



Patients  
Health Care  
Hospital  
Physician  
Clinical Research  
Service Providers

DATA

HEALTH

Health Care  
Doctor  
Hospital  
Pharmacist  
Nurse  
Dentist  
Phys. Ad.  
Surgeon  
Emergency

# GOVERNANCE AND THE EHR4CR INSTITUTE

Dipak Kalra  
EuroRec, University College London

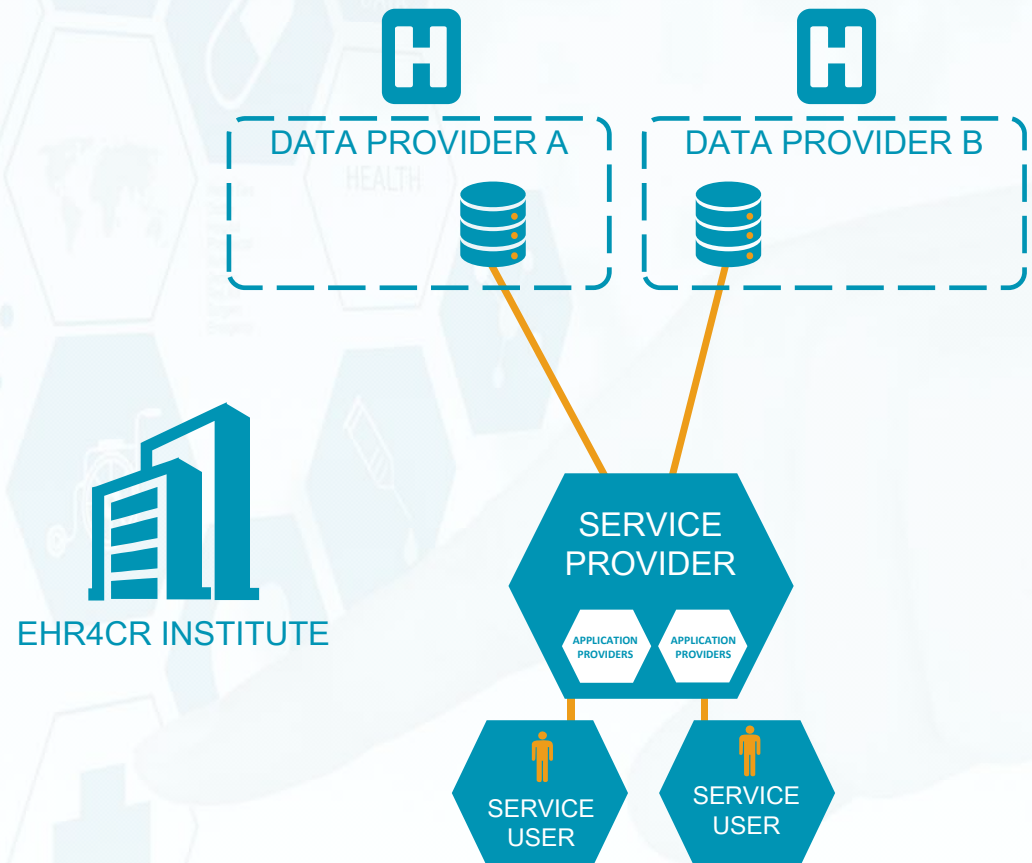
Christian Ohmann,  
European Clinical Research Infrastructure Network  
(ECRIN)



