.º 73/2015 of 27 of July and Law nº 49/2018, 14th of August.

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: ULS Coimbra - Local Health Unit of Coimbra, 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., Institute for Vision at the Federal University of S. Paulo, S. Paulo, Brazil, IPN - Instituto Pedro Nunes, L.V. Prasad Eye Institute, Hyderabad, India, José de Mello Saúde – Hospital CUF Coimbra, P-BIO – Portugal's Biotechnology Industry Organization, MIA Portugal – Multidisciplinary Institute of Ageing, SANO - Centre for Computational Personalised Medicine, UA – Universidade de Aveiro and others.

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.

III – GENERAL INFORMATION OF AIBILI



EVICR.net – European Vision Institute Clinical Research Network

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) n.º 2137/85.

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.

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:

- Protocol design and Statistical planning
- Study documents elaboration
- Contracting and Insurance
- Submission to the Regulatory Authorities
- Coordination and Study implementation
- Monitoring and Quality Control
- Periodic Reports to the Sponsor and/or Regulatory Authorities
- Statistical analysis and Final Study Report
- Medical Writing and Publication support
- Investigational Product Management
- Pharmacovigilance and Risk Management

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, and providing

support on modelling and conduct cost-effectiveness analysis of drugs and other medical products and therapies for market access. 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 (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).

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 ECRIN Data Centre requirements since 2016, meeting the ECRIN requirements for IT and Data Management within Clinical Studies and 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:

- Design and development of Electronic Case Report Forms (eCRF)
- Development of Digital Grading Forms
- Data Management
- Support Clinical Data Management Application (CDMA)
- Support Reading Center Platforms (studies.corc.pt)
- Users/key-users training

- IT support
- Long Term Data Storage.

CEC - Clinical Trial Centre

The Clinical Trial Centre (CEC) performs clinical patient-oriented research that involves characterizing disease progression and testing new therapies by carrying out controlled research in patients, i.e., clinical trials and clinical studies. It has been involved in studies focused on ophthalmology, diabetes and neurology. CEC has excelled in multinational randomized clinical trials and clinical studies with special emphasis in ophthalmology since 1991. CEC has dedicated facilities, qualified and experienced staff and the most updated ophthalmological equipment.

CEC is a certified Clinical Site of Excellence by the EVICR.net - European Vision Institute Clinical Research Network (CS 01), since 2005.

CNTM - Centre of New Technologies for Medicine

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

The goal of CNTM is innovation in eye imaging and transfer these technological innovations to the industry and, therefore to the market, bringing better diagnostic imaging technologies. It works closely with CEC, performing translational research in vision and imaging, and with CORC by developing software tools for grading analysis. The excellence of the work developed in CNTM is well demonstrated by frequent publications in peer reviewed international scientific journals.

CNTM has developed the concept of Multimodal Macula Mapping, and the algorithm developed in house, that led to the product Retmarker® that is available in the market and provides information to monitor the progression of diabetic retinal diseases by correlation of sequential fundus imaging and automatic lesion detection. Presently, another innovative solution, OCT-Leakage, a novel analysis on the permeability of the Blood-Retinal Barrier using non-invasive method was published in the European Patent and in the United States Patent and Trademark bulletins.

The process of technology transfer is initiated by innovation at the laboratory level well before the development of applications that can be later on tested in clinical studies. This research has led to R&D contracts with Industry.

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) performs central reading and grading of ophthalmology exams for multinational and multicentric clinical studies. It is also responsible for the Diabetic Retinopathy Screening Programmes of the Central and South Region of Portugal. Its receives and grades ophthalmology exams from all over the world, contributing to standardized results and high-quality data for ophthalmic research. By grading several features in different imaging modalities, CORC focus its activities in 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 that are subject of CORC grading and analysis 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 the following IT systems hosted on AIBILI's Data Centre certified by ECRIN: 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).

For grading activities, CORC uses licensed software from equipment suppliers (e.g., Cirrus (Carl Zeiss Meditec), 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) and other common applications for imaging edition and analysis (e.g., GIMP, XnViewer, ImageJ, etc).

