European Science Policy moving towards a higher level of societal impact: what about health innovation?

Rogério Sá Gaspar (Vice-President of EUFEPS)

Faculdade de Farmácia da Universidade de Lisboa, rgaspar@ff.ulisboa.pt
& iBB (Institute for Bioengineering and Biosciences) http://ibb.tecnico.ulisboa.pt/RG.html

Reference positions (last 5 years)

- University Governance
  - Pro-Rector (2016-2017), Vice-Rector R&D, University of Lisboa (ULisboa), Portugal (2013-2016)
  - General Council of University of Lisbon (UL, Portugal), 2008-2013
  - Vice-Dean, Research & Tech Transfer/ International Affairs (FFUL) 2012-2013
  - Head of Department Pharmaceutical Technology, FFUL, 2007-2013
  - President Department of Pharmacy Practice, FFUL, 2017-2018 and 2018-2022
  - President School Council FFUL (2018-2022)
  - Coordination group of the Portuguese Observatory for Health Systems (OPSS), editing annually the "Spring Report"
  - Member of the Management Board of ISBE (Institute of Evidence-Based Health)
- Research groups Leadership
  - Group Leader "Nanomedicine & Drug Delivery Systems" (iMed.UL), 2007-2013
  - Group Leader "Intracellular Trafficking Modulation for Advanced Drug Delivery" (iMed.UL), 2013-2014
  - iBB (Institute for Bioengineering and Biosciences) @ IST since 2017 (member of scientific coordination board)
- Scientific Societies / International bodies
  - SPCF, President Portuguese Society for Pharmaceutical Sciences (since 2016)
  - Foreign member of the Spanish Royal Academy of Pharmacy (RANF, since 2017)
  - EUFEPS, Executive Committee (2009-2013 and 2016-2020), Vice-President for the mandate 2019-2020, EUFEPS Council representing SPCF (since 2016); EUFEPS, Chair of Regulatory Science Network (2011-2014 and since 2016)
  - FIP, Vice-chair Regulatory Science Special Interest Group (2011-2014)
- Advisory positions (international)
  - External Advisory Board of RESTORE (Horizon 2020 project, NMBP, 2018-2022)
  - External Advisory Board of REFINE (Horizon 2020, project NMBP-761104, 2017-2021)
  - Advisory Board of NANOMED-ITN, (Horizon 2020, project Marie-Curie Action, MSCA-ITN-676137)
  - External Advisory Board of EuroNanoMedNet (ERA-NET in Nanomedicine, FP7/Horizon 2020, EU (active)
  - External Advisory Board of European Doctoral Program in Nanomedicine (NANOFAR, ERASMUS MUNDUS, 2011-2017)
  - Scientific Advisory Board of TRANS-INT (Large FP-7 project, 2012-2017, contract nº 281035)
  - Scientific Advisory Board of Z-Cube (Zambon group, Milano, Italy, 2011-2013)
- Editorial Board/International Advisory Board:

  Nanomedicine: Nanotechnology, Biology, and Medicine (IF2015= 6.155, Elsevier, 2010-2015), Frontiers in Bioengineering and Biotechnology (IF=5.122, 2018-today), WIRES – Nanomedicine and Nanotechnology (IF2015= 4.494, Wiley, 2009- today), International Journal of Nanomedicine (IF2015= 4.383, Dove Press, 2010-today), Drug Delivery and Translational Research (Controlled Release Society, Springer, 2011- today) (…)


Delegação da República Popular da China


infarmed
Instituto Nacional da Farmácia
e do Medicamento

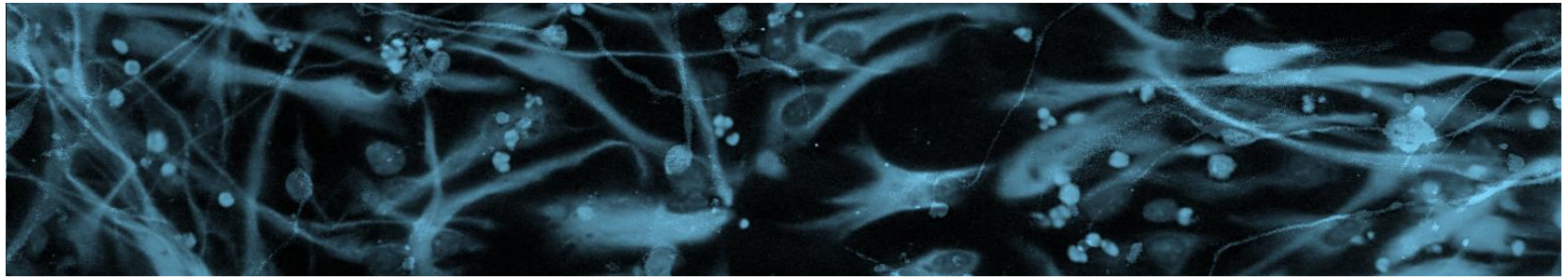

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
An agency of the European Union


HSA
Health Sciences Authority

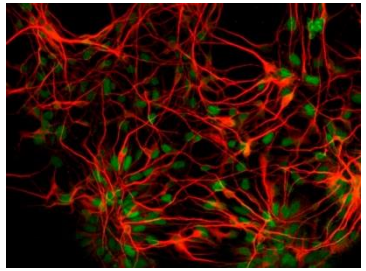

egulatory aspects of nanomedicine:
from research to healthcare
Rogério Sá Gaspar

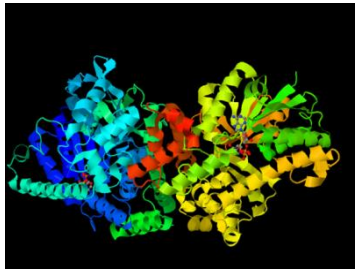
iBB, Institute for Bioengineering and Biosciences
University of Lisbon, Portugal

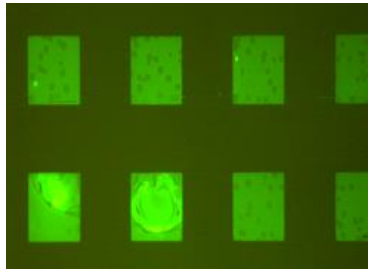
Research Groups



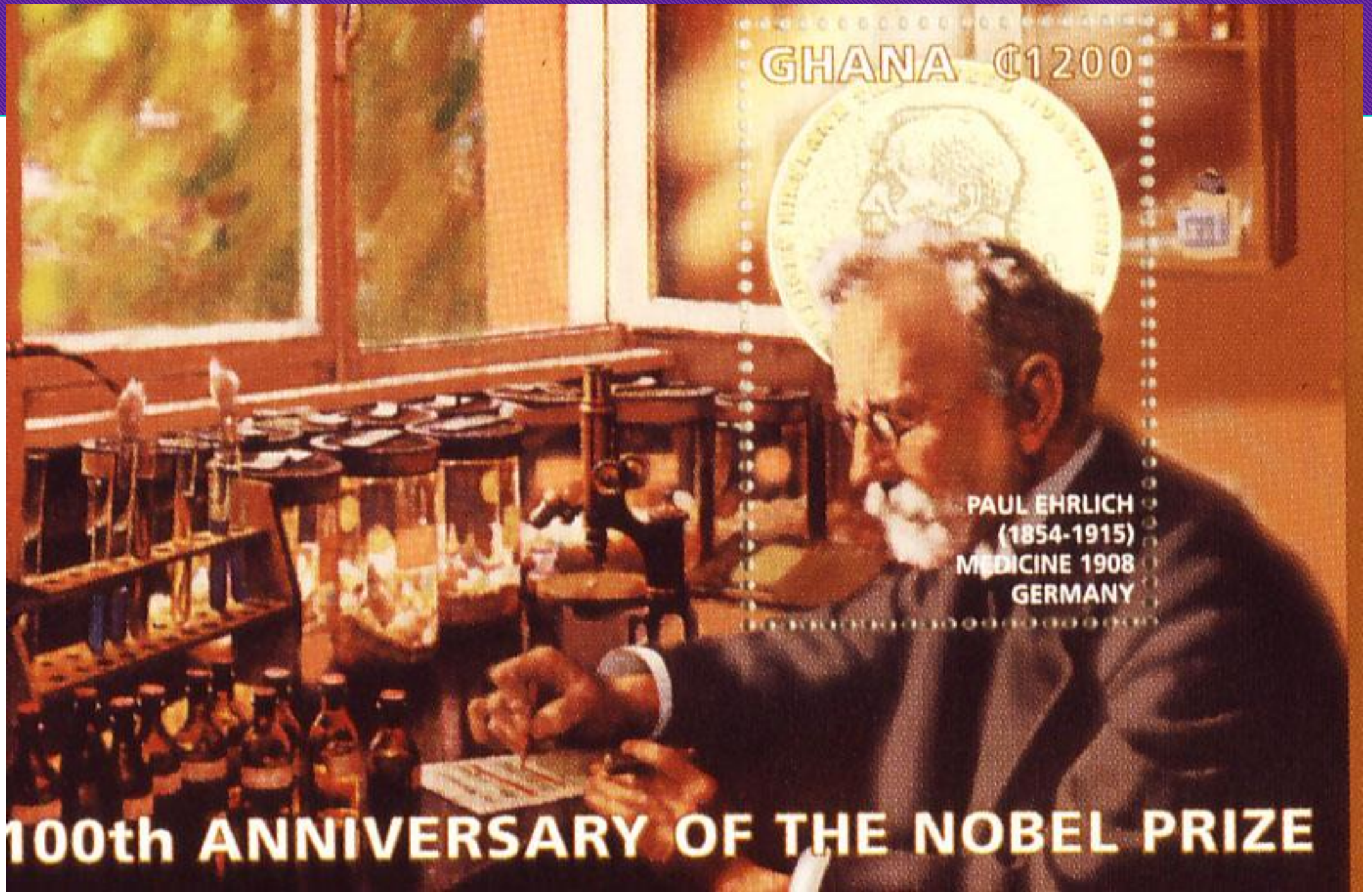
- Bioengineering (BERG)
- Biological Sciences (BSRG)
- Biospectroscopy and Interfaces (BSIRG)
- Stem Cell Engineering (SCERG)



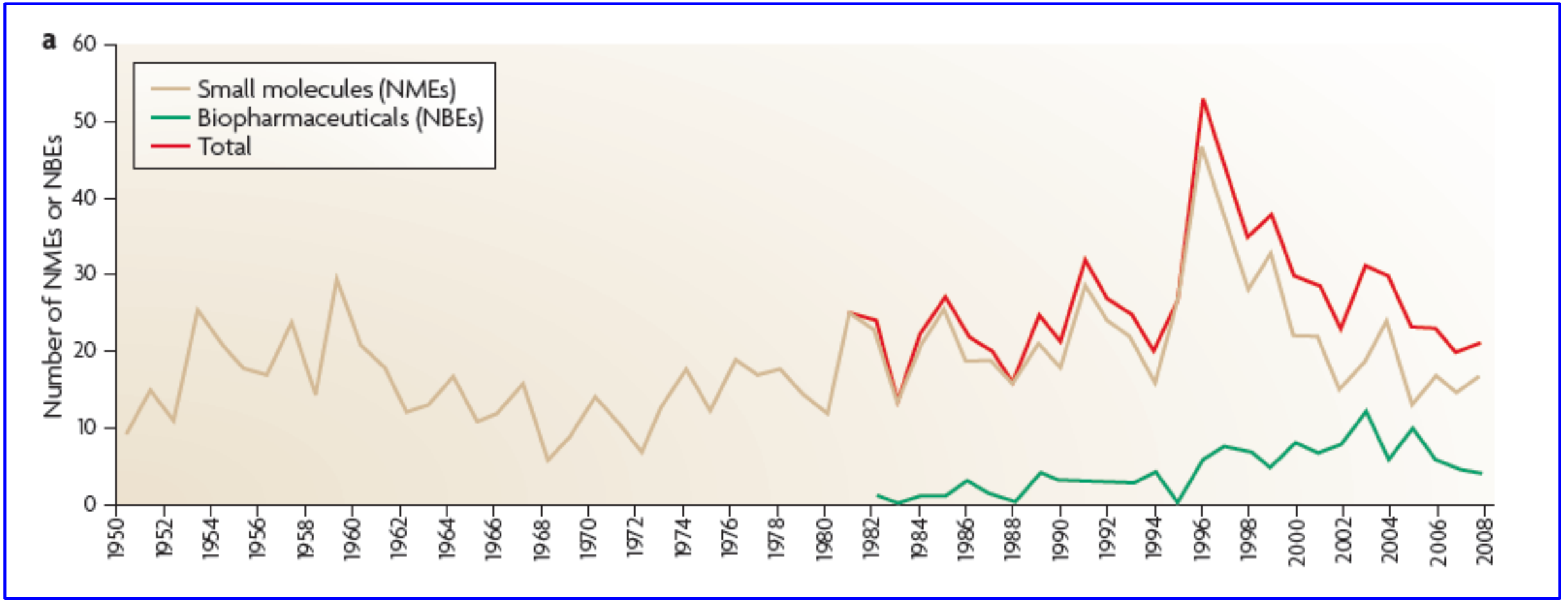




The views and opinions (hereby expressed) reflect ***only my personal opinion*** *and not the views of institutions or organisations with which I'm/I was affiliated either in the past or presently*

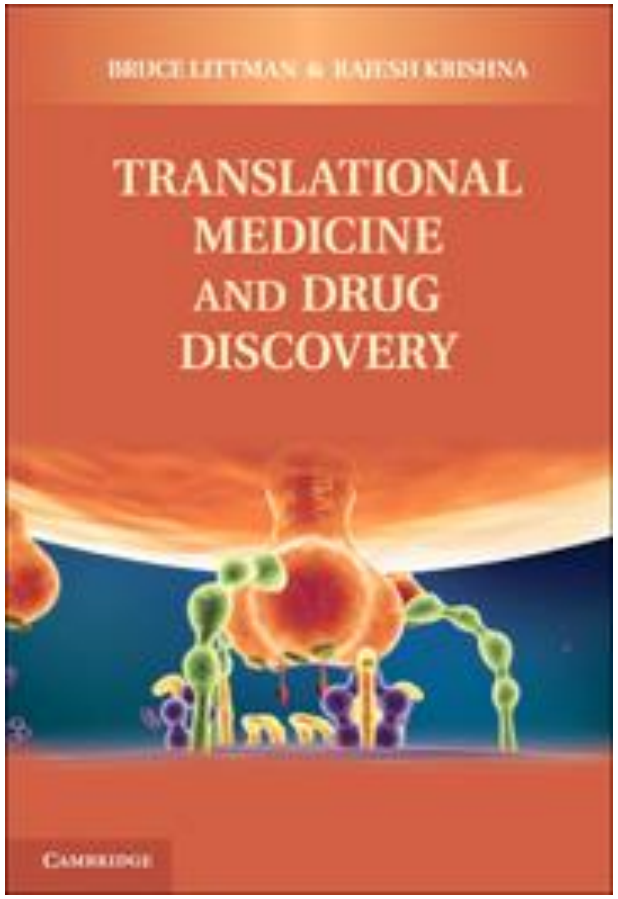


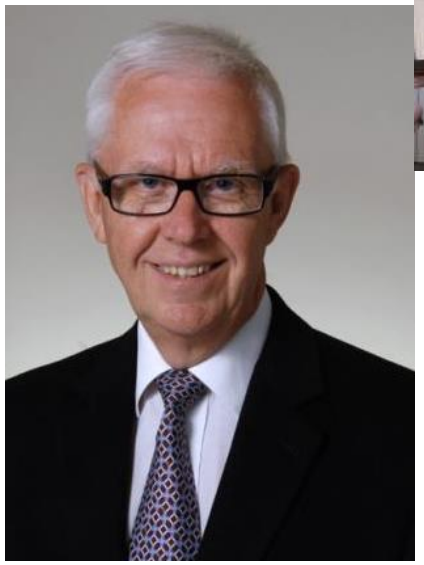
60 years of a stalemate…



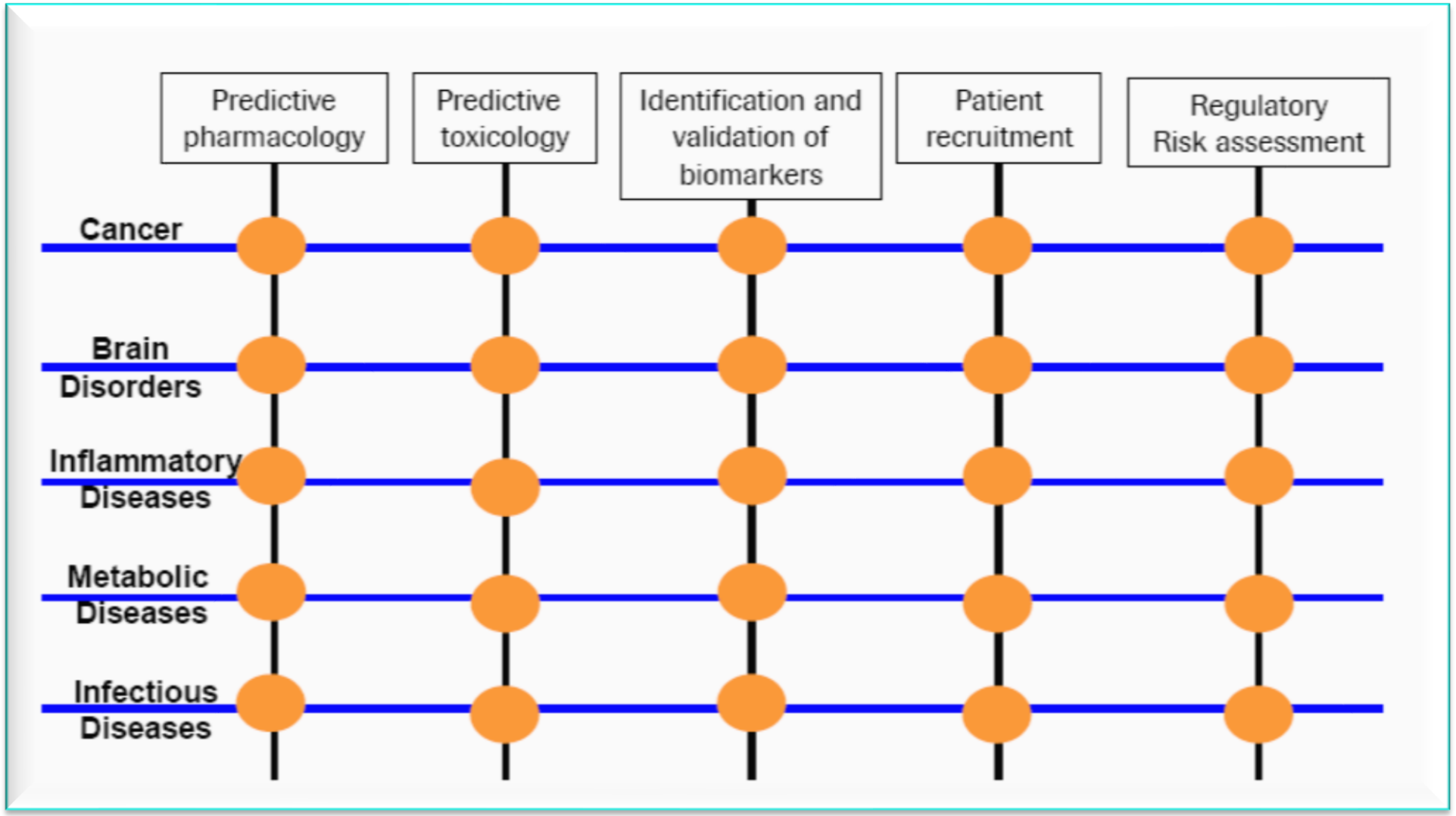
B.Munos, Nature Reviews in Drug Discovery (December 2009)

Towards research-driven PPPs…

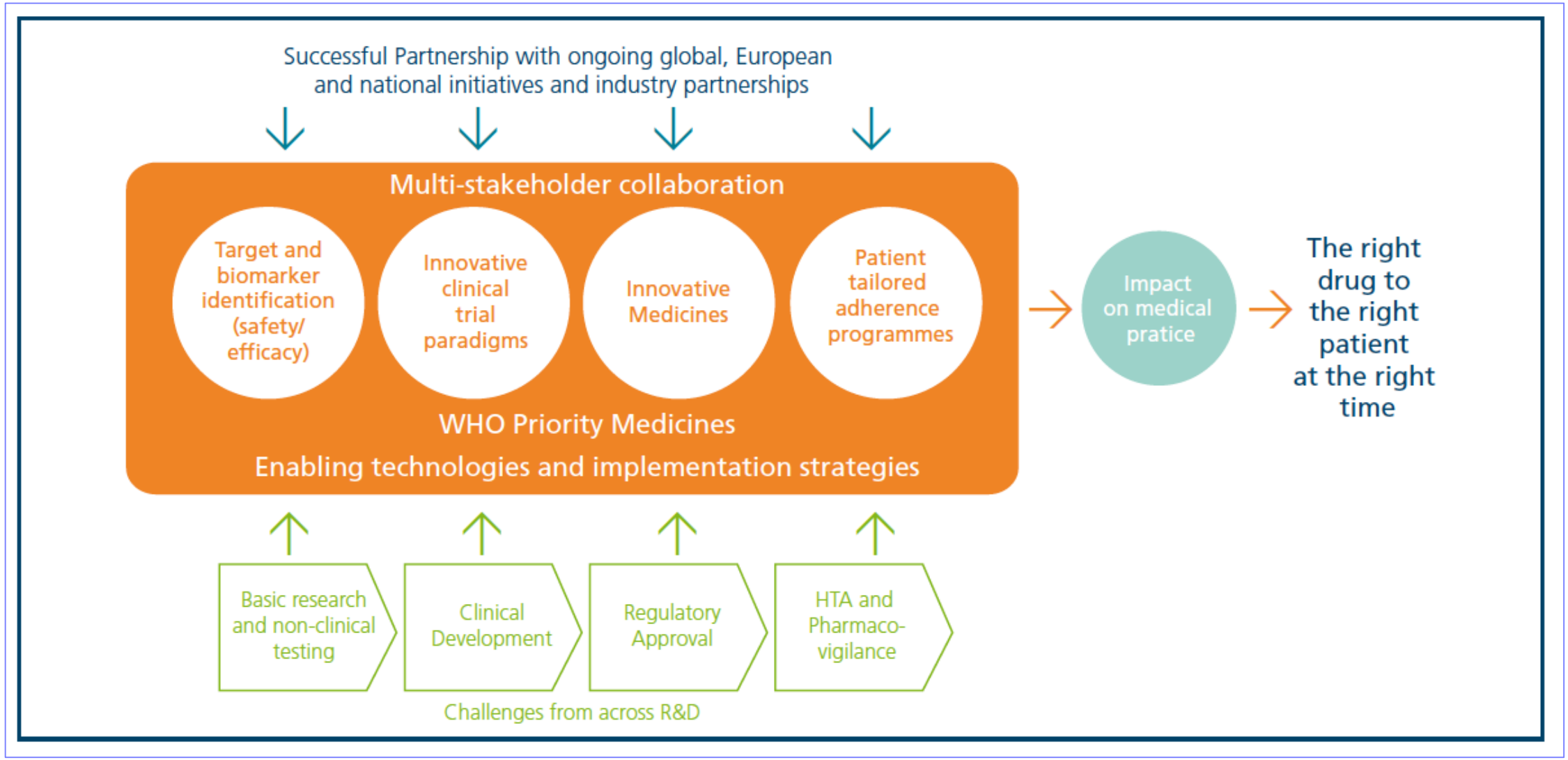




Innovative Medicines Initiative



IMI2, Strategic Research Agenda (SRA)



Innovative Medicines Initiative (IMI2)

Major Axis of Research

Biomarker identification/validation (precision medicine)

Reclassification of disease by molecular means

Target Identification and validation (human biology)

Derterminants of drug/vaccine Safety and efficacy

Innovative drug delivery methodologies

Manufacturing for personalised medicines

Target & Biomarker Identification (safety & efficacy)

Innovative Medicines

European Health Priorities

Innovative clinical trial paradigms

Patient tailored adherence programmes

Innovative methodologies to evaluate treatment effect

Adoption of innovative clinical trial designs

Benefit/Risk Assessment

Healthcare delivery: focus on the treatment programmes not just the medicine

Discovery and Development of novel preventative and therapeutic agents

Innovative adherence programmes

DRIVE CHANGE IN DELIVERY OF MEDICAL PRACTICE

IMI 2 budget (2014 – 2020)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc…

€1.638 bn

€1.425 bn

EFPIA companies

receive no funding

contribute to projects ‘in kind’

Other
€213 m

Associated Partners e.g. charities, non-EFPIA companies

IMI 2 total budget
€3.276 billion

EFPIA Partners in Research

IMI2 Associated Partners as of Sept. 2019

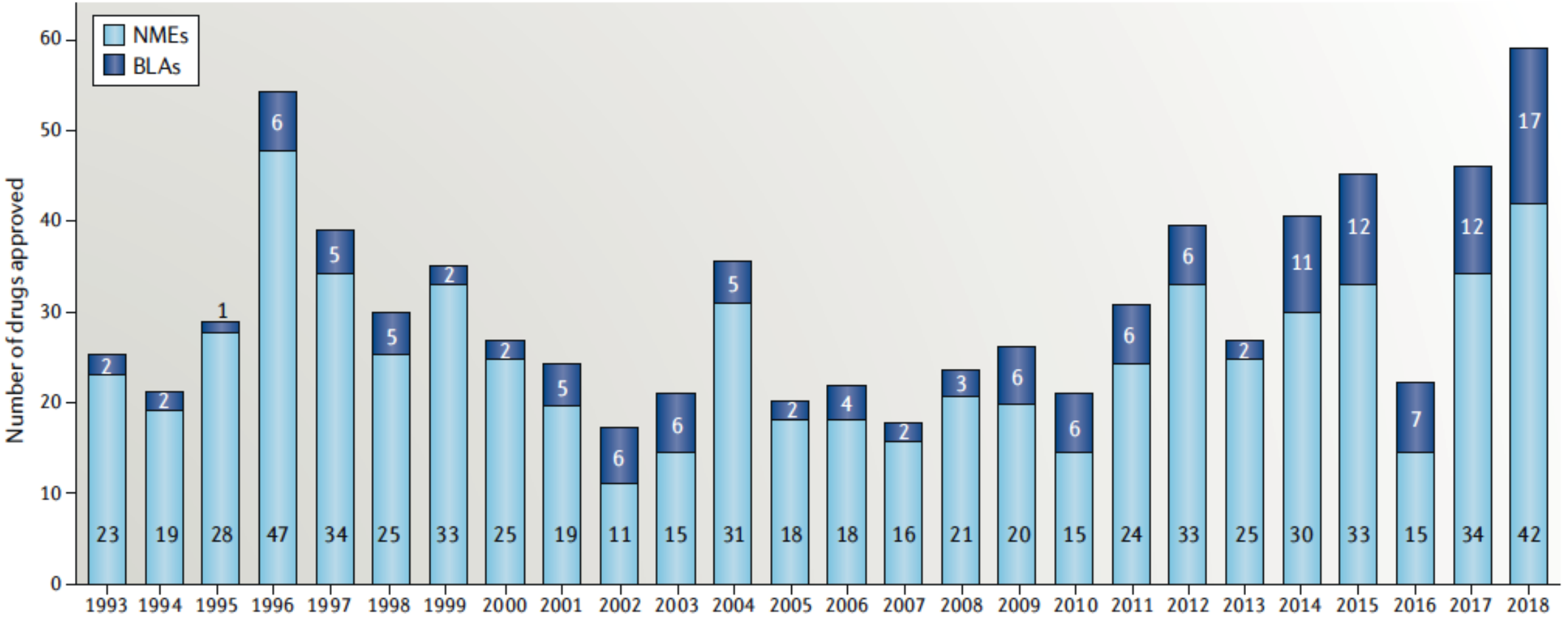
- Accelerate Diagnostics
- Autism Speaks
- Autistica
- BD Switzerland Sarl
- Bill and Melinda Gates Foundation (BMGF)
- Bio-rad Laboratories
- Cepheid Europe
- CHDI Foundation
- Children's Tumour Foundation
  Datapharm
- Diamond Light Source
  European Hematology Association
- International Diabetes Foundation
- Invicro
- JDRF
- KTH Royal Institute of Technology
- B. Helmsley Charitable Trust
- McGill University
- Medecine For Europe
- Medicines for Malaria Venture (MMV)
- Obesity Action Coalition
- Ontario Institute for Cancer Research
- Parkinson's UK
- Simon Foundation Autism Research Initiative (SFARI)
- Software AG
- Springworks Therapeutics
- T1D Exchange
- TB Alliance
  Trial Nation
- University of Dundee
- Wellcome Trust

Total Number of Associated Partners:	31
Total EUR committed:	**EUR** 166,062,214

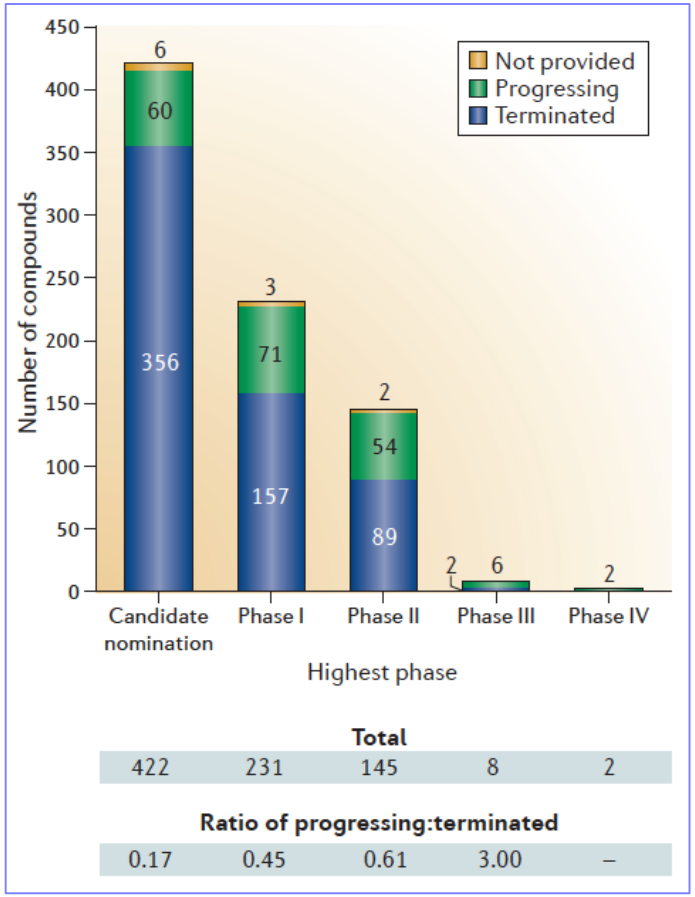
10 YEARS OF BREAKTHROUGHS
A HEALTHIER FUTURE

innovative medicines initiative

Pharma pipeline and historical cycles…



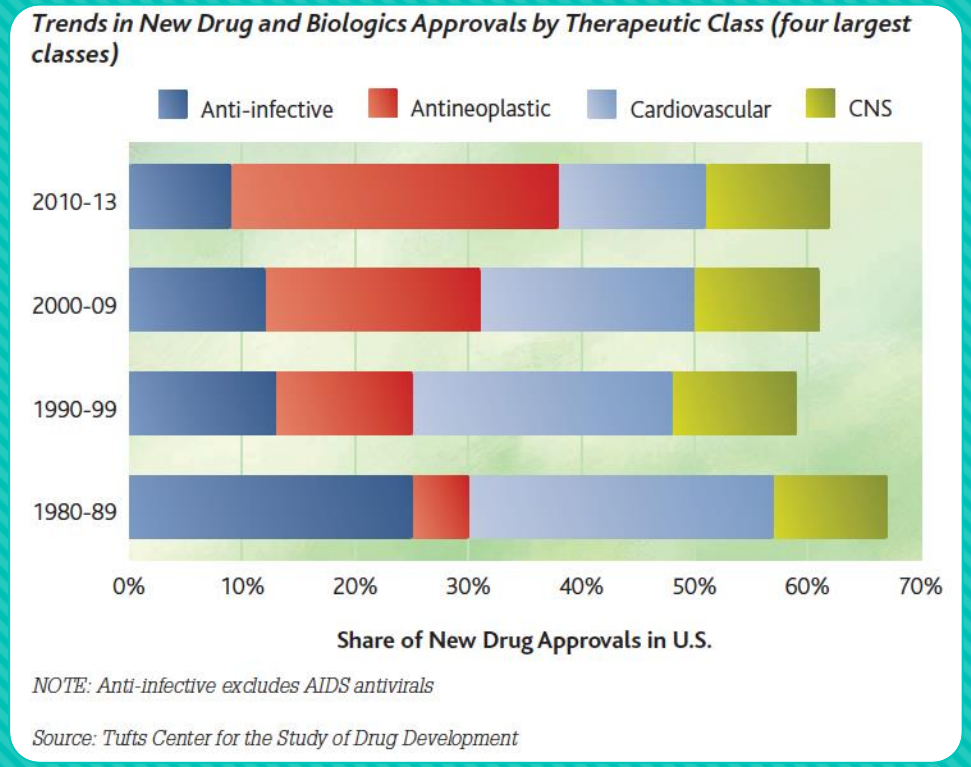
Primary cause of failure categories for terminated compounds*

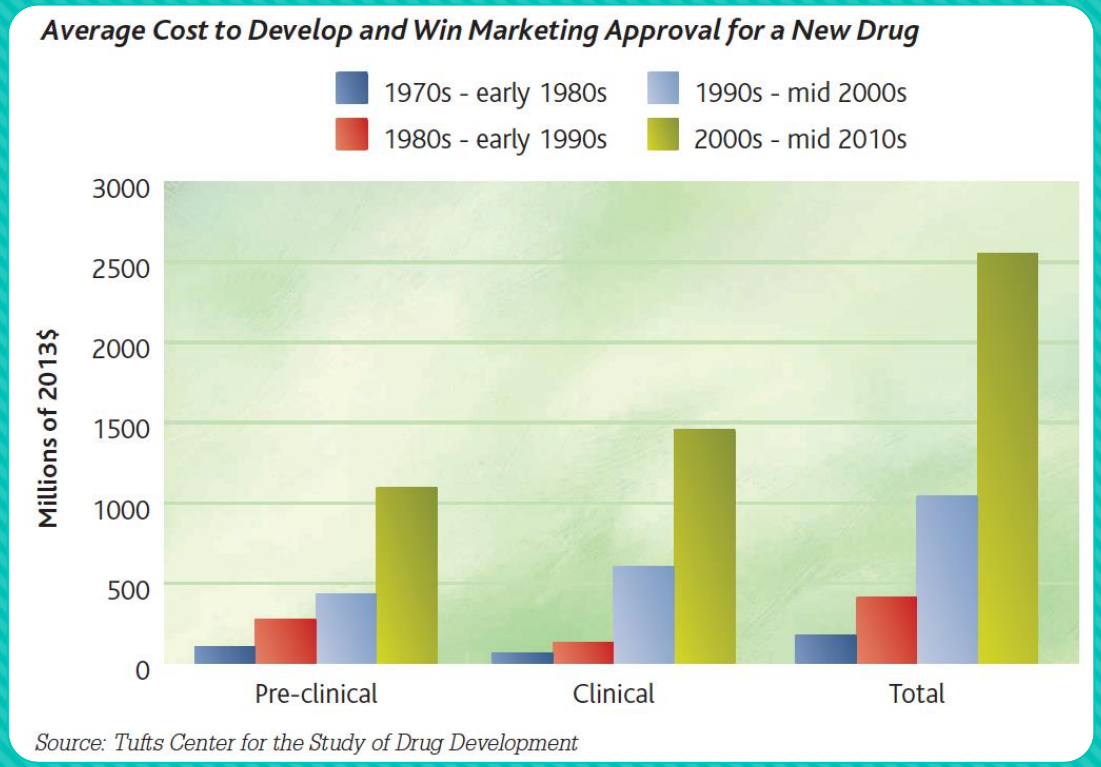


Termination reason	Overall	Period		Phase		
		2000–2005	2006–2010	Candidate nomination	Phase I	Phase II
Clinical safety	68 (11%)	48 (13%)	20 (8%)	5 (1%)	40 (25%)	22 (25%)
Commercial	40 (7%)	23 (6%)	17 (7%)	26 (7%)	10 (6%)	4 (4%)
Efficacy	55 (9%)	45 (11%)	10 (4%)	10 (3%)	14 (9%)	31 (35%)
Formulation	9 (1%)	4 (1%)	5 (2%)	8 (2%)	1 (0.6%)	0
Non-clinical toxicology	240 (40%)	144 (40%)	96 (40%)	211 (59%)	21 (13%)	7 (8%)
Patent issue	1 (0.2%)	0	1 (0.4%)	1 (0.3%)	0	0
Pharmacokinetics or bioavailability	29 (5%)	19 (5%)	10 (4%)	3 (0.8%)	25 (16%)	1 (1%)
Rationalization of company portfolio	124 (21%)	46 (13%)	78 (32%)	75 (21%)	29 (18%)	19 (21%)
Regulatory	2 (0.3%)	2 (0.6%)	0	1 (0.3%)	1 (0.6%)	0
Scientific	33 (5%)	28 (8%)	5 (2%)	13 (4%)	15 (10%)	5 (6%)
Technical	3 (1%)	3 (1%)	0	2 (0.6%)	1 (0.6%)	0
Other	1 (0.2%)	0	1 (0.4%)	1 (0.3%)	0	0
Total	605	362	243	356	157	89

*Table entries for each column indicate the total number and the percentage in parentheses.

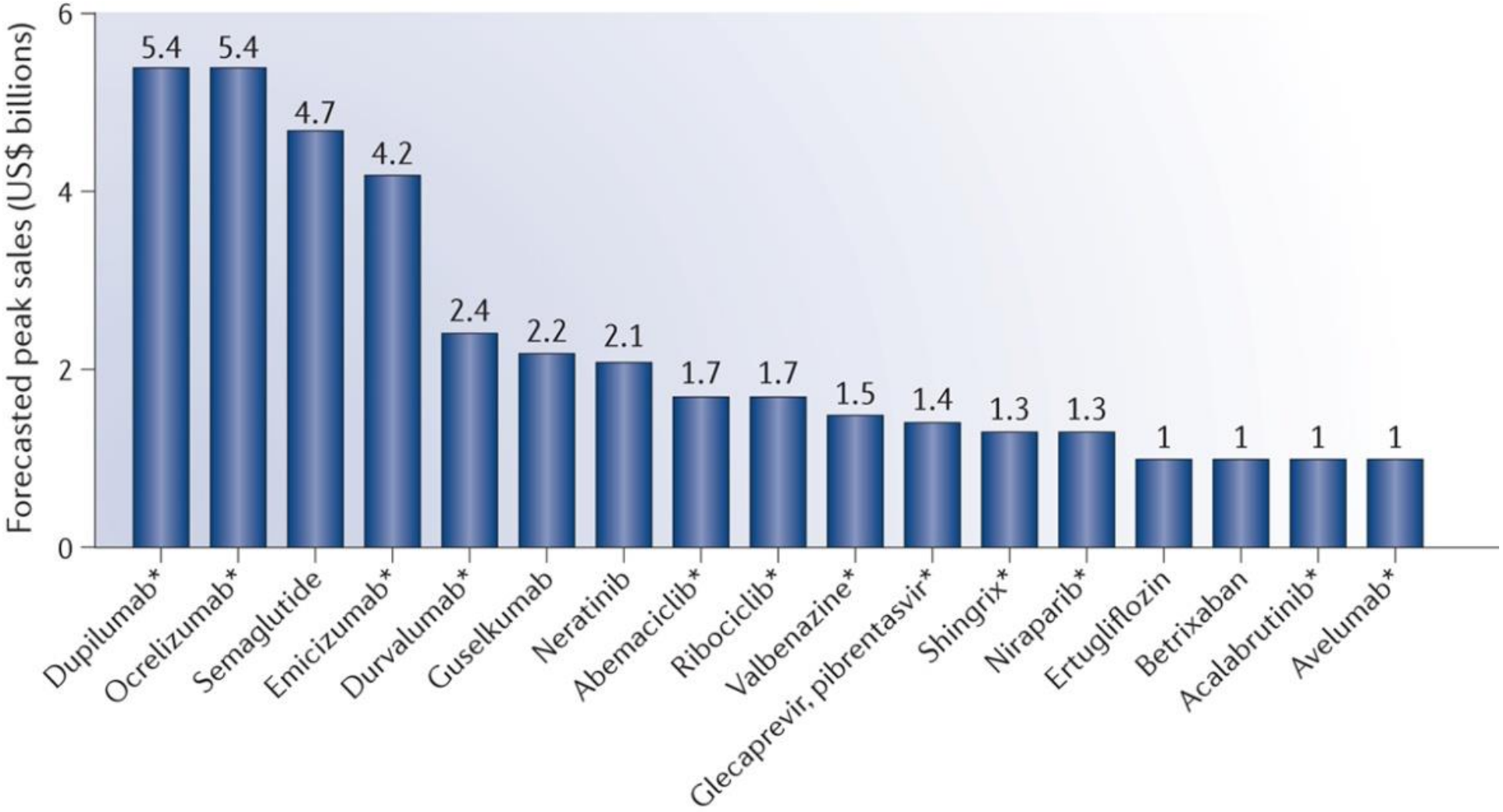
"An analysis of the attrition of drug candidates from four major pharmaceutical companies" - *Michael J. Waring, John Arrowsmith, Andrew R. Leach, Paul D. Leeson, Sam Mandrell, Robert M. Owen, Garry Pairaudeau, William D. Pennie, Stephen D. Pickett, Jibo Wang, Owen Wallace and Alex Weir,* ***Nature Reviews Drug Discovery, 14: 475-486 (July 2015)***





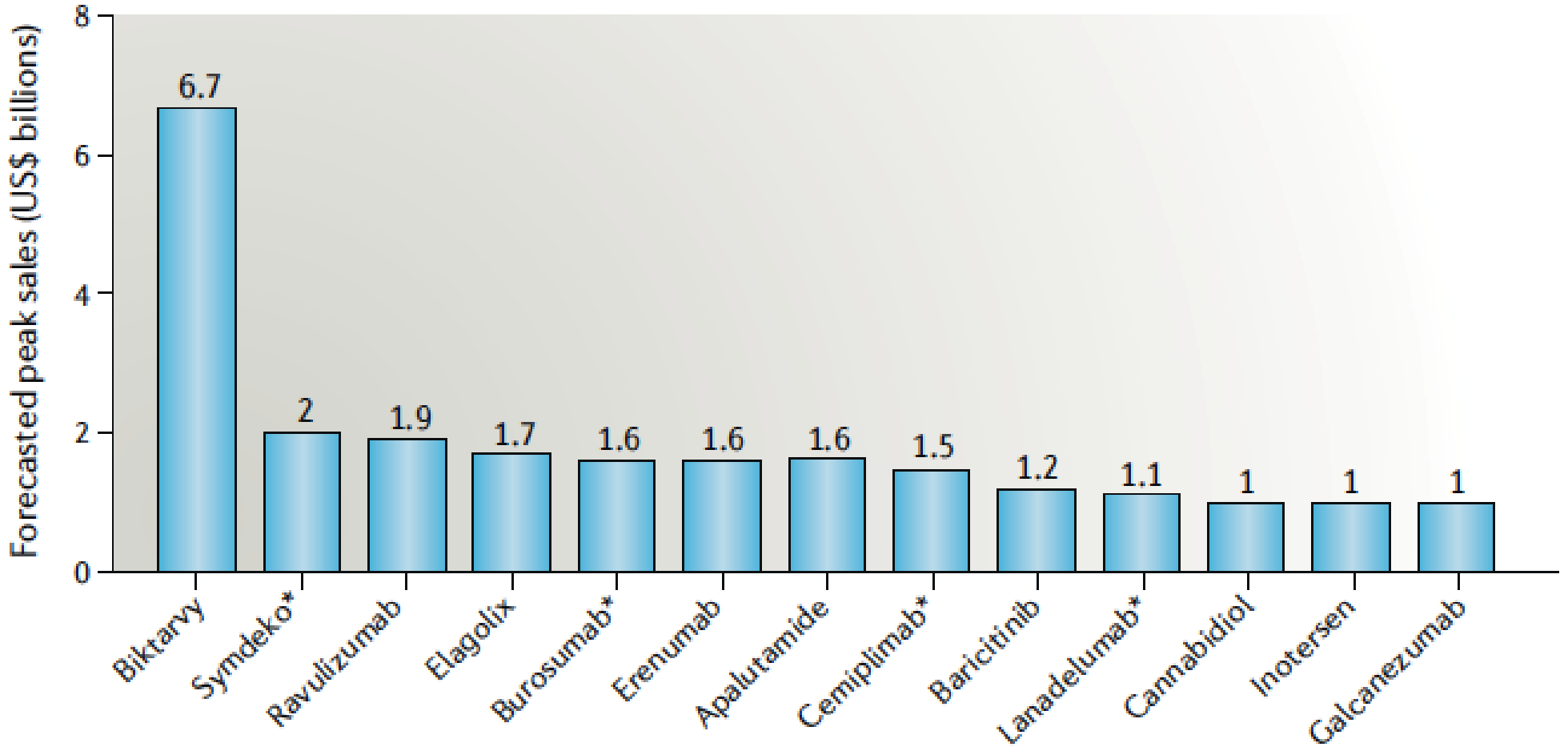
Therapeutic areas and growing costs in R&D

Potential blockbusters approved in 2017



Nature Reviews | Drug Discovery

Potential blockbusters approved in 2018



"Pharmaceutical sciences in 2020"

(FIP Conference/Workshop, 29 Participants, Amsterdam, 2008)

Academia

- Lyle Bootman - Dean, School of Pharmacy, University of Arizona, USA
- Rogerio Gaspar, - Professor, Faculty Pharmacy, University of Lisbon, Portugal
- Hideyoshi Harashima - Laboratory for Molecular Design of Pharmaceutics, Graduate School of Pharmaceutical Sciences, Hokkaido University, Japan
- Tatsuro Irimura - Professor, University of Tokyo, Japan
- Donald Light - Professor of Comparative Health Care, University of Medicine and Dentistry of New Jersey, USA
- Amin Rostami - Professor of Systems Pharmacology, University of Sheffield and Research Director, Simcyp Ltd, Sheffield, UK
- Malcolm Rowland - Professor Emeritus, School of Pharmacy and Pharmaceutical Sciences, University of Manchester, UK
- Geoff Tucker - Professor Emeritus, Academic Unit of Clinical Pharmacology, University of Sheffield and Chairman of Simcyp Ltd, Sheffield, UK

Research Centres and Consultancy Companies

- Daan Crommelin - Scientific Director, Top Institute Pharma, The Netherlands
- Charles Hoban - CEO, Cambridge Health Association, R&D Economics, Biopharmaceutics Collaboration, USA
- Mario Rocci - CEO, Prevalere Life Sciences, Inc, USA
- R.B. Smarta - Managing Director, Interlink Marketing Consultancy Pvt. Ltd. Mumbai, India
- Per Troein - IMS Health Strategic Alliances, UK

Regulatory Authorities

- Bruno Flamion - Professor, University of Namur, Belgium/ EMEA scientific committee
- Bert Leufkens - Professor, Utrecht University and Chair of the Dutch Medicines Evaluation Board, The Netherlands
- Malebona Matsoso - Director in Public Health Innovation and Intellectual Property (PHI) in the Office of the Director General, World Health Organization
- Robert Powell - Office of Translational Science and Clinical Pharmacology, FDA, USA
- Lloyd Sansom - Pharmaceutical Benefits Advisory Committee (PBAC), Australia

Pharmaceutical Industry

- Kumar Bhargava - Vice-President (New Business Ventures), Wyeth, USA
- Linda Hakes - Senior Vice President, Schwarz Biosciences GmbH, Germany
- Victoria Hale - Chairman and Founder, One World Health, USA
- Jacqueline Hunter - Senior Vice President, GlaxoSmithKline, UK

Banking and Finance

- Gunnar Casserstedt - Chief Financial Officer, Karolinska Development, Sweden
- Mike Powell - General Partner, Sofinnova Ventures, USA

Pharmaceutical Organizations

- Hans Linden – CEO, EUFEPS, Sweden
- Henri Manasse - Professional Secretary, FIP, USA
- Kamal Midha - President, FIP, Canada
- Vinod P. Shah - Scientific Secretary, FIP, USA

Media

- James Le Fanu - General Practitioner and medical columnist, UK

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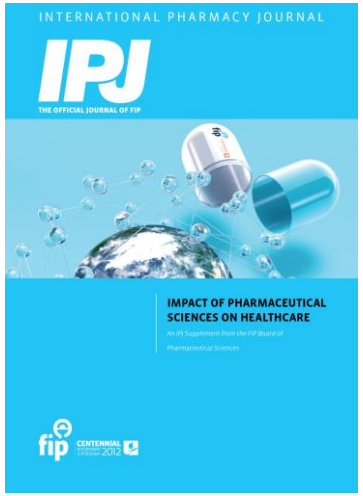
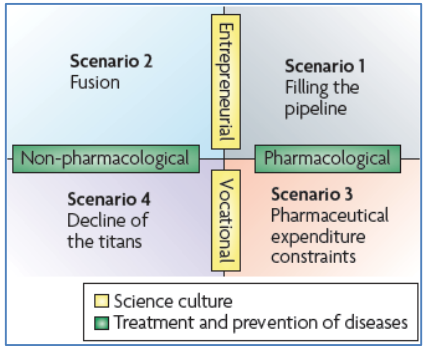
"Pharmaceutical sciences in 2020"

Table 1 | **The four scenarios and some key features**

Features	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Industry	Pharmaceutical companies remain dominant in innovation, with SMEs as suppliers of early-stage developments; governments are partners through PPPs	Traditional pharmaceutical companies decline as the life sciences become more focused on devices and lifestyle technologies; new types of businesses emerge at interfaces	There is strong pressure to contain drug prices in major markets; companies focus on niche markets in which added value can be shown more easily	A large part of drug development takes place in publicly funded institutes, in parallel with SMEs; pharmaceutical companies exist for confirmatory trials, production and regulatory approval
Regulation	Strong drive for harmonization; regulators are faced with high-tech and complex technologies	Major challenges for regulators to globally integrate regulations on various combinations of technologies, leading to a strong drive for harmonization	Little global harmonization; payers focus on cost reduction; mechanisms are tested for 'gradual' market authorization for new drugs	Regulators are crucial administrators as society has become strongly risk averse; there is a limited drive for global harmonization
Funding	Basic and applied sciences are well funded, predominantly by public and industrial sources, respectively; a substantial part of funding is channelled through PPPs	Applied sciences and basic sciences are well funded within academia through public funding; research on new care concepts is funded by health-care payers	Public funding is the main driver of academic research; limited funding is available for PPPs; industry works through its own R&D organizations and CROs	Academic funding comes mainly from public sources and stakeholders such as insurance companies and charities; there is little private funding and few PPPs
Academia	Academia works closely with industry, with a seamless transition from basic to applied science; entrepreneurship is highly valued	Research focuses on care approaches; academia spins off companies focused on lifestyle niches and care approaches; PPPs flourish at this interface	Academia is viewed as an important source of fundamental knowledge, but publicly funded collaborations between academia and industry are not seen as desirable	Academic research is strongly focused on alternatives to drug treatment; partnerships between academia and pharmaceutical companies are viewed with mistrust, so academia has few links with industry

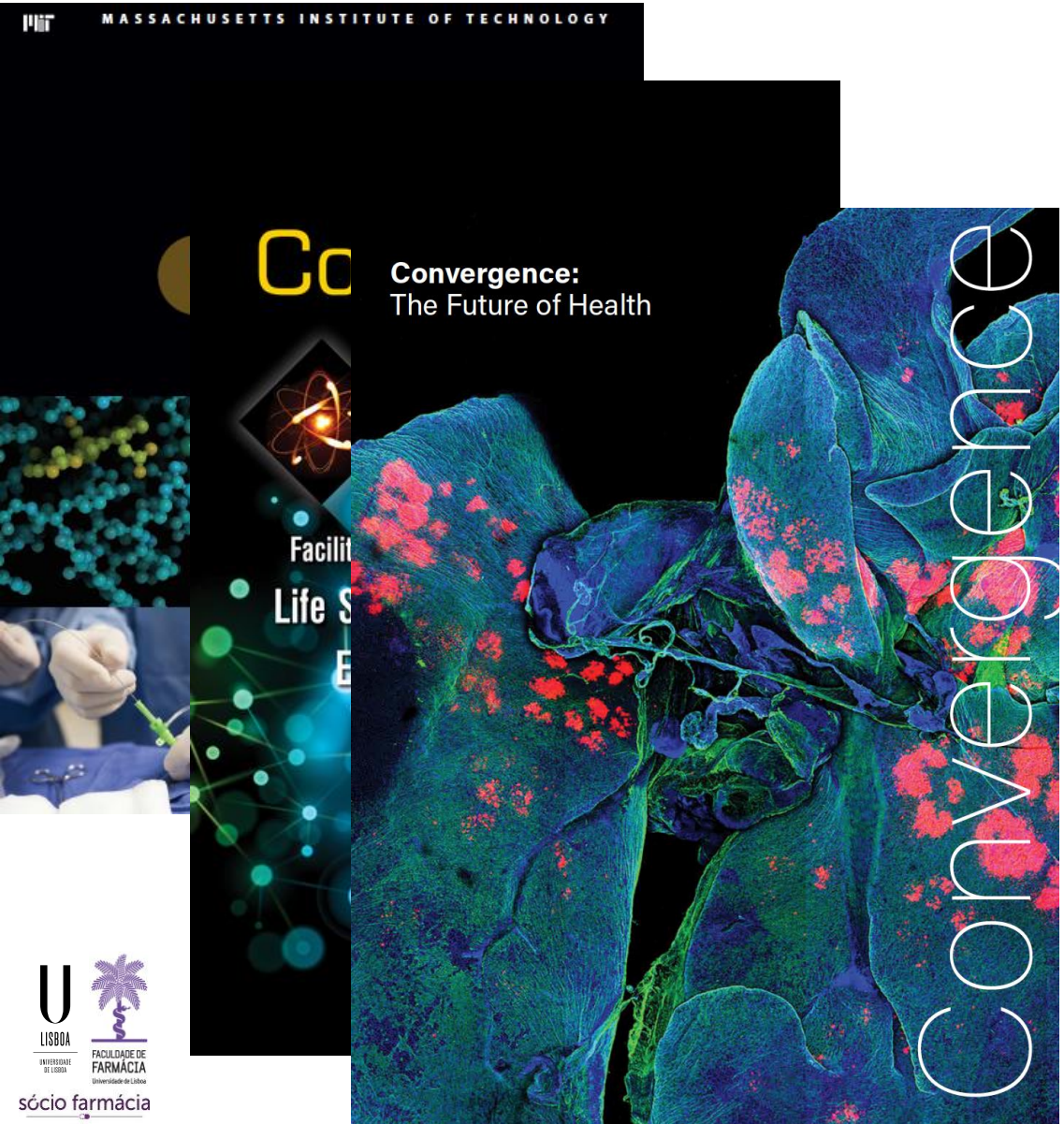
CRO, contract research organization; PPP, public–private partnership; SME, small-to-medium-sized enterprise.





"Pharmaceutical sciences in 2020"
Daan Crommelin, Pieter Stolk, Luc Besançon, Vinod Shah, Kamal Midha and Hubert Leufkens,
Nature Reviews Drug Discovery,
volume 9 | February 2010 | p.99-100

Nanomedicine:
The "CONVERGENCE" pathway...



The life sciences are in the midst of a revolution. Scientists are inventing ways to regenerate lost limbs and replace malfunctioning organs. Genomics and Big Data are being used to tailor treatments for patients' needs. Therapies to correct disease-causing genetic defects are now in clinical trials. ***Increasingly, patients play critical roles in their own care, from monitoring their health with wearable devices to shaping the direction of research on the diseases that affect them***.

The technologies driving these and other biomedical breakthroughs go well beyond health care. They impact food, energy, and the environment to improve the lives of millions—if not billions—of people. This revolution—called "Convergence"—is creating jobs, speeding products to market; improving agriculture, defense, the environment, and energy production; and helping to grow America's gross domestic product (GDP). The Convergence Revolution promises to enhance quality of life worldwide.

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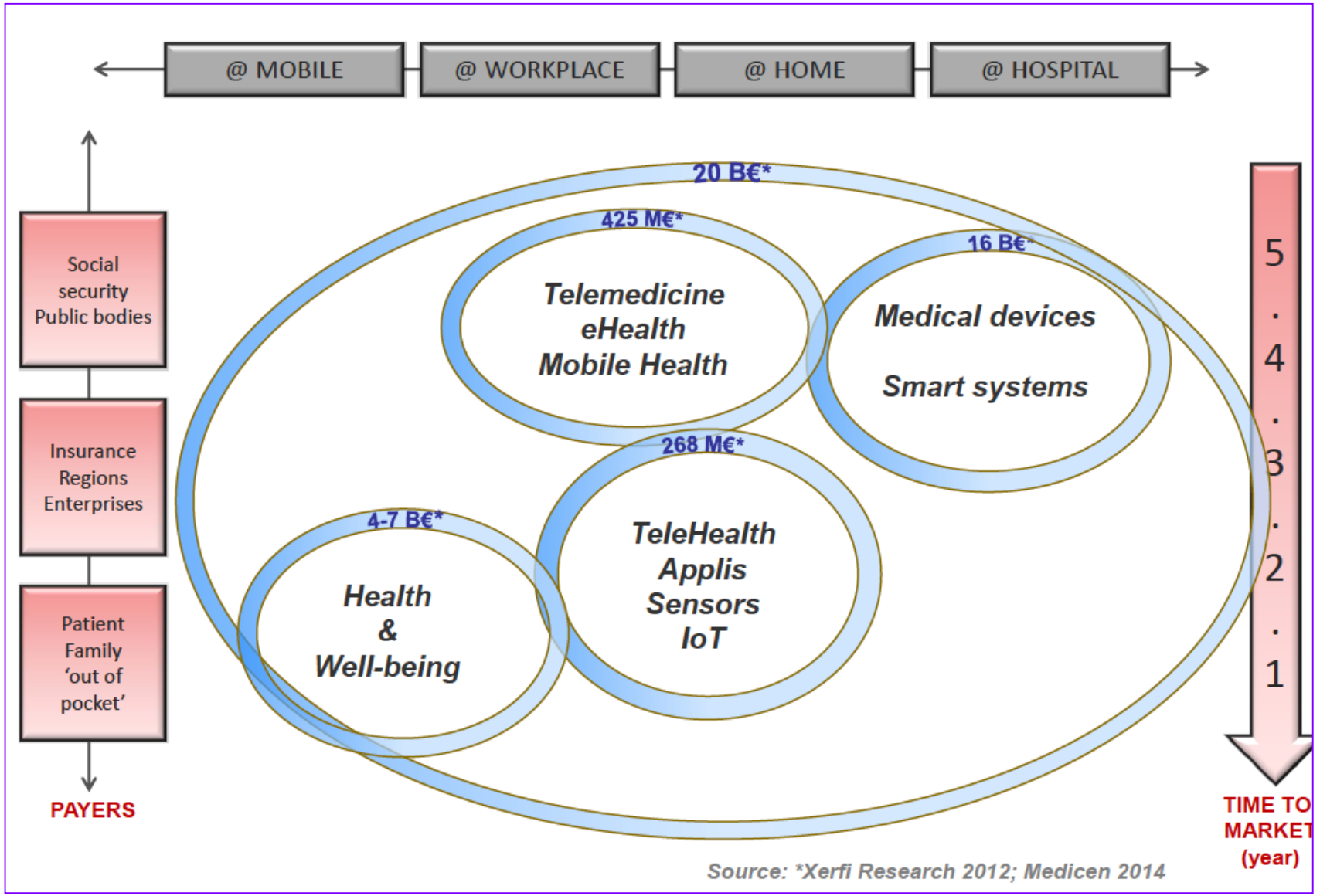
Top 10 innovations

- Next-generation sequencing (NGS)
- 3D-printed devices
- Immunotherapy
- Artificial intelligence (AI)
- Point-of-care (POC) diagnostics
- Virtual reality (VR)
- Leveraging social media to improve patient experience
- Biosensors and trackers
- Convenient care: Retail clinics and urgent care
- Telehealth
- Popular innovations that didn't make the list

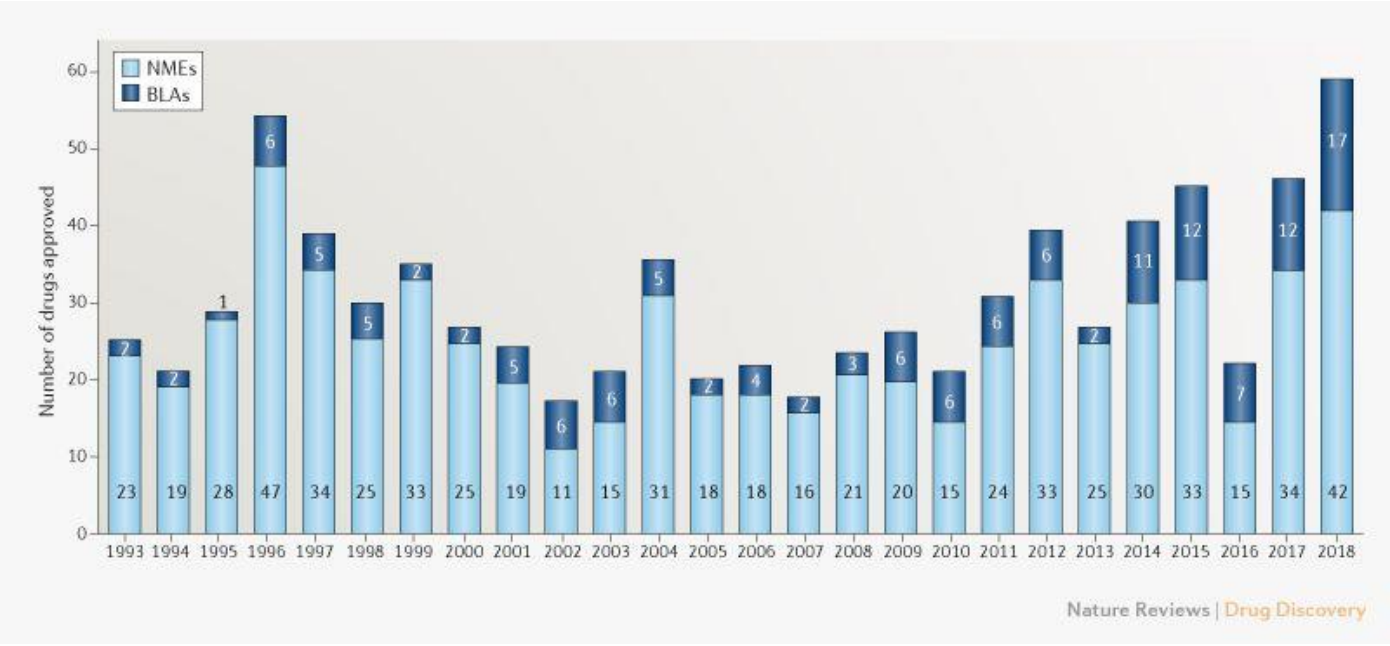
Artificial Intelligence (AI)

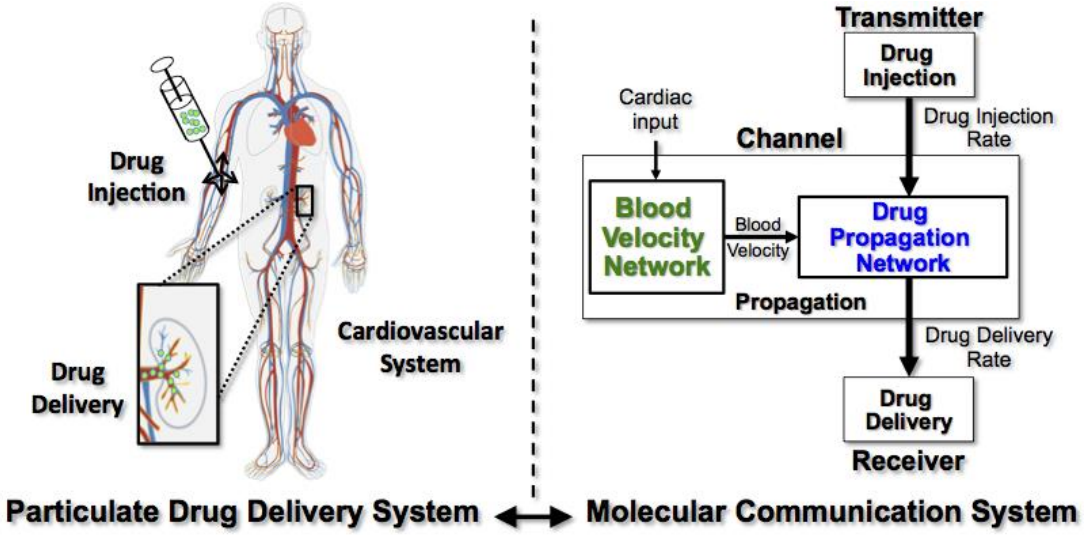
- **More for less:** AI, the ability of computers to think like humans, is anticipated to transform health care by completing tasks currently performed by humans with greater speed and accuracy, and using fewer resources.
- Within health care, AI includes clinical tasks such as **diagnosing patients and spotting disease outbreaks earlier**; **accelerating the development of new drugs and devices**; and **streamlining administrative duties such as approving claims and rooting out fraud**. Frost and Sullivan projects that 90 percent of US hospitals and insurance companies will implement AI systems by 2025.
- AI has the **potential to improve the accuracy, precision, and timeliness of patient diagnoses**, which could increase therapeutic success rates and decrease unnecessary medical interventions. Population health would improve with better understanding of behavior patterns that impact chronic disease outcomes. Streamlining administrative duties may improve operational efficiencies.
- **Increased adoption of AI** will likely depend on:
  - **Innovators' ability to decrease cost and improve accuracy of Technologies such as natural language processing, big data, and cognitive technologies;**
  - **Health care professionals' and patients' acceptance and trust of AI tools.**
- **Use case:** Watson Oncology is an AI solution that helps oncologists keep up with the field's rapidly expanding evidence base. A collaboration of IBM and Memorial Sloan Kettering, Watson Oncology provides individualized treatment options for patients based on their specific case details and existing clinical evidence. The technology will assist oncologists with the challenging task of synthesizing the latest research and best available information to improve patient care.

