A MEDICAL DEVICE INFORMATION SYSTEM AND ITS ARCHITECTURE

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Abstract: The paper describes a Medical Device Information System (MEDIS) that supports applicants in the submission of a new clinical investigation (CIV) proposal as well as National Competent Authority in the evaluation and monitoring CIVs carried out at national level. An overview of system design is provided in the description of its conceptual model and architecture as well as providing an example of the interface of the system developed.

1 INTRODUCTION

Progress in clinical research depends largely on the results of clinical investigations (CIV). CIVs are complex processes encompassing different steps, from specification and planning to execution and final result analysis. There are an increasing number of applications that support CIV data management, project management and data quality control, contributing to reduce time and costs and most importantly to improve research quality (Oliveira and Salgado, 2006).

However, not much attention has been put on information systems that support applicants in the regulatory submission of CIV proposals as well as National Competent Authorities (NCA) in the process of evaluating proposals and monitor CIV execution. The adoption od these systems contribute to reduce time for CIV start, enhance transparency of evaluation criteria and improve the monitoring of ongoing and concluded CIVs at national level.

The paper describes a Medical Device Information System (MEDIS) developed by the National Research Council within a project supported by the Italian Ministry of Health. MEDIS plays the role of both a registry of clinical investigation data and a content repository of documents submitted by manufacturers to the NCA to obtain the approval for the clinical investigation start. In particular, MEDIS supports manufacturers in the documentation submission process as well as NCA evaluators in assessing the regulatory documentation received. It also manages the communication among the different stakeholders and collects the data produced during the whole lifecycle of clinical investigations. A high level description of the CIV business process is described in details in previous works (Luzi et al., 2009, Pecoraro et al., 2010, Luzi et al., 2010). The design of the MEDIS system was based on the analysis of the domain of CIV on MDs in close collaboration with the office in charge for the evaluation of CIV proposals, according to national laws, European Directives (EU, 2007) and ISO technical norms (ISO, 2008). Moreover, MEDIS design has been based on the application of Health Level 7 (HL7) v.3 standards to develop a flexible and interoperable system. This paper presents the results of the MEDIS development describing in particular its architecture and giving an example of its interface.

2 MEDIS ARCHITECTURE

From an architectural point of view, MEDIS is a client-server three-tiered system. The high level description of the MEDIS system architecture is depicted in figure 1 using the UML Component Diagram notation. All the components of the MEDIS system reside at the application logic layer, using the Tapestry framework based on Java technologies such as JSP and Servlet. The MEDIS presentation layer is composed by two web clients providing specific interfaces for both applicants and

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NCA evaluators. The web pages are transmitted to the web client using the protocol HTTP. Moreover, the HTTPS protocol is used to guarantee both reserved transfers and secure channels over the web.

The application logic layer consists of a set of modules in charge of the following functionalities:

1) The authentication of internal users is managed by MEDIS, while external users access the system through a single sign on portal which controls their access to multiple and independent systems. The authorization of both external and internal users depends on their profiles. Each external user can access his/her portion of MEDIS system containing the list of submitted notifications together with those that are in the process of submission. Once a notification is submitted no change is allowed. The authorization of internal users depends on the role played in the evaluation of the CIV proposal (supervisor, medical/technical evaluator, administrative secretary). For instance each evaluator can access and modify only the evaluation report he/she is in charge of, while the supervisor can access the evaluation report only when the evaluator allows him/her to do it and use it to make a final evaluation report.

2) The enterprise data manager supports information related to external users, the role they are allowed to play in the notification submission (manufacturer, authorized representative) and the data related to organizations responsible for the notification or delegated to do it. The administrative secretary accesses this component and gives the users the right to initialize a new notification.

3) The DAM (Domain Analysis Model) component manages MEDIS conceptual model based on HL7 RIM. This component supports: a) the rules that validate the association between DAM objects; b) the rules that manages the workflow of the CIV lifecycle. The design of MEDIS DAM and related data model are described in details in previous works (Luzi et al., 2009). This component specifies the underlying workflow determining the allowed steps depending on the state of the CIV lifecycle enabling specific functionalities according to the CIV actual state as well as to the user profile.

4) The proposal data manager supports the acquisition of the notification, guiding applicants in the collection and submission of regulatory data and documents as well as verifying the completeness and consistency of data and documents submitted.

