



Innovative Medicines Initiative

Overview of the EHR4CR project Electronic Health Record systems for Clinical Research

Dipak Kalra UCL on behalf of the EHR4CR Consortium





- "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.





Partners







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







- 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 71	Medication	Verbatim Drug name	acety/salicylic 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/I
51	Laboratory Findings	SGOT (AST) in serum (LOINC 1920-8)	10 U/I
52	Laboratory Findings	SGPT (ALT) in serum (LOINC 1742-6)	20 U/I
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/I
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/I
69	Laboratory Findings	Beta HCG in serum (LOINC 21198-7)	5 U/I
70	Laboratory Findings	Cardiac troponin T (LOINC 6598-7)	0,05 ug/L

Value proposition - example components

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 Clinic Healt Econd

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

			~				
				ECONOMIC			
	1	POLITICAL		ECONOMICA	4L		
	Interest to at	ct long-term R&D investments in EU Health care		xpenditures on the rise (restrictive market)			
Access to		STRENGTHS	Car	cal industr		WEAKNESSES	
naceutical	Govts under pre-	The EHR4CR project to deliver a relia sustainable platform to re-use EHR data	able, cost-effective & for clinical research in EU	Pre-defined clin prioritization	ical research scenarios may which may affect long term	require further perspectives	zens
ď	Loss of clinical	EHR4CR to speed up/streamline clinical r benefits of patients to be positioned a	research processes for the s "first of its kind in EU"	Need to addres future-oriented pro	ss the two goals of establishi roject and of implementing a	ing EHR4CR as a working platform	
	Changes in legi changes in hea	The EHR4CR platform will be designed, engineered and tested by a multidisciplinary international research team composed of renowned experts from the public and private sectors		a within a short timeframe by re-using existing technologies The size of EHR4CR public-private research consortium carries alignment & coordination challenges & steep learning curves			
h	Dealing with n	The EHR4CR platform will offer added value services, including certification & accredication programs, in order to establish best practices and to build further customer value & trust		Lack of EHR vendors representation Risk that potential personnel turnover amongst EHR4CR partners			
or or	EHRs must m	The EHR4CR platform to be supported by a sustainable business model, a customized value proposition and a robust cost- benefit/During timeart assessment to access funding decisions		delays the EHRACK timelines & deliverables Interoperability challenge between available clinical databases EII fears each is a alabal orarisement			
ir	Need to involve to e	The EHR4CR platform will allow health care organizations to query their EHR repositories for clinical audit, patient safety and for		Expectation that much time is required to see benefits and concrete data use for R&D			
а	Address issu	clinically directed research, providing broader access to data providers and clinical data across multiple geographies & settings		Need to develop the EHR4CR business model in parallel to the platform architecture (alignment issues)			
5	Be aware o	The EHR4CR platform will benefit all stak optimize R&D and access to innovative	eholders and will allow to ve medicines in Europe	Need to clarify wi	hat stakeholders are expecte willing to pay for	ed to receive and	
rt	Political decis	Well established networks (pharma, hospitals, SMEs, etc.) Build awareness on the broad spectrum of new opportunities		Given the novelty of the EHR4CR platform, the business model & value proposition represent a new territory			
n	neede	EHR4CR to deliver hands-on experiences and hard facts for		There are currently no resources allocated for the development			
v	Growing	Pre-competitive efforts to focus on tran	sparency & collaboration	Sticking to traditional conventions might jeopardize innovation			
rc		Acceptance of EHR4CR for enhancing cli Profound knowledge of clinical research	inical research processes platforms & requirements	EHR4CR scient adoption and	tific publications plan is need d implementation at project	ted to support completion	
	He	OPPORTUNITIE	s		THREATS		
	Growing dem	Political willingness to make EU competi	itive in clinical research	Public fears, com	plexity, country-specifics & p	privacy protection	<
	Increased	Urgent need to conduct clinical trials fat	ster and at lower costs	The quality o	f EHR data will likely prove i	insufficient to	
	Increase	Economic pressure asking for sustaina solutions to streamline clinical research	able & cost-effective processes (which may	Incentive program	as for data providers for impl	roving data quality	
	Information to	Regulators/payers asking for more clinica	erly addressed) al/value-based evidence	will likely be need Need to build ince	ed (may delay the launch of antives to transform FHRs fro	EHR4CR platform)	
	Datients	The EHR4CR platform has the potential	to open new research	driven administra	ative tools towards a therap	y/research forcus	
	Patients wa	and allow basis for cross-company initat with public institutions, authorities an	ives and collaborations id hospitals/patients)	Further investm may be delayed, The level of access	ents in more robust EHR info , leading to more onerous sy	stem integration	
	consumers ma	Recent technological advances make t exploitation of the EHR4CR plat	the development and tform possible	EDC vendors may	rch may vary amongst stakeh v perceive the EHR4CR platfo	tolders orm as a threat to	
	Use of EHRs	Clinical research networks well establ cooperate (eg. hospitals, providers, ac	lished and willing to ademia, pharma, etc)	their business mo	odel (direct data transfer fror	m the EHR source)	
	Public, specialia	EHRs are well adopted in Europe, p environment for testing/deploying th Patiente demand quift access to in	providing an ideal he EHR4CR platform	Funding decisi advanced busin impact analyses 8	ions at times of economic cri iess model simulations, cost- & contractual guarantees (who propriority if property addres	sis will require -benefit/ budget hich may turn into	
	Best practices s	Innovation & emerging use of EHR suppo	rt scientific publications	Risk that seman	atics, interoperability, regula	tory, legislative,	
	People inco information (e	Opportunity to align public and private enhancing the quality and exploitat	sectors investiments in tion of clinical data	echical & priv Business model &	racy protection issues are mo a value proposition need to a	bre significant address "What's in	
	hea	Ethical aspects to support comprehensis company & cross-stakeholder transpi	ve data (building cross- arent source of data)	Need for a differe	entiated value proposition as	s other groups will	
	Important sta	Opportunity to build the basis for Opportunity for common promotions &	r objective R&D campaigns of involved	develop simil The EHR4CR plati	ar services (may turn into an form, business model & valu	opportunity) e proposition will	
		stakeholders towards missi Opportunity to drive public opinion by le and by putting patients first	on & goals everaging EHR4CR value and center	Even a single pr would jeopardize	ivacy breach that would iden a the EHR4CR platform (must	ntify one patient t be 100% secure)	

years ahead of industry

Emerging

zed

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.

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 Sundgren⁴ and Georges De Moor,⁵ on behalf of the EHR4CR Research Consortium

Centre for Health Informatics and Multiprofessional Education, University College London;
F Hoffman-La Roche, Basel;
Data Mining International, Geneva;
AstraZeneca, Mölndal;
University of Gent