# Road Map: Seeding the system

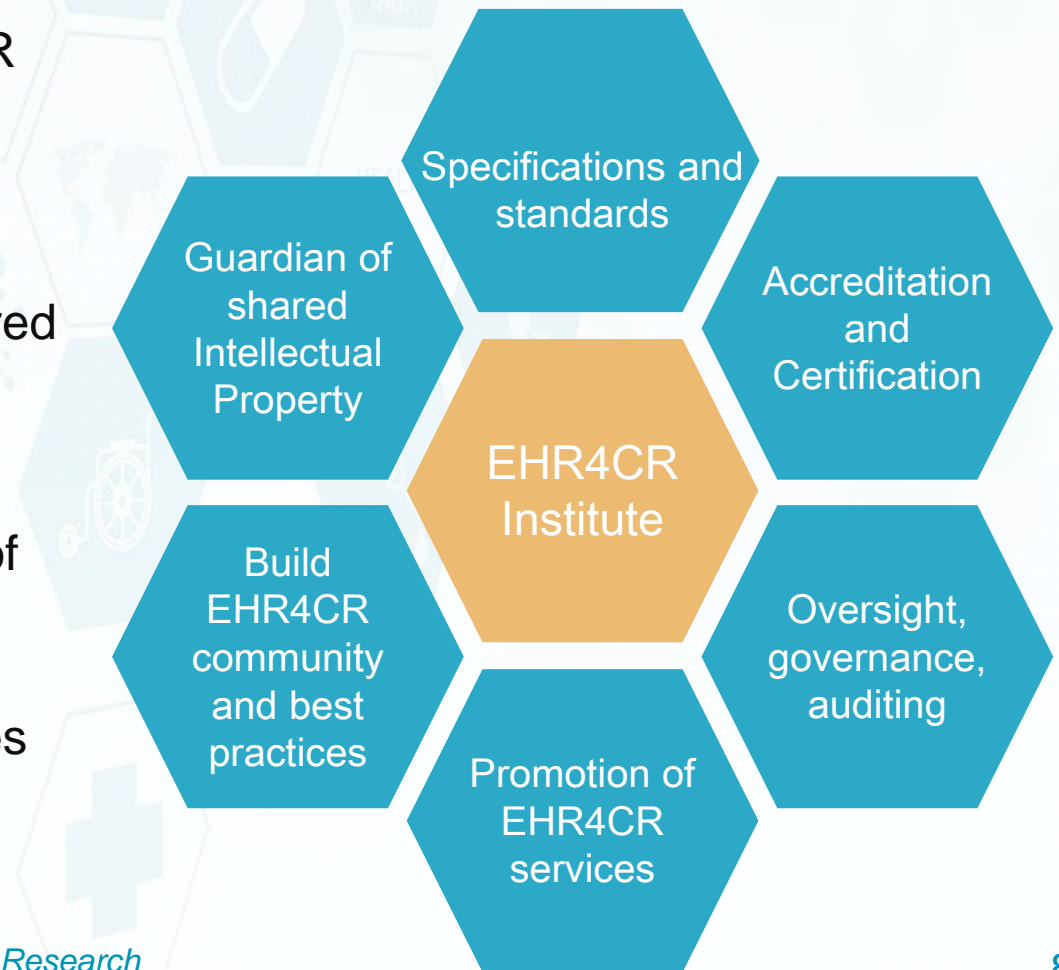
At project end, there will be

- A growing network of data providers
- First Service Provider(s)
- Committed service users
- Institute based in Belgium
  - Oversight and governance
  - Specifications
  - Shared IP
  - Standards
  - Certification of systems
  - Promotion

