



eHealth
week

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RIGA, LATVIA

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EHR4CR DEPLOYING INNOVATIVE CLINICAL TRIAL SERVICES

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on behalf of the EHR4CR Consortium

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EHR4CR

- Electronic Health Records for Clinical Research
 - Re-use of EHR data for optimizing Clinical trials
- Mandated by IMI
- One of the largest European public/private partnership projects in this area
- 4-year project (2011-2015)
 - **Extended into 2016** for making the transition to a sustainable platform
- Budget of € >16m

For more information:
<http://www.ehr4cr.eu/>



Brings together key stakeholders



35 participants including pharmaceutical industry, academia, hospitals, small and medium-sized enterprises, patient associations and public authorities

11 hospital sites

Advisory boards and other experts

Background

1993 - 1997

90

New
drugs on
market

2008 - 2012

55

New drugs
on market

Drug innovation is
slowing down...

- Changing landscape
 - Personalised medicine, chronic diseases, ageing population, ...
 - Increasing Regulatory complexity
 - Economic pressure
- R&D cost for new chemical / biological entity ~ **€1.17 billion** (2012)
- *Can Real World Data be a game changer?*

EHR4CR Focus: Clinical Trials

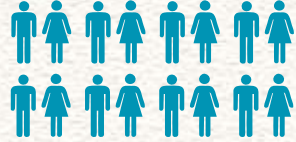
- Incomplete and delayed clinical trials are a sore spot of drug development
 - Waste of costly resources and slow access to new drugs



The percentage of studies that complete enrolment on time:

18% in Europe,

7% in the US¹



50%

of today's clinical trials fail to achieve the target recruitment rate⁴



Almost **half** of all trial delays caused by patient recruitment problems²



1/3 of protocol amendments are avoidable, at a cost of **\$0.5m**

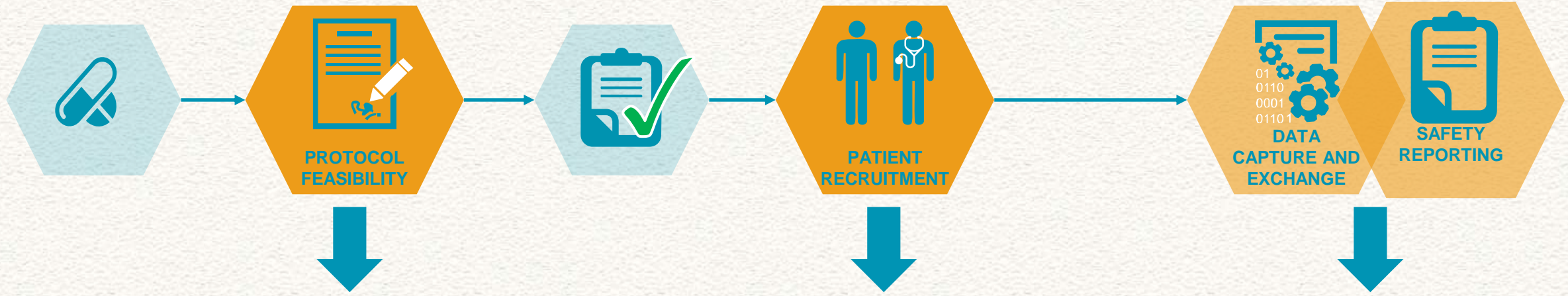


Each day a drug is delayed from market, sponsors lose³ up to **\$8m**

1. State of the Clinical Trials Industry: A Sourcebook of Charts and Statistics, Center Watch, 2008.
2. Study Participant Recruitment and Retention in Clinical Trials: Emerging strategies in Europe, the US and Asia, Business Insights, June 2007.

3. Beasley, "Recruiting" 2008
4. Tufts -<http://clinicalperformancepartners.com/wp-content/uploads/2012/07/Fixing-Feasibility-Final-Jan-2012.pdf>

EHR4CR: re-use of EHR data for Clinical Trial optimisation



- With no, or limited, access to actual patient data, trial design is based on models & discussions with expert clinicians.
- EHR4CR - Enabling **protocol testing with real world data** in potential trial sites!

- EHR4CR aims to speed up recruitment by **making EHR data searchable for investigators & ...**
- ... by establishing a unified communication path between sponsors and sites.

- EHR4CR facilitates **EHR data extraction** for applications used during trial execution (e.g. prefilling of CRFs of SAE reports).

Addressing common challenges for the re-use of health data for clinical research



Interoperability

- **Infrastructure & Syntax**
 - Harmonisation in a **Clinical Data Warehouse** partially through ETL (Extract Transform and Load) and partially through query mapping in the platform connectors.
- **Semantic**
 - Eligibility criteria formalisation using **coding-system agnostic query languages** for representing eligibility criteria.
 - Use of a Common Information Model.
 - CIM to site specific **information models transformation services** provide terminology conversion (e.g. PathLex, ICD-10, SNOMED, LOINC, ATC, ...), unit conversion, concept expansion, etc.



Scalability & Maintainability

- The platform is a **loosely coupled Service Oriented Architecture**, use of industry standards is maximised. This architecture ensures scalability and maintainability through modularity.



Security & Privacy

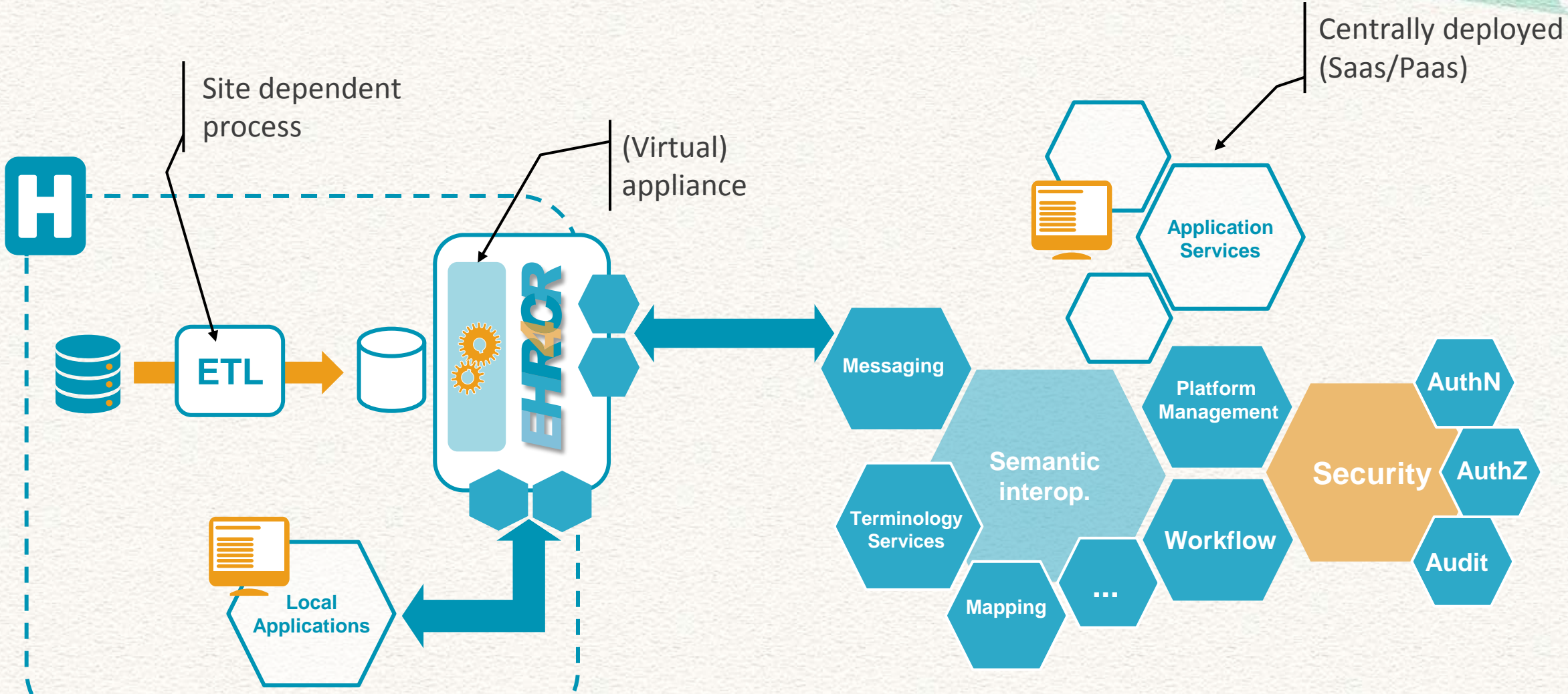
- Security relying on CIAM, an **advanced SOA security framework** designed for healthcare environments.



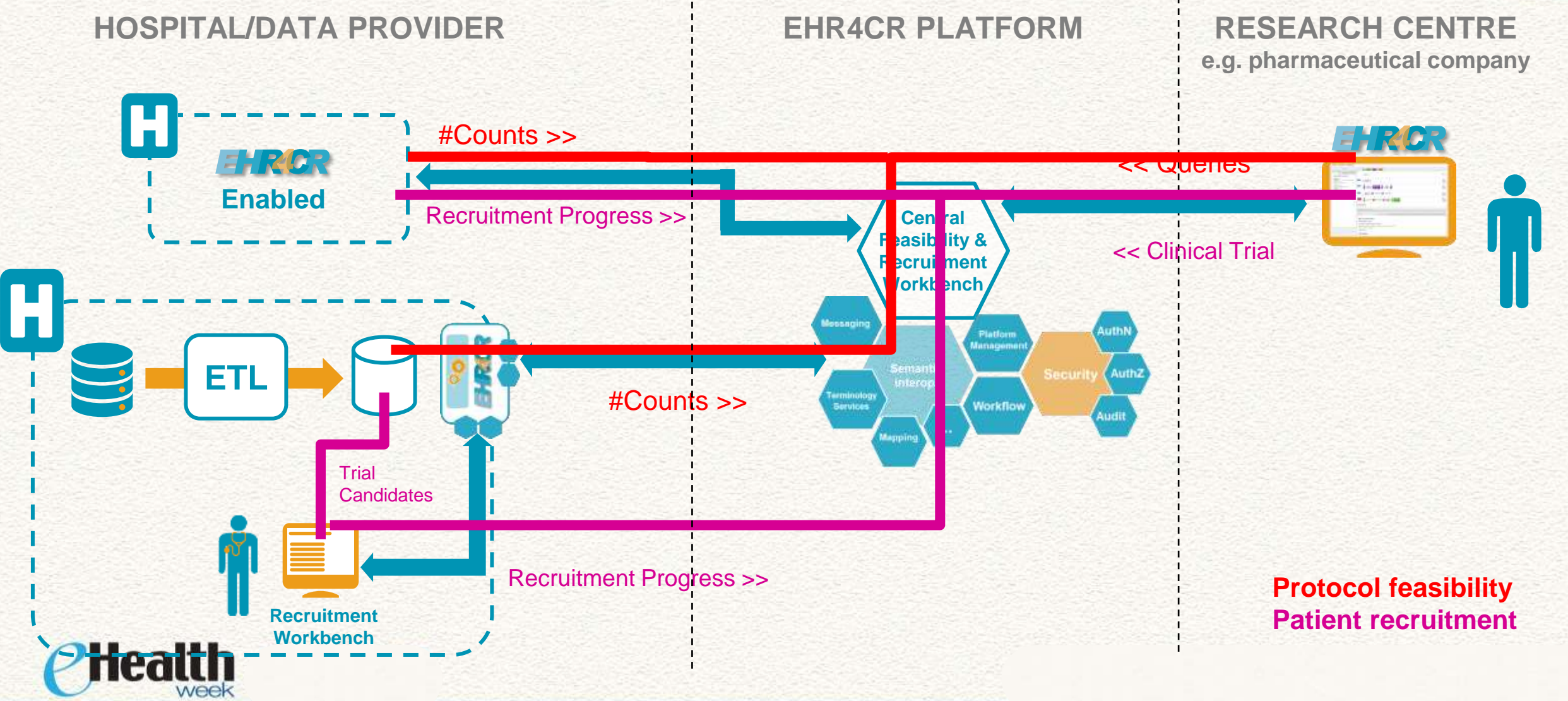
Confidence in data

- Data quality monitoring can be built in the site node software based on the EHR4CR query technology.

The EHR4CR Platform



The EHR4CR platform – dataflow



Where we are now...

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)



2015

Scaling up the solutions!

