

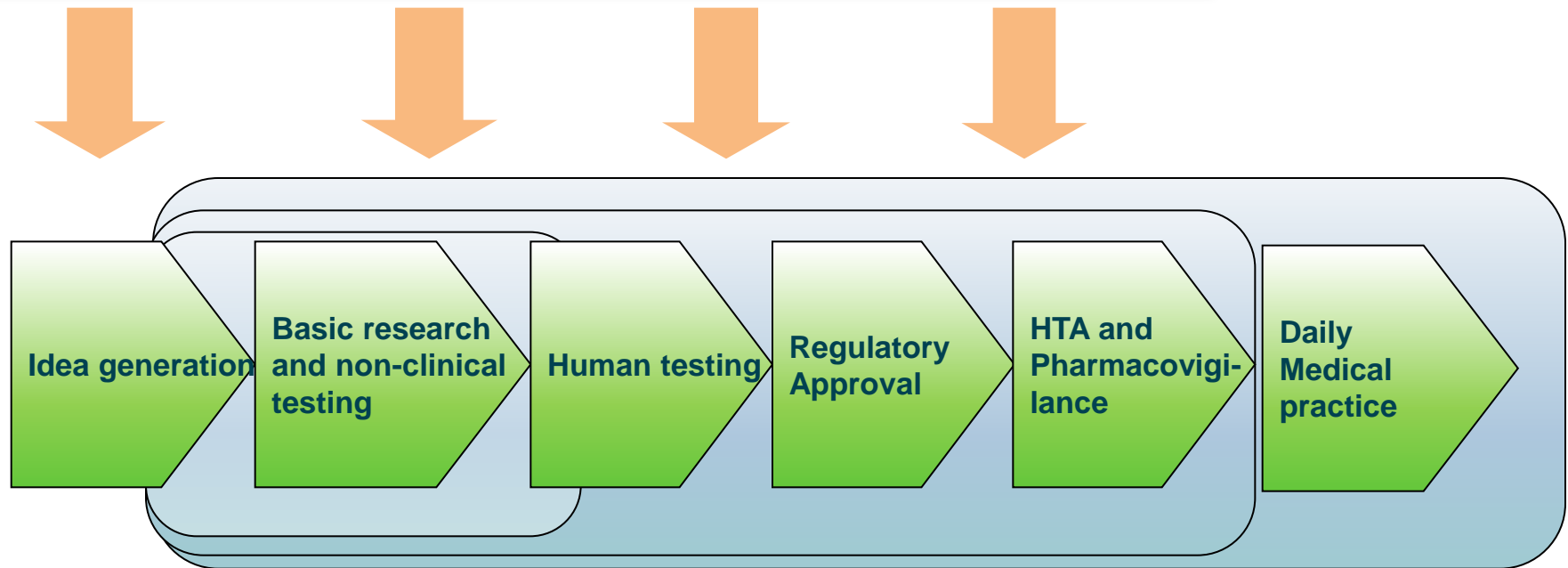


Industry Perspectives on IMI 2

Magda Chlebus, Director Science Policy, EFPIA
IMI 2 Info Day – Brussels, 30 September 2014

