A joint undertaking between Academia & Industry

Innovative Medicines Initiative

Overview of the EHR4CR project

Electronic Health Record systems for Clinical Research

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The problem
(as addressed in the 2nd IMI call 2009 / Topic 9)

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

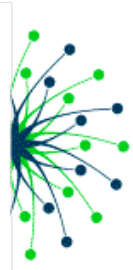
- **Gaps exist due to:**
  - the variety of existing (incomplete) technical solutions
  - regional diversity and individual approaches
  - the lack of a common viable business model across Europe

Electronic Health Records for Clinical Research

- 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.



EHR4CR
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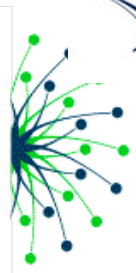
Partners

Westfälische Wilhelms-Universität Münster



Project Objectives

- To promote the wide scale re-use of EHRs to accelerate regulated clinical trials, across Europe

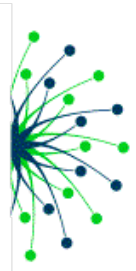
- EHR4CR will produce:
  - **A requirements specification**
    - for EHR systems to support clinical research
    - for integrating information across hospitals and countries
  - **The EHR4CR Technical Platform** (tools and services)
  - **Pilots** for validating the solutions
  - **The EHR4CR Business Model**, for sustainability

The EHR4CR Scenarios

- Protocol feasibility
- Patient identification recruitment
- EHR-EDC integration
- Pharmaco-vigilance

- across different therapeutic areas
  (oncology, inflammatory diseases, neuroscience, diabetes, cardiovascular diseases etc.)

- across several countries (under different legal frameworks)



Examples of benefits

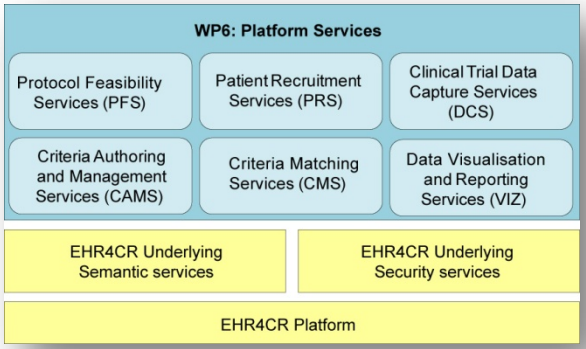
- **Academic perspective**
  - Provide tools and services to better plan and conduct academic trials (investigator-initiated trials)
  - Facilitate comparative effectiveness research

- **Pharmaceutical perspective**
  - Improve speed and quality of the 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

- **General Healthcare perspective**
  - Significant facilitation of the re-use of EHR data to allow more efficient management of public health issues
  - Closer co-ordination between care providers and patients, resulting in safer and more evidence-based diagnosis and treatment

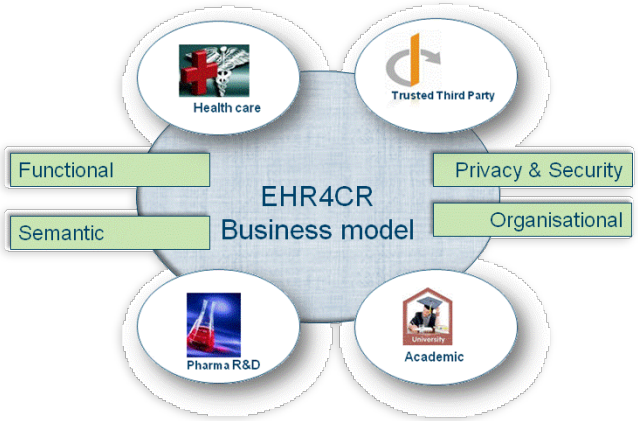
EHR4CR Technical Platform

- 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 to confidentially initiate participation requests via the patients' authorised clinicians
- Provide harmonised access to multiple heterogeneous and distributed 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



