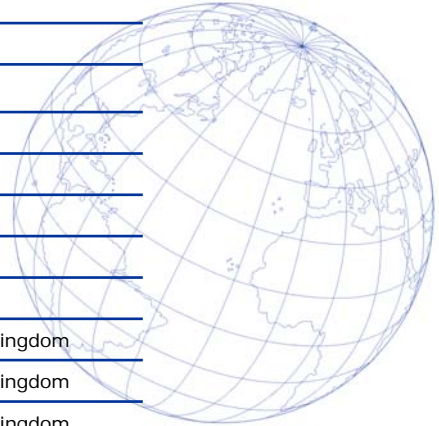


Project Coordinator

MicroArt, SL	Spain
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Project Contractors

Universitat de València	Spain
Universitat Autònoma de Barcelona	Spain
Instituto de Aplicaciones de las TIC Avanzadas	Spain
Pharma Quality Europe	Italy
Katholieke Universiteit Leuven	Belgium
University of Birmingham	United Kingdom
University of Edinburgh	United Kingdom
University of Southampton	United Kingdom



Project Summary

The HealthAgents project plans to create a Distributed and multi-agent-based Data Warehouse (d-DWH), and an associated, distributed Decision Support System (d-DSS). This system will provide advanced and distributed functionalities of data mining for analysis and interpretation of data of brain tumours. The d-DWH will include the world's largest network of interconnected databases (Data Marts) of clinical, histological, and molecular phenotype data of brain tumour patients. The d-DSS will facilitate evidence-based clinical decision-making using MR and genetic based tumour classifications and will include new criteria from the automated analysis of each local database. The d-DSS will be deployed using the strictest security policies.

PQE's Work package

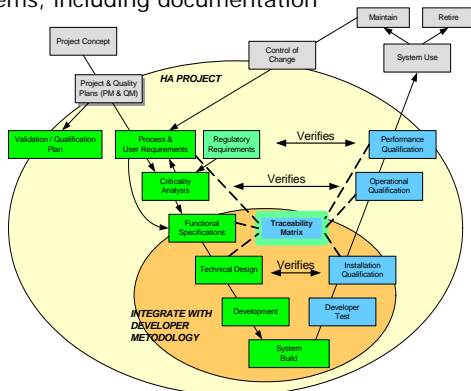
These typologies of computer systems, since used for collection, management and storage of data of brain tumours, must be compliant to regulatory standards and to electronic record management system standard. As a consequence, they must be validated in order to ensure that they continuously and satisfactorily execute the functions are designed to perform. PQE supported the partners involved in the development of the software required for the creation of the HealthAgents system with the assistance required for the implementation of the Quality System during software development activities, including all software validation activities and corresponding documentation.

Validation of the HealthAgents system:

Validation is applied to many aspects of regulated environment. In each case the purpose of validation is to demonstrate that the HealthAgents system continuously and satisfactorily executes the functions it is required to perform.

Activities and strategies for system implementation:

As far as the Software Developer Quality System is concerned, attention was focused on Software Development Methodology. That is the set of principles, practices and procedures, which were used to define, develop, and implement information systems, including documentation



Task Performed

Developing the Validation Master Plan (VMP).

strategy, activities, responsibilities, time schedule

Project User Requirements.

Process; Regulatory; General

Reviewing Software Developer Quality System.

Lifecycle, standard for coding, testing, documents

Developing Partner Document Guideline and Validation Document Templates.

Templates cover all the documents that have to be produced during software development in a regulated/controlled environment.

Planning, Specification, Testing and On going.

Developing IT Standard Operating Procedure (SOP) Templates.

Security, Change Management, Maintenance

Technical Document Review.

Performance (Process) Qualification (PQ).

The PQ demonstrates that system requirements have been met and that the system is capable of performing the activities according to the URS while operating in its specified operating environment

Test Result Review.

Test results analysis, failures description and corrective actions, if any

Developing Validation Report.

Overall result of system validation

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