Overview of the EHR4CR project

Electronic Health Record for Clinical Research

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Overview

• Innovative Medicine Initiative (IMI)
• Project Objectives
• Organization
• Work Packages
• Current Status
• Outlook 2013
About IMI

- A Public-Private Partnership between EU and EFPIA focused in research on needs common to the Pharmaceutical Industry and Patients at European level (2007-2017)

- Aims to removing major bottlenecks in drug development, where pre-competitive research is the key, and to re-invigorate the European bio-pharmaceutical sector

- IMI projects offers industry an opportunity to build new business models based on collaboration and transparency

- Coordinated research efforts with shared funding (EFPIA contributes with in-kind resources). Research focuses on fields of high industrial and policy relevance

- The IMI 2009 Call for proposal has 9 topics proceeding to stage 2 (final stage to become a project) addressing the two strategic pillars:
  - Predictivity of Efficacy Evaluation and
  - Knowledge Management (call topics 7,8 and 9).
**Overall Structure of Research Projects**

**IMI Call topics for proposals are conducted through a 2-stage process**

The first stage of the call process is addressing 'Applicant Consortia' (e.g. collaborations between academia, SMEs, patient organisations, non EFPIA industry, etc), to submit to the IMI JU an Expression of Interest in response to a call

- The second stage, following the first stage peer review, the 'Applicant Consortium' of the best Expression of Interest, and the 'EFPIA consortium' that already are associated to the topic, will be invited to form a full 'Project Consortium'

- The full project proposals will be evaluated based on consistency with the original Expression of Interest, on scientific excellence, the quality of the implementation plan and the potential impact

- Only full project proposals that have been favorably reviewed in the evaluation process can be selected for funding and will be invited to conclude a Grant Agreement governing the relationship between the selected project consortium and the IMI JU.

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*The IMI project principles are to ensure shared leadership roles (research) but to be coordinated by EFPIA*
Project objective & outputs

The EHR4CR project is developing a platform and business model for re-using EHR data for supporting medical research.

Output:
- Requirements Specification and Business Model
- Technical Platform (a set of tools and services)
- Different Pilots for validating the solutions:
  - for different scenarios (e.g. patient recruitment);
  - across different therapeutic areas (e.g. oncology);
  - across several countries (under different legal frameworks).
Project objective

*Emerging and Future EHR-Research Connectivity and Complexity*

**Current Divided**
- EHR systems holding source for data used in clinical trials may not meet essential regulatory requirements
- Clinical care data required for clinical trials is entered into EHR and into clinical trial systems
- Research holds source data and part of normal clinical care
- Redundant data entry, transcription errors and source issues cost healthcare and industry time and money.

**Integrated Future**
- EHRs used to...
  - Evaluate Patient Populations
  - Accelerate Patient Recruitment
  - Capture CT Data
  - Exchange CT Data
- The EHR becomes the patient data repository

**Interoperable Ideal**
- EHR and research systems work seamlessly together so that groups benefit from data access and mining capabilities across healthcare and research data sets
- Research systems and healthcare systems sit on same spine
- Systems conform to the same data exchange standards
Vision: Scalable Organisational Model for EHR re-use

- Regional interoperability
- National interoperability
- Cross EU States interoperability
- Connect different sources and services of EHR for support clinical research
- Federation of service providers – TTPs using the EHR4CR Business model
Benefits

• Accreditation and certification will enable research and clinical trials to be delivered more cost effectively. Both vendors of certified products and hospitals (source data) that will be accredited will have a competitive advantage.

• A new business model for re-using EHR data in research will aim at offering benefits for “all” stakeholders and strengthen the collaboration amongst “all” the partners in Research...!
Benefits (cont.)