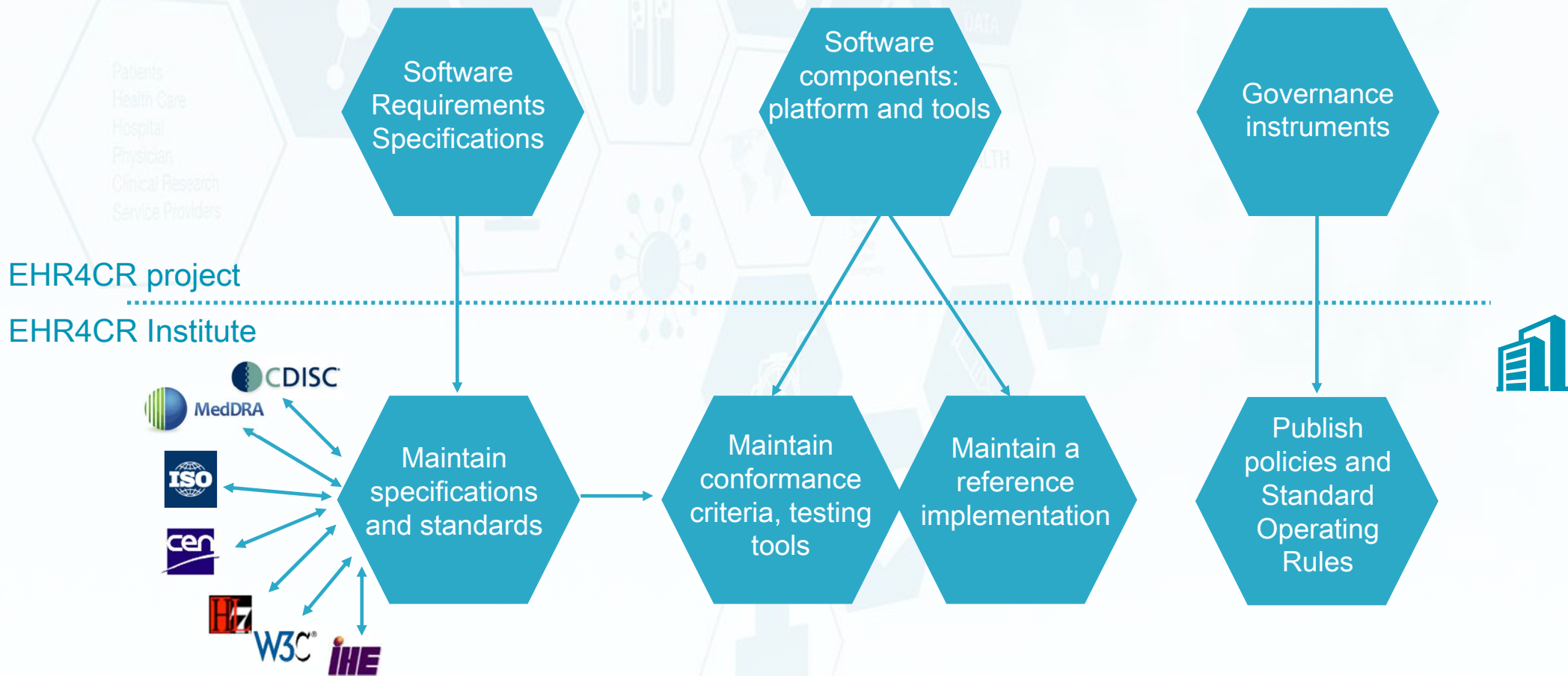


# The EHR4CR Institute

- Critical to the sustainability of EHR4CR
- Provides environment for EHR4CR ecosystem to develop
- Not-for-profit, formally registered company providing services to registered members (e.g. data providers, data users, service providers)
- Funded by license fee, subscriptions, certification, membership (cover cost of operations and providing services to registered members)
- Incomes reinvested to improve services & fund public interest research



# Develop resources



# Govern the ecosystem

The EHR4CR Institute will partner EuroRec, ECRIN and UKCHIP to:



Educate and train  
research and ICT  
staff

Accredit staff  
and organisations

RESEARCH  
SPONSOR

RESEARCH  
SPONSOR

ICT SOLUTION  
PROVIDERS

RESEARCH  
ORGANISATIONS

DATA PROVIDER



DATA PROVIDER



# Govern the ecosystem

The EHR4CR Institute will partner EuroRec, ECRIN and UKCHIP to:

