

Innovative Medicines Initiative (IMI) projects relevant for HTA

Irene Norstedt – Nathalie Seigneuret
23.03.2015, 4th HTA Network meeting Brussels

IMI: European's partnership for health

- Focus on patient and societal needs
- Integrate healthcare solutions
- Support the competitiveness of the European biopharmaceutical industry
- Move regulatory science forward
- Pool expertise, knowledge and resources, favour cross-fertilization between public and private partners
- Neutral trusted platform to align public and private interests

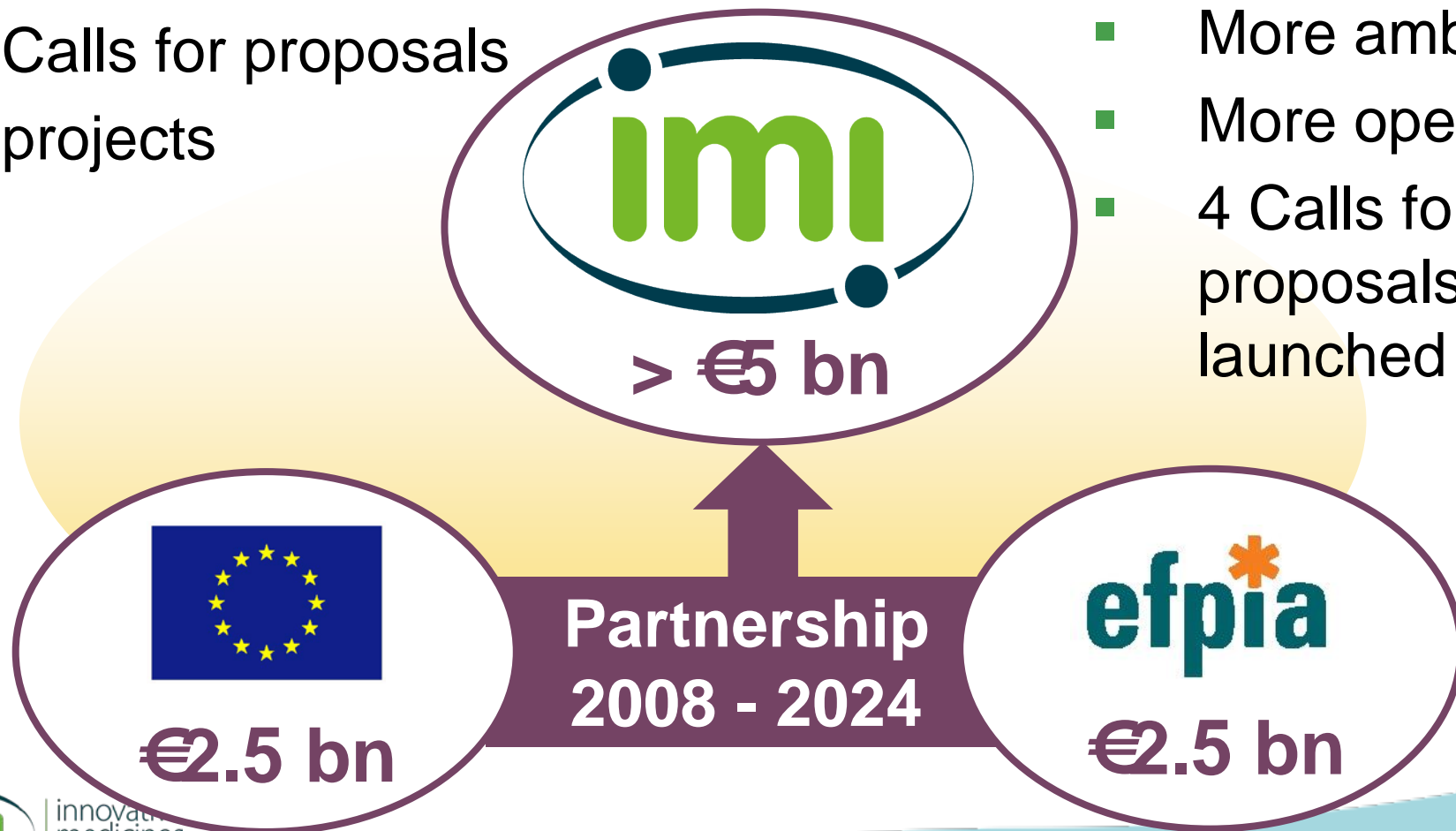
IMI – Europe's partnership for health

IMI 1 programme

- 2008-2013
- €2 bn budget
- 11 Calls for proposals
- 59 projects

IMI 2 programme

- 2014-2024
- Bigger budget
- More ambitious
- More open
- 4 Calls for proposals already launched



