



Connected Hospital Platforms, enabling secondary use e-HR  
4<sup>th</sup> National Clinical Trial Day - PRAGUE

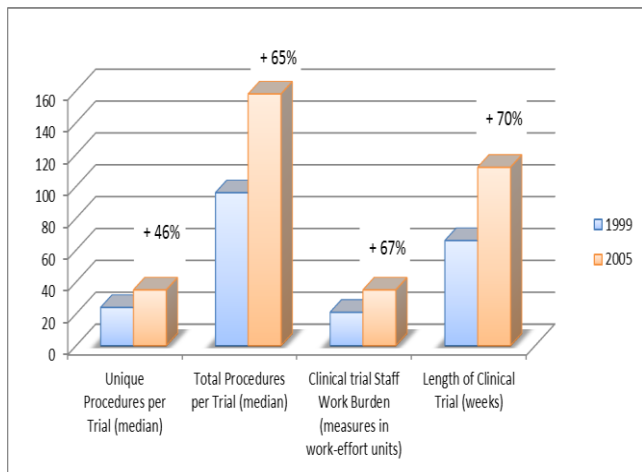
Àngels García Arellano – Clinical Study Unit - Spain



# Medical Innovation

## Change in paradigm

### THE GROWING COMPLEXITY OF CLINICAL TRIALS



Source: PhRMA Report 2010

## Health digitalisation offers new opportunities

Data directly obtained from patients and from the point of observation.

- **Electronic Medical and Health Records.**
- Wearable Devices /Connected Devices/ Electronic PRO/Study Apps / Portal.

Provide a platform for trustworthy re-use of EHR data to support innovation in clinical research and healthcare operations: access to RWD to optimize CT.

predict the number of eligible patients for a candidate clinical trial protocol

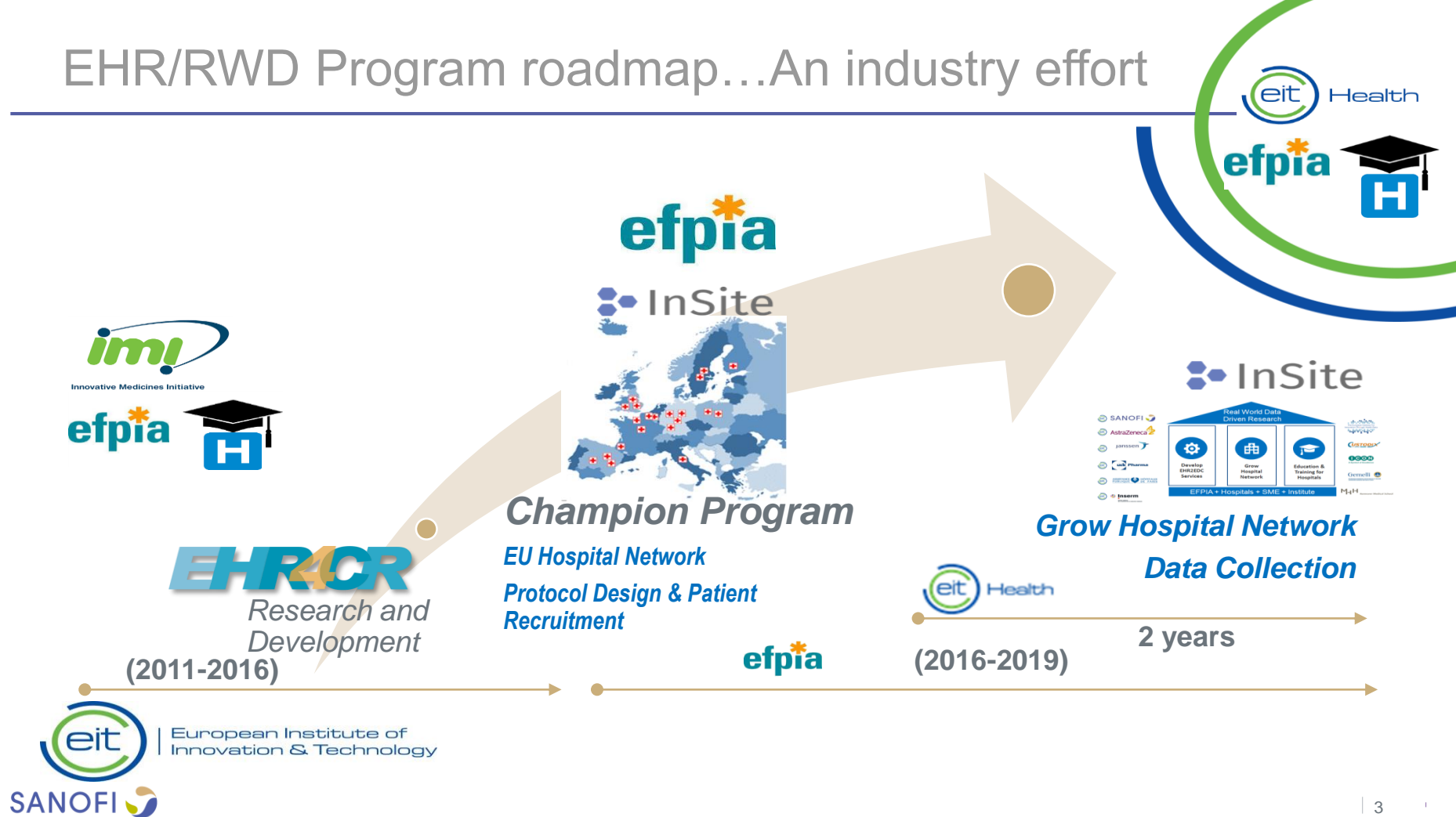
assess its feasibility and to locate the most relevant hospital sites

