

IMI

The Industry Perspective

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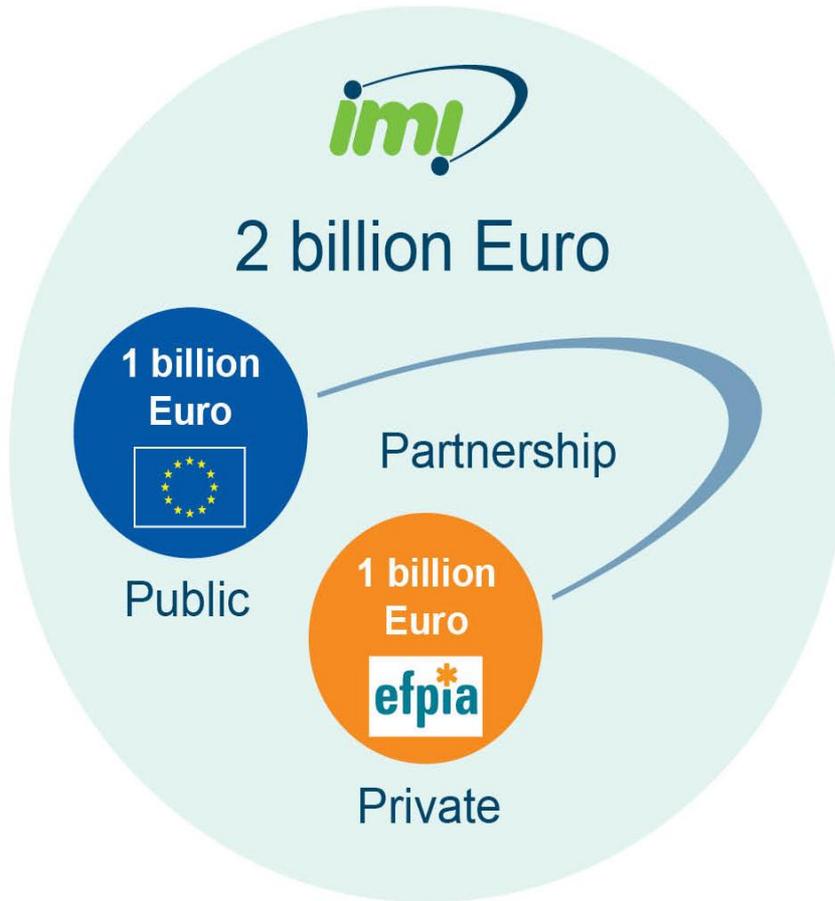
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www.diahome.org

IMI Vision



The **European Union and the pharmaceutical industry** have joined forces to make **drug R&D processes in Europe more efficient and effective** and enhance Europe's **competitiveness in the sector.**

The IMI Strategic Research Agenda (SRA) 2005



- Identified pre-competitive bottlenecks in R&D process
- Proposed recommendations to address these bottlenecks
- Proposed a new model of Public-Private collaboration to implement recommendations

