Clinical Research Support Infrastructures

Carlos Domingues
Data Centre and IT Director

ABOUT CLINICAL DATA CENTRE – HISTORY

AIBILI Data Centre was built in 2014 to store AIBILI's critical information and houses all AIBILI servers/systems: both clinical and administrative.

Specific Standard Operating Procedures (SOPs) were developed according IT best practices such as Information Technology Infrastructure Library (ITIL), and project management standards such as recommended by the Project Management Institute (PMI). We also comply with US FDA 21 CFR part 11 (Guidance for Electronic Records) and ISO 27001 (Information Security Management). (compliant but not certified).

GAMP5 V-model and methodology was customized to ensure production environments safety and integrity. As a result, AIBILI Data Center completed ECRIN Certification in 2016.

SGS

Certificate of Registration

Certificado de Conformidade

This is a Translation of PT04/01266

The Management System of

AIBILI – Associação para Investigação Biomédica e Inovação em Luz e Imagem

Azinhaga de Santa Comba - Celas
3000-548 COIMBRA, PORTUGAL

has been assessed and certified as meeting the requirements of

NP EN ISO 9001:2015

For the following activities:

Research and Development in New Technologies for Medicine with particular emphasis in the Areas of Imaging, Optics and Photobiology. Performance of Clinical Studies. Planning, Coordination, Monitoring of Clinical Research Activities. Health Technology Assessment. Grading of Eye Exams. Data Centre Activities.

This certificate is valid from

Este certificado é valido deade

02nd September 2019 until 01st September 2022

and remains valid subject to satisfactory surveillance audits

02 de setembro de 2019 a 01 de setembro de 2022, sujeito a auditorias de acompanhamento com resultados satisfatórios

Re certification audit due before 01st July 2022

Auditoria de Renovação a realizar antes de 01 de julho de 2022

Issue 11. Certified with SGS since September 2004

Versão 11. Certificado pela SGS desde setembro de 2004

The audit leading to this certificate commenced on 17th June 2019

A auditoria que levou à emissão deste certificado teve início em 17 de junho de 2019

Previous issue certificate validity date was until 01st September 2019

A data de validade do certificado anterior foi até 01 de setembro de 2019

Authorized by:
Autorizado por:

Luis Neves
Certification Management
Direção de Certificação

Luis Santos

IPAC acreditação A0003 ISO/IEC 17021-1 Sistemas de Gestão

ISO 9001 SYSTEM CERTIFICATION SGS

SGS ICS – Serviços Internacionais de Certificação

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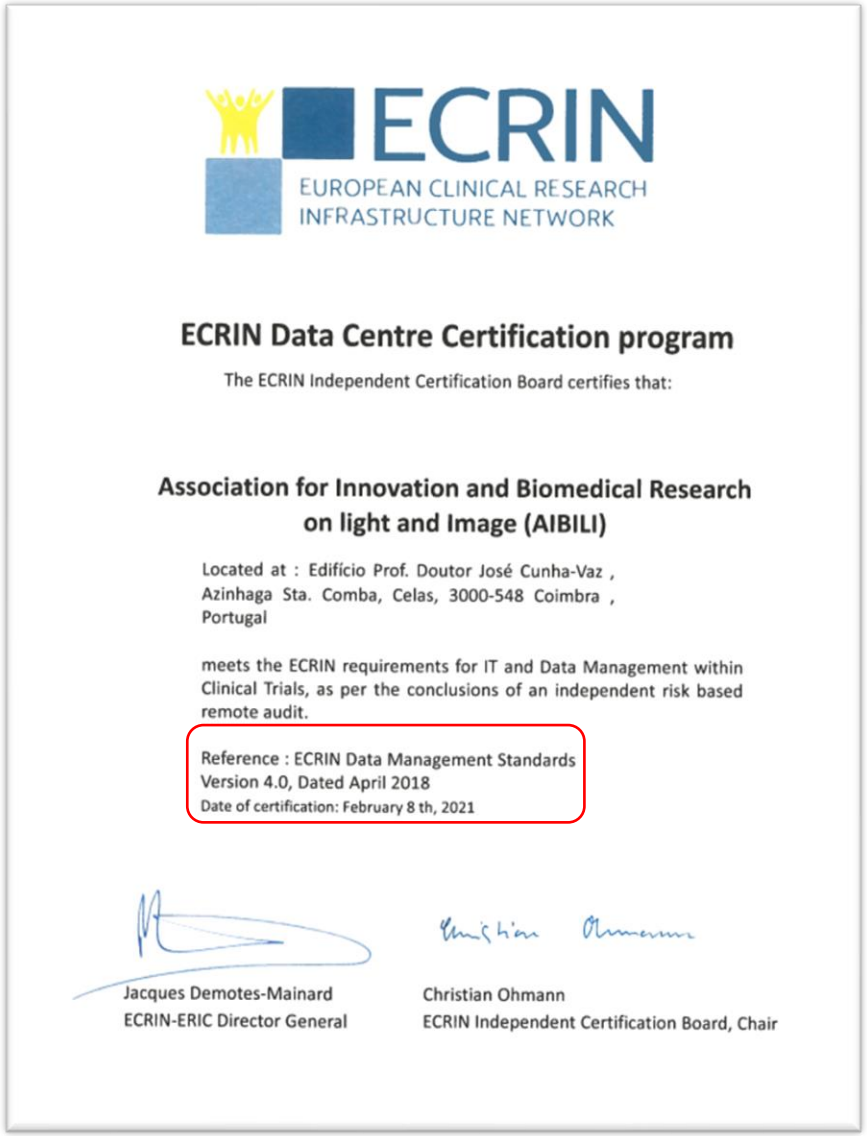
ISO9001 Certified since September 2016



