SALUS: Enabling the Secondary Use of EHRs for Post Market Safety Studies

May 2015

A. Anil SINACI, Deputy Project Coordinator

SRDC SOFTWARE RESEARCH & DEVELOPMENT CONSULTANCY

SALUS: Scalable, Standard based Interoperability Framework for Sustainable Proactive Post Market Safety Studies (http://www.salusproject.eu/)

- 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*
  - Pilots in **Lombardy Region (Italy)** and **Eastern Saxony (Germany)**
    - **WHO-UMC** and **ROCHE** is actively involved in pilot studies
- 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

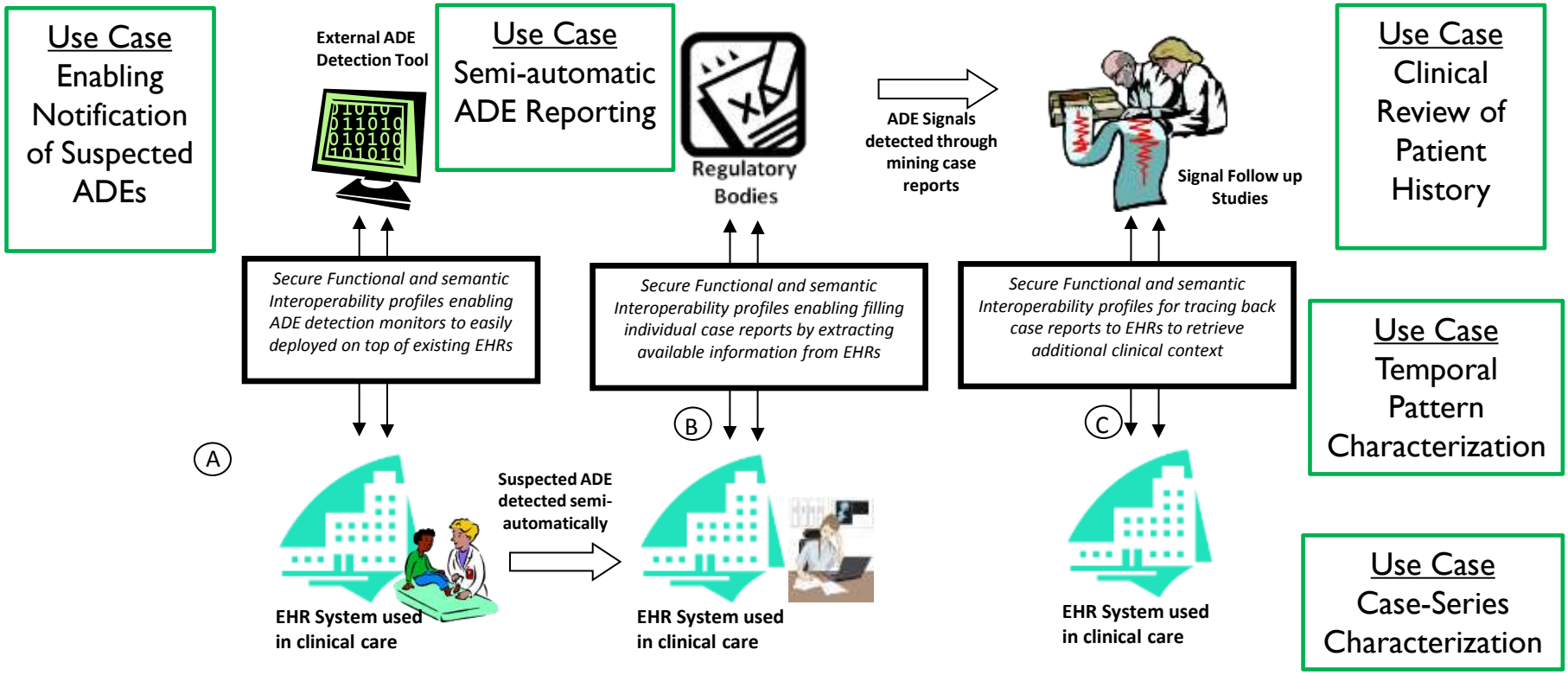
Motivation

- Clinical trials are focused and not adequate to ensure comprehensive drug safety
- Post market safety studies address this problem, but
  - Reactive based on spontaneous case safety reports
- It is estimated that medical practitioners report only about 5% of harmful drug side effects
  - Medical professionals do not always see reporting a priority
  - Detecting adverse events may not always be straightforward
  - ADRs are the fifth most common cause of hospital deaths
  - Approximately 6.5% of all hospital admissions in Europe are due to an adverse drug reaction (ADR)
  - ADEs cause 197,000 deaths per year in the EU, at a total cost of €79 billion

Objectives

- Enable effective integration and utilization of electronic health record (EHR) data to improve post-market safety activities on a proactive basis
  - screen the EHRs and notify the physician about possible ADEs by the help of pre-defined detection rules
  - help filling the ICSRs
    - avoid double data entry
  - 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

