Creation of OAIS-Compliant Archival Packages for Long-Term Preservation of Regulatory Metadata, Records and Dossiers

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Abstract – **The authors continue their previous research on the long-term preservation solution for complex digital objects preserved as archival information packages in the domain of pharmaceutical records by evolving the proof of concept application "ArchiMed" to the level of the prototype. The research is put in the context of the responsibility of Marketing Authorisation Holders for submitting medicinal products' dossiers to the National Competent Authorities, i.e., regulatory institutions, and the problems of long-term preservation of such records. The authors explain the problems those institutions are facing, the theory behind the long-term preservation concept and the requirements that digital preservation systems are facing with. The authors also explain the regulatory business process for better understanding of the organisational differences and technical issues on the European level. The differences between four formats of dossiers, NtA, CTD, NeeS and eCTD, are indicated. Based on the detected problems and previous proof of concept, the ArchiMed module was developed in order to further test its functionalities required by the digital preservation theory and to prove its conformance with the most important international standards like ISO 15489-1, ISO 14721: 2003 and others. The authors conclude that the proposed solution contributes to the regulation of archival procedures in the area of long-term preservation of regulatory records in the digital form. The paper shows how to regulate the regulatory process in the domain of control of medicines from the archival point of view with the aim of long-term preservation of important electronic records.**

Keywords – digital preservation, medicinal products, dossiers, OAIS, ArchiMed, regulatory business, Europe, eCTD.

I. INTRODUCTION

Marketing Authorisation Holders (MAHs) are responsible for submitting medicinal products' dossiers and National Competent Authorities (NCAs) as regulatory institutions are responsible for granting marketing authorisation for their medicinal products. Marketing authorisation is issued by NCA after the positive assessment of submitted dossiers. The EU Member States' NCAs started to receive electronic medicinal product dossiers published according to the electronic Common Technical Document standard (eCTD) [1][2]. An eCTD dossier consists of sequence(s), modules and sections of administrative records, summaries, quality records, non-clinical and clinical records, and XML backbone. It is recommended that a MAH organises the eCTD dossier for the same medicine always in the same root folder, but this requirement is not obligatory. Beside eCTD, there are several other standards for pharmaceutical records in circulation, and NCAs often have additional national requirements concerning records, which are not included in international standards and have to be submitted separately, usually in the *working-documents* folder.

MAHs and NCAs have difficulties with managing dossiers and other records and with preparing them for the long-term preservation. MAHs should be able to preserve their records in order to meet regulatory and legal requirements, to provide support for everyday business processes, to provide business continuity and legal evidence when needed. NCAs should prepare for digital archiving in order to react on time in case of any public safety incident. Additionally, they are often under supervision of national archival authorities. Difficulties in managing and preserving electronic dossiers and other records, in a MAH organisation, can result with failure when their headquarters or NCA asks them to show medicinal product records that were valid for the specific product in the specific period, when they are asked to show records that were submitted for particular market, or to show the latest state of the dossier. NCAs have similar difficulties and more serious obligations regarding demands of the public health. That is why we are proposing a better solution in managing and archiving regulatory dossiers and records. The proposed solution is a result of extension of our previous research [3] and integration with the newly developed application for managing regulatory processes. The concept that lies beneath the solution is strongly process-oriented and based on ISO 14721:2003 – Open Archival Information System Reference Model.

Next, the research that preceded the development of the proposed solution is presented followed by the detailed description of the regulatory business processes. Then, the proof of concept and integration into the prototype application is explained followed by the conclusion and information on the future research.

