

Planning and Designing of Digital Archival Information Systems

Arian Rajh

Agency for Medicinal Products and Medical Devices

Ksaverska cesta 4, 10000 Zagreb, Croatia

arian.rajh@almp.hr

Hrvoje Stančić

Department of Information Sciences

Faculty of Humanities and Social Sciences, University of Zagreb

Ivana Lučića 3, 10000 Zagreb, Croatia

hrvoje.stancic@zg.t-com.hr

Summary

Digital archival information systems can be planned and designed by following the most prominent records management methodologies like ISO 15489, related standards and DIRKS, or by following project management approach. Project management approach means planning and designing of digital archival information system as a cost and time-bound project and performing monitoring and evaluation activities in these perimeters. This approach can be done by following different project management methodologies like PRINCE2 or Project Cycle Management. The aim of this article is to explain these available options, to compare them and to make recommendations based on assessment of capabilities of an organisation in which the potential digital archival information system is to be planned and designed. Project cycle management is suitable methodology for organisations in which digital archive developers do not have sufficient administrative capabilities or enough staff with technical know-how to develop digital archive without outsourced technical assistance, but are allowed to apply for European financial aid, such as IPA or other funds in the future.

Key words: digital archival information system, planning, records management, ISO standards, DIRKS, PRINCE2, PCM, IPA, EU funds

1. Introduction

The process of planning and designing of digital archival information systems, with preparatory planning activities, as well as indicated implementation and post-implementation activities, such as evaluation of the system, can be conducted either by following prominent and internationally standardised record-keeping methodologies or by following project approaches. The aim of this article is to show what the available planning and designing options are considering

digital archival information systems. The differences between these two major options, standardised records management methodologies and project management methodologies, will be explained by showing their particular phases and other characteristics, compared and analysed.

The first option for planning and designing of digital archival information system is to use ISO 15489:2001 and ISO/TR 15489:2001 standards (HRN ISO 15489-1, HRN ISO/TR 15489-2). ISO 15489:2001 provides internationally recognised records management methodology for planning and designing of recordkeeping systems. Designing part in the process of planning and designing of digital archival information systems is additionally described in supplemental ISO documents such are ISO 26122:2008(E), ISO 23081-1:2006 (HRN ISO 23081-1) and ISO ISO/TR 23081-2:2007 (HRN ISO 23081-2). ISO 15489 recordkeeping planning and development process is elaborated in detail in DIRKS manual. Together with the reference model for open archival information system (OAIS, ISO 14721:2003) these ISO standards and pertaining DIRKS manual can provide inclusive methodology for planning and designing of digital archives.

ISO 15489 brings out the framework for entire recordkeeping practice in organisations. Although ISO 15489 can not be reduced to planning method, one of the most pragmatic parts of that standard is eight-step methodology used to plan and develop recordkeeping systems. ISO 26122 standard provides further insight in one phase of the ISO 15489 recordkeeping systems planning methodology because it recommends and standardises work process analysis for records. ISO 23081 standard can also help the developer of a digital archival information systems. This standard gives framework for defining and modelling metadata scheme and that is usually one of the most sensitive concerns when designing a recordkeeping systems. DIRKS manual describe each step of the ISO 15489's eight-step methodology in detail and it is recommended to refer to it in initial phases of establishing a digital archive.

The second option is to use project management approaches or methodologies in digital archives planning and designing stage. Project management is a domain that deals with projects' planning, execution and management phases. Projects are resource and time-bounded activities aiming to deliver measurable and clearly assessable results. There are numerous specific approaches in the project management but this paper is focusing just on PRINCE2 and Project Cycle Management (PCM) methodologies because of their paradigmatic value. Due to simplicity and comprehensibility of these methodologies they are considered as exemplary.

Planning and developing of a digital archival information system should be done systematically and methodologically. That means that planning and development of digital archives should be done by choosing and following one methodology or several coherent methodologies. Often it is not easy to decide which methodology to choose. The decision on methodology which is to be used for

planning and designing of a digital archive should be based on appropriateness of a specific methodology to the organisational capacities and restraints in which future digital archive will be designed and implemented. Such a decision depends on the level of readiness of an organisation to build or purchase, develop and upgrade, test and evaluate a digital archival system. Understanding what most common methodologies could offer and understanding the level of organisational readiness for activities of establishing a digital archive is a good foundation for deciding on a particular methodology.

An example of planning and designing of a digital archival information system in the Croatian Agency for Medicinal Products and Medical Devices is given later in the text.