Patients and health care perspective:
- Closer co-ordination between care providers and patients, resulting in safer and more evidence-based diagnosis and treatment
- Significantly facilitate re-use of EHR data to allow more efficient management of public health issues

Academic perspective
- Provide tools and services to better plan and conduct academic trials (investigator-initiated trials)
- Facilitate comparative effectiveness research, e.g. paediatric trials, trials on rare diseases, trials with biotherapy

Pharmaceutical perspective:
- Improve speed and quality of clinical patient recruitment process and study design by accurate understanding of real patient populations
- Support to conduct observational and outcomes research studies in real-world settings
EHR4CR Business model

EHR4CR business model will:

• Specify in detail the product and service offering;
• Include analyses and an impact analysis on multiple stakeholders;
• Deliver a self-sustaining economic model including sensitivity analysis;
• Define appropriate governance arrangements for the platform services and for pan-European EHR4CR networks;
• Define operating procedures and trusted third party service requirements;
• Identify the value proposition and incentives for each of the key players and stakeholders impacted by EHR4CR;
• Define accreditation and certification plans for EHR systems capable of interfacing with the platform;
• Provide a framework to define public and private sector roles in reusing EHRs for clinical research;
• Define a roadmap for pan-European adoption and for funding future developments.
EHR4CR Technical Platform

EHR4CR platform will:

• Support the feasibility, exploration, design and execution of clinical studies and long-term surveillance of patient populations;

• Enable trial eligibility and recruitment criteria to be expressed in ways that permit searching for relevant patients across distributed EHR systems, and initiate confidentially participation requests via the patients’ authorised clinicians;

• Provide harmonised access to multiple heterogeneous and distributed clinical (EHR) systems and integration with existing clinical trials infrastructure products (e.g. EDC systems);

• Facilitate improvements of data quality to enable routine clinical data to contribute to clinical trials, and importantly vice versa, thereby reducing redundant data capture.
The partners

- 11* Pharmaceutical Companies (members of EFPIA)
- 22 Public Partners (Academia, Hospitals and SMEs)
- 5 Subcontractors (Advisory Board).

* (Amgen, AZ, Bayer, Eli Lilly, Merck KgA, MSD, Janssen/J&J, Novartis, Roche, Sanofi and MSD Europe)
The partners

CDISC Asia Pacific Interchange, 21-Feb-2013, Singapore
Governance structure

Steering Committee - All Consortium participants
For annual project review, approval/removal of participants, approval of resource shift across work packages/project participants

Executive Committee - 11 Participants
Coordinator (AZ), Deputy Coordinator (Roche)
IMI JU Managing Entity (EuroRec) + All WP leaders
for operational project-leadership, continuous project review, issue resolution, proposal of changes within projects

Advisory Board
Ethics Board

Work Package Group 1
“Engagement & Business Model”
Leaders:
Public: UCL
EFPIA: Roche

Work Package Group 2
“Informatics Tools & Services”
Leaders:
Public: Custodix
EFPIA: Sanofi Aventis

Work Package Group 3
“Pilots”
Leaders:
Public: Univ. Münster
EFPIA: Amgen

Work Package Group 4: Project Management & Administration
EFPIA (AZ, Lilly) & Public partners (EuroRec, UCL)

All participants - Contributions to Work Package tasks
Overview of Work Package Groups
Work Package Group 1
Engagement & Business Model

Objectives

- **WP 1 (Specification & Evaluation)**
  - Review the ethical, legal and regulatory landscape in Europe
  - Define the use case scenarios applicable to the EHR4CR platform and business model.

- **WP 2 (Business model & Strategic road map)**
  - Develop a roadmap specifically for the EHR4CR platform, focusing on benefits, investments and adaptations needed
  - Develop a comprehensive business model to establish a durable European service to include specialized products requiring key partnerships for services to be provided

- **Example of tasks**
  - Governance Success Factors (e.g. identify the regulations and cross-border legislative issues that EHR4CR must address and comply with
  - Evaluation of the Pilots
  - Develop a Business model including product and service offering, governance arrangements, operating procedures, third party service requirements and proposals, accreditation and certification plans
Work Package Group 2
Technology Platform & Tools

Objectives

- **WP3 (Architecture and Integration)**
  - Define the architecture of the EHR4CR platform, provide a reference implementation and oversee the overall EHR4CR platform integration and operation.