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II. RESEARCH

Archival materials, in this case dossiers and other records created in the process of controlling medicines, are easily created by the use of information technology. The same technology also enables those materials to be easily changed or modified. For various usages in the everyday workflow this is an advantage but in the context of the preservation it should be looked upon as a disadvantage. Archived materials, once they become records, should not be changed in any way that affects their authenticity, integrity, reliability or usability, as defined by ISO 15489-1 [4]. This could be solved by storing those records in a safe place, only if the technology would not change substantially in the matter of few years. Kuny [5] is consenting with the Moore's law when stating: "Organizations are being asked to make fiscal commitments to creating complex technical infrastructures that change every 3-5 years and which require increasingly expensive technical expertise to keep functioning." Nevertheless, when the electronic records need to be preserved in the long-term it is not only the problem that the infrastructure, i.e., computer architecture, is changing quickly, but the software applications and file formats change as well. Therefore, to be able to read an old e-record it is necessary either to keep the original hardware/software solutions, which is highly unlikely and very expensive, or to use one of the other techniques, migration most likely, as in Thibodeau [6]. This means changing the records in order for them to function and be readable using the latest technology. How to do this without endangering authenticity?

The Authenticity Task Force [7] differentiates two kinds of establishing the notion of authenticity – the presumption and the verification of authenticity.

- *A presumption of authenticity* is an inference that is drawn from known facts about the manner in which a record has been created and maintained. The evidence that supports the presumption that the record creator created and maintained them authentic are enumerated in the Benchmark Requirements Supporting the Presumption of Authenticity of Electronic Records. A presumption of authenticity will be based upon the number of requirements that have been met and the degree to which each has been met. The requirements are, therefore, cumulative: the higher the number of satisfied requirements, and the greater the degree to which an individual requirement has been satisfied, the stronger the presumption of authenticity.
- In any given case, there may be an insufficient basis for a presumption of authenticity, or the presumption may be extremely weak. In such cases, further analysis may be necessary to verify the authenticity of the records. *A verification of authenticity* is the act or process of establishing a correspondence between known facts about the record and the various contexts in which it has been created and maintained, and the proposed fact of the record's authenticity.

In any case, it is best if it could be proved that the records are not changed in the way that their authenticity is questioned, or, when the migration is needed, that the authenticity was not compromised during that process. Both requirements could be answered by the properly established preservation environment with properly implemented and documented preservation processes and procedures. OAIS reference model [8] could be used to build such a system environment. Although it does not suggest the concrete technology to be used it presents a model to be built using the latest technology. By creating all the functional entities and their interrelated connections, a trusted digital preservation environment could be established. OAIS information model comprises of three types of information packages – submission information package (SIP), archival information package (AIP), and dissemination information package (DIP). It is important to understand that if both Marketing Authorisation Holder and National competent authority have implemented the digital archive according to the OAIS reference model than what MAH creates is a DIP from their standpoint while the same package is a SIP from the NCA's standpoint it is a SIP. We will refer to this notion later on in the explanation of the functions of the proposed solution for long-term preservation of authentic medicinal records.

In the process of long-term preservation the metadata are of the utmost importance. Dobreva and Ikonomov [9] state that "there are two key issues which need to be considered *vis-à-vis* metadata and preservation:

1. What metadata are needed for preservation purposes (...) (besides assuring a reliable preservation process, they should help the designated communities to understand the resources), and
2. How to preserve the metadata accompanying existing digital objects.

Having all these in mind, preservation metadata area provides many challenges. What preservation metadata to use? What minimum set needs to be supplied in order to guarantee a reliable preservation process? How to automate the creation of preservation metadata? How to guarantee that the digital resources developed within a particular project are accompanied by sufficient preservation quality metadata? And how to guarantee interoperability between multiple existing schemes? It is not easy for any organisation or project to make decisions regarding the metadata in this situation." Having acknowledged these problems and the fact that there are several main metadata standards, in our previous work [3] we have suggested the minimum set of metadata to be preserved mapped them across the different standards (METS, ISO 23081, ISO 14721:2003) for ease of the future preservation actions. Also, in our previous research we have developed a model for the long-term preservation of pharmaceutical records in the eCTD file format, determined the functionalities that an application intended for the creation of a complex electronic object record of a medicine, intended for the long-term preservation in a digital archive, should have, and created a proof of concept – ArchiMed – the application for archiving and long-term preservation of eCTD records. Upon the latest research we have determined the improvement possibilities and developed the application further, from the proof of concept to the prototype level, in order to be able to advance managing the regulatory processes.