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

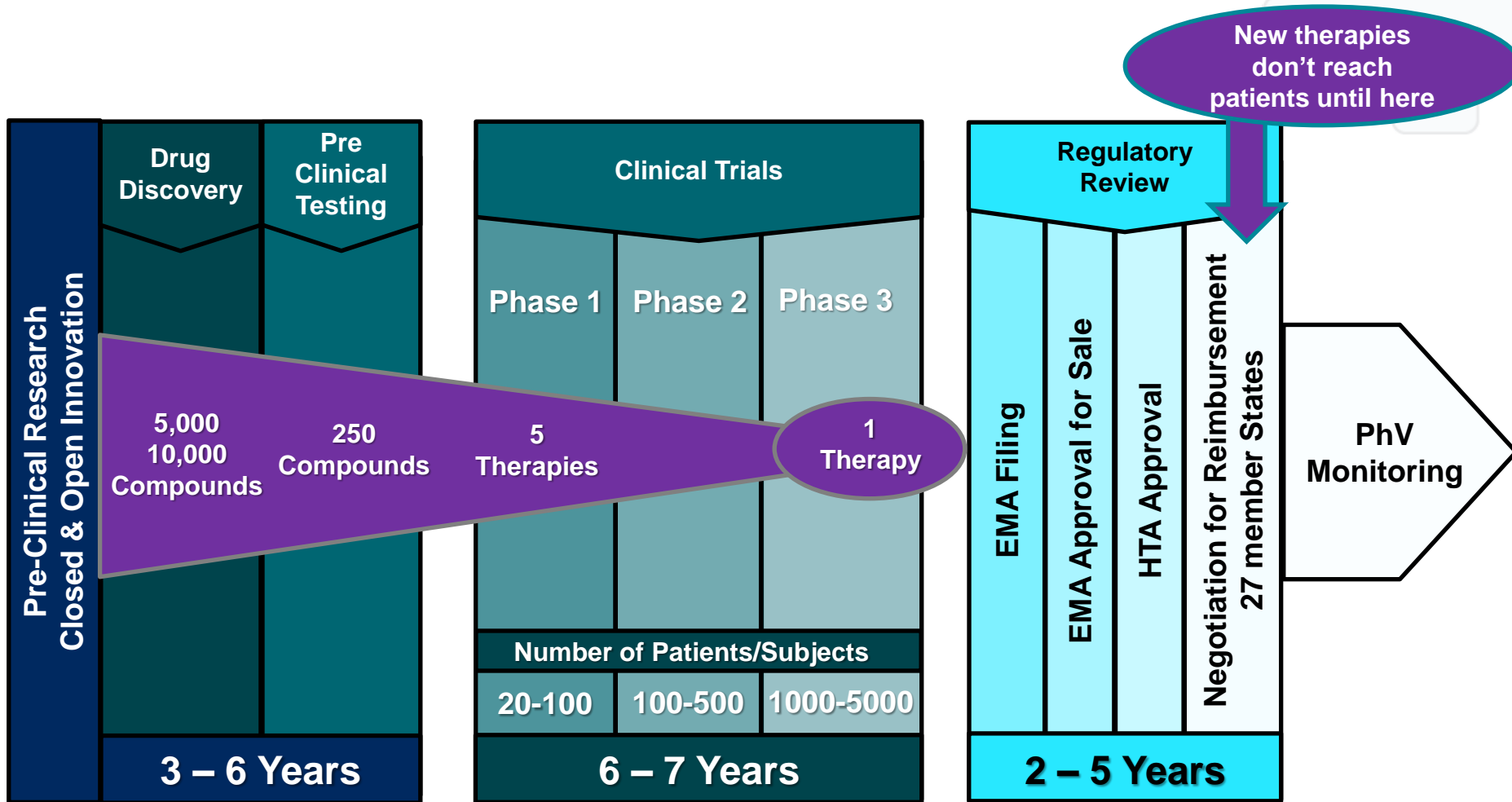


Primary focus of
early IMI calls
2007 SRA

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

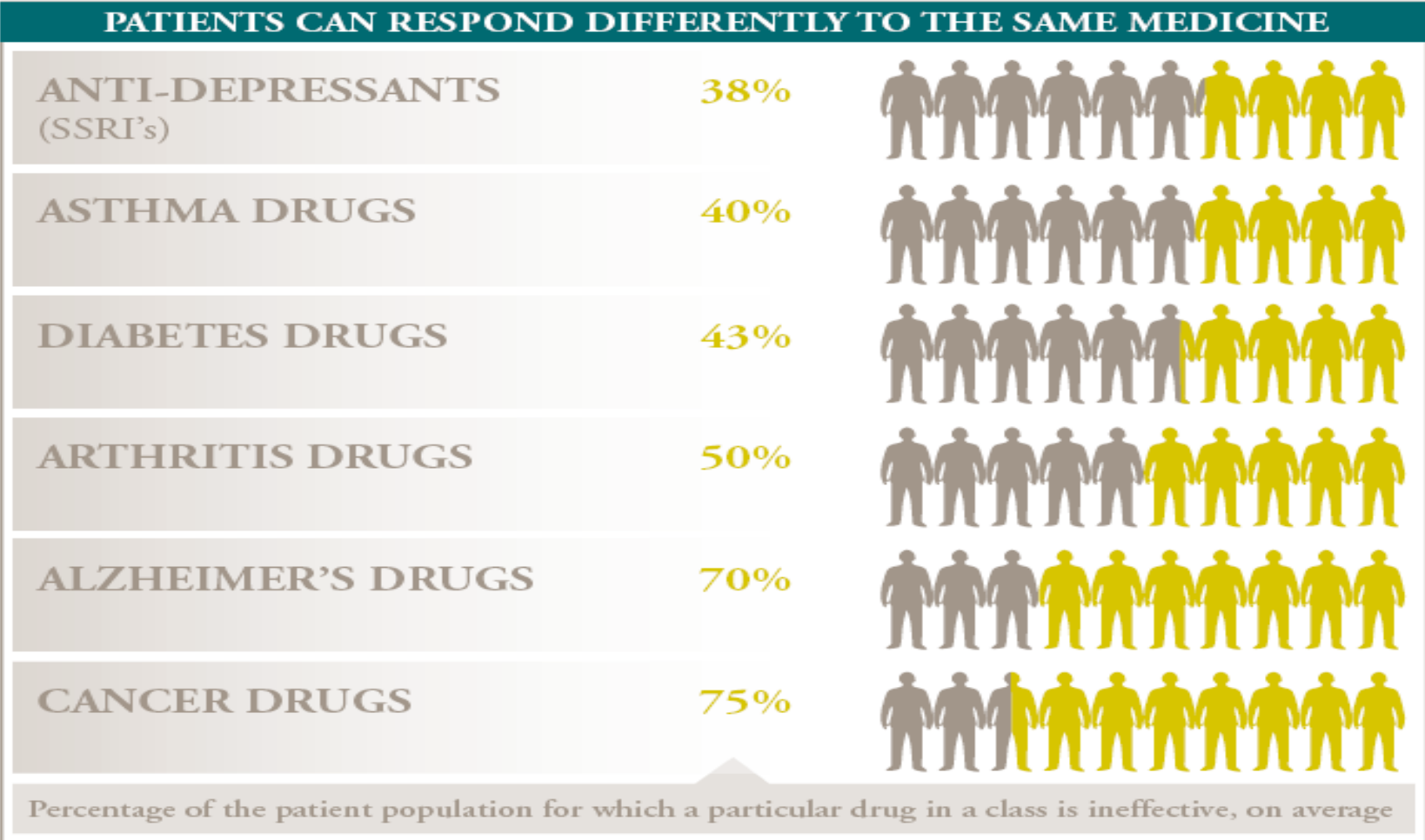