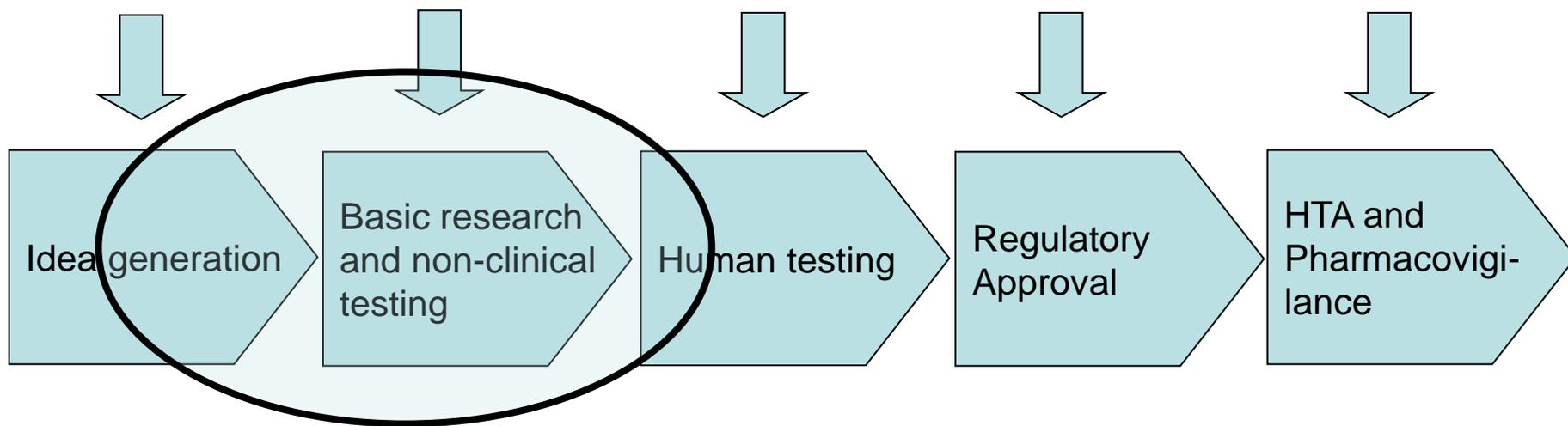
Experience after first 3 call rounds

Changes needed:

- Very good IP frame but add “help desk”
- More flexible and a continued submission and review process needed
- Simplification of financial processes
- Shorten time to grant
- Reduce red tape
- Improve communication and transparency

Reality after first 3 call rounds

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**

IMI – a game changing 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 is new ground. The industry has realized, that we can work together, pool resources and research and still compete at the same time.

IMI – a game changing PPP

- A public private partnership like IMI create more than new and important research projects, it:
 - Creates a common understanding and discussion of the current healthcare and R&D challenges
 - Creates greater mutual understanding and perspective on research, work processes and work culture
 - Creates a truly unique platform for dialogue
- IMI is also a reflection of a new understanding and view on the relationship between public and private players as partners and not competitors.

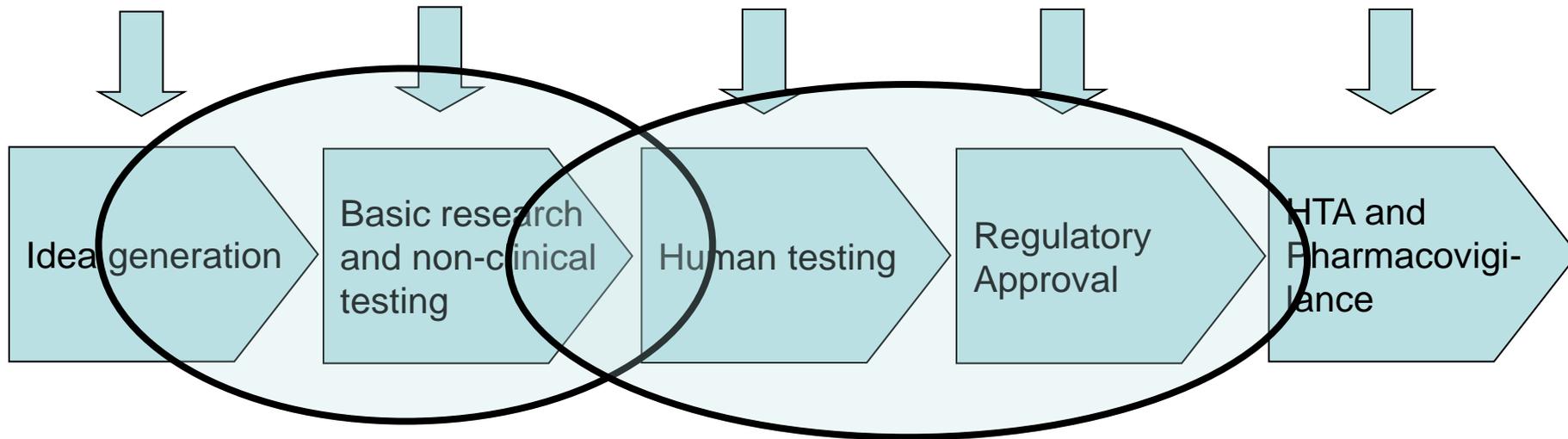
IMI – adjustment of strategy I

- Much of the original SRA have been addressed by IMI Calls 1-3
- Science has moved on since 2005
- The industry is changing – both where we operate, how we do research and what we can share
- The need for appropriate collaboration to tackle major challenges remains a priority!

