



European Federation of Pharmaceutical  
Industries and Associations



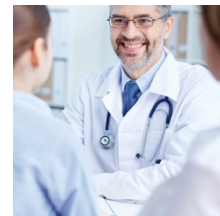
# Real World Data Platforms and Disease Interception

Author: Martine Lewi, PhD, MBA, MSc, Scientific Director, Janssen R&D

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**“Unlocking  
Tomorrow’s Cures”**





## AGENDA

- Changing trends in healthcare ecosystem
- Leveraging digital / RWD for Research & Development
- Future direction and value creation
- Key messages

# CHANGING TRENDS IN HEALTHCARE ECOSYSTEM

## Research & Development for “A world without disease”

Clinical manifestation

Onset of morbidity

No clinical manifestation

HEALTHY

INCUBATION

DISEASE



**PREVENTION**

Disease-specific approaches to warding off onset of disease initiation



**INTERCEPTION**

Arrest disease as it develops before clinical manifestations



**CURE**

Eliminate disease and reverse damage to restore full health

**DISEASE ELIMINATION**



# LEVERAGING DIGITAL / RWD FOR RESEARCH AND DEVELOPMENT

## Our perspective on clinical innovation and Digital

### R&D in 2017

- > 400 trials
- > 30 countries
- > 16.000 sites
- > 116.000 participants



### New opportunities

- digital biomarkers
- remote patient monitoring
- real-time access to EHR/RWD

### Mission

- Transform clinical development for patients, investigators and industry

### Approach

- Reduce cost of evidence acquisition and improve patient satisfaction

### Deliverable

- Clinical trial outcomes and new operational capabilities

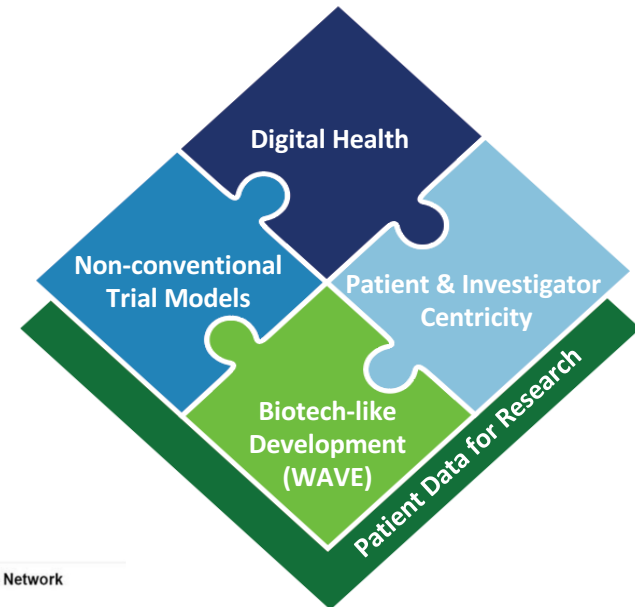
### Persistent challenges

### Recruitment

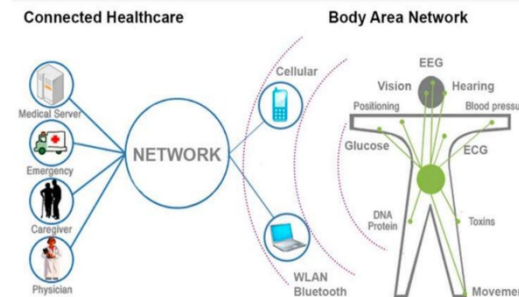
- Access to patients (data)
- Bring the trial to the patient

