Body:

There is a need for the development of an advanced environment for clinical research that enables seamless, secure and consistent integration of clinical care information in electronic health records with information in clinical trial systems. This will facilitate the early detection of patients’ safety issues as well as the identification of adverse events and the identification of a suitable critical mass of patients to participate in small or larger scale clinical trials.

Challenges & Highlights

Linked2Safety will produce an open and generic software reference architecture based on which a prototype platform will be delivered to support the reuse of semantically interlinked, interoperable electronic health records and electronic data capture information resources. This will in turn provide healthcare professionals, clinical researchers and experts from pharmaceutical companies with a user-friendly, sophisticated, collaborative decision-making environment to 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. Moreover, Linked2Safety will also produce an innovative Data Privacy Framework that will reassure compliance at European and National level with regard to the publication, access to and reuse of the patients’ personal and healthcare data, as well as an Organizational, Data Governance and Business model for the sustainability of the project results. Finally, in the context of showcasing the usability, applicability and adaptability of the proposed Linked2Safety framework, and to promote the awareness, use and adoption of the Linked2Safety research results to the interested stakeholders across the enlarged Europe, a set of proof-of-concept clinical research design studies will be piloted utilizing realistic data.

Potential applications & future issues

The main future issues are the establishment of a dissemination strategy, the identification of relevant stakeholders to the project, and the documentation of the dissemination actions (along with a set of evaluation metrics) that need to be conducted for raising the project awareness. Another future issue will be the collection of the data that will support the piloting phase of the project from the consortium’s clinical data providers, along with the analysis of the respective metadata, and preliminary identification of the possible trial showcase scenarios. As well as the constant monitoring and validation of the design specifications and early prototype developments of Linked2Safety following an iterative and incremental approach.

Project abstract:

The central asset for healthcare and public health is information. The European healthcare information space is fragmented due to the lack of legal and technical standards, cost effective platforms and sustainable business models. The potential gains in efficiency and effectiveness for primary care afforded by rapid and secure access to patient healthcare data in electronic form are widely recognized today across Europe. Common standards and interoperability will bring opportunities for a global approach for the benefit of patients, health systems and the market. The effective use of electronic health records has the potential to influence both the quality and the cost of health care positively.
Project research areas:
Web Search
Web of People

Project type:
E-Health

URL:
http://www.linked2safety-project.eu/

Research Area:
Web Governance

Status of the Project: