



Open for Business: Re-imagining Bioscience

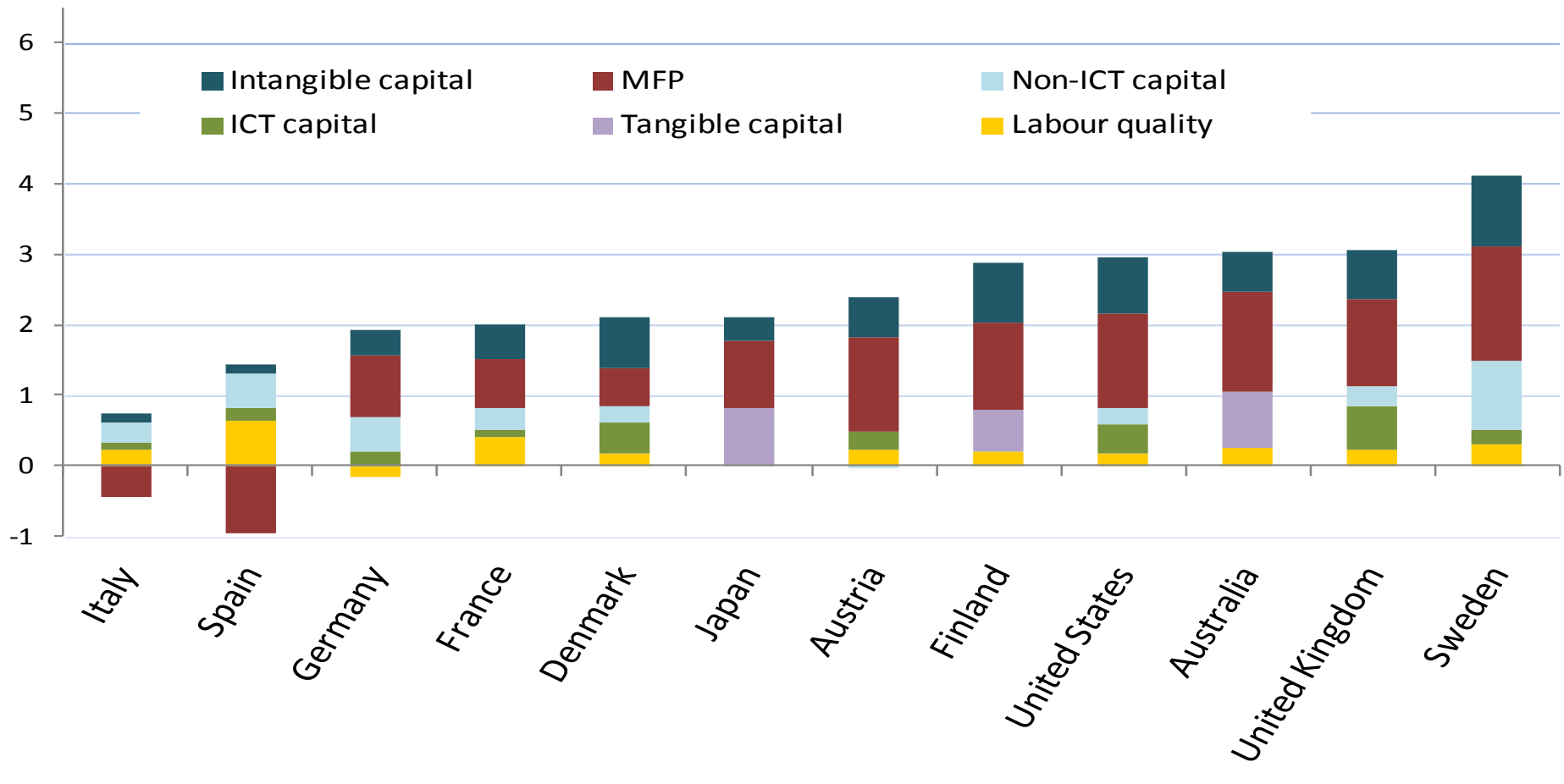
Iain Gillespie

18.10.2017 • IMI Stakeholder Forum | Open Innovation • Brussels, Belgium

Innovation is key to growth...



Contributions to labour productivity growth, 1995-2006, in %



* Investment in intangibles and multi-factor productivity growth account for between two-thirds and three-quarters of labour productivity growth.

Global Difference



Decomposition of cross-country differences in GDP per capita into their determinants, 2005

(United States = 100)

	GDP PPP per capita	TFP	Human capital	Physical capital	Employment
United States	100.0	100.0	100.0	100.0	100.0
Canada	83.5	72.0	103.3	105.8	106.0
Japan	72.6	52.6	100.4	130.7	105.1
China	9.8	13.6	57.3	105.2	119.5
India	5.2	12.7	47.7	98.3	87.1
Brazil	20.5	29.3	70.1	103.1	96.8
Russian Federation	28.6	31.5	84.9	97.4	99.3
EU27 + EFTA	64.7	67.8	91.2	114.1	91.3
Total World	22.8	27.9	64.2	104.2	95.8

Source: OECD.

Innovation can restore flagging productivity growth

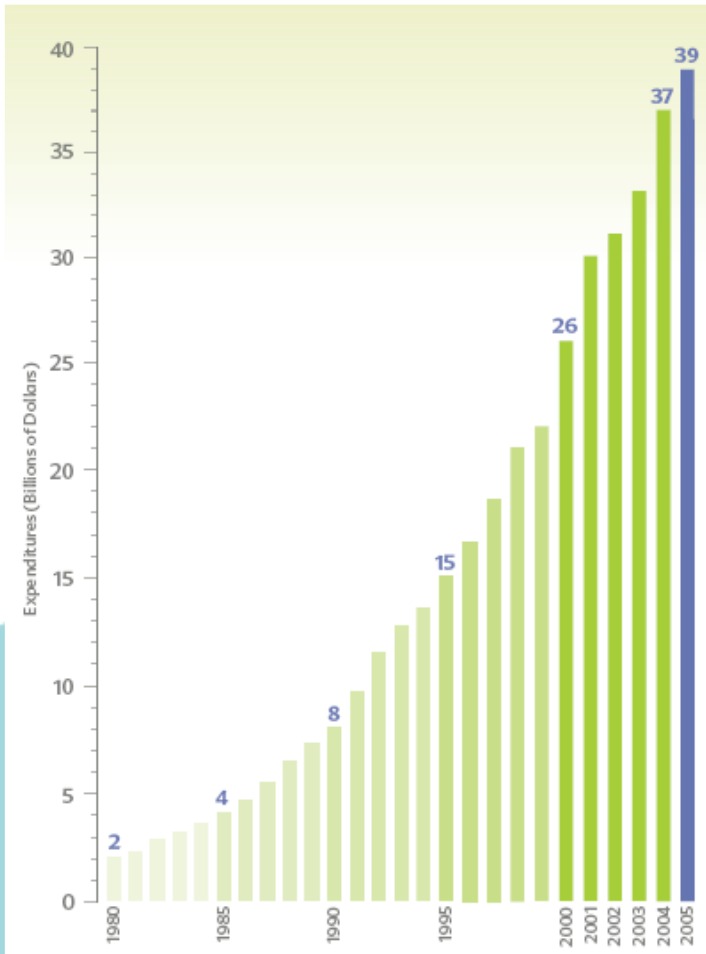
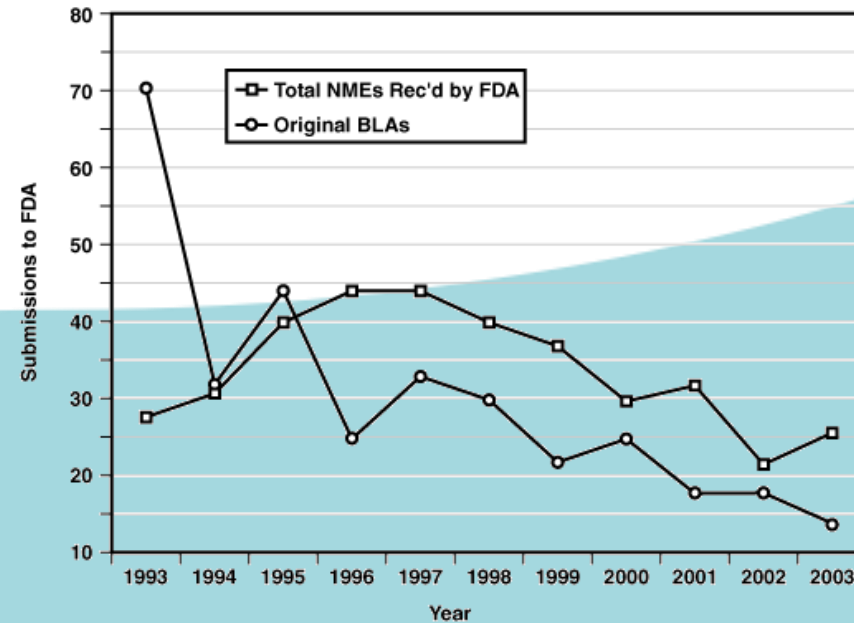


