From IMI to IMI2

The right prevention and treatment, to the right patient, at the right time

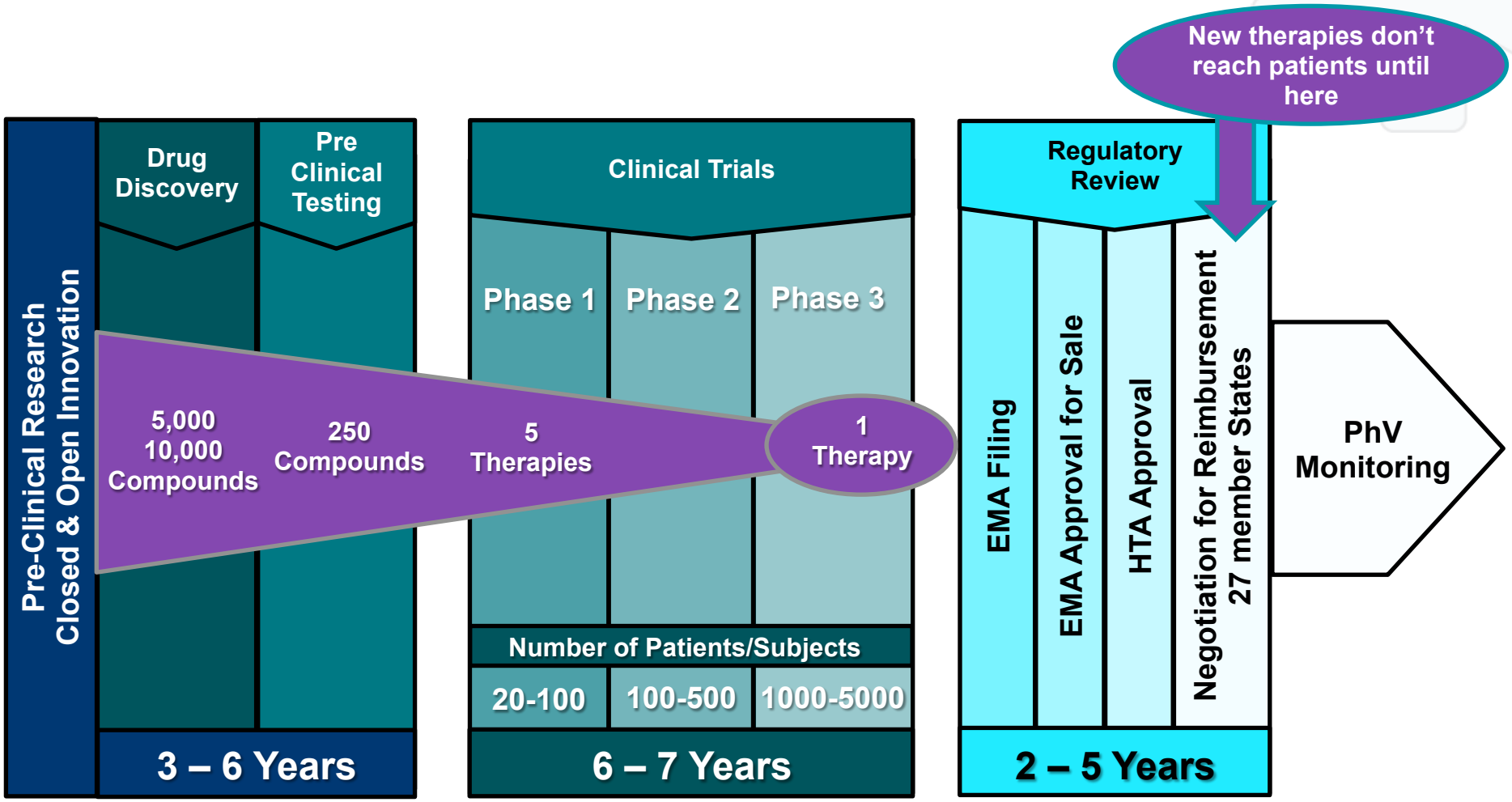
Magda Chlebus, Director Science Policy, EFPIA

IMI Info Day – Warsaw, 17 January 2013

European Federation of Pharmaceutical Industries and Associations

www.efpia.eu

The pathways to patients are expensive and slow



Total Cost: → **$2 - $4 Billion USD**

Sources: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org;

CBO, *Research and Development in the Pharmaceutical Industry*, 2006;

Forbes, Matthew Herper, "The Truly Staggering Cost Of Inventing New Drugs", February 10, 2012

"The average drug developed by a major pharmaceutical company costs at least $4 billion, and it can be as much as $11 billion."

