

**EUROPE
BIOBANK
WEEK**

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**Brendan Barnes: "Clinical Research and the European Association of
Pharmaceutical Industries and Associations (EFPIA)"**



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European Federation of Pharmaceutical
Industries and Associations

Clinical Research and the European Association of Pharmaceutical Industries and Associations (EFPIA)

Author: Brendan Barnes



EFPIA Mandate

“The aim of the European Federation of Pharmaceutical Industries & Associations is to promote pharmaceutical discovery and development in Europe and to bring to the market medicinal products in order to improve human health worldwide.”

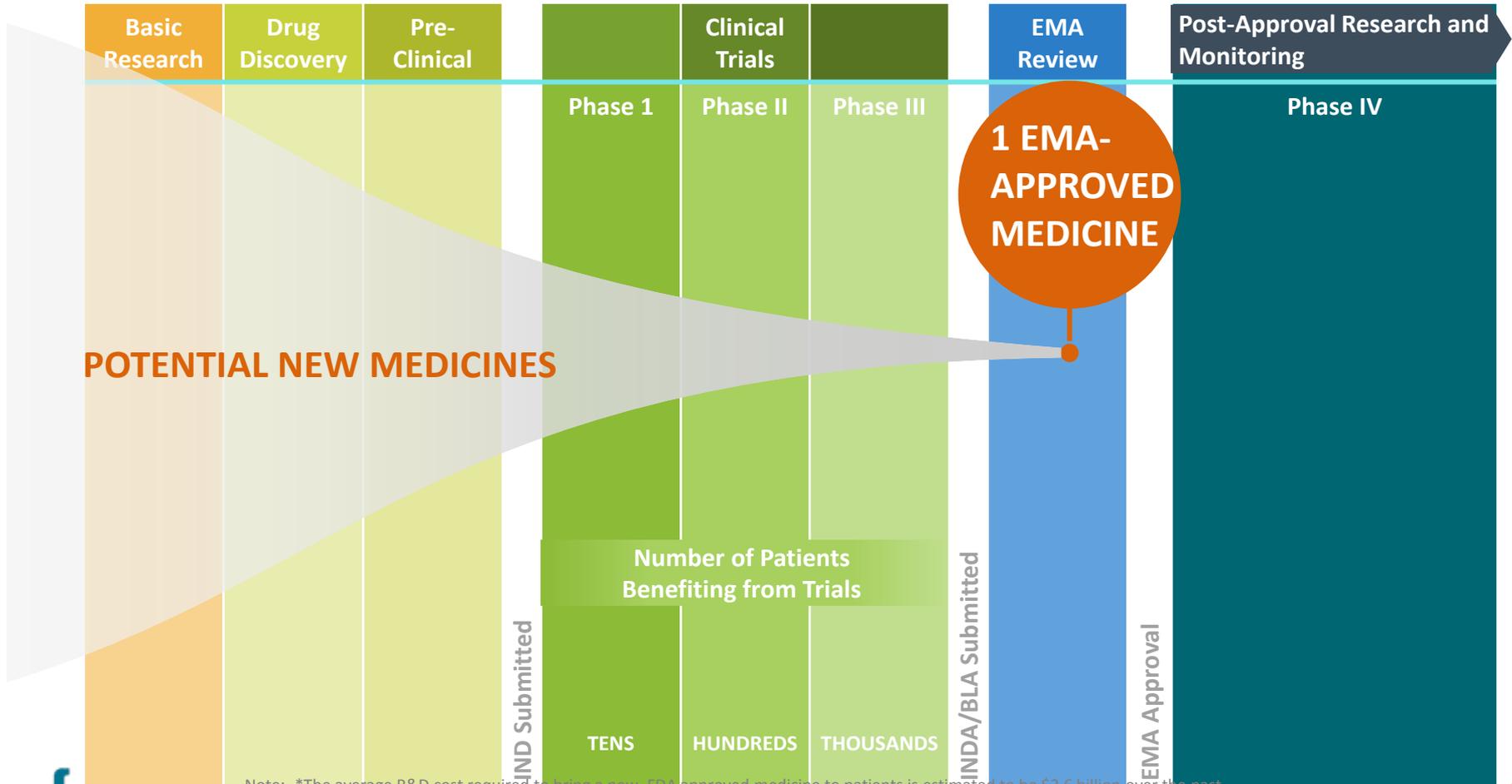
EFPIA, which has no profit-making purpose, pursues a mainly scientific aim, ensuring and promoting the technological and economic development of the pharmaceutical industry in Europe.

