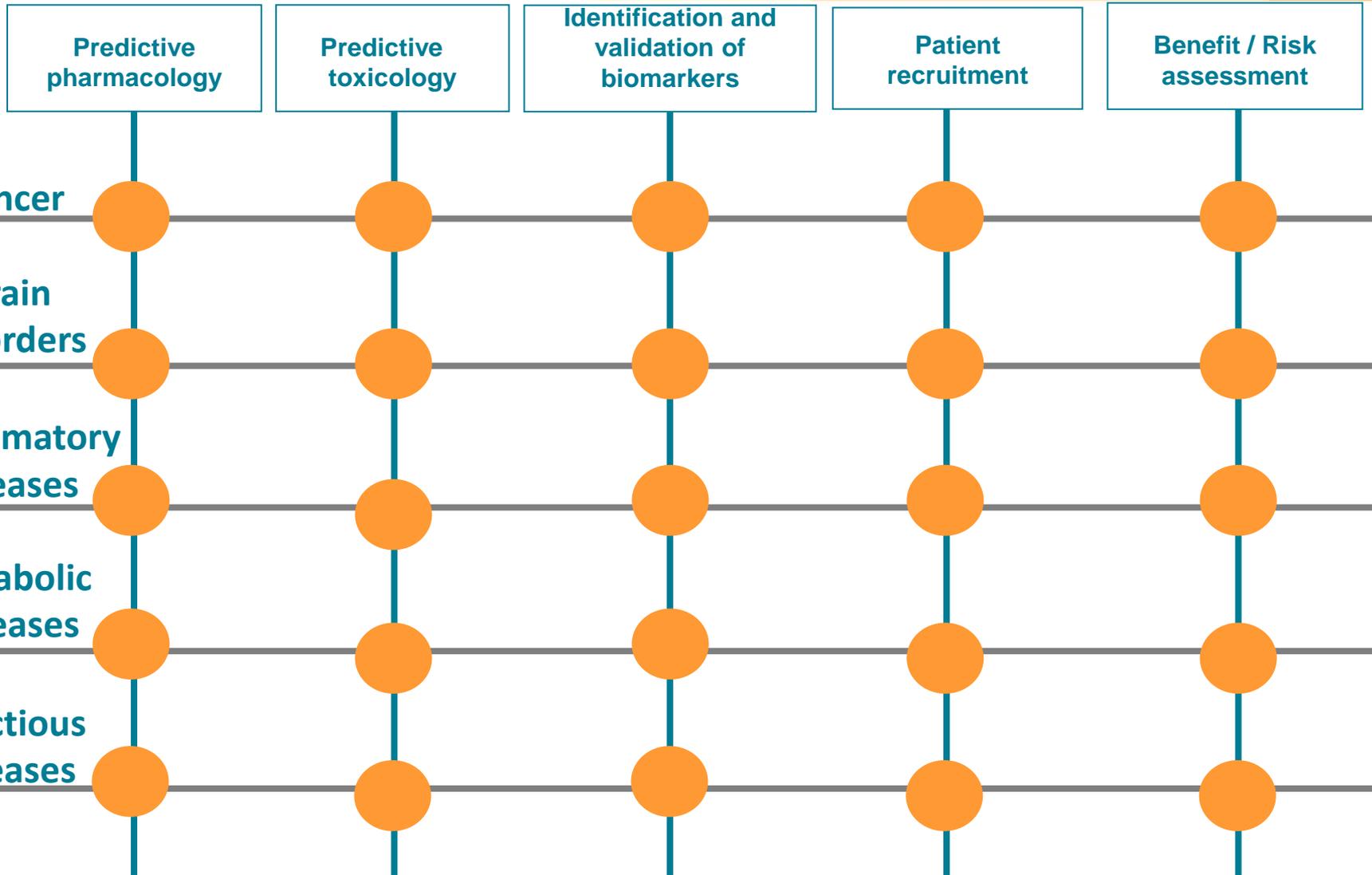
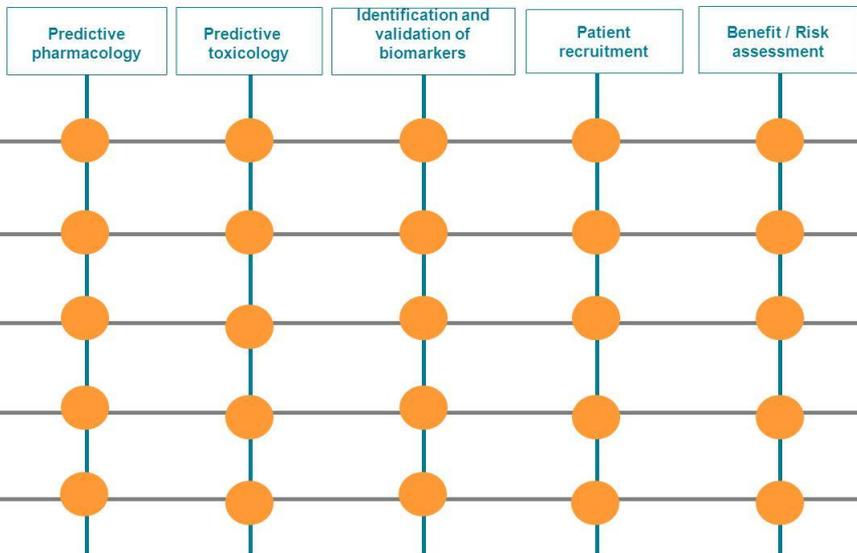