Figure 2: 10-Year Trends in Major Drug and Biological Product Submissions to FDA

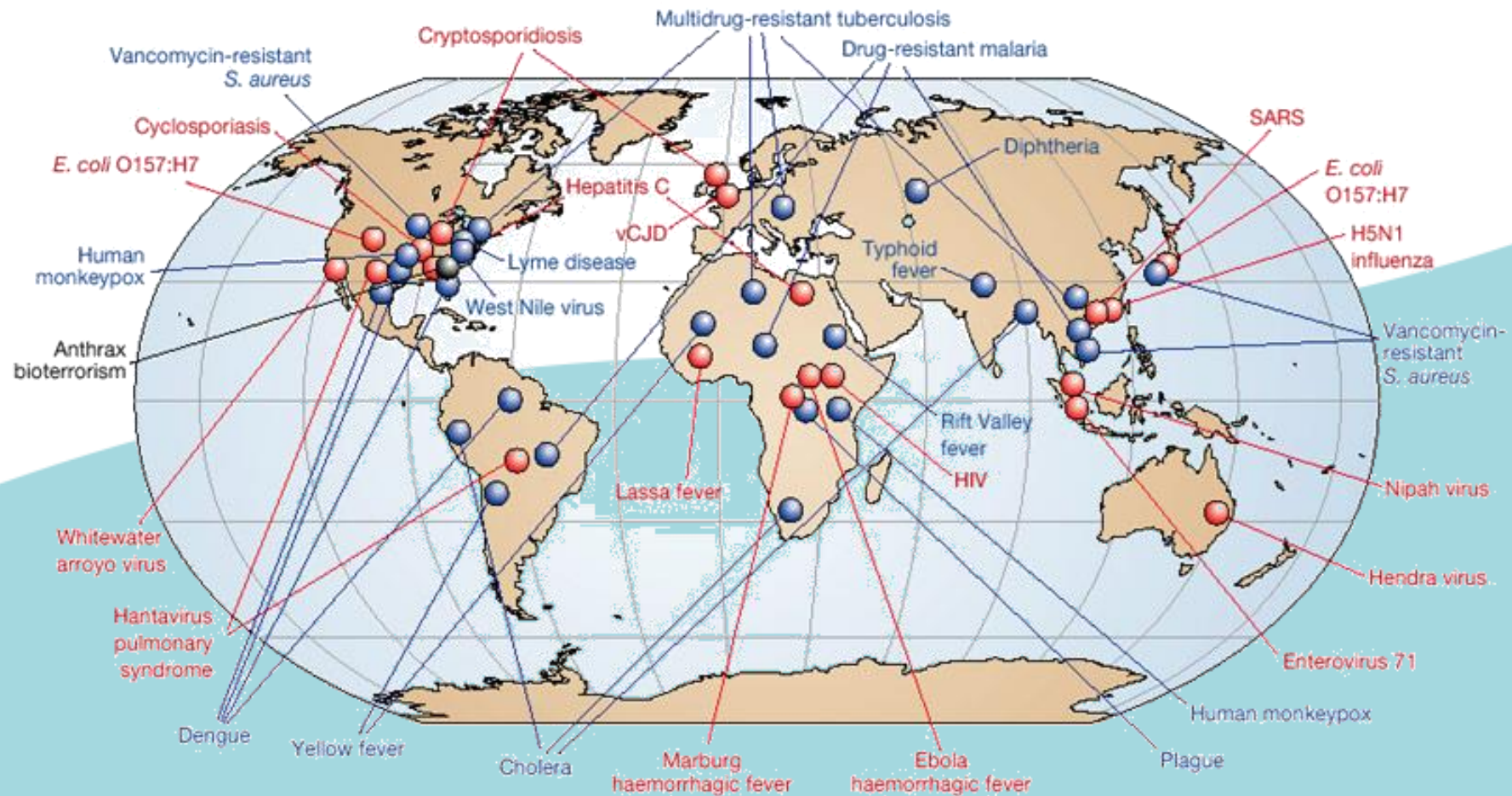


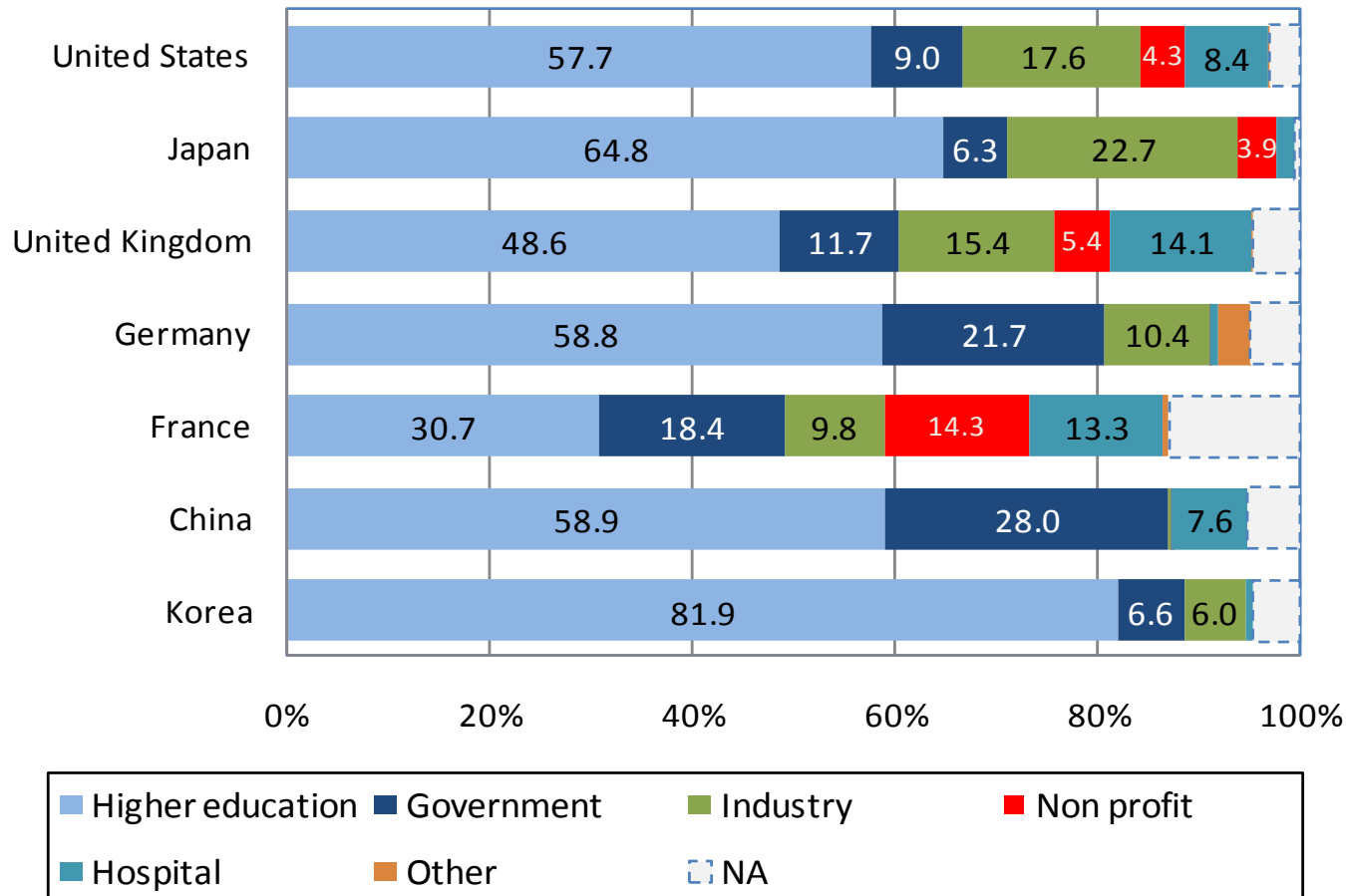
The figure shows the number of submissions of new molecular entities (NMEs) — drugs with a novel chemical structure — and the number of biologics license application (BLA) submissions to FDA over a 10-year period. Similar trends have been observed at regulatory agencies worldwide.

