Industry Perspectives on IMI 2

Magda Chlebus, Director Science Policy, EFPIA

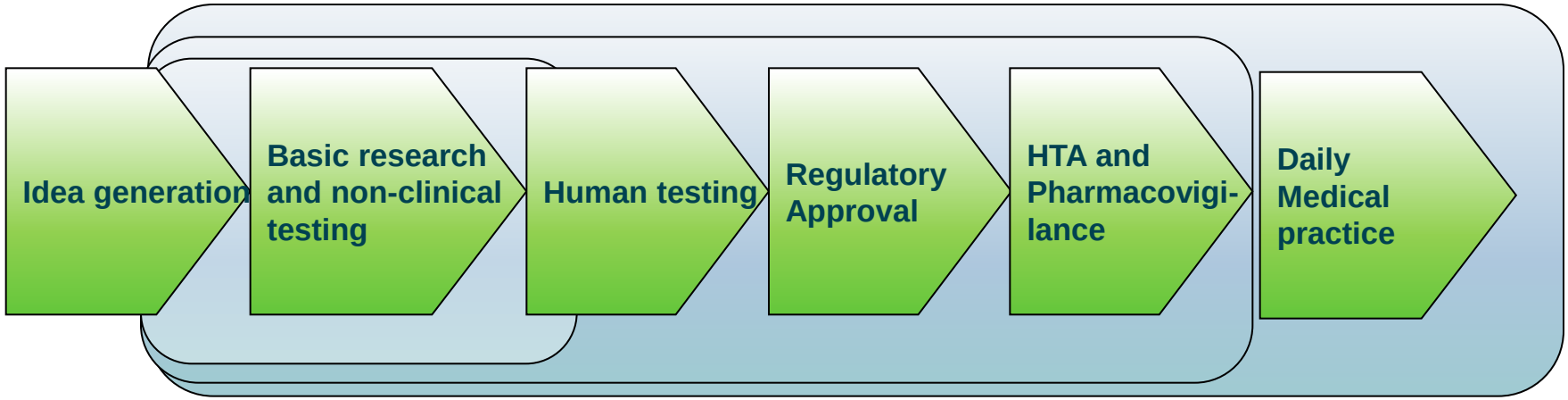
IMI 2 Info Day – Brussels, 30 September 2014