ECRIN

EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

ECRIN Data Centre Certification program

The ECRIN Independent Certification Board certifies that:

Association for Innovation and Biomedical Research on light and Image (AIBILI)

Located at : Edifício Prof. Doutor José Cunha-Vaz ,
Azinhaga Sta. Comba, Celas, 3000-548 Coimbra ,
Portugal

meets the ECRIN requirements for IT and Data Management within Clinical Trials, as per the conclusions of an independent risk based remote audit.

Reference : ECRIN Data Management Standards
Version 4.0, Dated April 2018
Date of certification: February 8 th, 2021

Jacques Demotes-Mainard
ECRIN-ERIC Director General

Christian Ohmann
ECRIN Independent Certification Board, Chair

ECRIN Certified since April 2016
(recertified by v4, on 8th, Feb 2021)

ECRIN CERTIFICATION SCOPE

https://ecrin.org/activities/data-centre-certification

General Standards (4)

GE01 Centre Staff training and support (4)

IT Standards (41)

IT01 Management of IT infrastructure (9)

IT02 Logical Security (7)

IT03 Logical Access (7)

IT04 Business Continuity (6)

IT05 General System Validation (9)

IT06 Local Software Development (3)

Data Management Standards (61)

DM01 Data Management Planning (1)

DM02 CDMAs - Design, Development and Validation (8)

DM03 CDMAs - Change management (7)

DM04 Site Management, Training & Support (9)

DM05 Data Entry and Processing (7)

DM06 Managing Data Quality (12)

DM07 Managing Data Transfers (5)

DM08 Delivery and Coding of Data for Analysis (8)

DM09: Long Term Data Storage (4)

Optional Standards (9)

ST01: Treatment Allocation standards (9)

ECRIN CERTIFICATION PROCESS

Since it was set up in 2014, 17 European data centres have been certified.

AIBILI IT INFRASTRUCTURE

- ✓ Redundant UPS and energy distribution
- ✓ Redundant Air-conditioning systems with temperature and humidity dynamic control
- ✓ Automatic fire extinguisher

- ✓ 24h monitoring with automatic notifications
- ✓ High security firewalls and intrusion detection / blocking systems

Security, Privacy and Compliance

IT and NETWORK Security

- Prevention Maintenance
- Encryption of non-physically secured data
- **Security management system**
  - Commitment to data protection
  - Access control management
  - Vulnerability Management
- Server failure and response