IMI – Strategic frame

Dr. Peter Høngaard Andersen

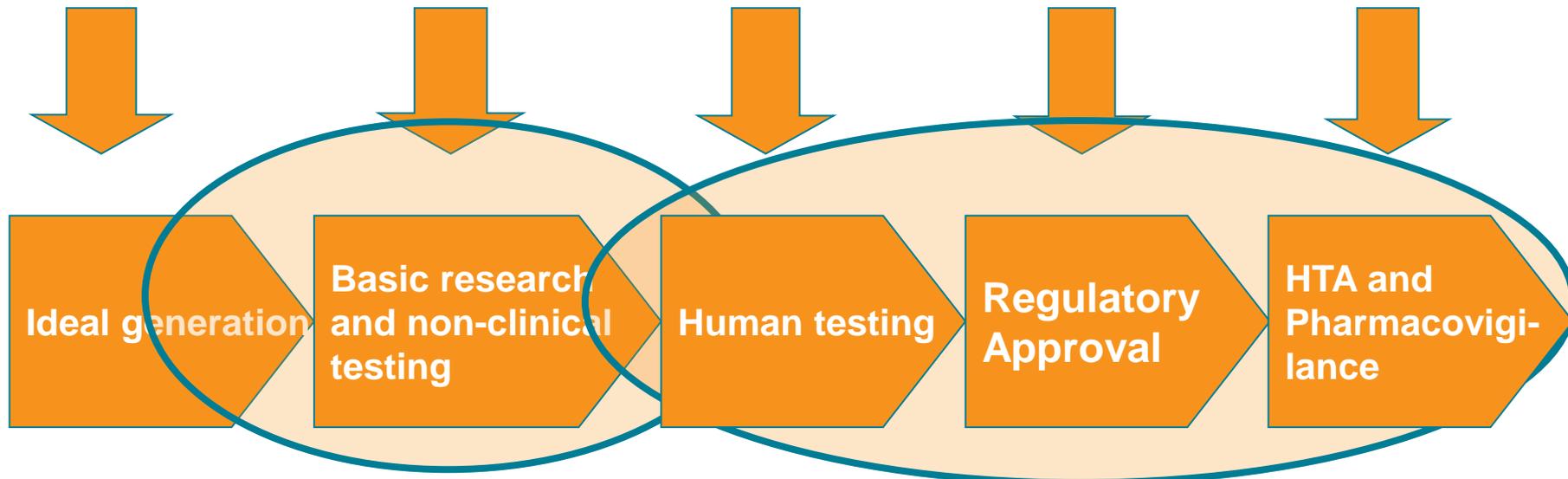
Chair, Research Directors Group, EFPIA





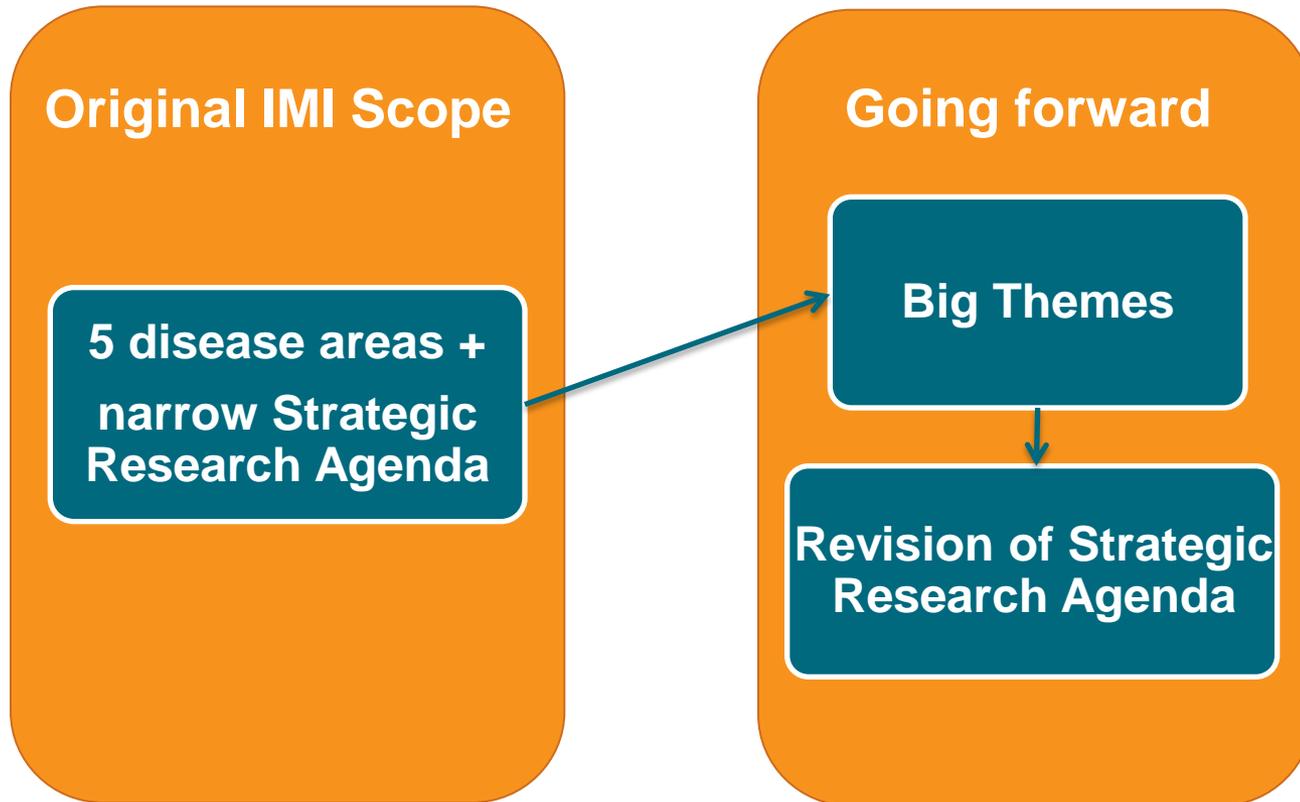
- The original SRA was based on the assumption, that a strong push would impact the entire value chain
- After the first series of calls most key areas were addressed, but it was also clear that bottlenecks in latter parts of the value chain were untouched
- In the early parts of IMI we had launched small and strongly focused projects, not game changing projects
- On this basis we initiated a “strategic revision process”