2. Planning and designing procedures based on ISO 15489, related standards and DIRKS methodology

ISO 15489 standard was prepared by the technical committee ISO/TC 46 Information and documentation. Its scope is records management, recordkeeping systems, recordkeeping policies, and synchronisation of records management with family of ISO quality management standards. ISO 15489 is linked with ISO documents for work process analysis and for records and metadata schemes development.

DIRKS manual was published by the National Archives of Australia in 2001, and it was revised in 2003. Although DIRKS manual in the first place represents expansion of the Australian recordkeeping standard AS 4390-1996 and application of the ISO 15489 standard to Australian archival practice, it can be useful to any archival expert planning to develop a digital archive.

ISO 15489 methods for developing recordkeeping systems consist of eight steps. These steps are not strictly consequent because some of them can be performed in iteration. ISO methodology includes preliminary investigation, business process analysis, identification of recordkeeping requirements, assessment of existing system(s), identification of recordkeeping strategies, design of recordkeeping system, implementation of the system and post-implementation review and testing. Strategy components for designing recordkeeping system or digital archive under ISO 15489 include system designing, system development, education of the staff, conversion of records for ingest into system, development of recordkeeping policies, benchmarking of the system according to policies that were developed, and development of retention policy and appraisal of the records. DIRKS manual describes given methodology with more detail about primary and feedback paths between particular steps.

After conducting preliminary investigation on the needs and requirements for the new digital archival information system, experts should analyse business activities and use this output to identify specific recordkeeping requirements and to design the recordkeeping system. At the same time, feedback from identification of recordkeeping requirement should enhance business process analy-

sis while feedback from designing of recordkeeping system should improve the identification of recordkeeping requirements. Output of identification of recordkeeping requirements should lead to identification and selection of appropriate recordkeeping strategies. After certain achievements in the design of a recordkeeping system, experts should start developing it and use feedback from the development to improve designing process. When the digital archive is finally implemented, it is necessary to use feedback of post-implementation review to verify significance and quality of identified recordkeeping requirements, and to constantly improve designed and implemented digital archive. Post-implementation feedback is expected to be also used in the future preliminary investigations for upgrading of newly built system or for designing another one.

ISO/TR 26122 (ISO/TR 26122:2008(E) Information and documentation – Work process analysis for records) is expansion of the ISO 15489. Its scope is narrower and it focuses on identification of relations between business processes and their context, business processes and legal requirements, hierarchical decomposition of business processes and sequential dependence of their immanent transactions. This procedure of ISO 26122 is directly related to the analysis of business processes and indirectly it affects identification of recordkeeping requirements and designing of a recordkeeping system because business processes are linked with records and characteristics of records are affecting design of systems.

ISO 23081 (ISO 23081 Information and documentation – Metadata for records, Part 1 and Part 2) represent ISO 15489 expansion related to designing of metadata elements and procedures which should be included in design of the system. Metadata are considered evidence of relationship between system and business context entities. Entities could be: records, business processes, business mandates or business rules, policies and legislation, and agents that conduct business and handle records. Metadata groups are: identity metadata, description metadata, use metadata, relation metadata, and event plan and event history metadata. With description of required metadata and metadata groups, ISO 23081 can provide digital archive developers with a valuable insight from the archival point of view which can facilitate various legal and business compliances of their future digital archival systems.

3. Planning and designing procedures based on PRINCE2 and PCM methodologies

A digital archival information system could also be set up through a project approach. This means that establishing of a digital archive must include strictly planned fulfilment of assumptions and preliminary prerequisites, scheduled activities, measurable results and explicated objectives according to one of the project management methodologies. Setting up a digital archive as a project requires very different planning and designing approach in comparison to the record management and recordkeeping methodologies.

PRINCE2 stands for **PR**oject **IN** Controlled Environment and it is process-based methodology for managing projects. PRINCE methodology was firstly developed in the United Kingdom, and is used since 1989 by the Central Computer and Telecommunications Agency. PRINCE2 methodology dates from 1996 as the second major improvement of PRINCE methodology and is a trademark of Office for Government Commerce of HM Treasury. Last revision was issued in 2009.

PRINCE2 manages projects through several phases: (1) start up the project; (2) directing a project; (3) initiating a project; (4) management of stage boundaries – a critical phase for project managers who have to keep their mind on the project scope at all times; (5) controlling a stage; (6) managing project delivery – a process which ensures that all outputs of the project meet previously stated requirements; and (7) project closing. PRINCE2 methodology also includes (8) planning phase which is initiated after start up a project phase, but conducted iteratively and simultaneously with other project phases.¹

The most important agents defined by PRINCE2 are Project board, Project manager and Team manager. A PRINCE2 project is organised according to customer-supplier relationship model in which customers are the future users of the planned digital archival information system. Various documents are produced in each of these project phases – business case, project initiation document, stage plan, team plans, quality logs, project report, lessons learned report, follow-on actions etc.