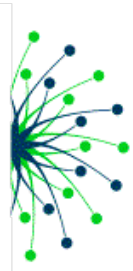
EHR4CR Business model

- 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



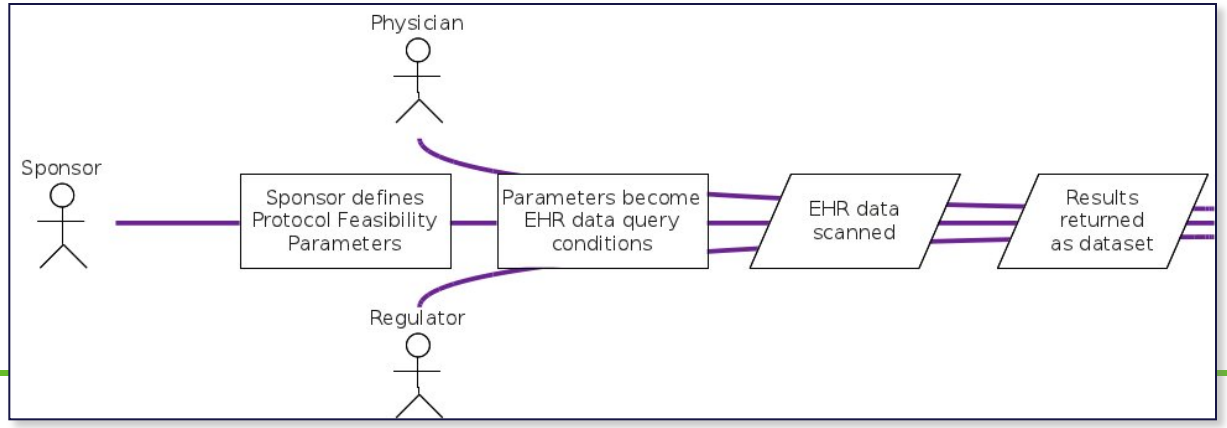
Year 1 focus: Protocol Feasibility

- The study feasibility process
  - Finding out if a protocol “viable”
  - Fine tuning the eligibility criteria to **optimize trial design**
- EHR4CR platform services
  - **Estimate a target patient population** that matches a set of criteria, by interrogating a multitude of different sites
  - Aid in **fine-tuning the eligibility criteria**
    - By returning information such as the geographical (and site) spread, age distribution , … of matching patients
    - Determine most and least discriminating criteria,
    - Compare different I/E criteria sets
    - Etc.



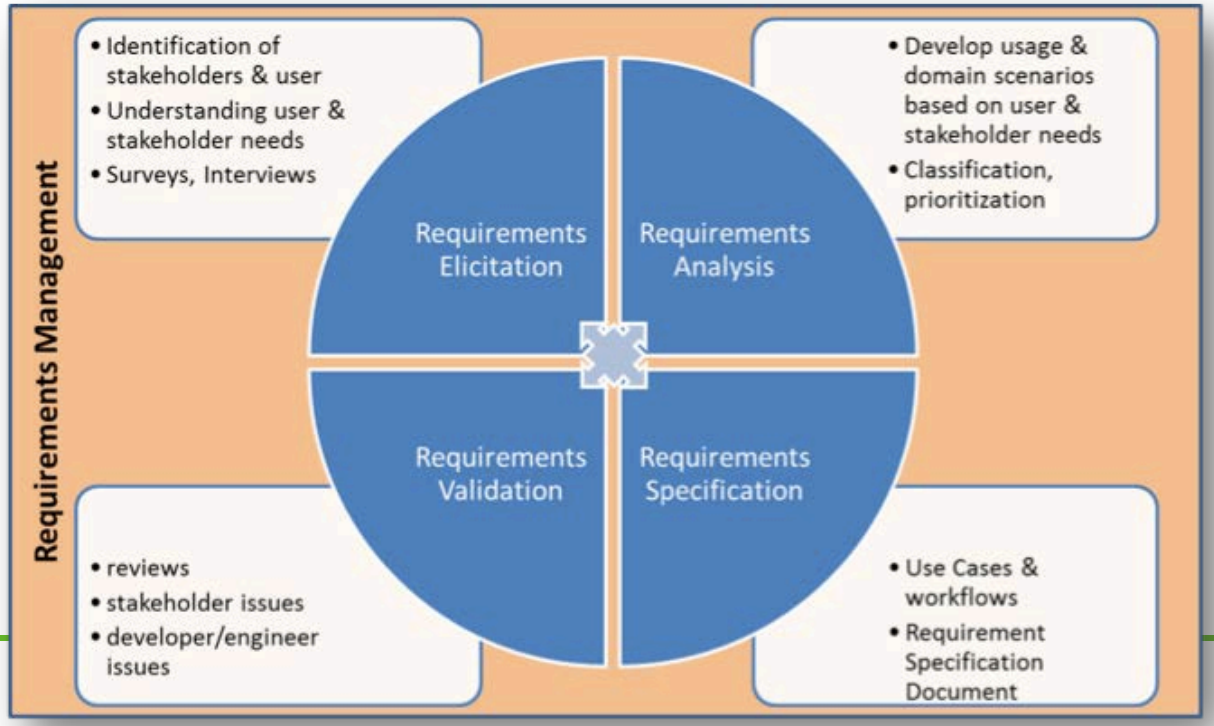
First year results (1)