European Federation of Pharmaceutical Industries and Associations

www.efpia.eu

Evolution of IMI – the road to IMI2

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



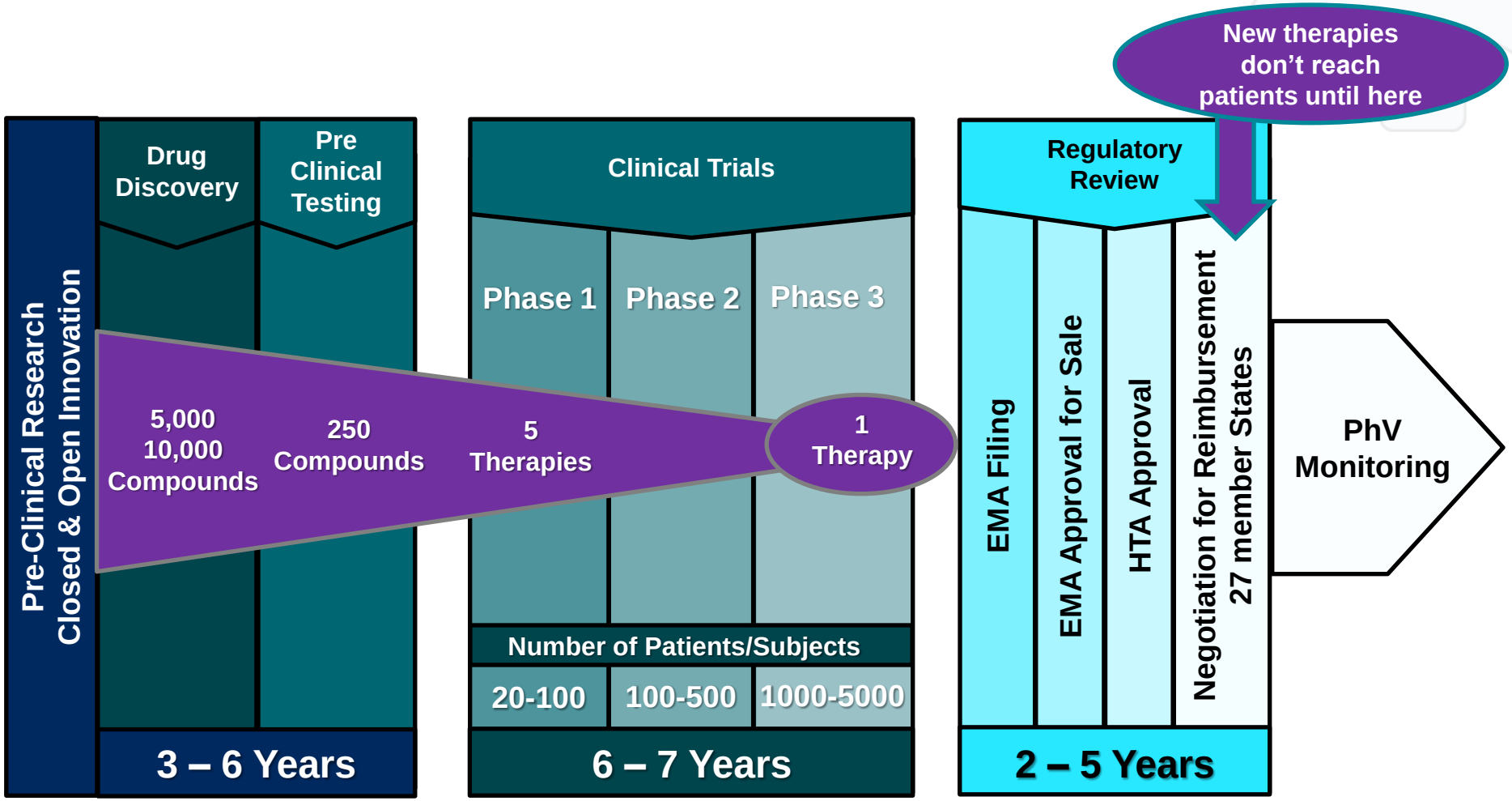
Primary focus of early IMI calls 2007 SRA

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

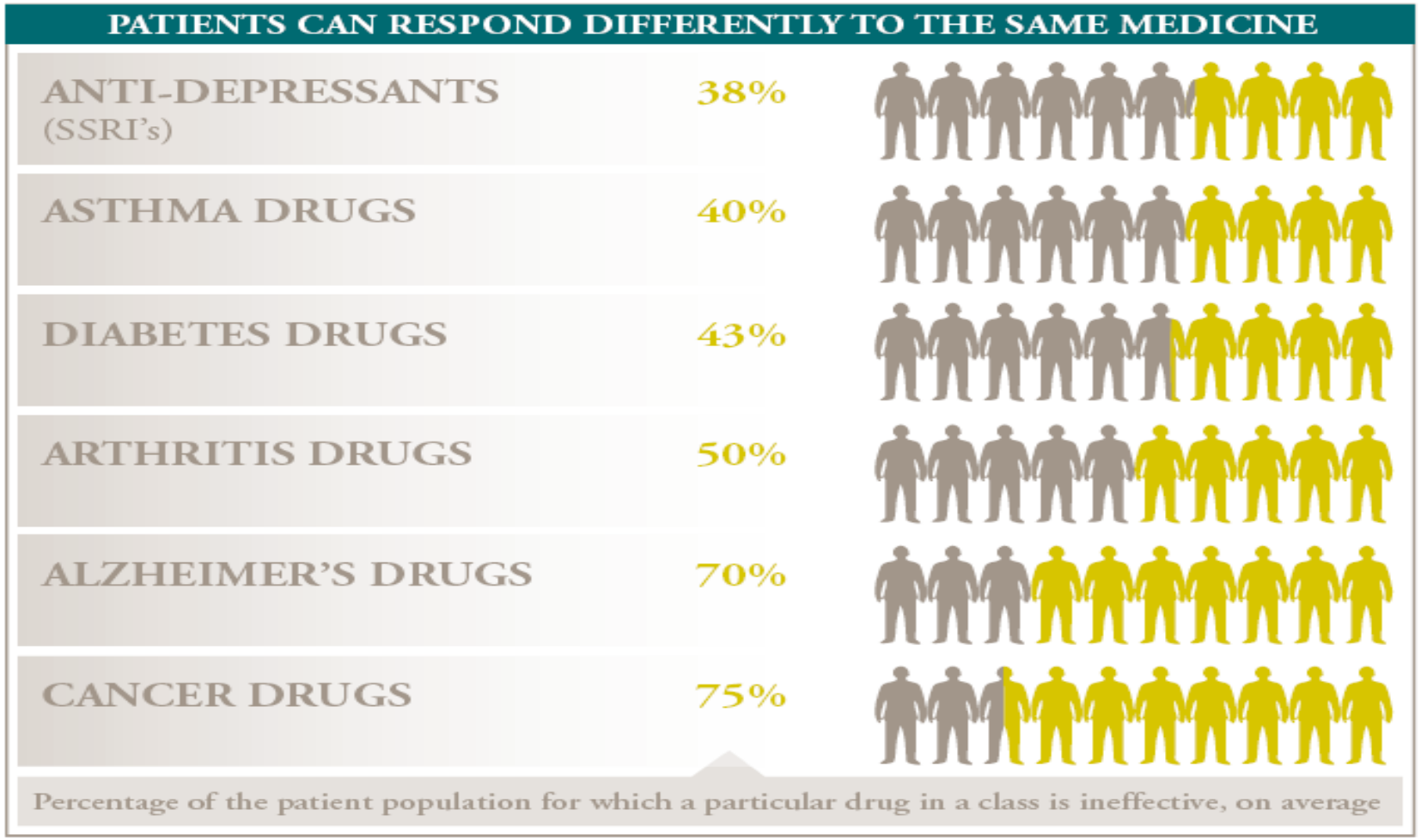
The pathways to patients are expensive and slow