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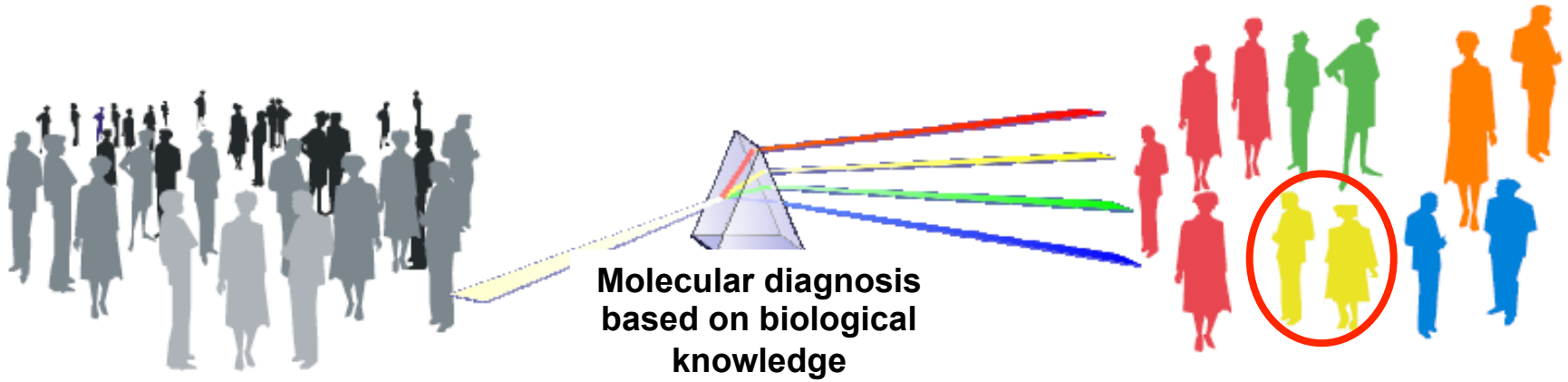
The Vision for IMI2 (and the Pharma industry)