- Gathering the viewpoints of critical decision makers
  - The wide-scale acceptability and positioning of EHR4CR is essential for its success. Pilot work was done with different from public bodies and ethics committees in Scotland, and used to develop a set of generic materials for use throughout Europe.
- Developing the protocol feasibility scenario.
  - Through detailed engagement with protocol managers within Pharma and the wider clinical research community, workflows were documented for establishing the feasibility of a trial protocol.

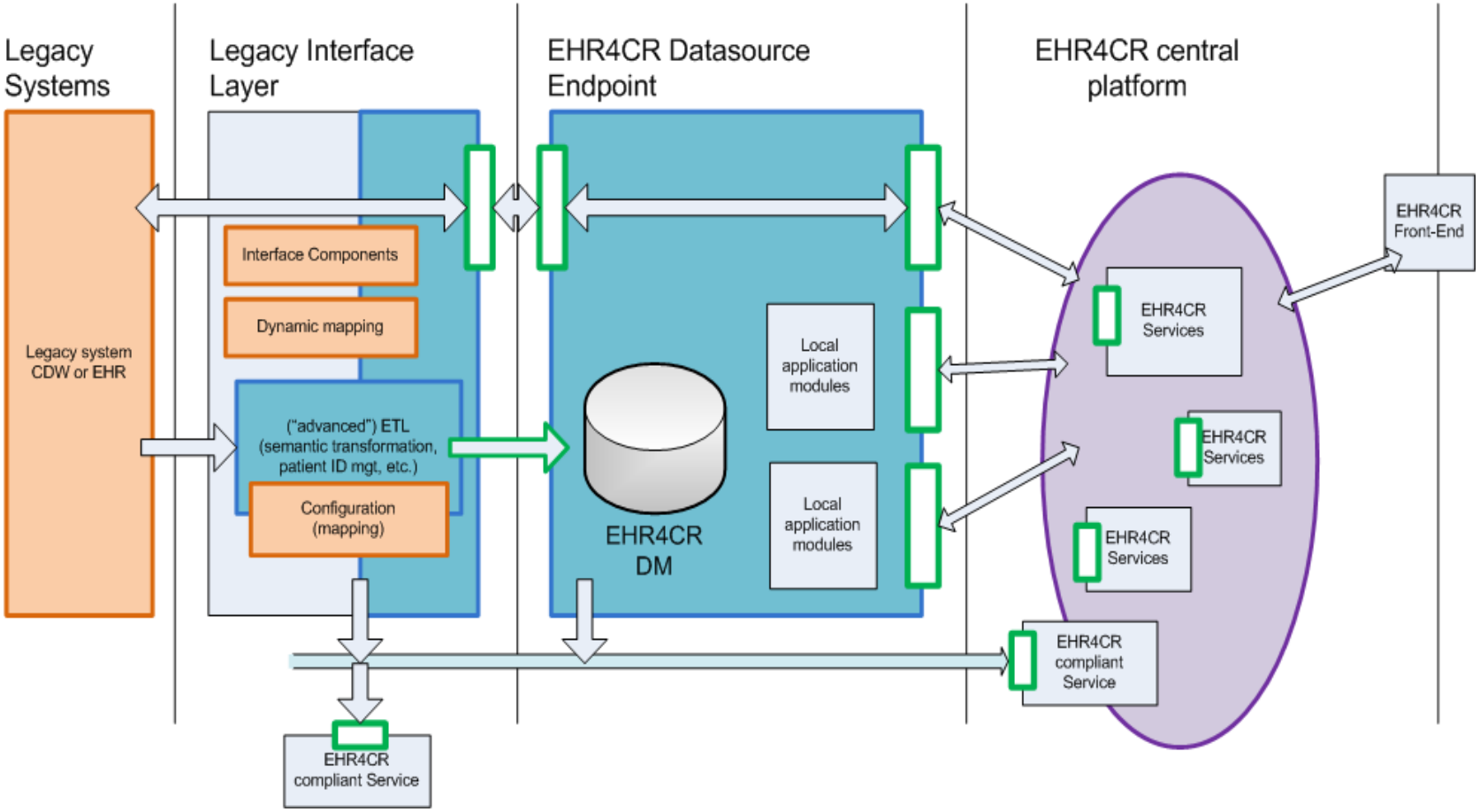


First year results (2)