And not only challenges
for industry !

IMI – adjustment of strategy II

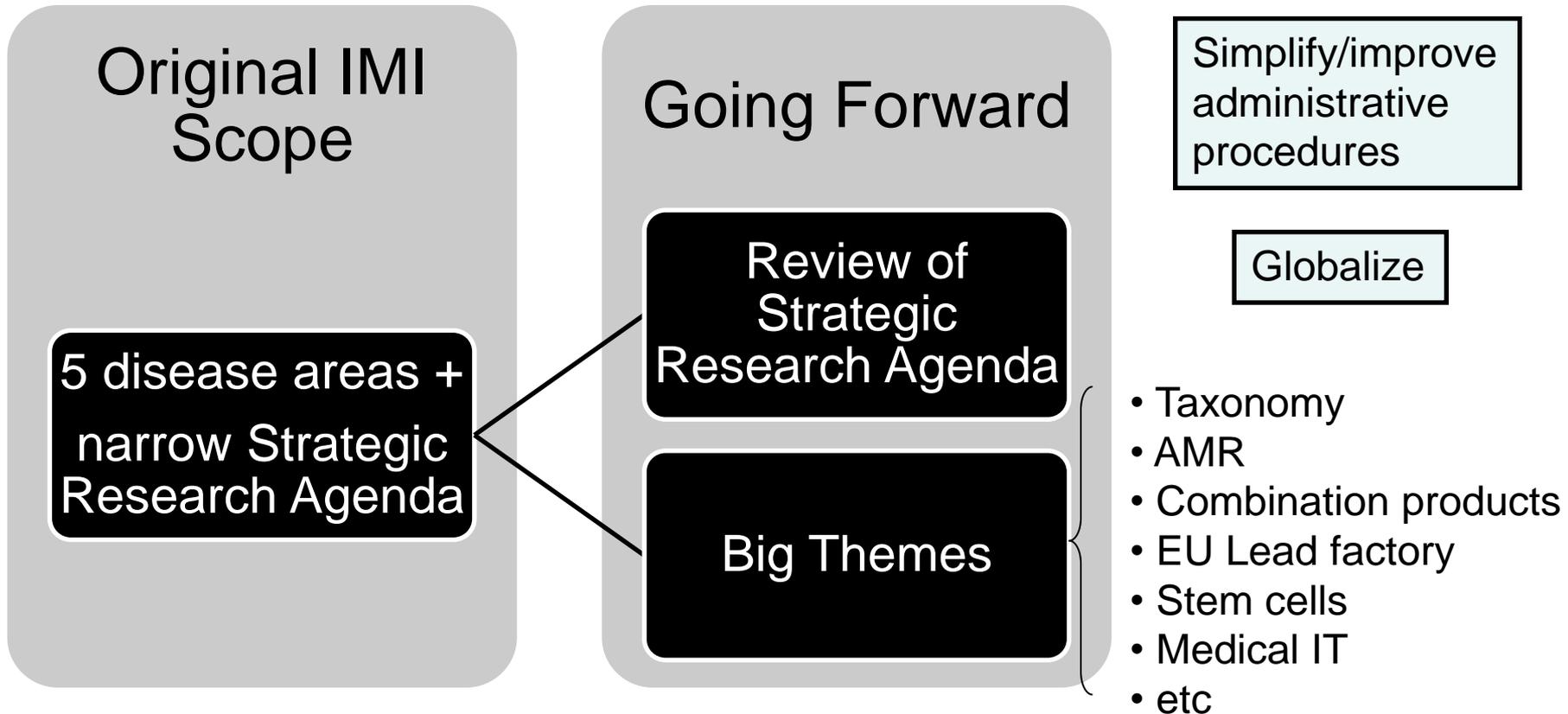
Make Drug R&D processes in Europe more efficient and effective and enhance Europe's competitiveness in the Pharma sector