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

Case Series Characterization Tool

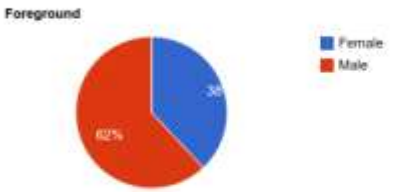
SALUS

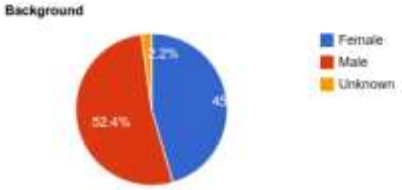
SALUS - Case Series Characterization Tool | Foreground | Background | Statistics | Risk Factor | Configuration | Results | Anil Sinaci

Results

Gender Distribution

Gender	Foreground	Background
Female	38% (41)	45% (15788)
Male	62% (67)	52% (18230)
Unknown	0% (0)	2% (755)





Average Age

Age Distribution

Country Distribution

Common Conditions

Condition	Foreground	Background
Angiopathy	80% (87)	52% (18303)
Arrhythmia	38% (42)	19% (6834)
Arterial disorder	71% (77)	45% (15968)
Biliary tract disorder	63% (68)	7% (2557)
Bronchial disorder	33% (36)	12% (4500)

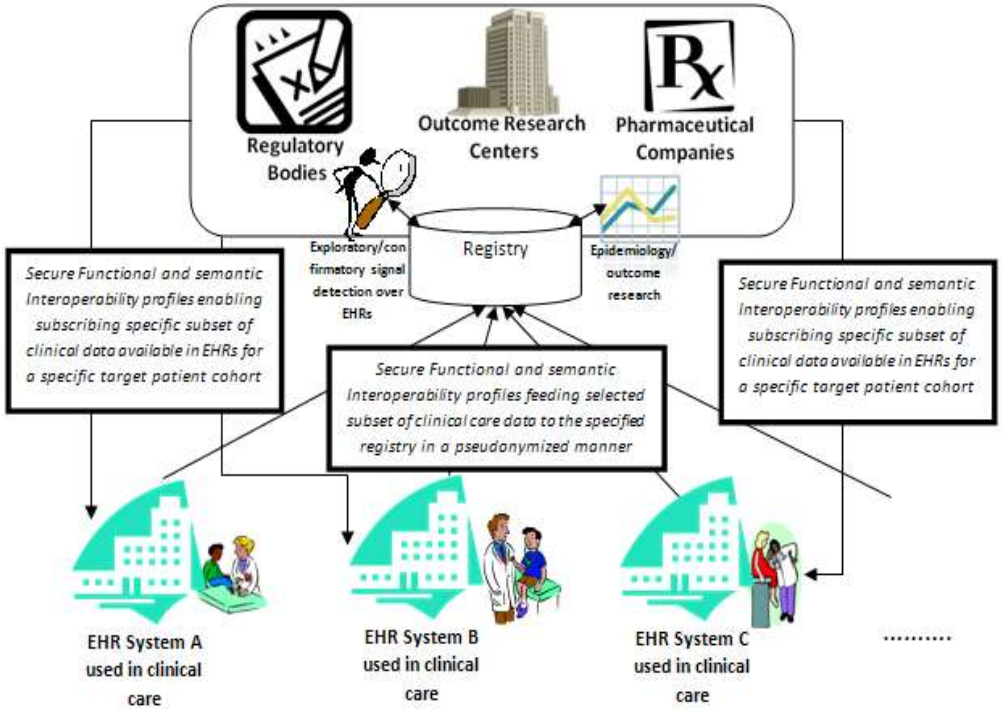
How SALUS enables exploratory/confirmatory signal detection and epidemiological research studies on top of heterogeneous EHRs

SALUS

Use Case

Temporal association screening on EHRs

- Open ended analysis, no prior hypothesis
- Generates associations that might become signals



