efp*ta



IMI2 Strategic Research Agenda
The Right prevention and treatment,
to the right patient, at the right time

Magda Chlebus
Director Science Policy
Barcelona, 13 January 2015

European Federation of Pharmaceutical Industries and Associations

www.efata.eu

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 <u>new regulatory</u> <u>pathways</u> aligned with science and technology development and <u>creating pull incentives</u>
- → Uptake by Regulators has started (guidance, biomarkers)

















IMI2: EU Parntership for Health For integrated healthcare solutions

- * Focus: stratified medicines and healthcare priorities
- Integrated solutions:
 prevention and treatment
- * End-to-end agenda: R&D, regulatory, access/healthcare practice
- * Multi-sector: within and beyond life sciences

Cash for public partners



European Commission From H2020

1638 mln

+ 1 bn in IMI1

Contributing own resource



EFPIA direct and indirect members

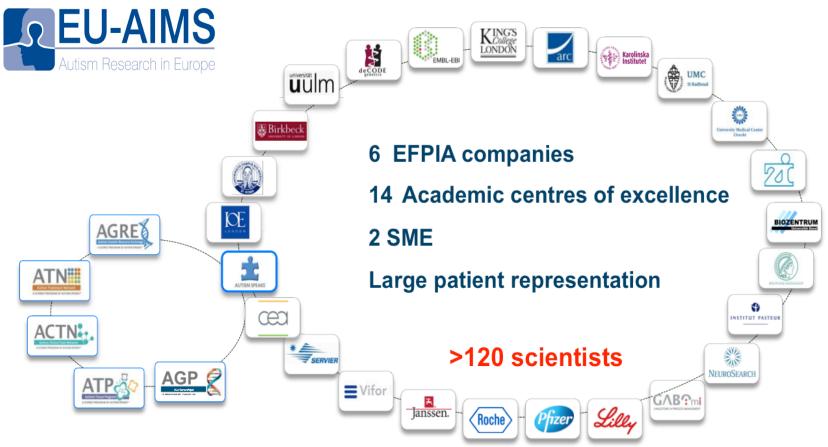
1425 mln

+ 1 bn in IMI1

Others 213 mln



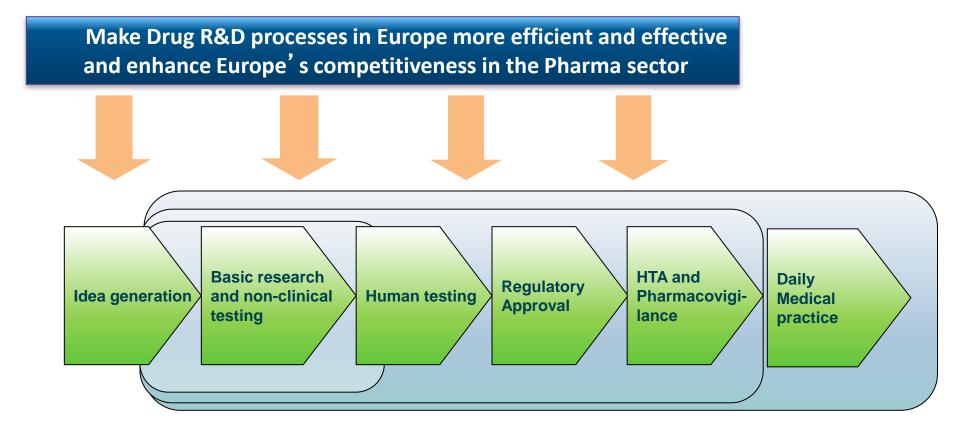




Budget: €35 million



Evolution of IMI – the road to IMI2



Primary focus of early IMI calls
2007 SRA

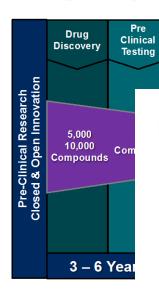
Shift to also addressing challenges in in society and healthcare 2011 SRA

IMI 2 includes real life medical practice 2013 SRA

SRA – Strategic Research Agenda

5

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



Total Cost: \$2 -

CBO, efpia Forbe

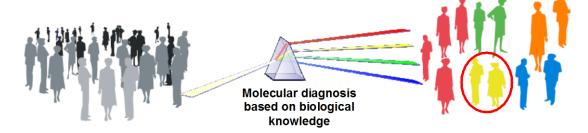


New therapies don't reach patients until here

General response rates to modern medicine

PATIENTS CAN RESPOND DIFFERENTLY TO THE SAME MEDICINE ANTI-DEPRESSAL **ASTHMA DRUGS** DIABETES DRUG ARTHRITIS DRU ALZHEIMER'S D CANCER DRUGS Percentage of the patient po efpia

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







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









Major Axis of Research

Biomarker identification/validation (precision medicine)

Reclassification of disease by molecular means

Target Identification and validation (human biology)

Derterminants of drug/vaccine Safety and efficacy

Innovative drug delivery methodologies

Manufacturing for personalised medicines

Target & Innovative **Biomarker Identification** clinical trial (safety & paradigms efficacy) European Health **Priorities** Patient tailored Innovative adherence Medicines programmes

Innovative methodologies to evaluate treatment effect

Adoption of innovative clinical trial designs

Benefit/Risk Assessment

Healthcare delivery: focus on the treatment programmes not just the medicine

Discovery and Development of novel preventative and therapeutic agents Innovative adherence programmes

DRIVE CHANGE IN DELIVERY OF MEDICAL PRACTICE



IMI2 scientific programme: First five big themes

Therapeutic Areas and Cross-cutting Themes

* Neuro-degeneration

Successfully prevent and treat dementia and other neurodegenerative diseases

Prevention and treatment of immunemediated disease

Advance immunological understanding to deliver new medicines and new and better vaccines

* Metabolic disorders

Tackle all phases of disease and its complications, including prevention and early interception

* Infection control

Address big societal problem related to multidrug resistance and develop new and better vaccines

* Translational Safety

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



How to submit a proposal for a project or a scientific question?

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 there is room for win-win collaborations

*Submit your ideas: http://imi.efpia.eu/



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