IMI 2
includes real life
medical practice
2013 SRA

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.”

Modern Medicines – non-responder rates

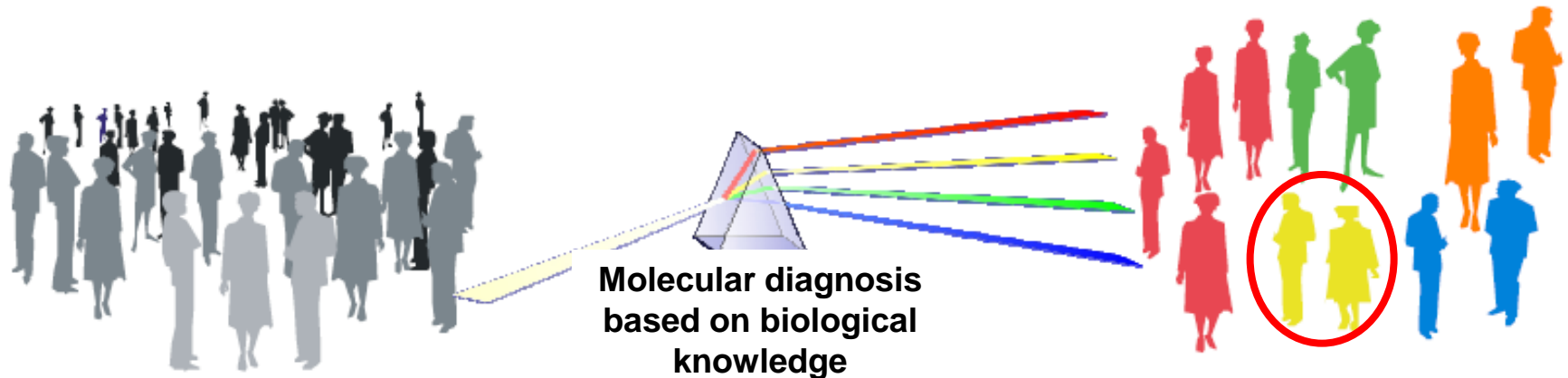


The Vision for IMI2 (and the Pharma industry)