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III. REGULATORY BUSINESS PROCESSES

Regulatory processes in the domain of control of medicines are very complex in Europe [16]. There are a lot of stakeholders involved and collaboration between them is difficult due to their organisational differences and technical issues. MAHs could submit dossier and other records for marketing authorisation, renewal of that authorisation or variation of authorisation for medicines placed on one particular national market, several European Member States' markets or for a single European Community market. If MAH sends application for more than one market, it has to opt between tree different procedures – centralised procedure, decentralised procedure or mutual recognition procedure. Selection of marketing authorisation procedure depends on the legal basis, type of application and MAH's sales strategy. As we will see later, this will be an important factor in the creation of digital archival records.

The *centralised procedure (CP)* is set aside for medicines applied to the single market of the Community. Marketing authorisation granted under this procedure is suitable for all Member States markets and this procedure is led by the European Medicines Agency. It is mandatory for innovative or biosimillar medicines developed by biotechnological manufacturing processes such as "recombinant DNA technology, controlled expression of genes coding for biologically active proteins (…), hybridoma and monoclonal antibody methods (…), medicinal products (…) containing a new active substance which (…) was not authorised in the Community" (for AIDS, cancer, neurodegenerative disorder, diabetes), and for orphan medicines [11]. Medicinal products with a new, unauthorised active substance for other treatments and medicines that significantly improve therapies or represent improvements in scientific or technological sense, and generic or hybrid medicines, which have reference medicinal product authorised by European Medicines Agency can also be authorised via the centralised procedure.

The *decentralised procedure (DCP)* is a marketing authorisation procedure that starts at the same time in a referent Member State and all other involved Member States. The referent member state is represented by NCA in the particular Member State that leads the process by producing assessment report. Assessment report is the basis for granting approvals in other NCAs.

The *mutual recognition procedure (MRP)* is a procedure of granting marketing authorisation in which applicant sends its application to other Member States after the medicine has been approved for market in the referent Member State.

The *national procedure (NP)* is reserved for one national market only.

Majority of NCAs have their own particular requirements regarding the dossiers and this makes submitting of application even more complex. That is the main reason why we have decided to shift back to business processes instead of focusing to the business process resources or dossiers. The main problem lies in usage of different formats of business process resources (dossiers). Although some of them have become obsolete on the conceptual level [12], some medicines, which are important for different markets do not have new documentation, some applicants are incapable of publishing technically valid electronic dossiers, and for stated reasons even now applicants submit dossiers in four different formats – NtA (Notice To Applicants), CTD (Common Technical Document), NeeS (Non-eCTD electronic Submission) and eCTD. NtA consists of four parts (administrative, pharmacological-biological, nonclinical and clinical part) and it is considered to be obsolete on the conceptual level. CTD, NeeS and eCTD share the same structure and granulation (administrative module, module of summaries, quality module, module for nonclinical data and module for clinical data), but CTD is a paper dossier, and NeeS and eCTD are e-dossiers. The difference between NeeS and eCTD is that NeeS does not contain XML backbone and thus does not enable the review software to monitor the lifecycle of contained files automatically. However, it is easier for MAHs to produce NeeS dossier because they do not have to invest in specialised publishing tools. Because of that majority of smaller generic pharmaceutical companies and MAHs prefer to use NeeS. Bigger companies work with eCTDs, but staff of their local MAHs subsidiaries lack the technological knowledge sufficient for producing technically valid dossiers. eCTD dossiers are a novelty even for NCAs' staff, despite the Heads of medicines agencies meeting in Reykjavik in 2005 during which the shift to eCTD was agreed.

