SALUS: Scalable, Standard based Interoperability Framework for Sustainable Proactive Post Market Safety Studies[1]

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Abstract. SALUS aims to facilitate resuse of EHRs for enabling pro-active post market safety studies through providing functional and semantic interoperability profiles and supporting open source toolsets enabling EHR systems and clinical research systems to communicate and exchange EHR data and meaningful interpretation of the exchanged EHR data. Implementing security and privacy mechanisms and open source toolsets are also essential ensuring that clinical information is shared in an ethical and safe way. Finally SALUS aims to provide a novel exploratory analysis framework for open-ended temporal pattern discovery for safety studies on top of disparate, distributed, heterogeneous EHR Systems.

Keywords. Interoperability of health data, Patient safety, Re-use of Electronic health records

Introduction

Pre-approval clinical trials cannot guarantee that drugs will not have serious side effects after they are marketed. Post-approval drug safety data studies aim to address this problem, however, their effectiveness is started to be discussed especially after recent examples of drug withdrawals. This is due to the fact that, current post market safety studies largely depend on the submission of spontaneous case reports where underreporting is a major problem. The need for a more proactive approach is apparent, where safety data from multiple sources are actively monitored, linked and analyzed. Effective integration and utilization of electronic health records (EHR) can help to improve post-market safety activities on a proactive basis [1]. In SALUS Project [2] which is funded by the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement no ICT-287800, we aim to create the necessary infrastructure to enable secondary use of EHRs in an efficient and effective way for reinforcing the post market safety studies so that patient safety can be ensured through early detection of rare adverse events, pharmaceutical industry can be fostered to enable faster medication innovation decreasing time to market new, safe and effective drugs, yet the load of overwhelmed medical practitioners can be reduced.

[1] The research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement no ICT-287800, SALUS Project (Scalable, Standard based Interoperability Framework for Sustainable Proactive Post Market Safety Studies).
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In particular we aim to:

- Strengthen the spontaneous reporting process by automated Adverse Drug Event (ADE) detection tools screening EHRs in a hospital so that ADE reporting burden can be eased within a clinical institute.
- Enable ADE reporting by extracting the available information from the EHRs in to the individual case safety reports, to avoid double data entry.
- Strengthening the current signal detection processes in Spontaneous Reporting System (SRS) centers for tracing case reports to their corresponding patient records to allow absolute reporting rates to be computed, and to provide additional information on extended parts of the underlying medical history of the patient.
- Enable real time screening of multiple, distributed, heterogeneous EHRs for early detection of adverse event signals. Relative to ADEs, EHRs cover extended parts of the underlying medical histories, include more complete information on potential risk factors, and are not restricted to patients who have experienced a suspected ADE [3]. This will facilitate proactive safety monitoring as a complementary approach to reactive signal detection based on spontaneous reports.
- Enable sustainable and scalable EHR re-use architecture facilitating wide scale outcome and effectiveness research, to be able to observe selected cohorts of patients over an extended period of time screening multiple, distributed, heterogeneous EHR systems to identify long term safety issues of a product

1. Methods

To achieve the objectives listed, the following activities are being carried out in the SALUS Project:

- Providing functional interoperability profiles to query EHRs for ADE identification, ADE reporting and signal follow-up studies and to subscribe clinical data for a selected cohort of patients for signal detection and outcome research over distributed EHRs.
- Identifying a core set of common data elements (CDE) as meaningful her fragments that need to be exchanged within the scope of post market safety studies. This will be based on the already existing standards and initiatives like BRIDG Domain Model [4], HL7 RCRIM standards [5], and CDISC Standards [6]
- Developing a Common Harmonized Ontology Set for Post Market Safety Studies from the selected CDEs
- Providing semantic mediation mechanisms that allows clinical research and clinical care systems to meaningfully interpret the clinical information exchanged by reasoning on top of the SALUS harmonized ontology set

- Providing the pseudonymization services, audit repositories, authentication and authorization services for ensuring the security and privacy of the clinical information shared among primary care and post market surveillance studies.

Through this technical and semantic interoperability architecture, we aim to enable accessing the structured EHRs through standard interfaces, and by reconciliation of the data models and terminology systems locally used by the heterogeneous EHR Systems.

2. Discussion and Expected Results

The SALUS project will foster integration of clinical care information from EHRs into clinical research systems to enable proactive post-marketing safety studies for early detection of potential safety issues. Such an environment will increase data availability and data accuracy for the clinical research community; reduce time spent on data entry for filling individual case safety reports by seamlessly retrieving data from EHRs; support wide scale longitudinal observational studies by enabling access to clinical care data stored in multiple distributed EHR Systems; decrease the time to detect the adverse drug events, as access to distributed EHR systems will drastically increase the scale of the safety studies; and facilitate participation by a greater number of clinicians and healthcare institutes in safety research.

SALUS Project has started its activities in February 2012, currently the consortium is actively working on identification of the use cases, and requirement specification. This study also includes the initial specifications of the functional interoperability profiles, the common set of core data elements required in these use cases. The consortium is also actively developing early prototypes: the first prototype enables conduct of a post market safety analysis study by a regulatory body to assess the validity of a reported adverse event, by collecting case safety reports from heterogeneous hospitals presenting medical summaries in HL7 CDA, and CEN/ISO 13606 EHR Communication format using diverse terminology systems, and seamlessly analyzing the collected reports although different EHR standards and terminology systems are used, and querying back the participating hospitals through semantic interfaces to learn about extended medical history of the patients [7]. All these preliminary results will be presented and demonstrated in MIE 2012.

References

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