Press Release

Linked2Safety

A next generation, secure linked data medical information space for semantically-interconnecting electronic health records and clinical trials systems advancing patients safety in clinical research

Linked2Safety is an FP7 project funded by the European Commission under the area of ICT for health. The vision of the project is to advance clinical practice and accelerate medical research, by providing pharmaceutical companies, healthcare professionals and patients with an innovative semantic interoperability framework facilitating the efficient and homogenized access to distributed Electronic Health Records (EHRs).

EHRs contain an increasing wealth of medical information. They have the potential to significantly help and advance medical research, as well as improve health policies, providing society with additional benefits. However, the European healthcare information space is fragmented due to the lack of legal and technical standards, cost effective platforms, and sustainable business models. Linked2Safety will be developing an innovative semantic interoperability framework, a sustainable business model, and a scalable technical infrastructure & platform for the efficient, homogenized access to and the effective, viable utilization of the increasing wealth of medical information contained in EHRs.

The Linked2Safety project aims to build the next-generation, semantically-interlinked, secure medical and clinical information space in the enlarged Europe. This will allow dynamically discovering, fruitfully combining and easily accessing medical resources and information contained in spatially distributed EHRs. Moreover it will leverage the reuse of electronic health records in clinical research, towards the early detection of potential patient safety issues, based on the genetic data analysis and the extraction of the bio-markers associated with an identified type of an adverse event. It also aims to support sound decision making, towards the effective organization and execution of clinical trials, allowing health carers and medical scientists to easily submit their own query and get homogenized access to high-quality medical data. Finally it aims to develop proof-of-concept pilot clinical trials design studies to validate and evaluate the Linked2Safety results.

The Linked2Safety project with the developed reference architecture, data protection framework, common EHR schema, lightweight semantic model and integrated platform will facilitate the scalable and standardized semantic interlinking, sharing and reuse of heterogeneous EHR repositories. This in turn will provide healthcare professionals, clinical researchers and pharmaceutical companies' experts with a user-friendly, sophisticated, collaborative decision-making environment. This will allow analysis of all the available data of the subjects, such as genetic, environmental and their medical history during a clinical trial leading to the identification of the phenotype and genotype factors that are associated with specific adverse events and thus early detection of potential patients' safety issues. It will also enable subject selection for clinical trials through the seamless and standardized linking with heterogeneous EHR repositories, providing advice on the best design of clinical studies.

It is expected that Linked2Safety will have multiple outcomes. One of them is the open, generic Linked2Safety Reference Architecture for enabling the reuse of semantically interlinked, interoperable EHR and Electronic Data Capture (EDC) information resources in clinical trials design and execution

advancing proactive patient safety and targeted patients selection. The project will also lead to the sustainable Linked2Safety Organizational, Data Governance and Business model. Furthermore it will result in the innovative Linked2Safety Data Privacy Framework that will reassure the compliance with the European and national legislation, with regard to the publication, access to and reuse of the patients' personal and healthcare data. A scalable, modular and extensible platform will also be implemented that will enable pharmaceutical companies experts, healthcare professionals and patients to have efficient, homogenized access to Electronic Health Records across the enlarged Europe. A semantic annotation, sharing and alignment of the EHR and EDC artefacts with the globally available medical resources and vocabularies will be available through the Linked2Safety Semantic EHR Model. Furthermore a demonstration of the use of the Linked2Safety framework will be shown through the implementation of a set of Research Showcases. Through the use of the project, a step-by-step cookbook will be created describing the Linked2Safety methodology outlining the guidelines for leveraging and reusing EHR. Finally the European academic, scientific and industrial stakeholders will have the ability to exploit the wide-scale dissemination of the project results.

A sample case study of the project is the following:

A phase III clinical trial coordinator accessingLinked2Safety can identify the number of subjects that match his selection criteria from all the relevant data sources in the Linked2Safety platform. Then he can contact the Linked2Safety Governance body for help in accessing the subjects needed to include in the trial. The Governance body will review the research proposal and will decide if, and which of the subjects can be invited to volunteer for the trial. The Governance body will simply act as a mediator between the clinical trial coordinator requesting the access, and the principal investigator(s) of the study(ies). Subjects will only be conducted by the institute they have signed the consent form with. All ethical, legal or other issues will then need to be addressed directly between the phase III clinical trial coordinator requesting the data and the institution(s) that actually holds the data.

Official Project Data
Project Identifier: FP7-ICT-2011-7-288328
Project coordinator: INTRASOFT International S.A.
Website: www.linked2safety-project.eu
Timetable: from Oct. 2011 to Sep. 2014
Total cost: € 4,411,664
EC funding: € 3,099,000
Instrument: STREP

Project Coordinator
Dr. Antonis Ramfos
Tel: +352 4410122186
Email: antonis.ramfos@intrasoft-intl.com

Dissemination Leader
Dr. Athos Antoniades
Tel: +357 22892685
Email: athos@cs.ucy.ac.cy

Partners
1. INTRASOFT INTERNATIONAL S.A. (Luxembourg) - Project Coordinator
2. NATIONAL UNIVERSITY OF IRELAND, GALWAY (Ireland)
3. THE UNIVERSITY OF MANCHESTER (United Kingdom)
4. GOTTFRIED WILHELM LEIBNIZ UNIVERSITAET HANNOVER (Germany)
5. CENTRE FOR RESEARCH AND TECHNOLOGY HELLAS (Greece)
6. UNIVERSITY OF CYPRUS (Cyprus)
7. SIVECO Romania S.A. (Romania)
8. UBITECH Ltd. (Greece)
9. ZEINCRO Hellas S.A. (Greece)
10. HOSPICES CANTONAUX CHUV (Switzerland)
11. THE CYPRUS INSTITUTE OF NEUROLOGY AND GENETICS [THE CYPRUS FOUNDATION FOR MUSCULAR DYSTROPHY RESEARCH] (Cyprus)