Infectious diseases globally



innovative
medicines
initiative





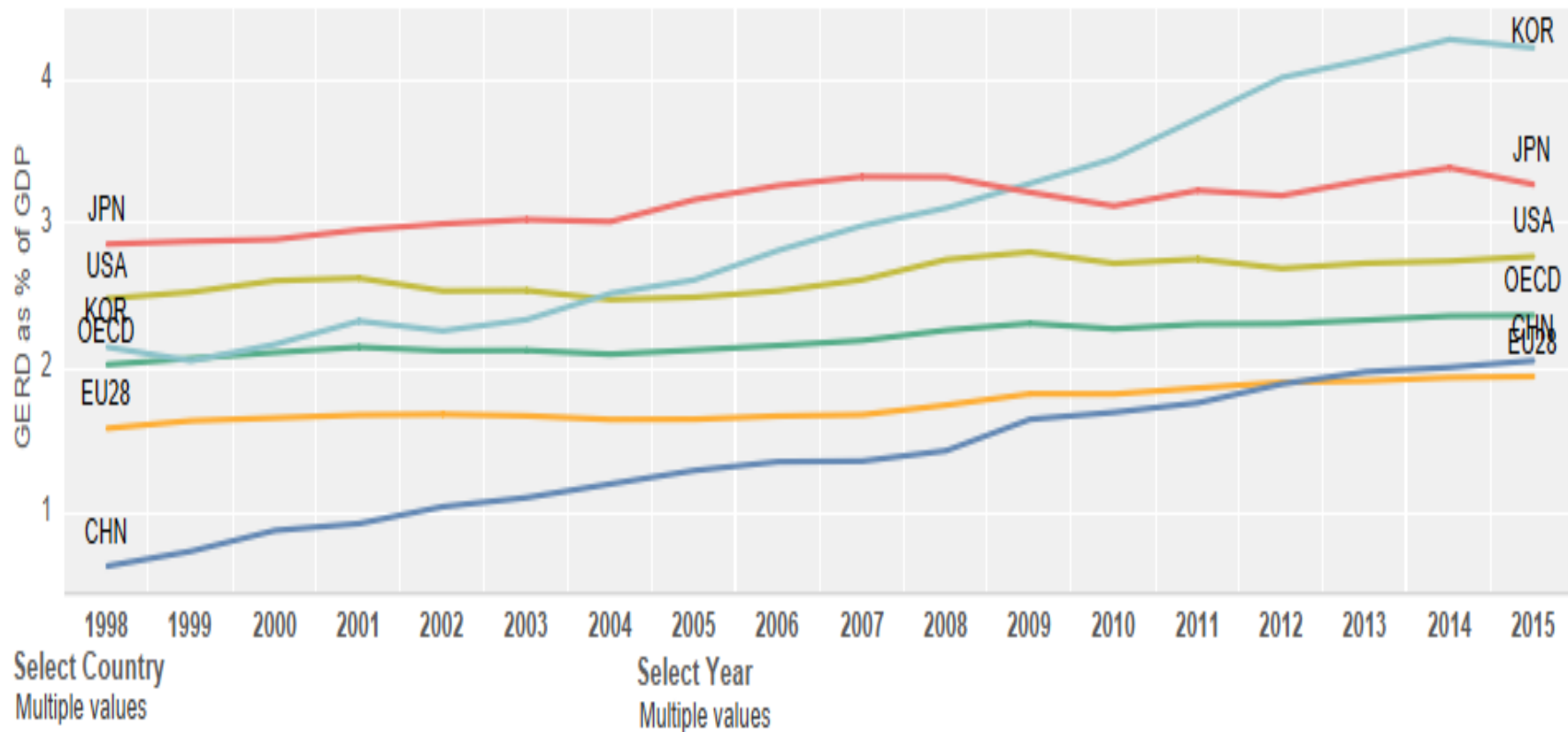
Reliance of patents on science citations

(biochemistry papers cited by pharmaceutical patents)

EU Research Intensity Still Lagging



R&D Intensity in OECD countries and other economies



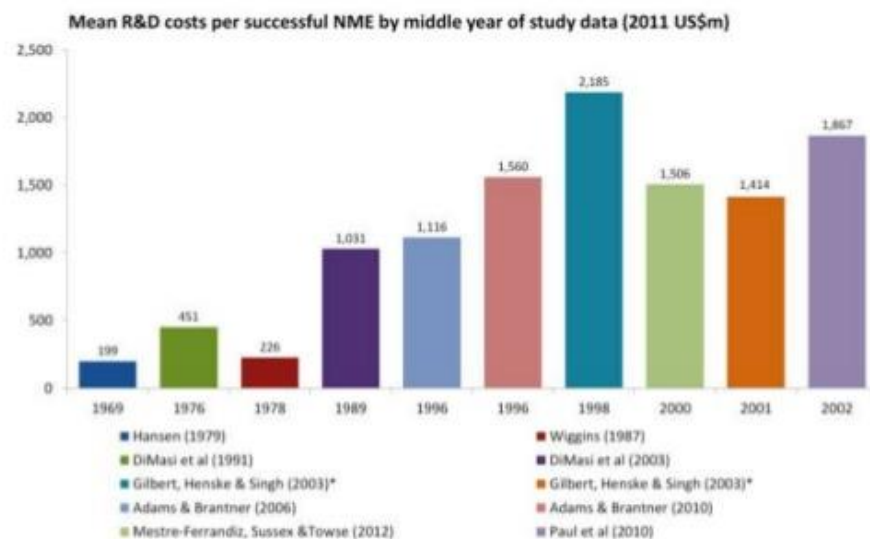
Source: OECD estimates based on OECD Main Science and Technology Indicators Database, July 2017.
 Data available here: http://www.oecd.org/sti/inno/rd_intensities.xls

Cost of Drug Development



R&D costs per successful NME =
\$1.5Bn (OHE, 2013)

Key Studies



*The authors performed two sets of calculations on the same data.

Source: Mestre-Ferrandiz, J., Sussex, J. and Towse, A. (2012) *The R&D Cost of a New Medicine*. London: Office of Health Economics.

Cost to develop and gain marketing approval for a new drug = **\$2.558 billion** (CSDD, 2016)

Based on estimated average out-of-pocket costs of \$1.395 billion and time costs (expected returns that investors forego while a drug is in development) of \$1.163 billion.

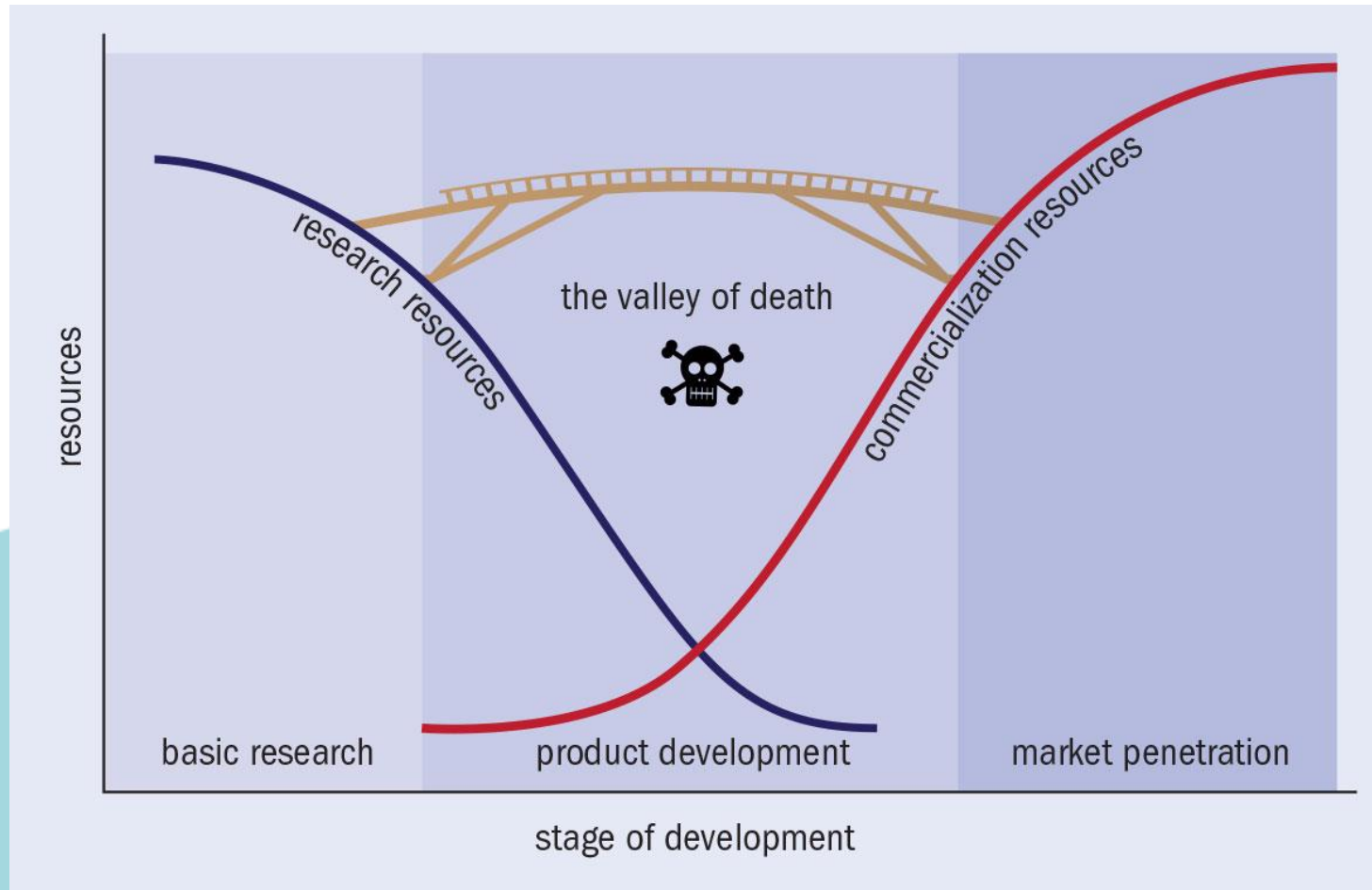
When post-approval R&D costs of \$312 million are included, the full, product lifecycle cost per approved drug, on average, rises to \$2.870 billion