From population → **to individual**



We "treat" a population.
Some respond and some don't

We "treat" a *targeted* population
They all respond

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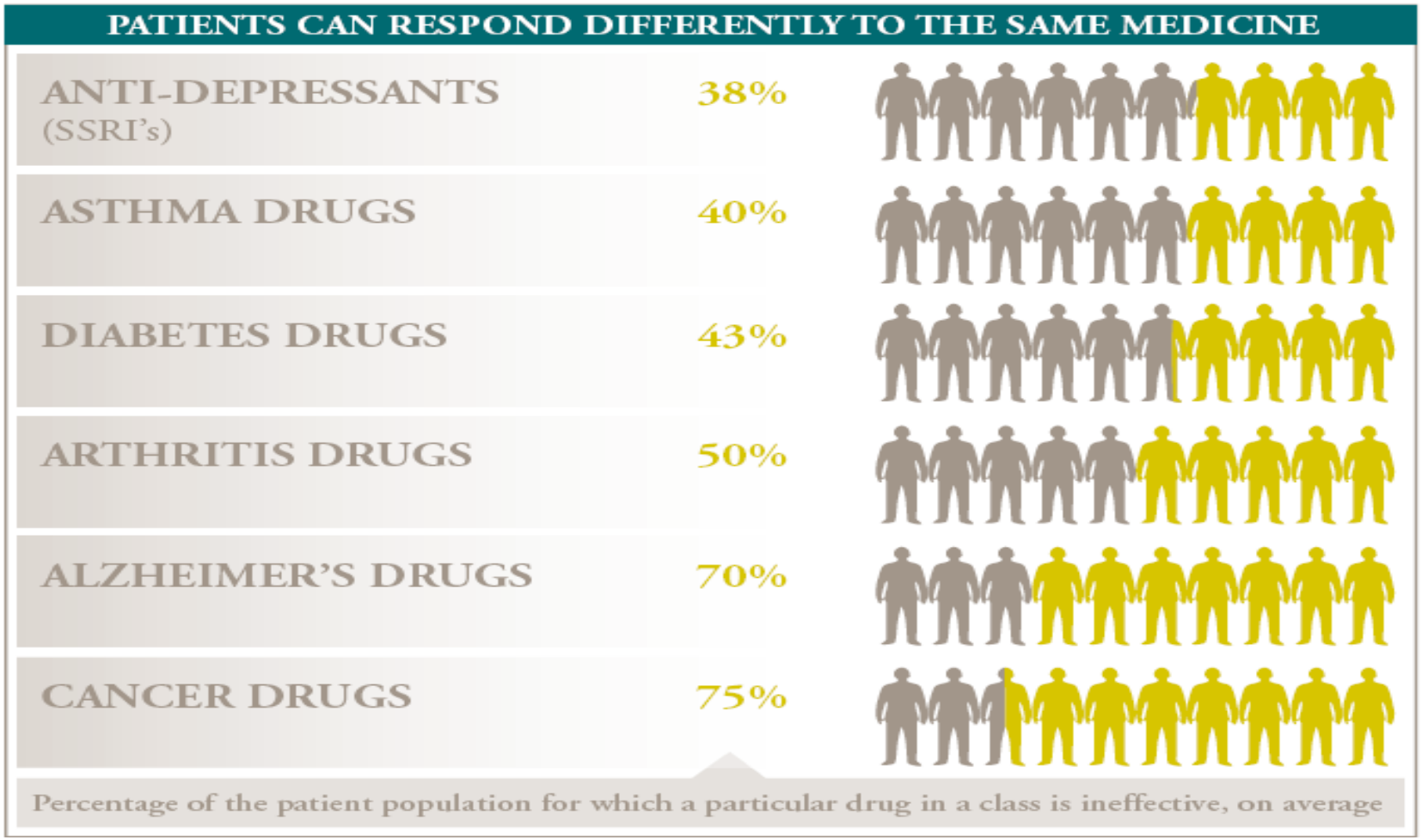
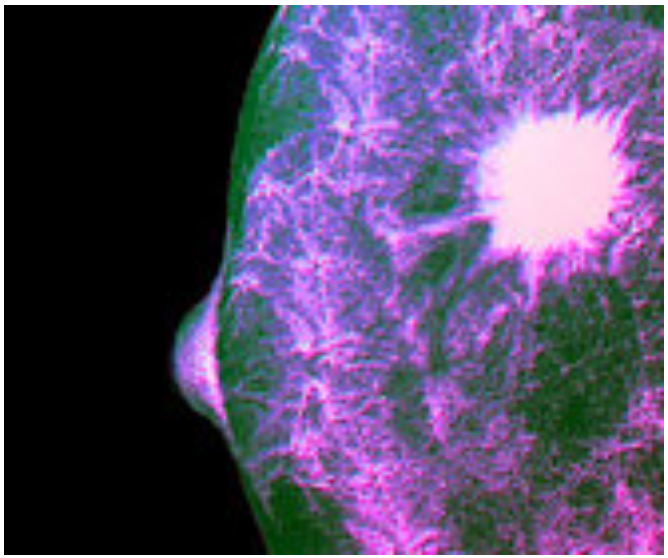
Modern Medicines – non-responder rates



Science is driving advances in diagnosis: breast cancer is actually 10 different diseases