PCM (**Project Cycle Management** methodology) is a different kind of project management approach. PCM has been used globally after it was adopted and popularised by the United States Agency for International Development (USAID) in the late 1960s. In 1993 European Commission started to use the same approach as an obligatory project planning methodology. PCM is also widespread due to its simplicity and transparency. Because of intelligibility of the logical framework diagram, PCM provides non-experts with valuable insight into project proposals to evaluate and approve them with less effort and in shorter time.²

PCM is divided in fewer phases than PRINCE2. It consists of five phases: programming, identification, formulation, implementation and evaluation phase. For internationally financed projects, in (1) the programming phase it is usually

¹ “PRINCE2 uses three levels of plans (...) Project Plan, Stage Plan, and Team Plan. In cases where a Stage Plan or Team Plan exceeds predetermined tolerances (time or money) then an Exception Plan can be produced to replace the plan that has exceeded its tolerances.” Adam, Azad. *Implementing Electronic Document and Record Management Systems*. New York: Auerbach Publications, 2007, p. 136. For more detailed explanation of development and implementation of digital archival information systems see Azad, pp. 127-140.

² There are several available methodologies useful for making decisions on adoption of project proposals like AHP (Analytic Hierarchy Process). However, PCM remains equally useful for decision-makers and for experts with responsibility to propose a project.

necessary to prepare strategic documents on the highest or higher levels so they could be used as the basis for later assessments on project proposals. Such documents are national and regional strategic plans, multi-annual indicative planning documents for selected future period, national progress reports or similar documents. In (2) the identification phase competent authorities together with the key players in each sector must recognize problems in sectors and perceive potential ideas that are proposed by project planners as solutions to the recognised problems. In (3) the formulation phase experts involved in project planning and designing have the most important role. They have to prepare the project proposal and other project documentation which will be the basis for achieving decision on project's launch or termination (go – no go decision). If the project is approved, formulation stage is followed by (4) the implementation of project activities and (5) the evaluation phase.

4. IPA projects and an example of digital archive project

The European Union's financial aid is allocated through the pre-accession programmes, the community programmes and the structural and cohesion funds. Instrument for Pre-Accession Assistance (IPA) has consolidated all former pre-accession programmes (CARDS, PHARE, ISPA, SAPARD). Croatia is involved in several groups of community programmes like FP7 (7th Framework Programme), CIP (Competitiveness and Innovation Framework Programme), IDABC (Interchange of Data between Administrations), Progress, Fiscalis, Marco Polo II, Media 2007 etc. At the moment the best way to launch implementation projects in Croatia is through FP7, if projects have strong research and development features and potential beneficiary is willing to cooperate with partners from various EU countries. If projects are set up to be solutions of some serious administrative problems, especially in the public sector, the best way is to apply them for IPA financial aid. IPA project should be placed under one IPA component and it should be linked to an issue stated in one of the negotiation chapters in order to justify the project and acquire financial help.

IPA 2009 TAIB (Transition Assistance and Institution Building) project "Preparations for eCTD and Implementation of Digital Archival Information System" planned in the Croatian Agency for Medicinal Products and Medical Devices (ALMP) will be used as an example of planning and designing a digital archival information system. This project deals with implementing new Europe-based eCTD standard for electronic pharmaceutical documentation³ and for that it is linked to strengthening the ability to assume the obligations of the EU membership and chapter of negotiations that deals with the free movement of goods.

3 eCTD – electronic Common Technical Document, standard for electronic resources for medicine' regulations (<http://esubmission.emea.europa.eu/whatisesubmission.htm>). These records consist of granulated folder structure (modules), PDF files and XML backbone files. eCTD standard facilitate communication between marketing authorisation holders that submit records and agencies that receive them, easily providing insight on last authorised version of registration documentation.

