SETTING THE SCENE: THE OPPORTUNITIES FOR EFFICIENT CLINICAL RESEARCH

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eClinicial Forum

EHR4CR
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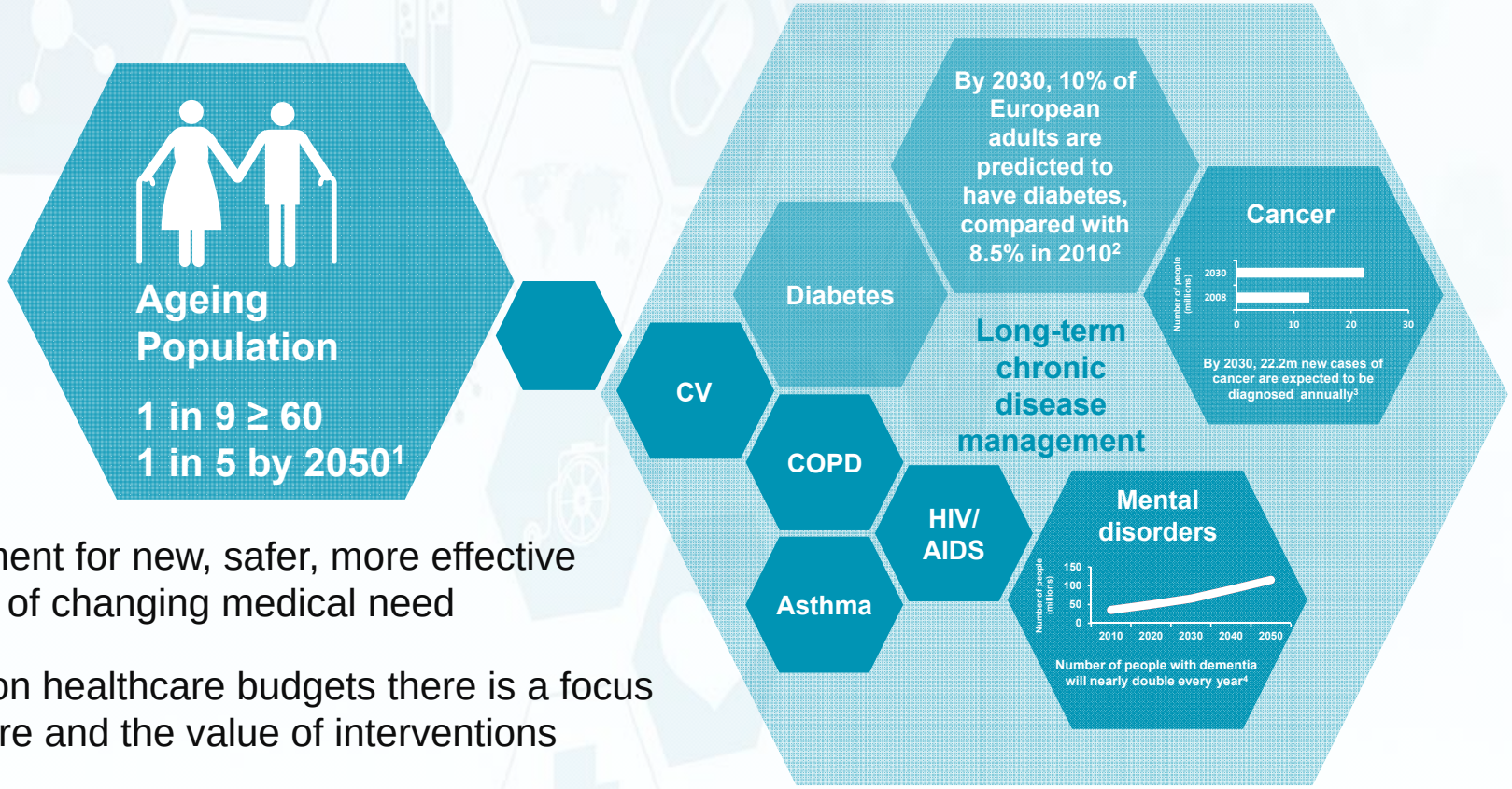
Healthcare needs have been changing



- There is a requirement for new, safer, more effective medicines in areas of changing medical need
- With the pressure on healthcare budgets there is a focus on best practice care and the value of interventions

1. http://www.unfpa.org/webdav/site/global/shared/documents/publications/2012/UNFPA-Exec-Summary.pdf
2. IDF Diabetes Atlas. Fifth edition. http://www.idf.org/diabetesatlas/europe. Last accessed October 2013
3. Bray F, Jemal A, Grey N, et al. Global cancer transitions according to the Human Development Index (2008-2030): a population-based study. Lancet Oncol 2012; 13(8):790-801.
4. Alzheimer's Disease International. http://www.alz.co.uk/research/statistics. Last accessed October 2013

