IMI – Strategic frame

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The original SRA focused on five disease areas, with core elements of Education & Training and Knowledge Management.

<table>
<thead>
<tr>
<th>Predictive pharmacology</th>
<th>Predictive toxicology</th>
<th>Identification and validation of biomarkers</th>
<th>Patient recruitment</th>
<th>Benefit / Risk assessment</th>
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</thead>
<tbody>
<tr>
<td><strong>Cancer</strong></td>
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<td><strong>Brain Disorders</strong></td>
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<td><strong>Inflammatory Diseases</strong></td>
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<td><strong>Metabolic Diseases</strong></td>
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<tr>
<td><strong>Infectious Diseases</strong></td>
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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.”
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

Primary focus of early IMI calls

Important to add if we want to address challenges in Industry and health care challenges in society
Revised Strategic Research Agenda

Original IMI Scope

5 disease areas + narrow Strategic Research Agenda

Going forward

Big Themes

Revision of Strategic Research Agenda
Revised Strategic Research Agenda

- 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:
## IMI – adjustment of strategy

<table>
<thead>
<tr>
<th>Stakeholder groups</th>
<th>Key players</th>
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</thead>
<tbody>
<tr>
<td>Member States</td>
<td>States Repr. Group, JPIs</td>
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<tr>
<td>Regulators</td>
<td>FDA and EMA</td>
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<tr>
<td>Healthcare</td>
<td>WHO</td>
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<td></td>
<td>Health authorities</td>
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<tr>
<td>SMEs/Biotech</td>
<td>Europabio, European Biotech Network, EBE</td>
</tr>
<tr>
<td>Patients</td>
<td>EPDA, EGAN, EPF, EURODIS</td>
</tr>
<tr>
<td>Learned societies and funding bodies</td>
<td>ESF, EUROHORCs, CPME, etc.</td>
</tr>
<tr>
<td>HTAs</td>
<td>European HTA network and national HTA bodies</td>
</tr>
</tbody>
</table>
IMI evolution: Less red tape and more flexibility

- NonEU in kind contribution – up to 30%
- Additional funding for exploitation of new scientific opportunities
- Possibility to include competitive projects (FP7 FET FOCUS CT) – piloted under AMR
- Extension of publication deadlines – 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.
From IMI to Horizon 2020
Challenges for Society and Industry - I

- Healthcare challenges continue to raise 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
Challenges for Society and Industry - II

- 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
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.
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 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)
Hever Meeting Academia Regulators

EFPIA workshops

Development of SRA for Horizon 2020

Submission of SRA frame for Horizon 2020

Consultation with stakeholder groups

Horizon 2020 Up-n-running

Oct 2012

2013

2014
An evolution that started with IMI

- 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