ALMP is a national competent authority with mandate to control and to approve pharmaceuticals for the Croatian market. Heads of Member States' agencies agreed in Reykjavik in 2005 that the European agencies will shift to electronic records for registration of medicines from 2009 onwards and this should be obligatory for Croatia after accession. Since eCTD records will be used, ALMP needs to develop a digital archival information system in order to receive the documentation from marketing authorisation holders in pharmaceutical industry and other European agencies, to process it, maintain it and preserve it as evidence of registration activity. The project also deals with digitisation and micro-filming of the existing paper records with the aim to interlink them with eCTD records and thus maintain business critical resources in a unique digital archive. The project was developed by PCM methodology. In identification phase ALMP stated the problem of potential inability of co-operation with the EU Member States' agencies after their shift to the eCTD resources. The problem was addressed to the Croatian Ministry of Health and Social Welfare, so it could be included in the analysis of problems in the health sector and financial help could be requested.

In the formulation phase the project fiche was drafted and submitted to The Central Office for Development Strategy and Coordination of EU Funds (CODEF)⁴. For this project the project fiche was linked with Stabilization and association agreement, Accession partnership, National programme for the integration of the Republic of Croatia into the European Union, Croatia progress report, European partnership, and Multi-annual indicative planning document in order to justify the project and financial help requested. *Overall objective* of the project is Croatian participation in the European medicines network based on sharing current common standards. *The purpose* of the project is implementation of current European-based digital resources for regulation of medicines.

The project consists of three major groups of activities: (1) related to business process analysis and redesign, (2) related to digitisation and microfilming of paper records, and (3) related to development and customisation of digital archival information system.

Business process analysis activities involve business process analysis, redesign of business processes and definition of workflows. Digitisation and microfilming activities involve preparation for digitisation and microfilming of approximately sixteen million pages, digitisation, microfilming, and disposition and weeding-out of paper according to the retention schedule. Development of digital archival information system activities consist of development and customisation of the document and records management software.

The project predicts two instruments and therefore the implementation of activities will be divided to two contracts. The first contract will be fee-based ser-

⁴ CODEF (Croatian: SDURF) is the governmental authority with mandate to prepare development strategy related to the Croatian accession, and monitor strategy implementation.

vice contract and it will cover business process analysis and digitisation and microfilming activities while the second contract will be global price service contract and it will cover activities of development and customising document and records management software.

After the project fiche was drafted, controlled by CODEF and pre-approved by the Delegation of European Commission and other authorities with such mandate, the Agency started to work on tendering dossier for the project. Tendering dossier in this particular case includes Terms of Reference for both contracts. All activities are planned to be outsourced due to the lack of particular experts, and administrative and space capacities in the Agency⁵.

At the moment of writing this paper the IPA project "Preparations for eCTD and Implementation of Digital Archival Information System" is in final part of formulation phase and tendering procedure is predicted to start after signing of Financial agreement for IPA 2009 cycle between the EU authorities and the Croatian authorities.

5. Comparison of methodologies and recommendations for digital archival information system planning and designing

ISO-based and project management based approaches described in this article can be compared by the number of their phases and by emphasis on particular exertion in each phase. Because of various number of phases that derive from different methodologies, for this comparison it was necessary to consider a wider common delimiter of phase boundaries and thus to establish division of methodologies into wider common phases. Delimiters of phase boundaries were defined according to the issues that need to be assessed during lifecycle of potential digital archive. Issues that need to be assessed in particular lifecycle moments are: stated problem, proposed solution, planned activities, and results of the implementation. In this sense the stated problem is firstly assessed by its relevancy, secondly by accordance of solution compared to the problem, thirdly by adequacy of planned activities for implementation, and finally by the quality of accomplished results. After defining delimiters it was easier to define common phases for all selected methodologies and to compare them. Methodologies could thus be divided to (1) initial phase, (2) planning phase, (3) designing and implementation phase and (4) final and post implementation phase. It is showed that in PCM's initial phase is more emphasised than in ISO 15489, DIRKS and PRINCE2 methodology while ISO 15489, related standards and DIRKS approach are mostly focused on the planning phase and PRINCE2 on the designing and implementation phase.

⁵ The Agency collaborated in preparation of the tendering dossier with the Central Finance and Contracting Agency (CFCA, Croatian: SAFU). CFCA is the Croatian governmental implementation agency for decentralised EU fund implementation system and is in charge of preparing projects for tendering and implementation and for monitoring financially related aspects of projects.