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

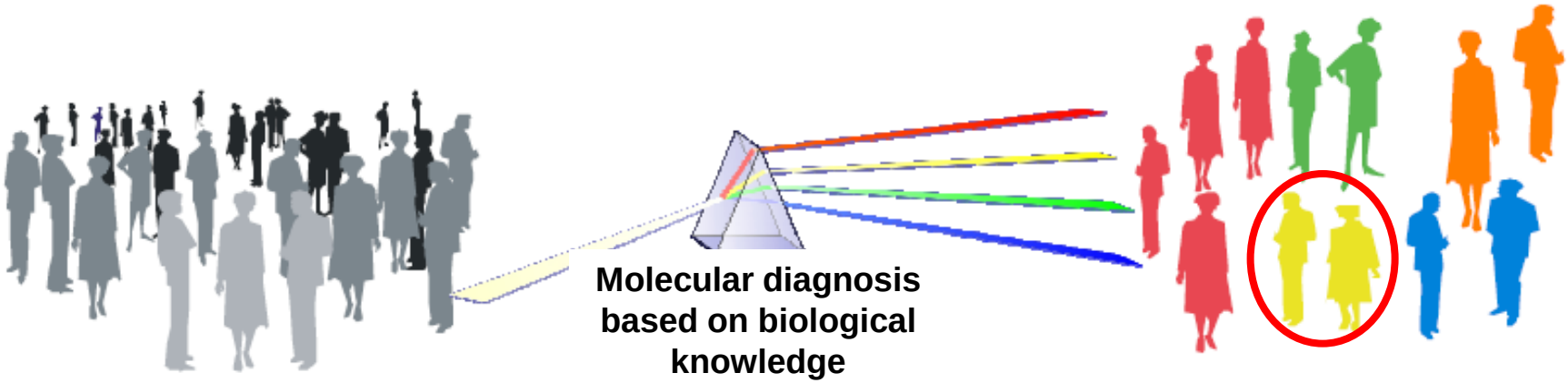
efpia

Modern Medicines – non-responder rates



The Vision for IMI2 (and the Pharma industry)

From population → to individual



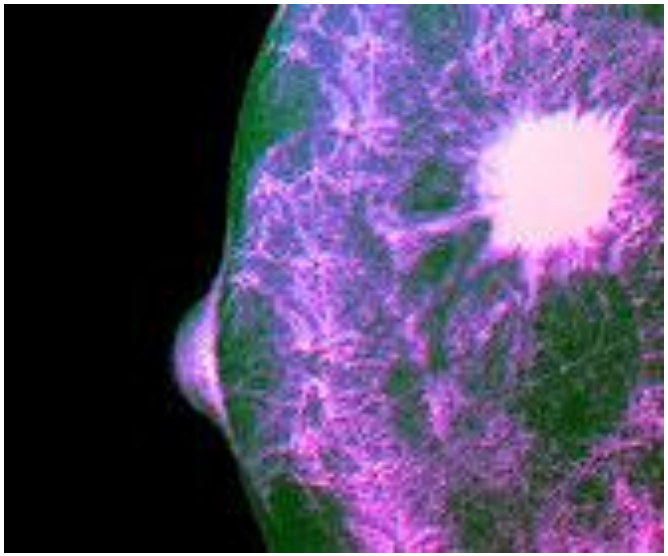
We "treat" a population.
Some respond and some don't