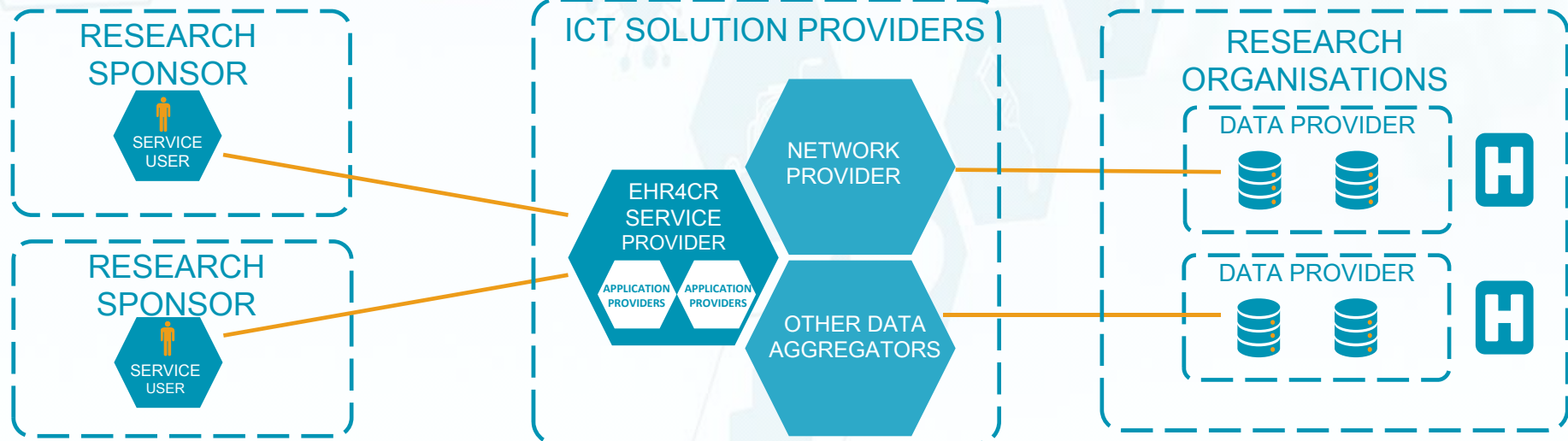


Educate and train research and ICT staff

Accredit staff and organisations

Certify service providers and EHR systems

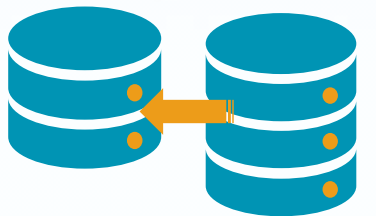
Oversee and audit governance & security



# Ensure an environment for trustworthy re-use

## Segregation

*of EHR4CR data from EHR*



De-identified data for Clinical Research

Patient health records

## Control

*lock/unlock access by hospital*



## Governance

*independent institute ensures data are accessed in a trustworthy way*



EHR4CR Institute

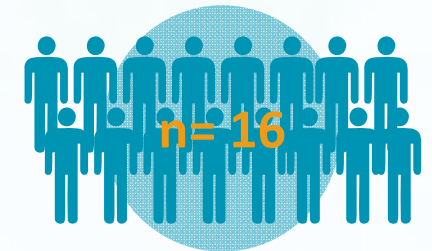
## De-identification

*individual patient data are anonymous*



## Consolidation

*only aggregated patient numbers leave the hospital*



# Promote EHR4CR

Promote benefits to hospitals

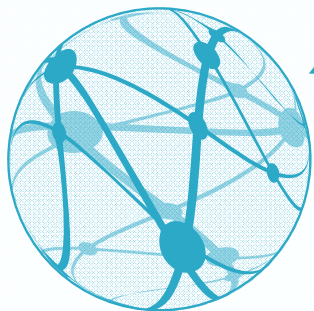
Public awareness of the benefits to patients

Promote benefits to pharma

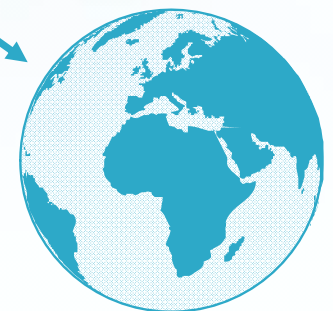
Collate evidence of benefits across stakeholder groups

- faster and more efficient clinical trials
- better information for public health
- improved quality of EHR data
- good practice in privacy protection
- successful eHealth/eResearch ICT sector
- positive patient and societal acceptance

Grow a Network of Excellence



Promote EHR4CR globally





# EuroRec



*The EuroRec Institute promotes the high quality design, implementation and adoption of Electronic Health Record systems (EHRs) in Europe*

