Electronic Health Records for Clinical Research

THE EHR4CR PROJECT SHOWCASES ACHIEVEMENTS

EHR4CR Stakeholder Awareness, Berlin 21 November 2013

The EHR4CR project is one of several projects making up the Innovative Medicines Initiative (to date one of the largest public-private partnerships). This pan-European collaboration brings together large biopharmaceutical companies, patient organisations, academia, hospitals, small- and medium-sized enterprises and public authorities with a common aim... How to provide adaptable and scalable solutions for reusing data from Electronic Health Record (EHR) systems for Clinical Research.

The project is currently achieving its ambitious targets for the development of a technical platform to deliver needed tools and services together with a business model for sustainability. Although it will only complete in 2015, the meeting in Berlin provided an opportunity for consortium members to brief key stakeholder groups from the service industries and to exchange information on needs, as the project starts to prepare for commercialisation by external partners.

EHR4CR in a Nutshell

Global healthcare is faced by a changing paradigm for disease management driven by an aging population, the advent of personalised medicine and the growing need to deliver safer, more efficacious and cost effective treatment options. To meet these challenges, the research community needs to speed up the development of innovative drugs in areas of medical need by improving the efficiency of research and development.

Clinical research is the most costly, time consuming and complex part of R&D and it therefore offers the greatest opportunity for improvement. Access to patient data is key to managing today’s bottlenecks in clinical research. The EHR4CR project imagines a future environment where health records are seamlessly integrated with healthcare networks and research platforms, and where EHR information can be used across organisations, regions and countries.

Even first steps towards this future ideal will allow clinical researchers to:

1. Optimise clinical protocol design...
   By being able to test inclusion and exclusion criteria before the start of a clinical trial.
   *Today... A third of protocol amendments are avoidable and over 40% of amendments occur before first patient first dose. These failures are the result of a reliance on local expert opinion rather than across region statistics on patient demographics.*

2. Improve patient recruitment...
   By providing tools for sites to identify clinical trial candidates by electronically searching EHRs and by engaging with other treating physicians.
   *Today... 50% per cent of clinical trials fail to achieve the target recruitment rate because of the lack of empirical data to accurately estimate recruitment potential and the absence of local tools to identify potential candidates*
Electronic Health Records for Clinical Research

3. Improve the capture and exchange of clinical trial data...
By electronically transferring de-identified data between EHR and research systems under investigator control.
Today... Over 40% of clinical trial data is duplicated by entering it manually into both healthcare and research systems. As a result transcription errors significantly increase the workload for monitoring, querying, and responding to entry errors. Complex processes must be put in place to manage the data 'source'. All of this greatly impacts the workload for the investigator and reduces the time available for routine patient care.

4. Improve the detection and reporting of safety events...
By electronically transferring de-identified data between EHR and research systems under investigator control.
Today... adverse events are probably under reported. One of the reasons... it takes time for a physician to complete a CIOMS form. A more efficient process that directly reuses the local EHR system will enhance completeness, quality and timeliness.

Addressing the Research Challenges
Nobody ever said that it would be easy and it was clear that there would be significant challenges in sharing de-identified patient data. But the project has set out to prove that these challenges are surmountable, with the right technological solutions and with the right environment. Key challenges being addressed by the project include:

1. Interoperability
One of the fundamental problems has been how to share de-identified electronic patient health records when they are held within separate, disparate and incompatible systems using different data models, and with different European languages. Where data quality, uniformity and organisation is extremely variable, making it difficult to integrate and use. Having 11 hospitals in 5 countries within the collaboration has allowed the project to test that the projects leading-edge but robust technology solutions can operate within the geographical and cultural diversity of Europe.

2. Ethical, privacy and legal issues
Although 95% of stakeholders are in favour of the reuse of EHR data, 95% also rate compliance with ethical, legal and privacy requirements as the highest, or equal highest driving force for success of EHR4CR. As a result, the protection of patient data and confidentiality is at the core of the project and is critical to gain acceptance with the general public, patients, and medical professionals. Experts ensure that the project complies with ethical, legal and privacy requirements (that differ from country to country). Security features and controls ensure that only de-identified data can ever be searched, that only aggregate numbers leave the institution, and that EHR data is only shared—within the hospital—with a clinical research team if the patient has given specific consent.

3. Integrity and trustworthiness of data
The public, provider, users and regulators all need assurance that the requirements for high-quality clinical research data (Good Clinical Practice) are met by systems operating to the desired level of security, confidentiality, integrity and general trustworthiness. So a robust governance structure is essential for trustworthy reuse of EHR for Clinical Research. A Code of Practice and EHR4CR Institute will govern the actions of all parties using the EHR4CR services and will control and monitor use of the platform and services by ensuring that:

- Only approved users are formally registered and given secure log in credentials
- Users have no means of requesting or obtaining patient level data through the services
- State of the art information security measures are used throughout
- Audit logs are captured at key communications points
Towards a Scalable, Sustainable Ecosystem

Demonstrating the viability of a sustainable business model is a crucial first step to success and has been a core element of the EHR4CR project. A sustainable EHR4CR business model must include various elements to connect providers and receivers of EHR data through different services operating within an ecosystem that is scalable, financially sound and trusted both providers and users.

During 2014 the project will be engaged in activities that will put in place key components of the ecosystem that will mature, expand and improve post-project. As a part of this process, cost: benefit analyses are being undertaken for key stakeholder groups that will be published during 2014.

Engagement is Key

Integration of clinical research data with patient health records will remove important bottlenecks to research in Europe and will increase access to innovative treatments for patients.

EHR4CR has identified and addressed some key challenges in developing its technical solutions and business model. New opportunities for service providers and data providers, but engagement from stakeholders is key to the future success and sustainability of EHR4CR services. This first exposure in Berlin will be followed with further events with other stakeholder groups, such as hospitals. The second in the planned series of Stakeholder Awareness Conferences will take place in Brussels on April, 9 2014 on EC premises.

Figure 2: The envisaged EHR4CR free market ecosystem post-project will operate under the auspices of an EHR4CR Institute

SUPPORTED BY

The EHR4CR project is partially funded by the IMI Programme.

The Innovative Medicines Initiative (IMI) is a unique public-private partnership designed by the European Commission and European Federation of Pharmaceutical Industries and Associations (EFPIA). It is a pan-European collaboration that brings together large biopharmaceutical companies, small- and medium-sized enterprises (SMEs), patient organisations, academia, hospitals and public authorities

www.ehr4cr.eu