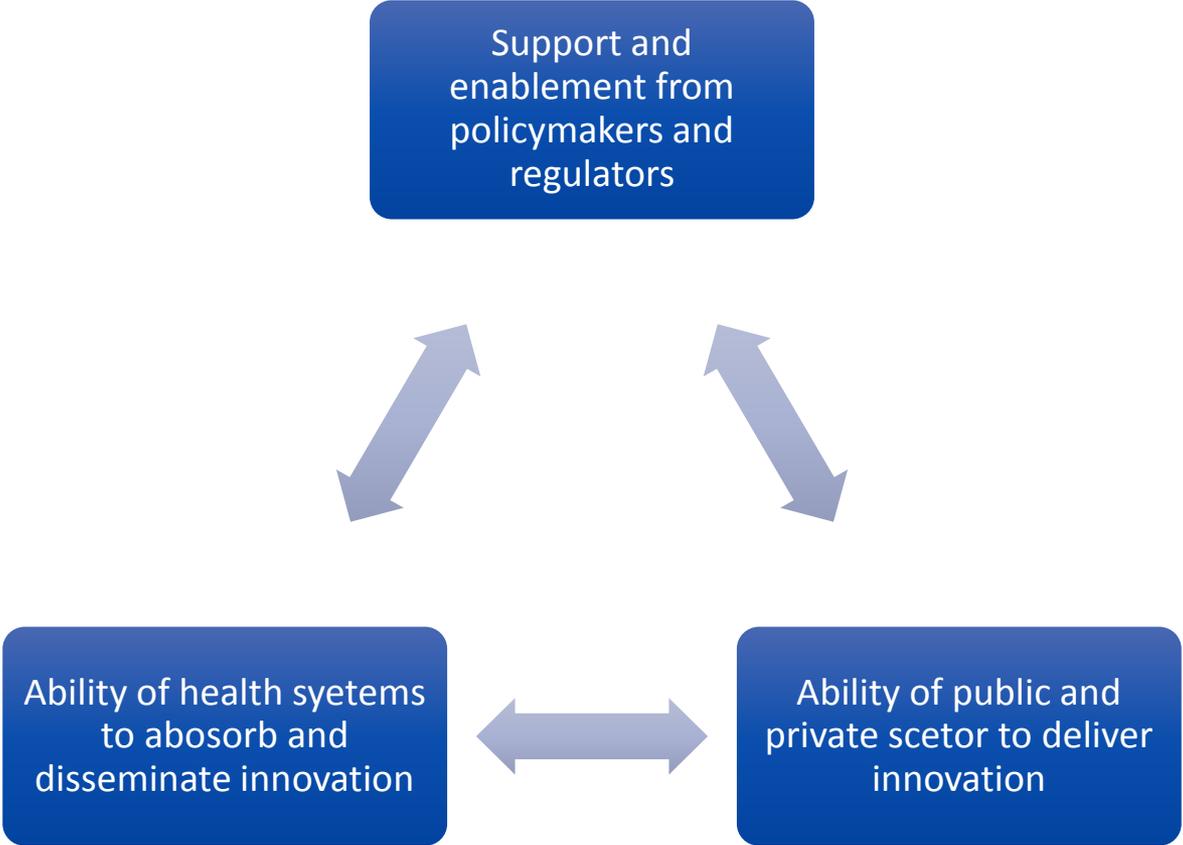
EFPIA's represents the pharmaceutical industry operating in Europe. Its direct membership includes **33 national associations** and **40 leading companies**. Two specialised groups within EFPIA represent vaccine manufacturers – **Vaccines Europe - VE**, with 12 member companies and **European/emerging bio-pharmaceutical companies – EBE** with 51 member companies.

“**Partners in Research**” is constituted of non-pharma companies that collaborate in the IMI public-private membership. This constituent entity, created in June 2014, counts 9 members.