- European independent not-for-profit organisation
- **Mission:** to promote the successful development and deployment of optimum quality eHealth systems that provide value and realisable benefits to all stakeholders
- Overarches a permanent network of national ProRec centres, providing services to industry (developers and vendors), healthcare systems and providers (buyers), policy makers and patients

## Current areas of focus include:

- Re-use of EHRs for research
- EHR systems certification in Europe
- Semantic interoperability
- Person centred care



*Electronic Health Records for Clinical Research*

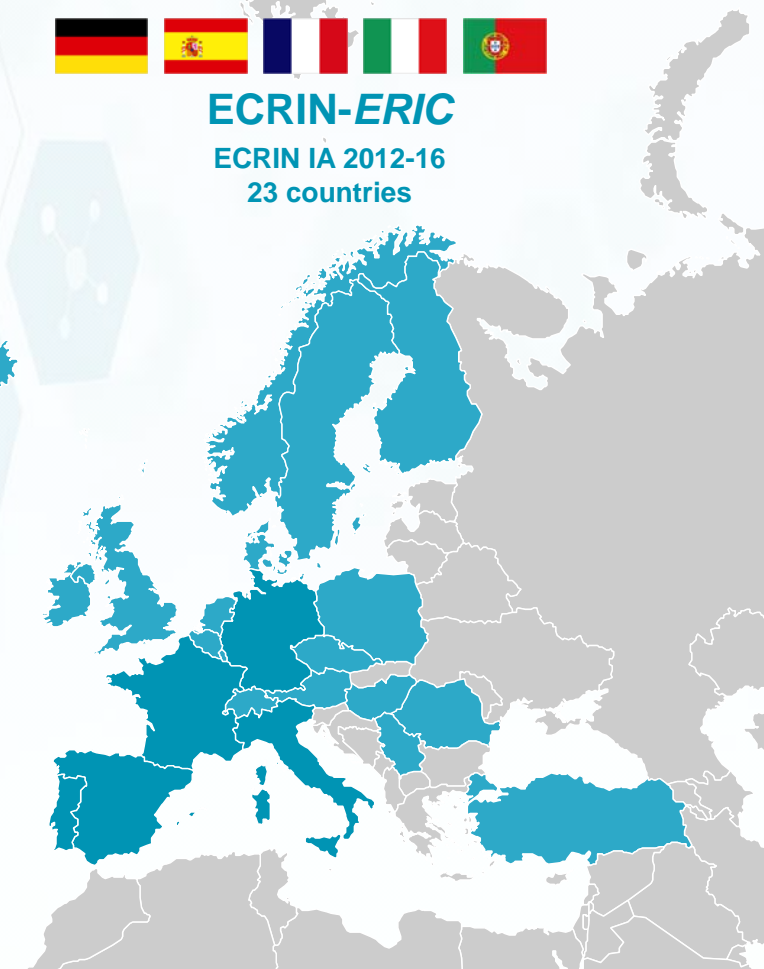
# ECRIN: European Clinical Research Infrastructure Network



- Public infrastructure supporting multinational clinical trials in Europe
  - based on connection and coordination of national networks and hubs of clinical trial units
- Capacity development at national and European level
  - regulatory database, investigator training
  - risk-based monitoring tools, data management tool
  - structuring investigation networks
  - QA policy, data centre certification
- Operational support to multinational trials



**ECRIN-ERIC**  
 ECRIN IA 2012-16  
 23 countries



## Information and consultancy during the preparation of the trial

- Information on regulatory and ethical requirements
- Information on sites and participant recruitment
- Information on clinical trial units
- Information on insurance
- Information on cost and funding opportunities
- Information on contracting
- Adaptation to local context
- Methodological support

Full protocol

Scientific evaluation

Logistical assessment

Contract with sponsor

## Services during the conduct of the trial

- Interaction with competent authorities
- Support with insurance contracting
- Adverse event reporting
- Monitoring
- Data management
- Investigational medicinal product management
- etc.

Portfolio of 23 trials, 3 published

*Electronic Health Records for Clinical Research*