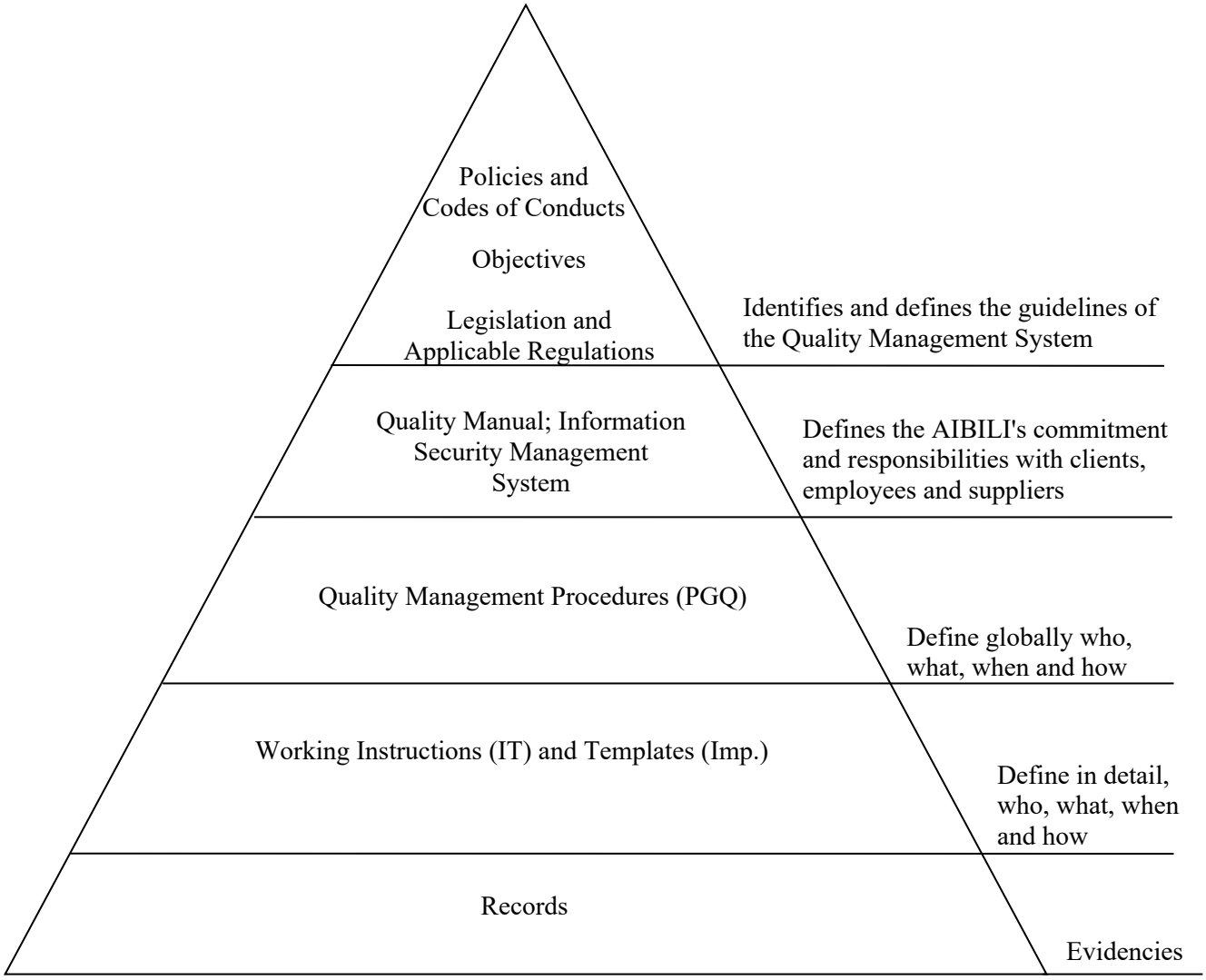
For management, CORC uses the CORCMS – CORC Management system, an internal custom-designed web-based tool being designed to support managing activities of CORC and of CORC studies/services.

CORC has all the necessary human resources for its activities, namely Medical Project Coordinators, a vast team of Graders, Study Coordinators, Data Manager and IT Specialist for software/applications development.

III – GENERAL INFORMATION OF AIBILI

- The AIBILI **Quality Management System (QMS) is an integrated system** 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.

- AIBILI structured its Quality Management System (QMS) and supports it through a hierarchical set of documents that are described below.



AIBILI Operational Manual is organized by PGQs, ITs and Imp. and structured as stated in Appendix 1.

