

Innovative Medicines Initiative - A Public Private Partnership success story

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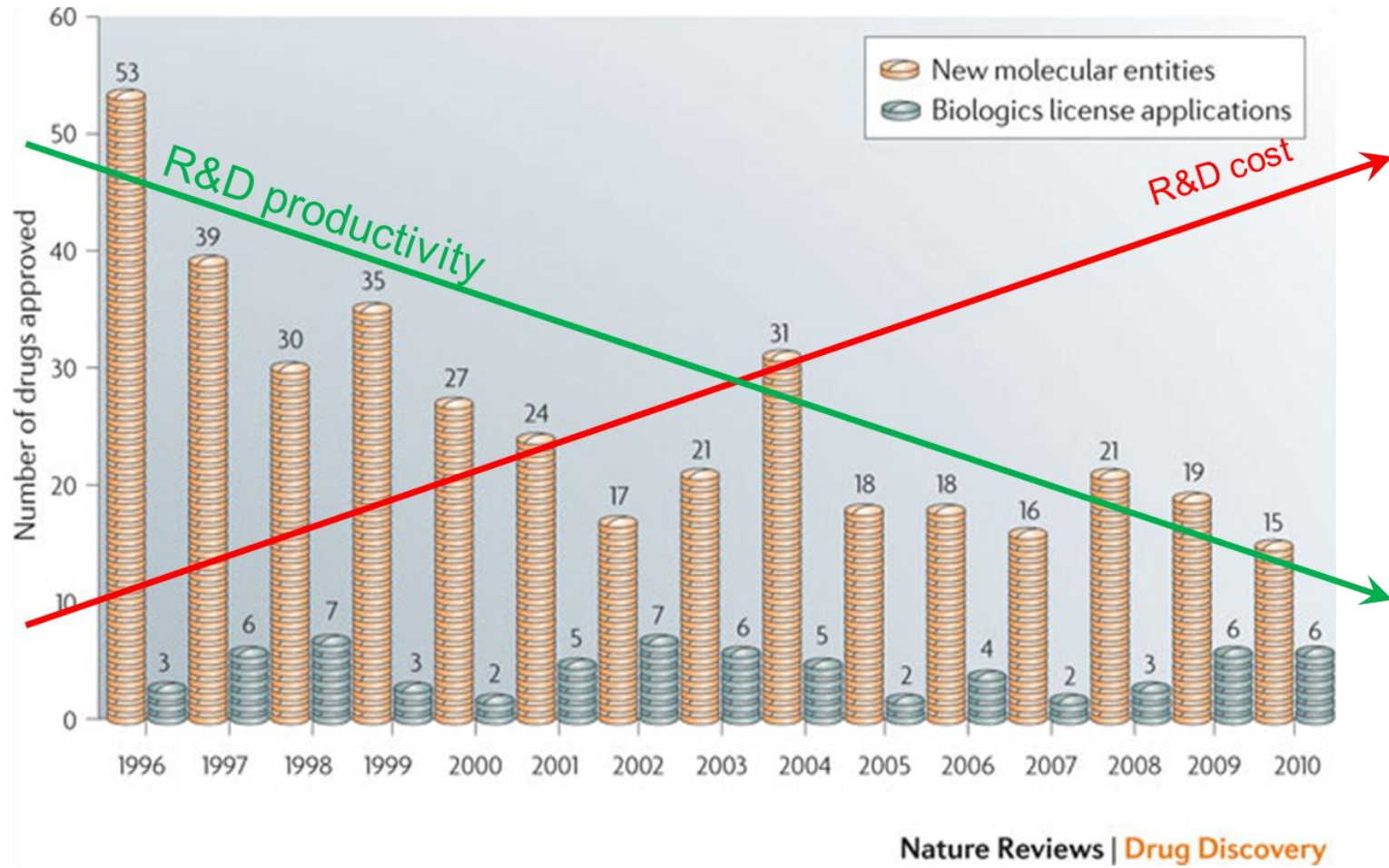
Director Science Policy

Gdansk, 25 September 2012

- Proof of concept for new public private collaborations in pharmaceuticals
- Open collaboration to define and address common challenges (with competitors and public partners)
- Tangible deliverables after less than 2 years – at a pace that no other funding scheme allows
- A neutral platform for dialogue defining common agenda/ priorities (with health and regulatory authorities)

More science...