identify patients who may be eligible for particular clinical trials

**EHR4CR**



# EHR/RWD Program roadmap...An industry effort



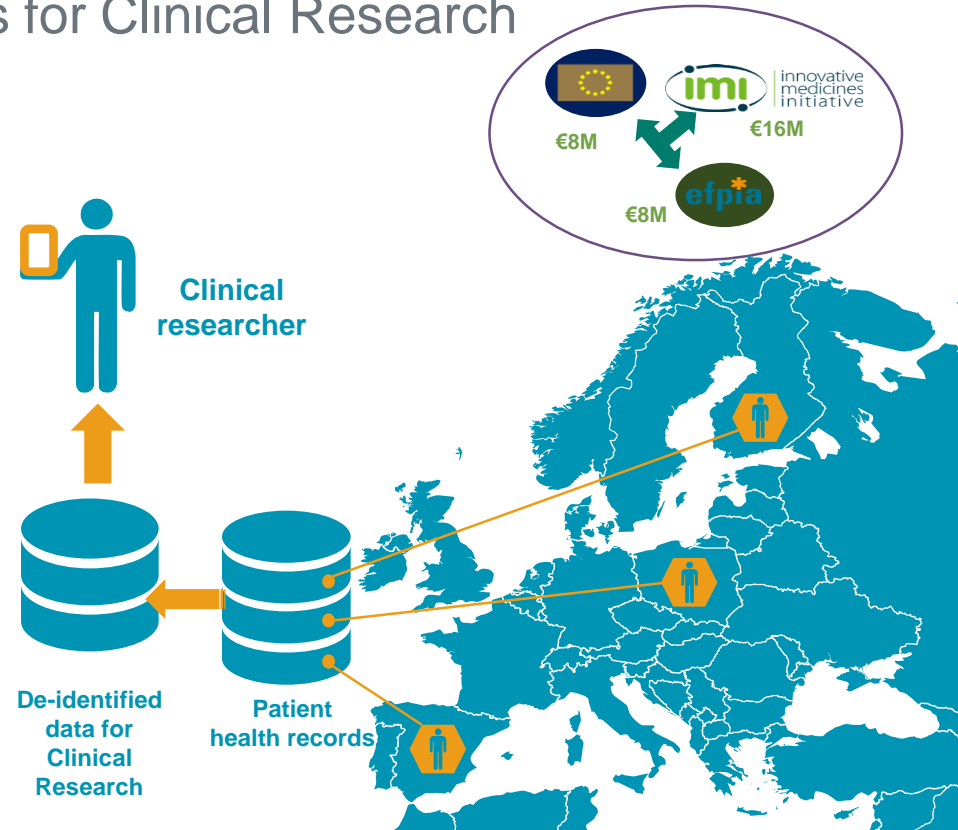


# IMI EHR4CR Project

## EHR4CR – Electronic Health Records for Clinical Research

4+1 year project (2011-2016), 35 partners, budget >16M€

- Bringing together multiple stakeholders
- Overcoming barriers that limit access to EHRs for research
- Developing a platform and services for trustworthy re-use of EHR data within and outside Europe





# The Consortium; a Mix of Academic & Pharma



10 Pharma Companies

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

11 hospital sites

Advisory boards and other experts

efpia

The European Institute For Innovation Through Health Data

- **EHR4CR Platform** - Interoperable system connected to several hospitals
- **Champion Program**- Using the RWD platform in real life and validating the Business model
- **The European Institute for Innovation Through Health Data (i-HD)**: An institute to regulate and manage the ecosystem



