A pan European platform for the Re-use of EHRs
The EHR4CR Champion Programme

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TRANSFoRm
Outline

- The EHR4CR project & objective
- Scaling up towards a pan-European platform supporting clinical research
  - Champion Program with 7 Efpia companies and Custodix as the first EHR4CR service provider
  - Governance via the European Institute for Innovation through Health Data

www.ehr4cr.eu
The EHR4CR project

- **EHR4CR** – Electronic Health Records for Clinical Research
  - 4+1 year project (2011-2016), 35 partners, budget >17M€

- **Objectives & Scope**
  - Provide a platform for **trustworthy re-use of EHR data** to support innovation in clinical research and healthcare operations.
  - Unlocking **Health data** for optimising clinical trials.

- **Status**
  - Extended into 2016 for making the transition to a sustainable platform.
  - Initiating a **Champion Programme**, connecting hospitals to an operational platform, building up experience with pharma.
  - The **European Institute for Innovation through Health Data** – an independent governance body.

For more information: [http://www.ehr4cr.eu/](http://www.ehr4cr.eu/)
The EHR4CR objective

- Research and develop a trustworthy service platform able to unlock clinical information stored in EHRs for improving clinical research
  - Clear focus on three (3) relevant use cases

- Enabling protocol testing with real world data in potential trial sites rather than with guestimates.
- Speeding up recruitment by making EHR data searchable for investigators and establishing a unified communication path between sponsors and sites.
- Facilitating EHR data extraction for applications used during trial execution (e.g. prefilling of CRFs and of SAE reports).
Brings together key stakeholders

35 participants including pharmaceutical industry, academia, hospitals, SMEs, patient associations and public authorities

11 hospital sites

10 Pharma Companies

Advisory boards and other experts
Status of the EHR4CR project...

Project pilots
- Feasibility & Recruitment
- 12 studies, different therapeutic areas
- De-identified data from >500k patients over 11 sites

Pilot hospitals
- 11 major hospitals in 5 countries.
  - Germany (WWU, FAU)
  - France (AP-HP, U936)
  - UK (UoD, UoG, UoM, UCL, KCL)
  - Switzerland (HUG)
  - Poland (MuW)

Operational pan-European platform
- EHR4CR Champion Program
- Permanent network of clinical sites giving access to millions of patients in close to real time
- Trial design and recruitment supported by real-world evidence on a European scale
- Governance by the with European Institute for Innovation through Health Data

Scaling up the solutions!
- Technology
- Operations
- Governance
- Sustainability

EHR4CR - IMI research project
SCALING UP: TOWARDS A PAN-EUROPEAN PLATFORM SUPPORTING CLINICAL RESEARCH
2015 – 2016 Champion Programme

“A multi-stakeholder collaboration aiming to accelerate and ensure the future of clinical research in Europe.”

The Champion Programme serves to

- Further validate and improve technology
- Define (refine) the rules of engagement for a sustainable ecosystem
- Start building a network of hospitals
- Engage with European Institute for Innovation through Health Data which aims to govern the EU data re-use ecosystem
Value for pharma & research organisations

Clear value proposition for research organisations

Better trial design
- Optimising clinical protocol design will reduce costly corrective measures such as protocol amendments, late addition of new trial countries or sites.

Quicker achieved recruitment targets
- Computer assisted patient identification tools result in accelerated identification, fewer patients missed,…

Overall increased efficiency
- Further automation and optimisation of the clinical trial process by use of a central platform result in an overall increased efficiency.

Improve trial success rate
- The number of trials failed due to failure to recruit will be reduced.

Reduce cost
- Less manual work, less corrective measures, etc. lead automatically to a decrease in total trial cost. Pharma will also avoid the expense and time and effort of opening trial sites which will not yield enough patients.

Increase revenue
- The platform will reduce the elapsed clinical trial time, which in the end translates into a quicker time to market and thus additional revenue (increased time on market under patent protection).
Value for hospitals

Value generated at multiple levels: clinical research, overall care provision and revenue

Better patient care
More patients will get access to trial drugs and innovative care pathways at no additional cost to the hospital.
Physicians participating in clinical trial are in general more up to date with medical science.

Increased income
Cutting cost will no longer be sufficient to deal with the overall healthcare budget decrease. Hospitals need to search for new revenue streams, the clinical trial platform will help them to attract more trials and thus income.

Access to tools
Participation to the clinical trial platform includes free access to a set of tools to explore and analyze patient data.
Anyone familiar with the cost of clinical IT systems understands the value of this benefit.

Better quality data
The clinical trial platform stimulates hospitals to focus on the quality of their data. Improved monitoring, performance benchmarking, reporting and management (e.g. reimbursement coding) drives optimization of patient care and improved internal management.