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

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

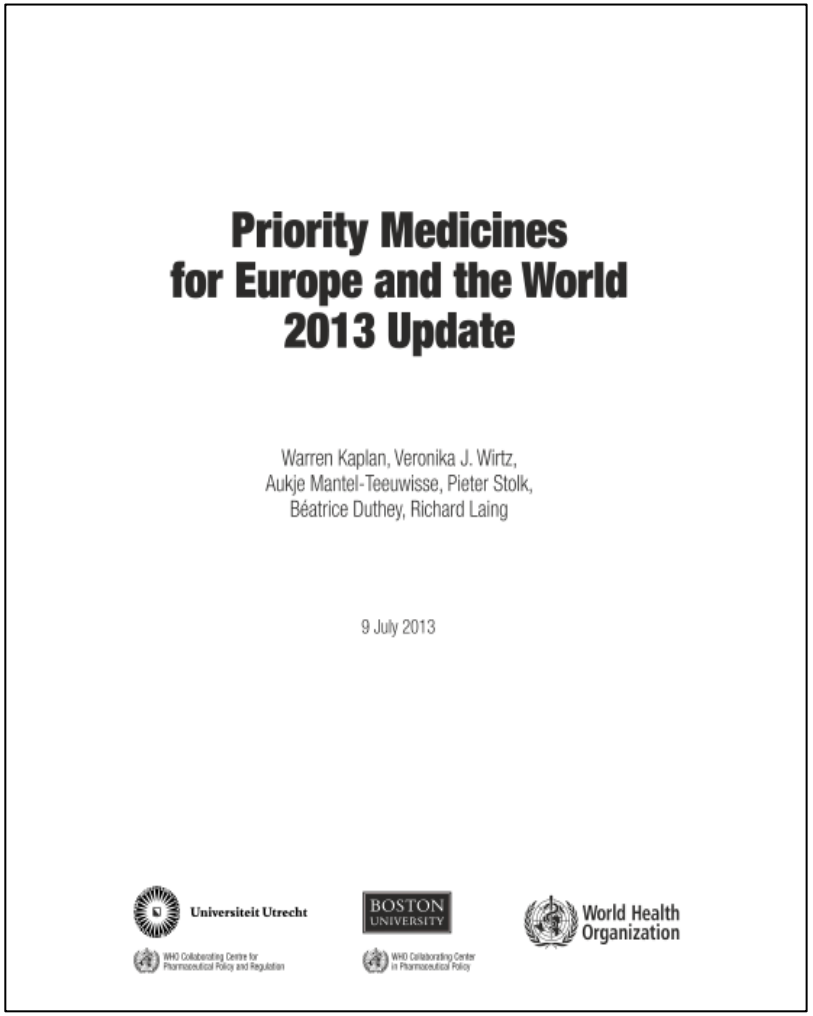
Thursday April 19 2012

"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

efpia

Strategic Research Agenda

Comprehensive framework for a 10-year programme

Prepared with input from 80+ organisations (internet and targeted)