This need has driven Life Science innovation

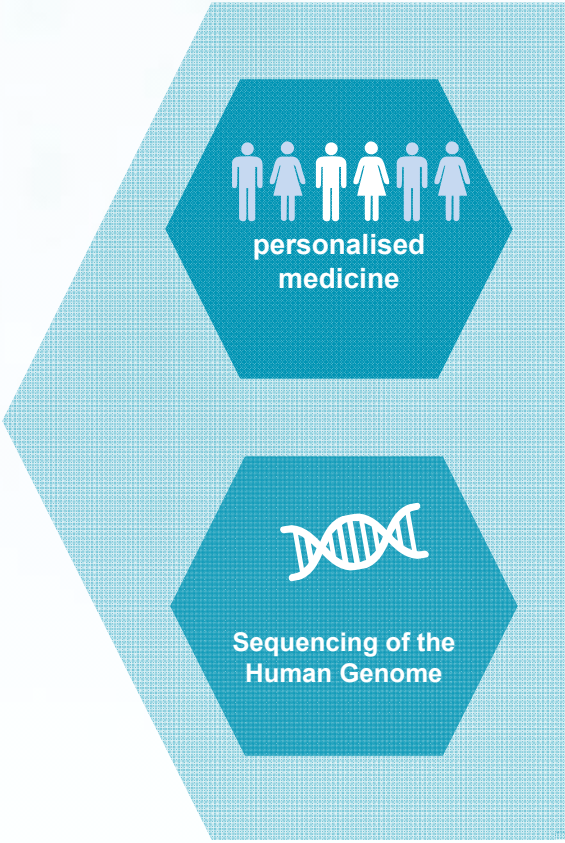
A large number of medicines are in development in order to…

- leverage new science
- expand treatment options
- improve quality of life
- provide value for money

Medicines in Development in 2012

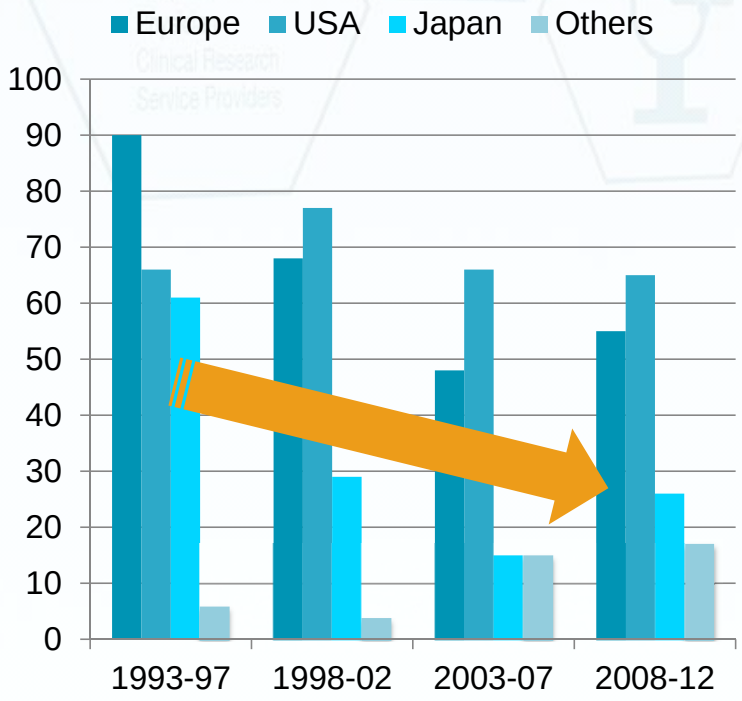
Alzheimer's Disease 72	Cancer 948	Colorectal Cancer 85
Cardiovascular Disorders 252	Arthritis 76	Lung Cancer 141
HIV/AIDS 88	Diabetes Mellitus 212	Leukemia 139
Parkinson's Disease 24	Mental Disorders 255	Skin Cancer 85
Rare Diseases* 460	Respiratory Disorders 398	Breast Cancer 132

