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Opportunities for Clinical Research in European Hospitals: The EHR4CR Platform

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Key Points

• Moving towards deployment of EHR enabled clinical research in Europe

• Piloted IT platform services are about to be scaled up to a commercially supported service

• Hospitals will be offered higher efficiency in participating in clinical research

• ICT helps pharmaceutical industry to speed up the delivery of innovative medicines to healthcare

Introduction

Electronic Health Record (EHR) data is now being generated across Europe at an enormous rate, but the data which could help transform healthcare research and clinical trials is underutilised and disconnected.

Electronic platforms to allow clinicians and researchers to easily access patient data - in a way that remains compliant with data privacy, ethical, regulatory and legal policies - are therefore now vitally needed.

Three primary stakeholders need to be involved in the development of such a platform:

• Hospitals providing the Electronic Health Records data;

• Academia and industry using the data; and

• Technical service providers, whose tools and services will allow the parties to connect and collaborate securely.

Currently hospitals only connect with industry and academia on a one-to-one basis, and as a result it becomes difficult to reach the most appropriate patients.

The EHR4CR services encompass:

• Clinical Trial Feasibility (distributed queries);

• Patient Identification and Recruitment (distributing trial protocols to sites and collecting follow-up information on recruitment status from sites);

• Clinical Trial Execution and Serious Adverse Events Reporting (mainly EHR extraction).

New IT Platform Services

Setting these stakeholders within a digital ecosystem the EHR4CR platform now allows industry and academia to more easily access these data sources in order to identify patients who may be suitable to participate in clinical trials.

Specially constructed and robustly deidentified databases within each hospital, containing extracted summaries of health records, will be networked to the EHR4CR platform to enable research queries to be distributed, analysed locally at each site, and the results aggregated at regional, national and European levels. A simplified view of the EHR4CR platform is given in Figure 1.

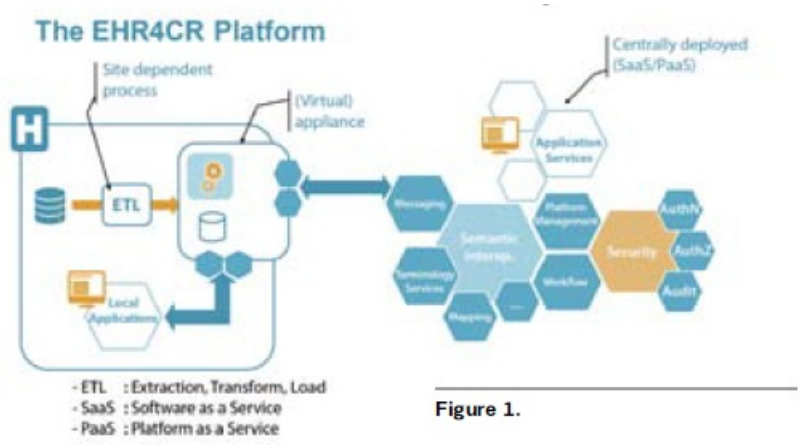

Figure 1.

Data will be anonymised and aggregated to protect patient privacy, but service users will be able to differentiate patients by e.g. disease area, geography or administrative domain.

Patient identification for recruitment into clinical trials always occurs inside the hospital, and will be undertaken by treating physicians to determine if their patients may be contacted to invite them to participate in a particular clinical trial. Any further use of electronic health record data will only take place with a patient's fully informed consent.

The EHR4CR platform is supporting distributed querying to assist in clinical trials feasibility assessment and patient recruitment, and links EHR systems and Electronic Data Capture (EDC) systems to enable clinical researchers to obtain key information about a patient's health and healthcare history before they arrive for a screening visit (but after patient consent has been obtained).

The platform is currently being piloted at several hospital sites across Europe. These sites are themselves active in clinical research, and are able to provide exemplary local governance requirements to complement the inputs from the EHR4CR Ethics Board.

Governance and the European Institute for the Use of Health Data

Such developments require acceptance from patients, the public and the research and health service communities. Therefore, in parallel to the technical developments, senior level decisionmakers, ethics boards and industry executives have been involved in consultations to provide strategic insights into the most robust and acceptable technical and procedural approaches that should be taken to ensure privacy protection and compliance with European and national/regional regulations on data protection.

State-of-the-art information security measures are therefore used throughout the EHR4CR platform and a Code of Practice and Standard Operating Rules will govern the actions of all parties using the services.

Before project end a European Institute for the Use of Health Data will be established with the main remits of: governance, quality assurance, education and promotion. It will develop resources (e.g. maintenance of conformance criteria and testing tools) and governance frameworks, and provide services to registered members such as data providers, service providers and data users (see Figure 2). It will work closely with industry, such as EHR system vendors, and clinical research organisations to encourage the adoption of standards and specifications so that the benefits of using electronic health records to advance research are not locked into individual hospitals and products, but can be analysed securely on a European scale. It will also work closely with hospitals to help them to assess and improve the quality of their data, which will not only benefit research but direct patient care, and help them to make more effective use of healthcare resources.

