PROJECT REFERENCE

PRODECIS CE Marking

From concept to product

The aim of PRODECIS is to support Radiation Oncologists with the decision making between two valid treatment plans (photon or proton radiotherapy). The estimated clinical complications and the cost-efficiency of the treatment options are calculated by using validated toxicity prediction and cost-efficiency models.

Computation services are separated into three levels: dosimetric, toxicity and cost effectiveness. On the dosimetric level, Dose–Volume Histogram (DVH) calculation algorithms are used to extract relevant DVH metrics from both photon and proton plans that are required for the second toxicity computation level. On the toxicity level, several validated Normal Tissue Complication Probability (NTCP) models are used. These models are compliant to the TRIPOD Type 4 standard. On the cost effectiveness level, a published Markov model is used to assess the number of Quality Adjusted Life Years (QALY) and costs resulting from each treatment.

Quantitative treatment comparison

Due to the continuous development of new cancer treatments and the sophistication of existing radiotherapy, it has become increasingly challenging to identify cost effective treatments for a specific patient. A multifactorial Clinical Decision Support System (CDSS) could help meet this challenge by combining clinical information (e.g. information about the patient or tumour), dosimetrics and cost variables with expert knowledge (e.g. on a specific treatment modality) to make a quantitative treatment comparison. Such a tool facilitates individualised radiotherapy treatment.

Given its favourable dose distribution in tissues surrounding the target tumour, proton therapy is correlated with lower toxicity levels than photon therapy. As a result, many oncology centers around the world have introduced proton therapy over the last decade. However, planning studies show that not all patients would significantly benefit from this more expensive treatment. The PRODECIS platform has been developed to justify patient stratification for a fair and efficient use of the more expensive proton treatment.

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About ptTheragnostic

ptTheragnostic B.V. started as a spin-off company of Maastro Clinic (MC) and Maastricht University Medical Center (MUMC) in 2014. The company was acquired in December 2015 by DNAmito Inc. based in Cupertino, California, bringing in necessary investments and an experienced management and commercialization team supported by world class clinical and product development teams. ptTheragnostic aims to achieve more effective, individualised radiation therapy for cancer patients. Taken together, ptTheragnostic is the service company for patient stratification in radiotherapy.

Role of ICT Healthcare

ICT Healthcare was asked to create and deliver all necessary documentation for CE Marking compliant to ISO 13485 / IEC 62304. ptTheragnostic chose ICT Healthcare for their extended knowledge in these areas. PRODECIS is a CE Class I medical device with Software Class A.

The ICT QA/RA officer made sure all steps for the classification where done in the right order and all procedures were followed.

The ICT Architect wrote the required documentation. The researchers that develop the research models and scientific publications were the main sources of knowledge. In several meetings, the researchers were interviewed by the ICT Architect, after which he wrote the structured documents according to the standards and regulations. Some administrative functions for e.g. user and license management were specified and implemented by ICT Healthcare as well.

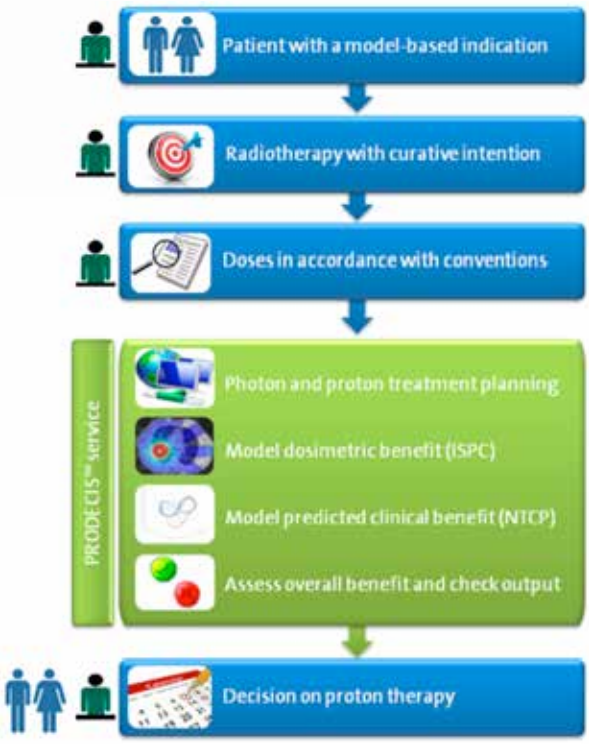
Additionally, the PRODECIS software had to be structurally tested. The ICT Architect designed the required test cases, assuring that the test coverage did meet the regulations for the CE classification for PRODECIS.

Keywords
CE Classification, ISO 13485 / IEC 62304, ICT QMS, SVN, Trac, Photon Therapy, Proton Therapy

PROJECT RESULT

CE Marking implies close cooperation between the different involved stakeholders, from end-users to the software engineers to quality assurance officers. ICT Healthcare successfully accomplished this task by working closely together with PRODECIS and involving all stakeholders as one team.

Since the area of CE Classification was new for the customer, ICT Healthcare guided the customer through the whole process. The ICT QA officer was actively involved applying the ICT Quality Management System and adjusting deliverables to the customers needs. The entire product with all its technical file contents, required for CE Classification, was prepared and delivered to PRODECIS according to schedule. The last step of offering the entire product for CE Marking was the responsibility of the customer.



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