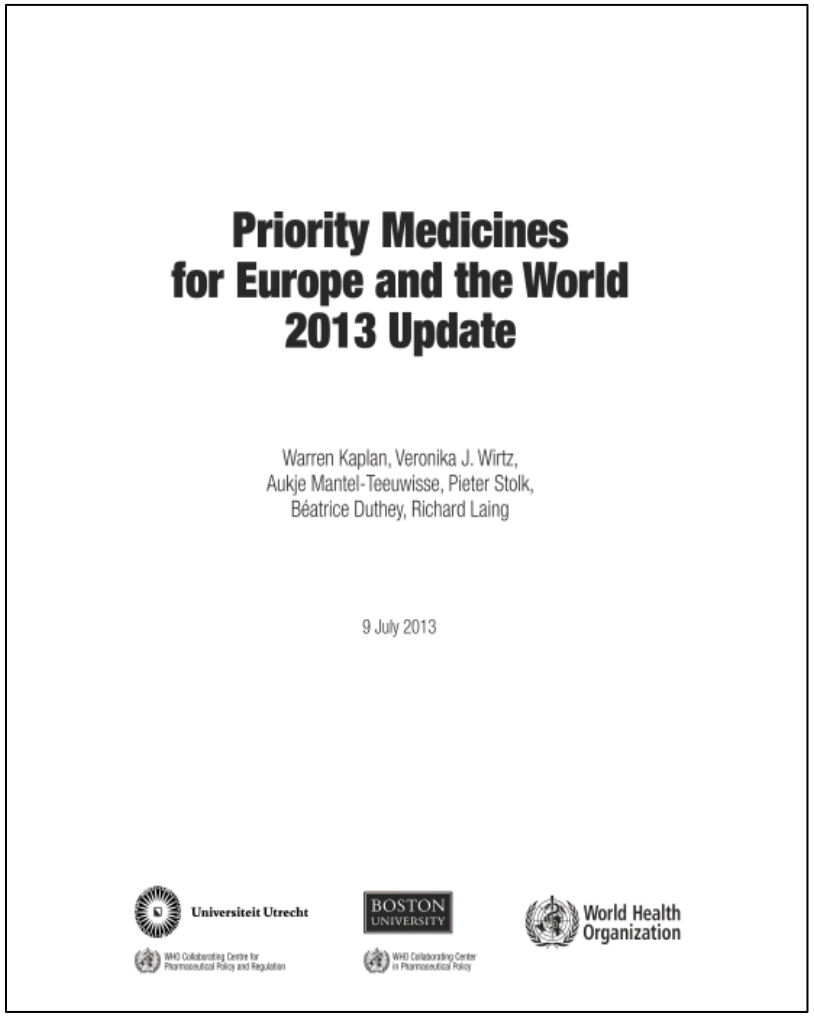
Thursday April 19 2012

"A landmark study has reclassified the country's most common cancer in breakthrough research that could revolutionise the way we treat breast tumours… scientists found breast cancer could be classified into 10 different broad types according to their common genetic features."



http://www.nhs.uk/news/2012/04april/Pages/breast-cancer-genetic-diversity-mapped.aspx

Unmet medical needs



- Burden of disease on patient and society = total cost of disease for healthcare and social security
- Unmet need:
  - No treatment
  - Inadequate treatment (resistance or treating symptoms, not cause)
  - Inadequate formulation for specific population (geriatric, pediatric, etc)
- Barriers and incentives