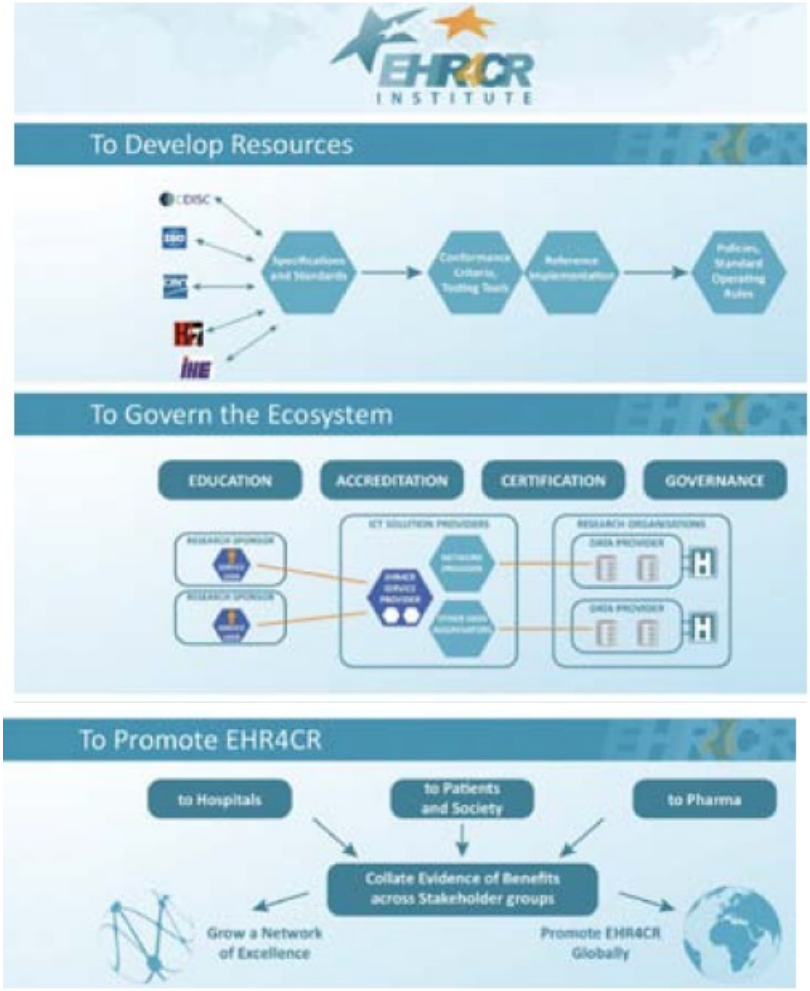

Figure 2.

To enable wide adoption by EHR vendors and quality assurance of the EHR4CR platform within hospitals, the project will also provide governance through accreditation/ certification programmes for establishing best practices. Acceptance and success will be made more robust by building on the well-accepted accreditation/certification mechanisms for clinical research units, platform service providers and EHR systems to prove their compliance with predefined criteria. This will serve as a powerful means for ensuring the reliability and trustworthiness of the research partners for the pharmaceutical industry (e.g. of data providers such as hospitals), and for controlling and monitoring the use of the platform(s), ensuring that anyone who uses the services complies with specific standards and requirements.

One of the most important functions of the Institute will be to regulate and monitor the use of the EHR4CR platform, ensuring that anyone who uses the services complies with specific standards and requirements. These standards will guarantee the overall trustworthiness of the electronic health records being analysed. The Institute will also work with societal stakeholders such as patient associations, health ministries and sponsors of clinical research to promote the value of publicly funded and pharmaceutical industry clinical research whilst strongly protecting patient privacy.

Since the platform architecture will in the near future accommodate connection with a variety of sources (e.g. with data unlocked from primary care settings, registries, mobile health sources etc.) -and thus not only with Hospital EHR data sources - the scope of the Institute will allow for collaboration with other big health data projects that are established or being established within countries and across Europe.

Conclusions

The platform is well placed to deliver a sound, useful and well accepted solution for the (re-)use of hospital EHR information to support clinical research studies. By investing substantial effort in the design of a robust business model framework and in the development of compelling value propositions across multiple stakeholder groups, EHR4CR is stimulating a marketplace of multivendor product offerings.

The new platform services will offer benefits to hospitals:

• Enhance the quality of patient-level EHR data for clinical research, and improve quality of care and health outcomes;

• Generate a new additional income stream by contributing EHR data into research;

• Conduct clinical trials more efficiently and increase hospital participation in a larger number of clinical trials;

• Improve hospital recognition as a clinical research centre of reference;

• Engage in a highly dynamic clinical research environment to improve the overall quality of care and knowledge transfer.

The intent of the new non-profit European Institute for the Use of Health Data (to be established before end 2014) is to attract new actors to join this network and to encourage pharmaceutical companies to continue to collaborate pre-competitively to evolve the services to meet new needs and to accelerate and improve the quality of clinical research. For the industry this will provide innovative integrated and cost-effective solutions to optimise the R&D value chain. For patients, it will prove to be a genuine revolution that accelerates the delivery of innovative medicines into healthcare and engages patients more in the clinical research agenda.

Further Information

The Electronic Heath Records for Clinical Research (EHR4CR) consortium organised a Pan-European Conference in April 2014 in which decision-powered delegates both from hospitals (with excellence centres from 24 countries represented) and from 14 global pharmaceutical companies participated.

The EHR4CR project runs over 5 years (2011-2015) with a budget of €17 million and involves 34 academic and private partners (10 pharmaceutical companies). To date it is one of the largest of the Innovative Medicines Initiative (IMI) public private partnerships. The project is developing adaptable, reusable and scalable solutions (tools and services) for reusing data from Electronic Health Record (EHR) systems for clinical research purposes.

Animation video on You Tube
https://www.youtube.com/watch?v=Wcsl064F2pk

Conference programme http://www.ehr4cr.eu/9april2014/

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