# What were the challenges addressed

Key challenges to overcome in integrating EHR and CR



**Complying with ethical, legal and privacy requirements that differ from country**

***Accreditations***



**Provide a platform that enables access to many, different EHR systems**

***Standards, Specifications,***



**Ensuring the correctness, completeness and accuracy of the data (quality assurance)**

***Certification***



**Sustainability within a scalable business model**

***Innovative Business Model***

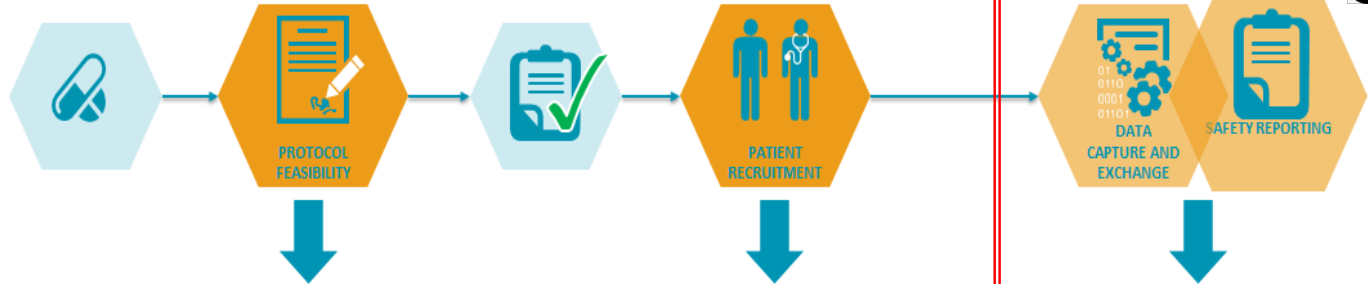


March '17





# Where are we in this journey ?



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).

- Enabling **protocol testing with real world data**
- Eligibility criteria vs real pat. Pop.
- Funnel analysis
- Amendment avoidance

Complex CT in Psychiatry  
EudraCT 2016-003990-17





# Main Research Platforms



TriNetX's advanced analytics modules provide intelligence on which criteria have the most impact as well as the rate at which new patients present



*Getting Real About Real World Data*



InSite is building a community dedicated to accelerating clinical research through Real World Data in a secure & trustworthy way

- **Feasibility**
- **Recruitment**
- **EHRs to EDC**

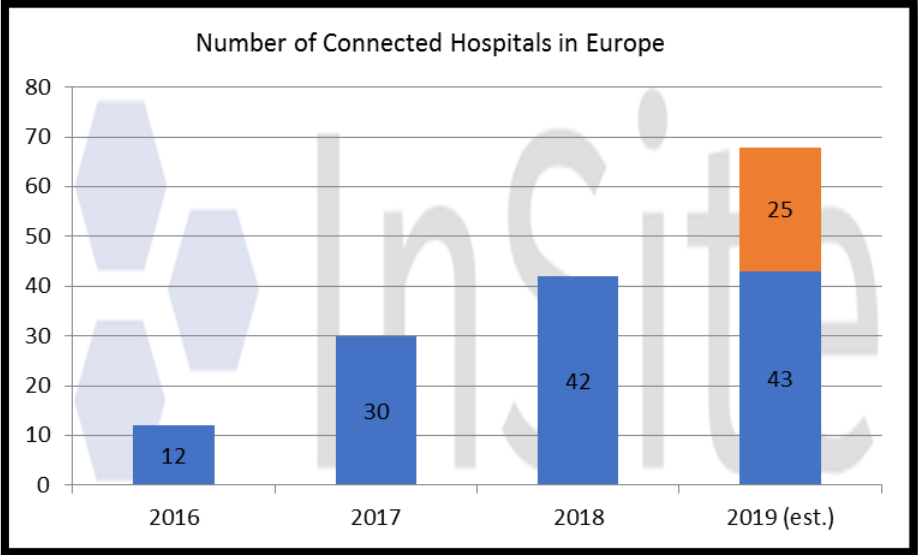


TriNetX, InSite Unite to Establish World's Largest Clinical Research Network

Acquisition of Belgium-based Custodix Promises to Bring New Pharmaceutical-Sponsored Clinical Trials to Healthcare Organizations Throughout Europe



# Connected Hospital Network – Europe





# Value for the Hospitals

## Patient Centred Clinical Intelligence:

Make **smarted decisions** through analytics and dashboards and by exploring your own patient population



Academic Trials: **Promote your own Clinical Studies** at a preferred rate. Get access to the central platform to find patients easier and faster.



Assess and ensure hospital quality data. **Better data means better data care.**



Be **active part** of a Clinical research network. Obtain an **early overview** of **upcoming sponsor** trials design and choose



Be **visible** to sponsors and **attract clinical trials**







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