March 10, 2016 –Tufts Center for the Study of Drug Development

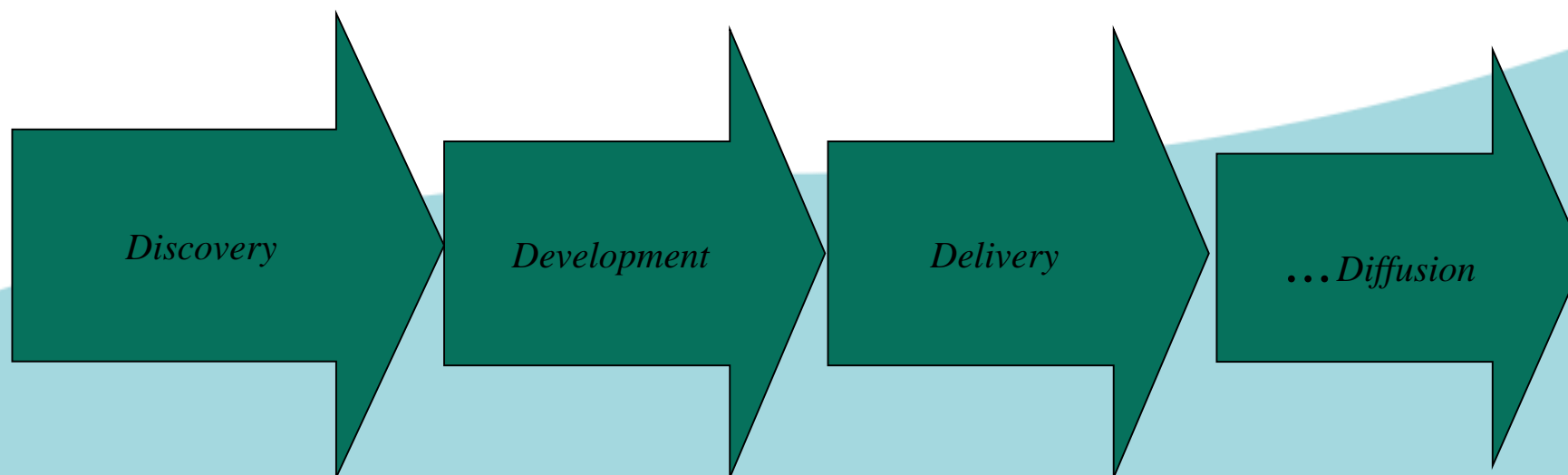


The R&D Cost of a New Medicine

Overcoming the Valley of Death



Linear Model



The Innovation cycle

Research
Policy and Behaviour
Network collaborations

DISCOVERY

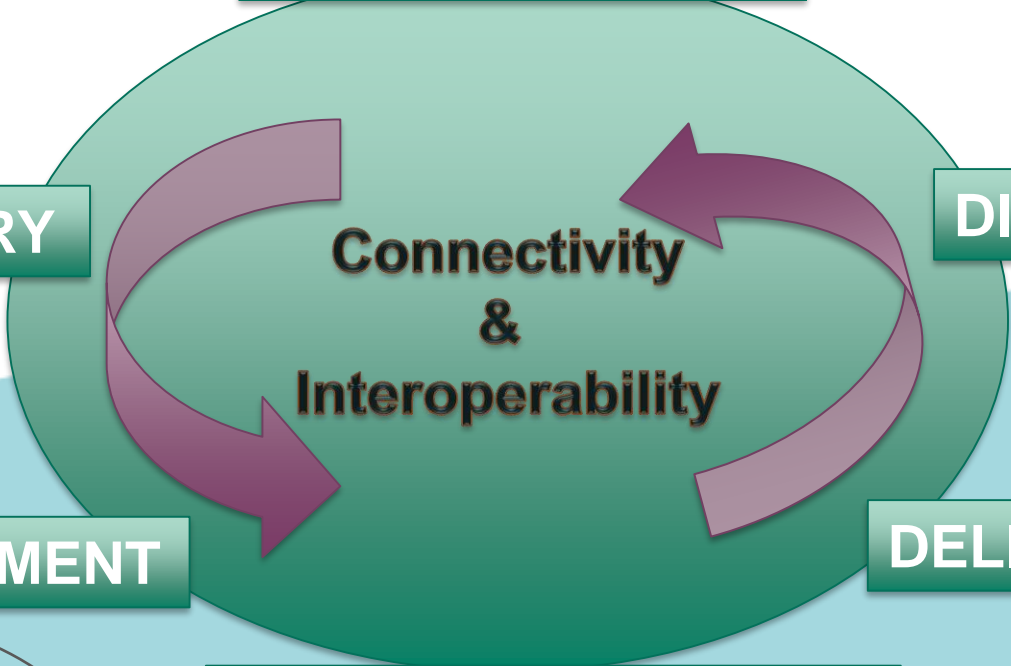
IDENTIFICATION of NEED

Match innovation and market needs

Enabling environment?