Because of situation described above the dossier-centric approach has resulted in the operational problems for MAHs and NCAs and in insufficiencies of records management technologies so far. Typical large IT vendors usually do not have enough know-how for regulatory affairs' processes, especially for NCAs' processes. MAHs and NCAs respond to these difficulties by avoiding the use of the eCTD dossiers, because, for using electronic dossiers in-house, processes and organisation of work should be carefully designed and heavy, non-scalable, partially operational and very expensive typical IT solutions should be invested into [13]. That is the very reason why we are suggesting turning back to the root problem. It means satisfying the requirement for managing regulatory processes and regulatory affairs first, and then managing dossiers and documents.

Our first goal is to focus on the regulatory business processes. They are supported by carefully designed metadata and by a process of metadata inheritance starting from the regulatory processes themselves and going all the way to the related archival packages with their components and files. Metadata can be colected even reversibly, from XML of the eCTD dossier back to the process.

Our second goal is to automate the creation of archival information packages (AIPs) and dissemination information packages (DIPs). Dissemination information packages are packages of content prepared for dissemination to NCAs or to other stakeholders from MAHs' perspective. For NCAs they will be considered as submission information packages. AIPs should enable long-term preservation of content with pertaining metadata in a manner that they logically encapsulate content and enable reporting about the content. Reports can provide information necessary for long-term preservation activities, i.e., information about the containing filetypes that might become obsolete and need to be migrated.

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IV. PROOF OF CONCEPT AND INTEGRATION INTO THE PROTOTYPE APPLICATION

Previously developed proof of concept application "ArchiMed"[3] was improved and is being integrated with the newly developed application for managing regulatory affairs' processes called "READY", produced by Nanokinetik. ArchiMed is being integrated into READY on the module level. The newly created prototype made of READY and ArchiMed has functionalities for managing regulatory processes and managing dossiers as well as other documents and metadata as the OAIS-compliant information packages.

Information packages, in the previous, self-standing, ArchiMed application were divided into SIPs (1 and 2) and AIPs. SIP 1 represented the package for eCTD or NeeS dossiers, and SIP 2 represented the package for *workingdocuments*. AIPs were used for archived content in the external repository.

In the new prototype the information model was redesigned (compare with [3]) and now it additionally encompasses flexible AIPs and DIPs – as a category reserved for content prepared for MAH–NCA communication. DIP prepared as described is a SIP from NCAs' perspective and the basis for creation of NCAs' AIPs (see Figure 1). The main difference between AIPs and the other packages prepared by the new prototype is that AIPs can be versioned, which means that new components and files can be added, while DIPs/SIPs cannot be modified or deleted at all. This restriction is introduced because the content sent or received by NCA should have quality of non-repudiation. Each version of AIPs can be tracked reversibly so AIPs have broad long-term preservation prospect and quality of authenticity at the same time. Authenticity is supported by versioning, tracking and protection of each version, and every part of its content, by the MD5 checksum. For the purpose of the development of the new prototype, content of packages was redesigned and a new category of component was added into the prototype data model. It is positioned on a level between package and file, introduced for enabling adding, editing or deleting large "chunks" of information previously prepared by the READY application or other external system. Files and components are categorized. In this sense stand-alone files also pertain to one category. Non-file components are *eSubmissions* (category which describes structure of root folders, sequences, modules, sections, and files), *workingdocuments* (category with possibility to pre-define or import directory structure for files required by a particular NCA) and other categories created according to the business needs. The new prototype also introduced changes related to metadata describing packages and functions.

The main objects of ArchiMed module are:

- package (AIP in OAIS context),
- disseminated package (DIP/SIP in OAIS context, depending on the standpoint),
- component, and
- file.

The metadata was coded according to the international standards ISO 14721:2003 Open Archival Information System – Reference Model [8], ISO 23081 Metadata for records [14][15], and METS scheme [16]. Different metadata groups from the stated standards and scheme were reduced to a common denominator. The intention was to have possibility of mapping ArchiMed metadata to OAIS, ISO 23081 and METS metadata groups. Even external metadata, which are extracted from the content or READY application, can be mapped to the standards, i.e., metadata on an eCTD document type definition version belongs to OAIS provenance preservation description information, ISO 23081 use metadata group and to METS techMD class of descriptive metadata section [3]. Some metadata describing packages are also functioning as identifiers – hash strings and metadata related to the validity of package and validity check intervals.