### Retention

- Improve patient experience
- Unobtrusive trials



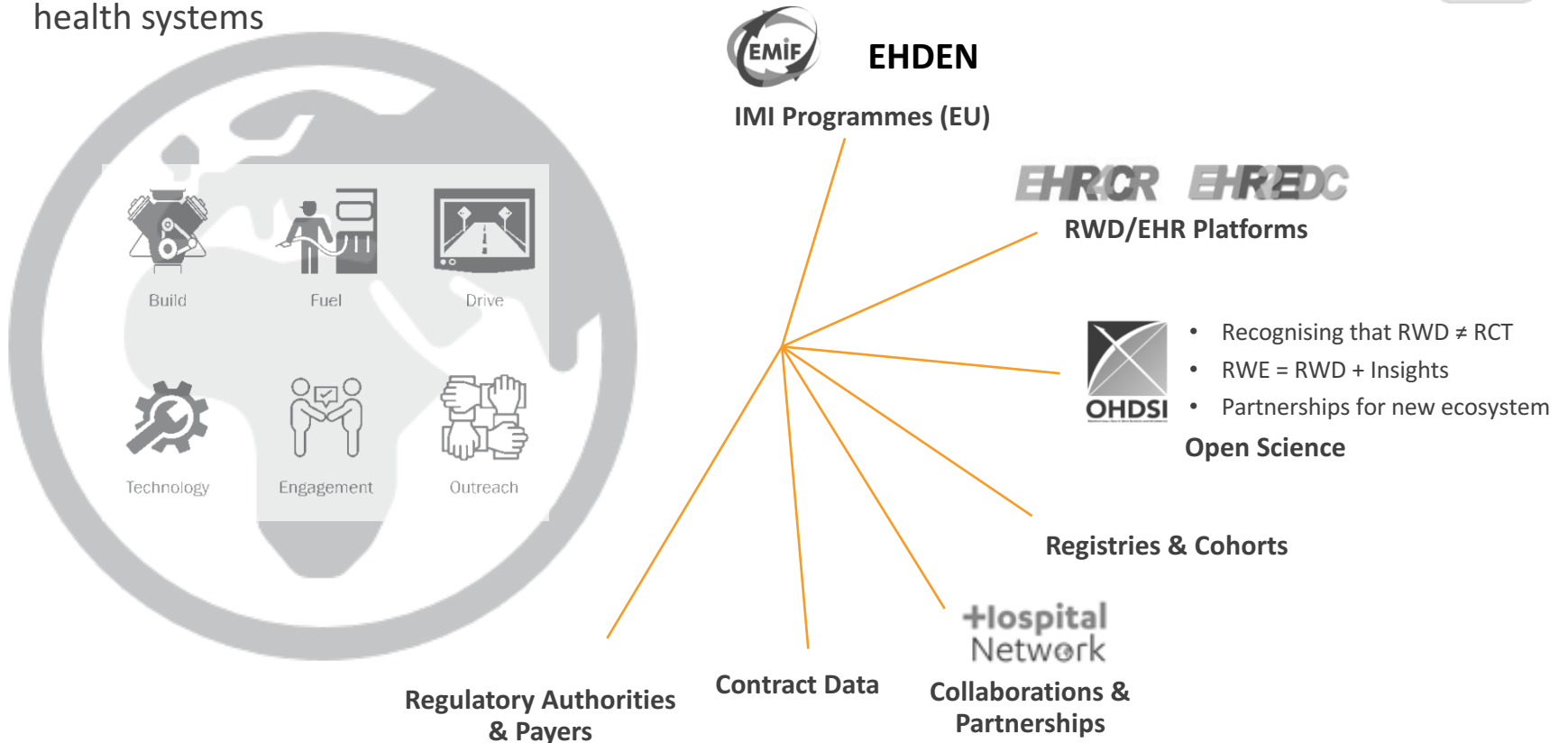
### CONNECTED HUMAN



# LEVERAGING DIGITAL / RWD FOR RESEARCH AND DEVELOPMENT

## Our perspective on clinical innovation and RWD

Optimizing various aspect of R&D through data, insight & knowledge solutions, applying FAIR principles, harmonisation, analytics, machine learning to enable learning health systems



IMI EMIF - <http://www.emif.eu/>

IMI/EHDEN - <http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/imi2-2017-12-04.html>