- Our understanding of disease biology has exploded in recent years
- The cancer area is generally most advanced and in some instances this has resulted in true personalized medicine
- With the increased understanding of disease and disease biology positive data are emerging also within prevention
- All together – the outline for better treatment regimes is emerging



Wardlaw, 2010. FDA drug approvals. Nature Reviews Drug Discovery, 2011, 10, 62-63

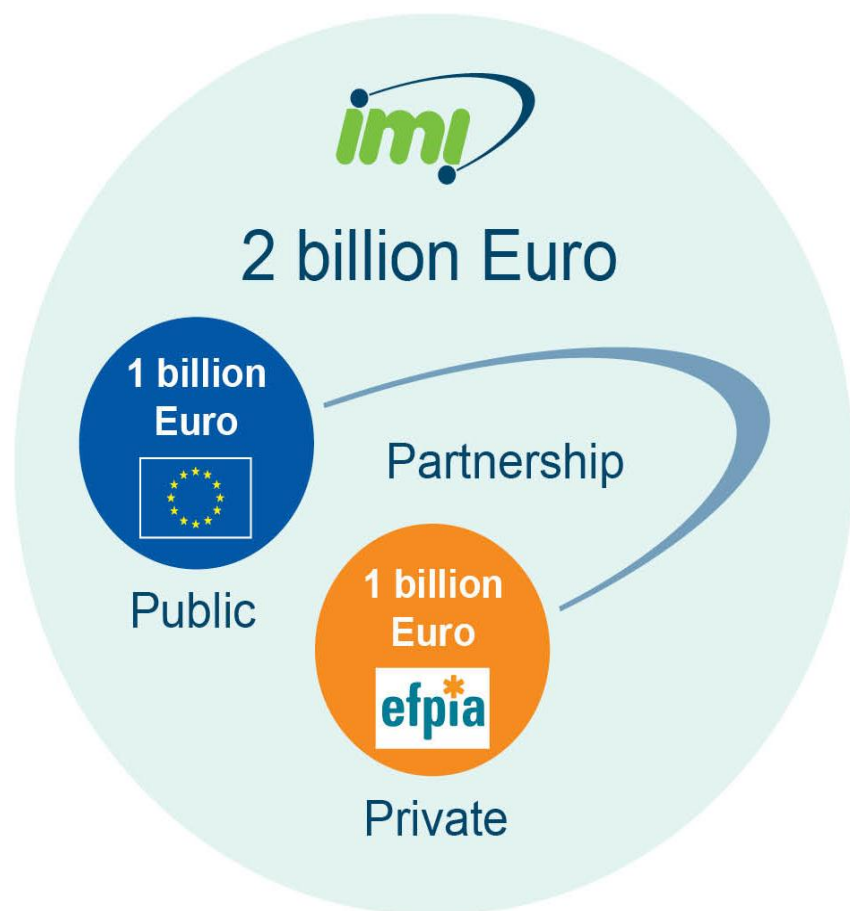
Challenges for society and industry

Society

- Healthcare challenges continue to raise around the world
- A lot of these challenges are not addressed
- Pressure on healthcare systems and budgets continue to rise

Industry

- Costs for developing new drugs continue to increase
- Pharma incentive systems and profitability are under pressure
- We are pushing towards Personalized Medicine but in general, progress in basic science is not translated to medical innovation and benefits to patients



The European Union and the pharmaceutical industry

have joined forces to make

drug R&D processes in Europe more innovative and efficient

and enhance Europe's

competitiveness in the sector

by forming

the biggest PPP in Life Science

(adopted on December 20, 2007
by the European Council)