Project ideas from industry and third parties will be screened against it

http://goo.gl/jqMP9g

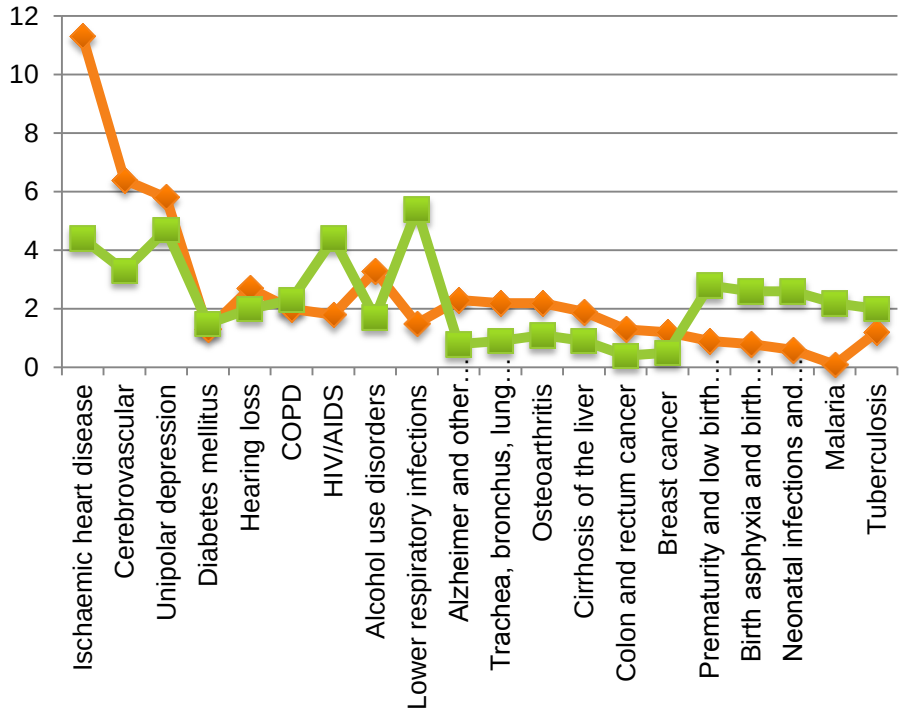
efpia
European Federation of Pharmaceutical Industries and Associations
Vaccines Europe
An industry for healthy lives
ebe
european biopharmaceutical enterprises
imi
Innovative Medicines Initiative

efpia

Therapeutic areas covered by the IMI2 SRA

WHO 2013 report on priority medicines for Europe and the World

Percentage of DALYs for top 20 high burden diseases and conditions



Therapeutic Areas in IMI2 SRA

(no priority order)