IMI 2 – building on successes of IMI1



- Non-competitive collaborative research
- Competitive Calls for proposals
- Open collaboration in public-private consortia
 - Data sharing, dissemination of results...
- Industry contribution is in kind

Changes – from IMI 1 to IMI 2

Scientific focus

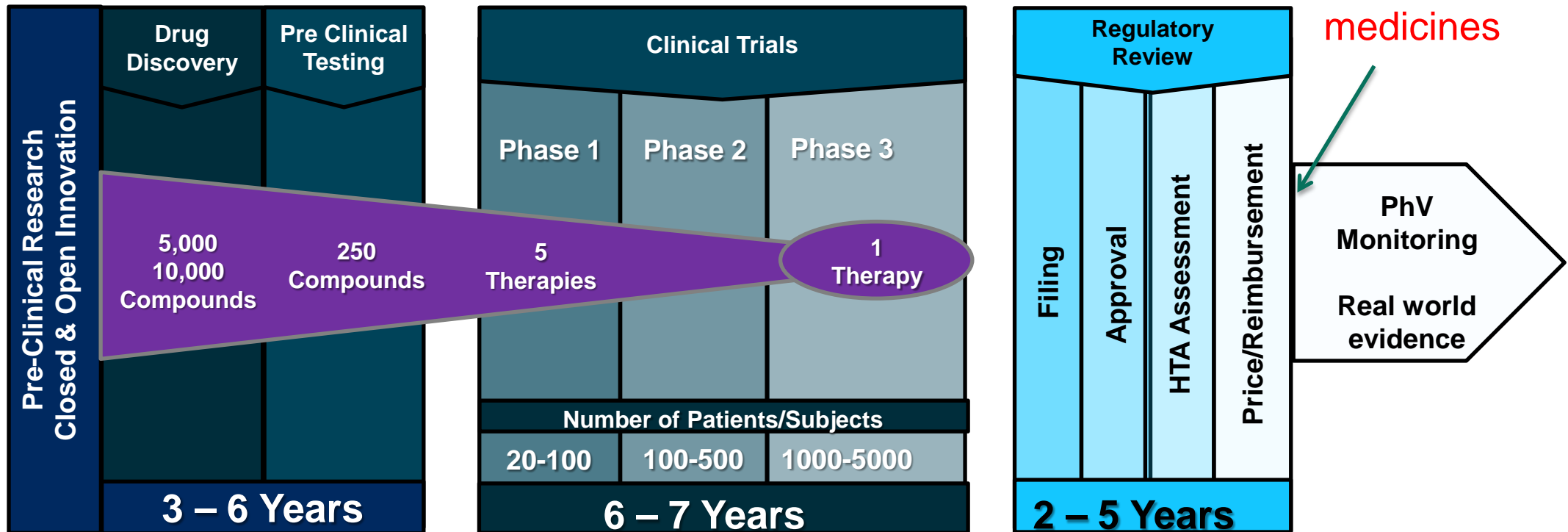
- Addressing **healthcare priorities** identified by the WHO 2013 report
- Strategic Research Agenda aimed at progressing the vision of **“stratified” medicines: prevention, treatment and health management**
- **End-to-end approach;** product lifecycle **from discovery, through development to healthcare delivery and** patient access to innovative medicines

Rules & procedures

- More entities eligible for funding
- Simpler funding rules aligned with H2020
- **Collaboration across sectors** to harness all knowledge and technologies which can contribute to IMI2 vision - diagnostics, imaging, IT, medical devices, ...and with non industrial associated partners
- Simpler reporting procedures

