Web-PACS for Multicenter Clinical Trials

J. A. Hernandez, César J. Acuña, Ma. Valeria de Castro, E. Marcos, Member, IEEE, M. López, and Norberto Malpica, Member, IEEE

Abstract—Medical information systems are not designed for clinical trials using clinical imaging. This paper presents a conceptual model for clinical trials based on medical imaging from two complementary points of view: a technical model and a business model. A Web information system (WIS) for supporting multicenter clinical trials has been designed to implement the proposed model. We show that our approach overcomes the actual limitations by facilitating medical image management in the context of clinical trials or cooperative research.

Index Terms—Clinical trial, medical imaging, picture archiving and communication systems (PACS), Web.

I. INTRODUCTION

MEDICAL imaging is increasingly incorporated into clinical trials. New clinical studies in psychiatry, neurology, cardiology, oncology, etc., obtain their results through longitudinal tests with large-image samples, from patients and controls subjects, using magnetic resonance imaging (MRI), computerized tomography (CT), or positron emission tomography (PET).

New needs arise in medical image management that exceed the capabilities of hospital information systems and clinical departments. In multicenter clinical trials, images from patients are acquired in different scanners at different hospitals, making it necessary to establish an acquisition protocol for all the scanners. Radiological departments or medical imaging units can store and transmit images using picture archiving and communication systems (PACS) and report them using radiological information systems (RIS). These clinical information systems are oriented to individual patient information management, but not to group management with different experimental conditions. Management of groups of patients and of the mathematical procedures applied to them are not available in these types of software tools.

The images are gathered from the different scanners and stored and processed in one specific center. Centralization allows the use of specific tools for mathematical analysis and postprocessing in the same manner over all samples. Analysis standardization is, thus, guaranteed, independently of the site of acquisition. In summary, it provides a centralized procedure adjusted to a specific protocol.

Images are usually stored in digital imaging and communications in medicine (DICOM) format. This format contains the patient data and technical parameters of each image. However, currently, it is not possible to store information about the clinical trial together with the images, such as the postprocessing procedures applied, algorithm parameters, and in general, information for further qualitative and quantitative analysis. The lack of this information associated to the images is a major drawback for a complete automation of the procedures. It requires the researcher to store part of the information aside from the images files. For example, in functional magnetic resonance studies, the experimental conditions, the number of acquisition per epoch, or the task done by the subject, are data needed for processing the images in a right way. Our approach considers that clinical trials based on medical imaging are analogous to clinical trials based on analysis of substances in specialized laboratories. Therefore, the creation of medical image analysis labs for quantitative image analysis with standard procedures would improve the current procedures, and would allow the introduction of quality controls in clinical-trial procedures.

Our main aim is to provide a new tool for supporting clinical trials involving different hospitals and research institutions, mainly, though not restricted to, the neuroimaging environment, with all of the advantages of a Web service. Similar tools have been designed for cardiology and cancer multicenter trials [1]–[4], but no medical images were involved in these cases.

Regarding medical imaging, some previous works have approached similar problems. Brown et al. [5] designed a database oriented to supporting lung image analysis protocols. Liu et al. [6] proposed a database tool to support multicentric trials. In their model, management is carried out at a central site.

We have previously proposed a new Web architecture for medical image management [7]. This solution allows to develop clinical trials based on medical imaging. In this paper, we present the conceptual model for design and an improved version of the architecture.

Section II describes a model design with two different approaches to the problem. One of them is oriented to technical aspects and the other one to business. This second approach is considered necessary for the sustainability of the technical model in a competitive environment. Section III describes the technical implementation using a new application architecture for Web services based on XML with a new design and new technical aspects with respect to our previous work [7].

II. DESIGN

We describe two models. The first one is a detailed description of all the technical tasks related with the acquisition and processing of medical images in a clinical trial. Research units at hospitals, universities, or in the pharmaceutical industry, with
César J. Acuña is working toward the Ph.D. degree and is an Assistant Professor in the Department of Software and Computing Systems, Rey Juan Carlos University, Móstoles, Madrid, Spain. He is the coauthor of numerous publications presented at national and international conferences and has participated in several research projects. His current research interests include Web portal integration, semantic Web services development, service-oriented computing, and model-driven engineering.