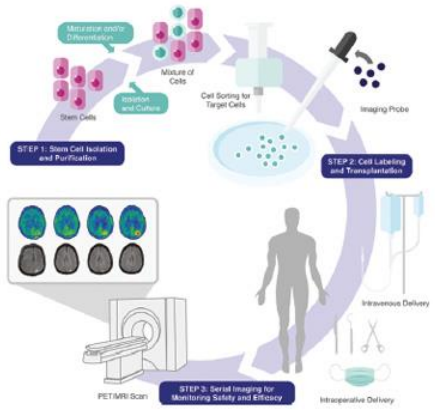
Bridging areas on Health research and innovation (Health sciences/Healthcare)

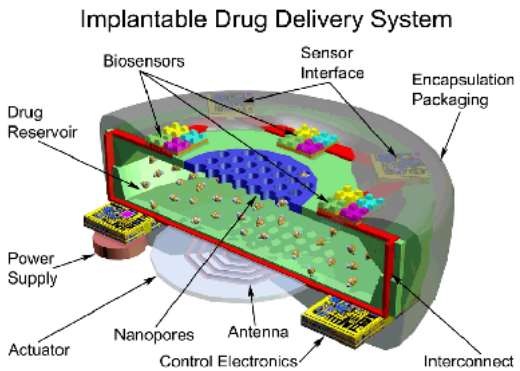


Trends in new medicinal products: hybrid nanotechnologies from pharmaceuticals to incorporated ICTs









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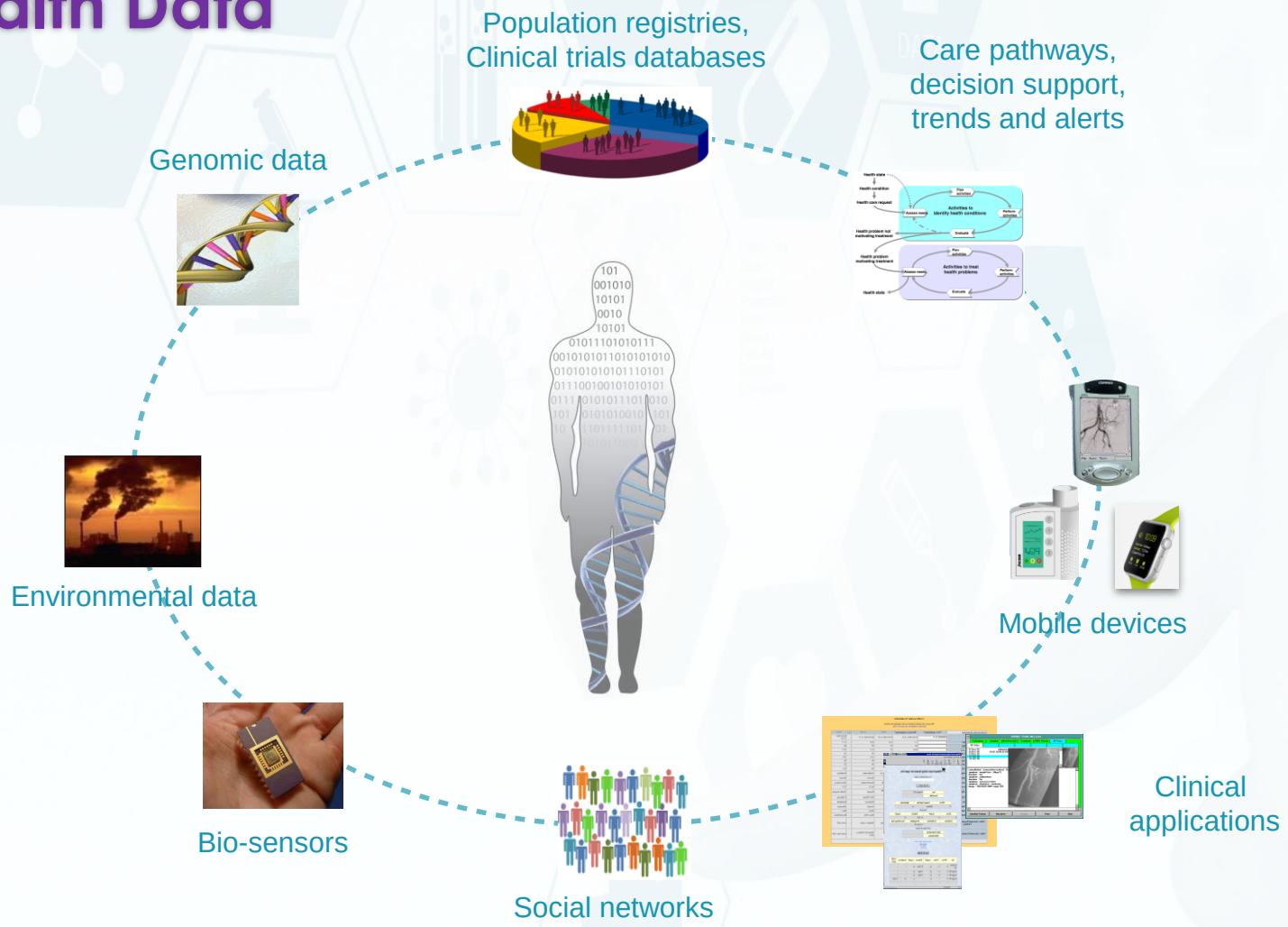
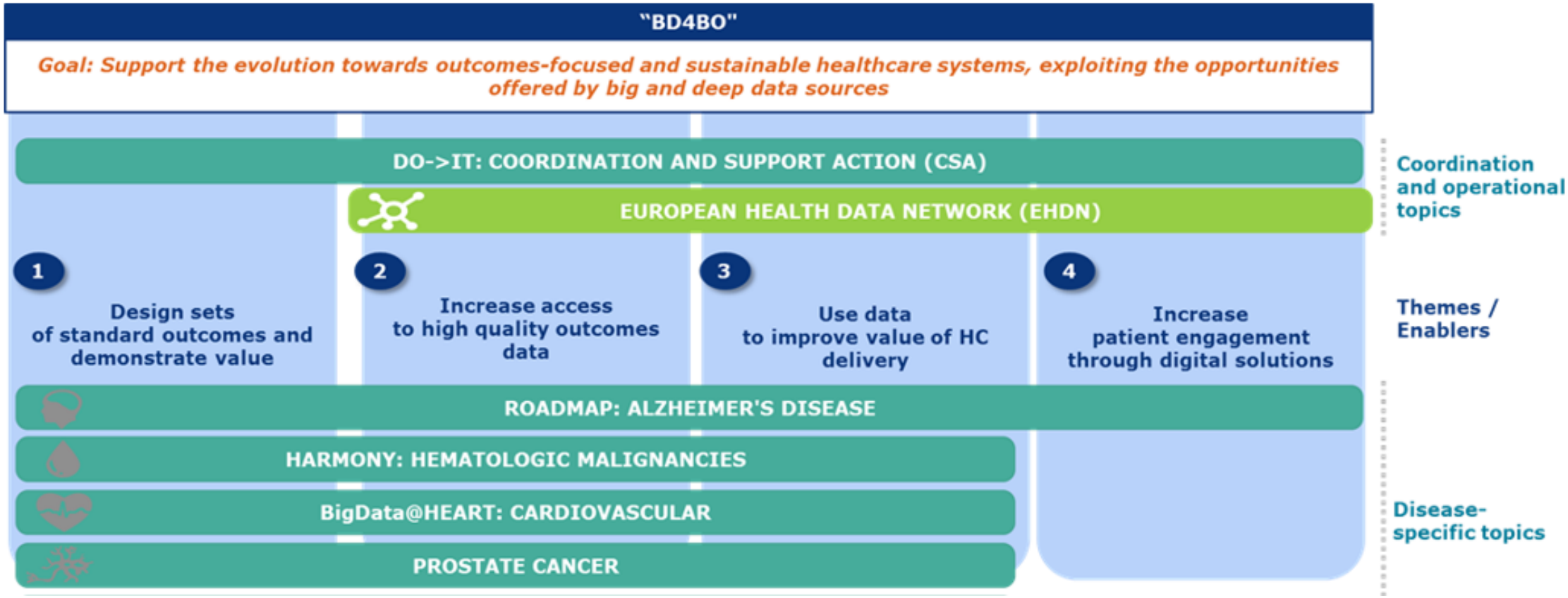
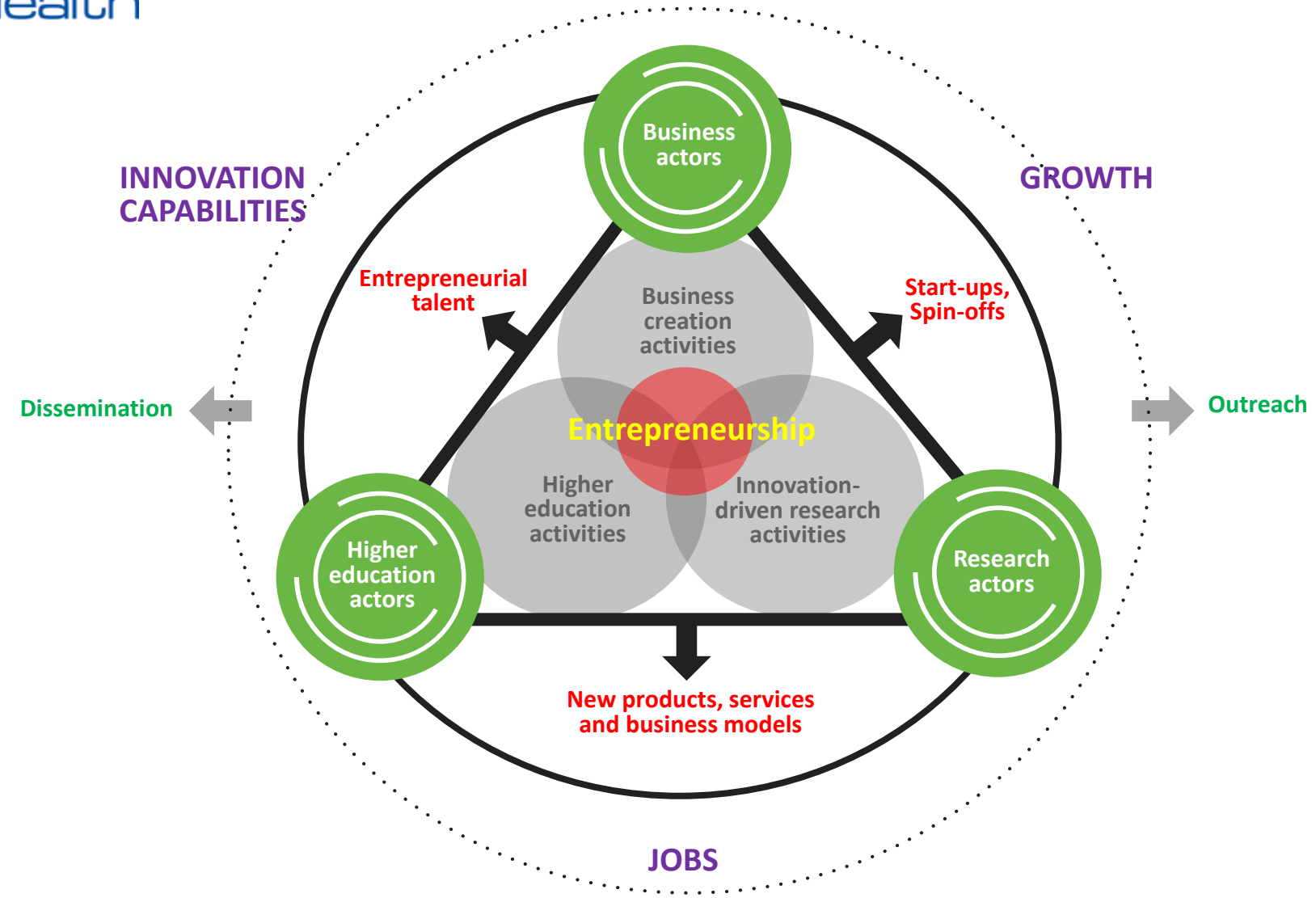
“Big” Health Data

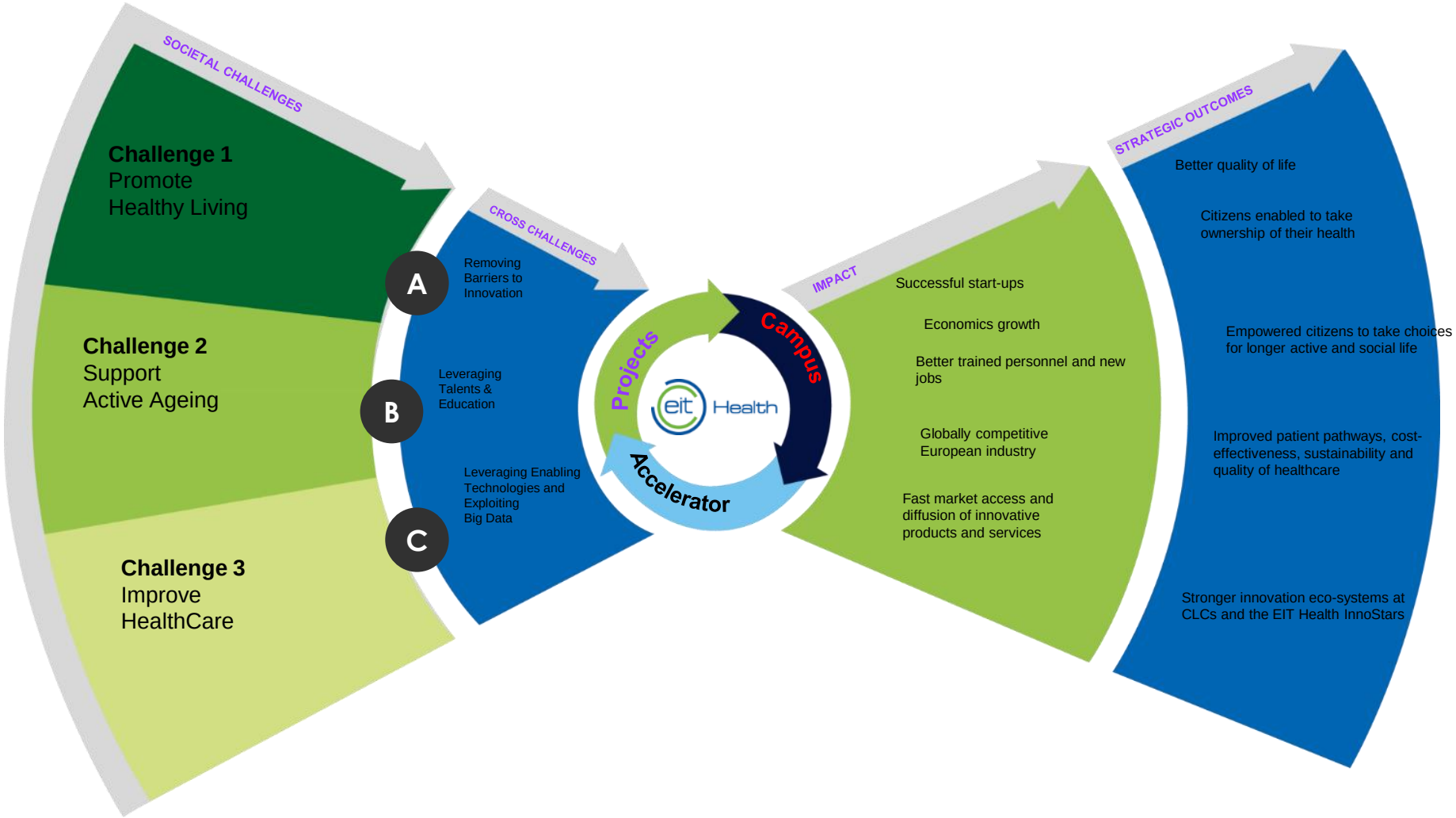


The Big Data for Better Outcomes programme at a glance




INNOVATION CAPABILITIES
GROWTH
Business actors
Entrepreneurial talent
Start-ups, Spin-offs
Business creation activities
Dissemination
Outreach
Entrepreneurship
Higher education activities
Innovation-driven research activities
Higher education actors
Research actors
New products, services and business models
JOBS

Connecting high potential areas with an integrated innovation processes



PRIMARY PURPOSE OF THE PRODUCT:	ADDRESS A MEDICAL CONDITION	MANAGE OR PREVENT A MEDICAL DISORDER OR DISEASE	OPTIMIZE MEDICATION	TREAT A MEDICAL DISEASE OR DISORDER
To support product claims of risk, efficacy, and intended use:	Regulatory enforcement discretion (without explicit oversight)	Third-party validation of efficacy and safety claims by regulatory or equivalent national body	Third-party validation of efficacy and safety claims by regulatory or equivalent national body	Third-party validation of efficacy and safety claims by regulatory or equivalent national body
Product claims related to a medical disorder or disease:	No efficacy claims regarding a medical disorder or disease	Low to medium risk claims *(e.g., reduce rate of disease progression)*	Medium to high risk claims *(e.g., improve efficacy of adjunctive therapies)*	Medium to high risk claims *(e.g., direct efficacy claims on clinical outcomes)*
Clinical evidence generation:	Clinical trials and ongoing evidence generation required	Clinical trials and ongoing evidence generation required	Clinical trials and ongoing evidence generation required	Clinical trials and ongoing evidence generation required
Patient access to product:	Direct-to-Consumer (Prescription *not* required)	Over-the-Counter OR Prescription required	Over-the-Counter OR Prescription required	Prescription required
Relationship to concurrent therapies:	Works independently OR Indirectly supports another therapy	Monotherapy OR Directly supports a concurrent treatment	Directly supports a concurrent treatment	Monotherapy OR Directly supports a concurrent treatment

Examples of digital therapeutics on the market or under development include:

- Combined software and hardware program to improve asthma and COPD control and optimize healthcare utilization
- Digital therapeutic utilizing adaptive sensory stimulus software for the treatment of ADHD delivered through an engaging video game experience
- Digital therapeutic used as an adjunct to standard, outpatient treatment for Substance Use Disorder (SUD)
- Digital sleep improvement program featuring Cognitive Behavioral Therapy (CBT) techniques
- Digital therapeutic engaging individuals with Type 2 diabetes, hypertension, and obesity, and their providers, to improve self-management and outcomes
- AI-based digital diagnostics and personalized therapeutics for pediatric behavioral healthcare
- Neurologic Music Therapy to address motor, speech, and cognitive dysfunction caused by neurologic disease or injury
- Digital delivery of physical exercises, behavioral therapy, and education for chronic back pain patients
- Personalized digital program to help people prevent the onset of diabetes and other chronic diseases
- Basal insulin dose calculator for adults with Type 2 diabetes
- Intervention tool to train cognition in concussion patients

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FACULDADE DE FARMÁCIA Universidade de Lisboa
sócio farmácia

New areas...