- A formal and validated Software Requirements Specification
  - Requirements were informed by the Scenario workflow, supplemented through interviews with pharma & academic experts.
  - Contains ~75 use cases, over 200 requirements, a first user interface mock-up and a set of generic non-functional requirements.

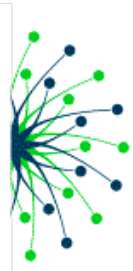


EHR4CR platform architecture



First year results (3)

- An inventory of pilot site EHR data items
  - including a concept for local interfaces at the Hospital sites.
- A top list of data elements has been identified containing 81 EHR data elements, by comparing commonly used eligibility criteria by the EFPIA partners with available data elements in the EHR/CDW and CDMS at the pilot sites.
  - The current listing represents the first version of the data inventory.
  - To validate and refine the data inventory a data export at all pilot sites has been performed.
  - This has delivered information on the availability of the data elements at the sites.

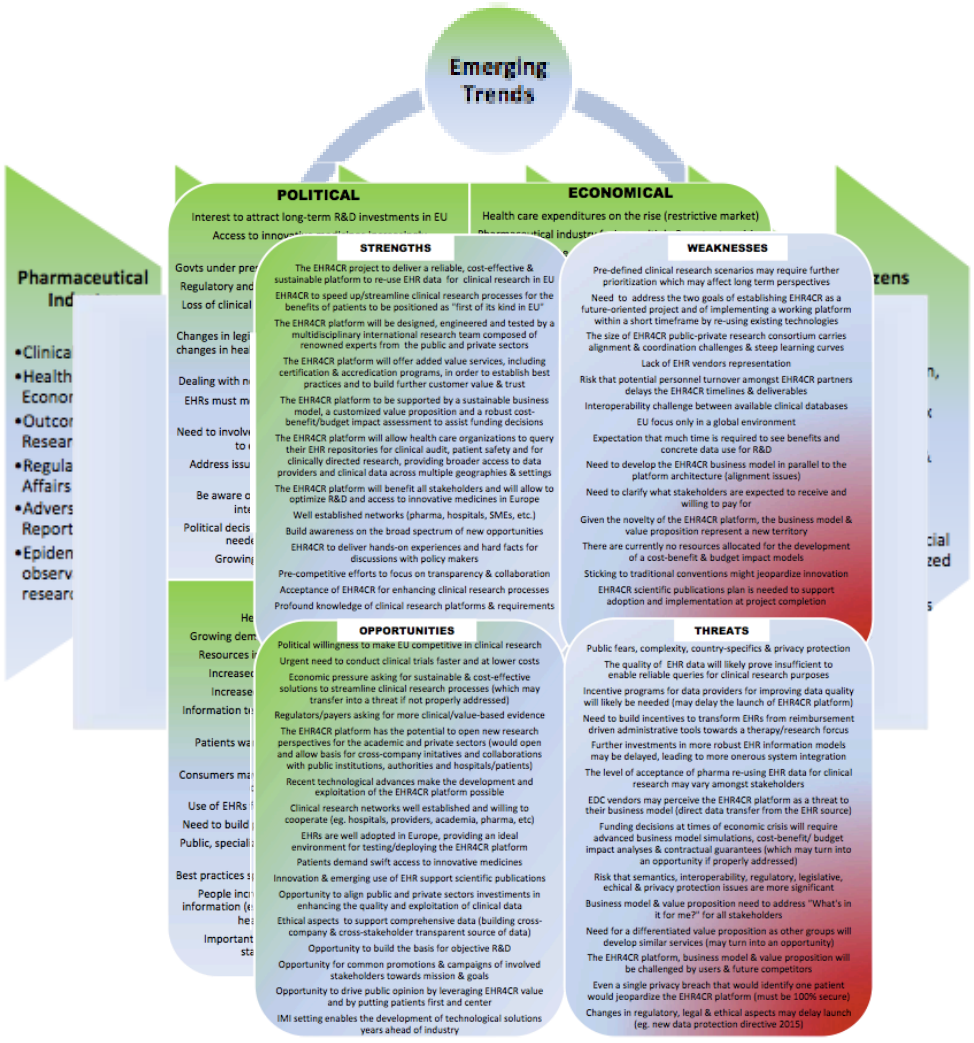


Frequently occurring data items

37	Laboratory Findings	Date / Time of Laboratory Finding	*14.7.2011, 10.00*
38	Laboratory Findings	Total Cholesterol in serum (LOINC 2093-3)	*240 mg/dl*
71	Medication	Verbatim Drug name	*acetylsalicylic acid*
72	Medication	Dosage	*100 mg/day*
73	Medication	Route	*p.o.*
74	Medication	Medication start date	*06/06/2011*
75	Medication	Medication end date	*06/07/2011*
76	Scores / Classification	Date of Score / Classification	*14/07/2011*
77	Scores / Classification	Karnofsky-Score	*80%*
78	Scores / Classification	ECOG-Performance Status *(Eastern Cooperative Oncology Group)*	*2*
79	Scores / Classification	TNM-classification	*T3 N1 M0*
80	Scores / Classification	NYHA-Status *(New York Heart Association)*	*NYHA II*
81	Scores / Classification	RECIST	*CR (complete remission)*
