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

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SRDC Ltd, AGFA Healthcare

Convergence Meeting: Semantic Interoperability for Clinical Research & Patient Safety in Europe

- A STREP funded under Objective ICT-2011.5.3b) Tools and environments enabling the re-use of electronic health records which aims to
  - Enable effective integration and utilization of electronic health record (EHR) data to improve post-market safety activities on a proactive basis
    - Build the necessary interoperability architecture for enabling ADE detection tools, signal validation and strengthening processes and real time screening of multiple, distributed, heterogeneous EHRs for early detection of adverse event signals
    - Enable semantic interoperability for reuse of EHRs in drug safety research
    - Build novel framework for open-ended temporal pattern discovery on top of the electronic health records
    - Ensure security and privacy
  - Pilots in Lombardia Region (Italy) and Eastern Saxony (Germany)

- Partners
  - SRDC Ltd, Turkey (coordinator)
  - EUROREC, France
  - WHO- UMC, Sweden
  - OFFIS, Germany
  - AGFA Healthcare, Belgium
  - ERS, Netherlands
  - LISPA, Italy
  - INSERM, France
  - TUD, Germany
  - ROCHE, Switzerland
Objectives

• Address the interoperability gap between clinical care and research domains:
  – Use of electronic health record (EHR) data to improve post-market safety activities on a proactive basis
  – EHR covers extended parts of the underlying medical histories, include more complete information on potential risk factors, and not restricted to patients who have experienced a suspected ADE
    • Denominator is missing in SRS data

• 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
How SALUS extends current spontaneous reporting system to seamlessly exploit the already existing clinical data at EHRs

An ideal system for ADR surveillance would combine the strengths of case reports with those of EHRs
How SALUS enables exploratory/confirmatory signal detection and epidemiological research studies on top of heterogeneous EHRs

- Screening of heterogeneous EHR data for adverse event signals detection
- Carrying out outcome research to identify long term effects of drugs

@ SALUS - January 2013
Selected Use Cases

• Enabling Semi-automatic Notification of Suspected ADEs and Reporting ADEs within a Hospital
  – Enabling Notification of Suspected ADEs
  – Enabling Semi-automatic ADE Reporting

• Supporting Clinical Evaluation of a Potential Signal through Accessing the EHRs
  – Characterizing the cases and contrasting them to a background population
  – Temporal pattern discovery

• Running Exploratory Analysis Studies over EHRs for Signal Detection
  – Temporal association screening on EHRs
  – Manual clinical review of relevant medical history

• Using EHRs as secondary use data sources for Post Marketing safety studies
  – Estimate incidence rates of CHF in diabetic patients with a recent acute coronary syndrome (ACS) event on different diabetic medications
Characterizing the cases and contrasting them to a background population

- During investigation of Nifedipine and myocardial infarction at the Uppsala Monitoring Centre 20 out of 82 cases were found to originate from SALUS connected health facilities
  - The analyst logs in to SALUS as an authorized user validated to see summarized statistics from the health care facility data connected through the SALUS architecture
  - The query is sent through the SALUS framework specifying that summarized statistics for Nifedipine and myocardial infarction contrasted against Nifedipine in general is to be returned
  - SALUS automatically highlights events and covariates that are substantially more (or less) common in patients with myocardial infarction after Nifedipine than in patients on Nifedipine in general. This allows the analyst to:
    - Identify potential risk factors and confounders like age, smoking/alcohol habits, prior prescriptions of other medications associated with medical conditions such as diabetes etc.
    - Find predisposing factors and co-morbid conditions like deep vein thrombosis indicating cardiovascular disease by comparing the medical events prior to the medical event of interest for the 20 cases to the medical events occurring in close relation to the drug prescription for all patients.
    - Characterize the outcome and course of the disease by looking at the events occurring after the medical event in question.
Challenges to be addressed in SALUS

- The problem of Interoperability
  - Syntactic and Semantic
- The ability to exchange information
  - access
- The ability to use the information once it has been exchanged
  - understand
- Security and privacy
- Intelligent tools to analyze the collected content
Technical Interoperability

- Achieving syntactic and functional interoperability between EHR Systems and clinical research systems
  - (1) to seamlessly query heterogeneous EHR systems for analysing and detecting possible ADEs, pre-filling case safety reports and for enabling signal follow-up studies to trace the safety reports back to the related EHRs
  - (2) to seamlessly specify the target eligible patient group for enabling set up of continuous safety studies that screen EHRs
  - (3) to specify the requested clinical data by intelligent data analysis tools for the selected group of patients
  - (4) to transfer the specified de-identified clinical data to the clinical data registries for the selected patients for safety analysis
  - Transaction definitions!
  - Content agnostic