- **Data / Digital Technologies**
- **Biopharmaceutical R&D+Innovation**

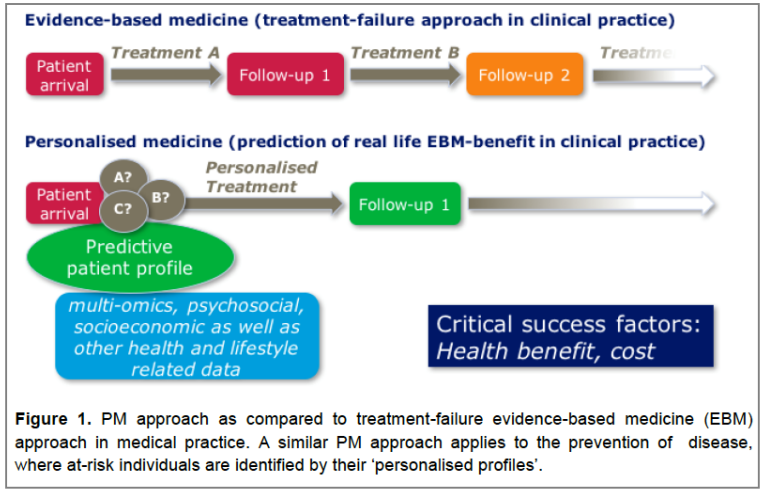
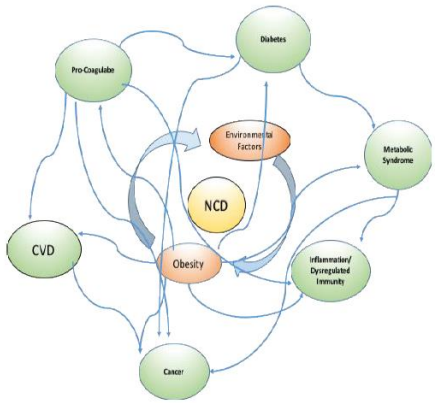
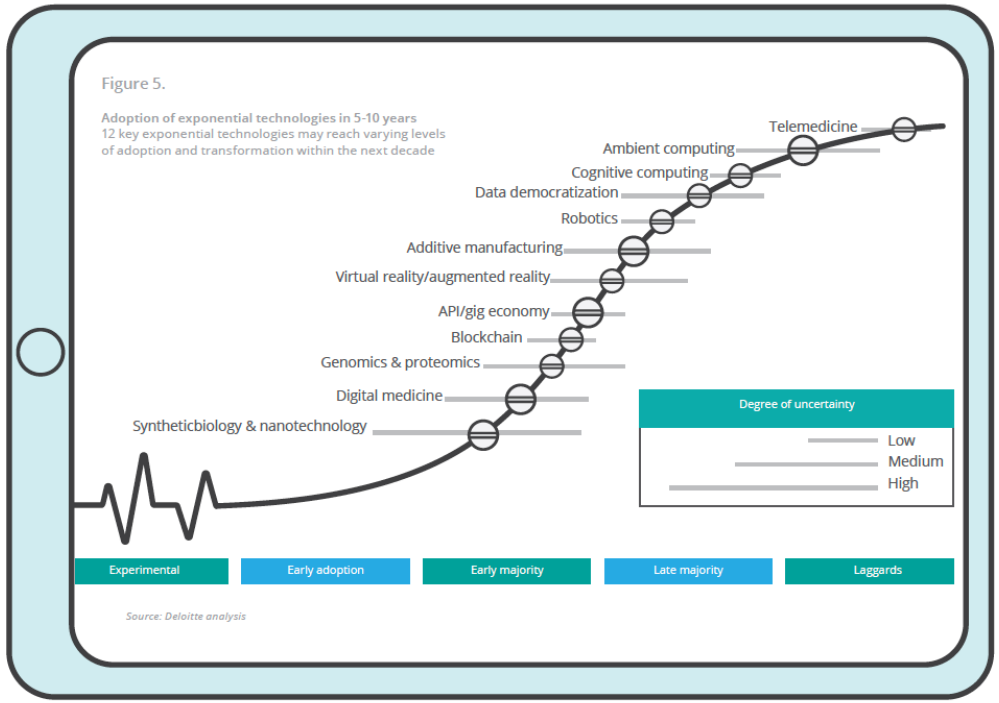


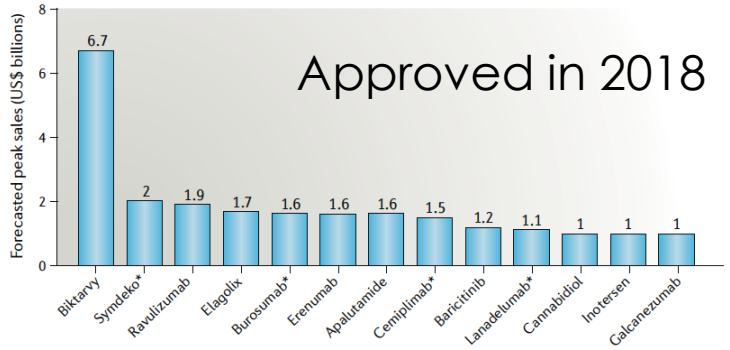
Figure 1. PM approach as compared to treatment-failure evidence-based medicine (EBM) approach in medical practice. A similar PM approach applies to the prevention of disease, where at-risk individuals are identified by their 'personalised profiles'.



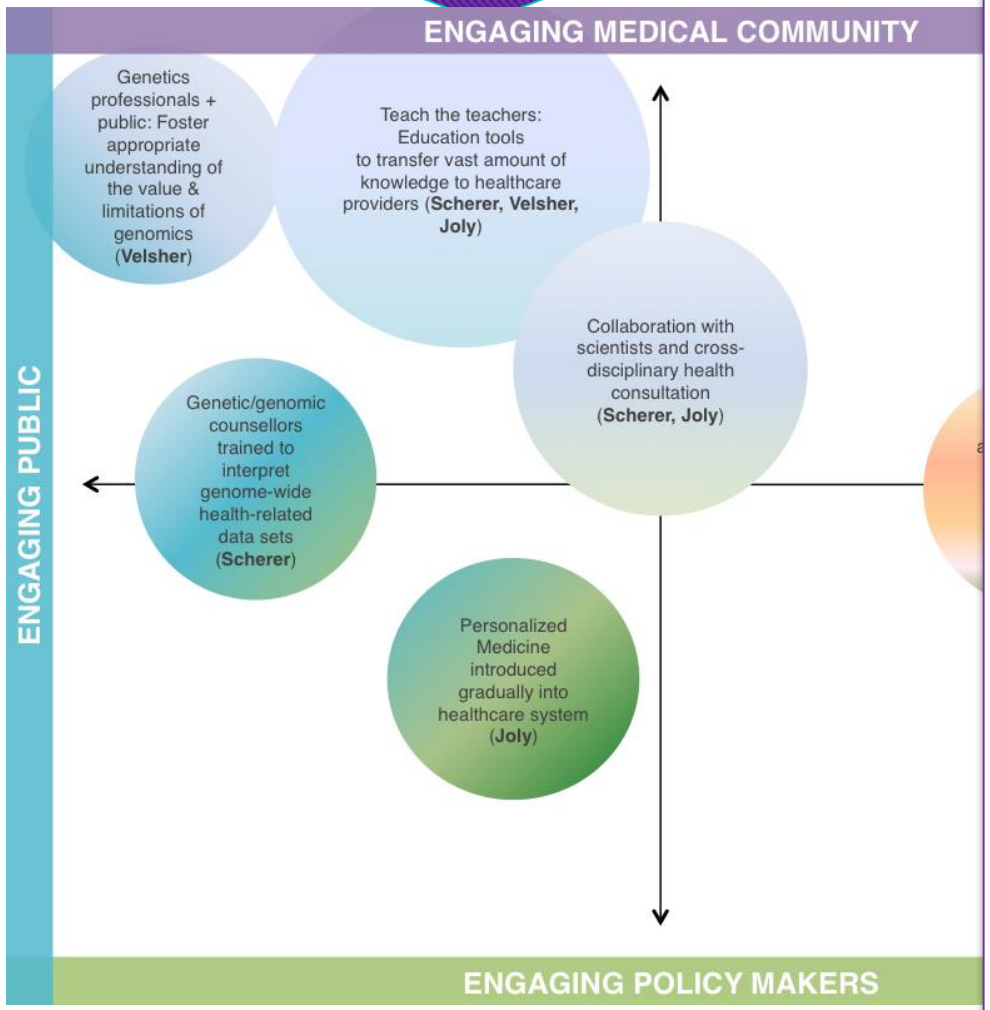


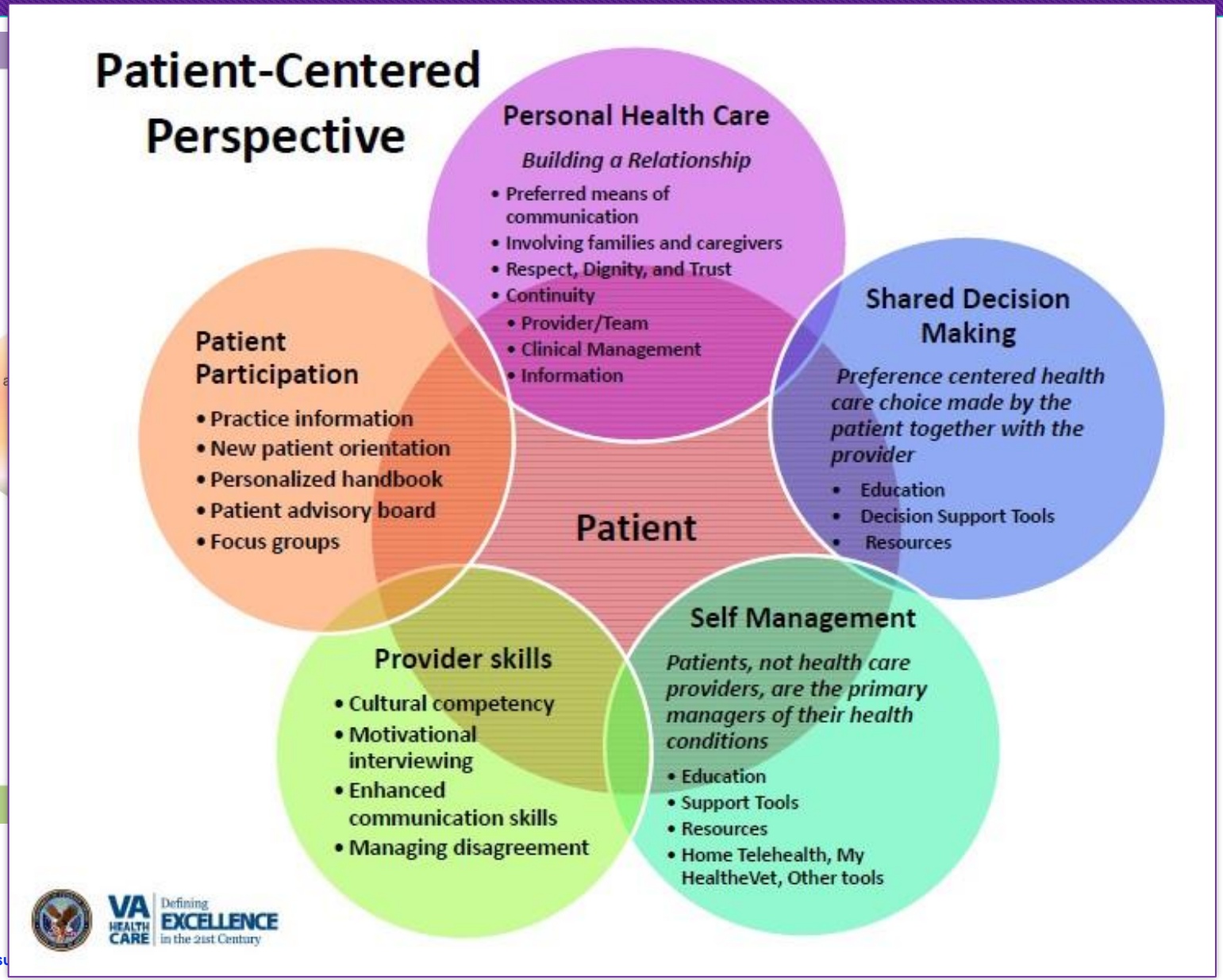
R&D integration
Specialisation/Personalised care
Manufacturing capacity

Nature Reviews | Drug Discovery



Health innovation with societal impact





Personalized Medicine in Canada: A Visual Summary, Allie Janson Hazell (Dec 22nd, 2011)
http://www.thegenoscape.com/2011/12/22/personalized-medicine-in-canada-a-visual-su

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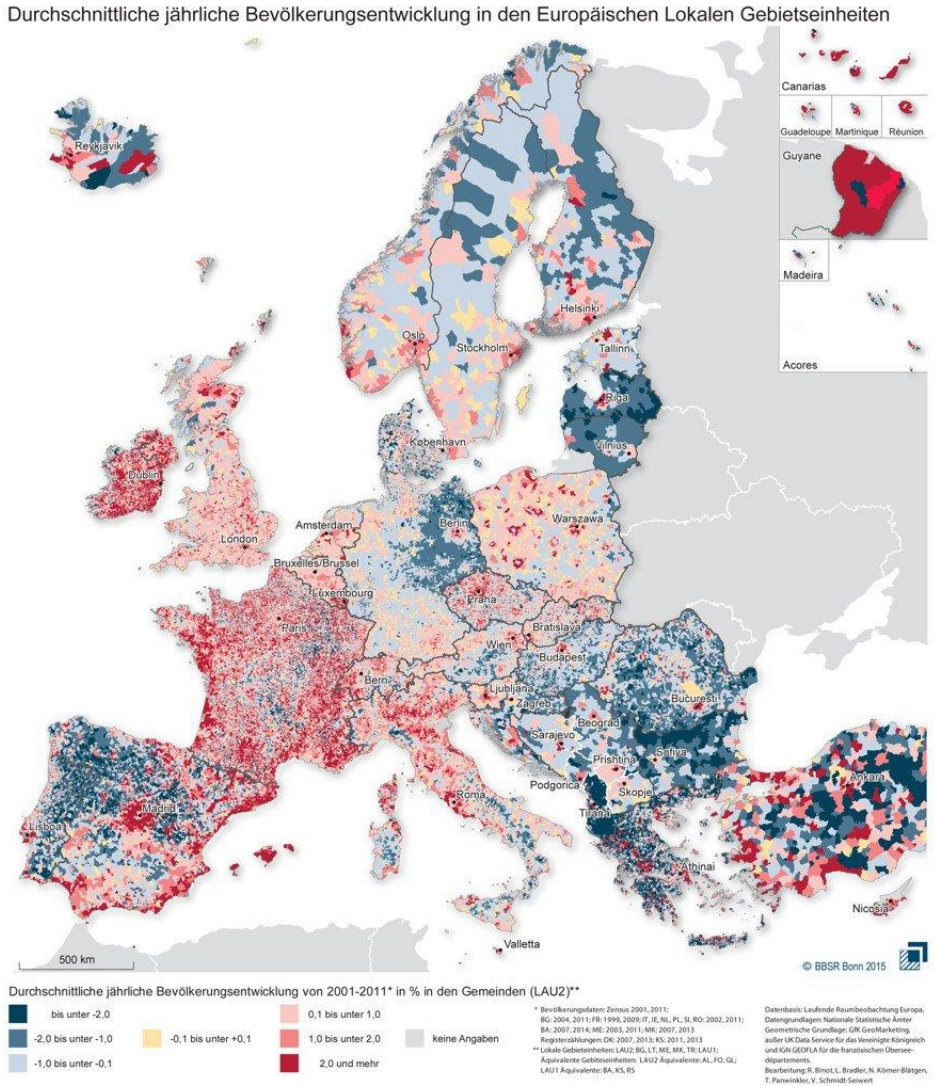
Human development and pattern changes in geographical distribution

