Newsletter

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Bennet Lodzig – Institute for Legal Informatics, Leibniz Universität Hannover

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Prof. Dr. Norbert Graf, Ruslan David

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Universität Des Saarlandes

eureca

Enabling information re-Use by linking clinical REsearch and CAre

Introduction

Project aims and progress

Anca Bucur, Project Coordinator

The goal of the **EURECA** project is to enable seamless, secure, scalable and consistent linkage of healthcare information residing in EHR systems with information in clinical research information systems, such as clinical trial systems, supporting the two currently separated worlds of clinical research and clinical practice to connect and benefit from each other.

Main barriers of secondary use of EHR data for research and of enabling a consistent feedback loop to care are the lack of common technology standards and concept terminologies. While solving the interoperability issue in healthcare at generic level is not a realistic approach, **EURECA** aims at semantic interoperability on domains of concepts (i.e. describing specific clinical areas). We start from disease- and treatment- related sets of concepts in the oncology domain and demonstrate our solution in concrete clinical scenarios. On top of the achieved semantic interoperability we build software services and tools to support more efficient research, better care and improved patient safety.

The **EURECA** objectives are captured in the clinical scenarios and technical use cases that were elaborated in the first year of the project. These objectives were also directly addressed by the **EURECA** initial prototypes that were demonstrated in the first project review. These prototypes address semantic interoperability, information extraction, trial recruitment, trial feasibility, integration of a Personal Health Record, data mining.

The main tasks during the first year of the **EURECA** project (February 1st, 2012 – January 31st, 2013) have focused on the following objectives:

- Define the clinical scenarios, the user needs, the legal, ethics and regulatory requirements.
- Carryout extensive state of the art reviews concerning relevant technologies, tools and services.
- Select relevant standards for the development of the **EURECA** solutions.
- Define the technical use cases and the first version of the **EURECA** architecture.
- Build the development environment, i.e. create the set-up allowing the components and tools to be designed and built.
- Carry out preliminary work for information extraction and develop first prototypes.
- Build the initial semantic interoperability solution and several **EURECA** prototypes implementing relevant functionality as defined in the **EURECA** use cases.
- Set up collaborations with relevant initiatives and disseminate our results.

Data Protection in EURECA

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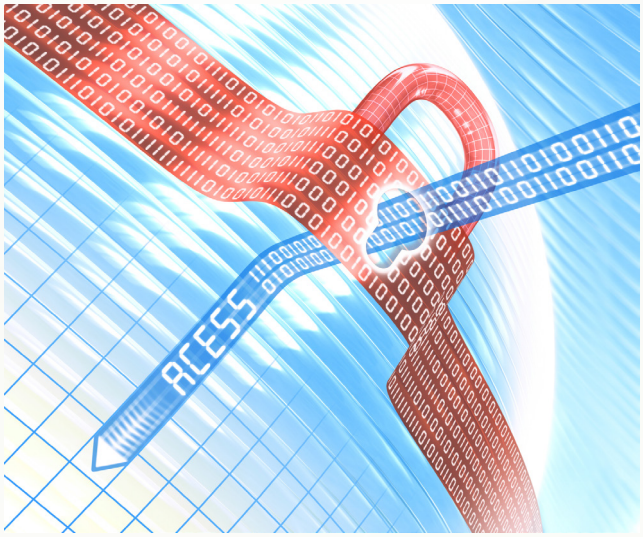

In order to develop **EURECA** tools and services and to deploy them in clinical care and research settings, sensitive patient data processing is unavoidable within the **EURECA** project. The Institute for Legal Informatics (LUH) developed – in cooperation with other partners, in particular CUSTODIX - a complex data privacy framework that ensures compliance of data processing activities with current International, European and National Data Protection legislation throughout the lifecycle of the project. This framework deals with the concerns of patient privacy and self- determination stemming from the re-use of patient data. At the same time, it takes into account the project user needs by ensuring that the project aims and targets are not endangered by the implementation of the privacy framework.

