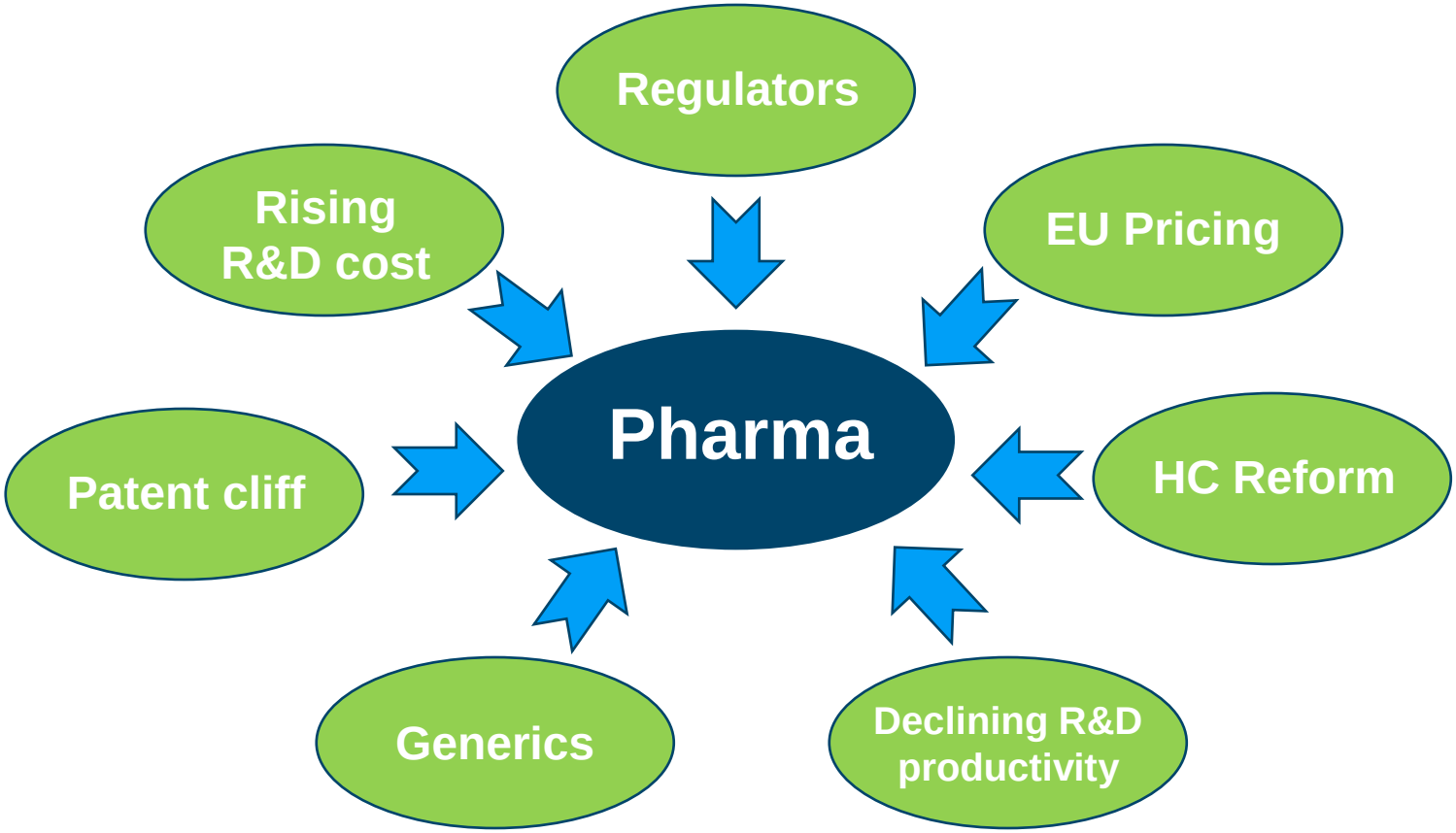
Crash Course IMI2 – What is it?

25 September 2014 - Budapest

Magali Poinot, Legal Manager

Objectives and operations

The way in which pharmaceutical companies develop new medicines is changing



New approaches needed

Sci Transl Med 29 January 2014:
Vol. 6, Issue 221, p. 221ed2
Sci. Transl. Med. DOI: 10.1126/scitranslmed.3008294

EDITORIAL

DRUG DISCOVERY

Turning the Titanic

Elias A. Zerhouni

"Deciphering the complexity of human diseases and finding safe, cost-effective solutions that help people live healthier lives requires **collaboration across scientific and medical communities throughout the health care ecosystem**.