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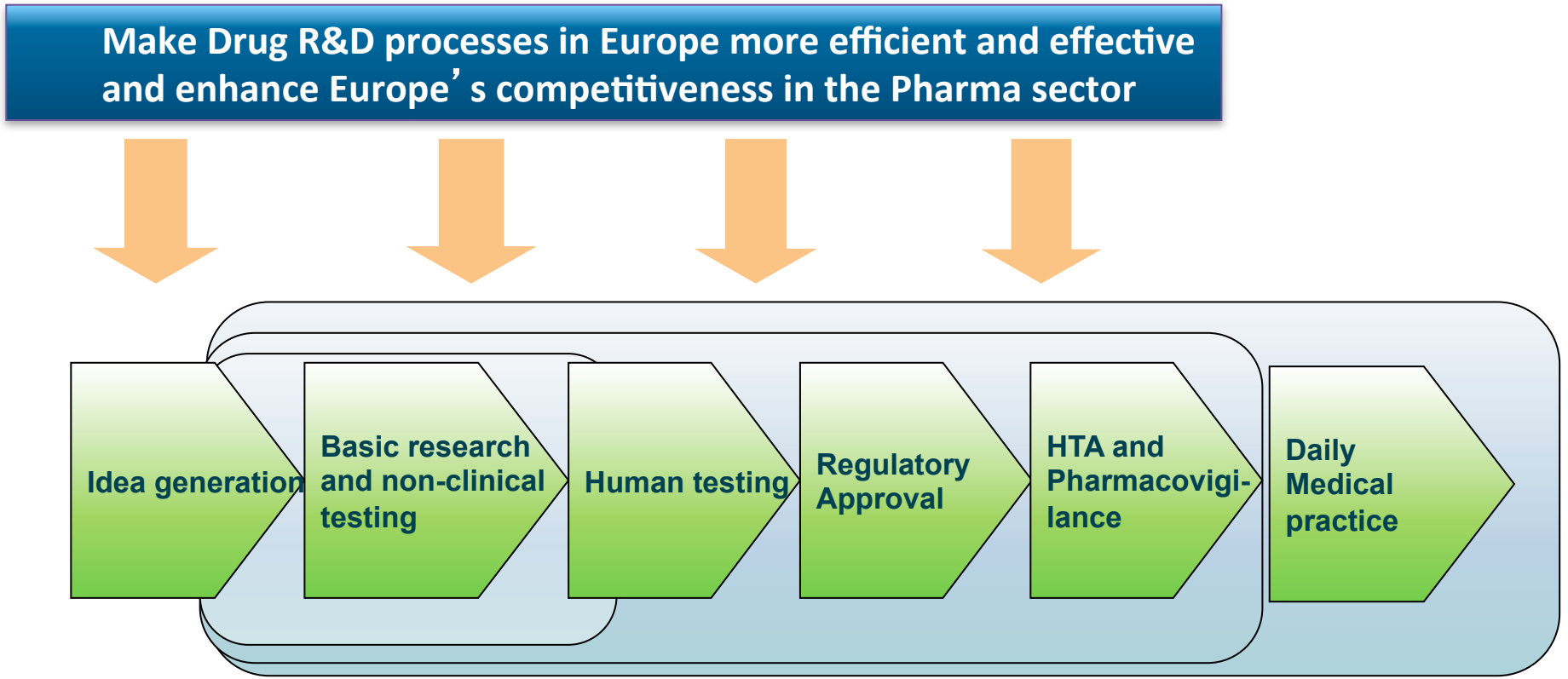
Evolution of IMI – the road to IMI2