Disseminated package contains similar metadata and it could be created out of one or more components form one or more packages because it represents what is going to be sent from MAH to NCA. Component related metadata include identifier, hash strings and relation metadata for connection component with a particular package. File metadata additionally take account of file types, extensions and version of file formats, because ArchiMed enables content analysis and reporting for preservation purposes. This is the realisation of the *Preservation planning* function of OAIS functional model. Other component metadata are inherited from the READY application and the content. The content related metadata is metadata about applicant, agency, invented name, active substance etc.

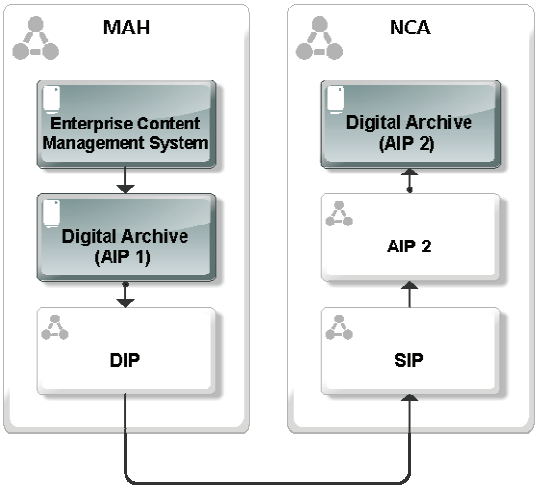

Figure 1. Conversion from the MAHs' Archival Information Package (AIP 1) to the Dissemination Information Package (DIP) intended for the National Competent Authorities (NCAs) where they receive it as the Submission Information Package (SIP) and preserve as AIP 2.

Functions of ArchiMed module prototype are divided to package functions, component and file functions, and reporting functions.

1. *Package functions*

1.1. *Create package* – function inserts new AIP to database and creates basic information from input para-

meters. Function also adds version number of AIP and generates MD5 hash for every file in the component, every component of the package and for the whole AIP package. XML file with metadata is created and value of MD5 hash function is added into the XML metadata file. If the hash check interval is set, function *check package* will be called on particular date and time.

1.2. *Edit package* – function updates package information in database and raises the version of the package. All package attributes can be edited by using this function (i.e., components and files can be added into package). The new XML metadata file is created, MD5 check is recalculated and its new value is embedded into the XML file.

1.3. *Delete package* – deletes package from the database.

1.4. *Create dissemination package* – creates package that will be delivered to NCA, local MAH, or other regulatory affairs' stakeholder.

1.5. *Get package* – function returns package or packages information from the database. Packages are retrieved according to the selected descriptors, i.e., function gets all packages for a particular medicinal product that was valid for particular period.

1.6. *Get all packages* – function returns all packages' information from the database.

1.7. *Check package* – function performs MD5 hash check on a specified package.

1.8. *Check all packages* – function performs MD5 hash check on all packages and finds invalid ones.

2. *Component and file functions*

2.1. *Select component type* – function categorizes components. Files and components are categorized (they have a value of component type attribute; in this sense stand-alone files also pertain to one category). All additional components except *eSubmission* and *workingdocument* should be defined with *Add component type* function. Function *Select component type* is called after *Create package*, *Add component/file* or *Edit package*.

2.2. *Add component type* – each structure should be defined as a component of the package.

2.3. *Delete component type* – function deletes unnecessary component type if there is no package containing component of such type in the database.

2.4. *Add component/file* – function inserts new component into a package. Function is also called when creating a package. It generates MD5 hash for the created component(s) and file(s). *Valid-until* metadata can be used for adding information about validity of the component (i.e., when MAH receives license that is valid until a defined date). This information can be imported and mapped from the READY application's metadata.