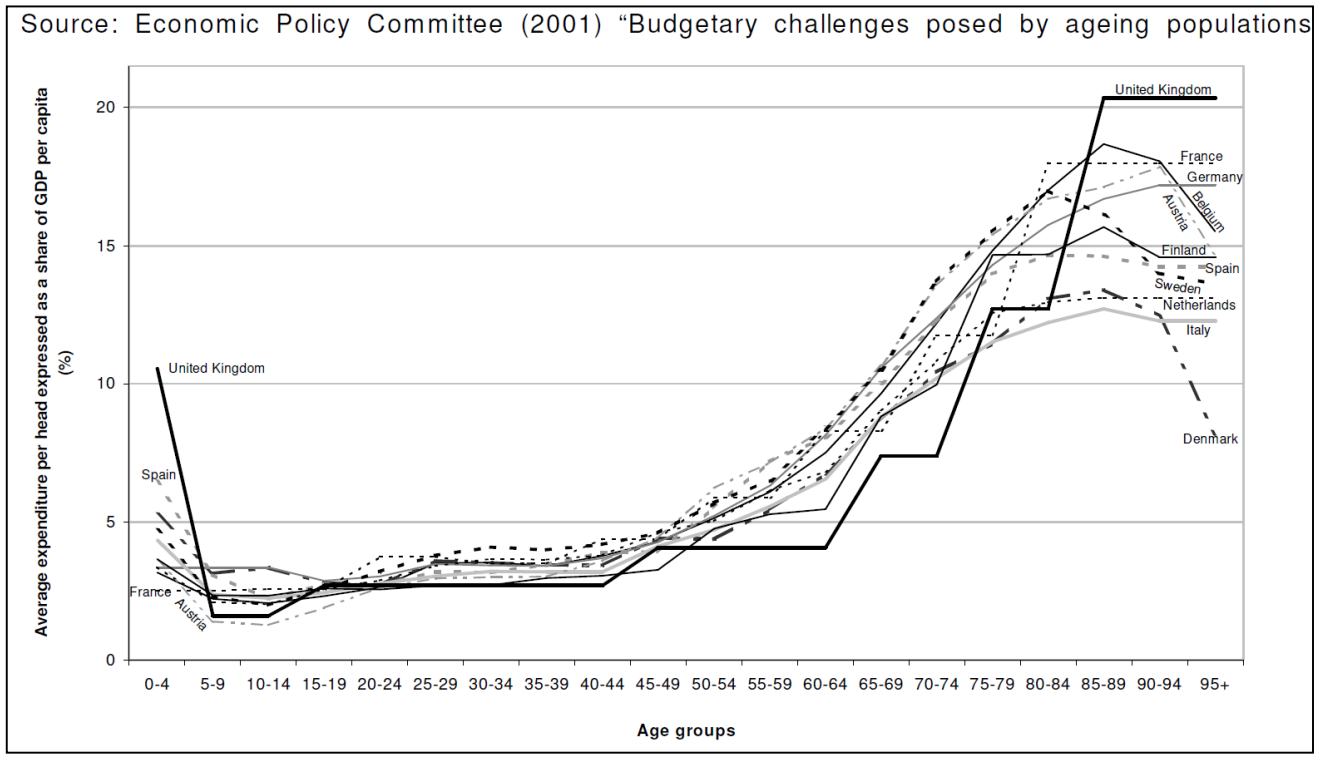


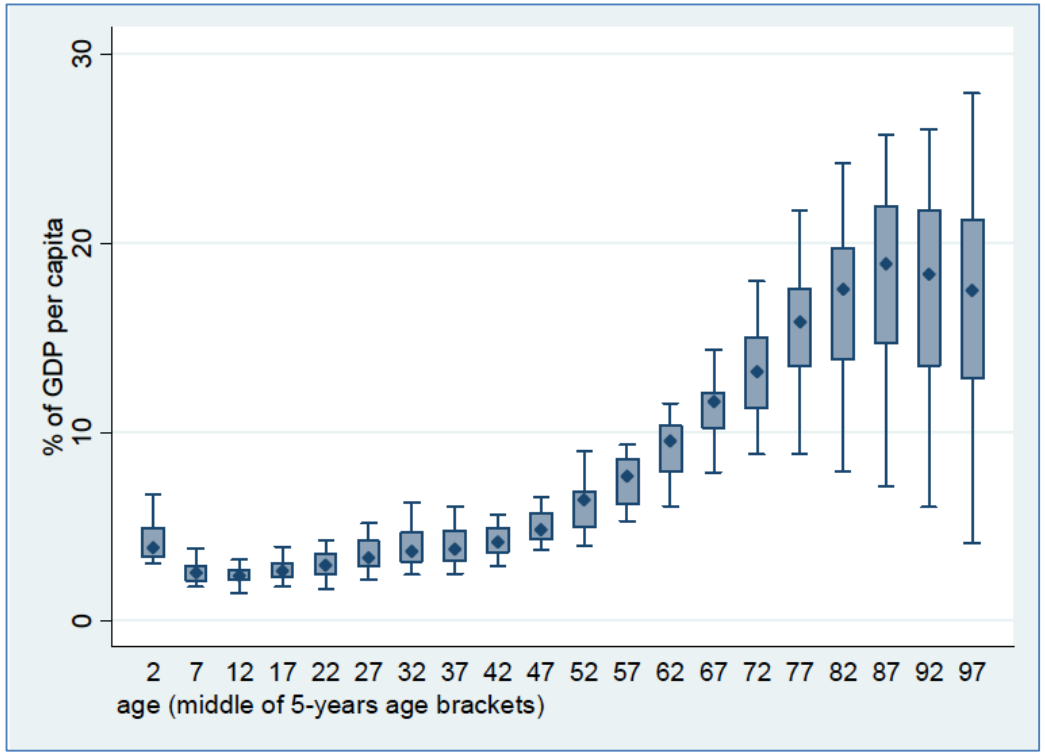
Median age (years)

	2010	Changes in median age	2060
CY	34.2		50.1
SK	37.2		53.0
PL	38.0		53.8
RO	38.5		53.1
PT	41.0		55.1
ES	40.2		54.0
MT	40.2		52.4
HU	39.9		50.7
BG	42.4		53.0
LT	38.7		49.2
CZ	39.5		50.0
IT	43.3		53.6
GR	41.8		51.8
DE	44.3		54.0
SI	41.5		51.1
EU27	40.1		49.3
IE	34.3		43.1
LU	38.9		47.0
AT	41.8		49.1
EE	40.5		47.1
LV	41.2		47.7
NL	40.8		46.9
UK	39.8		44.3
BE	41.1		45.4
FR	40.0		44.0
FI	42.0		45.1
DK	40.6		43.2
SE	40.7		42.4
China	34.6		49.2
Japan	44.9		57.6
Russia	38.0		46.4
India	25.5		32.2
USA	37.1		40.3

Impact of demographics on healthcare…

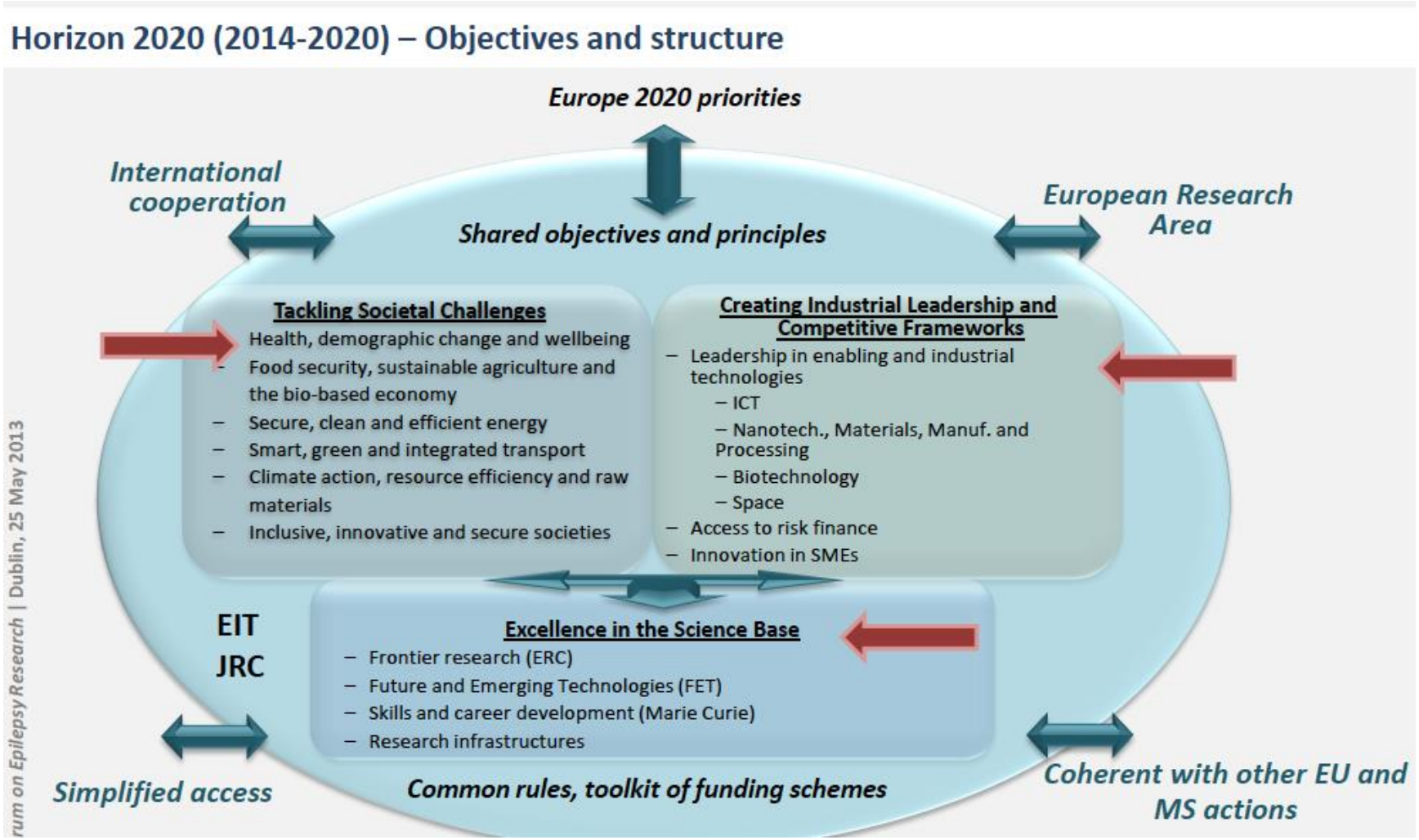
Source: Economic Policy Committee (2001) "Budgetary challenges posed by ageing populations

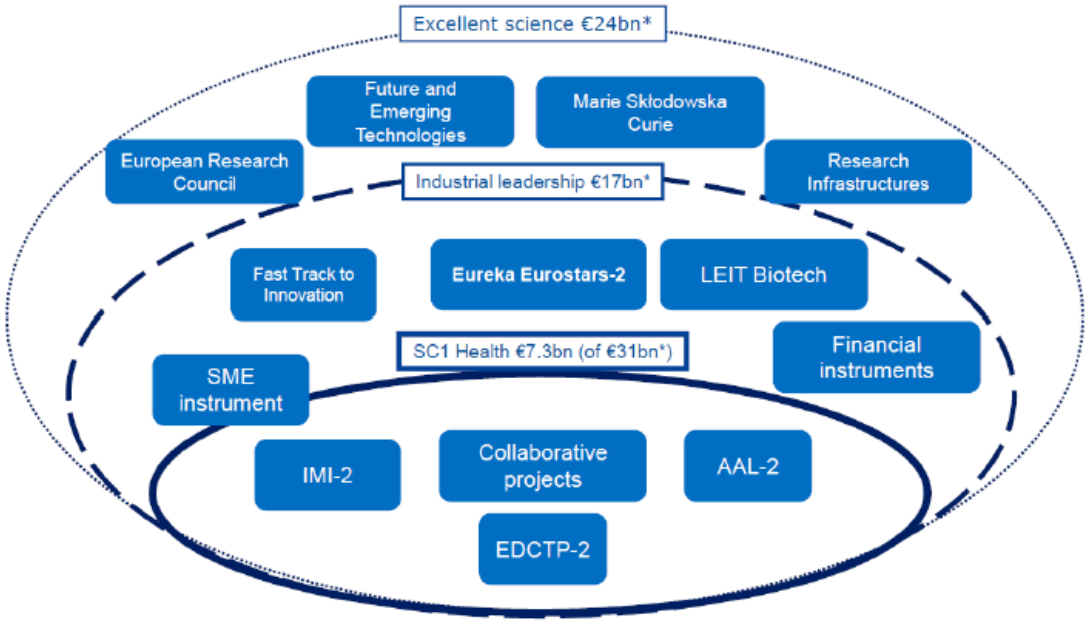




Public Spending on health and long-term care: a new set of projections
(OECD Economic Policy Papers, 06, June 2013)

Horizon 2020

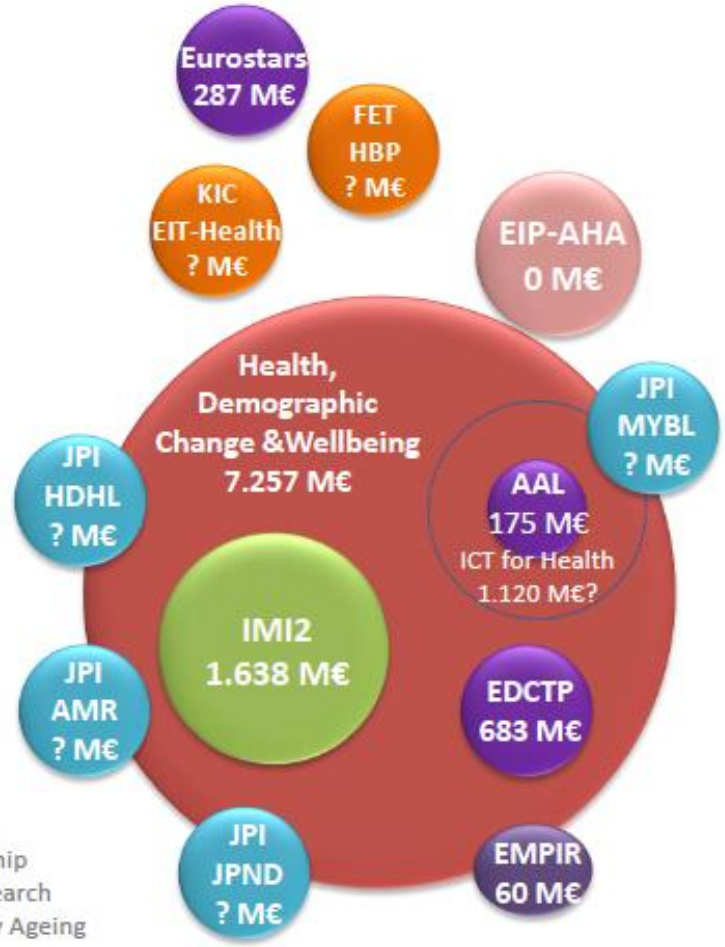




* Figure to be updated following EFSI investments in 2015

1. *Understanding health, wellbeing and disease*
2. *Preventing disease*
3. *Treating and managing disease*
4. *Active ageing and self-management of health*
5. *Methods and data*
6. *Health care provision and integrated care*

- HBP: Human Brain Project
- JPI: Joint Programming Initiative
- IMI: Innovative Medicines Initiative
- AAL: Active and Assistive Living programme
- KIC: Knowledge and Innovation Community
- FET: Future and Emerging Technologies
- JPI MYBL: More Years, Better Lives
- JPI HDHL: Healthy Diet for Healthy Life
- JPI AMR: Joint Programme in Antimicrobial Resistance
- JPND: Joint Programme in Neurodegenerative Disease Research
- EDCTP: European & Developing Countries Clinical Trials Partnership
- EMPIR: European Metrology Programme for Innovation and Research
- EIP-AHA: European Innovation Partnership on Active and Healthy Ageing



European Science Policy

Horizon Europe

European Commission proposal: **7th June 2018**

European Parliament vote: **17th April 2019**

- The European Commission has proposed a total budget of €161.6 billion for the four programmes: **€94.1 billion for R&D in Horizon Europe**; €16 billion for space; €9.2 billion to boost Europe's digital capabilities in the Digital Europe programme; and €42.3 billion for the Connecting Europe infrastructure programme, of which €3 billion would be spent on digital infrastructure.

Horizon Europe's association rules are to be discussed as part of negotiations on the EU's overall long-term budget, which was originally supposed to be finalised in time for the **next EU summit in Sibiu, Romania on 9 May** – six weeks after the UK was due leave the EU on 29 March.

Currently, member states are deadlocked over the EU budget and Commission proposals to increase richer countries' contributions, while cutting money paid to poorer member states.

In December 2018, budget commissioner Günther Oettinger pushed the **budget deadline back to October 2019.**

Horizon Europe

Our vision

A sustainable, fair and **prosperous** future for **people** and **planet** based on European values.