The framework is split up into two phases: The project development, and the exploitation phase. This is a necessity, as project user-needs vary in the lifecycle of the project. At this moment, the project is in the development phase.

Within the development phase, project partners need to develop technical tools and applications which shall enhance the clinicians' needs in the clinical care and research environment. Technical partners are dependent on the retrieval of medical data to carry out this task. The privacy framework in this phase of the project, which is developed from a baseline that was first constructed in the European FP6 medical project ACGT, puts each **EURECA** partner under rigid contractual obligations in order to safeguard compliance with data protection rules. The contracts are drawn up between a central data protection point, the Center for Data Protection (CDP), and the individual partners participating in **EURECA**.

Obligations within the contracts comprise:

- to not share data that was not collected in line with data protection law;
- to pseudonymise data using a state-of the-art tool prior to sharing data;
- to put appropriate technical and organisational measures in place to ensure data safety and privacy;
- to only process data in line with **EURECA** policy.

Furthermore, the contracts ensure that re-identification of patients from project data is unreasonable. For this reason, a penalty clause is enforced which severe sanctions for any privacy breach by a project partner. The data is then coded a second time so that the re-identification of patients cannot be achieved with reasonable means under any circumstances.

In the project exploitation phase, the various **EURECA** tools and services are deployed. The privacy framework needs to adhere to different user needs, while at the same time, ensuring compliance of all data processing operations with the legal and ethical requirements and establishing a high level of patient privacy. Due to the diverse applications that are being developed in **EURECA**, a static privacy framework, similar to the one used in the project development phase, does not fulfill the user needs. Therefore, a more flexible framework has been constructed that applies the privacy preserving elements (informed consent, anonymisation / pseudonymisation of data, access controls, privacy impact assessments and contractual obligations) in a process orientated way with regards to the sensitivity of data processing within the project.

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On these grounds, three different domains have been set up within the exploitation phase. In the care domain, patient data is processed by **EURECA** tools and applications for care or care supportive purposes, for example to find the best treatment for a specific patient. This processing may be carried out without obtaining specific data processing consent of the patient (while patient consent for care is and needs to be obtained as usual). Patient privacy is preserved by implementing rigid access controls and a clear cut purpose limitation policy. In the research domain, data of different sources (e.g. medical literature, but also care data) is processed by **EURECA** tools and applications for research purposes, for example to design trials, create data models or to develop new clinical guidelines. Therefore, different requirements have to be met.

Personal data needs to be rendered 'anonymous' before it is further processed. As 'anonymity' is not understood as a status, but as a process, access controls, contractual obligations and privacy impact assessments are put in place to ensure that data can be considered as being 'anonymous'. If data cannot be anonymised due to the research purpose, it shall be pseudonymised prior to the processing operation and will then remain under full protection of the relevant data protection laws. Lastly, if personal data needs to be processed due to the research purpose, this is only legitimate on the grounds of a valid consent given by the patient. If personal data is processed, access needs to be restricted to the treating physician, the investigator (or principal investigator) conducting a specific trial, or the clinical trials chairman.

In the trial support domain, data stemming from the care domain is processed for other than research purposes by **EURECA** tools and applications, especially to screen patients for trials or to find the most suitable trial for a specific patient. This is personal data processing which may only be carried out if the patient has given informed consent to the processing operation. Data shall be pseudonymised wherever and whenever the purpose of data processing allows this, in order to ensure that patient data that refers directly to a patient is only processed when this is – due to the processing purpose – absolutely necessary.

The data privacy framework is suited to the current (European) data protection regime. Severe effects of the implementation of a (proposed) General Data Protection Regulation on the data privacy framework of **EURECA** are not expected. However, the LUH team will keep an eye on the upcoming developments so that adjustments to the framework can be made whenever necessary.

Working across projects

how EURECA interlinks with other FP7 projects?