Indeed, we must acknowledge that **no single institution, company, university, country, or government has a monopoly on innovation**."

Innovative Medicines Initiative:
Europe's partnership for health

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IMI 1 programme

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

IMI 2 programme

- 2014-2024
- Bigger budget
- More ambitious
- More open

IMI 2 total budget

€3.3 bn

€1.7 bn

€1.4 bn

Other

€225 m

From topic definition to project start

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Topic definition phase

EFPIA consortium

Identification of topic and willingness to collaborate by EFPIA companies

STAGE 1

Hospitals
Academic research teams
SMEs
Patients' organisations
Regulatory authorities

Submission of Expressions of Interest by applicant consortia
&
Evaluation by independent experts

STAGE 2

Applicant consortium
EFPIA consortium

Preparation of Full Project Proposal
&
Evaluation by independent experts/ethical panel

Negotiation phase

Signature of Project Agreement and Grant Agreement

Call Launch → **Invitation to selected team to merge with EFPIA team** → **Start of the negotiation phase** →

Role of The Programme Office

A neutral broker:

- To **implement** programmes and activities in the **common interest** of **all** stakeholders
- To **monitor** the use of public funds and industry investment
- To **guarantee** fair and reasonable conditions for optimal knowledge exploitation and dissemination
- To **facilitate** the interaction between stakeholders, including Intellectual Property agreements
- To actively **communicate** and promote IMI and its activities

Achievements

The IMI community

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Calls 1-8 ➡ 46 projects ➡ > 6000 researchers

61% of projects reported some form of **PATIENT INVOLVEMENT**

REGULATORS ON BOARD OF **12** PROJECTS

50% of projects have **REGULATORY AUTHORITIES** representatives in Scientific Advisory Boards

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The IMI portfolio

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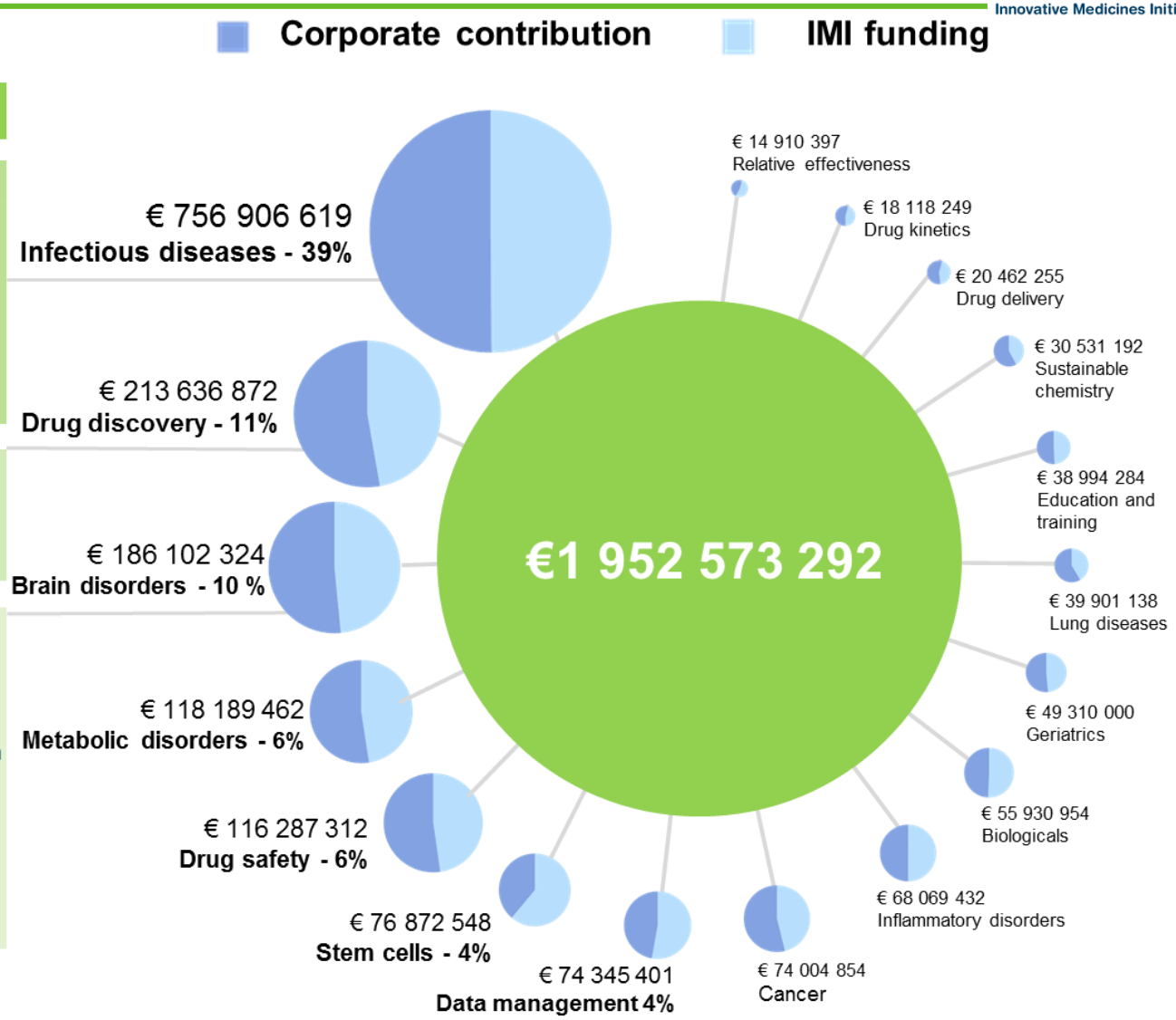
Partners