- Tackling **climate change** (35 % budgetary target)
- Helping to achieve **Sustainable Development Goals**
- Boosting the Union's **competitiveness and growth**

Horizon Europe: Preliminary structure

European Commission

May 2019 | Version 25

Horizon Europe

Pillar 1

EXCELLENT SCIENCE:

reinforcing and extending the excellence of the Union's science base

European Research Council

- Frontier research by the best researchers and their teams

Commission proposal: € 16.6 billion

Marie Skłodowska-Curie Actions

- Equipping researches with new knowledge and skills through mobility and training

Commission proposal: € 6.8 billion

Research Infrastructures

- Integrated and inter-connected world-class research infrastructures

Commission proposal: € 2.4 billion

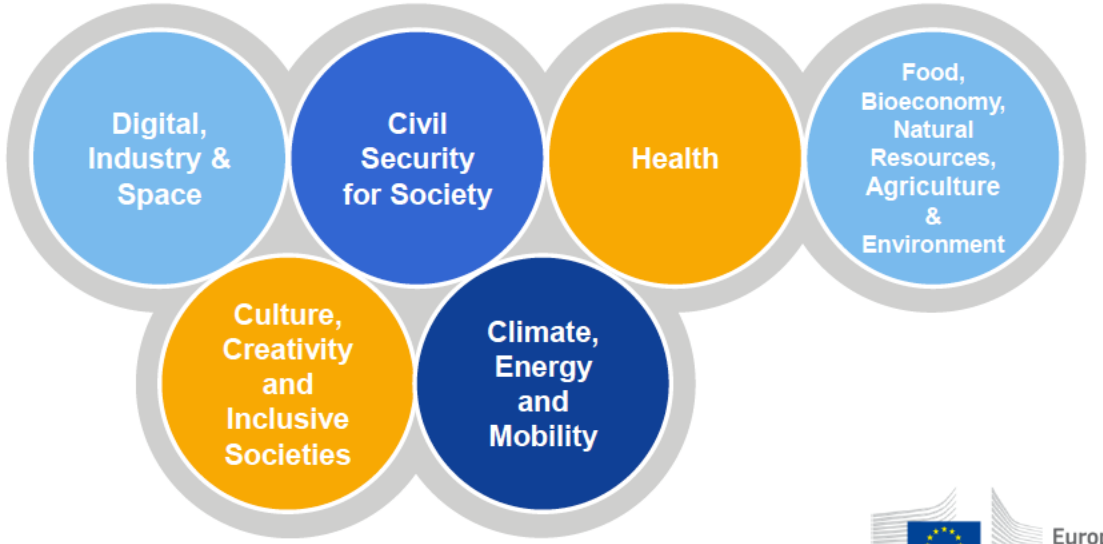
May 2019 | Version 25

European Commission

Pillar 2 - Clusters

Global Challenges & European Industrial Competitiveness: boosting key technologies and solutions underpinning EU policies & Sustainable Development Goals

Commission proposal for budget: € 52.7 billion



May 2019 | Version 25

European Commission

Horizon Europe

Pillar 3

INNOVATIVE EUROPE:

stimulating market-creating breakthroughs and ecosystems conducive to innovation

European Innovation Council

- Support to innovations with breakthrough and market creating potential

European innovation ecosystems

- Connecting with regional and national innovation actors

European Institute of Innovation and Technology (EIT)

- Bringing key actors (research, education and business) together around a common goal for nurturing innovation

Commission proposal: € 10.5 billion, incl. up to € 500 million for ecosystems

Commission proposal: € 3 billion

May 2019 | Version 25

European Commission

Widening Participation and Strengthening the European Research Area: optimising strengths & potential for a more innovative Europe

Widening Participation and Spreading Excellence, e.g.

- Teaming & twinning
- ERA Chairs
- COST
- Support to NCPs
- Brain circulation and excellence initiatives
- "Hop-on"

Common understanding: At least 3.3 % of Horizon Europe budget

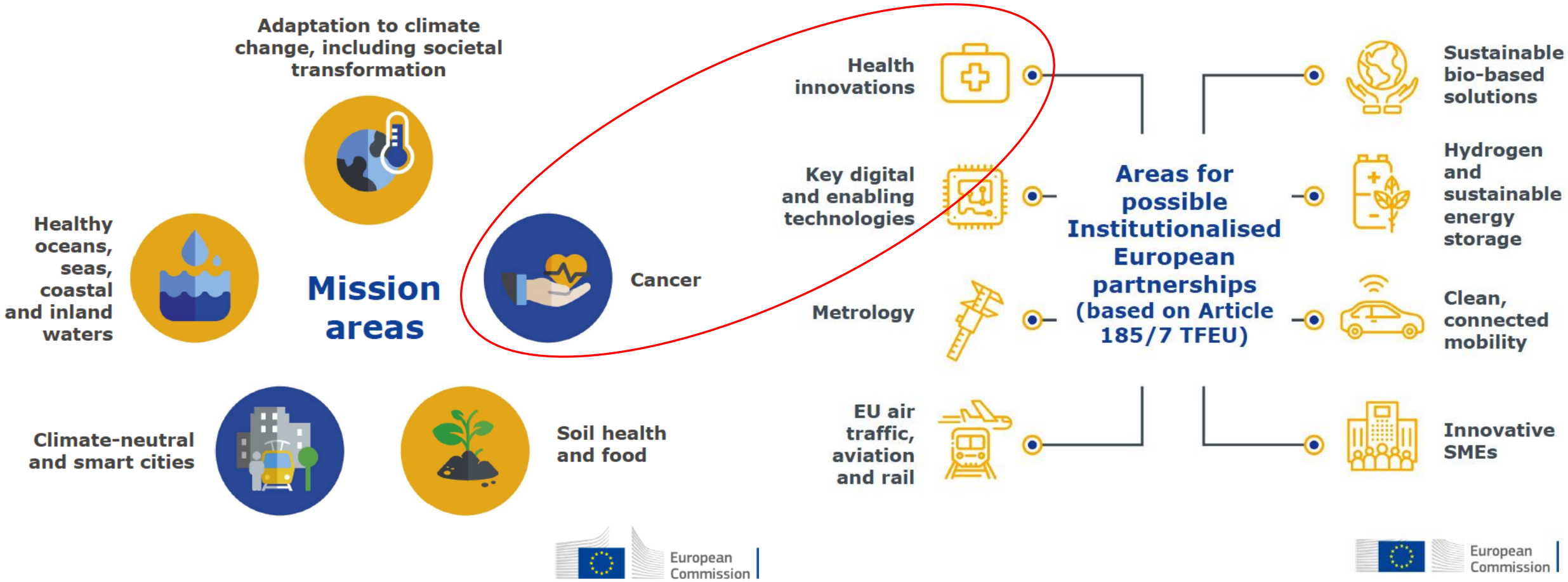
Reforming and enhancing the European R&I system

- Scientific evidence & foresight
- Open Science
- Policy Support Facility
- Attractive researcher careers
- Citizen science, Responsible Research & Innovation
- Gender equality

May 2019 | Version 25

European Commission

Horizon Europe



Horizon Europe

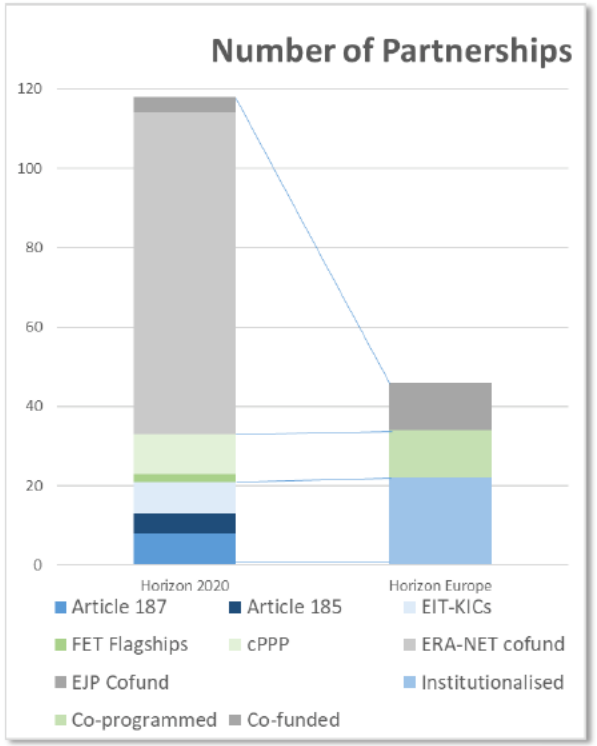
Emerging Partnership portfolio Horizon Europe

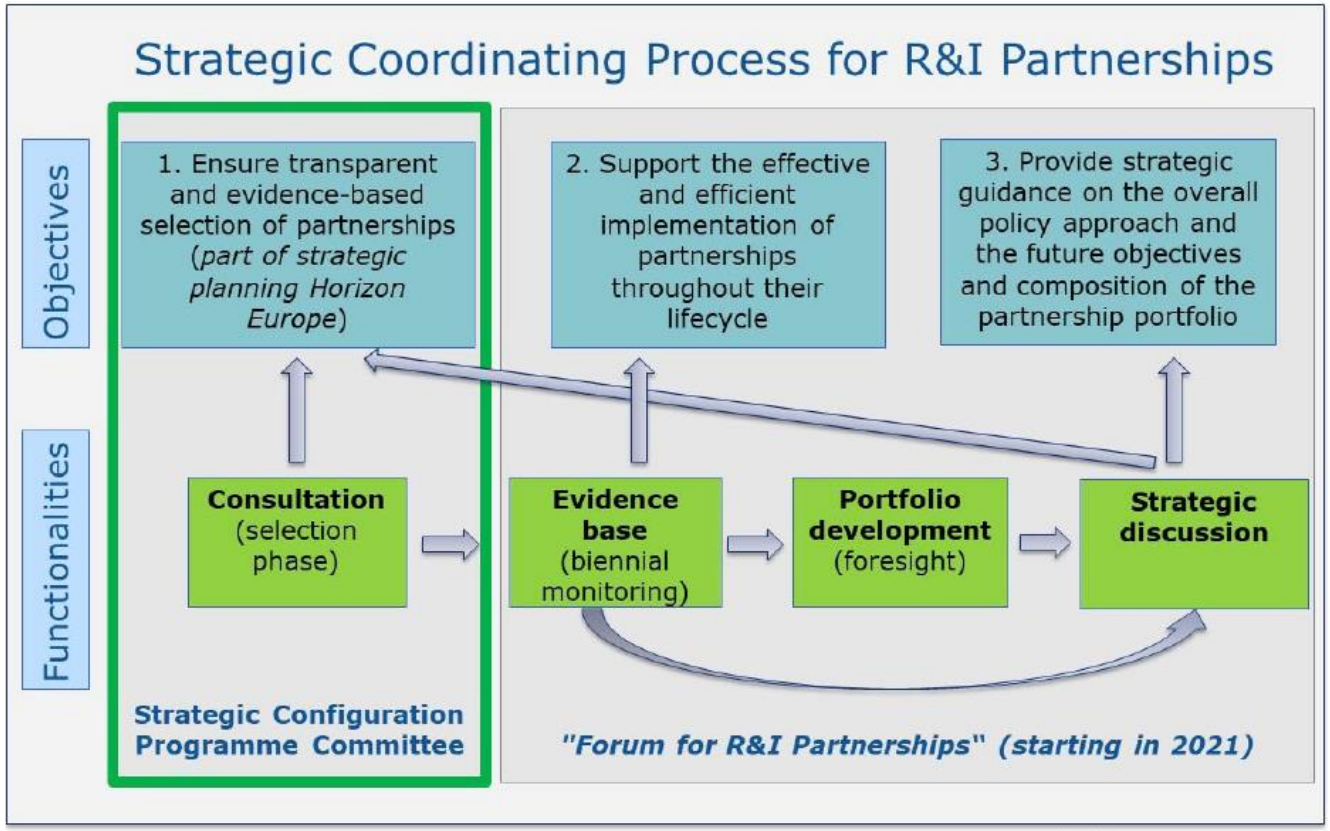
Rationalisation and reform achieved so far:

- Reduction from >120 (of all types) to currently 45;
- 6 new topics;
- 28 reformed continuations;
- 11 mergers and reforms;
- 35 partnerships candidates in Pillar II;
- 11 partnership candidates outside pillar II (9 EIT-KICs, SMEs, Open Science Cloud).

EU contributions/budgets:

- To be decided at a later stage following the overall MFF and Horizon Europe budgetary envelopes;
- To be determined once there are agreed objectives, and clear commitments from partners.





Horizon Europe: moving towards Innovative Health Initiative ?

Health

Rationalisation and reform:

Overall number reduced from 13 to 7, of which

- 4 are reformed continuations of current partnership topics;
- 3 partnerships that would build on existing actions or merge existing partnerships;
- No discontinuation, but merging.

CF: Co-funded
CP: Co-programmed

Current candidates	Type
▪ EU-Africa Global Health Partnership	A185/7, CP, CF
▪ Innovative Health Initiative	A187, CP
▪ European partnership for chemicals risk assessment	CF
▪ Pre-clinical / clinical health research	CF
▪ Large-scale innovation and transformation of health systems in a digital and ageing society	CF
▪ Personalised Medicine	CF
▪ Rare Diseases	CF
In addition: EIT Health	KIC

What is the context and problem definition?

Context:
Europe has an **ageing population** and a **rising burden of diseases**. • Developing innovations is **often long, costly and risky**, while healthcare systems are under budgetary **pressure.** • Opportunity of **convergence of industry sectors** (pharma, med. tech., digital).

Problem:
Innovations are slow to reach the patients and users, or do not reach them at all if companies are unable to prove their safety and efficacy or if payers of the healthcare systems cannot afford them.

Causes:
• **Lack of complete understanding** of diseases • **Weak translation** of research into actual products and services • **Insufficient integration** of technologies and health interventions • **Barriers to digitalisation** • **Market failures** • Lack of adequate **business models**.

Earlier interventions:
IMI and IMI2 partnerships • Excellent in **promoting public-private cooperation** • Fostered **knowledge sharing** between pharmaceutical companies • Established **critical mass** for drug development • Initiated collaborations with non-pharmaceutical companies • **Opportunity** now for broader **cross-sectoral collaboration**

Horizon Europe: moving towards Innovative Health Initiative ?

What are the objectives, expected impacts and scope?

Partnership:

EU and health related industries (such as pharmaceuticals, diagnostics, medical devices, imaging, biotech and digital industries) • European **collaborative platform** for **precompetitive and integrative R&I**.

Overall objective:

Accelerate the development of **safer** and **more effective innovative healthcare interventions** that respond to **unmet public health needs**, and that can be taken up by healthcare systems.

Specific objectives:

• Facilitate **technology integration** to: progress disease understanding; enable the delivery of innovative health products and services; enable the combination of innovations along the healthcare pathway; overcome barriers to digitalisation, via standards, interoperability, etc. • Contribute to methodologies for **better assessing the value** of innovative interventions.

Expected impacts:

• Contribute to the **sustainability of the healthcare systems** • **Faster time-to-market** for innovative products • **New business** models • Incentive for industry to invest in **unmet public health needs** • Facilitate the delivery of **cost-effective** interventions • Improved **health outcomes** • Cross-sectoral industry **collaborations.**

Why do we need an institutionalised European Partnership?

Requirements?

The magnitude and systemic nature of the problem addressed requires mass knowledge and resources sharing, and long-term, concerted actions from a broad range of stakeholders: academia, industry, SMEs, patients, regulators, healthcare providers, professionals, payers.

An institutionalised Partnership?

Can bring together the **broad spectrum** of stakeholders required with strong governance • **Deepest integration** of partners and activities • Creates a **long-term** dedicated implementing structure • **Strong engagement** and **up-front commitment** from partners • Leverages **contributions from industry** • Strong positioning of the EU in the **governance** • Exploits the well-known **IMI brand**.

Regular HE calls for proposals?

Could **not attract as many industry participants**, in a **cross-sectoral** manner, if industry is not involved in setting long-term research agendas • Do not offer the **scale** to maximise impacts • No **long-term** commitment from industry to anchor investments in Europe.

Horizon Europe: moving towards Innovative Health Initiative ?

Maintaining an innovative, sustainable and globally competitive health industry

1. **Efficient innovation management strategies**, including intellectual property, to translate breakthrough technologies into health care applications.

2. **Efficient collaboration with regulatory authorities and health care providers** for an optimal time to patient access.

3. **Novel methodologies and metrics adapted to new tools, technologies, digital solutions and interventions for their assessment, validation and translation into health care practice**, including ethical aspects, their societal effects and integration into regulatory frameworks, and for allowing swift access by health care providers, patients and healthy citizens.

4. **Regulatory authorities supported with better methodologies and interdisciplinary approaches** to assess new health technologies and interventions.

5. **New European standards and quality assurance schemes developed** for submission to standardisation bodies and implementation by stakeholders.

6. **Safe and clinically validated tools, technologies and services** developed and delivered by European health industry that meet the needs of citizens, patients, health care providers and systems.

7. **Greener pharmaceuticals and health technologies**.


Orientations
towards the first Strategic Plan
implementing the research and innovation
framework programme Horizon Europe

CO-DESIGN
VIA WEB OPEN CONSULTATION
Summer 2019

Horizon Europe: moving towards Innovative Health Initiative ?

European Partnerships: The "***Health Innovation partnership***" *(Innovative Health Initiative)* will provide a cross-sectoral collaborative platform bringing the pharmaceuticals, diagnostics, medical devices, imaging and digital industries together with public stakeholders.

It will contribute significantly to "***Enabling the digital transformation of health and care in the Digital Single market***" by supporting precompetitive R&I in **areas of unmet public health and accelerating the development of people-centred health care innovations that can be taken up in health and care systems**.

It intends to overcome barriers that prevent exploiting the **full potential of digitalisation and data exchange, through standards, methods and tools for interconnectivity and interoperability as well as to deliver tools, data, platforms, technologies and processes that enable the delivery of innovative health products and services to predict, prevent, intercept, diagnose and manage diseases more efficiently, that meet the needs of the end users and payers**.

A strong synergistic link will be created with the European partnership on 'Large-scale innovation and transformation of health systems in a digital and ageing society', thereby warranting the usefulness, transferability and the potential uptake of the developed health solutions into public health systems. **This partnership would be the successor initiative of the IMI2 partnership programme based on Article 187 TFEU**. **It will be launched in 2021.**

Embracing innovation: Next steps

Regardless of where leaders choose to focus first, there are several next steps that they should consider:

- Build ecosystems
- Embrace nontraditional sources of knowledge
- Pilot, experiment, and scale
- Experiment with new business models
- Focus on change management
- Be agile

"Health care leaders should focus on innovations that have the potential to positively impact their specific business models."

Rogério Sá Gaspar

Faculdade de Farmácia da Universidade de Lisboa

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