Policy
Environment
Energy
Health
Etc.
Market Demands
Tools
Flexibility

DIFFUSION



DEVELOPMENT

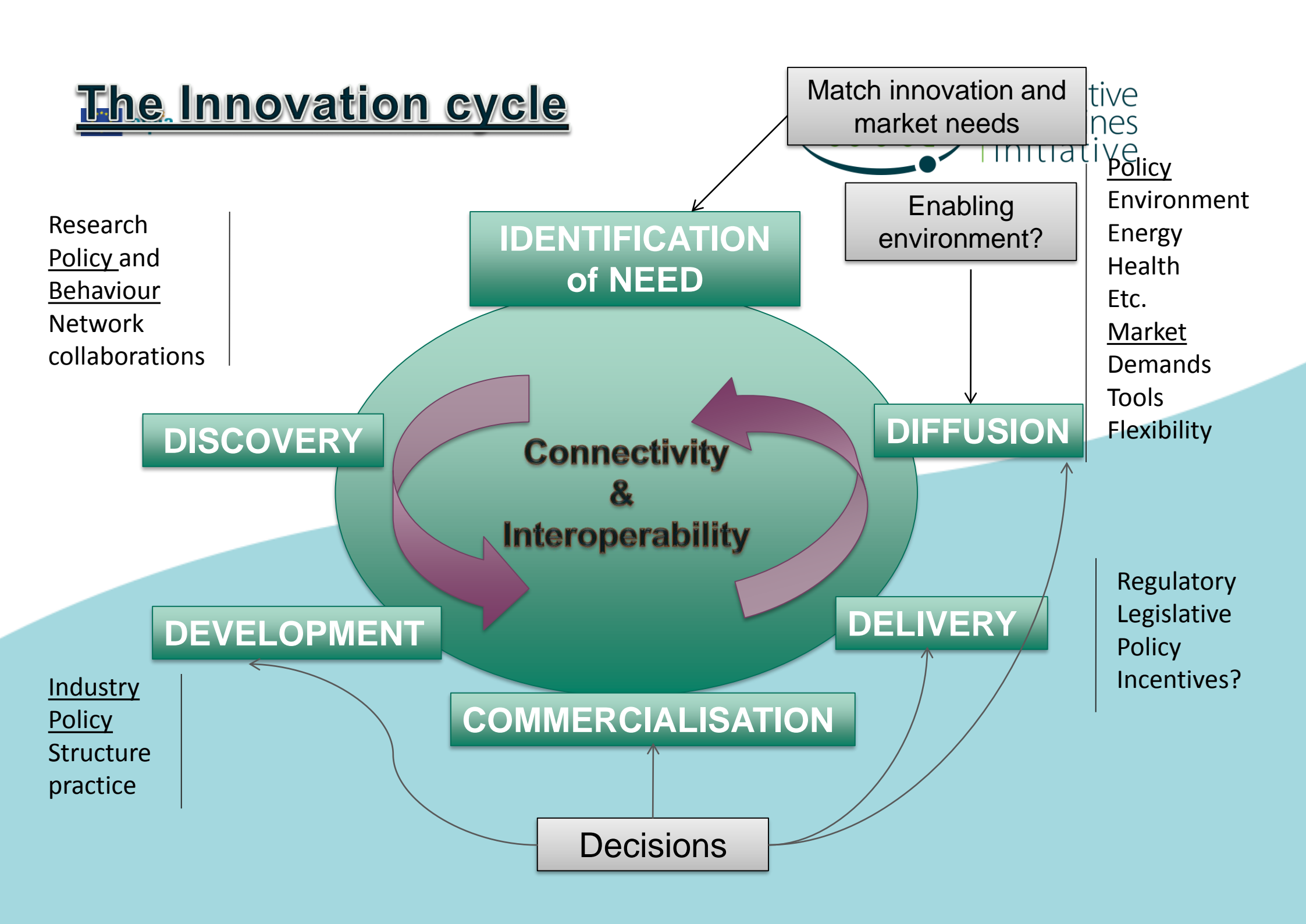
DELIVERY

Regulatory
Legislative
Policy
Incentives?

COMMERCIALISATION

Industry Policy
Structure
practice

Decisions

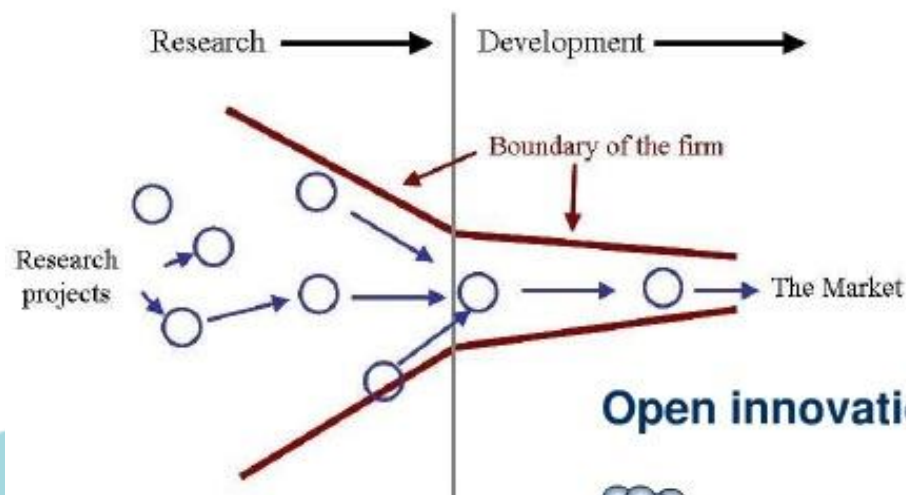


What is Open Innovation?



innovative
medicines
initiative

Open Vs Closed Innovation



Open innovation

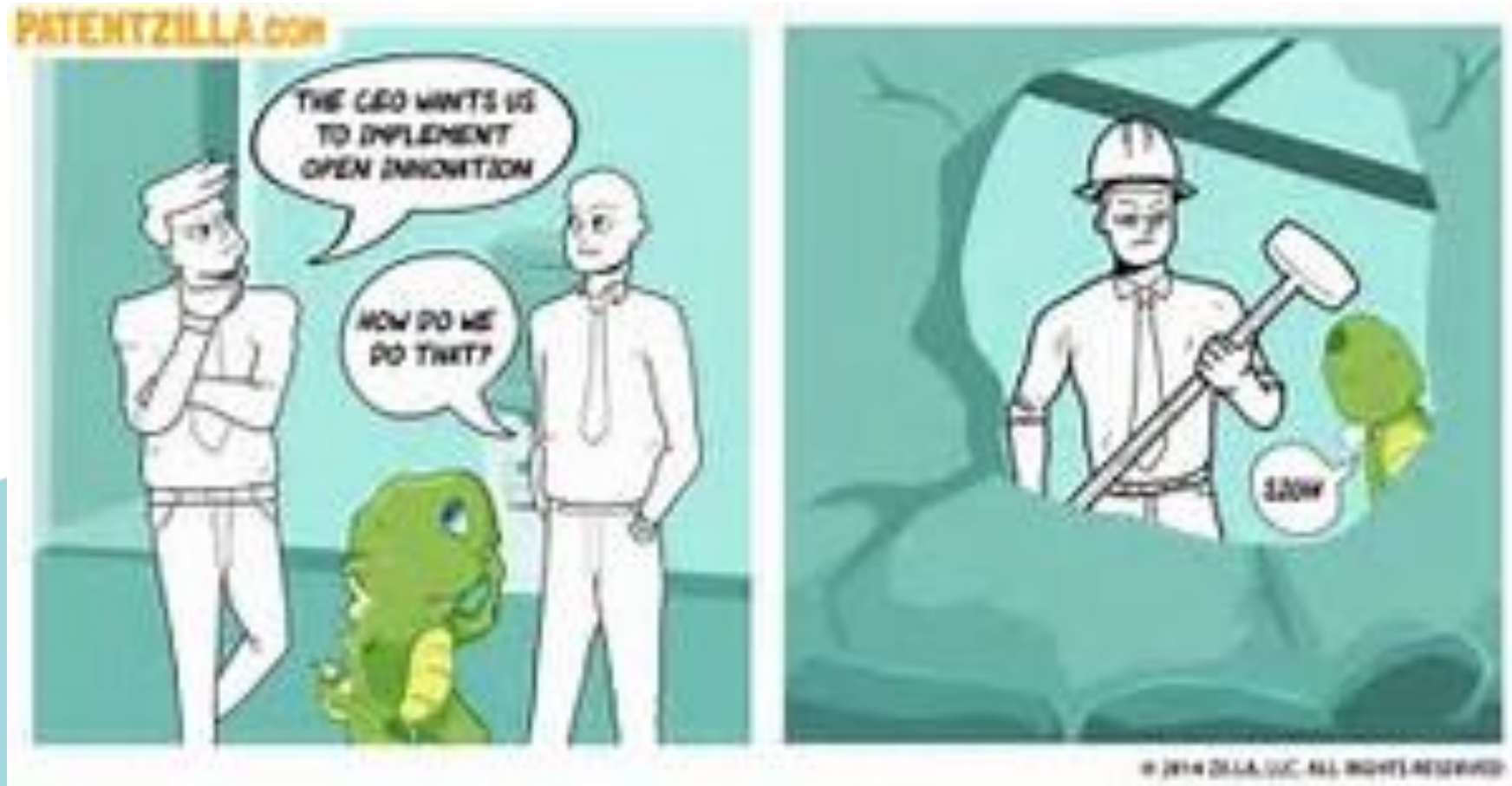


***Then:* Closed Innovation**

- ❑ Approach: “not invented here”
- ❑ Innovation:
 - Strategy independent of overall business strategy
 - Performed in-house
 - Internal pool of innovators
- ❑ Outputs:
 - Incorporated in firm’s products and services.
 - Product revenues finance next cycles of in-house R&D