- **WP 4 (Semantic Interoperability)**
  - Provide tools and services to ensure semantic interoperability between varying and disparate data sources (EHRs and CDMS), allowing for consistent interpretation of data

- **WP5 (Data protection, Privacy & Security)**
  - Provide the core security services for the EHR4CR platform and ensure that data and process flows are optimised for data protection and compliance

- **WP 6 (Platform Services)**
  - Design and implement end-to-end solutions (tools and services) that address the requirements of the different EHR4CR scenarios (e.g. clinical trial protocol feasibility)

**Example of tasks**

- Inventory of re-useable and available relevant solutions and components
- Knowledge Models Mapping and Management Services and Tools
- Core Security Services (AAA - Authentication, Authorisation, Audit)
- Clinical Trial Protocol Feasibility Services (PFS)
Overview of Platform services

WP6: Platform Services

- Protocol Feasibility Services (PFS)
- Patient Recruitment Services (PRS)
- Clinical Trial Data Capture Services (DCS)
- Criteria Authoring and Management Services (CAMS)
- Criteria Matching Services (CMS)
- Data Visualisation and Reporting Services (VIZ)

EHR4CR Underlying Semantic services

EHR4CR Underlying Security services

EHR4CR Platform
EHR4CR concept overview
Objectives

- WP7 (Pilots)
  - Demonstrate the functionality of the tools and services provided by Work Packages 3-6 and to evaluate the EHR4CR platform in terms of clinical study design and execution with a specific focus towards a set of mutually acceptable medical domains agreed between the pilot sites and the EFPIA partners
  - Pilots evaluations will occur at several large academic hospitals, interfacing with EHR systems, with a specific focus towards a set of mutually agreed medical domains between the pilot sites and EFPIA partners (e.g. Diabetes, Oncology).

- Example of tasks
  - Develop Interfaces between local EHR/CDW and CDMS systems and the uniform access layer
  - Execute pilots on
    - Protocol Feasibility, Patient Recruitment, Clinical Trial Execution, Drug Safety Monitoring)
  - of the inventory of local data sources and the matching of EFPIA clinical studies with suitable clinical data providers
Pilot Scenarios 1 and 2

1) Protocol Feasibility
   - Study Inclusion/Exclusion criteria are posted to the platform
   - Platform converts into queries sent to the connected hospitals
   - Hospitals return patient numbers

2) Patient Recruitment
   - Sponsor identify potential investigators in hospitals with sufficient potential patient numbers and proposes contract
   - Investigator use platform to identify suitable patients and recruit them into study
Pilot Scenarios 3 and 4

3) Clinical Data Capture
- Sponsor post eCRF in CDISC ODM format to the platform
- Investigator logs in onto the platform and enter data
- Data is sent both to the hospital EHR system as HL7 message and to the sponsors data management system as CDISC ODM file

4) Adverse Events Reporting
- Severe Adverse Event is identified
- Platform launches SAE reporting form pre-filled with medical data retrieved from EHR system
- Form is checked for accuracy and completeness by investigator then submitted to both the European Medicines Agency and the sponsor
Work Package Group 4
Management

Objectives

- **WP 8 (Training & Communication)**
  - Support the communication and training between all EHR4CR Work Package Groups and Work Packages and promote EHR4CR services to prepare for EHR4CR platform exploitation
  - Widely disseminate the EHR4CR outcomes and communicate with other EC FP or IMI projects in Europe and globally

- **WP 9 (Management)**
  - Coordinate the work of the EHR4CR project, administer day-to-day operations, manage the collaborative efforts of the Work Packages
  - Ensure that the scientific work being conducted is delivered on time and on budgets through optimal project management, including quality monitoring, planning, reporting and financial control

- **Example of tasks**
  - Project Website development and maintenance, Project collaboration space
  - Dissemination and liaison activities in EU
  - Coordination and managing of IMI JU funding, Project management office
  - Total quality management
  - Computer systems validation
Project plan overview

WP3: Management

WP1: Specification & Evaluation

WP3: Architecture and Integration
WP4: Semantic Interoperability
WP6: Services & Tools
WP5: Data Protection, Privacy & Security

WP7: Pilots
- Protocol Feasibility
- Patient Identification and Recruitment
- Clinical Trial Execution
- Adverse Event Monitoring

