



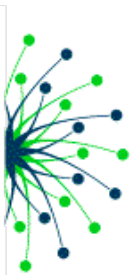
A joint undertaking between Academia & Industry



Innovative Medicines Initiative

Overview of the EHR4CR project

Electronic Health Record systems for Clinical Research



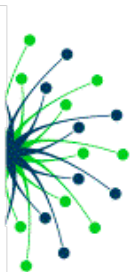
Sławomir Majewski – The Medical University of Warsaw

Electronic Health Records for Clinical Research

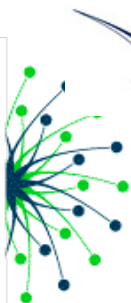


Innovative Medicines Initiative

- The **IMI EHR4CR project** runs over 4 years (2011-2014) with a budget of +16 million €
 - 10 Pharmaceutical Companies (members of EFPIA)
 - 22 Public Partners (Academia, Hospitals and SMEs)
 - 5 Subcontractors
 - One of the largest public-private partnerships
- Providing adaptable, reusable and scalable solutions (tools and services) for reusing data from EHR systems for Clinical Research.
- EHRs offer significant opportunity for the advancement of medical research, the improvement of healthcare, and the enhancement of patient safety.



Partners



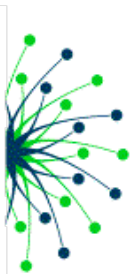


There is a consensus that:

“A sustainable model for using EHR data for research purposes in Europe is required “

However, different gaps exist due to:

- variety of existing technical solutions
- regional diversity and non-standard approaches
- lack of a common working model across Europe





The expected outputs of the project are:

- **Requirements specification**
 - for EHR systems to support clinical research
 - for integrating information across hospitals and countries
- **New EHR4CR Model**
- **New EHR4CR Technical Platform**
 - a set of tools and services



The Project Outputs also involve: 

- **Protocols for validating the solutions:**

- ✓ **for different scenarios**

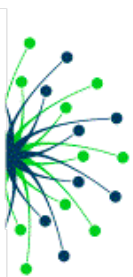
- ✓ (e.g. protocol feasibility, patient recruitment...)

- ✓ **across different therapeutic areas**

- ✓ (e.g. oncology)

- ✓ **and across several countries**

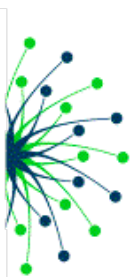
- ✓ (therefore under different legal frameworks)



Main EHR4CR Scenarios include:



- Clinical protocol feasibility studies
- Patient identification and recruitment
- Clinical trial implementation
- Adverse event reporting

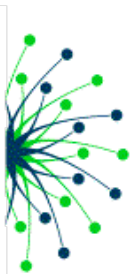


Disease Areas planned to be included in different Study Sites (=Pilots) are related but not limited to:



- Oncology
- Neuroscience
- Diabetes
- Cardiovascular diseases
- Respiratory diseases

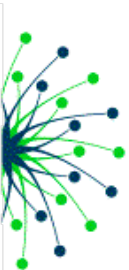
(Disease areas differ between particular study sites)



Potential Benefits include:



- Accelerated adoption of a more **harmonised** approach throughout Europe
 - Strengthened **collaboration** in research across Europe, and...
 - Improved **cost effectiveness** of research and clinical trials
-



Socio-economic impact



EHR4CR represents a multi-disciplinary approach with benefits for:

- *patients*
- *clinical researchers*
- *hospital data providers*
- *EHR system vendors*
- *participating EFPIA companies*
- *benefits for the IMI program (the IMI key objectives)*

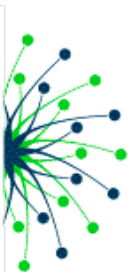


Expected Impact for patients:



Patients

- Faster drug to market
- Enhance access to drug information
- Improved personalized treatment capability



Examples of benefits



From General Healthcare perspective there should be:

- Significant facilitation of the use of EHR data to allow more efficient management of public health issues
- Better co-ordination between care providers resulting in more efficient diagnosis and safer treatment

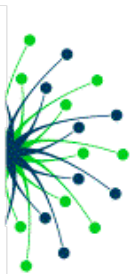
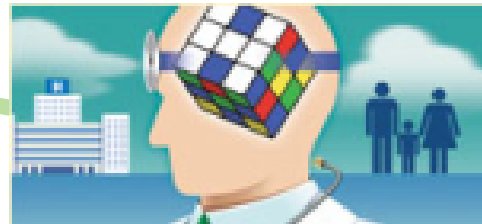


Expected Impact for:



Providers/Health Community

- Enhance patient safety
- Improve quality of healthcare
- Reduce healthcare costs





From Academic perspective:

- New tools and services to
 - plan and
 - conduct academic trials (investigator-initiated trials), and...