IMI/EHR4CR - <http://www.ehr4cr.eu/>

eIT/EHR2EDC - <https://www.eithealth.eu/ehr2edc>

OHDSI - <https://www.ohdsi.org/>

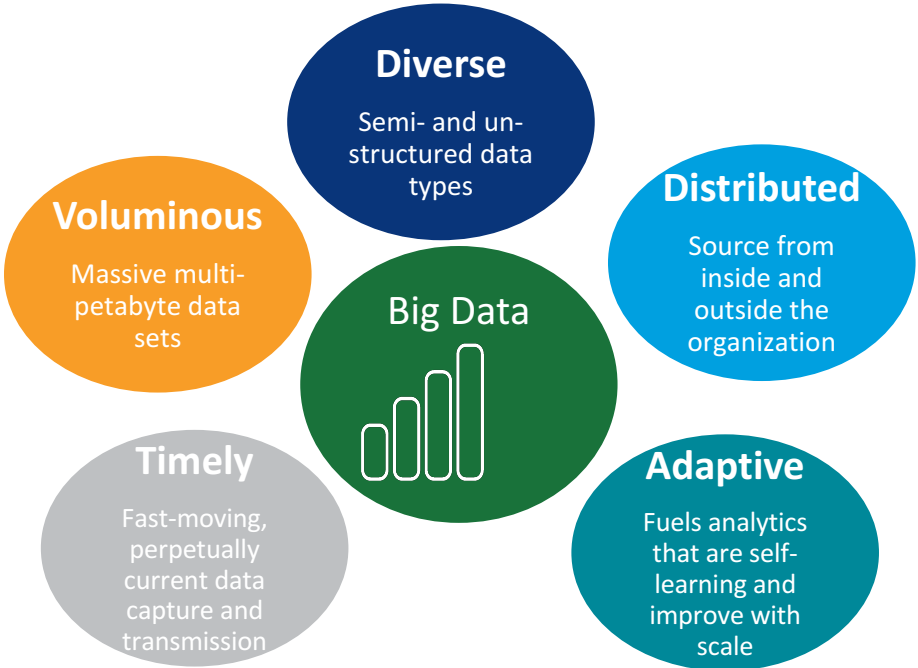
Janssen Clinical Innovation / Patient Data for Research - <http://www.janssen.com/clinical-trials/innovation>

# LEVERAGING DIGITAL / RWD FOR RESEARCH AND DEVELOPMENT

## RWD defined ...

RWE is generated using data typically collected in **usual health care settings**. RWE is most commonly **generated using a range of non-interventional (observational) studies**, including:

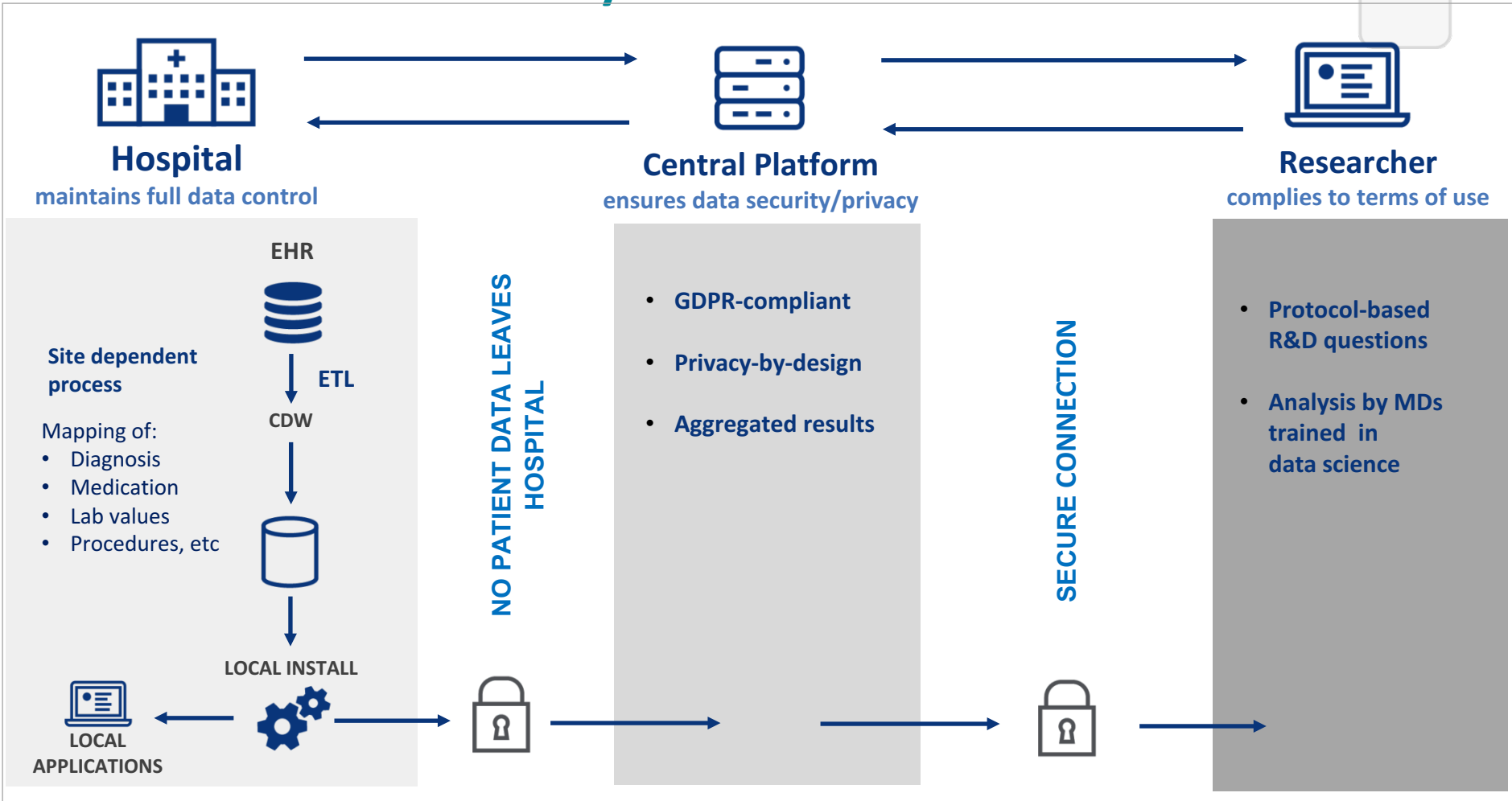
- **Primary data** collections such as **registries** collecting prospective and/or retrospective data, or **surveys** collecting cross-sectional or retrospective information.
- Analyses of **secondary data that includes (electronic) medical records, insurance claims data, and government databases** which provide data typically used for retrospective analyses.