- SALUS WP5: Functional Interoperability Toolkits for secondary use of EHRs in Post Market Safety Studies
  - Task 5.1 Subscription Based Interoperability Profiles and Open Source Toolsets
  - Task 5.2 Query Based Interoperability Profiles and Open Source Toolsets
  - Task 5.3 Interoperability Profiles and Open Source Toolsets for Reporting Activities for Post Market Safety Studies
Proposed Approach

• Two complementary approaches will be followed:
  – By providing a semantic interoperability layer on top of the functional interoperability profiles to be developed in WP5: clinical research and clinical care systems can communicate through using well accepted standards like HL7 CDA, CEN EN 13606 archetypes, and CDISC ODMs within the scope of well defined transactions, yet be able to meaningfully interpret these syntactically different but semantically similar content models
  – By enabling the development of semantic interfaces on top of the clinical information sources, so that clinical data exchange among clinical care and research systems can be handled based on a common semantic model

• Provide a migration path from clinical care and research systems that can communicate through semantically enhanced functional interoperability profiles to clinical care and research systems that support full-fledged semantic systems enabling semantic interfaces through our harmonized patient safety ontology.
Current Progress in WP5

• Tasks 5.1 & 5.2 (Subscription/Query Based Interoperability Profiles)
  – Related available interoperability approaches have been examined
    • HL7 CRFQ
    • IHE QRPH Profiles: IHE RFD, IHE CRD
      – Form based interaction, not query/subscription based, focusing on case safety reports
    • IHE PCC Profiles: IHE QED, IHE CM
      – Subscription/query based, yet not specialized for population based queries
    • Representing eligibility queries:
      – HL7 HQMF queries
      – HL7 Study Design Message
  – Now, the Consortium is working on the extensions to IHE QED and CM Profiles to pass population based queries
  – In parallel with this, we will be actively involved in IHE DEX Profile as co-author
    • Exploitation of metadata registries for flexible mapping of medical summaries to research data required by Clinical research systems (like CRF forms, safety reports)
    • Based on our IEEE TITB publication...
Introduction
The Semantic Interoperability Platform (SIP)

- A simple thing (?
  - Put a semantic layer on top if any resource
  - Define a common ontology (or a system to mediate between ontologies)
  - Query data as if everything behaves as one virtual system
Semantic Interoperability and Service

access different sources as if they were one global and virtual information source

Semantic Interoperability Platform

Orbis  CDA  Arch  ...
Integrating the different approaches

- Portal
- Reporting
- Monitoring

- X (HL7)
- Y (CEN)
- Z

- Semantic Mediator
- Warehouse
- Repositories

- Sem. Resources
- detection
- reporting
- Sem. services ...

Formalize ASAP
Due to the fact that this user scenario needs to process identifiable clinical patient data, because the treating physician needs to validate the collected information and possibly provide additional clinical input, the most likely option is to deploy this solution at each of the local clinical settings. Thus the involved services will be completely independently deployed at both TU Dresden and LISPA.

The solution comprises of the services mentioned next.
From data to formal resources

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<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>GUI</th>
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CIS: Clinical Information System
CTMS: Clinical Trial Management System
DDO: Data Definition Ontology
DO: Domain Ontology
DSQ: Domain SPARQL Query
DSSQ: Data Set SPARQL Query
GUI: Graphical User Interface
SQL: Structured Query Language

- **At development (deployment) time**: creating "formal library"
- **At any time**: formalizing upfront (triple cache)
- **At runtime**: formalizing (via querying) and deducing (via reasoning with rules)
  - Using formalisms declared in ontologies

- Fixed query link
SALUS Semantic Interoperability Platform aims to build a semantic architecture, where data will be mediated to one another through common models, created as a set of semantic resources (common data elements, domain ontologies, terminology systems).
Identification of SALUS common data elements (CDEs)

• Collected and merged the different data requirements of our pilot application scenarios

• At the end of this step, we had our Common Data Elements (CDEs) as a matrix
<table>
<thead>
<tr>
<th>Selected SALUS Scenarios/Related EHR Sections</th>
<th>Selected SALUS Scenarios/Related EHR Data Items</th>
<th>Enabling Notification of Suspected ADEs</th>
<th>Enabling Semi-automatic ADE Reporting</th>
<th>Characterizing the cases and contrasting them to a background population</th>
<th>Temporal pattern characterization</th>
<th>Running Exploratory Analysis Studies over EHRs for Signal Detection (Temporal Association Screening)</th>
<th>Using EHRs as secondary use data sources for Post Marketing safety studies (Calculating incidence rates of CHF in diabetic patients with a recent acute coronary syndrome (ACS) event)</th>
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Identification of content models