50	Laboratory Findings	Alkaline Phosphatase (LOINC 6768-6)	*100 U/l*
51	Laboratory Findings	SGOT (AST) in serum (LOINC 1920-8)	*10 U/l*
52	Laboratory Findings	SGPT (ALT) in serum (LOINC 1742-6)	*20 U/l*
53	Laboratory Findings	Total Bilirubin in serum (LOINC 1975-2)	*1 mg/dL*
54	Laboratory Findings	Direct Bilirubin in serum (LOINC 15152-2)	*0,1 mg/dL*
55	Laboratory Findings	Total Protein in serum (LOINC 2885-2)	*7 g/dl*
56	Laboratory Findings	HbA1c Blood (LOINC 4548-4)	*5%*
57	Laboratory Findings	CRP in serum (LOINC 1988-5)	*1 mg/dL*
58	Laboratory Findings	PTT Blood (LOINC 3173-2)	*30 s*
59	Laboratory Findings	INR Blood (LOINC 6301-6)	*1*
60	Laboratory Findings	Haemoglobin Blood (LOINC 718-7)	*14 g/dL*
61	Laboratory Findings	Haematokrit Blood (LOINC 4544-3)	*40%*
62	Laboratory Findings	Platelets Blood (LOINC 777-3)	*200 * 10E9/l*
63	Laboratory Findings	Erythrocytes (LOINC 789-8)	*5 * 10E12/l*
64	Laboratory Findings	Leukocytes (LOINC 6690-2)	*5 /nl*
65	Laboratory Findings	Neutrophils Blood (LOINC 770-8)	*60%*
66	Laboratory Findings	Lymphocytes Blood (LOINC 736-9)	*30%*
67	Laboratory Findings	Eosinophiles Blood (LOINC 713-8)	*3%*
68	Laboratory Findings	TSH in serum (LOINC 11579-0)	*0,8 mIU/l*
69	Laboratory Findings	Beta HCG in serum (LOINC 21198-7)	*5 U/l*
70	Laboratory Findings	Cardiac troponin T (LOINC 6598-7)	*0,05 ug/L*

Value proposition - example components

- Business Model Environment Matrix
- Market Segmentation
- Business Model Template
- PEST Analysis Matrix
- SWOT Analysis Matrix



EU EHR4CR e-Survey
Respondents

- Total of 203 EU respondents
  - 78 internal
  - 125 external
- Sub-groups
  - Academic Centres (42)
  - Pharma industry (67)
  - IT providers & EHR/EDC vendors (38)
  - Clinical research organizations/sites (28)
  - Patient advocacy groups (4)
  - Health agencies (4)
  - Other relevant sectors (20)
- Highly experienced
  - Median > 15 years of experience