SECURITY, PRIVACY AND COMPLIANCE

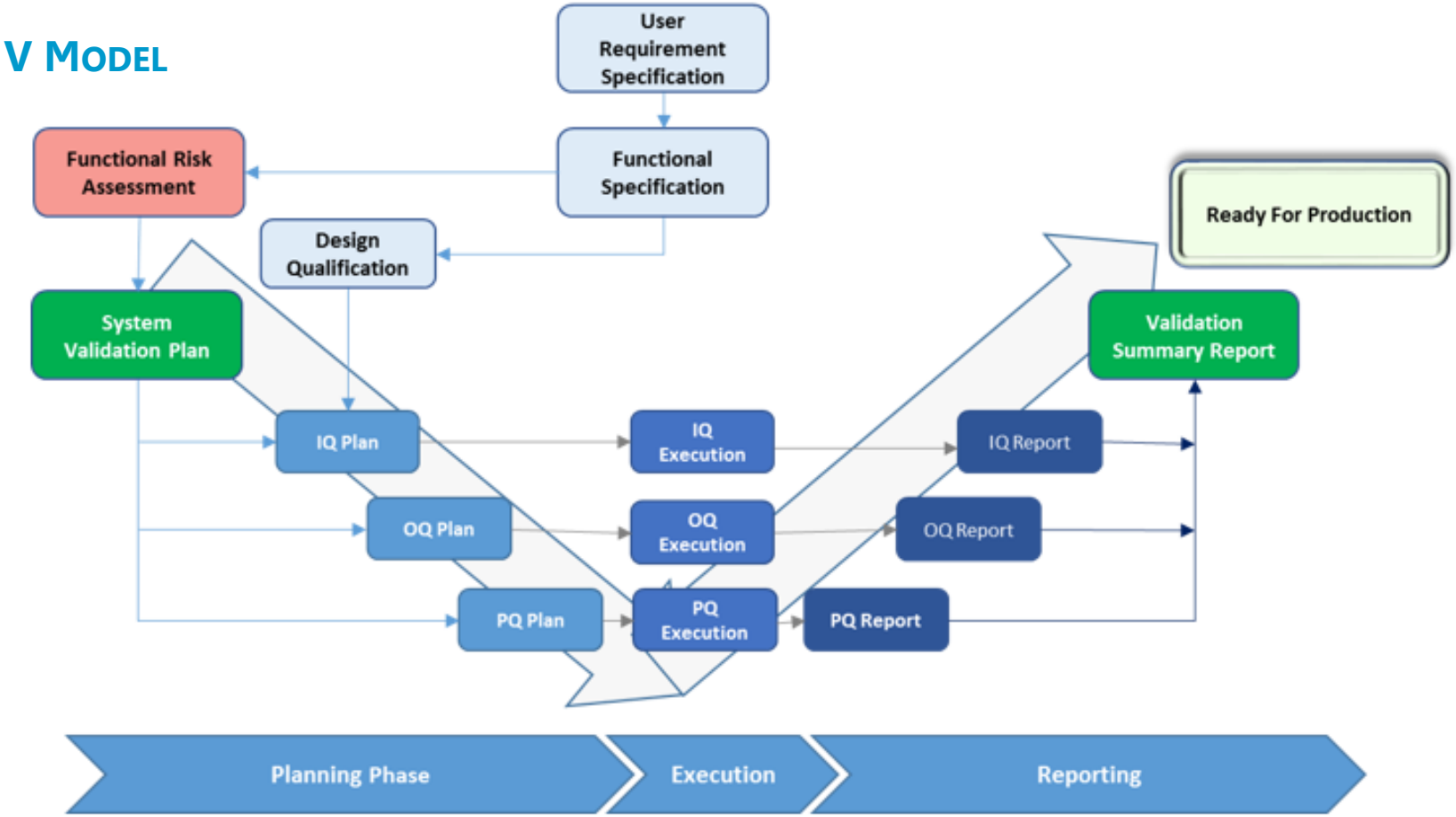
GDPR COMPLIANCE IN CINICAL TRIALS (RGPD -PORTUGUESE)

- The relevance of the informed consent (IC)
- Data minimization
- Data owner rights
- Personal and special category data
- Anonymization and Pseudonymization of personal data
- International data transfer and Open Innovation*
- Exceptions for research under GDPR

*https://academic.oup.com/spp/article/47/5/616/5780440

VALIDATION

GAMP®5 V MODEL



Validation is the process of “establishing **documented evidence** that provides a **high degree of assurance** that a specific process will consistently **produce a product meeting its pre-determined specifications** and quality attributes".

Validation MASTER PLAN

GAMP®5 V -MODEL

REVISION LOG

Master Validation Plan Version	Section	Reason for Changes	Date
V.0	All	---	<yyyy-mm-dd>

Table of Contents

Validation
MASTER PLAN

GAMP®5
V-MODEL

3.1 Information systems

Systems	SVP	URS	FS	FRA	DQ	IQ	OQ	PQ	VSR
[redacted]	☑	n/a	n/a	n/a	n/a	☑	☑	☑	☑
[redacted]	☑	n/a	n/a	n/a	n/a	☑	n/a	n/a	☑
[redacted]	n/a	n/a	n/a	n/a	n/a	n/a	☑	☑	☑
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[redacted]	☑	☑	☑	☑	☑	☑	☑	☑	☑

Legend:
SVP- System Validation Plan; URS- User Requirement Specification's; FS -Functional Specification; FRA- Functional Risk Assessment; DQ- Design qualification; IQ- Installation Qualification Plan and Report; OQ- Operational Qualification Plan and Report; PQ- Performance Qualification Plan and Report; VSR- Validation Summary Report;

