

RadiomiX

Revolutionizing Precision Medicine with Quantitative Imaging Biomarkers

RadiomiX concerns the high-throughput mining of large amounts of quantitative features, derived from (standard-of-care) medical imaging for knowledge extraction. RadiomiX is in particular promising within decision support systems, which allow for better clinical decision-making. It contributes to optimizing personalized medicine and improved care for patients.

OncoRadiomics has developed an innovative imaging analysis software RadiomiX. It enables the extraction of unique quantitative image features (and associated radiomic signatures) from standard medical images to guide personalized cancer diagnosis and treatment. Within the scope of the project, ICT Healthcare developed a secure online SaaS (Software as a Service) application which is ISO 13485 / IEC 62304 compliant as well as created all applicable documentation for CE Class I submission

Professionalising of a working prototype

OncoRadiomics developed a working RadiomiX prototype in MATLAB specifically tailored for research purposes. The prototype was a standalone application, which lacked important features to be suitable as a clinical grade software, such as secure multi-user access, support for multiple platforms and an intuitive user interface. Furthermore, for clinical use, the application needed CE Marking accompanied with proper documentation.

ICT Healthcare created a future proof, well documented, maintainable, multiuser, multilingual, multitenant SaaS environment. The environment consists of two different areas:

- The clinical version where the intended users can upload the DICOM files of one patient for analysis. This version needs the CE marking.
- The research version where researchers can upload hundreds of patients for analysis (no CE marking required).



The application is created using Microsoft .NET technology and the ICT SmartPortal on Microsoft Azure Cloud. The Environment works with secure (HTTPS-) connections and secure login features. Above that, all data submitted to the system is encrypted and pseudonymized as soon as it is uploaded to guarantee both privacy and security.

About OncoRadiomics

OncoRadiomics is a privately held Life Science spin-off company established in Liège (Belgium) in 2016 and currently owned by Benelux Health Ventures. Its intellectual property (IP) originates from Maastricht Radiation Oncology (MAASTRO) Clinic and from its own research. Exploiting the information embedded in medical images, the company develops products and services with the ultimate goal of providing higher quality care for cancer patients while minimizing total treatment cost at the same time. Key personnel include co-inventors Ralph Leijenaar as the Chief Technology Officer (CTO), Seán Walsh as Chief Scientific Officer (CSO) and Philippe Lambin as Chief Medical Officer (CMO).

For more information, visit their website: www.oncoradiomics.com.

Role of ICT Healthcare

The customer chose ICT Healthcare because of the extended knowledge of creating secure SaaS Applications and preparing for CE Marking. ICT works compliant to ISO 13485 / IEC 62304.

The ICT Architect worked closely together with the CTO (Chief Technology Officer) of OncoRadiomics to elaborate detailed specifications, defined the architecture and created the designs for the RadiomiX product. We successfully managed to embed the MATLAB mathematical models and the anonymizing software into the online multiuser environment, what was never done before.

Keywords

CE Marking, .NET, C#, Microsoft Azure, DICOM, Microsoft VSTS, SVN, Trac, ISO 13485, IEC 62304, SaaS, MATLAB, SmartPortal

PROJECT RESULT

The RadiomiX software as well as all the documentation applicable for CE Marking was delivered on time and within budget. The developed application not only works perfectly but has also been upgraded to a professional look and feel. All documentation is according to the latest regulations and the product is submitted for CE Class I, with software classification A.

During the whole project, ICT Healthcare worked closely together with the customer acting as one team, having regular team meetings and guiding the customer through the whole process and at every level starting from the engineers up to the management. The customer was very pleased with the process and the guidance during the development of the RadiomiX product.

Because of the good cooperation and project result, we are granted to take care of the product support and maintenance and further development for the upcoming years. As an additional service, ICT Healthcare performs a yearly audit to verify that the product still meets the (updated) regulations with respect to CE Marking and will adapt accordingly.

The ICT QA/RA officer planned and moderated the risk sessions and guided the customer through the whole CE process making sure all deliverables where on time and fulfilled the needs of the regulations. In the whole process, involving the intended users is crucial. So, in the case of RadiomiX, ICT Healthcare involved multiple oncologists attending risk sessions, demos and performed usability assessments.