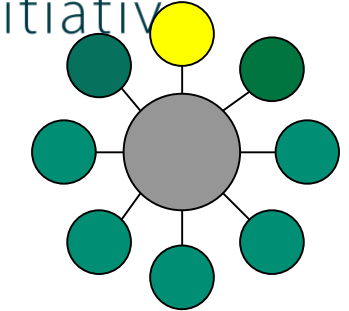
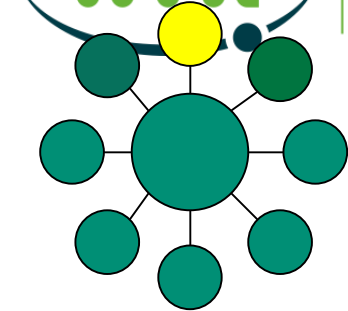
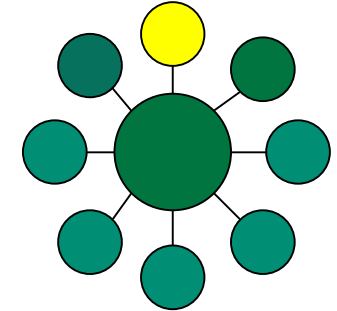
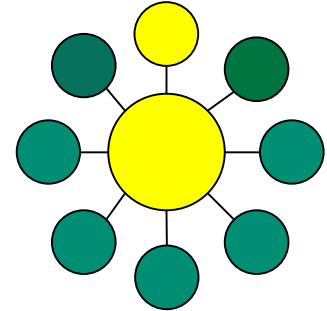
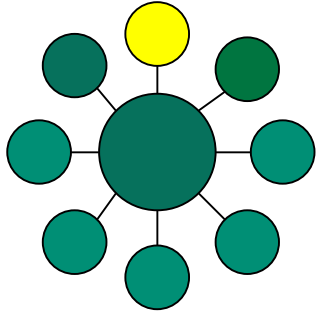
***Now:* “Open“ Innovation**

- ❑ Approach: “proudly found elsewhere”
- ❑ Innovation:
 - Business strategy drives targets
 - Technology developed cooperatively or acquired
 - Work with many innovators and users/consumers
 - Leverage own IP
- ❑ Outputs:
 - Both internalized and externalized (*licensing, spin-offs, venturing*)





innovative medicines initiative



Driver

Academia & Foundations

Regulators

Government

Industry (Pharma)

Company (Solution Provider)

Examples

SNP Consortium

Predictive Safety Testing Consortium

Innovative Medicines Initiative

International Serious Adverse Events Consortium

High-Risk Plaque Initiative

Description

Independent 3rd party to coordinate effort and provide data for public access

Identify the most informative tests and tools with regulatory acceptance built in

Support faster discovery and development of medicines through coordination and funding

Collaboration between companies to share cost and resource for individual use

Development of novel biomarkers and tools to license

Academia/Foundations
 Government
 Industry (Solution Providers)

Regulators
 Industry (Pharma)

(From Joe Fezcko, Pfizer)



Consortia by the Numbers



innovative
medicines
initiative

<10

Number of pharmaceutical consortia 7 years ago

1.7m

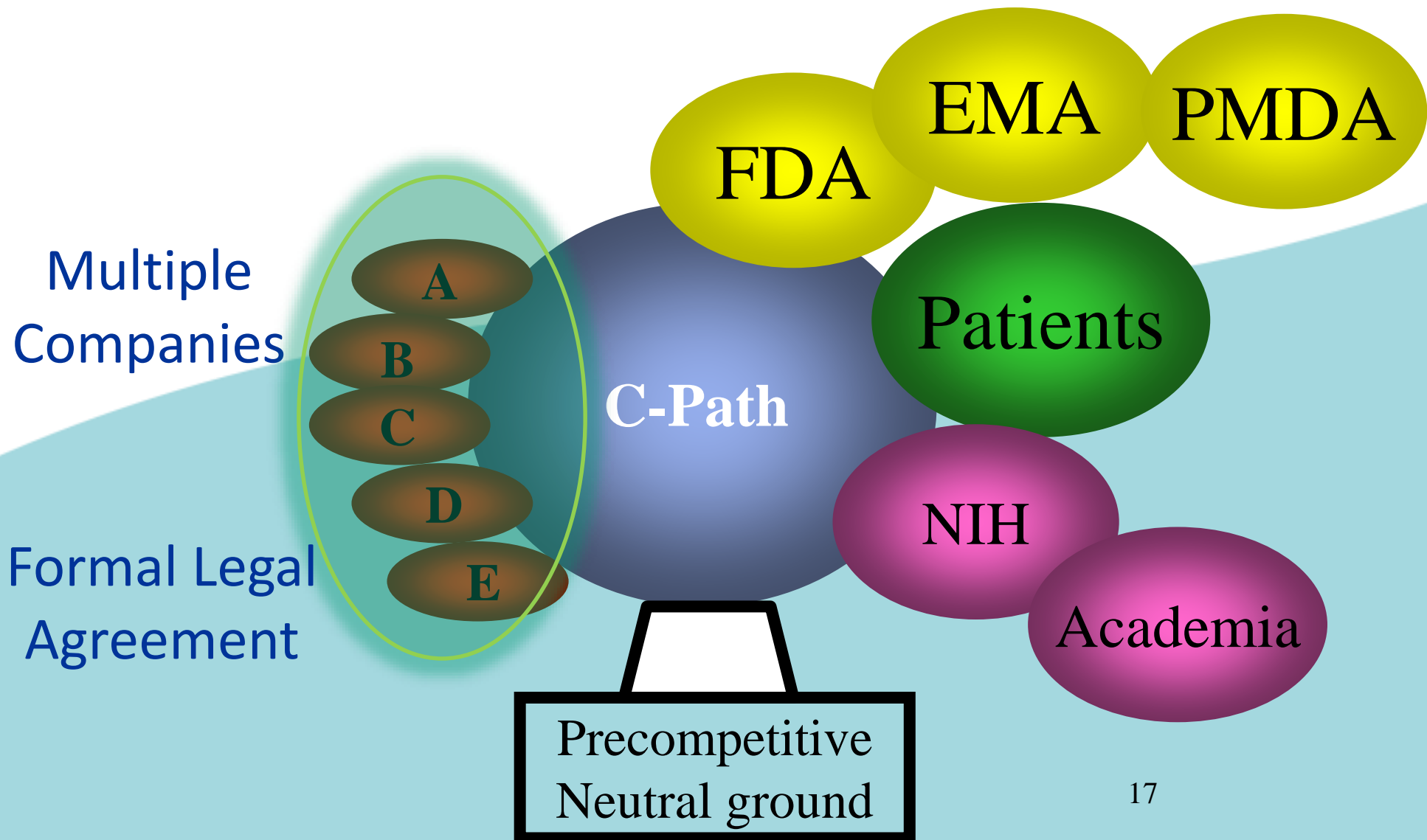
Number of Google hits when searching for 'pharmaceutical consortia'

>40

Over 40 consortia and public-private partnerships focused on discovering and developing new medicines

>1b

Estimate of total annual budget (USD) for major consortia



- **IMI is the largest Public Private Partnership in the world**
- **IMI's overall goal is to reinvigorate the biopharmaceutical sector in and to build a more collaborative ecosystem for pharmaceutical R&D**
- **Research projects bring together biopharmaceutical companies, SMEs, regulators, academia and patients organisations to work together in collaborative projects**
<http://www.imi.europa.eu>





International Leverage



The SGC (Structural Genomics Consortium) is a not-for-profit, public-private partnership with the directive to carry out basic science of relevance to drug discovery.

Funders: AbbVie, Bayer Pharma AG, Boehringer Ingelheim, Canada Foundation for Innovation, Eshelman Institute for Innovation, Genome Canada through Ontario Genomics Institute [OGI-055], Innovative Medicines Initiative (EU/EFPIA) [ULTRA-DD grant no. 115766], Janssen, Merck KGaA, Darmstadt, Germany, MSD, Novartis Pharma AG, Ontario Ministry of Research, Innovation and Science (MRIS), Pfizer, São Paulo Research Foundation-FAPESP, Takeda, and Wellcome.



GARDP

Global Antibiotic Research
& Development Partnership



innovative
medicines
initiative

A joint DNDi / WHO initiative



Develop and deliver up to four new treatments through improvement of existing antibiotics and acceleration of the entry of new chemical entities.

Build a robust pipeline of pre-clinical and clinical candidates with up to four candidates brought into pre-clinical or clinical development.

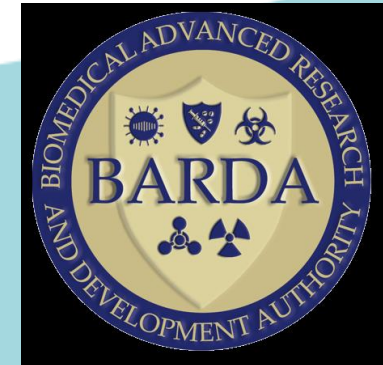
Secure EUR 270 million to execute its R&D programmes, build a highly experienced R&D team, and establish a dedicated entity.

Support and advocate for appropriate use of antibiotics, sustainable access, and suitable financing of R&D for new antibiotic treatments.