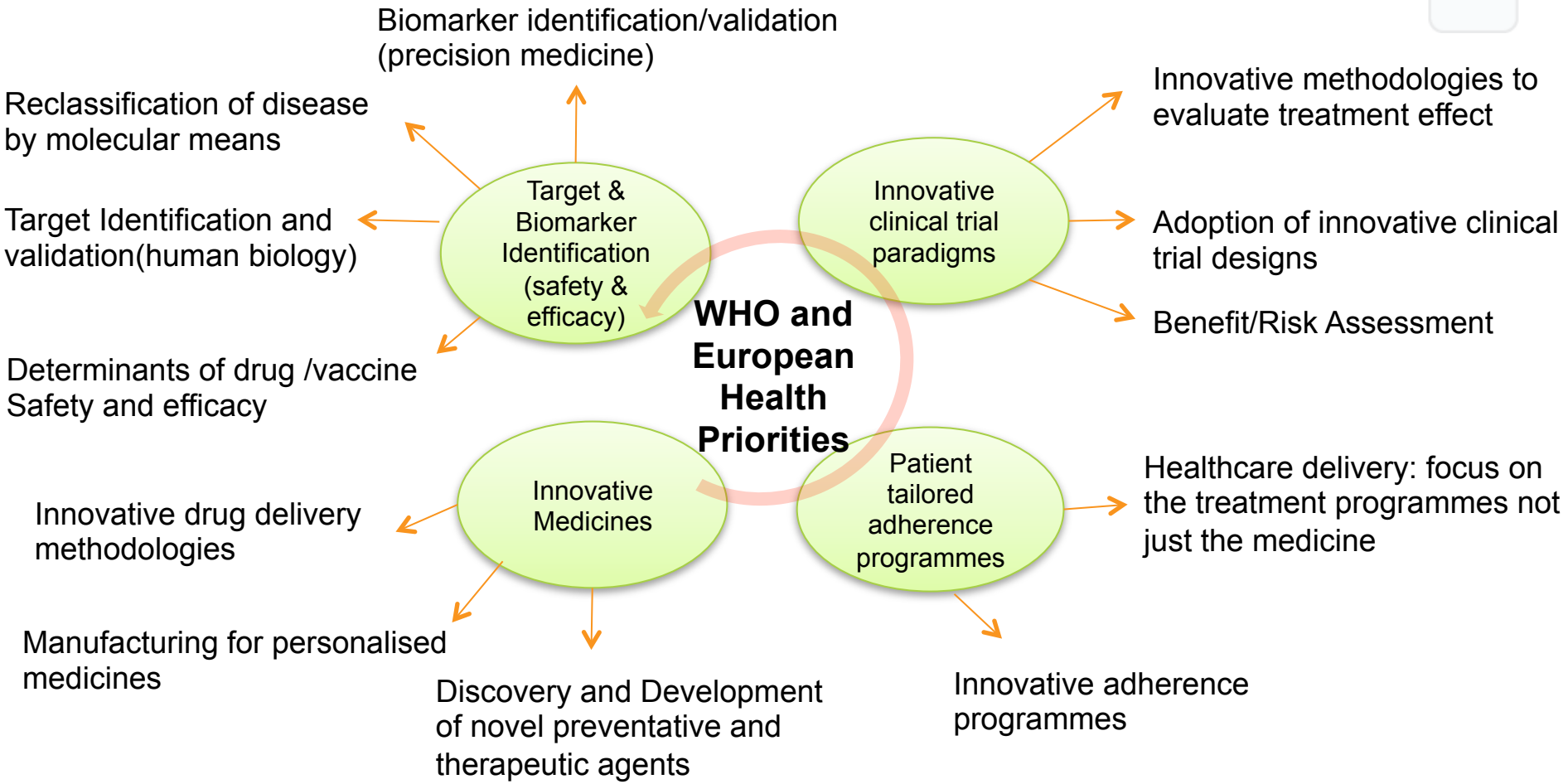
Primary focus of early IMI calls 2007 SRA

Shift to also addressing challenges in in society and healthcare 2011 SRA

IMI 2 includes real life medical practice 2013 SRA

SRA – Strategic Research Agenda

Major Axis of Research



Drive change in delivery of medical practice

SRA – proposed deliverables

Axis of research	Measurable outcome by 2020
Reclassification of diseases by molecular means	Reclassification of four diseases by molecular means supporting personalised medicine approach
Target identification and validation	Up to 10 new targets identified and up to 5 clinically validated
Predictors of drug efficacy and safety	Predictability of non-clinical efficacy and safety models improved by up to 10%
Innovative methodologies to evaluate treatment effects	Novel biological endpoints to support internal decision making and where possible clearly linked to clinical relevance implemented with regulatory approval for at least four diseases
Benefit/risk assessment in individual patients	Development of an IT framework to allow real-time monitoring of benefit/risk including direct engagement with the patient
Adoption of innovative clinical trial processes designs and improved access to medicines	Adoption of innovative clinical trial designs and approaches to real world data collection resulting in increased efficiency and decreased cost of clinical development in at least two diseases. Establishment of at least two new clinical trial networks in areas with high unmet need
Development of novel therapeutic agents through new research models and associated regulatory pathways	Development of at least two new therapies or preventions in areas with high unmet need and limited market incentives Validation of at least two novel delivery mechanisms for new drugs Up to 40% savings on the manufacturing costs of at least one novel therapy

Strategic Research Agenda – public consultation

Preliminary draft open for comments from June 2012 to June 2013 – more than 70 contributions received in two rounds