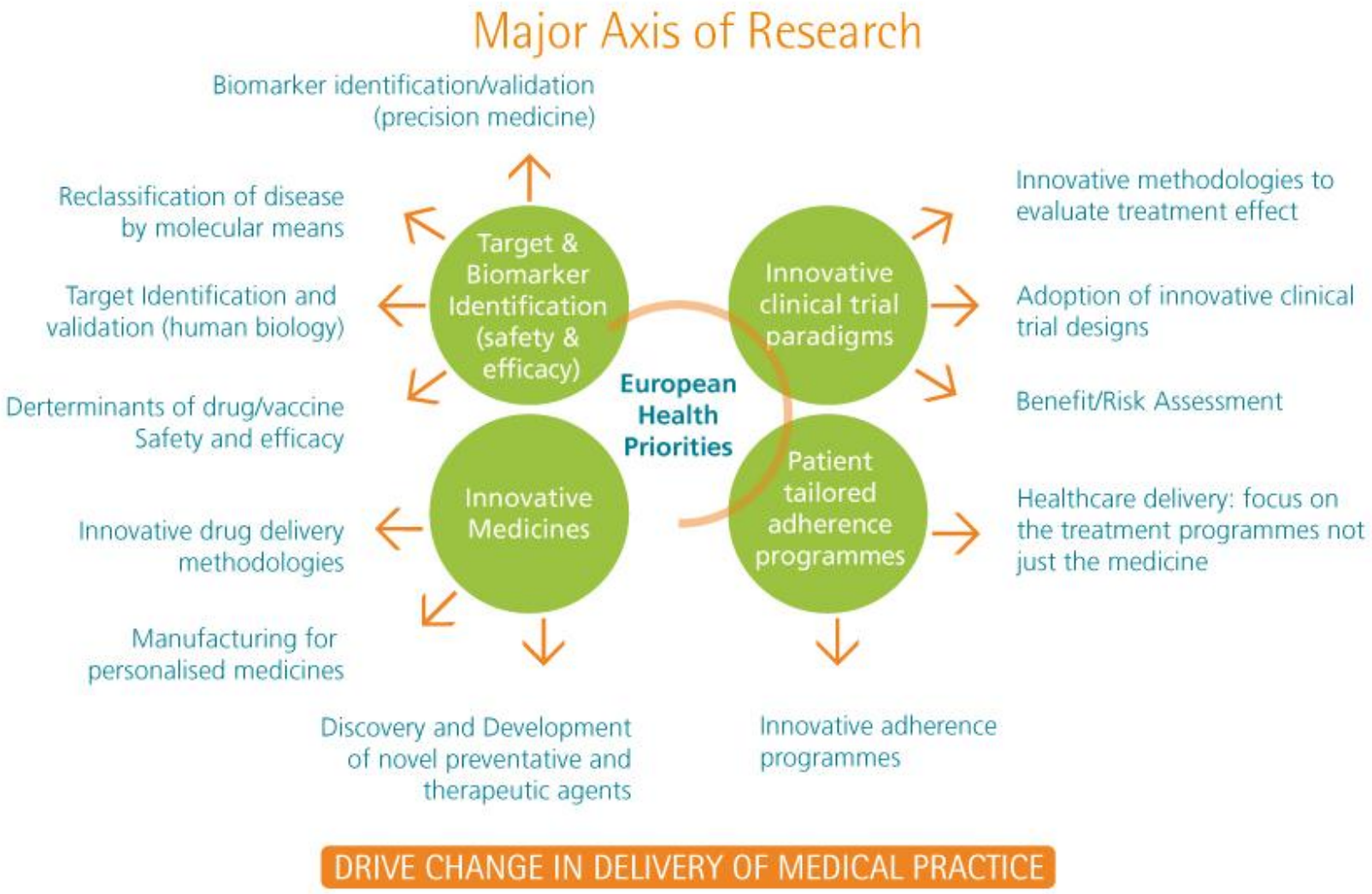
6. EUROPEAN HEALTH PRIORITIES

- 6.1. Antimicrobial resistance
- 6.2. Osteoarthritis
- 6.3. Cardiovascular diseases
- 6.4. Diabetes
- 6.5. Neurodegenerative diseases
- 6.6. Psychiatric diseases
- 6.7. Respiratory diseases
- 6.8. Immune-mediated diseases
- 6.9. Ageing-associated diseases
- 6.10. Cancer
- 6.11. Rare/Orphan Diseases
- 6.12. Vaccines

06

efpia

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



etpia

IMI2 scientific programme: First five big themes

Therapeutic Areas and Cross-cutting Themes

1. **Neuro-degeneration**
   Prevent and treat dementia and other neurodegenerative diseases
2. **Immune-mediated disease**
   Advance immunological understanding to deliver new medicines and new and better vaccines
3. **Metabolic disorders**
   Tackle all phases of disease and its complications, including prevention and early interception
4. **Infection control**
   Multidrug resistance (including antimicrobials, antivirals, vaccines) and develop new and better vaccines
5. **Translational Safety**
   Predictors of safety and development of point of care for safety biomarkers
   New human biology platform to predict toxicity and safety during early drug development

Differentiating Enablers for all themes

Towards early and effective patient access to innovative prevention and treatment solutions (MAPPs):

- Target validation based on human biology
- Stratified medicine, precision medicine
- Innovation in clinical trials
- Data generation and interpretation (knowledge management)
- Prevention, disease interception, patient adherence (incl. societal acceptance of vaccines)
- Effect on medical practice and outcomes (health/disease management)
- Regulatory framework (including pharmacovigilance)
- Patient access

Success will be driven by

- Focusing on the challenges of the future
- Leveraging the value added for working together, across sectors, effectively use resources and expertise
- Focusing on strategic, game changing, think big – around broader therapeutic areas
- Change in research, regulatory, and healthcare practice

Objectives – extract from IMI2 Regulation:

- increase the success rate in clinical trials
- where possible, reduce the time to reach clinical proof of concept in medicine development
- develop new therapies for diseases for which there is a high unmet need and limited market incentives
- develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;
- reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks;
- develop tools, standards and approaches to assess efficacy, safety and quality of regulated health products.

efpia

Innovative Medicines Initiative

http://imi.efpia.eu/

Conclusions

- Focused: stratified medicines and healthcare priorities
- Healthcare solutions: prevention and treatment
- End-to-end: R&D, regulatory, access/healthcare practice
- Multi-sector: within and beyond life sciences
- Submit your ideas: http://imi.efpia.eu/

efpia

Magda Chlebus

Director Science Policy

magda.chlebus@efpia.eu

www.efpia.eu & http://imi.efpia.eu/

Twitter: @MagdaEFPIA

European Federation of Pharmaceutical Industries and Associations

www.efpia.eu