5) The CIV data manager supports the evaluation team to write an evaluation report focused on crucial aspects such as MD characteristics, risk analysis and procedures planned for patient safety. This component makes it also possible to share the report among the evaluation team as well as to edit the official communication of CIV approval or deny. Moreover, it supports the communication between applicants and NCA during the CIV performance, allowing applicants to notify important steps reached by an ongoing CIV and register clinical protocol amendments and/or serious adverse events. This component also manages the acquisition of the report of CIV final result.

6) The Dossier Manager supports the storage and retrieval of documents uploaded as well as those created during the CIV lifecycle (i.e. NCA internal documents and communications). Through the XML component filled electronic forms are transformed in XML documents and then in PDF (Report builder) in order to produce a digital signed document.

7) The vocabulary/classification manager connects MEDIS to external systems to retrieve data such as vocabularies, classifications, and nomenclatures (i.e. MESH, MD repertoires, etc.).

Functionalities used in the above-described components that manage the CIV lifecycle are:

a) The communication exchange that supports the information flow between applicants and the NCA evaluation team (e.g. request for data and/or document integration; reports of amendments and/or serious adverse events), and also takes track of the communication exchange.

b) The control of the completeness and consistency of the data and documents uploaded in a single form or in a correlated set of forms.

c) The dynamic generation of the electronic forms depending on the user, the MD under investigation, and the state reached in the workflow, so that certain types of communication is allowed only in a specific phase of the CIV lifecycle.

d) The legal authentication of the documents and data submitted through a digital signature.

Finally, the persistence layer is divided into:

1) A relational database containing information on applicants and their belonging organization, as well as the organization that delegates them to submit CIV proposals.

2) A relational database that contains data describing MD and CIV instances, data tracking the CIV lifecycle workflow and metadata related to documents stored in the content repository.

3) A content repository in charge of archiving documents uploaded as attachments of the

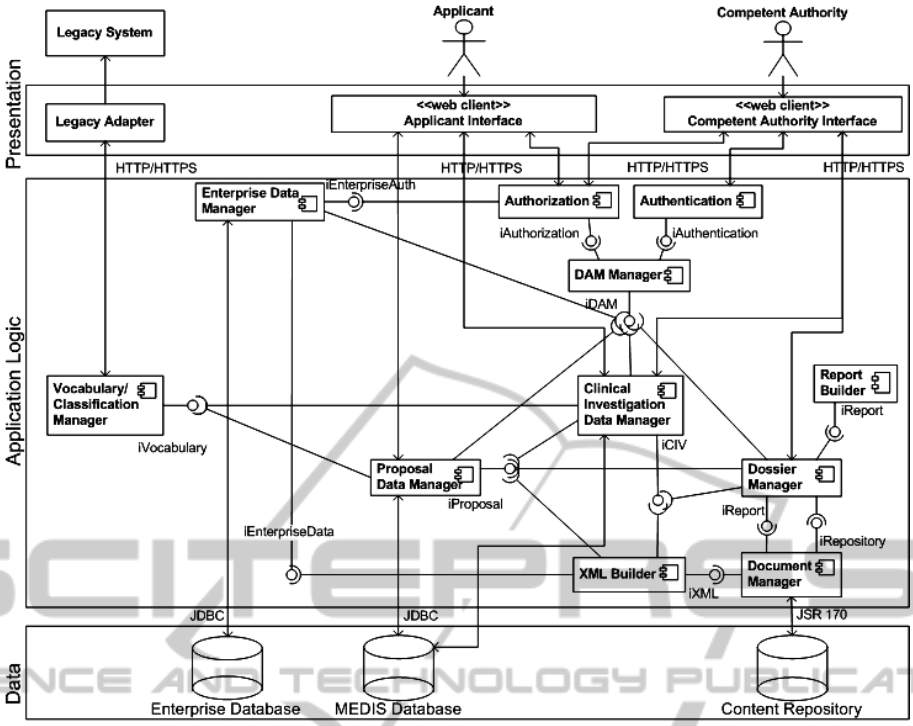

Figure 1: Architecture of the MEDIS system.