Table 1: Methodologies compared by their phases with common phase delimiters

ISO 15489 and DIRKS	PRINCE2	PCM
Preliminary investigation	Starting up the project	Programming
Business process analysis	Planning	Identification
Identification of record-keeping requirements	Directing a project	Formulation
Assessment of existing system/systems	Initiating the project	Implementation
Identification of record-keeping strategies	Controlling the stage(s)	Evaluation
Design of recordkeeping system	Managing product delivery	
Implementation	Managing stage boundaries	
Post-implementation review and testing	Closing the project	

	Initial phases (assessment of problems)
	Planning phases (assessment of solution)
	Designing and implementation phases (assessment of activities)
	Final and post-implementation phases (assessment of results)

Each methodology could be used for planning, designing, implementation and evaluation of digital archival information system, but selection of methodology must depend on an estimation of the most critical phase in setting up the particular digital archive and on current state of affairs in organisation in which the archive will be established. Estimation of the most critical phase means that designers of the digital archive must recognise potential risks in advance. PCM should be considered if approving and initiating the project are at stake. It is also possible to use more than one methodology, for example, to prepare proposal document using PCM and to implement digital archive using an approach which is more adequate for solving implementation related entanglements. Selection on the basis of type of current organisational environment in which digital archive will be set up refers to administrative, financial and other capacities of organisation, including human resources.

As the case of ALMP showed, the selection of financial aid (fund) and other instruments was made by estimating potential project scope, costs and technological characteristics and by examining the possibility of compliance with strategic and negotiating documents for Croatia, which is necessary to have for pre-accession help. Since PCM is mandatory methodology for IPA projects, and estimation showed that the Agency's project would be perfect IPA candidate, this methodology was used from the beginning of project planning. Even if the Agency decided to develop digital archive with its own means PCM would be used because of decision making process that have to deal with approving substantial financial assets for the project. However, in the implementation phase

team leaders that serve either under the first or under the second contract will be allowed to use different development methodologies if it will be shown that advantages of the proposed methodology prevails PCM advantages in further development of the digital archival information system.

It can be concluded that PCM emphasise initial phase and is most adequate for decision-making on necessity of particular projects. Therefore it should be primarily used to evaluate projects before implementation. PRINCE was developed for project managers as it is based on implementation of issues related on project activities. ISO 15489 standard and DIRKS manual have a wider scope and are not limited to the recordkeeping systems, such as digital archival information systems. They are primarily developed as reference methodologies that can be used for establishing whole records management environments by cautious planning of recordkeeping policies and systems.

References

- Adam, Azad. Implementing Electronic Document and Record Management Systems. New York: Auerbach Publications, 2007
- Begičević, N.; Divjak, B.; Hunjak, T. Decision making on project selection in high education sector using the Analytic hierarchy process. // Proceedings of the ITI 2009. Lužar-Stiffler, V.; Jarec, I.; Bekić, Z. (ur.). Zagreb: SRCE, 2009 (547-552)
- Dirks manual – Users Guide, Part I. National Archives of Australia, 2003. http://www.naa.gov.au/Images/dirks_part1_tcm2-935.pdf (July 2009)
- Divjak, Blaženka (ur.) Projekti u znanosti i razvoju: Europski programi. Varaždin: Tiva tiskara, FOI, 2009.
- Europski fondovi za hrvatske projekte. priručnik o financijskoj suradnji i programima koje u Hrvatskoj podupire Europska Unija. Zagreb: SDURF, 2009
- HRN ISO 15489-1 Information and documentation – Records management – Part 1: General (ISO 15489-1:2001)
- HRN ISO 15489-1 Information and documentation – Records management – Part 2: Guidelines (ISO/TR 15489-2:2001)
- HRN ISO 23081-1 Information and documentation – Records management processes - Metadata for records – Part 1: Principles (ISO 23081-1:2006)
- HRN ISO 23081-1 Information and documentation – Records management processes - Metadata for records – Part 2: Conceptual and implementation issues (ISO/TS 23081-2:2007)
- ISO 14721:2003 Space data and information transfer systems – Open archival information system – Reference model
- ISO/TR 26122:2008(E) Information and documentation – Work process analysis for records.
- Komunikacija i vidljivost. Priručnik za vanjske aktivnosti EU. Zagreb: SDURF, 2008
- Načini pružanja pomoći, sv.1. Smjernice za upravljanje projektnim ciklusom. Podrška učinkovitoj provedbi vanjske pomoći EK. Zagreb: SDURF, 2008
- PIU Manual_version 4.0. April 2009. <http://www.safu.hr/hr/Dokumenti> (April 2009)
- Practical guide to contract procedures for EC external actions. 2009. http://ec.europa.eu/europeaid/work/procedures/implementation/practical_guide/index_en.htm (May 2009)
- Priručnik za komponentu I programa IPA: Pomoć u tranziciji i izgradnja institucija. Zagreb: SDURF, 2007
- Strateški okvir za razvoj 2006.-2013. Zagreb: Vlada Republike Hrvatske, SDURF, 2006