McKinsey (2012) 'The Big Data Revelation In Healthcare'  
[http://assets.ngin.com/attachments/document/0029/2296/The\\_Big\\_Data\\_Revolution\\_in\\_Healthcare\\_\\_June\\_2012\\_.pdf](http://assets.ngin.com/attachments/document/0029/2296/The_Big_Data_Revolution_in_Healthcare__June_2012_.pdf)

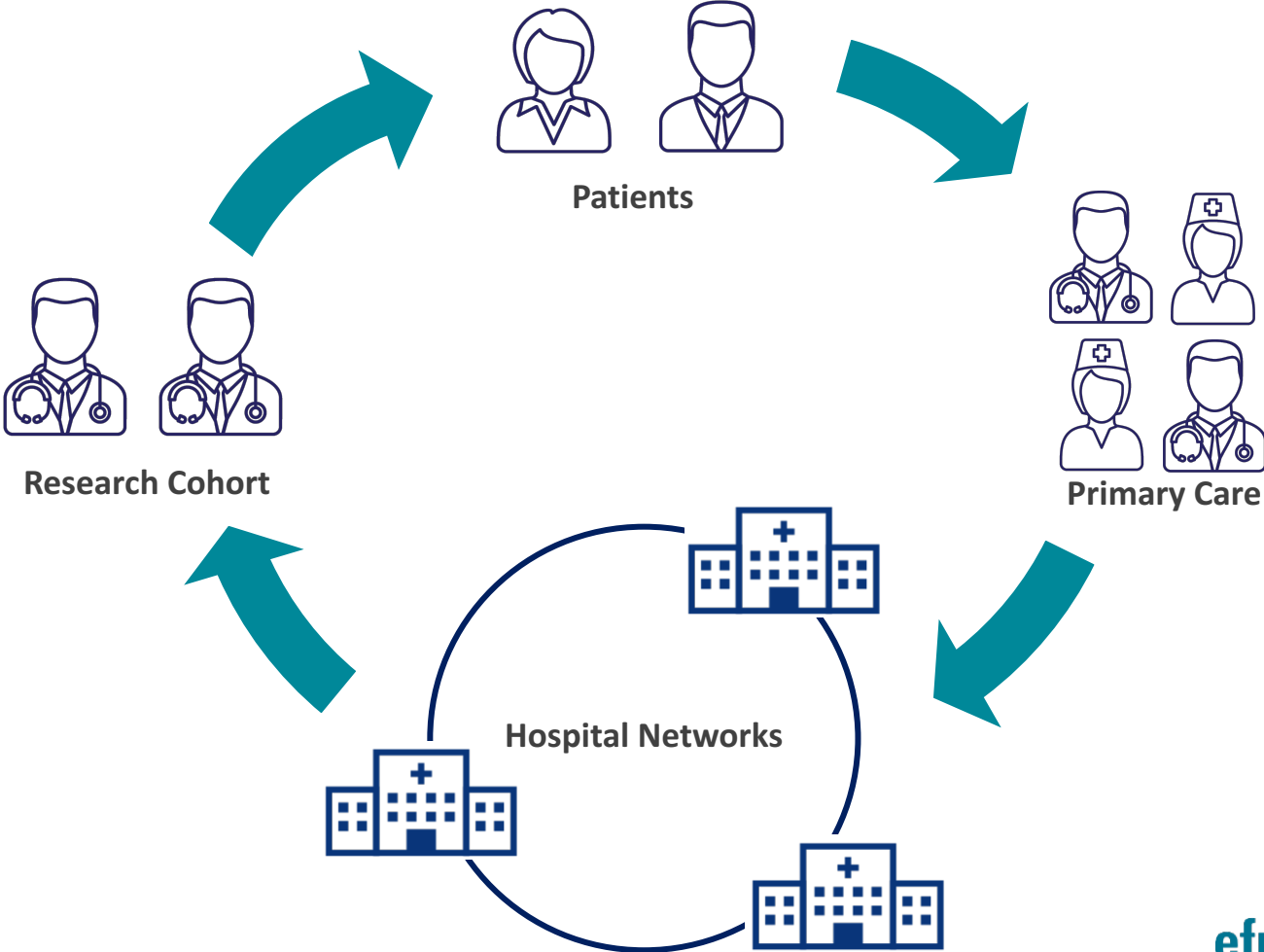
# LEVERAGING DIGITAL / RWD FOR RESEARCH AND DEVELOPMENT

## Federated data management ensures secure access to RWD