2.5. *Edit component/file* – function updates component in a package, i.e., edits component for new version of the package.

2.6. *Delete component/file* – function deletes component and/or files from a package in order to prepare new version of the package.

2.7. *Check component/file* – function performs MD5 hash check on a specified component in a package (component could be a file).

3. *Report functions*

3.1. *Check expiration* – function returns all packages that expire before the defined date.

3.2. *Filetype report* – function returns statistical data for every file type in repository per package and per component in the package. Function should be used for preparation of the migration of independent files and files in components (all components in a package) into new version of the package.

3.3. *Sent to partners report* – function returns all disseminated packages that have been sent to the selected partner (MAH should be able to prove which package was sent to which NCA).

For the example of proof of concept and integration into the prototype application see Figure 2.

V. CONCLUSION AND FUTURE RESEARCH

We have put this research in the context of the regulatory processes in the domain of control of medicines. We have described the difficulties the Marketing Authorisation Holders have with managing dossiers and other records and with preparing them for the long-term preservation. Upon researching the relevant resources and clarifying the digital preservation requirements, we have explained the regulatory business process and possible marketing authorisation procedures, as well as the types of records created and used. In this research we have argued not only the importance of long-term preservation of digital records created in the process of controlling medicines but the importance of their preservation of the authentic records too. In any legal dispute involving digital medicinal products' dossiers it is very important that it is possible to prove their authenticity, integrity, reliability and usability. In that sense the records should be preserved in the way that any change, intentional or unintentional, is detected. It is also important that the system is capable of automatic records' validation possibilities, background or initiated at any time. The system we have proposed is having these characteristics and is also capable of checking the expiration state of the records, of reporting the file types in the archive thus facilitating the migration procedures etc. We have developed the prototype application READY. Previously developed ArchiMed proof of concept has been developed as READY's module. We have also presented the ArchiMed module's package functions, component and file functions, and report functions.

It is important to point out that the prototype application is fully consistent with the OAIS's functional model's Preservation planning function. It preserves records' authenticity,

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integrity and reliability by calculating the hash values both for individual files and packages. It enables and facilitates preservation of usability by detecting file format types and format versions, which is very usable for the long-term preservation planning. Therefore, in our opinion, it presents a valuable contribution to the regulation of archival procedures and long-term preservation of regulatory metadata, records and dossiers. We are expecting that stakeholders and end-users will be using READY application since it is going to be consistent with the Best archiving practice (guidance) that are just being put together at the EU level. Also, the new pharmacovigilance legislation will require, starting from 1 July 2012 at the EU level, that all documentation changes are to be tracked. READY application could improve intra-EU collaboration in the area of DCP and MRP procedures since the national agencies should work together on the preservation of regulatory records.

The future research will be focused on the development of the fully functional application from the prototype described here. It will be necessary to study the additional functionalities that the application intended for the long-term preservation of the regulatory digital records and dossiers should have in order to make Marketing Authorisation Holders, National Competent Authorities and in the end – patients certain that the sensitive and important records will be properly preserved for the needed period of time.

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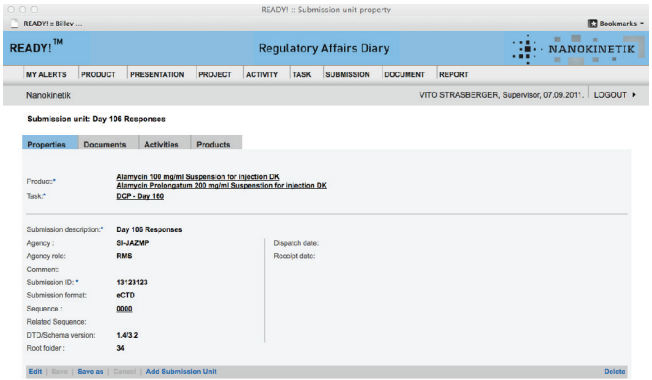

Figure 2. READY Application