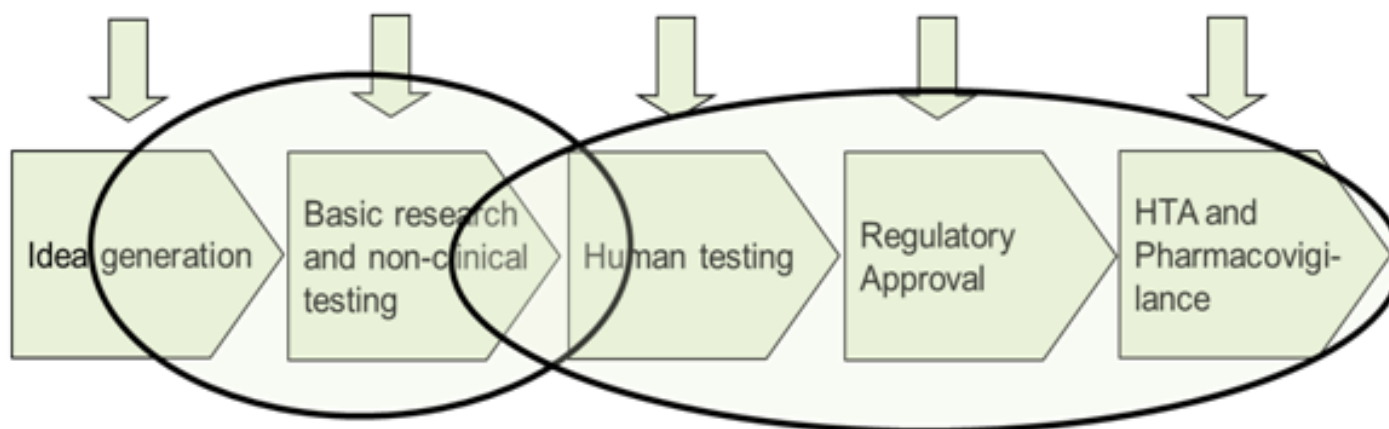


Innovative Medicines Initiative

IMI strategy – evolving from bottlenecks in EU pharma Industry

VISION

**Make Drug R&D processes in Europe more efficient and effective
and enhance Europe's competitiveness in the Pharma sector**



**Primary focus of
early IMI calls**

**Important to add if
we want to address challenges in
Industry and health care challenges
in society**

**Make Drug R&D processes in Europe more efficient and effective
and enhance Europe's competitiveness in the Pharma sector**



- Diseases, e.g. cancer, diabetes, schizophrenia, depression...
- Tools, e.g. stem cells, knowledge management infrastructures
- Biomarkers identification
- Safety
- Pharmacovigilance and Health Technology Assessment
- Education and Training

First successes after less than 2 years



IMI – a unique PPP

- The Innovative Medicine Initiative (IMI) is a unique and first of its kind public private partnership where academia, the European Commission, SMEs and the industry cooperate.
- Industry has always worked closely with academia, but working side by side with competitors and building big PPPs with many public and private partners is new ground.
- Working together, pooling resources and bringing the best researchers from the public and private sector together is essential for many reasons....

- A public private partnership like IMI create more than new and important research projects, it creates:
 - Common understanding of the current healthcare and R&D challenges
 - Common understanding of excellence in research, which has been a challenge so far
 - Greater mutual understanding and perspective on research, work processes and work culture
 - A truly unique platform for dialogue, free of conflict of interest
 - ... and strengthens networks of excellence which attract more R&D
 - Commercial opportunities for spin offs, SMEs, etc.
- IMI is also a reflection of a new understanding and view on the relationship between public and private players as partners and not competitors or opponents.

This would not have happened without IMI...

Projects where up to 15 big companies work together and with many public partners

Projects which address directly societal and regulatory questions and needs in a multistakeholder setup

- Opportunities to rationalise R&D models directly discussed with decision makers (clinical trials, biomarkers, safety assessment methods)
- Real life data collection and analysis (coming soon)
- Vaccines effectiveness (just launched)
- Pharmacovigilance (led by regulators)
- Patient perspective (leading patient role)

This would not have happened without IMI...