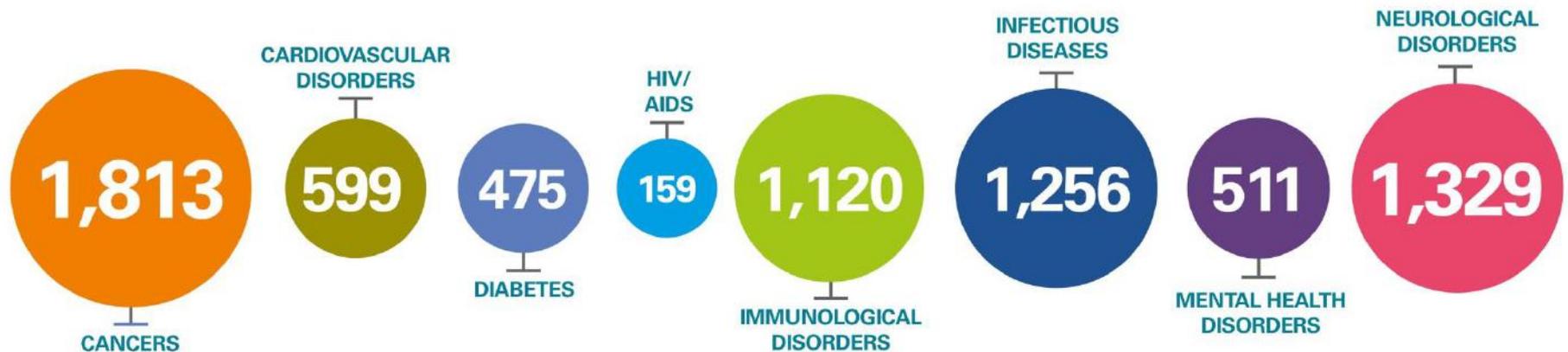
The biopharmaceutical research and development process

From drug discovery to EMA approval, developing a new medicine on average takes at least **10 years**





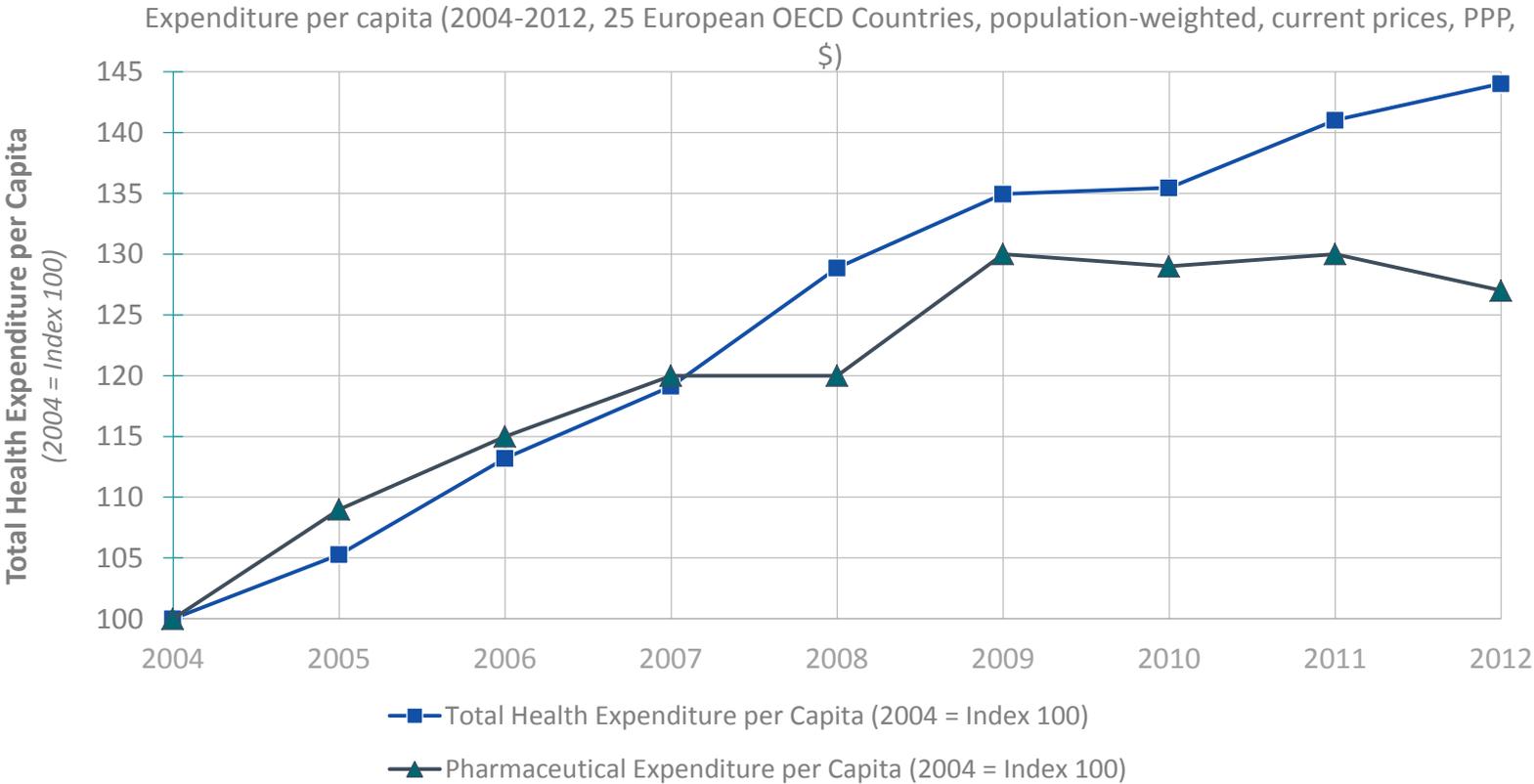
Despite the challenges, with over 7,000 medicines in development, new diagnostic techniques, genomic research and advances in data analytics there are many reasons to be optimistic about a *Healthier future for Europe*





