



Industry Perspective of IMI2

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

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IMI delivers on Innovation and Health

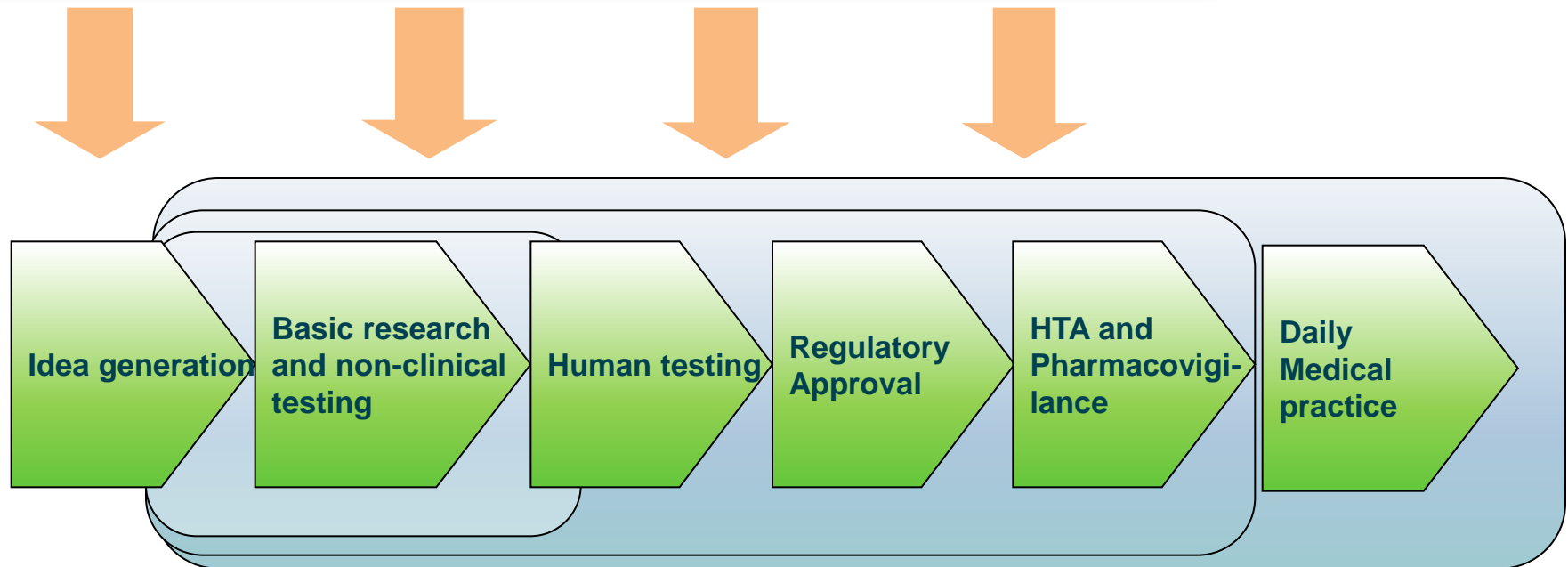
- * Established robust validated models for Alzheimer, Diabetes, Schizophrenia, Asthma
- * Developed clinically relevant biomarkers for Alzheimer, Diabetes, Schizophrenia, Asthma
- * Established Robust tools for drug safety prediction, prevention and monitoring
- * Establishment and regulatory submission of key standards and tools for drug development in infectious diseases, COPD, diabetes
- * Improved clinical trial design and process in schizophrenia, pain, autism
- * Co-funding by EU of antibiotics development
- * Projects launched and planned on use of real life data and alignment of regulators and payers data requirement

- Many of the above pave the way for new regulatory pathways aligned with science and technology development and creating pull incentives
- Uptake by Regulators has started (guidance, biomarkers)



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

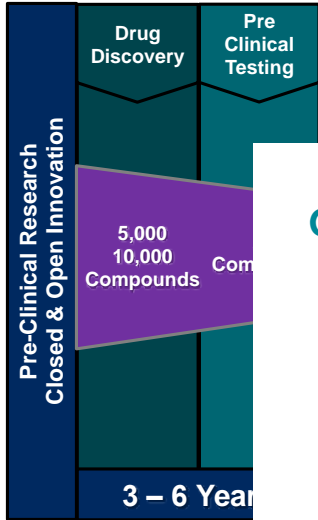


Primary focus of
early IMI calls
2007 SRA

Shift to also addressing
challenges in society
and healthcare
2011 SRA

IMI 2
includes real life
medical practice
2013 SRA

Current EU pathways are expensive and slow in getting new therapies to patients



Total Cost: \$2 -



Source: CBO, Forbe



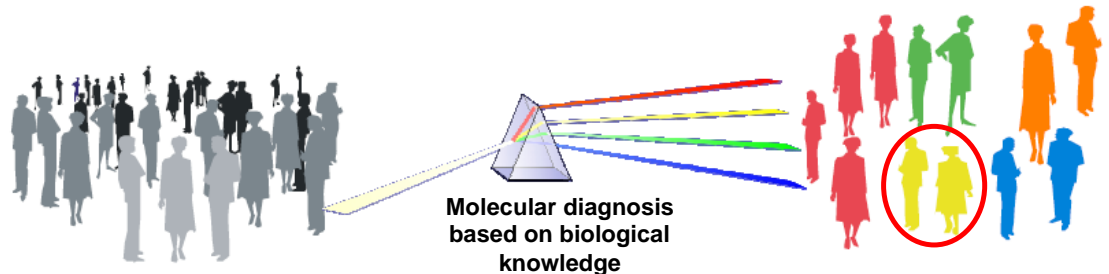
New therapies don't reach patients until here

