PRECISE4Q

PREDICTIVE MODELLING IN STROKE

DELIVERABLE

Project Acronym: **Precise4Q**

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D2.6 – Written concept which is approved by the regulation authorities

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Authors and Contributors	Paulo Rodrigues (QMENTA); Nikola Lazovski (QMENTA); Catalina Martínez Costa (MUG); Jose Antonio Miñarro Giménez (UM)			
Responsible Author	Paulo Rodrigues		**Email**	paulo@qmenta.com
	Beneficiary	QMENTA	**Phone**	+34 933 282 007

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CO	Confidential, restricted under conditions set out in Model Grant Agreement	
CI	Classified, information as referred to in Commission Decision 2001/844/EC	

Revision History, Status, Abstract, Keywords, Statement of Originality

Revision History

Revision	Date	Author	Organisation	Description
0.1	22/10/19	Paulo R	QMENTA	Initial Draft
1.0	30/10/19	Paulo R	QMENTA	Final Review

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Abstract (for dissemination)	This document describes the different standards followed by the QMENTA Cloud Platform.
Keywords	Standards, ISO 13485, HIPAA, GDPR, security

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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Executive Summary

In this document we further elaborate about how QMENTA Cloud Platform follows different industry standards concerning data security, privacy, software development and other formal business processes.

1 Protected health information (PHI)

All data is safely stored in compliance with HIPAA and the FDA Title 21 CFR Part 11. The privacy of patients' private health information (PHI) is respected at all times with automated de-identification as well as end-to-end encryption.

The platform manages protected health information (PHI) contained in medical images and derived data in secure segregated network and encrypted data transmission.

2 Data Jurisdiction

When creating a new study to host and share data, users can easily choose a data center's location from a list of countries in Europe, North or South America, or Asia Pacific.

The selection of data location is important to comply with the EU-US Privacy Shield, as well as any additional national jurisdictions. The Shield highly regulates the transfer of personal data from EU to US and recommends limiting the transatlantic data transfer only for necessary situations.

3 Encryption

Communication between client's web browser and the cloud infrastructure is through an encrypted and authenticated channel, with a strong protocol (TLS 1.2), a strong key exchange (ECDHE_RSA), and a strong cipher (AES_256_GCM).

4 Security controls

A rigorous security framework is ensured with the implementation of administrative, physical, technical, organizational, documentational, retentional, and other measures of security control. QMENTA platform is compliant with strict industry standards such as HIPAA.

Requirement	**Compliance on QMENTA's platform**
Administrative Safeguards	The platform covers all required procedures, including risk assessment and workforce security. A contingency plan is built together with our cloud partners.
Physical Safeguards	Datacenter security is handled by our cloud partners. QMENTA has implemented workstation securities.
Technical Safeguards	QMENTA platform offers access controls, audit trails, and user authentication. Additionally, QMENTA provides a local app to strip out Protected Health Information (PHI) from the datasets before transferring them onto the platform.
Organizational Requirements	A Business Associate Agreement (BAA) is signed

	between QMENTA and its clients & its cloud providers.
Organizational Requirements	QMENTA team has built required procedures and documents them in a repository.

Table 1 Security control requirements

5 ISO 13485

QMENTA's Quality Management System (QMS) is a company-wide initiative, which has enhanced the quality of QMENTA's products & services and improved the system on patient safety. We have implemented a PDCA (Plan – Do – Check – Action) cycle to improve product development procedures and to be able to analyze the system for opportunities for improvement with a risk-based approach.

QMENTA offers the safest and highest quality products & services to our customers, employees and shareholders, which meet applicable regulatory, statutory, and customer requirements by following our QMS standards.

QMENTA thus complies with quality management procedures for its strategic planning, product design, product realization, test & release, monitoring & improvement, and support processes.

1) Strategic planning

QMENTA collects all business requirements from our customers and relevant regulations in order to determine, keep records of, and trace project objectives, scope, restrictions, milestones, resources, success measurements and more for functional requirements and software tests.

2) Product design

We follow the Agile lifecycle model adapted to the requirements of IEC 62304 for the development of our software to offer products with superior quality and fewer risks. In addition, we conduct design reviews to evaluate the specifications, user interface or architecture in order to see if the product will achieve the business requirements and if the system is optimized and record all of our user and functional requirements.

3) Product realization

We set up the requirements for each release, define Epics & smaller tasks accordingly to maintain a good balance between structure, flexibility, and effectiveness, and conduct an assessment for each task.

4) Test & release

To conduct software validation and verification, we trace the implementation process and check if the requirements are met in the final product and follow change control procedures to make sure that the software changes are implemented properly. The new version is released subsequent to the approval of the change request and the necessary tests.

5) Monitoring & improvement

Our customers' feedback is very important. Both their feedback and complaints are collected in our internal system to ensure that the problems are solved. We take corrective and preventive measures for the main issues pertaining to product quality. Moreover, to provide a high-quality service for our customers, we conduct regular reviews of our QMS.

6) Administration

We have documented and implemented some critical procedures to support the run of the QMS such as information security and data integrity to make sure we deliver a high-quality product to our customers.

6 Ethical Applications

The University of Tartu (UOT) has already initiated the research application for the Estonian Committee on Bioethics and Human Research and is ready to be signed by the project partners. After that an application to the Estonian Genome Center is required.

The University of Linköping has initiated the process to get the approval from the ethics committee for the CARDIPP dataset.

For the Riksstroke dataset the ethics approval is ready to be signed by the corresponding partners. After the signature an application to the registry will be done.

GUTTMANN institute has shared with the partners a data processing agreement that has being already signed by some partners.

After the signature they can access the data according to their roles (cf. deliverable 2.4). As mentioned before, AOK due to strict local security requirements, will not allow to integrate their data into the project data warehouse.

CUB, that is in the process of getting access, will be allowed to access AOK data through a proprietary AOK system.

7 Conclusions

QMENTA follows highest industry standards concerning data security and cloud architecture is designed to deliver high standards in security, HIPAA, GDPR, FDA Title 21 part 11, and ISO 13485.