- Technology
- Operations
- Governance
- Sustainability

Operational pan-European platform

2016 – 2017

Operational pan-European platform

- Permanent network of clinical sites giving access to millions of patients in close to real time
- Fully **compliant** with governing legislation
- **Reaching out** to the rest of the world
- Providing trial design and recruitment supported by **real-world evidence** on a European scale



Services and service model

Bringing added value to Clinical Sites (data providers) at an early stage

- **Attract more clinical trials**
- Access to trial drugs and innovative care pathways resulting in **better patient care** delivery
- Free **access to tools** to explore and analyse patient data.
- Support in process towards **better data quality**
- visibility and **reputation** in the scientific community

Starting with a simple service offering for Research Organisations



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

A screenshot of a dashboard with a table. The table has several columns and rows, likely representing trial details and recruitment progress. The interface includes a header with navigation options and a sidebar.

Trial recruitment services

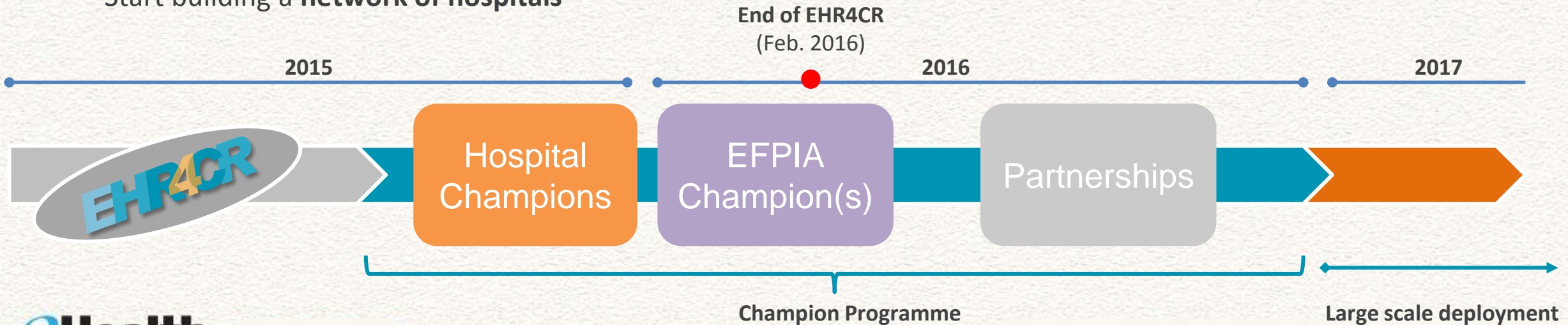
- **Distribute trial protocols** over multiple sites in a uniform way
- **Track recruitment progress** in real time
- **Optimal recruitment due to tools** provided to hospitals

Bootstrapping the network

“Champions are prepared to invest (manpower, time) because they believe that the clinical platform will eventually bring benefits to ALL stakeholders”

Champion Programme

- Provides a “soft” entry for all stakeholders (no-risk)
 - Allows to grow confidence and acceptance
- Basic functionality, but **no compromise** on security & privacy
- Goals
 - Further **validate** and improve technology
 - Define (refine) the rules of engagement for a **sustainable ecosystem**
 - Start building a **network of hospitals**



Champions



Clinical Sites (Hospitals)

- Contribution
 - Assist in **connecting to their IT systems** and with importing and mapping data
 - **Commit** to joining the network (when/if milestones are reached)
- Benefits
 - Early **access to technology** and ability to use it for internal experiments with clinical data management (IT, mapping of data, etc)
 - Increase **reputation** in scientific community (demonstrable innovation, publications, etc.)
 - Premium version of **local site applications for free**
 - Steer development



Research Organisations

- Contribution
 - **Bring hospitals** to the network
 - **Commit** to become a customer (when/if milestones are reached)
- Benefits
 - **Favourable service fees**
 - Opportunity to **prioritise the functionality** and flow of the services as they are further developed
 - Steer the growth path with respect to pathology and site selection

Champion Programme



As details of Champion Programmes are being worked out, the **fieldwork has already started**

- Research organisation Champion shortlist
 - 1st wave candidates: **AstraZeneca, Sanofi, Janssen**
 - Further interest: Bayer, Amgen, GSK + Pfizer (non EHR4CR partner)
- Additional collaborations
 - **InterSystems** - system integrator
- Clinical site Champion engagement
 - EHR4CR partner hospitals are considering further engagement
 - 1st wave candidates: APHP, Erlangen , Munster
 - 3 Hospitals outside EHR4CR are **already implementing**
 - **UZ Gent, CHRU Lille, AZ St-Elisabeth Zottegem**
 - 1st wave Pharma is contacting their partner sites