Total healthcare expenditure has been growing since the 1990s while the **pharmaceutical spending declined from 2010 to 2013**

Across Europe, expenditures on total healthcare are growing faster than growth in pharmaceutical expenditures



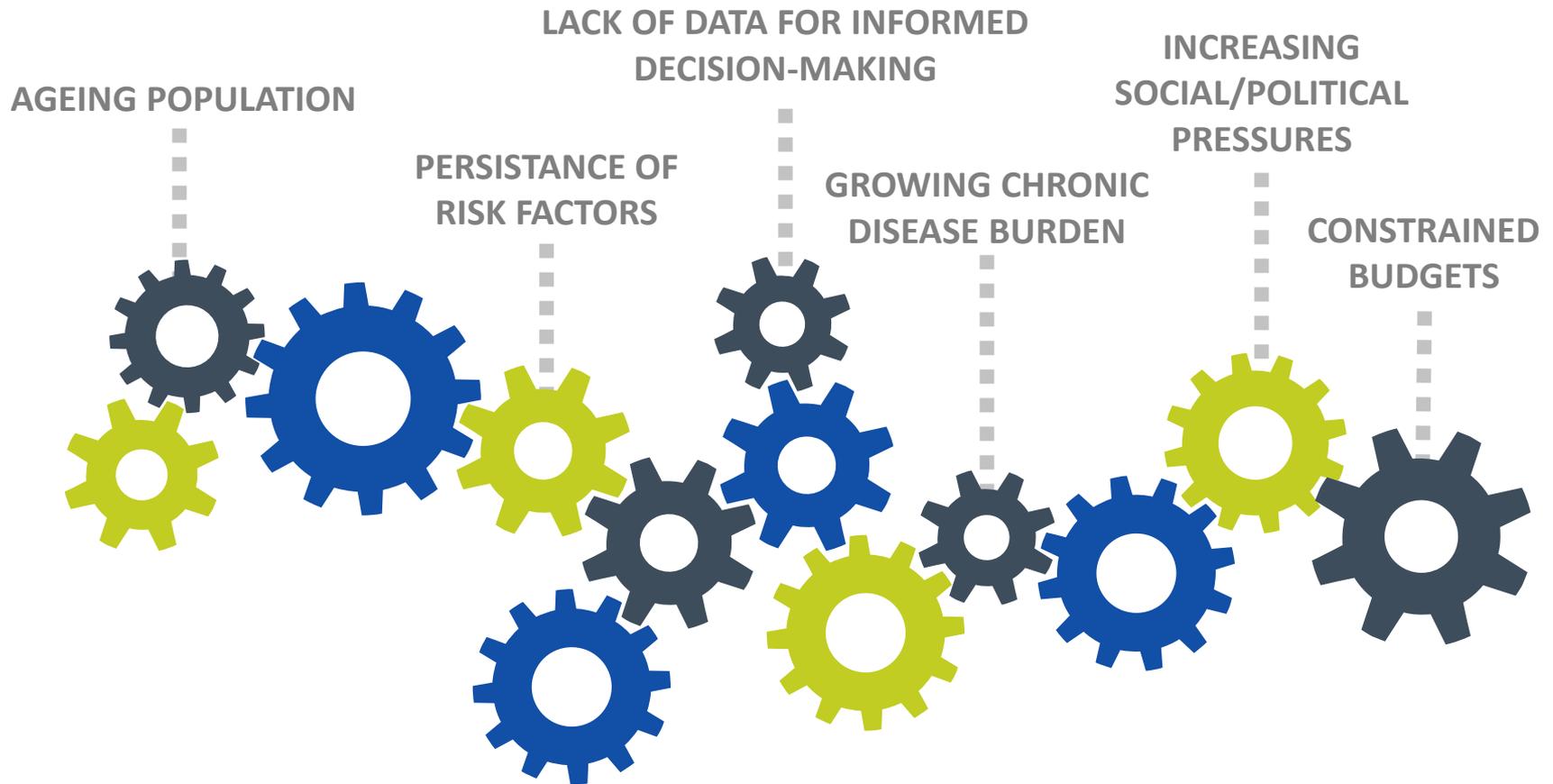
The Future Pipeline



- * Many areas of unmet need where innovation is advancing
- * New types of intervention (advanced therapies)
- * More integrated approaches (combination treatments, multiple morbidities)

High Impact Indications
Solid Tumours
Haematological Cancers
Alzheimer's Disease
Respiratory Infections
ALS
Cystic Fibrosis
Huntington's Disease
Haemophilia B
β -Thalassemia
Diabetes
Heart disease
Back and Neck Pain
Cirrhosis of the Liver
Unipolar Depression

Healthcare systems across Europe are facing unprecedented challenges, driven by an ageing population and an increased prevalence of chronic disease



Despite the progress of public health across countries in Europe, significant health inequalities persist. There are **significant variations in outcomes** for patients between countries but also within countries, which cannot be explained by different levels of investment in health and healthcare



Why outcomes-based healthcare?



- 1 EU health systems face significant **sustainability challenges**, which will increase further given ageing populations
- 2 **Outcomes vary greatly** across Europe, which cannot be explained by spending differentials or risk factors alone
- 3 By **focussing on outcomes**, systems can achieve better care, improve equality, and reduce wasteful spending
- 4 **Smarter resource allocation** across all types of interventions rewards innovation that delivers superior outcomes