- Facilitate comparative effectiveness research



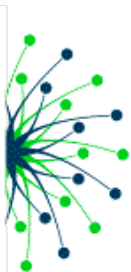
Examples of benefits



From Pharmaceutical perspective:

- Improved speed and quality of
 - patient recruitment process and
 - study design by
 - accurate understanding of real patient populations

- As well as additional support to conduct observational and outcomes research studies in real-world settings

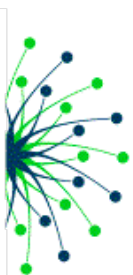


Expected Impact for pharma industry:



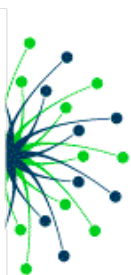
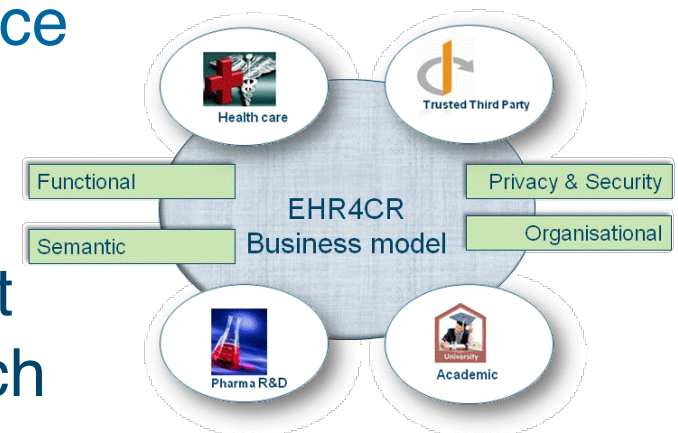
Pharma industry

- Improve targeting the right patient population & indication
- Increase number effective sites & enrollment rate, shorten trial time & cost
- Enhance patient safety



The EHR4CR model will also:

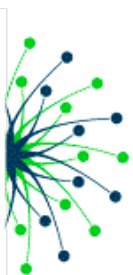
- Define operating procedures and service requirements
- Provide a framework to define different roles in using EHRs for clinical research
- Define a plan for international cooperation and for funding future developments





EHR4CR platform will also support:

- feasibility
- design
- progress of clinical studies
- long-term follow-up of patient populations





EHR4CR platform will:

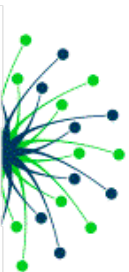
- Enable trial eligibility and recruitment criteria to be expressed in ways that permit searching for relevant information across EHR systems





EHR4CR platform will:

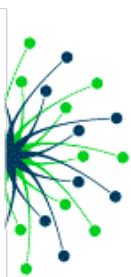
- Provide harmonised access to multiple heterogeneous clinical systems and integration with clinical trials infrastructure products
- Facilitate
 - improvements of data quality
 - reducing redundant data capture



Key principles



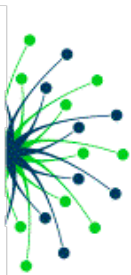
- 1. The EHR4CR platform **will not** hold a centralised repository of patient level EHR data across the network of registered hospitals. It will hold queries, result sets and audit logs.
- 2. Patient level data **will not** cross national boundaries via the EHR4CR platform. Only aggregated result sets will be transferred into the platform.
- 3. Patient level data **will remain** local to each hospital, or to each hospital plus its local research environment.
- 4. EHR4CR components and services that analyse patient level data and generate patient level extracts of data **will be deployed** locally at each site and operate exclusively at a local level to enable identification of potential patients and, if they are suitable, their recruitment.



Key principles



- **5. Aggregated result sets** (patient counts) will be communicated from each hospital site to the central platform for onward propagation to research entities to refine clinical research protocols and to identify sites which are suitable for a clinical trial.
 - In order to validate the platform (only during the research phase of EHR4CR) these counts may be compared with the actual numbers screened and recruited for similar historic trials.



Key principles



- **6.** Once finally deployed and in real use, platform will hold a register of research entities and hospitals with collaborative relationships (possibly with which specific departments within each hospital) and will only forward aggregated data to research entities in accordance with those relationships.
- **7.** An EHR4CR Code of Practice for all users of the EHR4CR platform will restrict the use of aggregated query information for mutually predefined and approved purposes such as protocol feasibility and refinement.
 - *Use of the EHR4CR platform to analyse hospitals' prescribing practices or outcomes for sales/marketing or benchmarking purposes will not be permitted*





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