EUR 56 million
Germany, Luxembourg,
Netherlands, Monaco,
South Africa, Wellcome
Trust, UK

CARB-X

Xccelerating Global Antibacterial innovation





New Partnerships



AstraZeneca collaborates with Microsoft on 'drag and drop' drug discovery simulation **21 September 2016 (Drug Discovery Today)**

A new biologist-friendly, 'drag and drop' computer modelling system for key cancer signalling pathways is expected to speed up drug discovery and reduce the need for 'wet' lab experiments.





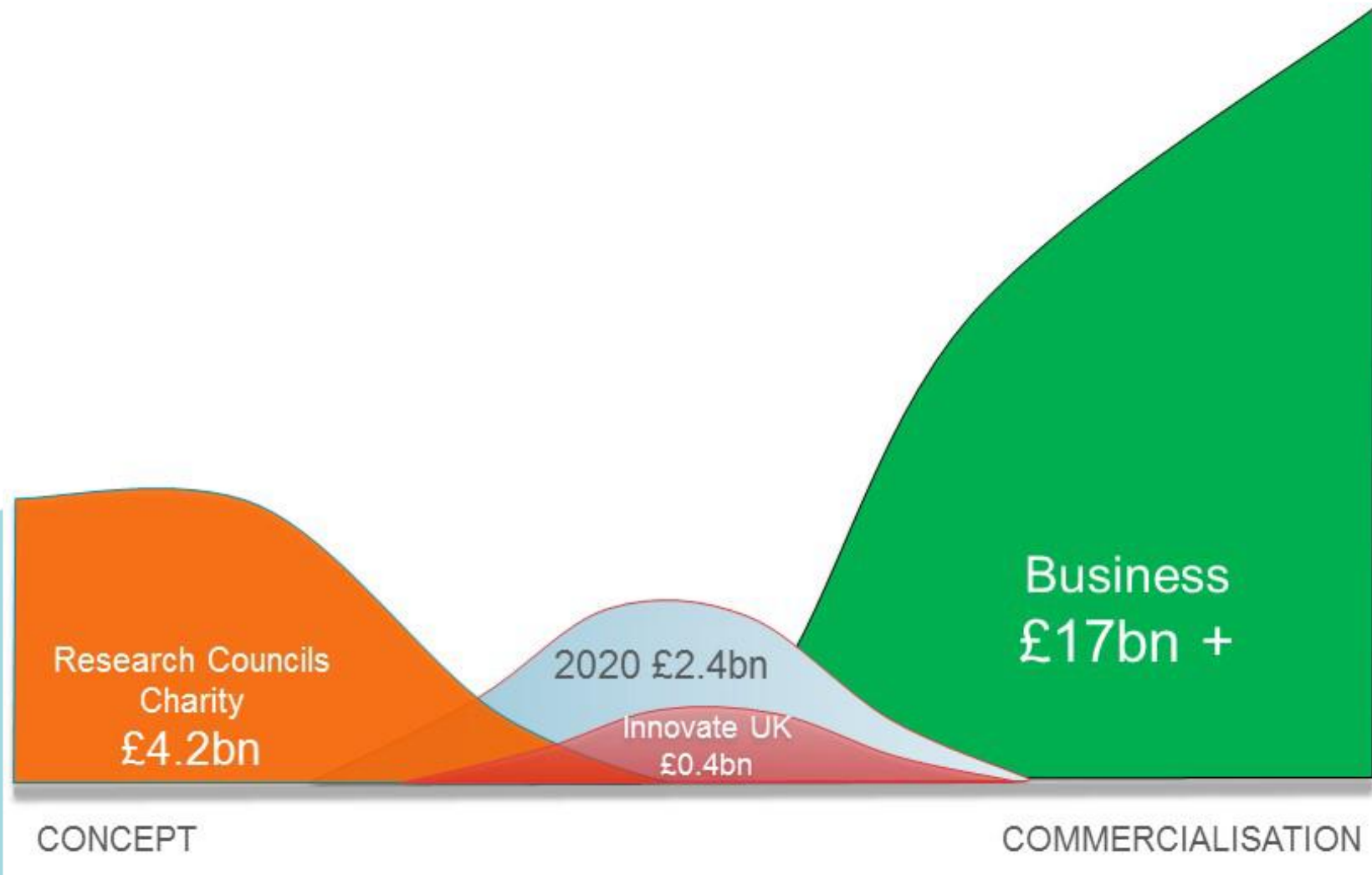
Disruptors?



- **A new generation of PPPs**
- **Multi-sector**
- **Multi disciplinary**
- **Tied into health service delivery**



Shift in UK Fund Profile





The Changing Research Funding Environment



- **Tie expenditure to innovation, productivity and growth**
- **Fund more downstream/ translational research**
- **Give business greater demand side leadership over investment priorities**
- **Bigger, more cross-disciplinary, challenge based research, delivered by consortia**
- **More focus on international partnership (international research collaboration as soft power)**
- **No let up on excellence with impact**

Increasing Demands on Match

- **A rise in collaborative research means a rise in demands for match**
- **How can assets be used most imaginatively and effectively**
- **Rules of the game need to enable agility**



Under-utilised knowledge

- Information associated with failed and abandoned projects (e.g. data from utility testing of molecular markers)
- Proprietary knowledge and know-how that if aggregated, integrated and made interoperable and searchable (e.g. human genome project, SNPs consortium)
- Databases that are presently maintained in-house but could be scaled and shared (e.g. toxicology data)
- Intellectual assets that could be of higher value out-of rather than in-house (e.g. developing a means by which firms could access one-another's' compound libraries)
- Promising lead molecules which are not taken forward into Phase II trials due to lack or cost of capital or poor market expectations, where approaches to securitize late stage development could have value

Associated partners



- [Autism Speaks](#)
- [Autistica](#)
- [Bill and Melinda Gates Foundation](#) [International Diabetes Federation](#)
- [JDRF](#)
- [Leona M. and Harry B. Helmsley Charitable Trust](#)
- [Simons Foundation Autism Research Initiative \(SFARI\)](#)
- [T1D Exchange](#).
- **Fantastic Organisations**
- **Why so few?**
- **Where are the partners for disruption?**



Tech convergence and disruptors

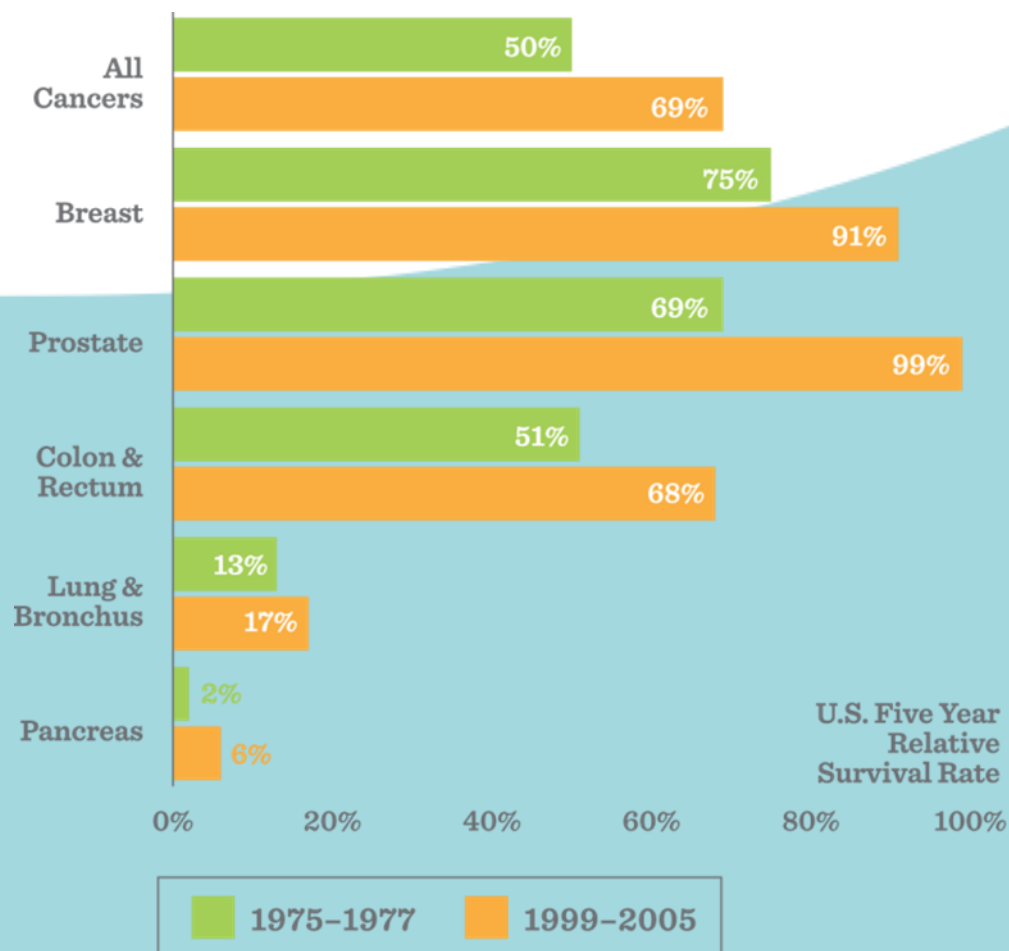


- **Data analytics**
- **AI**
- **Engineering**
- **Nutrition**
- **Patients**

Does the Governance Model for IMI still work?