from a variety of different EHR sources



# FUTURE DIRECTION AND VALUE CREATION

## Emerging integrated health regions in EU provide opportunities for data-driven research collaboration



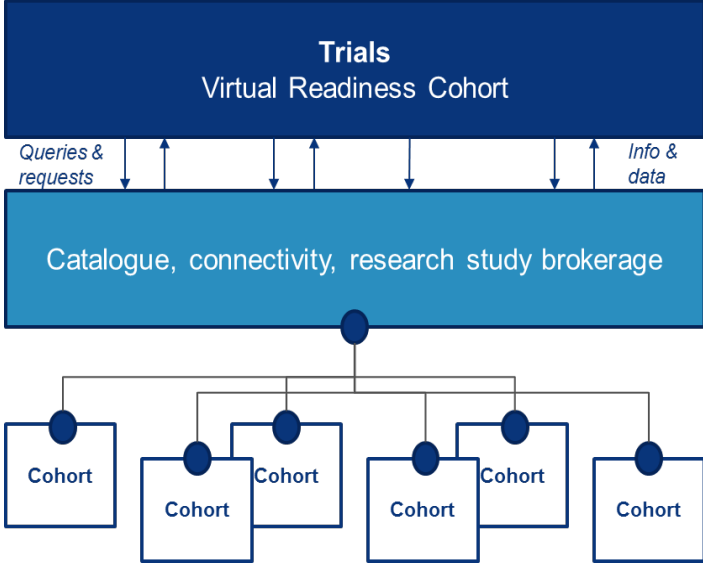




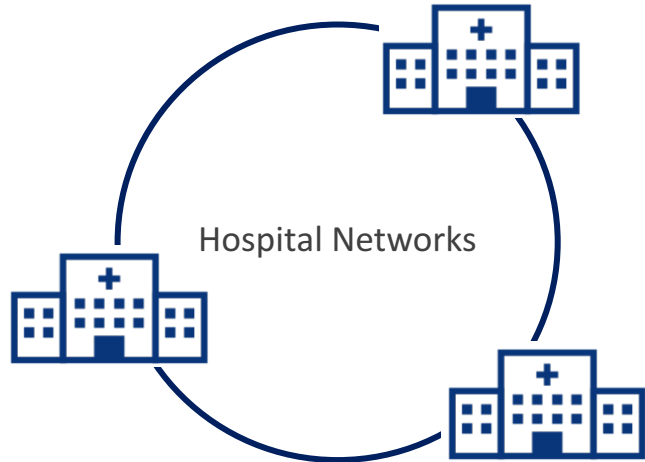
# FUTURE DIRECTION AND VALUE CREATION

## EHR/RWD enables health learning systems and accelerates advancements in medical science

Based on specialty datasets  
(e.g. cohorts)