Growing the technology

Continuous development as the programme advances and the network is expanded

The top screenshot shows the 'Feasibility study overview' page. It features a search bar and a table with the following data:

TITLE	AUTHOR	LAST MODIFIED	Protocol
Protocol Diabetes Compound 3	Joanna Smith	Today 13:20	NocompoundHPB0001
Protocol NocompoundHPB0001 Exploratory...	S...		
Protocol Exploratory Research Study	J...		
NocompoundHPB0001 Exploratory Research	D...		
Protocol Diabetes Compound 2	J...		
COPD Protocol	J...		
Protocol NocompoundHPB0001	J...		
Protocol Oncology Compound 2	S...		
Protocol Oncology Compound 1	S...		
Hypertension	J...		

The bottom screenshot shows the 'Experiment V3 - protocol' page. It includes a search bar, a 'Query status: Executing' section with a table of results, and sections for 'Included criteria' and 'Excluded criteria'.

Country	Sites	Response
Belgium	3	3
Germany	3	3
Finland	1	1
Total	3	3

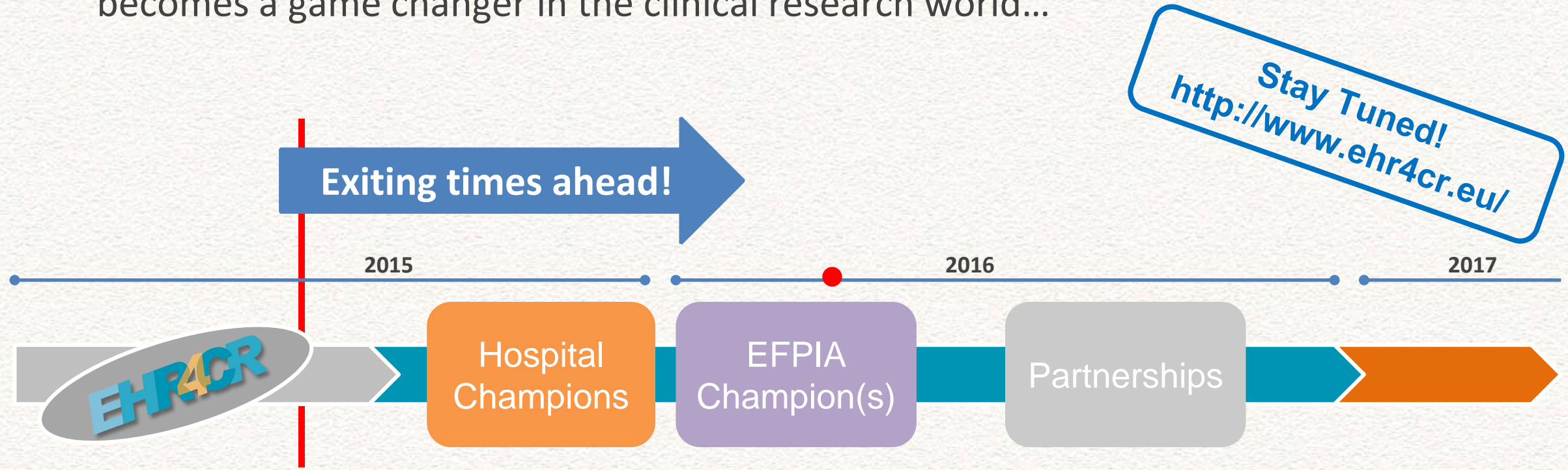
Continuous improvement

- Reduction of time to connect a site
 - Improve ETL and mapping through tools, standard templates, etc.
 - Standard integration profiles through collaboration with EHR vendors
- Handling unstructured data
 - Phase I: extract structured data from unstructured (NLP) during import (no core platform change).
 - Phase II: enhance platform with unstructured search.
- Expand and maintain core dataset
 - Based on clinical trial needs and reality of available data.
 - Improve management tooling.

Summary



The coming months will determine whether EHR4CR is “just another project” or becomes a game changer in the clinical research world...



Stay Tuned!
<http://www.ehr4cr.eu/>



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