New Drugs for Bad Bugs (ND4BB)

- In response to the EU strategy on combating antimicrobial resistance industry and the EU joined forces for an R&D initiative under IMI to revitalise industrial antimicrobial resistance research in Europe and bring new treatments to patients
- Through
 - progressing molecules already available
 - Identifying new molecules for most deadly pathogens
 - Creating a strong clinical investigators excellence network

Next project under this topic is planned for publication in November !!!

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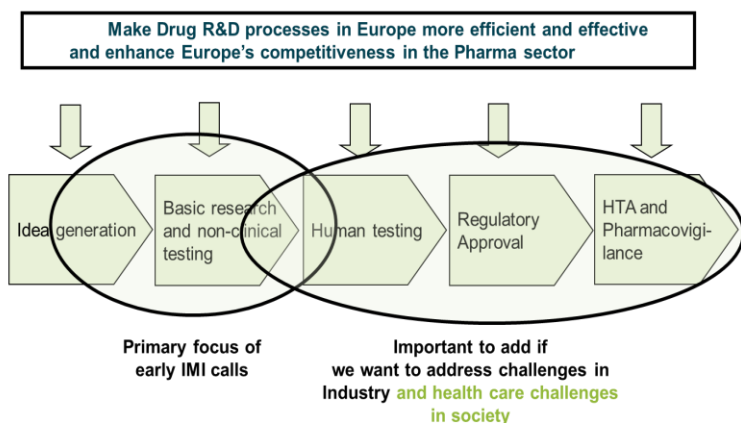


- Taxonomy of diseases
 - Web based media mining
 - Combination therapies
 - iPS infrasture and research
 - Antimicrobial resistance
 - Clinical trials design
-
- And a number of projects/ideas submitted by various interest groups

New generation PPP under Horizon 2020 – scientific contents

Evolution that started in IMI

IMI strategy – evolving from bottlenecks in EU pharma Industry



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Horizon 2020: An opportunity we can't let go

Horizon 2020 is a unique opportunity and driver for creating the changes needed for both the industry and society.

Horizon 2020 provide a frame for developing a new forward looking frame for a Public Private Partnership in the Healthcare area, which should focus on open innovation and game changing projects.

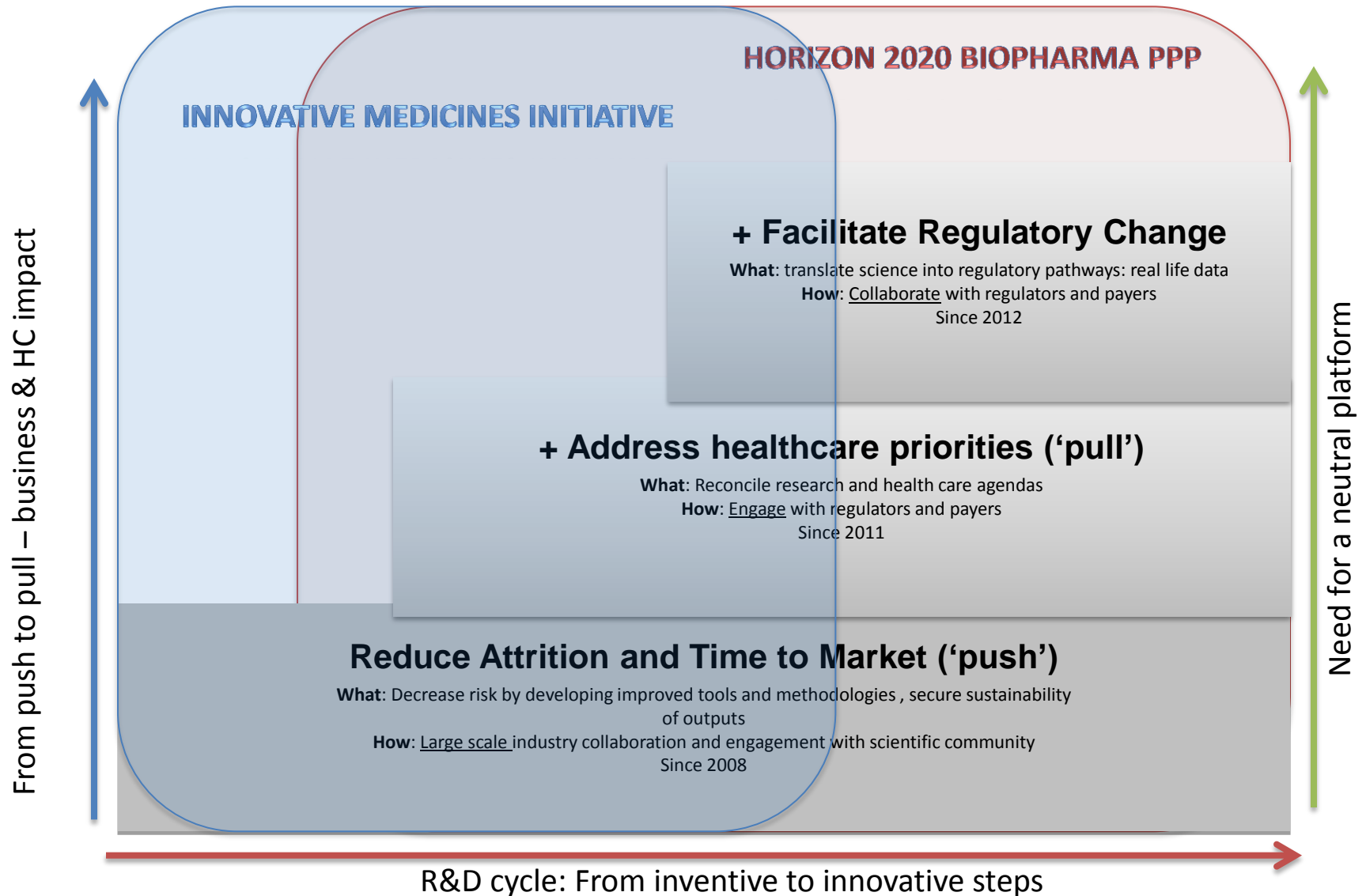
Horizon 2020 should focus on the shared interests which society and industry have in solving the major healthcare challenges facing us.