General response rates to modern medicine

PATIENTS CAN RESPOND DIFFERENTLY TO THE SAME MEDICINE	
ANTI-DEPRESSANT (SSRI's)	
ASTHMA DRUGS	
DIABETES DRUGS	
ARTHRITIS DRUGS	
ALZHEIMER'S DRUGS	
CANCER DRUGS	
Percentage of the patient population that responds to the medicine	



Science offers new opportunities



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

We treat a *targeted* population
They all respond



IMI2 vision – towards integrated healthcare solutions

- * Addressing **healthcare priorities** identified by the WHO 2013 report
- * Strategic Research Agenda aimed at progressing the vision of **stratified medicines: prevention, treatment and health management**
- * Entire product cycle **from discovery, through development to healthcare delivery and access models**
- * **Collaboration across sectors** to harness all knowledge and technologies which can contribute to IMI2 vision - diagnostics, imaging, IT, medical devices, ...

IMI2 Strategic Research Agenda

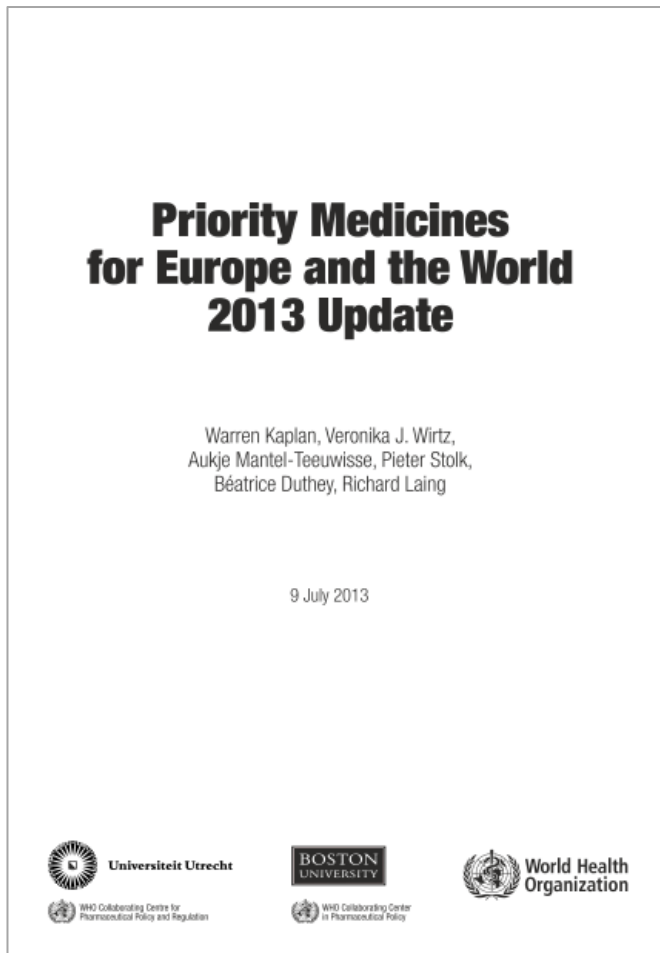


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Strategic Research Agenda for
Innovative Medicines Initiative 2

- * Priorities: WHO report on priority medicines
- * Input: 70+ scientific, research, patient, regulatory organisations
- * Endorsed by the IMI Scientific Committee