Based on "general" datasets  
(e.g. hospital data)



... enhancing the medical knowledge to improve prevention, interception and cure

## FUTURE DIRECTION AND VALUE CREATION

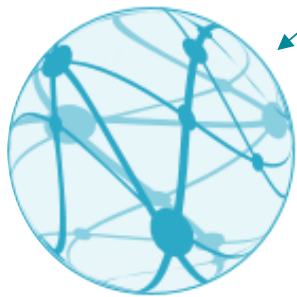
# A European *think tank* enabling learning systems based on EHR/RWD

Value to healthcare

Value to research

Value to patients and  
to society

Grow a Network of  
Excellence



**Demonstrate benefits of using health data on a large scale:**

- outcomes evidence to improve care
- faster and more efficient clinical research
- information for public health decisions

Promote and  
collaborate globally



Enriching knowledge and enhancing care through health data ...  
supporting the transitioning towards disease interception and prevention



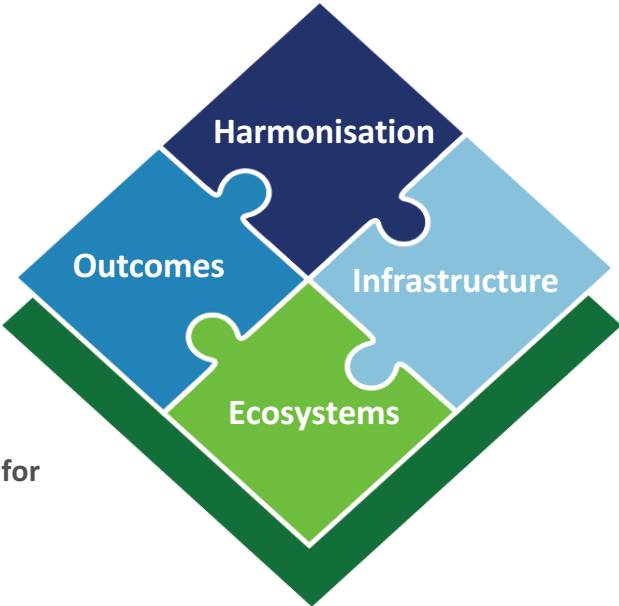
# FUTURE DIRECTION AND VALUE CREATION

## European Health Data & Evidence Network (EHDEN) realizes a secure data sharing environment...

Aim is to link 100 million health records across EU via a common data model (OMOP), supporting research, the BD4BO IMI2 programme, and outcomes-based healthcare

- Advance skill base in EU via certified & qualified SMEs
- Harmonisation fund to support mapping to CDM

- Incorporation of outcome standards (e.g. ICHOM)
- Supporting evidence base in EU for outcomes-based research and medicine



- Building on prior and current (IMI) projects
- Accelerate platform and supporting research process

- Federated network of increasing number of Data Custodians and Sources
- Evaluation and incorporation of 'novel' data sources
- Utilisation of FAIR Principles

EHDEN will be an IMI consortium of 11 EFPIA partners and a public consortium of 11 partners, planned to commence October 2018

## KEY MESSAGES

# Unlocking Cures ... Towards a “World Without Disease”

1. Patients are waiting for a new health model, which puts prevention and disease interception at the foreground, besides more targeted and personalized treatments.
2. Data and knowledge driven research collaboration are the engine to accomplishing this major shift in the health care ecosystem.
3. Europe has built a strong foundation in data and knowledge driven initiatives ... A strong vision, strategy and tactics aiming to achieve these patient-focused goals are in place ... **strong policies can support these accomplishments.**

**Open the discussion on this topic with attending policy makers**

THANK YOU!

Q&A

UNLOCKING  
TOMORROW'S  
CURES

efpia