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- From IMI to Horizon 2020
- From European to Global
- From bottlenecks in industry to a shared agenda between society and industry on healthcare challenges

EVOLUTION OF INDUSTRY/EU PPP CONCEPT FROM BOTTLENECKS IN INDUSTRY TO BOTTLENECKS IN SOCIETY



Contents – key principles

- **Societal bottlenecks:** move from scientific and technological challenges in the industry only to addressing industry bottlenecks and resolving healthcare and societal challenges.
- **Holistic view on disease burden** (not just primary care focus)
- **Starting point:** health priorities, e.g. priority medicines and diseases as outlined in the 2004 WHO report (under revision)

- What is different from current agenda?
 - Beyond technology platform – aligning health, research and regulatory agendas
 - Translating new sciences and technologies into health/societal benefits: drive necessary change in regulatory pathways and healthcare delivery
- “Healthy living – from conception to grave”
 - Prevention and therapy
 - High priority disease areas covered by 2004 WHO and main healthcare policies e.g. antimicrobial resistance, cancer, diabetes, autoimmune diseases, neuro-degeneration, psychiatry, vaccination ...
 - As well as cross cutting themes such as technology developments, population specific developments, delivery mechanisms, ...

- Examples of axes of activities within priority medicine area:
 - Understanding and classification of diseases
 - Target identification and clinical validation
 - Safety of compounds
 - Methodologies to evaluate treatment effects
 - Development and regulatory approval of novel therapeutic agents
 - Preventive and therapeutic vaccines (specific work stream)
- This is current snapshot – the agenda will continue to evolve
 - Continued consultations with key actors of the biomedical scientific community, healthcare professional and patients – tell us what your needs are!!
 - The agenda will have to adapt to scientific progress and developments in other R&D structures

Conclusions

- PPPs in health and pharmaceuticals work in a neutral set up free of conflict of interest
- They connect dots between R&D and healthcare agendas
- They deliver quickly and allow direct application of outputs in real life
- They create business opportunities and networks of excellence to attract more R&D
- Many projects concern areas of expertise and strenght present in Poland and other CEE countries – do not hesitate, apply!!!