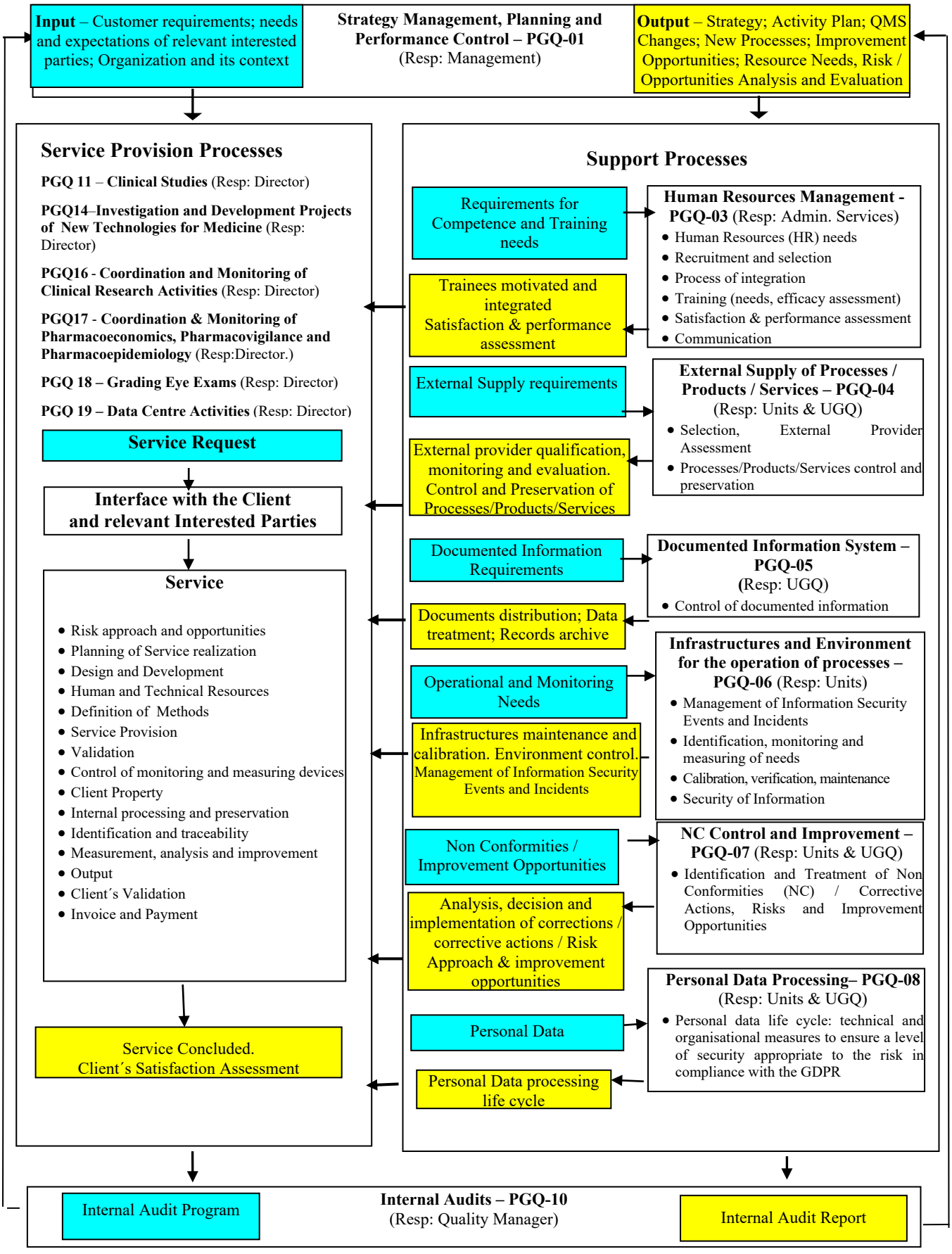
III – GENERAL INFORMATION OF AIBILI

The correlations of AIBILI QMS with ISO 9001:2015 are listed in Appendix 2, Principles of Good Clinical Practices in Appendix 3, AIBILI QMS correlation with ECRIN Data Centre requirements is in Appendix 4, GDPR Correlation in Appendix 5. ISO/IEC 27001:2022 is currently being implemented and ISMS – Information Security Management System Manual (ISO/IEC 27001:2022) is available for consultation in AIBILI website https://www.aibili.pt/downloads/

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

APPENDIX 1 – QUALITY MANAGEMENT SYSTEM – PROCESSES INTERRELATION

The Quality Management System (QMS) is supported by processes with the following interrelation:



APPENDIX 2 - CORRELATION WITH NP EN ISO 9001:2015

Quality 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 - Law nº21/2014, 16 of April changed by the Law n.º73/2015, 27 of July and Law nº 49/2018 of 14 August

Quality Manual and Procedures	GCP Requirements applicable to AIBILI- Articles of Law nº21/2014, 16 of April and those changed# by the Law n.º 73/2015, 27 of July																																	
	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 Responsability; ** Sponsor´s Responsabilities; & applicable to Regulatory Authorities.

Legend: ■ applicable; not applicable

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

Quality 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;