

### Project Coordinator

Universitat de Valencia Spain

### Project Contractors

Universitat Autònoma de Barcelona	Spain
St George's Hospital Medical School	United Kingdom
University Medical Centre Nijmegen	Netherlands
Stichting Katholieke Universiteit	Netherlands
INSERM U594	France
MICROART, S.L.	Spain
Hospital San Joan de Deu	Spain
Pharma Quality Europe, s.r.l.	Italy
Hyperphar Group SpA	Italy

### Project Contractors

Katholieke Universiteit Leuven	Belgium
Philips Medical Systems Nederland B.V	Netherlands
Siemens AG, Medical Solutions	Germany
SCITO, S.A.	France
Universidad Politécnica de Valencia	Spain
Deutsche Krebsforschungszentrum Heidelberg	Germany
BRUKER BIOSPIN SA	France
University of Birmingham	United Kingdom
INSERM U318	France
Medical University Lodz	Poland
Fundación para la Lucha contra Enfermedades Neurológicas de la Infancia	Argentina

### Project Summary

eTUMOUR aims to create a comprehensive Web-accessible Decision Support System (DSS) for analysis and interpretation of in vivo Magnetic Resonance Spectroscopy and Imaging (MRS & MRI) data of brain tumours. It includes a database of clinical, histological, metabolic (NMR HR-MAS) and molecular phenotype data from brain tumour patients. The DSS will facilitate evidence-based clinical decision-making using MR and will include new criteria such as genetic based tumour classifications.

### PQE's Work package

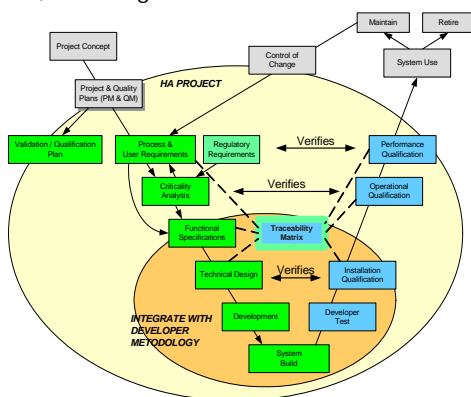
Provide the participants involved in the software development with the framework for implementing a Quality System for software development activities, including all software validation activities and corresponding documentation. Provide evidence that the Clinical Centers involved in data acquisition follow adequate procedures that can assure the integrity and quality of the collected data.

### Validation of the eTumour system:

Validation is applied to many aspects of regulated environment. In each case the purpose of validation is to demonstrate that the eTumour 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

#### Computer System Validation lifecycle

PQE proposed the GAMP V model specifying the overlap between Software Development lifecycle and Validation lifecycle. PQE described and provided the template of the main documents that should be produced during Computer System Validation process.

#### Audit

The audits were carried out to guarantee that methodologies and controls associated with the development, implementation and maintenance of the eTumour system are adequate.

#### Communication flow

PQE defined the project communication process. The communication process is the means by which a person responsible for a specific task/action/etc. implement them, and feedback is the communication component that enables him/her to ensure a task/action/etc has the desired result.

PQE proposed to build trusting relationship, that means: (i) following policies and guidelines, (ii) make expectations clear, (iii) provide feedbacks that are useful, (iv) maintain a positive tone, (v) demonstrate concern for the involved stakeholders.

#### Document Management flow

The purpose of the process was to raise an issue/action/concern to a higher-level of management for resolution, particularly when resolution cannot be reached at the lower level. When a resolution cannot be reached, the issue should be escalated to ensure a decision is made before it causes impacts to the project.

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