Ma. Valeria de Castro received the M.Sc. degree from the National Technological University, Bahía Blanca, Argentina. Currently, she is working toward the Ph.D. degree and is an Assistant Professor in the Department of Software and Computing Systems, Rey Juan Carlos University, Móstoles, Madrid, Spain. She has coauthored numerous publications presented at national and international conferences and has participated in several research projects. Her current research interests include Web services engineering, Web services modeling, service-oriented computing, and model-driven engineering.

E. Marcos (M’00) received the Ph.D. degree in computer sciences from the Polytechnic University of Madrid, Madrid, Spain, in 1997. From 1993 to 1998, was an Assistant Professor at Carlos III University, Madrid. Since 1998, she is an Associate Professor at Rey Juan Carlos University, Madrid, where she teaches and manages databases. She also teaches M.Sc. courses in software engineering. She has coauthored several books and has published several book chapters and articles in journals and conferences. She has participated and managed several research projects. She is the Leader of the Kybele Research Group. Her current research interests include model-driven engineering, Web-information-systems development, and philosophical foundations on information-systems engineering.

M. López received the B.Sc. degree in IT systems from the Polytechnic University of Madrid, Madrid, Spain, and the M.Sc. degree in computer science from Rey Juan Carlos University, Madrid. Currently, he is working toward the Ph.D. degree and is an Assistant Professor in the Department of Languages and Systems in Informatics, Rey Juan Carlos University. He also is a Researcher for the Kybele Research Group. He is the coauthor of numerous papers and has participated in several research projects. His current research interests include database design and software engineering of distributed systems and grids.

Nurberto Malpica (S’96–A’04–M’04) received the M.Sc. degree in telecommunication engineering from the Universidad Politécnica de Madrid (UPM), Madrid, Spain, in 1995, and the Ph.D. degree from the Medical Image Technologies Group, UPM, in 2004.

He worked for three years in the design and deployment of teleradiology systems. From 1999 to 2004, he was with the Medical Image Technologies Group. Currently, he is an Associate Professor in the Computer Science and the Telecommunications Schools, Rey Juan Carlos University, Madrid. During 2004, he was a Postdoctoral Researcher at Gregorio Marañón Hospital, Madrid. His current research interests include medical-image management and analysis, with a special interest in image segmentation and motion analysis.
informatics support. Available commercial software tools have drawbacks when handling functional imaging, and are not adapted to multicenter studies.

We have proposed a model for clinical trials using medical images from patients as a diagnosis test, and we have designed a Web-based PACS that implements the workflow of the model. To guarantee the sustainability, a complementary business model has also been proposed.

The representation of medical image files using XML facilitates the integrated organization, query, and retrieval and processing of the medical images by means of an XML database, in a web context. Centralized processing ensures that variability in the results is only due to controlled experimental conditions or to the specific phenomenon under study.

All the information about the specific processing stages applied in a study is stored together with the images and the results, which allows to perform retrospective analyses.

The database, of images and results, can serve as a historical archive, either to increase the sample size in future studies or for further epidemiological studies.

The modular architecture will allow to incorporate easily the constant changes that occur in methods and image formats.

It will also help to adapt the image processor module to the grid computing paradigm and to transform the database into a distributed database in order to store and to process larger quantities of images.

ACKNOWLEDGMENT

The authors would like to thank J. Alvarez-Linera, M.D., of Ruber International Hospital for system trials with real study cases and R. Wierringa for his collaboration in the development of the value model.

REFERENCES


J. A. Hernandez received the M.S. degree in physics from the Complutense University of Madrid, Madrid, Spain, in 1992, and the Ph.D. degree in bioengineering from the Polytechnic University of Madrid, Madrid, in 1999.

Currently, he is an Associate Professor at Rey Juan Carlos University, Móstoles, Madrid, Spain, and Head of the Medical Image Analysis Laboratory of the "Madrid R&D" Network of laboratories. His current research interests include biomedical image and signal processing, functional magnetic-resonance imaging analysis, medical image management, and electronics for bioengineering.