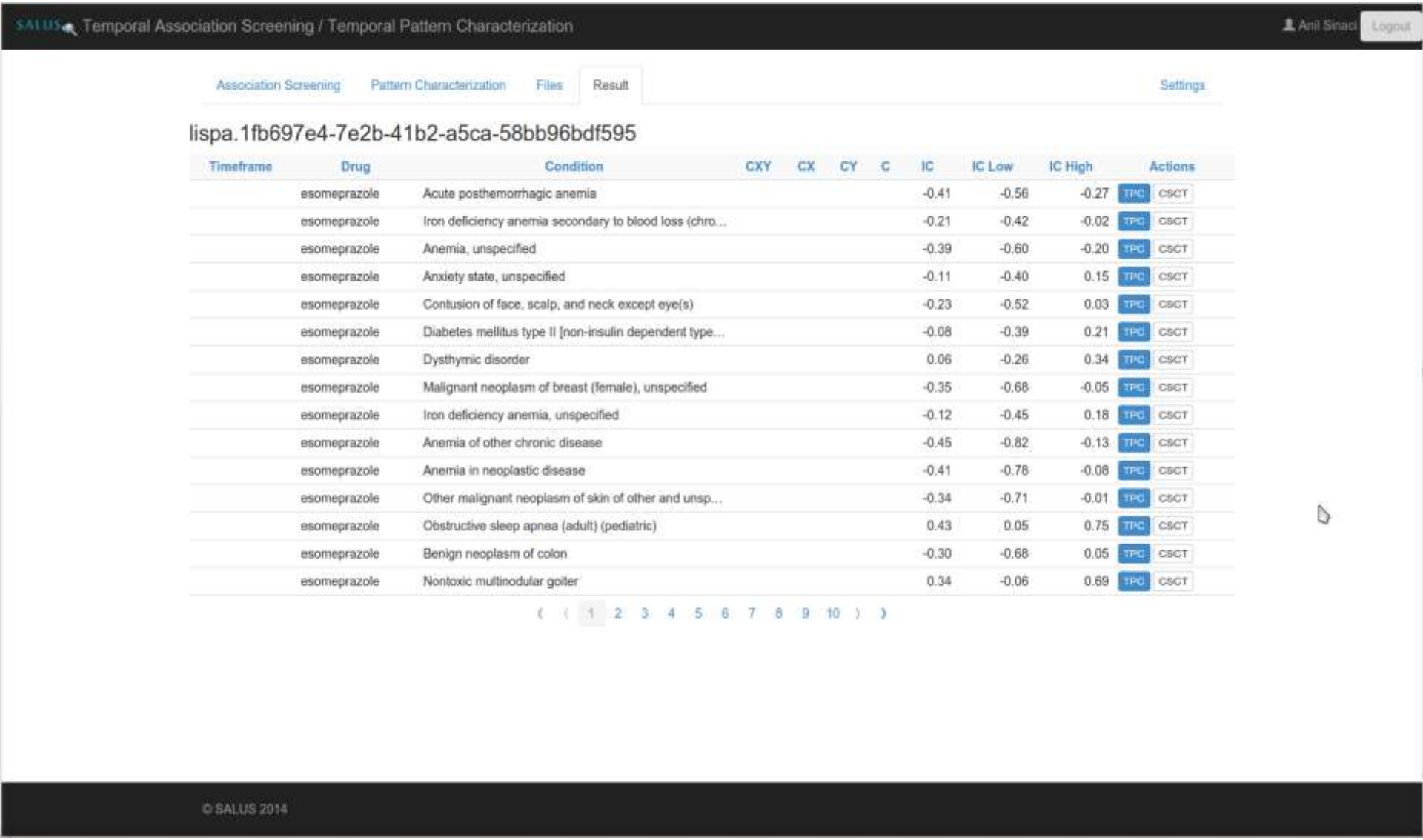
Use Case

Using EHRs as secondary use data sources for Post Marketing safety studies

- ROCHE→ Estimate incidence rates of CHF in diabetic patients with a recent acute coronary syndrome (ACS) event

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

Temporal Pattern Association Tool



Deployment and Validation

LISPA deployment and validation

- ~16 million patients
- ~550 million ambulatory diagnosis records
- ~30 million inpatient diagnosis records
- ~80 million condition records
- ~275 million drug prescriptions
- ~800.000 pregnancy records
- ~35 million vaccination records
- ~2 million allergy records

TUD deployment and validation

- ~945,000 patients
- ~13 million diagnosis
- ~114,000 adverse events
- ~56 million lab results
- ~3.8 million procedures
- ~10,000 immunization
- ~2.2 million medication forms

Validation Results

- System Usability Scale (SUS)
  - For each end-user tool
  - *Usability*
  - Scores: Around average ~68
- Health-IT Usability Evaluation Scale (Health-ITUES)
  - For each end-user tool
  - *Efficacy*
  - Satisfactory grades
- Specific questionnaires
  - For some end-user tools
  - *Viability* and *Social Acceptance*
- *Specific validation reports*
  - *Focus Group Meetings*

Results in summary

- Using the SALUS system, it is now possible to
  - detect Adverse Drug Events on patient summaries
  - prefill Individual Case Safety Reports (ICSRs) with available patient data
  - submit ICH E2B (R2) based case safety reports to regulatory bodies
  - perform effectiveness studies on available EHR data by submitting various queries for different purposes such as case series characterization and temporal association screening
  - perform post market drug surveillance on selected cohorts coming from different EHR sources and make analytical calculations

Challenges and lessons learned

- Interoperability Challenge
  - Profiling approach
    - IHE QED, CM
    - **IHE DEX**
  - SALUS provides the facilities to achieve interoperability & demonstrates its applicability through selected use cases
- Accessing EHR Sources for secondary use
  - Even at analysis time, we encountered problems
  - There should be clear incentives for Hospitals
- Performance Challenge
  - Dealing with real data of millions of people

SALUS

Thank you for listening…

Questions

A. Anil SINACI

SRDC SOFTWARE RESEARCH & DEVELOPMENT CONSULTANCY