

Summary of PVEOut Exploitation Strategy

Background

The PVEOut tools have been developed by participating scientific partners in the framework of an EC funded project in the "Quality of Life" programme of the 5th EU framework. The PVEOut project features five leading research institutions in Europe with regard to image processing applied to neurology and neuro-radiology. To guarantee an exit to the market an industrial partner, Rasna Imaging Systems, is also part of the Consortium. According to one of the leading partners, Dr. Mario Quarantelli of CNR in Naples (I), the goal of the project can be summarised as follows: "If the method gains primacy, I would expect it to remain a standard tool as long as NM images maintain actual resolution"; and more, on the industrial side: "the advantage in participating in this project is to obtain such a technology in a sector where the one who does the first move has a considerable advantage".

The Market and Marketing Model

Rasna Imaging Systems is a medical software manufacturer. The company markets its products and services through OEM channels in Europe and the U.S.. Therefore, Rasna Imaging Systems will employ such channels, either existing at the present stage or in development, to deliver the PVEOut tools on to the market. This will ensure a wider access to and faster time to the market. In this context, initial market assessment shows a potential end-user base of 50 to 100 sites across Europe, where the minimum conditions for the deployment of PVEOut tools can be met. Specifically, the eligible sites must have an NM, an MRI and a DICOM network. However, intended use of the PVEOut tools, makes this product potentially non-marketable on the U.S. market due to regulatory limitations. An agreement on the transfer conditions of the PVEOut tools must be reached by the participating partners on or before the end of the project.

Prototype Production

The PVEOut Prototype production is the next-in-the-line activity in the PVEOut project timeline. This activity is deemed to be completed by the next plenary meeting to be held in January 2003. In order to build a "marketable" prototype, all the PVEOut modules must be integrated in to a "single" application so that all involved procedures are streamlined and all parameters are traced and stored. Further to that, all information on patient and examination must be aligned to existing image management systems since integration of diverse IT systems across any health-care enterprise is a market requirement (cfr. IHE Technical Framework, <http://www.rsna.org/IHE>). The integration of the PVEOut Prototype with the IHE guidelines, the wide usage of standards such as DICOM and HL7, it is a way to ensure a successful market exploitation. To this end the IHE gives a method to effectively integrate this prototype as an Image Creator actor, generating images and "evidence documents".

To take full advantage of existing Rasna Imaging Systems technologies and products, the PVEOut tools will be "plugged" on to a medical image/report management product foundation. The foundation is a primary manager and repository of DICOM Structured

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Reporting objects and it is a multi-platform application. DICOM Structured Report is a flexible “databaseable” document based on DICOM Part XVI which provides unambiguous “semantic” documentation of diagnosis/procedures, in addition to context, observer or previous evidence information. It also links text with images and other information and maintains interfaces with DICOM modalities and with HL7 information systems. Finally, it may provide a coded entry using standardized lexicons.

The PVEOut Prototype will have the following functionality:

- ❖ It creates an image library with all input instances
- ❖ It provides procedures tracing
 - Processing steps
 - Includes status of each step (if provided)
 - Parameters being used in processing (if provided)
- ❖ It provides a wide range of output material
 - Images (original and processed)
 - Annotations
 - Evidence positioning
 - Measurements
 - Parameters
 - Boolean states (benign/malign or true/false)

Such an approach brings several advantages from a “clinical” perspective: it ensures QA of process, it ensures the “reproduceability” of the processing conditions and, last but not the least, it could ease the “clinical” validation of the product. Also, deployment in hospitals is fairly easy, since the integration is straightforward thanks to the use of the latest and highly proven DICOM and HL7 and the multi-platform approach.