Source: PhRMA 2012 Profile of the Pharmaceutical Industry

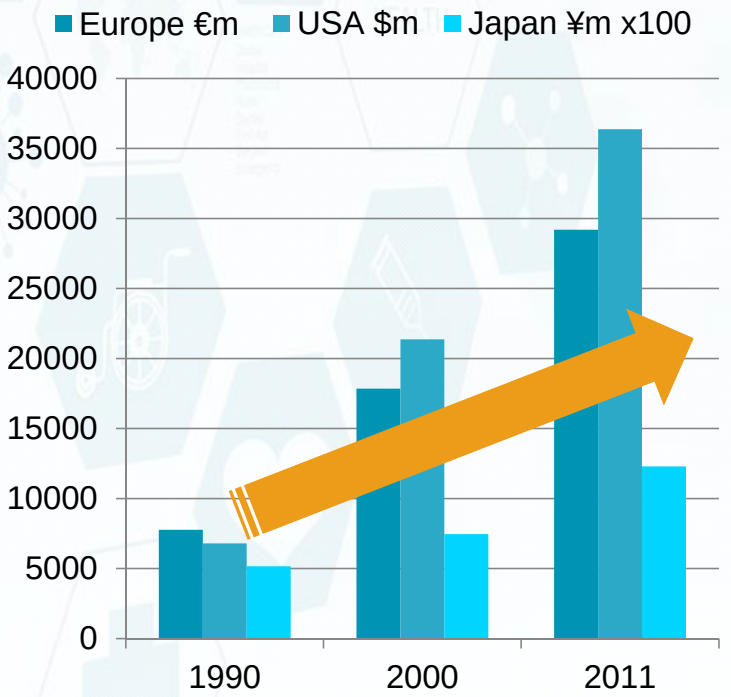


But this comes at a time of challenge

Fewer new chemical or biological entities are brought to the market…[1]



…despite increased R&D investment

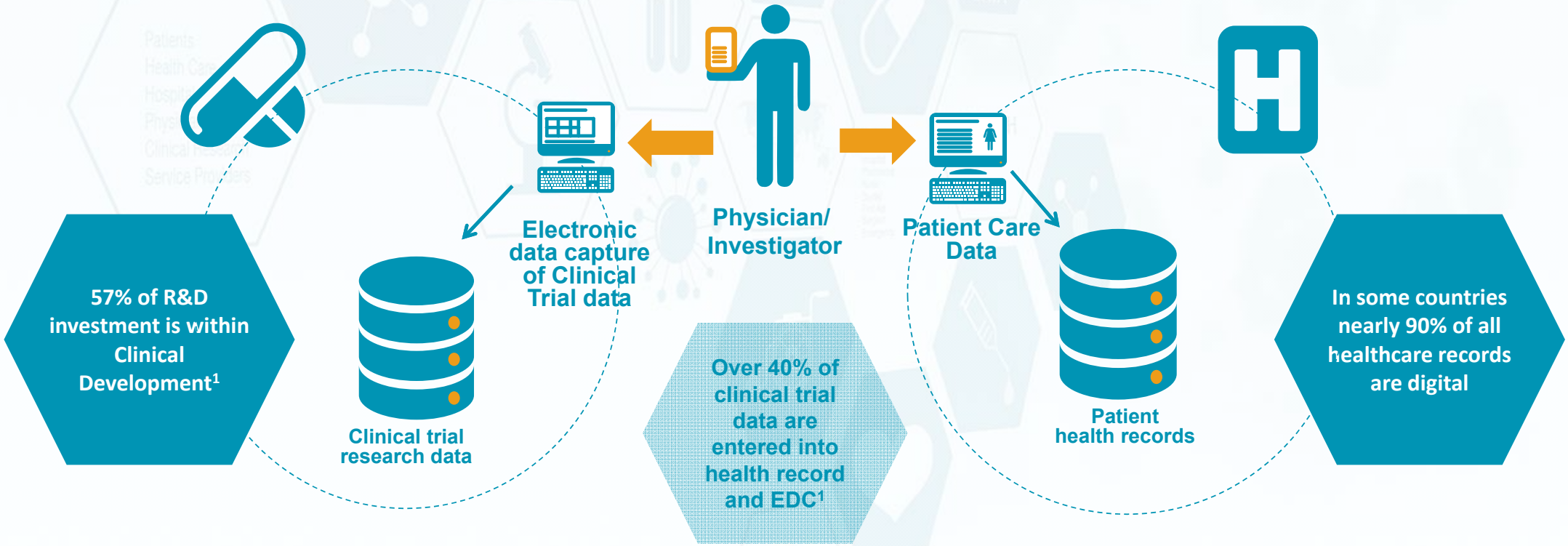


57% of R&D investment is within Clinical Development[1]

The number of drugs invented per billion dollars of R&D investment has been cut in half every nine years for half a century[2]

1. EFPIA. The Pharmaceutical Industry in Figures. 2013 2. Nature Reviews Drug Discovery, 2012

Parallel industry-centric growth in ICT



The inefficiencies become obvious at the clinical trial interface

1. Integrating Electronic Health Records and Clinical Trials: An Examination of Pragmatic Issues, Michael Kahn, University of Colorado.

