EHR4CR Executive Summary

Introduction

The EHR4CR (Electronic Health Records for Clinical Research) project is a vast research program led jointly by EU academic and industrial partners. The EHR4CR project is funded by the Innovative Medicines Initiative (IMI) under the 7th EU Framework Programme (FP7) of the EU Commission as a public-private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA), for an overall contribution estimated at €16 millions. The EHR4CR consortium draws its expert partners from academia, 20 research organizations, 4 Small to Medium Enterprises (SMEs), 10 EFPIA companies and is an example of the scale of collaboration made possible through IMI.

The EHR4CR project, which will run over 4 years, will demonstrate how data held within EHRs can be re-used to enhance clinical research processes in Europe. The EHR4CR project will build, validate and deploy a Europe-wide innovative technological platform to re-use EHRs data for clinical research purposes. The EHR4CR platform will streamline existing clinical research processes with the aim to better position and attract further R&D investments in Europe, to optimize access to innovative medicines and to improve health outcomes. In particular, the EHR4CR project proposes to deliver a state of the art interoperable platform and a sustainable business model that will allow to re-use EHRs data for clinical research, in compliance with applicable legislative, regulatory, ethical and privacy protection requirements and policies, including the provision of advanced certification and accreditation programs.

Context

The development of new medicines is critical to advance improvements in healthcare. As most new medicines are developed by the pharmaceutical industry in collaboration with academic and healthcare organizations, clinical research programs are overseen by national and international regulatory bodies. However, the discovery and development of new medicines that are effective and safe for routine use in patients have become increasingly complex, labor intensive and challenging. This is, in part, due to the need to conduct large clinical trials that provide definitive evidence of clinical benefits and safety. Specific issues include the difficulty in evaluating patient populations, optimizing protocol design and identifying suitable patients for clinical trials, as well as the manual and redundant re-entry of data, the reliability of data sources for clinical trials, and the difficulty in detecting and reporting infrequent adverse events.

In parallel, unmet medical needs, aging populations, the trends towards personalized medicines and the escalation in health care expenditures are building unprecedented organizational and economic pressures on health care systems and on the pharmaceutical industry. The average cost of clinical trials has increased threefold over the last 12 years (Drug Discovery & Development 2005). In 2006, the cost of researching, developing and achieving regulatory approval for a new chemical or biological entity was estimated at € 1.1 billion. Furthermore, between 1990 and 2008, R&D investments in United States grew by 5.6 times whilst in Europe it only grew by 3.5 times. This confirms Europe's relative lack of attractiveness for pharmaceutical R&D investment. Today, there is rapid growth in the research environment in emerging economies such as China and India, resulting in closures of R&D sites in Europe and openings of new sites on the Asian continent (EFPIA Key Data 2009).

With blockbuster drugs currently losing patent protection (representing tens of billions of Euros in lost revenues), lengthy clinical development processes (which can last 8-10 years), and the ever increasing challenges of achieving timely market access for innovative medicines, developers need to boost their research pipelines and transform current clinical research models to help bring innovative medicines to market faster and at lower cost (Tufts 2011 Outlook report). Developers are thus exploring innovative and more efficient approaches to designing and conducting global clinical trials.
Recent developments in electronic health records (EHRs) provide the opportunity to re-use the patient level data they contain for clinical research purposes, including for assessing the safety of new medicines. Given the considerable progress that has been made towards seamlessly integrating EHRs within existing health

care networks, this truly offers new possibilities to researchers from the private and academic sectors to conduct clinical trials more efficiently, to address significant unmet medical needs more expediently, to improve patient safety, and to provide faster access to innovative medicines to optimize health outcomes.

There is thus a growing realization that the ability to effectively integrate and inter-operate advanced EHRs systems within health care networks for clinical research represents a breakthrough opportunity to enhance research, to speed up and streamline existing clinical research processes and to build greater efficiency. However, such developments require to secure acceptance from the patients, the public and the health service community, as well as to define and test the most suitable scenarios, in compliance with relevant legal, ethical, regulatory, privacy protection requirements and policies.

EHR4CR Deliverables

The EHR4CR (Electronic Health Records for Clinical Research) project has declared an ambitious objective: to establish an innovative and scalable pan-European platform and service framework to enable all health care stakeholders and the pharmaceutical industry to utilize hospital electronic health records (EHRs) for clinical research.

The EHR4CR project will deliver a robust platform that is market-ready and accompanied by a portfolio of relevant services and service providers. In order to provide sustainable and cost-effective solutions, the EHR4CR platform will also be supported by an innovative business model and a customized value proposition. For the first time, the EHR4CR platform and business model will provide a systematic, structured and scalable approach to the re-use of EHRs data for clinical research in Europe.

More specifically, using the most advanced and reliable technological advancements, pre-defined clinical research scenarios and disease areas, the EHR4CR platform will deliver a platform that will combine data from heterogeneous clinical systems for clinical research purposes (e.g. protocol feasibility, patient recruitment, clinical trial data capture, drug surveillance reporting). This will be achieved by aligning previously isolated medical informatics progress (e.g. semantic interoperability, privacy enhancing techniques and standards) with an entirely new integrated approach that will enable the re-use of EHRs clinical data for clinical research through optimal data extraction and aggregation, de-identification, linkage and security. This will reduce redundant data capture and provide a seamless environment where multiple heterogeneous clinical EHRs systems will be integrated with clinical research infrastructures (e.g. Electronic Data Capture systems).

To ensure that the use of EHR systems for clinical research consistently delivers high quality and cost-effective solutions in Europe, the EHR4CR platform will be designed using high quality standards and governance, including advanced accreditation and certification programs. The EHR4CR platform will also be supported by a sustainable business model. For that purpose, evidence-based approaches will be used throughout the development of the project to design and test the most attractive and robust business model for Europe. In particular, a EHR4CR business model “innovation” process will be deployed to regularly monitor the environment and gather relevant multidisciplinary strategic input that will inform the design of the business model over the project duration. These measures will allow to align the most favorable conditions for a successful pan-EU implementation at project completion, which will lead the way towards attracting further R&D investments for clinical research in Europe.

EHR4CR Expected Benefits

EHRs can now seamlessly integrate with existing research platforms and healthcare networks to create new opportunities for many stakeholders, including the pharmaceutical and bio-pharma industries. The development and integration of EHRs systems for medical research can generate substantial efficiency gains. Moreover, by enabling the re-use of EHR patient level data for clinical research, the innovative EHR4CR platform and business model will make Europe more attractive for R&D investments and provide patients faster access to innovative medicines for improved health outcomes, thereby benefiting the medical, research and academic community, patients and society.