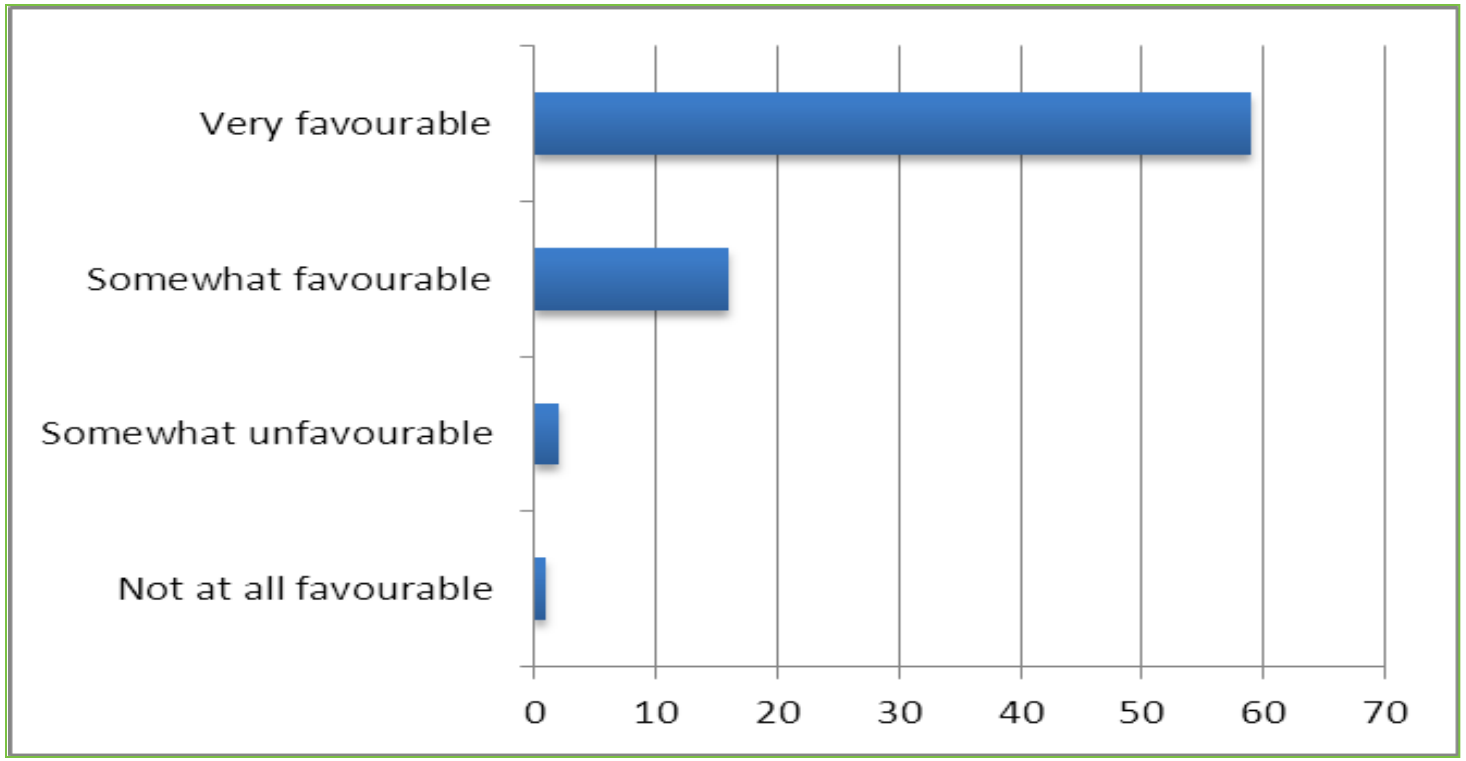
- Total of 23 EU Countries

- Primarily from
  - UK (39)
  - Germany (36)
  - Belgium (24)
  - Sweden (21)
  - Switzerland (15)
  - France (14)

EHR4CR e-Survey Results

Key Opportunities

- High percentage of respondents were in favour of re-using EHR data for research