From population



to individual



We “treat” a population.
Some respond and some don’t

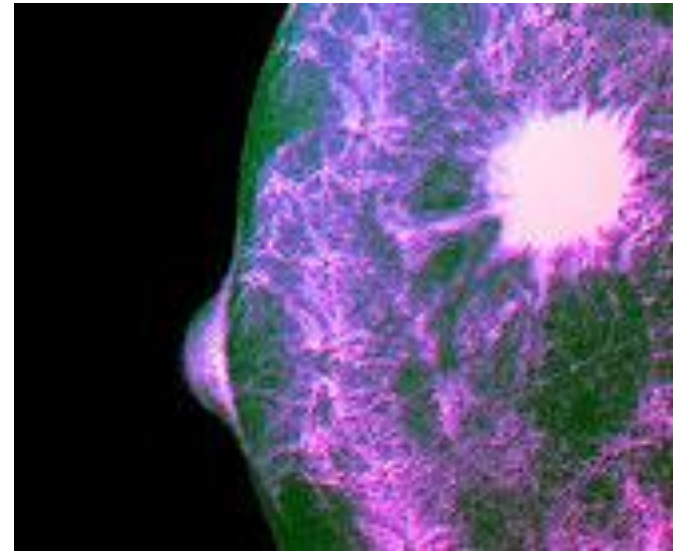
We “treat” a *targeted* population
They all respond

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



Priority Medicines for Europe and the World 2013 Update

Warren Kaplan, Veronika J. Wirtz,
Aukje Mantel-Teeuwisse, Pieter Stolk,
Béatrice Duthey, Richard Laing

9 July 2013



- * 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

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>



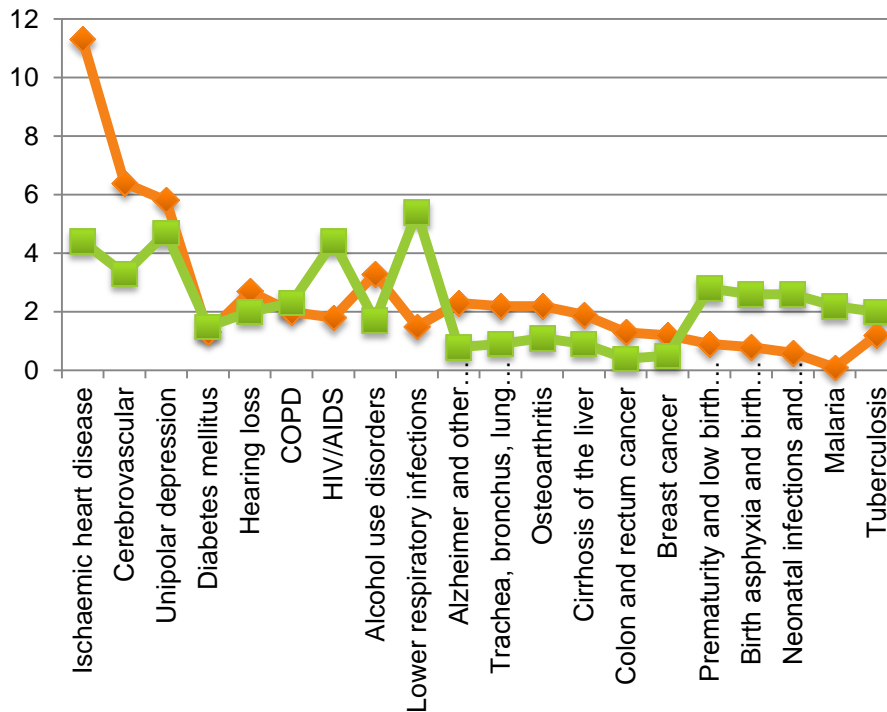
The right prevention and treatment
for the right patient at the right time

Strategic Research Agenda for
Innovative Medicines Initiative 2

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)