Invitation to submit proposals for projects which are in line with the obejctives and can help achieving our goal:

http://efpia.eu/documents/48/63/SRA-PUBLIC-CONSULTATION

SRAconsultation@efpia.eu

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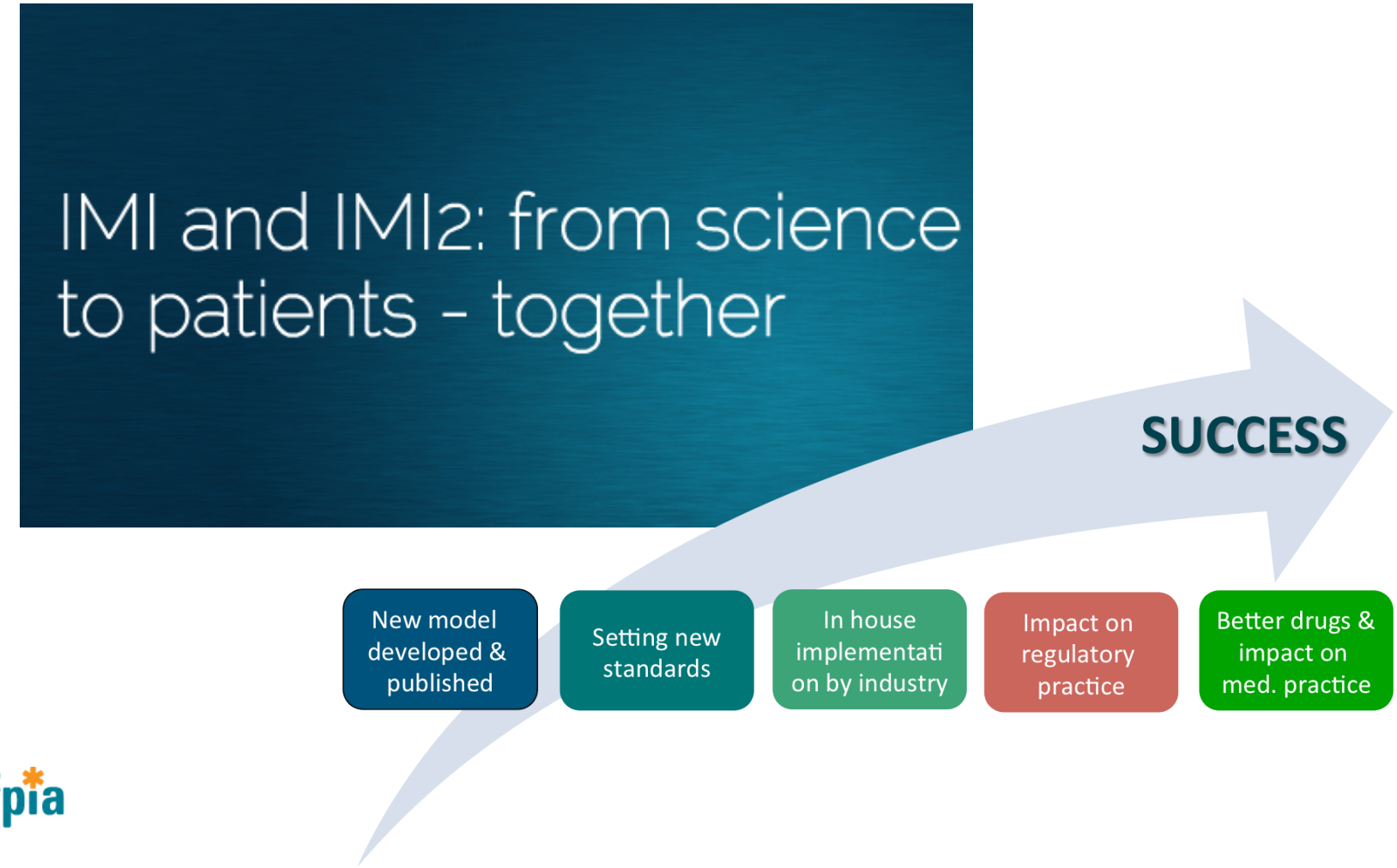
Success will be driven by

- Focusing on the challenges of the future
- Leveraging the value added for working together, including Public private collaborations across sectors, build an effective research ecosystem, effectively use resources and expertise, pre-competitive and competitive research, risk sharing
- Focussing on strategic, game changing, think big – around broader therapeutic areas (not indications)

Right prevention and treatment, for the right patient, at the right time …



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Discussion

- Is there anything missing in the vision of the Strategic Research Agenda?
- What programmes/projects would contribute to realising the SRA vision?
- What are the strenghts of Polish R&D ecosystem in light of the SRA?
- The right information, to the right players, at the right time: dissemination/sources of information to enhance participation

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