Enhanced reputation
Hospitals and their physicians participating in more clinical trials will get greater visibility in scientific community. Which on its turn will attract more research (trials), top-class physicians and more patients (once reputation gets picked up by the media).
Governing the EHR4CR ecosystem

The needs…

Educate and train research and ICT staff
Accredit staff and organisations
Certify service providers and EHR systems
Oversee and audit governance & security

… shared by multiple research projects
i~HD has been formed because a complementary, neutral and not-for-profit organisation is needed

- to play a central role in governing and expanding a trustworthy health data driven ecosystem including EHRs and EHR4CR platform services;
- to act as a connector between health care and clinical research standards, that are presently developed in silos and impair the interoperability and pooling of health data for research;
- to promote the adoption of healthcare standards and of data quality, to enable more effective, safer and better integrated healthcare;
- to promote to society the importance of using health data for research, to improve efficiency through reduced duplications, delays, costs enhance speed and efficiency in clinical studies.
CLOSER LOOK AT CHAMPION PROGRAM
Initial services

Starting with a simple service offering for Research Organisations

- Initial focus is on building the network and introducing the technology in hospitals
- The two services should be able to demonstrate the value of this initiative to all stakeholders
- Piloting new services will be done as the need arises
- The service offering will be expanding as the technology matures

Protocol feasibility services
- **Optimise** protocol eligibility criteria by **instantaneously** testing them out in multiple sites in various countries
- Directly **identify the countries and specific sites** to approach for participation

“Protocol Feasibility services” cover a broader application domain than expected from the name. The service allows patient populations, hospitals and databases to be remotely and securely clinically assessed (distributed query). These services are invaluable for **trial design**, **site selection**, **pharmaco-economics**, etc.

Trial recruitment services
- Distribute **trial protocols** over multiple sites in a uniform way
- **Track recruitment progress** in real time
- **Optimal recruitment due to tools** provided to hospitals
The EHR4CR platform – dataflow

HOSPITAL/DATA PROVIDER

ETL

Recruitment Workbench

Trial Candidates

#Counts >>

Recruitment Progress >>

RESEARCH CENTRE
e.g. pharmaceutical company

#Counts >>

Protocol feasibility service

<< Queries

<< Clinical Trial

Patient recruitment service
Evolution towards a mature platform service

Custodix commits to being an EHR4CR service & platform provider

Other know-how & experiences
InSite central platform screenshot

PFS Authoring criteria (queries)

Clinical concept quick search

Clinical concepts to design queries with (ICD, LOINC, SNOMED, etc.)

Designing feasibility queries (i.e. eligibility criteria)
InSite central platform screenshot

PFS viewing results

Country summary

Site summary
EfpiA Champion Programme summary

The Champion Programme is designed to provide a low-risk entry for all stakeholders into this innovative approach to efficient use of Real World Data. It is a key step in building the EHR4CR envisaged ecosystem of network of hospitals, service providers and pharma users.

- **Objectives**
  - Validating and further improving the platform together with Custodix (first Service and Platform Provider) by connecting 15-30 hospitals during 2015-2016.
  - Define (refine) the rules of engagement for a sustainable ecosystem (including defining the governance role of the European Institute of Innovation in Health Data).

- **Scope**
  - Evaluate platform services for Protocol Feasibility, Patient Identification & Recruitment across multiple therapeutic areas (TAs) with a broad geographical coverage in Europe and reaching out to the US.

- **Outcome**
  - A proven ecosystem for acceleration of clinical research through Real World Data, ready to further expand geographically and data source wise (registries, research data bases, PHR, mHealth apps data, …)

- **Status**
  - 7 EFPIA Champion companies (Amgen, AZ, Bayer, GSK, Janssen, Roche, Sanofi) constitute the core EfpiA Champions
  - Initiation autumn 2015
First important steps from an European Private Public R&D project...towards an entirely new collaboration model that have a potential to become a game changer in the clinical research world…

### Vision
To be the trusted gateway to eHealth information for research and knowledge discovery to transform healthcare worldwide.

### Values
- Provide flexible, scalable and interoperable solutions
- Ensure full compliance with relevant ethical, legal, regulatory, and privacy protection standards and policies
- Deliver innovative, customer-focused and sustainable value-added services
- Optimize healthcare connectivity by enabling adoption, collaboration, accountability and transparency

### Mission
Delivering sustainable value-added solutions for the trustworthy re-use of eHealth data and information to improve global clinical research.
Thank You!

Contact us: comms@ehr4cr.eu

Developing a platform and services to re-use EHR data

Deployment of a sustainable network

Overcoming barriers that limit access to EHRs for research

Driving innovation in research and healthcare operations

Supported by

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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.