Challenges in development pathway

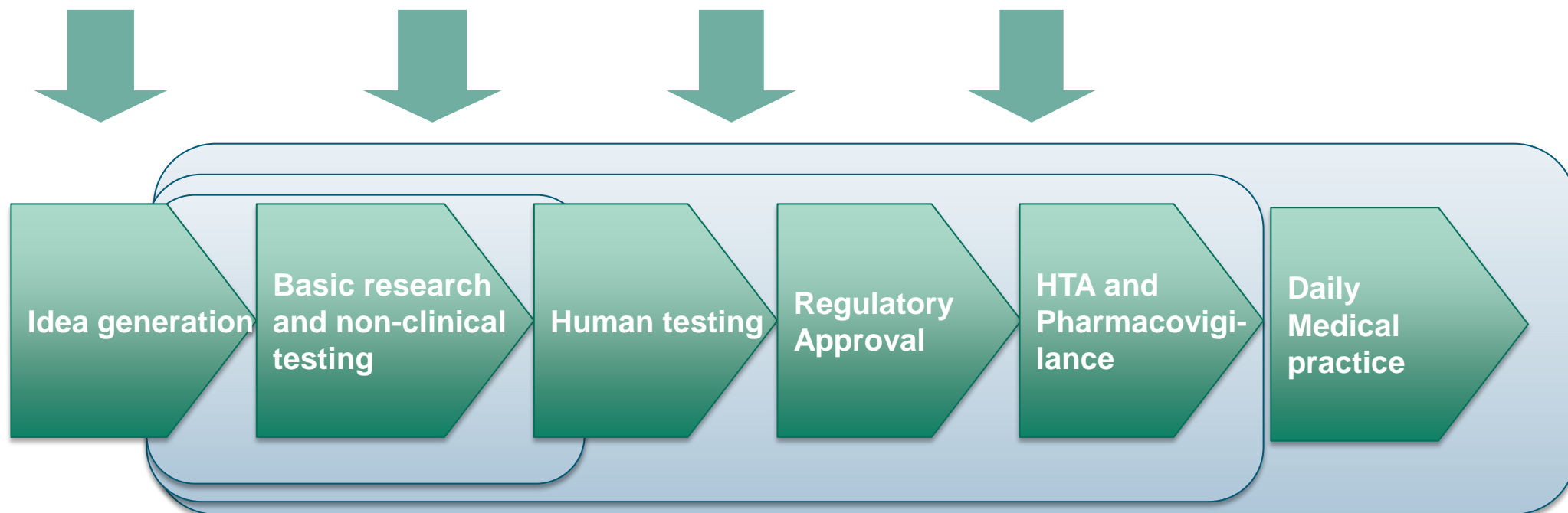
Patients access to innovative medicines



➔ New paradigms to provide science-based evidence and help informing the whole product life-cycle for early patient access to innovative prevention and treatment options

Evolution of IMI – from bottlenecks in industry to bottlenecks in industry and society

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**

IMI2: Strategic Research Agenda

Priority Themes

1. Neuro-degeneration
2. Immuno-inflammation
3. Metabolic disorders
4. Infection control
5. Translational Safety

Support Technologies

1. Imaging
2. ICT
3. Medical devices....

Enablers

Patient access to innovative solutions (MAPPs):

- Target validation
- Stratified medicine, precision medicine
- Innovative trials
- Data generation and interpretation
- Prevention, disease interception
- Patient adherence
- Health disease management
- Regulatory framework
- Reimbursement/patient access

Goals of IMI 2 programme

- **Increase the success rate of clinical trials** of new medicines & vaccines
- **Speed up the earlier stages** of drug development
- **Develop new treatments** for areas of **unmet need**
- **Develop new biological markers** to **diagnose** diseases and **assess** treatments
- **Improve the drug development process** by creating tools to assess the efficacy, safety and quality of medicines



IMI ongoing projects

GETREAL - Incorporating real-life clinical data into drug development

For Pharma R&D and healthcare system decision makers to **jointly understand how real world data and analytical techniques** can best be used to improve the value of information available at marketing authorisation: contributing to **better informed and more consistent assessments** underpinning patient access to new medicines.

www.imi-getreal.eu



Overview of the project

Developing a framework for the assessment of development strategies that provide evidence of relative effectiveness

Understanding how different pre-authorisation clinical studies could inform the assessment of relative effectiveness

Operational aspects of conducting pragmatic/adaptive clinical trial designs pre-launch

Promoting best practice in evidence synthesis and predictive modelling of relative effectiveness

Project management, Governance, Dissemination

Key deliverables

- Decision-making framework to aid the design of drug development strategies
- Recommendations for regulatory and HTA policy development
- Guidance on methodologies for:
 - conducting and analysing RE research pre-authorisation
 - using EHR in conducting studies pre-authorisation
 - conducting data synthesis of wide range of source studies of different types
- Guidance to address operational, statistical and ethical issues in conducting pragmatic/adaptive designs pre-authorisation
- Software for conducting data synthesis
- Training & education

Current status

Many achievements....