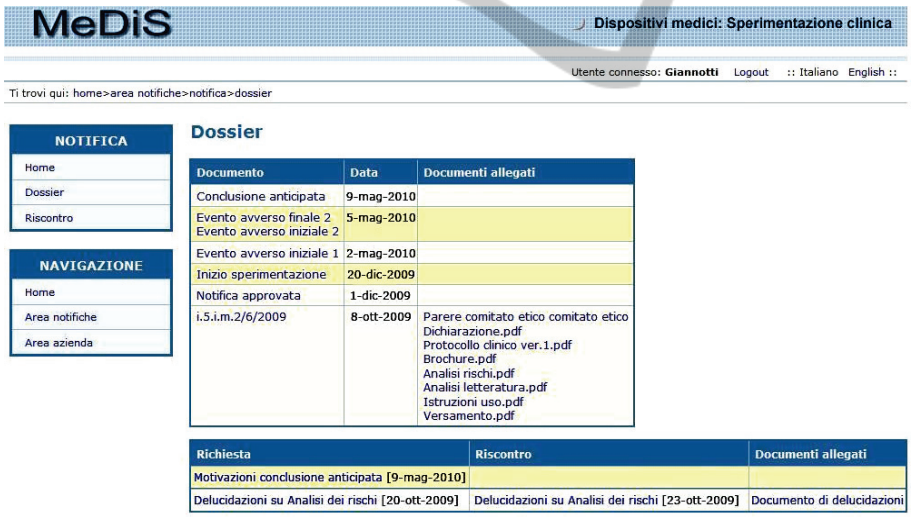

Figure 2: MEDIS interface for accessing the dossier documents.

notification or generated by the system starting from the data filled in the electronic forms.

3 DOSSIER MANAGEMENT

One of MEDIS features is represented by the content management component. Data and documents exchanged between NCA and applicants are closely related to the different phases of the CIV lifecycle. Given the amount of data and documents exchanged, their legal value that includes also the management of different document versions, a Dossier manager component was developed (see § 2).

An example of the MEDIS interface showing a representation of the Dossier is depicted in Figure 2 showing the entry point to retrieve detailed information of each CIV. Each Dossier has it own

unique identification code that identifies the set of the different types of related documents (technical and administrative) collected during CIV process. On the left side MEDIS provides two menus, the upper one is dynamically created according to the state of the notification. In this case it allows an applicant to access the dossier as well as to reply to a received request of further information (Riscontro). The lower menu allows the applicant a) to access the notification area (Area notifiche) where the user can view its CIV proposals and/or make a new one, b) to access the Organization area (Area Azienda) to view and update information on the manufacturer and/or authorized representative. On the right side, the upper table shows the list of documents exchanged during the CIV lifecycle, note that each document type is linked to the attached documents (Documenti allegati). In this case the notification identified by the code i.5.i.m.2/6/2009 (meaning the 6th notification of pre-market CIV received in the year 2009) gathers all regulatory documents submitted for the CIV approval. The lower table shows the list of requests (Richiesta) and eventually the related response (Riscontro) given by the applicant. In both tables applicants can access the full text of the document selected clicking on each item of the list.

4 CONCLUSIONS

MEDIS is a NCA's information system developed to support both CIV applicants to correctly submit trial proposals and NCA to evaluate them as well as monitor CIVs carried out at national level. Moreover, MEDIS was designed on the basis of HL7 v.3 methodology and standards in order to make the system interoperable with other National registries and in particular with the European Databank on Medical Device (EUDAMED) that is also developing an European system comprising information on CIVs. At the moment the MEDIS system has to be validated by real users in order to test system performance and functionalities.

The role played by the content management component has been described in this paper considering it one of the main feature of NCA's information systems. The Dossier management has the function of storing and retrieving documents and data exchanged in the different phases of the CIV lifecycle.

Moreover, clinical protocols describing CIV on MDs as well as investigator's brochures have been analysed both in their structure and content following the recommendation of Good Clinical Practice (ISO, 2008) that guide applicants to correctly write these technical documents. On the basis of these features, our future intension is to adopt HL7 CDA standard to further specify the structure and semantic of CIV documents, taking also into account BRIDG conceptual model (Fridsma et al., 2007). This is in line with the MEDIS design and development based on HL7 RIM and it would further improve document exchange as well as information retrieval of meaningful parts of these documents.

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