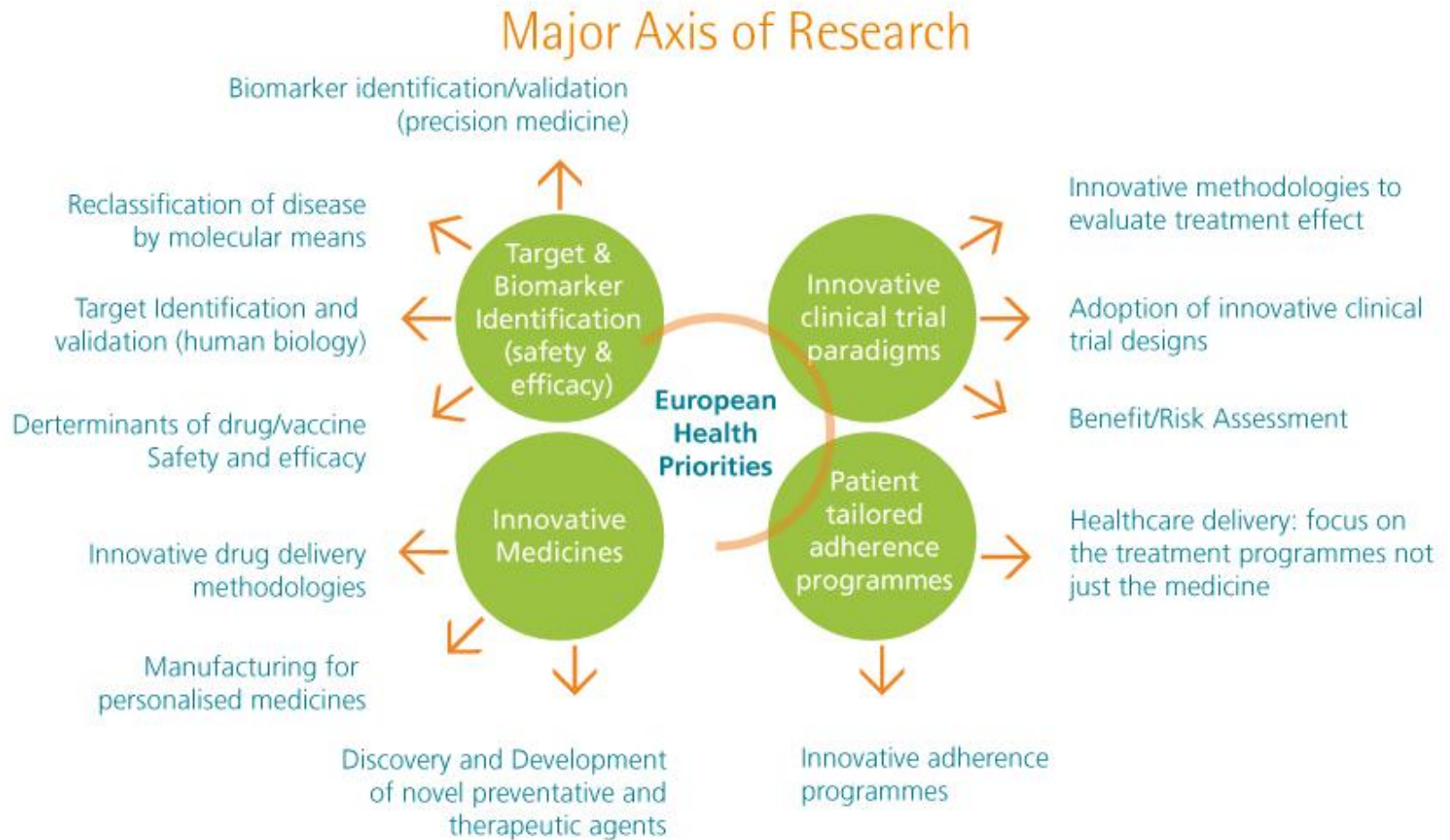
—◆— Europe
—■— World

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

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



DRIVE CHANGE IN DELIVERY OF MEDICAL PRACTICE

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

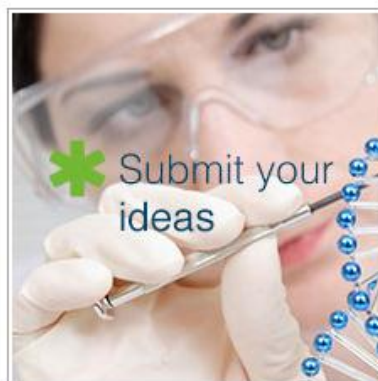
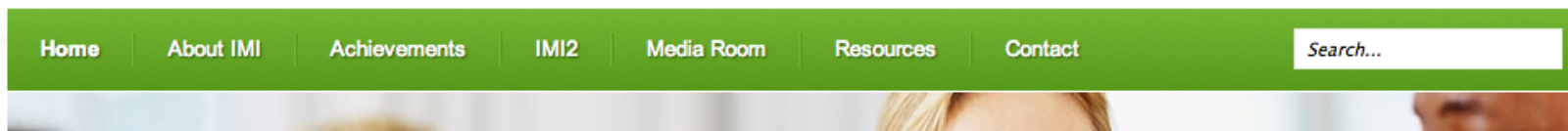
Success will be driven by

- * 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.

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/>



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