IMI and IMI2: from science to patients

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IMI – the success story

* Proof of concept for new public private collaborations in pharmaceuticals – today the largest PPP in healthcare research

* IMI connects the dots: science, research, health, regulatory and clinical practice

* IMI works: tangible deliverables after less than 2 years – a pace that no other funding scheme allows
Our reality

★ Evolving business model
  → Shift from in house to external collaborations
★ R&D productivity challenges
  → Outputs vs cost
★ Regulatory and healthcare systems not ready for new sciences outputs
  → based on symptomatic approach to disease
★ Disconnect between pipeline focus and healthcare challenges
  → uptake of innovation is slow
★ Healthcare systems managing disease/ill-condition and not healthy living
  → the entire burden of disease does not drive health policy choices
★ PPPs and other collaborative schemes are mushrooming in other regions (US, Japan, China, …)
  → competition and coordination
Is the current R&D model sustainable?

The Evolution of IMI: From bottlenecks in industry – to bottlenecks in Industry and Society

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

Idea generation

Basic research and non-clinical testing

Human testing

Regulatory Approval

HTA and Pharmacovigilance

Primary focus of early IMI calls
2007 SRA

Shift to also addressing challenges in society and healthcare
2011 SRA

SRA – Strategic Research Agenda
IMI implements EU policies

Pharmacovigilance

Personalised medicine conferences and workshops

2011 Conference
European Perspectives in Personalised Medicine
Square-Brussels Meeting Centre, Brussels, Belgium - 12-13 May 2011.
The virtuous cycle of R&D investments

- Healthcare policies
- External sources of funding for R&D
- Scientific excellence, networks, infrastructure
- Regulatory framework
- R&D friendly science policies
- Industrial policies (including IP)
From bottlenecks in industry to bottlenecks in society – fulfilling the promise of science

Reduce Attrition and Time to Market (‘push’)
What: Decrease risk by developing improved tools and methodologies, secure sustainability of outputs

+ Facilitate Regulatory Change
What: translate science into regulatory pathways: real life data

+ Address healthcare priorities (‘pull’)
What: Reconcile research and health care agendas

R&D cycle: From inventive to innovative steps

Need for a neutral platform

From push to pull – business & HC impact
The Strategic Research Agenda for IMI2: A Three dimensional approach

- The right prevention and treatment for the right patient at the right time

- An ambitious agenda built on IMI success story: excellent science, excellent results, excellent collaborations

- To deliver on the promises of science and make real impact
Healthcare Solutions: Effective delivery of the right prevention and treatment, to the right patients, at the right time

- Discovery and development of novel preventive and therapeutic agents
- Healthcare delivery and reimbursement
- Benefit/risk assessment in individual patients
- Adoption of innovative clinical trial designs
- Innovative drug delivery, manufacture, and adherence approaches

WHO and European Health Priorities

- Predictors of drug/vaccine efficacy and safety
- Innovative methodologies to evaluate treatment effect
- Reclassification of diseases by molecular means
- Target identification and validation (human biology)

Common Standards for Data/Knowledge Sharing

Cross-industry/ regulator /HTA / payer/patient collaboration
The measures of success

- New model developed & published
- Setting new standards
- In house implementation by industry
- Impact on regulatory practice
- Better drugs and impact on medical practice