• Within the scope of Task 4.1, we have identified and presented the content models to be used in SALUS
  – A harmonization of HL7/ASTM CCD, IHE PCC and HL7/IHE/ONC Consolidated CDA templates based on HL7 CDA -> SRDC
  – OMOP Common Data Model (CDM) templates -> SRDC
  – ICH E2B(R2) templates -> INSERM
  – ISO/CEN EN 13606 archetype library -> ERS
• These are able to cover the data requirements of SALUS pilot applications; hence the SALUS CDEs
• Also, provided mappings at the conceptual level between pairs of these standards (e.g. CDA to E2B(R2), CDA to OMOP CDM)
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<td>cda:text/</td>
<td>Problem</td>
<td>0..1</td>
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<td>cda:statusCode/</td>
<td>-</td>
<td>1..1</td>
<td>CS</td>
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<td>Start Date</td>
<td>0..1</td>
<td>TS or IVL&lt;TS&gt; (for effective Time)</td>
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<tr>
<td>cda:effectiveTime/high</td>
<td>End Date</td>
<td>0..1</td>
<td>TS or IVL&lt;TS&gt; (for effective Time)</td>
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<td>1..1</td>
<td>CD</td>
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</table>
SALUS Draft Common Information Model

• Taking into account the most prominent clinical care standards and initiatives, we have created the SALUS Draft Common Information Model (CIM), which most effectively represents all the CDEs that we have identified

• Similar models that we have analyzed
  – greenCDA representation of HITSP C32 specification,
  – HL7 Clinical Statement Model,
  – hQuery,
  – ASTM CCR,
  – Mini-Sentinel, ...

• We have created the patient-centric SALUS Common Information Model, as an entity model

• It is broad enough to cover not only SALUS requirements

• Yet, it is concise and does not include unnecessary classes that are very specific to clinical trials, etc. (one reason to give up BRIDG DAM)
SALUS Draft Common Information Model - Content

• Patient is the starting point of SALUS Draft CIM, and it covers metadata about the patient:
  – id
  – name, surname, title
  – gender, birth date, birth place, address
  – marital status, race, ethnicity, religion, etc.

• and, medical information:
  – health professionals
  – healthcare providers
  – encounters
  – allergies
  – conditions (problems, diagnoses, etc.)
  – family history
  – immunizations
  – medications
  – pregnancies
  – procedures
  – lab results
  – social history
  – vital signs
How CDEs are created and how they will be used by SIL?

Task 4.1 Content Model Creation

1. Imports existing Domain Models, and domain ontologies as a basis, identifies and maintains CDEs as an ontology conforming to ISO-IEC 11179 Repository Metamodel

Content Models

Task 4.2 CDE Repository

2. Produces content models as HL7 CDA templates, EN 13606 templates, Archetypes, etc. (SIAMS?)

-- This is based on the selected Pilot Scenarios --

3. Content Models are imported to CDE Repository as “Content Model Ontologies”

4. “Content Model Ontologies” are annotated with Terminology Codes

5. Matching CDEs are found, “Content Model Ontologies” annotated with these CDEs If necessary new CDEs are created

Task 4.3-4.4 Semantic Mediation Framework

6. A part of SALUS Resource Set is created from CDEs

7. Annotated Content Model Ontologies are loaded

8. Using Annotated Content Model Ontologies, “Mapping Definitions” between these and SALUS Semantic Resource Set is created

9. Using “Mapping Definitions”, Clinical Content represented in Content Models can be semantically mediated to/from SALUS Semantic Resource Set
Proposed Semantic Mediation Approach

1. Case Series Characterization Tool
   - SALUS Functional Interoperability profile for subscribing specific subset of clinical data available in EHRs for a specific target patient cohort

2. Eligibility Criteria based on OMOP CDM
   - OMOP CDM based Criteria Ontology instance

3. Ontology Normalization Component
   - Eligibility Criteria Semantic Query based on SALUS Common Ontology

4. SALUS Semantic Mediation Framework
   - Ontology Alignment through Reasoners

5. Ontology De-normalization Component
   - Eligibility Criteria represented through HQMF Model

6. SALUS Functional Interoperability profile for subscribing specific subset of clinical data available in EHRs for a specific target patient cohort

7. EHR System used in clinical care

1a. EHR based Signal detection tools (Semantic aware)

2a. SALUS Semantic Resource Set

3a. Alignment Rules

5b. Semantic Interface of ORBIS

6b. ORBIS DB

7b. EHR System used in clinical care (Semantic aware)
Another Look to WP4-WP5 Interaction
Case Series Characterization revisit
Project timeline

Month 1, 5
Project Information


**Publications**
- Providing Semantic Interoperability between Clinical Care and Clinical Research Domains, Accepted for publication in IEEE Transactions on Information Technology in BioMedicine
- Semantic-sensitive extraction of EHR data to support adverse drug event reporting, SWAT4LS Workshop, Paris - France, 30 November 2012
- Two MedInfo Submissions
- One Panel Discussion submission to AMIA Clinical Research Informatics meeting (In cooperation with EHR4CR)
- ISO/IEC 11179 Metadata Registry implementation has been presented in Apache TCon

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