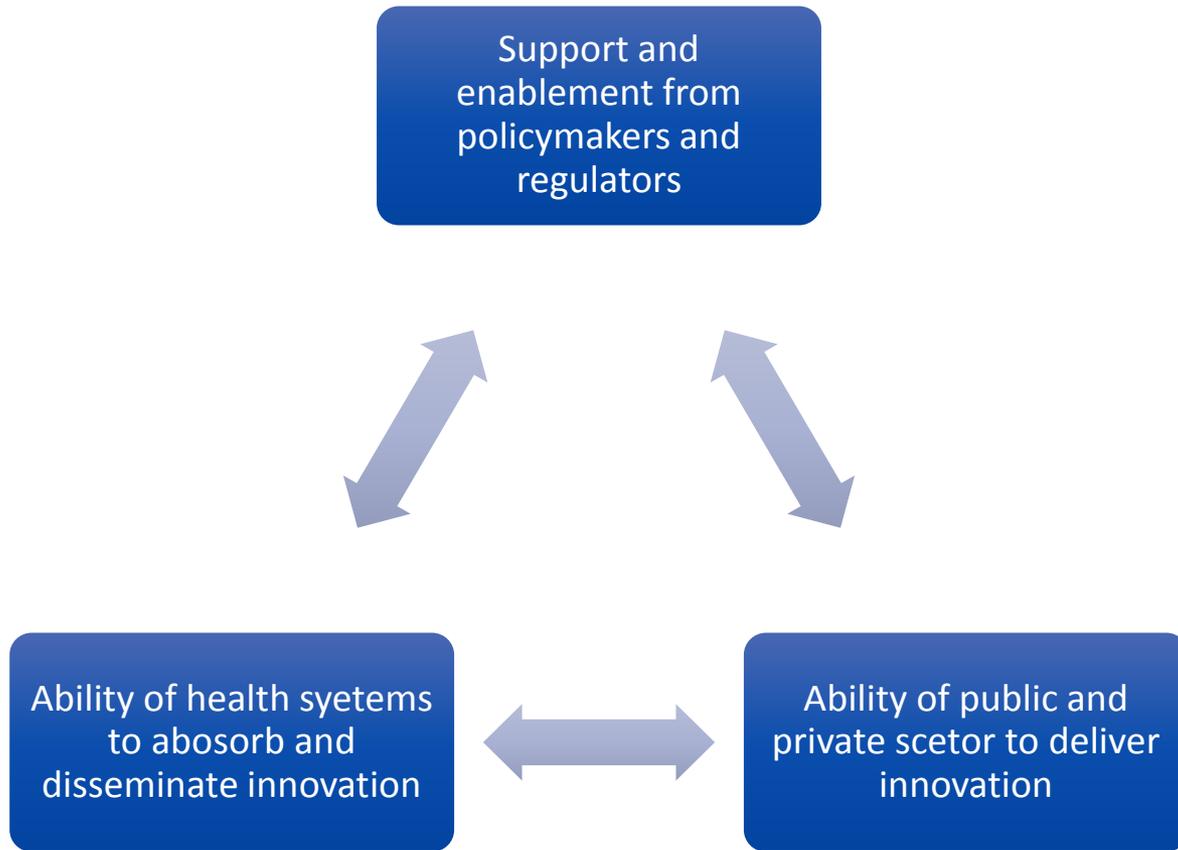
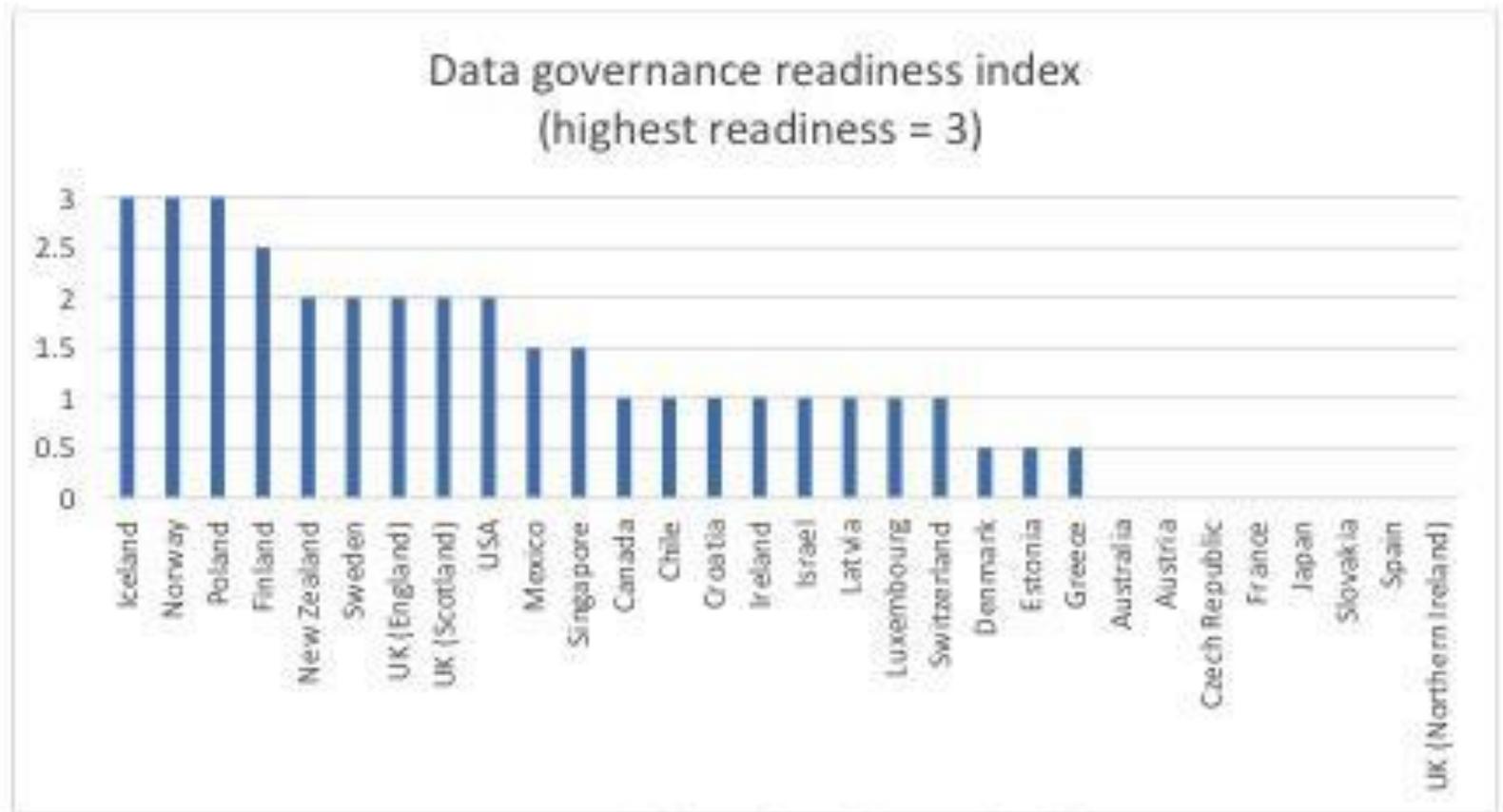


Figure 5: Data governance readiness varies greatly among countries



Source: HCQI Survey of Electronic Health Record System Development and Use, 2016.