WP2: Business Model & Road maps

Reference Implementation of the Platform

Reference sites

WP8: Liaison, Communication, Dissemination & Training Activities

CDISC Asia Pacific Interchange, 21-Feb-2013, Singapore
Consortium Building 2009-2010

- IMI Call for projects October 2009
- 30 proposals received by February 2010
- EHR4CR consortium selected by independent experts named by European Commission and EFPIA
- Full Consortium of 34 private and public partners developed a full project proposal submitted to IMI in June 2010
- Project approved by IMI in August 2010
- Contracts finalization September 2010 to February 2011
- Project Launch March 2011
- The project is coordinated by AstraZeneca and EuroRec acts as managing entity for public partners. Roche acts as deputy coordinator.
Progress 2011

Project start: March 1st 2011
- Kick-off meeting, 3-4 March 2011, AstraZeneca, Göteborg, Sweden

Work Package Group 1: Engagement & Business Model
- Kick-Off Workshop, 5-6 April 2011, Novartis, Basel, Switzerland

Work Package Group 2: Technology Platform & Tools
- Kick-Off Meeting, 4-6 May 2011, Sanofi, Paris, France

Work Package Group 3: Pilots
- Kick-Off Meeting June 23-24, 2011 at Novartis in Basel

Work Package Group 4: Management
- Workshop for developing a integrated project plan for the first 18th months, May 16th (Finalised on June 7th)

Alignment: Steering Committee, Ethics and all Work Packages
- Meeting on 18-21 October 2011, Sanofi, Frankfurt, Germany
Progress 2012

March 2012 (after one year)

- All Work Packages Deliverables on time, on budget
- Phase 1 Requirements Finalized, Platform Build starting

Legal and Ethical Governance Workshop

- June 2012, TMF, Berlin

“Hackatons” = IT Integration Workshops

- June @ APHP, Paris and September 2012 @ Univ. Münster

Pilot Preparation Workshop

- September 2012, Univ. Münster

Scenarios 2 and 3 Requirements Workshop

- October 2012, APHP and Sanofi, Paris

First Pilot run for Scenario one: Protocol Feasibility

- October-November 2012

Steering Committee Meeting

- 4-5 November 2012, Novartis & Roche, Basel
Outlook 2013

- Second pilot run for Protocol Feasibility
  - January 21 – February 1
- Protocol Feasibility Demonstrator finalized
  - March 2013 (on schedule: 2 years after start)
- Finalize Patient Recruitment Scenario
- Run Patient Recruitment Pilot
- Finalize Scenarios for
  - Clinical Data Capture
  - Automated Adverse Event Reporting
Summary

- **EHR4CR** will move beyond the current state-of-the-art by combining previously isolated informatics progress
  - E.g. semantic interoperability, privacy enhancing techniques, and standards) with an entirely new approach to reusing EHR data for supporting medical research, underpinned by a comprehensive business model for governance, acceptance, adoption and sustainability.

- The project will demonstrate the viability and scalability of the **EHR4CR business model** through pilots
  - E.g. platform services designed for protocol feasibility, patient recruitment, and clinical trial data capture.

- The IMI EHR4CR project runs over 4 years with a budget of €16 million and involve 34 recognised European academic and industrial partners.

- The EHR4CR is the largest public-private partnership to date with the goal to tie interoperability aspects together to provide adaptable, reusable and scalable solutions and be the first step to a pan-EU capability for clinical research with integrated interoperability for clinics across countries in Europe.
General Information

- The IMI EHR4CR project runs over 4 years (2011-2014) with a budget of €16 million and involves 33 partners (academic and industrial).
- The EHR4CR project is one of the largest public-private partnerships aiming at providing adaptable, reusable and scalable solutions (tools and services) for reusing data from Electronic Health Record systems for Clinical Research.
- Electronic Health Record (EHR) data offer many opportunities for the advancement of medical research, the improvement of healthcare, and the enhancement of patient safety.

Issues

- "A sustainable business model for using EHR data for research purposes in Europe is required".
- Gaps exist due to:
  - the variety of existing (incomplete) technical solutions
  - regional diversity and individual approaches
  - the lack of a common viable business model across Europe

http://www.ehr4cr.eu/
Thank you for your attention!

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