Primary focus of early IMI calls

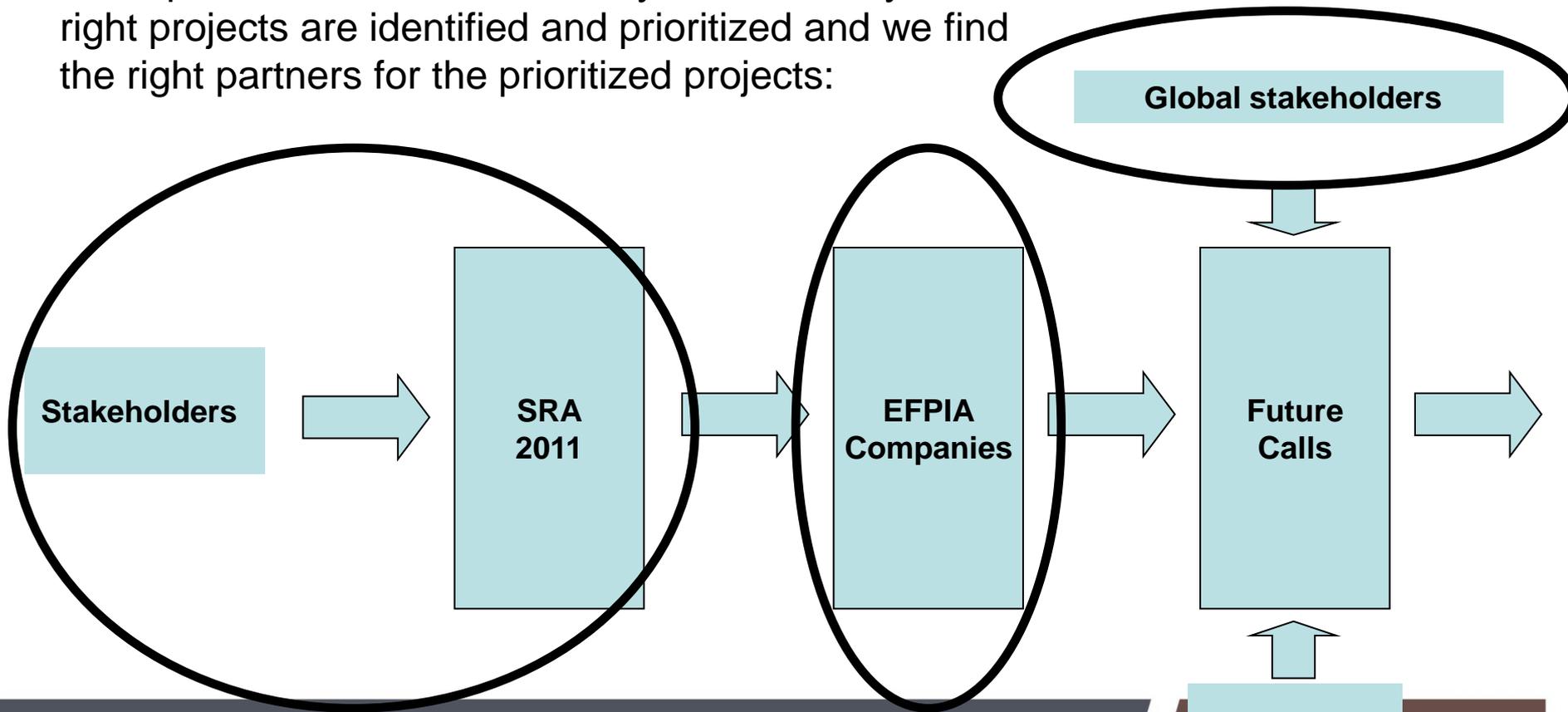
Extended focus if we want to make EU competitive and address major health care challenges in society