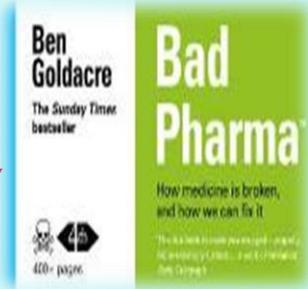
data collection, investment costs, and public concerns represent key barriers for uptake

Barrier	Details
 Data collection burden	Providers/ physicians want to focus on curing patients, not inputting data into systems
 Publication incentives	Objective to be first to market with a scientific discovery incentivises keeping data in “walled gardens”
 Performance transparency	Providers may fear transparency might display them as low performers (rightly or wrongly, e.g., if unadjusted for case complexity)
 Investment costs	Payers/ providers/ governments may shy away from investment in favour of short-term savings
 Privacy concerns	Public concerned about stigmatisation/ embarrassment and negative consequences of their data becoming public (e.g., denial of insurance)



Learning from the past: building trust and explaining positive benefits are crucial

Data Transparency



- Industry principles have led to increased data-sharing often through collaborative platforms
- Survey of progress underway with results available at end of year

Animal Welfare



- Major public attacks by animal rights activists on industry at beginning of century
- Lack of communication around the need for animal testing to save lives meant public understanding was low

Care.data



- UK NHS project to extend medical records database with data collected in GP practices was put on hold due to public "big brother" accusations
- The NHS had failed to communicate benefits of putting health data to use and to win the hearts and minds of the public

The EU data architecture for health research needs to be operate seamlessly across borders and institutions and offer high levels of security and accountability. Many of the issues below need to be approached in a joined-up, inclusive and transparent way



The challenges facing healthcare systems and the scientific community can only be addressed through successful collaboration