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**





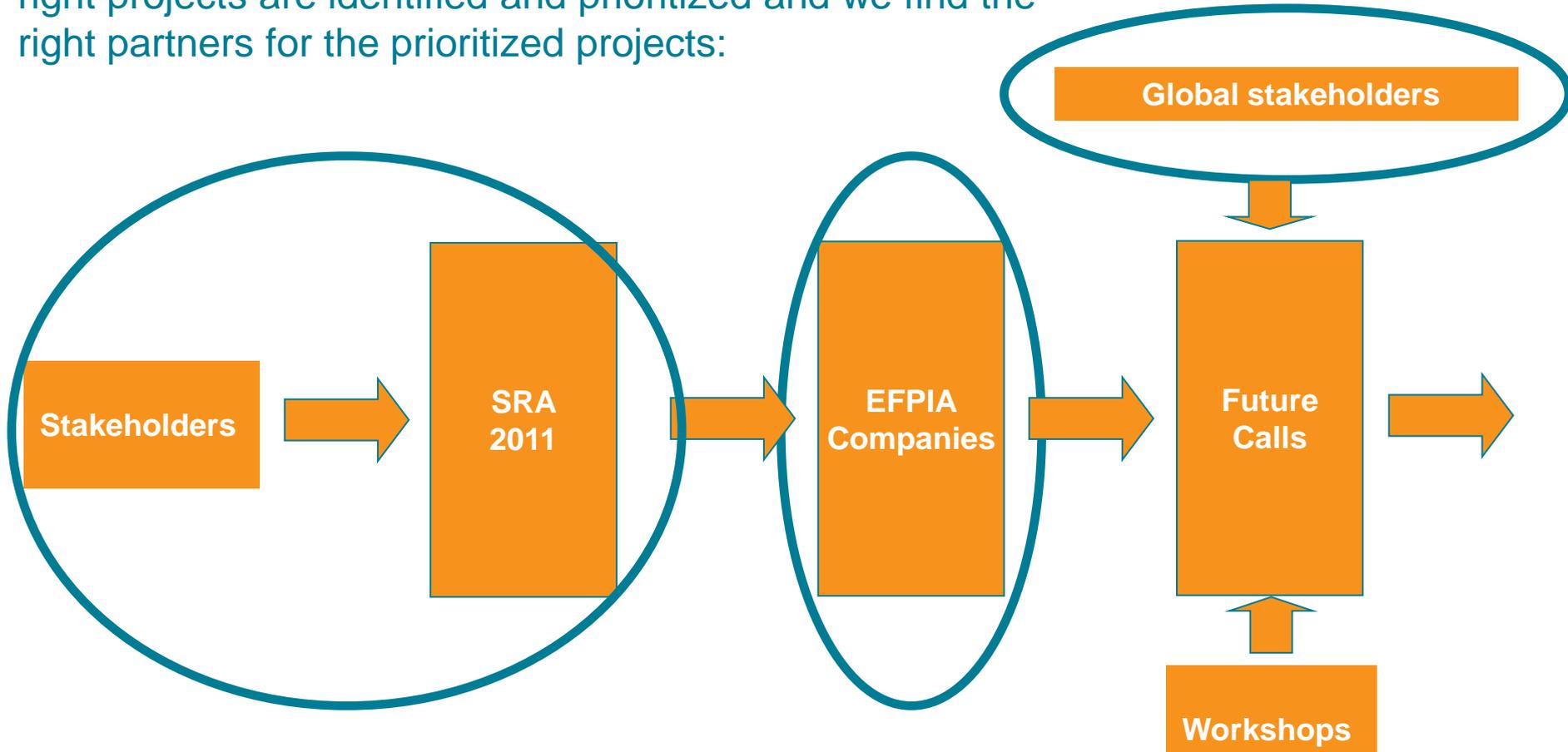
The Innovative Medicines Initiative (IMI)
Scientific Research Agenda
Revision 2011



Date of Preparation: 16 June 2011
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- Stronger link to stakeholders
- Much broader frame including the complete Pharma value chain
- More open regarding progress in science
- Have build in the fact that the industry now operates very differently and always with a global perspective
- The need for collaboration to tackle major challenges in Industry and society is a build in priority
- Focus on product development in areas of high societal need with limited incentives

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:



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

- ✓ NonEU in kind contribution – up to 30%
- ✓ Additional funding for exploitation of new scientific opportunities
- ✓ Possibility to include competitive projects (up to 3 CT) – piloted under AMR
- ✓ Extension of public access to data 2014
- ✓ Decrease administrative burden: Financial and reporting process
 - ✓ Shorten time to grant
 - ✓ Reduce administrative burden
 - ✓ Improve communication and transparency



- 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 has demonstrated that IP-issues can be solved and integrated as a natural part of a public private partnership

- 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.