IMI – adjustment of strategy III



IMI – adjustment of strategy VI

We have now redefined the frame in our Scientific Research Agenda – changed our concept to “bottlenecks in Society AND Industry” - and would like to ensure that the right projects are identified and prioritized and we find the right partners for the prioritized projects:



IMI – adjustment of strategy V

Stakeholder groups	Key players
Member States	States Repr. Group, JPIs
Regulators	FDA and EMA
Healthcare	WHO Health authorities
SMEs/Biotech	Europabio, European Biotech Network, EBE
Patients	EPDA, EGAN, EPF, EURODIS
Learned societies and funding bodies	ESF, EUROHORCs, CPME, etc.
HTAs	European HTA network and national HTA bodies

IMI – whats next

The new strategy are being launched:

- First stem cell program launched in 2011 – next round in 2012
- EU Lead factory – early March
- AMR – as we speak
- Several new projects based on stakeholder input in maturation stage

Last calls late 2013 to run max until 2019

Life after IMI ?

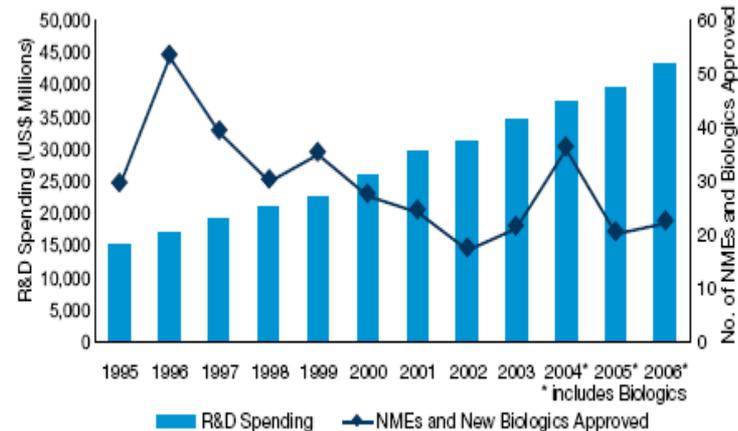
- Healthcare challenges continue to raise around the world
- A lot of these challenges are not addressed



Industry challenges

- **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**

R&D spending has soared but number of NME's has been constant



Sources: FDA/CDER Data, PhRMA data, PricewaterhouseCoopers analysis
Note: Data on R&D spending for non-PhRMA companies are not included here, because they are not available for all 11 years

Healthcare challenges are not meet

Challenge of the future

In general, healthcare priorities does not reflect relative disease burdens, see e.g., WHO prioritized diseases and medicine

Today's health challenges – tomorrow's socio-economic burdens:

not only from increasing healthcare costs, but also from loss of productivity and impact on the social sector.

Key healthcare challenges

Growing elderly population

Diseases caused by change in lifestyle

Neglected diseases in developing world

Have we realised the issue ?

Political awareness

- Political awareness on the healthcare and R&D challenges starts to increase. The current situation on antimicrobial resistance has shown, what happens if innovation and new drugs are not rewarded i.e, the push-pull mechanisms are not functional.
- A similar situation will very likely appear within brain diseases, if the situation is not addressed.

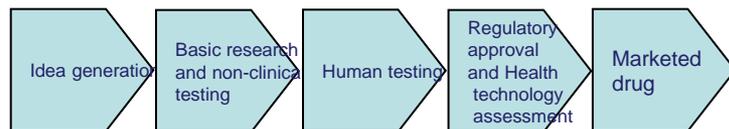
Industry perspective

- Also the pharmaceutical industry has realised the challenges facing their core business. Pooling resources and working closer together both within industry and with the public sector is one of the cornerstones in meeting the challenges.
- Public private partnerships like IMI will be key in the future.

After IMI – a new PPP in Horizon 2020 ?

Industry recommends a new PPP under Horizon 2020 focused on the shared interests between society and industry in addressing the major healthcare challenges facing us and that this new PPP is based on open innovation, and the IMI experiences and game changing projects are prioritized

From “bottlenecks” in industry to “bottlenecks” in society



Thank you