

DPEX FINAL REPORT

AWARD HOLDER	HOSTING INSTITUTIONS
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INTRODUCTION

This report details all DPE Exchange programme activities that took place between the 22nd of September and the 03rd of October 2008, carried out by Arian Rajh, employee of Croatian Agency for Medicinal Products and Medical devices (Agency) and PhD course attendee at the Faculty of Humanities and Social Sciences in Zagreb, Croatia.

The activities were carried out in the following Portuguese institutions: INFARMED, Torre do Tombo (TT), Centro de documentação da União Europeia in Lisbon (EDC Lisbon) and Centro de documentação da União Europeia in Coimbra (EDC Coimbra). Two of them were planned with the exchange proposal and the other two was visited on the basis of hosts' recommendations and arrangements. Visit to the TT was arranged by hosts from INFARMED, and host from European Documentation Centre in Coimbra suggested a visit to the European Documentation Centre in Lisbon as an excellent opportunity. As the national archive, TT has legal obligation to monitor documentation procedures and policy in INFARMED, disposal of their records according to the retention plan and results from microfilm quality control. TT is also conducting broad consultation activities for various national authorities. Activities at INFARMED and TT took place in the first week of exchange visit to Portugal.

Award holder was accompanied by Hrvoje Stančić during visit to INFARMED and TT. Hrvoje Stančić works as assistant professor at the Faculty of Humanities and Social Sciences in Zagreb and he also coordinates DPE's activities in Croatia. Prof. Stančić was sent by the Faculty as their representative as the Faculty and the Agency are planning a joint project with a goal to create best model for integration of digitized and digital records and to establish a OAIS based system that will prepare the Agency for working with new medical technical documentation and collaboration with the other similar European agencies. This joint project

is still being prepared, but initial scientific part of the project has been submitted to the Croatian Ministry of Science, Education and Sport. The next phase of the project will be applied to EU funds Calls for proposal at the time such Calls are announced.

During the same week award holder has visited EDC Lisbon in order to retrieve relevant additional documentary sources. Visit to EDC Coimbra took place the next week. In EDCs award holder had opportunity to find additional information about EU legislation, funding and project financing in order to place his research into the context of European policies and strategies.

INSTITUTIONAL CONTEXT

INFARMED is Portuguese national competent authority for evaluation of medicinal products, medical devices, cosmetic products and body hygiene products. INFAREMED has a broad scope of regulatory activities and it includes also inspection and pharmacovigilance activities. This institution is located in the new part of Lisbon, near airport station. INFARMED has over 300 employees and they work in four facilities. INFARMED cooperates with European Medical Agency (EMA) and various European national institutions with same responsibilities; it started an ISO process of quality level evaluation, called Benchmarking of European Medicines Agencies (BEMA), aiming to develop regulatory system based on a network of agencies operating to best practice standards, and three years ago it started a group of broad reorganising programmes (EVOLVERE).

Torre do Tombo is the Portuguese national archive, located in Lisbon, with a mandate to supervise archival activities in public institutions and to monitor their procedures that deal with their documentary resources. TT is also a consultant authority for public institutions' archives and that way it supports processes of digitisation and implementation of new working principles such as working in paperless environment, implementation of electronic signature and establishment of electronic records management systems and repositories.

European Documentation Centre in Lisbon, organised at the University Lusíada in Lisbon, holds valuable documentary resources and information sources for subjects of European matters such as European integration, politics, financing and strategy plans for different common European interests. This EDC is the oldest institution of that type in Portugal. European Documentation Centre in Coimbra, organised at the University of

Coimbra, as a service to a Centre for interdisciplinary juridical and economical studies, is a similar institution like the previous one, but with some differences in the resources that it maintains. EDCs receive official records from several European institutions, due to their agreement with the European Council, organize and index those records and make them available to researchers and general public. University of Coimbra is located at the top of Alcaçova hill and it is known for beautiful architecture and original student traditions. It is also known for one of the best preserved baroque libraries. Bibliotheca Joanina dates from 18th century and holds collection of approximately 200,000 valuable volumes.

TEAMS

The team from INFARMED with which I have had the most contact included Helder Mota Filipe, Fatima Canedo, Valdemar Cristovao, Augusto Fragoso, Celia Alves, Margarida Morgado, Pedro Manuel Santos, Fernanda Hoja, Rui Fragoso, Isabel Pereira, Monica Galo, and Pedro Oliviera. Members of the team were mostly INFARMED's employees and some of them are employers of outsourced IT companies that participate with INFARMED in EVOLVERE program's projects. Helder Mota Filipe is a member of the executive board and Valdemar Cristovao is responsible for INFARMED's IT unit. Augusto Fragoso is a project planner and Isabel Pereira is responsible for INFARMED's archive. Pedro Oliviera is a Portuguese delegate in EMEA's Telematic Implementation Group that I participate in. In Torre do Tombo I was received by Anabela Ribeiro (aribeiro@iantt.pt) who works as their project leader, in EDC Lisbon help for my research was provided by Jorge Isidor, assistant of Helder da Rocha Machado. In EDC Coimbra I was advised and guided by Maria da Saudade Miranda and her team.