European Federation of Pharmaceutical
Industries and Associations

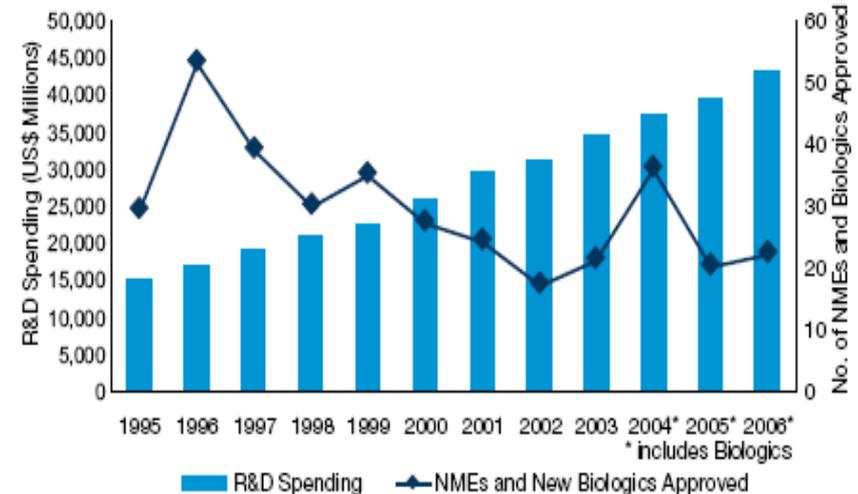
From IMI to Horizon 2020

- Healthcare challenges continue to rise around the world
- A lot of these challenges are not (yet) addressed
- Today's health challenges will be tomorrow's socio-economic burden: not only from increasing healthcare costs, but also from loss of productivity and impact on the social sector



- Cost for developing new drugs continue to increase
- Pharma incentive systems and profitability under pressure
- Progress in basic science is not translated to medical innovation and benefits to patients
- Health care (and research) priorities does not reflect relative disease burdens, see e.g., WHO prioritized diseases and medicine
- No overall strategy in the health care area are in place in EU

Figure 2: R&D spending has soared but the number of NMEs and biologics approved by the FDA is down