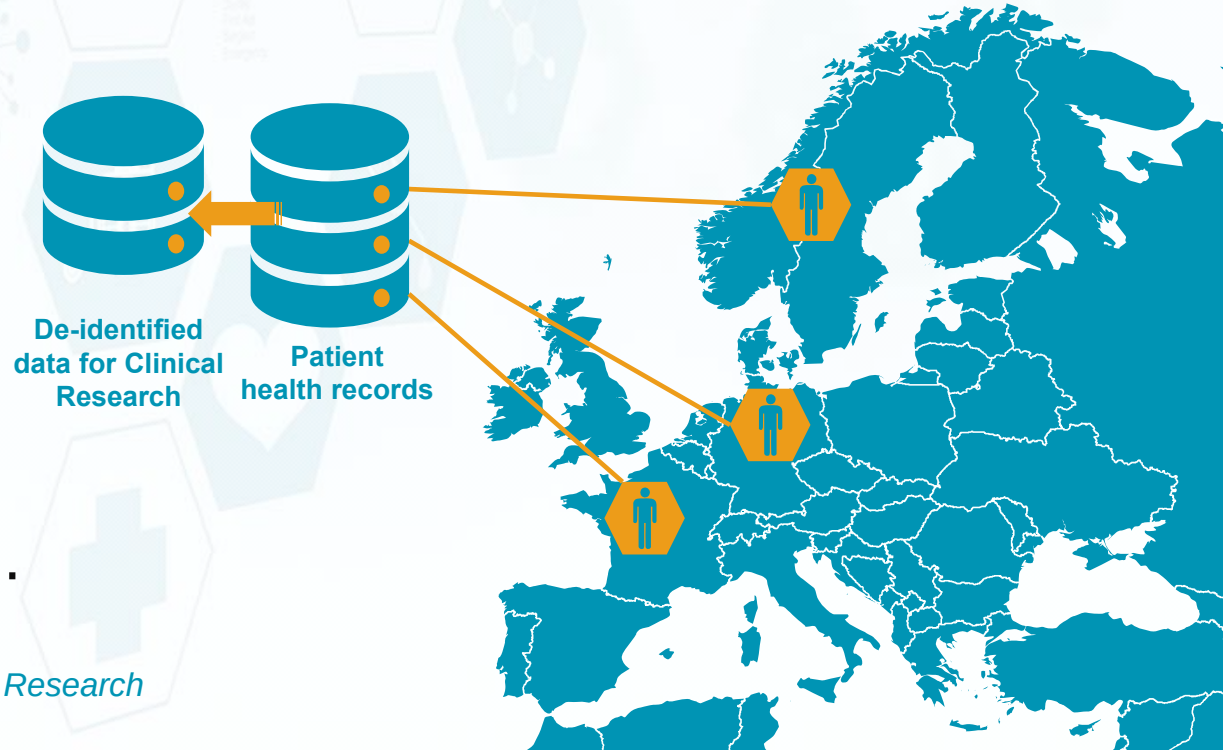
The clinical trial journey today is fragmented with many hurdles

There is a need to bridge the gap

We have imagined an environment where de-identified patient data can be re-used within healthcare and research for clinical research purposes…

- Across countries
- Across systems
- Across sites

…to speed up protocol design, patient recruitment, data capture, safety reporting…



Improved access to health record data…

…will speed up protocol design, patient recruitment, data capture & safety reporting