RISK ASSESSMENT

REGISTO DE RISCOS POR PROCESSO / PROCESS RISK LOG

	Probability		
Impact	L	M	H
L	L	L	M
M	L	M	H
H	M	H	H

L - Risco Baixo / Low Risk
M - Risco Médio / Medium Risk
H - Risco Elevado / High Risk

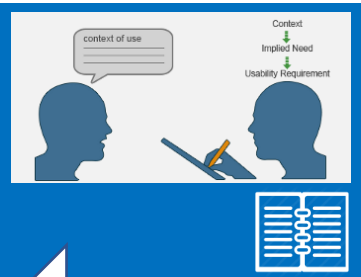
Processo/ Process: General IT Risks (IT 05-4; IT 19-2 a IT 19-5; IT 19-8; IT 19-7 when applicable)

Versão / Version: 0 **Data / Date:** 27/03/2017

No.	Descrição do Risco / Risk Description	Probabil. / Probability (P)	Impacto / Impact (I)	Factor Risco / Risk Factor	Plano de Ação / Action Plan: Ação / Action (Mitigação (Prevenção) / Mitigation; Contingência (correcção) / Contingency)	Responsab.	Data Prevista / Forseen Date	Estado / Status (aberta / open, fechada / closed, eficaz/não eficaz_decisão, etc.) // Data / Date
1	Natural disasters (External Fire, Flood, Earthquake, Hurricanes)					SA	Bianual DC Report	
2	Fire Caused by equipment's					IT	Bianual DC Report	
3	Disruption of power supply					IT/SA	Bianual DC Report	
4	Loss of Telco's systems (voice or data)					IT/SA	Bianual DC Report	
5	External Regulation (New,Update)					IT/SA	Bianual DC Report	

Risk Assessment - Example

STUDY DEVELOPMENT METHODOLOGY



Critical

Critical

Critical

Risk Analysis (functional / technical)

- ❑Service Request / Evaluation
- ❑Service Specification
- ❑Agreement (tasks, milestones, responsibilities , etc.)
- ❑List of variables

- ❑ eCRF specification (protocol & variables)
- ❑CDMS Comment tracker (iterative)
- ❑Rules specification & implementation
- ❑CDMA Risk Assessment
- ❑Data Management Plan
- ❑ Training Plan
- ❑CDMA Approval

- ❑Study validation plan
  - Validation Strategy
  - Pass/Failure Criteria
  - Prototype Testing (variables, rules, exports, etc.)
- ❑CDMA validation
- ❑Study validation report
- ❑eCRF user manual

- ❑Site lists
- ❑User requests
- ❑Users logs
- ❑Data monitor
- ❑Data amendments
- ❑Database lock
- ❑Long Term Storage

Change Requests

SOFTWARE DEVELOPMENT

Software development: all types of organized code written by AIBILI technicians (internal or in outsourcing regime) packed as an application, used to directly support clinical data management.

Other commercial software, simple code and scripts used for data extraction, transformation, imports or export are managed by “General System Validation” and “Extracting and Reporting Data” procedures.

Waterfall

Requirements agreed one time with the client

Milestone 1 – End of the Assessment phase.

Milestone 2 – End of the Functional Specification phase

Milestone 3 - End of Development

Milestone 4 - Ready for validation

Product go-live and production support

SCRUM

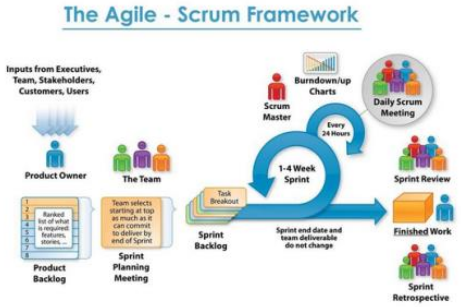
Requirements are managed interactively

Milestones occur at the end of each sprint/version

Regular development versions and backlog updates

Version sign-off from from the product owner

Backlog refinement



Long Term Storage

Technology and procedures for archiving and preserving data in a long term. Local backups, offsite encrypted backups, WORM disks (write once read many), etc.

OUR COMMITMENT

- Security and Compliance
- High Availability
- Scalability and Continuous Improvement
- User/Client commitment

CONTACTS:

CARLOS DOMINGUES

Edifício Prof. Doutor José Cunha-Vaz
Azinhaga Sta. Comba, Celas
3000-548 Coimbra
Portugal

Phone: +351 239 480 150
E-mail: cdomingues@aibili.pt

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