Therapeutic areas covered by the IMI2 SRA



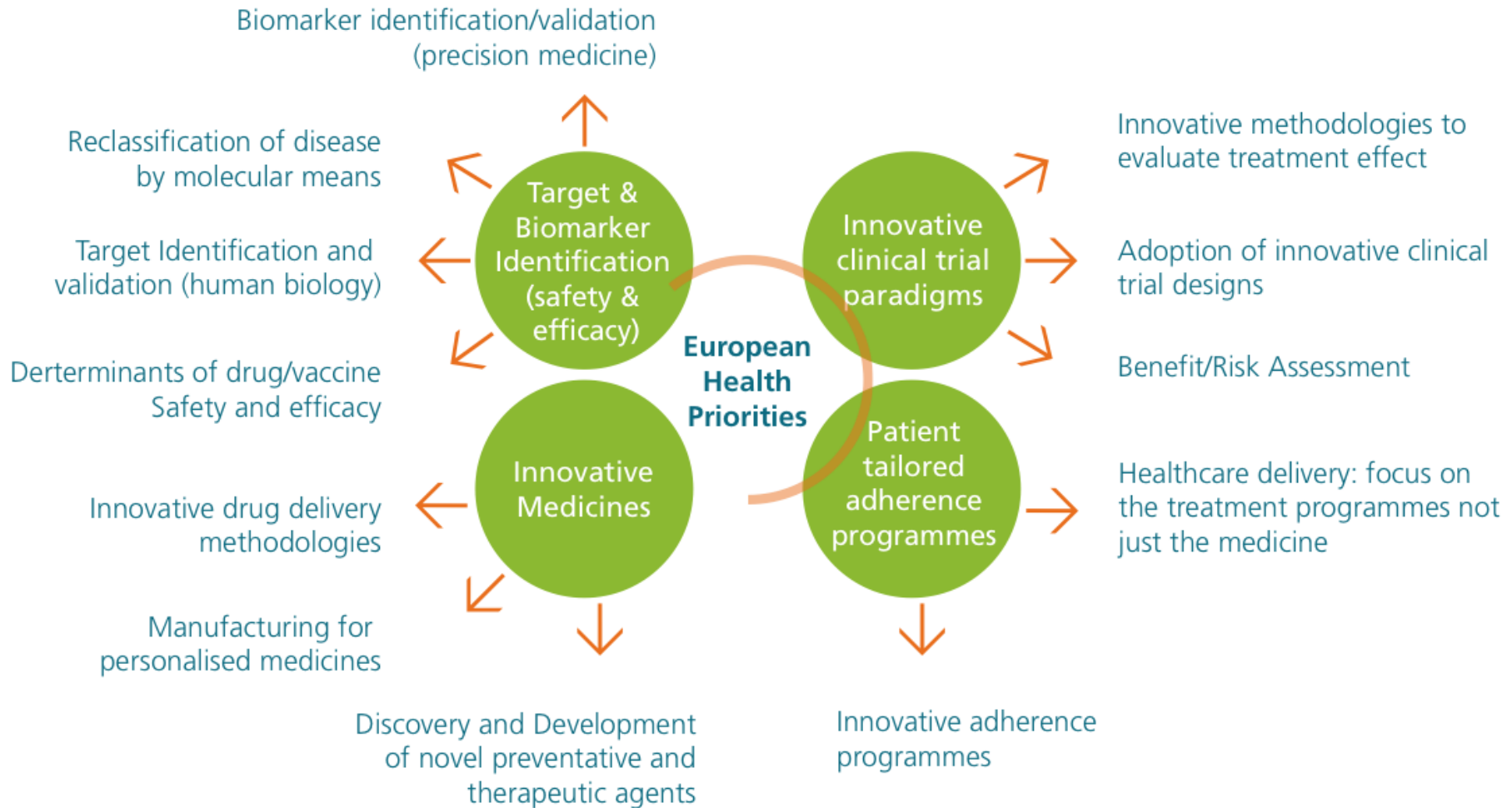
Therapeutic Areas in IMI2 SRA (no priority order)

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

Major Axis of Research



DRIVE CHANGE IN DELIVERY OF MEDICAL PRACTICE

IMI2 scientific programme: First five big themes

Therapeutic Areas and Cross-cutting Themes

1. Neuro-degeneration

- Successfully prevent and treat dementia and other neurodegenerative diseases

2. Prevention and treatment of 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 (type 2 diabetes, obesity, dislipidemia, hypertension)

4. Infection control

- Address big societal problem related to multidrug resistance and create incentives for reinvestment (including antimicrobials, antivirals, vaccines) and develop new and better vaccines

5. Translational Safety

- identification of predictors of safety and development of point of care for safety biomarkers & Development of 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

Outputs expected from the new SGG process

* Strategic Governing Groups :

- * Will ensure a coordinated strategic approach
- * Will improve efficiency of idea generation
- * Will allow more coherent planning and exploitation of results
- * Provide a structure for review and integration of proposals from industry and third parties
- * Allow improvement of internal processes for getting commitment and speeding up the idea generation process
- * Will provide a more structured engagement with other sectors, key stakeholders

Therapeutic focus areas

- * Neurodegeneration
 - * Leads: Janssen, Lilly, Abbvie
- * Immunology
 - * Leads: GSK
- * Diabetes/ Metabolic Disorders
 - * Leads: Sanofi, Lilly, Servier
- * Infection control
 - * Leads: AstraZeneca
- * Translational safety
 - * Leads: Sanofi, Bayer, Janssen, Novartis

Cross cutting themes

- * Data and Knowledge Management
 - * Leads: Janssen, Pfizer
- * Medicines Adaptive Pathways to Patients (implemented as Coordination and Support Action)
 - * Leads: Amgen, Janssen

First five big themes



* Prioritisation/selection criteria

- Field of unmet need
- Patient-centric approach
- The science appears ready to make a big change over the next decade
- Added value of PPP to make a difference (including collaboration with other industry sectors/technologies)
- Synergies/complementarity with similar initiatives

* While keeping focus on prioritised questions, there is sufficient room for other projects within the SRA

- e.g. Oncology; Rare/Orphan Diseases; Psychiatric Diseases; Respiratory Diseases

Innovative Medicines Initiative

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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 – there is room for win-win collaborations
- * Submit your ideas: <http://imi.efpia.eu/>



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