PATIENTS PROTECTED BY LEGAL AND PRIVACY PROTECTION STANDARDS & REGULATIONS

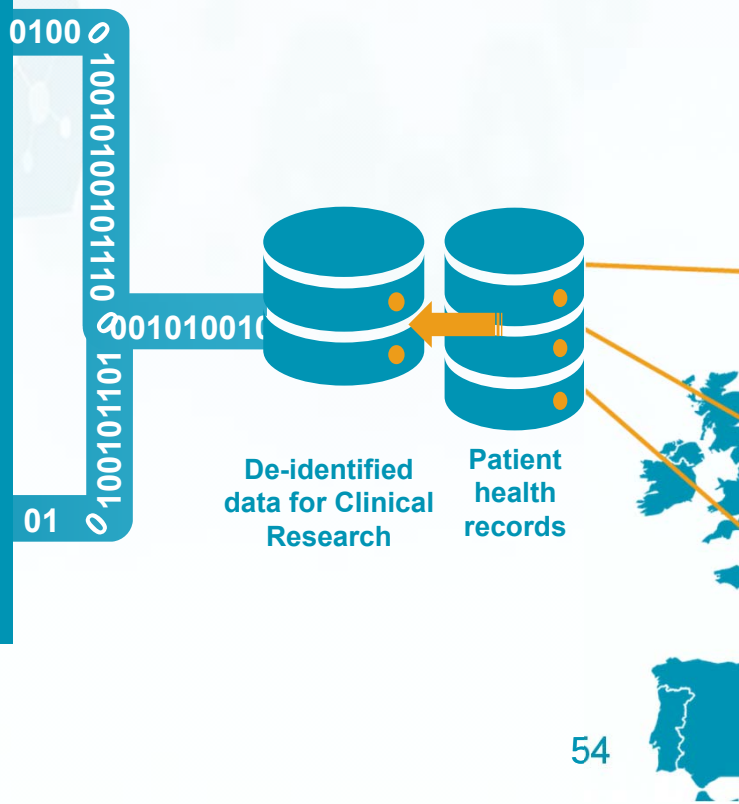
What is the impact of protocol criteria on the size of the patient population for the trial?

Which countries and sites offer the best chance of success?

Where are patient candidates and who is the treating physician?

What patient data can be pre-populated into the clinical trial records?

What are the safety issues and have they been reported?



There is growing recognition of the value of re-using EHRs for Clinical Research

In 2010, OECD Health Ministers met in Paris to discuss how to improve value in health care. In their final communiqué, they underlined the importance of better health information systems and called for more and effective use of health data that has already been collected

OECD, 2013

Health data constitutes a significant resource in most OECD countries and it makes economic and ethical sense to use this data as much as possible: to improve population health and to improve the effectiveness, safety and patient-centeredness of health care systems

Action is already being taken to re-use EHRs

- 22 of 25 OECD countries report a national plan or policy to implement electronic health records and 20 report starting its implementation
  - 18 national plans include the secondary use of the data
  - 13 countries are using data from electronic record systems to monitor public health, eleven countries to conduct health research and nine countries to monitor patient safety[1]
- In the UK, a new NHS system will allow anonymised patient information to be stored centrally and shared to help improve care and research

In 2014, patient groups in the UK joined together to promote the benefits of sharing patient records for clinical research

1. OECD (2013), "National electronic health record systems", in OECD, *Strengthening Health Information Infrastructure for Health Care Quality Governance: Good Practices, New Opportunities and Data Privacy Protection Challenges*, OECD Publishing. doi: 10.1787/9789264193505-8-en

This can create value for hospitals

Better patient care
Improved route to inclusion in clinical trials. Enhances treatment options, giving patients access to trial drugs and care pathways with no cost to the Trust

Improved clinical research
Improved efficiencies and interconnectivity with other hospitals facilitates, streamlines and enriches clinical research

Enhanced reputation
Greater visibility of hospital/clinicians in scientific community. Improved ability to participate in/conduct clinical trials

Income stream
Better placed to generate income from clinical research. At a time of squeezed budgets, income from research can help drive innovation and efficiency with better outcomes for patients

Better quality EHR data
Improved monitoring, performance benchmarking, reporting and management (e.g. reimbursement coding) Drives optimisation of patient care and improved efficiencies

But a win for all stakeholders is critical

Pharma, academia, CROs
Clinical trial development will become more efficient by reducing the time it takes to bring new drugs to market, thus generating substantial value

Hospitals
Able to participate in more clinical research programmes, benefiting their patients

Health authorities
Access to new and better evidence to underpin health policy, strategy and resource planning

Health community/ governments
Able to offer improved quality of healthcare with reduced healthcare costs

EU
More attractive for R&D investment

Patients
Faster access to safe and effective medicines, improving health outcomes across Europe

Public Private Partnerships can achieve something that individual groups cannot realise alone

- Political support
- Engage multiple stakeholder communities
  - biopharmaceutical companies, patient organisations, academia, hospitals, small- and medium-sized enterprises (SMEs) and public authorities
- Transfer of knowledge
- Public deliverables
- Consensus and synergy

Supported by

The EHR4CR project is partially funded by the IMI Programme.

The Innovative Medicines Initiative (IMI) is a unique public-private partnership designed by the European Commission and European Federation of Pharmaceutical Industries and Associations (EFPIA). It is a pan-European collaboration that brings together large biopharmaceutical companies, small- and medium-sized enterprises (SMEs), patient organisations, academia, hospitals and public authorities