- Conference presence in 2014, publications under way
- Public consultation till 27 March 2015 on 2 documents:
 - Report on Current Policies and Perspectives on real world data
 - Glossary of key terms in the area of relative effectiveness and real-world data.
- Case study topics identified
- Pilot workshops carried out
- Research framework and literature reviews on E2E gaps finalised

...Despite challenges

Short project, high profile, interdependency and collaboration between partners, data sharing and identification of case studies

SPRINTT - Sarcopenia and physical frailty in older people: multi-component treatment strategies

To validate an **interventional paradigm** for **identifying at-risk individuals living in the community** and evaluate innovative therapeutic interventions against physical frailty and mobility disability

www.mysprintt.eu

SPRINTT Objectives

- **Creating an operational definition of at-risk (sub-populations)** with undisputable unmet therapeutic need
- **Qualification of muscular anabolism and catabolism biomarkers** in at-risk (sub-) populations
- **Validation and implementation of practical clinical methodologies** for testing clinically meaningful interventions for the screening, prevention of Physical Frailty and Sarcopenia and its complications (falls, mobility disability, hospitalisation etc...)
- Developing scientific and regulatory consensus on **therapeutic indication, biomarkers and development clinical methodology**
- Developing a **health-economic model** of physical Frailty and Sarcopenia in a real life setting

Other IMI projects

- **Benefit/risk assessment**

PROTECT: Testing methodologies and software solutions, recommendations for B/R decisions processes and supporting tools, e.g graphical representation

www.imi-protect.eu

ADVANCE: Framework for B/R assessment of vaccines

www.advance-vaccines.eu

- **Electronic Health Records for Clinical Research**

EHR4CR: Open IT platform that unlocks the information stored in EHR for improving clinical research by offering multitude of services (e.g. protocol feasibility based on real world data, site selection, patient recruitment...)

www.ehr4cr.eu

- **PRO**

PROACTIVE: PRO for capturing physical activity in COPD

<http://www.proactivecopd.com/>

Other IMI projects

- **EHR/Cohort/registries**

EMIF: Leverage of existing patient health data on > 40 M adults & children from EHR data sources (population-based registries, hospital-based databases, national registries, biobanks, etc.).

www.emif.eu

- **Modelling/Simulation**

DDMoRe: Public drug & disease model repository supported by an open source interoperability

➡ framework CT simulation, model-based adaptive optimal design...

www.ddmore.eu

- **New Business Model**

DRIVE AB: new economic models for development of novel antibiotics

<http://drive-ab.eu/>



Upcoming projects

Coordination and Support Action – Enabling platform for Medicines Adaptive Pathways to Patients

- Build a platform with relevant stakeholders for the coordination of MAPPS-related activities within IMI2
 - **Gap analysis** – lessons learnt from existing IMI projects
 - **Informing research activities** – facilitate the inclusion of tools/methodologies in IMI2 research projects
 - **Knowledge management** – horizon scanning of non IMI activities
- Recommendations should contribute to align understanding of impact of MAPPs versus current paradigm
- **CSA expected to be launched June 2015**

Discovery and validation of novel endpoints in dry age-related macular degeneration and diabetic retinopathy

- To evaluate novel endpoint candidates for dry AMD and DR
- ➔ technical, medical and health-economical appropriateness of methods, and bridge preclinical and clinical studies

Methods in scope:

- Visual function testing beyond best corrected visual acuity
 - Electrophysiology
 - Imaging methods to assess retinal structures
 - Patient reported outcome tools and QoL-related endpoints
 - Soluble and genetic biomarkers
 - Combinations of these methods
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- **Full proposal under preparation**

Knowledge repository to enable patient focused medicine development

- **Objective**

To have Patient Inspired Knowledge Hub (PIKH) that enables sharing noncompetitive information with and by users from patient groups, regulators, health authorities, academia and industry.

➔ facilitate and enable the incorporation of patient input into the drug development processes, used broadly by stakeholders in a uniform (standardized) way among a range of stakeholder organizations

- **Deadline for submission of proposals: 24 March 2015**

Remote Assessment of Disease and Relapse (RADAR)

Vision: Generate Patient Centric Data and Move from diagnose and treat to predict and preempt

Objectives

- Characterisation and prediction of changes in disease state in central nervous system (CNS) disorders via non-invasive remote sensing.
- Focus on unipolar depression, multiple sclerosis and epilepsy.
- **Deadline for submission of proposals: 24 March 2015**