ACTIVITIES AND RESULTS OF THE EXCHANGE

Hosts from INFARMED have set a conference with presentation of EVOLVERE programs and projects. EVOLVERE follows governmental initiative SIADAP, which aims to evaluate and improve public administration in Portugal. INFARMED has been evaluated by

audit companies Accentura and Delloite in 2004. They suggested reorganization and establishment of new information system. Infarmed is also involved in Benchmarking of European Medicines Agencies (BEMA) process, i.e. implementation of ISO quality standard for medicines national competent authorities. EVOLVERE lasts for three years and it is divided into several operational programmes (OP). INFARMED team presented ten EVOLVERE operational programs: Business process OP, Evaluation of medicines OP, Quality control OP, Human resources OP, Administration and financing OP, Communication OP, Information technology OP, Inspection OP, Pharmacovigilance OP and Medical products OP. Operational programs are supervised by strategy committee and different user committees, depending on particular programme. Program leaders are not IT people but business people (accessors etc.). Conditions for running EVOLVERE are: support from INFARMED's management, business process analysis and technology consolidation. Presentations have shown their record management solution and solution to the problem of combining eCTD tool called EURS is YOURS into their information system and particular applications such as contact management application. INFARMED's information system consists of business process management component, application extender component, repository and record management system, so it is basically a custom-made enterprise solution. EURS is YOURS is a tool for uploading, organizing and reviewing of electronic Common Technical Document (eCTD), which is becoming a new worldwide standard for medicines documentation. Since European Medical Agency (EMA) has a contract with the manufacturer of that tool, for some regulatory procedures national competent authorities can use EURS without any costs. INFARMED's information system was developed by their experts and experts from outsourced companies and it was made following requirements of ISO 15489 standard and MoReq specification. Capacity of their new repository is 130 TB. The following day award holder had the opportunity to see INFARMED's archive. It has 18 employees divided in inventory team, user service, microfilming team and quality control team. Most of archival records are stored in the same building. After approving medical product for market, records are sent to archive and microfilmed. Then microfilm is tested for quality parameters in INFARMED and in TT, and after that records can be destroyed due to the retention plan. Another solution will be proposed in the joint project of Faculty of Humanities and Social Sciences and Croatian Agency. Part of the project deals with the authenticity of electronic records and proposition will be not to make analogue copies (microfilm) of digital and digitized records but to establish mechanism of corroboration based on electronic document legislation and new technologies. On the following day after

conference in INFARMED, award holder visited TT and had an opportunity to get acquainted to Portuguese national archive strategy for digital challenges. They aim to establish modern repository with capacity for acquisition of digital archives from other institutions and to increase their council activities. Award holder was able to see their repository room and digitization process in progress. Their demonstration included an overview of the indexation; with extraction of metadata from scanned documents and organisation of that metadata into database.

During this exchange visit, Hrvoje Stančić and award holder held presentations about (1) Croatian Agency and regulatory framework in Croatia, (2) Faculty of Humanities and Social Sciences, (3) Digital Preservation Europe and its activities in Croatia, (3) our pilot study of suitability of optical media for long term preservation and (4) archive in Croatian agency. INFARMED's employers were also interested in Croatian agency's pharmacoeconomics application and algorithms used to make tracking of consumption of medical products more automated. Hrvoje Stančić and award holder suggested to Isabel Pereiro and Anabela Ribeiro that their participation at the next INFuture conference, which will be organised in Zagreb in November 2009. INFuture conferences deal with the future of information sciences and it would be interesting to hear about future achievements in INFARMED and Portuguese national archive's future activities.

On the following day award holder spent most of the day visiting EDC in Lisbon, learning how to use their sources and examining official documents like EC's Final panel report *Five year assessment: Research and technology development in information society technologies*. Next week award holder was received in ECD in Coimbra, where he examined legislation resources and official European authorities' publications, CD-ROM databases and portals with valuable sources for setting projects financed from EU funds. It was also an occasion to learn about principles of making and using thesauri, on the examples of ISO 2788-1986 and ISO 5964-1985 standards and Eurovoc thesaurus, and that knowledge can be used in some later phase of the joint project.

Result of the exchange is a new competence for award holder and that is the aptitude to identify all the components required to establish a model of hybrid archive capable depositing digitized and digital-born records (and metadata for conventional records). The other result is gaining partial experience of setting up EU projects due to the examining relevant sources in EDCs.

Characteristics of the model:

- Ingest of metadata for paper records

- Ingest of digitized records with all essential metadata, indexes and with affirmation of their authenticity
- Ingest of migrated digital records (NeeS records = non-eCTD electronic records) with upload of migration metadata and indexing
- Ingest of digital-born records (eCTD records = electronic Common Technical Document), indexing these records, and combining IS with eCTD specialised tool
- Business process component for workflow, tasks and records' lifecycle
- OAIS compliant, eCTD specification and NeeS Guidance compliant

CONCLUSIONS AND PRACTICAL INFORMATION ON THE EXCHANGE

In award holder's opinion, Croatian Agency needs a modern archive information system because without it would be impossible to carry out evaluation processes for medical products based on eCTD resources and to cooperate with other national competent authorities from EU in the near future. Preconditions for that are making the initial model and setting up the project in order to make realisation of that project possible. Initial model has been made during this exchange visit and the next step will be to establish cooperation with Croatian national contact points for coordination of European funds. If it will be possible due to the award holder's schedule, award holder would like to present some results of this exchange visit at Archives, Libraries and Museums (<http://public.carnet.hr/akm/>) congress next month in Poreč, Croatia. This exchange visit will also impact award holder's PhD thesis.

DPEX programme award made it possible for the award holder to learn and gain very valuable experience from experts who work in INFARMED, TT and EDCs. The award holder was received extraordinarily well by his hosts at all levels. Award holder appreciates the given opportunity and would like to thank DPEX programme and all his hosts.

Arian Rajh works for Croatian Agency for medicinal products and medical devices; participates in EMEA's Telematics Implementation Group on electronic submission and attends PhD study at Faculty of Philosophy and Social Sciences in Zagreb. Arian Rajh has published articles in various scientific journals (archival science, literature, sociology, life sciences). Award holder graduated in archival science and comparative literature and during that time he has won several prizes (Rectors award 2003/2004, best student prize for outstanding academic achievements 2005, City of Zagreb scholarship 2003/2004).