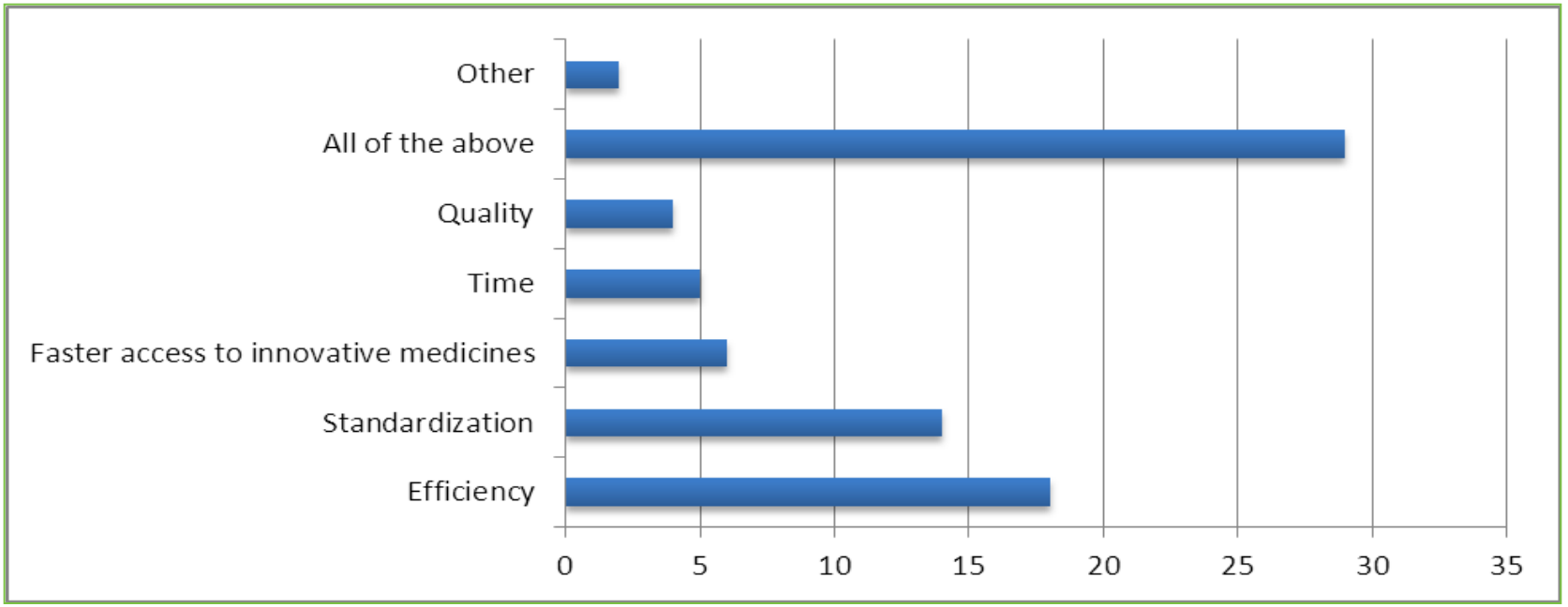
EHR4CR e-Survey Results
Key Challenges

- Nearly all respondents rated the following aspect as the strongest driving forces and challenges to overcome for implementing EHR4CR services
  - Compliance with legislative, regulatory ethical and privacy protection requirements
  - Systems interoperability
  - Demonstrating value for money
- Other key challenges
  - Gaining acceptance from patients and all stakeholders perceived the greatest hurdle (93% respondents)
  - Delivering high quality services in real life settings
  - Developing a platform that is flexible and which can address multiple clinical research scenarios

EHR4CR e-Survey Results

Expected Benefits

- Improved efficiency perceived as the most important gain from EHR4CR services, followed by standardization.
  - However, a higher proportion of respondents stated that improved efficiency, standardization, faster access to innovative medicines, time optimisation and quality were all equally essential expected benefits of the EHR4CR platform



EHR4CR e-Survey Results
Expected Benefits

- Perceived most distinctive advantages of the EHR4CR platform to **patients** are:
  - Faster access to safe and effective medicines (75%)
  - Improved patient safety from early detection and reporting of adverse events (75%)
- Similar high rankings across all respondents.

Acknowledgement & publication

iHealth Connections Volume 1 Issue 2, December 2011 at
http://www.touchbriefings.com/ebooks/A1v2rp/ihealth12/resources/1.htm

Business Strategy

Case Report from the EHR4CR Project—A European Survey on Electronic Health Records Systems for Clinical Research

Dipak Kalra,[1] Andreas Schmidt,[2] HWW Potts,[1] Danielle Dupont,[3] M Sundgren[4] and Georges De Moor,[5] on behalf of the EHR4CR Research Consortium

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