What Impact and Whose?

- Peer review
- Universities
- Firm level actors
- Audit programmes
- Broad perspective
- Risk appetite



The Role of Patients



Its all about people and their health

They are the ultimate market

Are they sufficiently involved in decision making?

Where is the social science?



Intellectual Property



“Open Innovation Model, dynamic system of knowledge sharing, create and exploit knowledge from IMI projects, wide access of participants affiliates and 3rd parties”.

- **Different actors, different models**
- **SMEs, ICTs etc**
- **Is conservatism hindering impact?**



Future Markets – Today's Collaboration?



Europe can't do this alone.

- Talent is becoming increasingly global
- So is research – and innovation
- Markets already are
- The trick will be to develop competitiveness through new partnerships

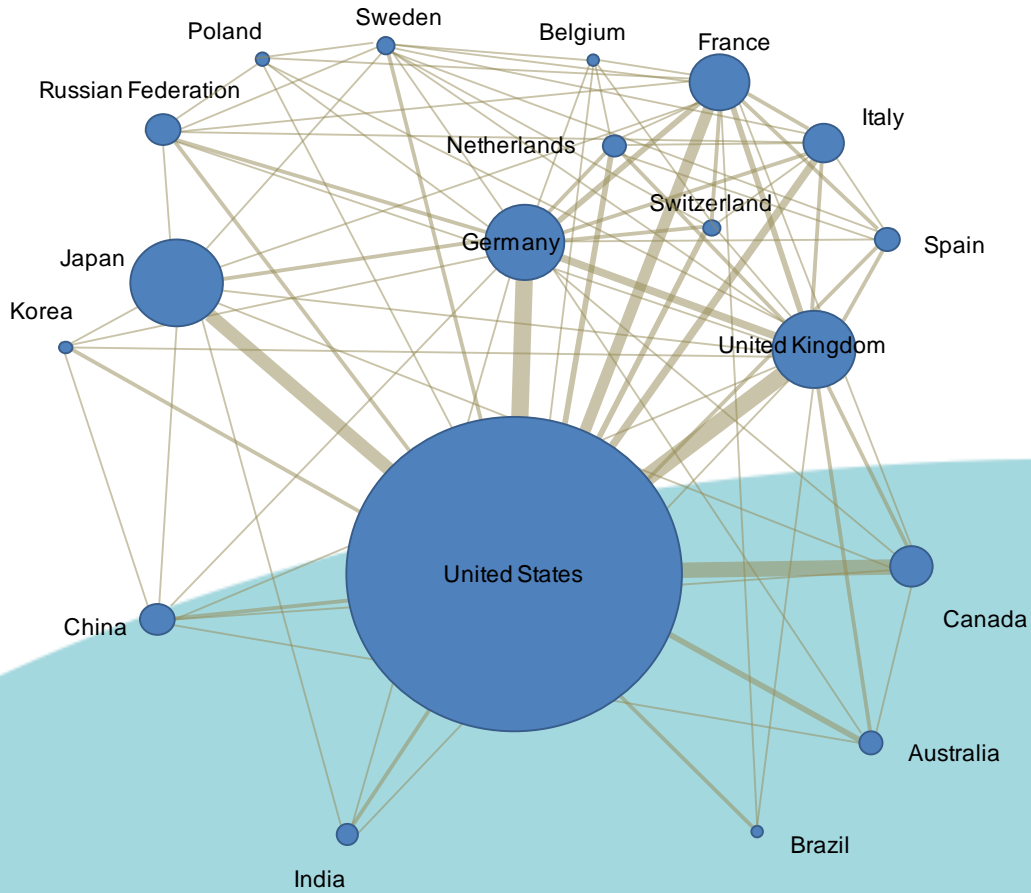
The Three Os

- Open Innovation
- Open Science
- Open to the World

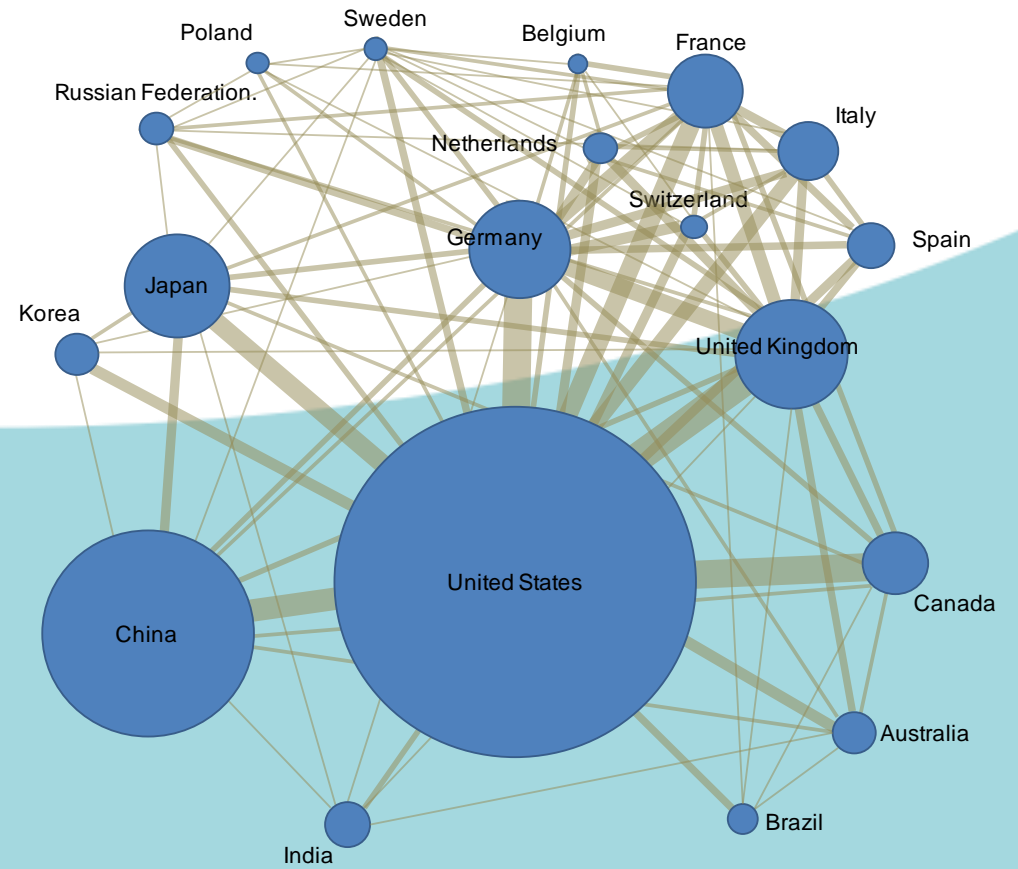
*Research & Innovation
A Vision for Europe*



1998



2008



Brexit



“If managed carefully, EU exit may be used as a catalyst to take steps to speed the growth of the life sciences sector in the UK””The UK must deliver a whole new set of opportunities if it is to keep its existing companies and grow new ones”

Health Advanced Research Programme (HARP)

Establish a coalition of funders to create the HARP to undertake large research infrastructure projects and high risk “moonshot programmes”, that will help create entirely new industries in healthcare,

The Future



“25 years ago mobile phones and the internet were in their infancy. Their expansion might have been a predictable technological development but the human response was perhaps unforeseeable. The way these technologies have made the world smaller and faster, and their effects on the people living in it, could not have been predicted. We can speculate on the problems posed by antibiotic resistance, climate change, and the resultant changes in patterns of infectious disease, but the course these events will take is largely influenced by the human reaction to these situations, of which we are all a part”

Health of the UK population in 2040
August 14, 2015

THE
LANCET



Some Challenges (Opportunities?)



- **International Partnership**
- **Governance**
- **Risk appetite**
- **Use all our assets wisely**
- **Impact matters**
- **Agility does too**

Thank you

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www.imi.europa.eu

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