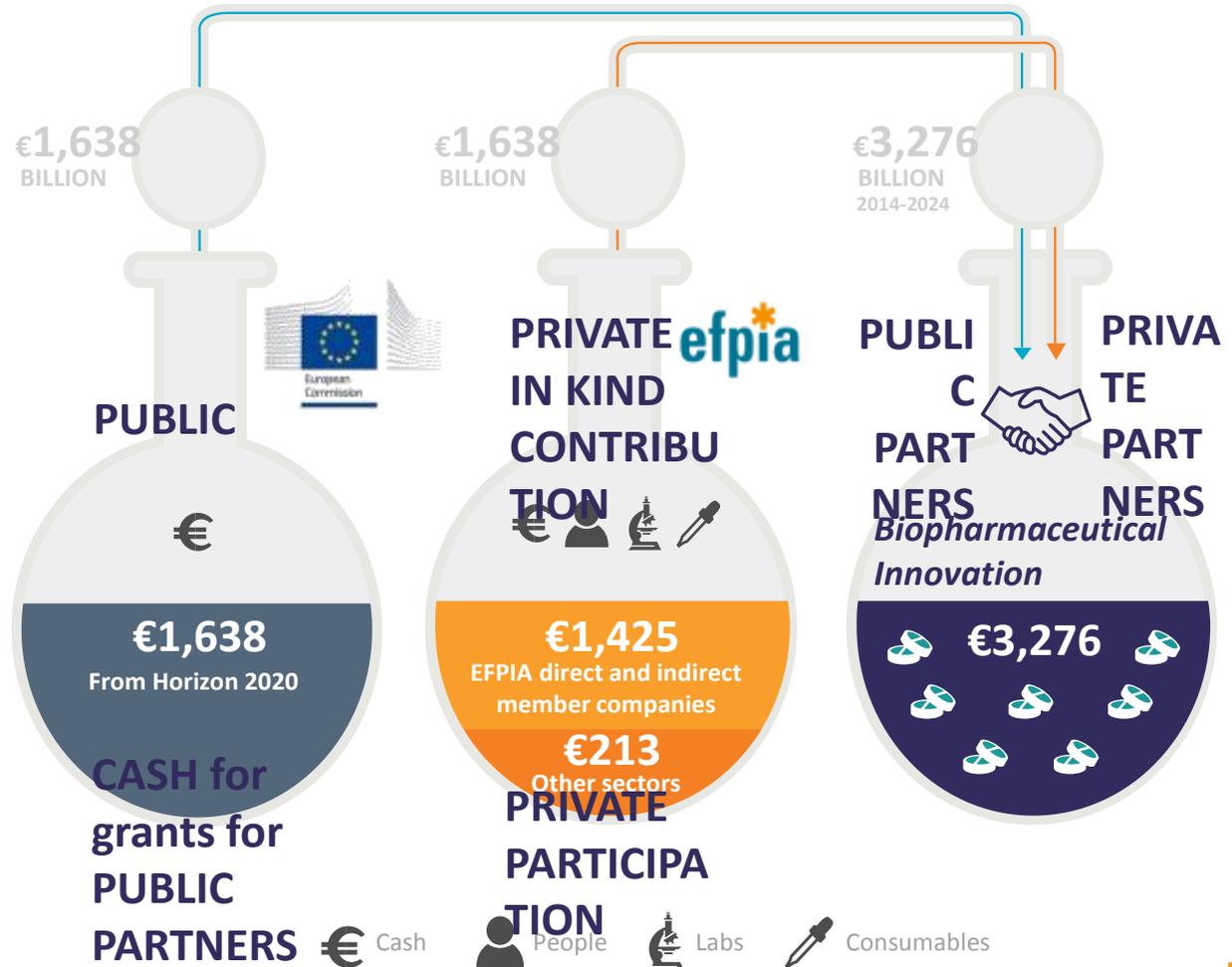


The Innovative Medicines Initiative (IMI) is **the world's largest public-private partnership**

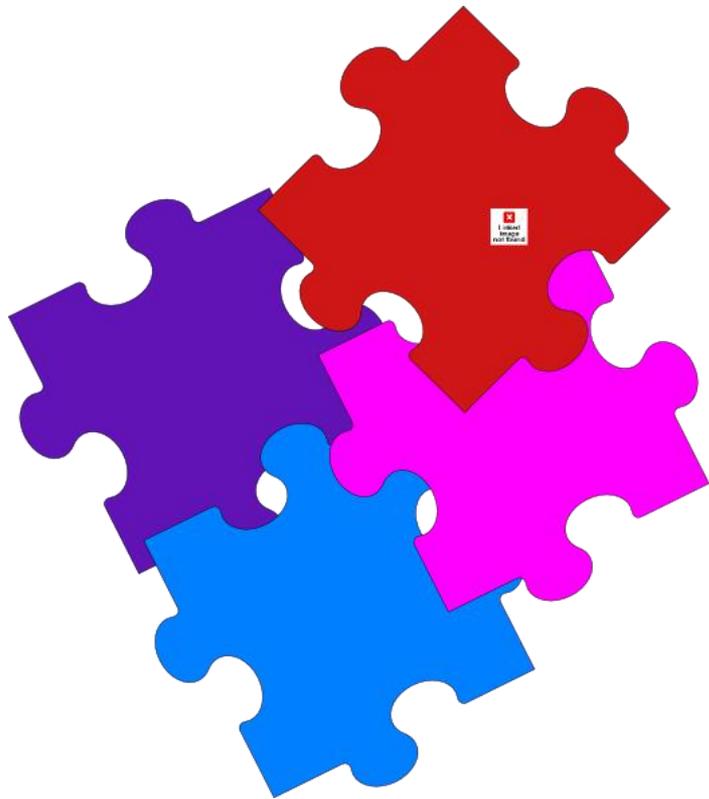
IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.

Through the IMI 2, a joint undertaking between the European Union and the pharmaceutical industry association EFPIA, a **€3.3 billion budget for the period 2014-2024** has been established.

IMI 2 Partnership and Funding Overview²



Source: Health Advances analysis; ¹IMI website; ²EFPIA 2014 Annual Report.



- Moving to the next stage
- Over-arching concept is a common research strategy for Europe
- based on early integration of payers, patients and researchers
- Improved understanding of our respective roles
- Further development of the value chain
- Multi-stakeholder governance
- Balancing competition and cooperation

Thank you



The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.