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

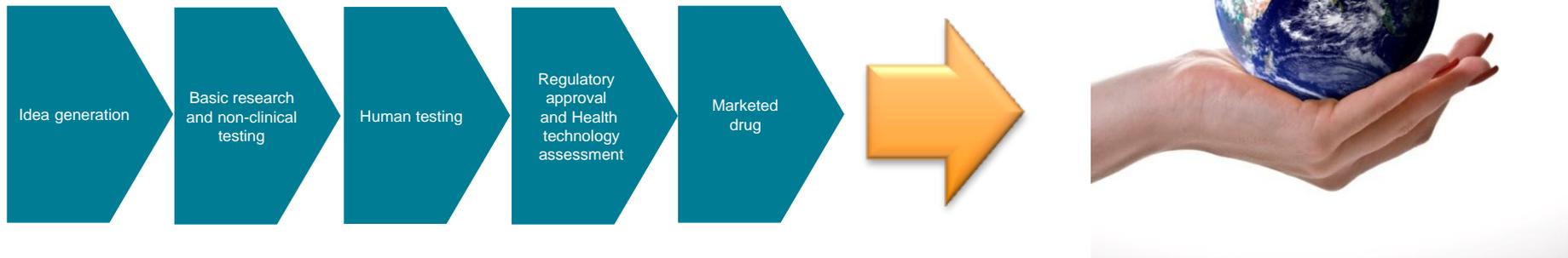
Political awareness

- 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

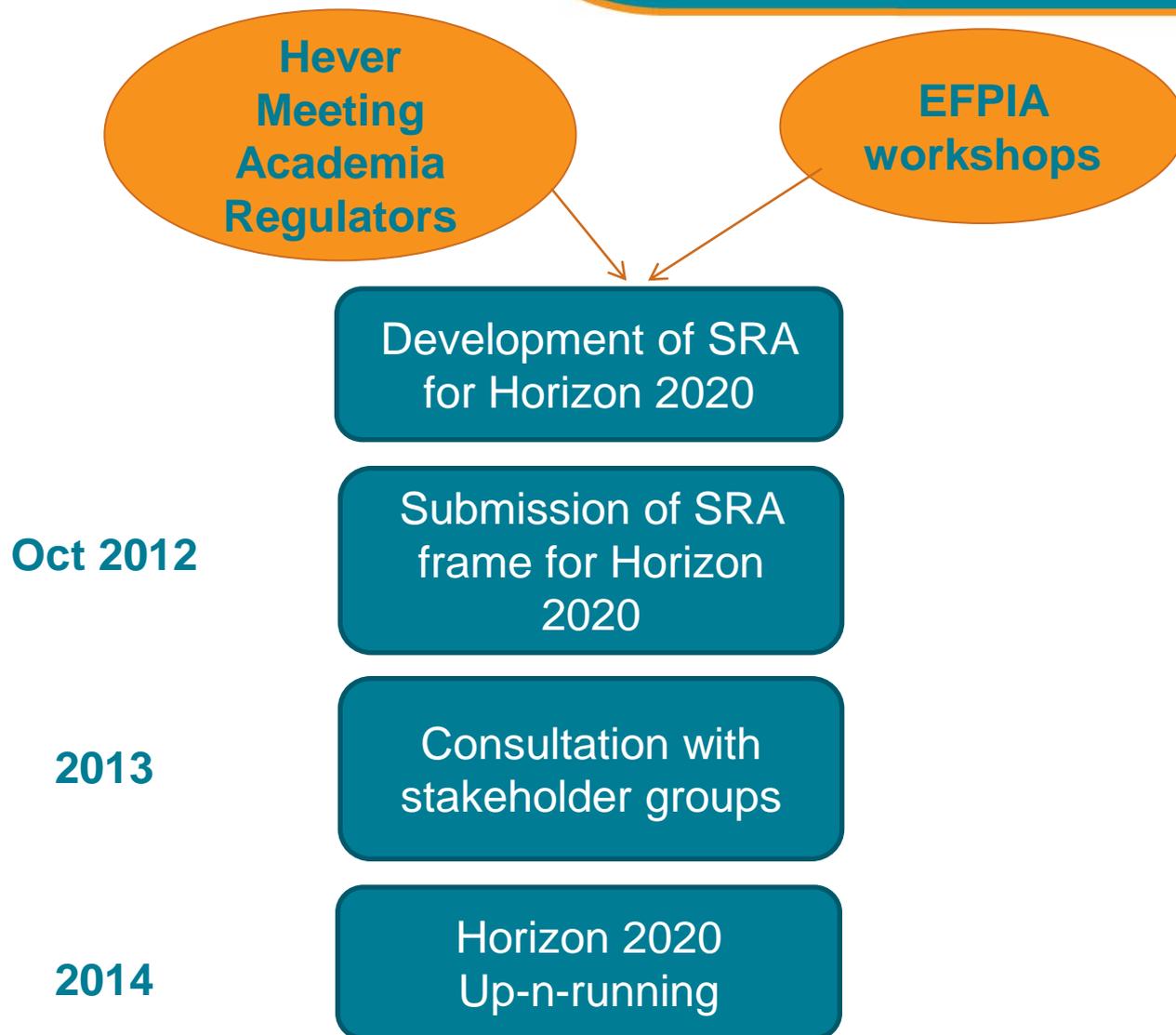
- Also the pharmaceutical industry has realised the challenges facing their core business. Pooling resources and working closer together both within industry and with the public sector is one of the cornerstones in meeting the challenges.
- Public private partnerships like IMI will be key in the future.

- 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 we all have in solving the major healthcare challenges facing us.



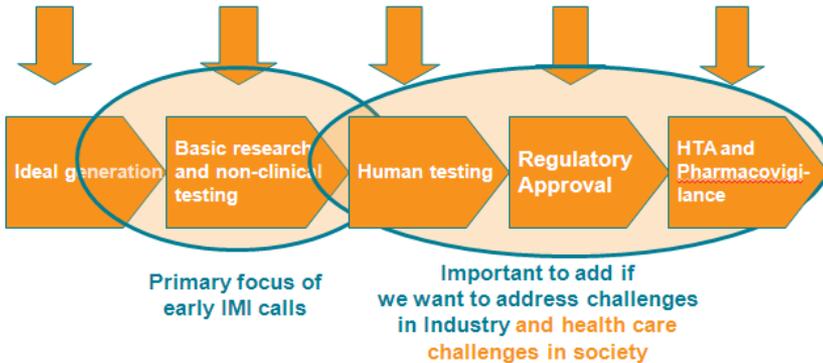
→ **Connecting** health, wealth, research and regulatory agendas

- **Health:** WHO report on priority medicines for Europe and the world (update in 2013)
 - **Research:** EFPIA concept paper on biomedical research PPP objectives & Copenhagen Research Forum
 - **Regulatory:** EFPIA concept paper on R&D models and incentives
-
- **Flexible legal frame** to ensure the full potential and future adaptation of healthcare projects to the needs of society
 - **Key driver** for growth and job creation in EU going forward why a visionary budget needs to be ensured (but not geographically limited to Europe)



Integrating the full value chain

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



Horizon 2020: An opportunity we can't let go

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- 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 have in solving the major healthcare challenges facing us.



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

Thank you for your attention

Dr. Peter Høngaard Andersen