Prof. Dr. Norbert Graf, Ruslan David

Norbert Graf

EURECA is one of the projects funded under the Virtual Physiological Human (VPH) theme. Many of the partners of **EURECA** are enrolled in other European projects dealing with VPH in providing frameworks, tools and services to enhance translation research. Decision support for the individual patient is one of the major challenges in this context. To avoid "inventing wheels" several times a close cooperation between these projects is mandatory. Such collaboration is set up in common meetings between the different projects. The following issues are of main interest: legal and ethical framework, data, semantic interoperability and tools, services.

One of the top **EURECA** priorities is to assure the semantic interoperability among Electronic Health Record systems (known as EHR) and Clinical Trial Management Systems, also known as CTMS. The ability for the CTMS to integrate with an existing EHR system is a challenging task for many hospital information systems. Solutions in this area will enhance the seamless, secure, scalable and consistent access to study patients from a centralized hospital repository for health care professionals. All **EURECA** partners are working together to build software services that help to securely interconnect the EHR and CTMS systems. Successful linkage will deliver advanced benefits for patients, including early detection of patient safety events, prompt reporting capabilities, and more efficient recruitment of eligible patients to trials. The system will also enable long term follow up of patients.

We are proud to conclude that **EURECA** project's goals are strongly linked to other research projects and initiatives. All have been successfully identified and described for possible interactions and collaboration. Of special interest is the work package related to the user needs and the technical requirements for the proposed IT environment. We analyzed and provided detailed user scenarios internally and in linkage with a wide community of other European funded research projects:

- ACGT Advanced Clinico Genomic Trials on Cancer (ACGT), **http://www.eu-acgt.org**
- p-medicine, **http://www.p-medicine.eu**
- IMI EHR4CR, **http://www.ehr4cr.eu**
- INTEGRATE, **http://www.fp7-integrate.eu**
- MyHealthAvatar, **http://www.myhealthavatar.eu**
- CHIC project (web site is under development)

Activities related to semantic interoperability and ontology are as well strongly linked with other projects. For example, we are exploring the possibility of integrating the Health Data Ontology Trunk (HDOT) developed in the p- medicine project, where HDOT plays the central role of the middle-layer ontology. Here we are focusing on assuring the increased semantic interoperability and a proper semantic access both to EHR and clinical trial data. The ultimate goal is the possibility to develop a new generation of clinical decision support systems where computerised guidelines can be directly applied to the extracted patient data, helping also clinical practitioners to improve patient treatments and outcomes.

In addition we are continuously exploring existing software and IT solutions. One of them is a flexible, interoperable and ontology based CTMS, named ObTiMA, http://www.obtima.org. It has been primarily developed in ACGT and optimized in p-medicine. ObTiMA will provide clinical trial data of Nephroblastoma disease for **EURECA** according to the identified user needs and requirements. Such tools serve as examples how the 'working across projects' strategy has cutting-edge benefits and resource saving results.

Furthermore, building up legal frameworks in the different projects that are based on earlier results of linked projects will avoid inconsistencies between frameworks and will develop standards to facilitate the access to and sharing of data by end-users, which remains one of the most challenging tasks.

Partner profile

Universität Des Saarlandes

The Saarland University was founded in 1948 in co-operation with France. Today the University counts 15.500 students of whom 7 percent are foreign students. The Saarland University has 8 faculties and provides the broad spectrum of disciplines typical of a classical universitas litterarum.

At the Faculty of Medicine (University Hospital), located in Homburg / Saarland more than 1800 people are studying medicine. There are 36 hospitals or institutions treating more than 54.000 inpatients and nearly 190.000 outpatients each year. Participants from the Saarland University is the department of Paediatric Oncology and Haematology, that is responsible for the care of patients in the Saarland and the surrounding area. The focus in research of the Department of Paediatric Oncology and Haematology is nephroblastoma (clinical study and trial and basic research in cooperation with different institutes) and brain tumour.

Role in EURECA.

An important role of the Saarland University is being the link between clinicians and IT-people to bridge the gap between research and clinical daily practice. UdS will be leader of WP2, dealing with the user requirements for the **EURECA** tools and services. UdS will also actively participate in the development of the semantic interoperability environment and in the development, deployment and evaluation of several relevant **EURECA** services.