AiCuris	**Johnson&Johnson**
Animal Health	Medimmune
Division of Sanofi	**Merck**
Astellas	Merck Sharp
AstraZeneca	& Dohme Corp
Basilea	**Merial**
Boehringer Ingelheim	Novartis
Cubist	**Pfizer**
GSK	Rempex
Janssen	**Sanofi**

AstraZeneca	**Novartis**
Bayer	Pfizer
Janssen	**Sanofi**
Lundbeck	UCB
Merck	

Abbott	Janssen
AbbVie	**Lundbeck**
AC IMMUNE	Merck
Amgen	**Novartis**
Astellas	NOVO NORDISK
AstraZeneca	**Orion Corporation**
BIOGEN IDEC	Pfizer
Boehringer Ingelheim	**Roche**
Eisai	Sanofi
Eli Lilly	**SERVIER**
ESTEVE	UCB
Grunenthal	**Vifor**
GSK	



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IMI scientific output

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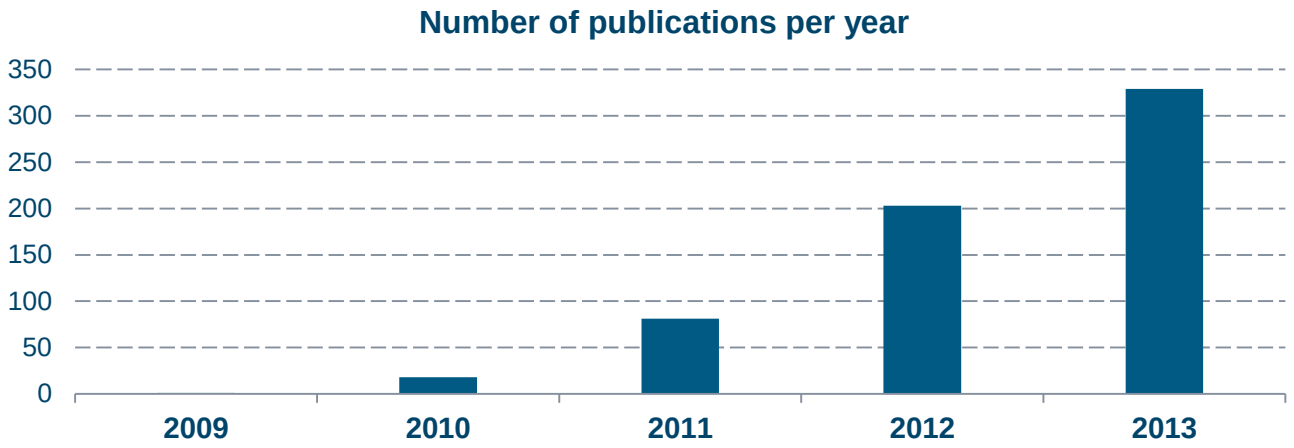
708 PUBLICATIONS

3709 CITATIONS

2.6 CITATION IMPACT

26% HIGHLY CITED



Science AAAS

PLoS one www.plosone.org

nature

PNAS

JAMA The Journal of the American Medical Association

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Collaboration delivers excellence

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Collaboration **BETWEEN SECTORS**

61%

of IMI publications

collaboration **BETWEEN INSTITUTIONS**

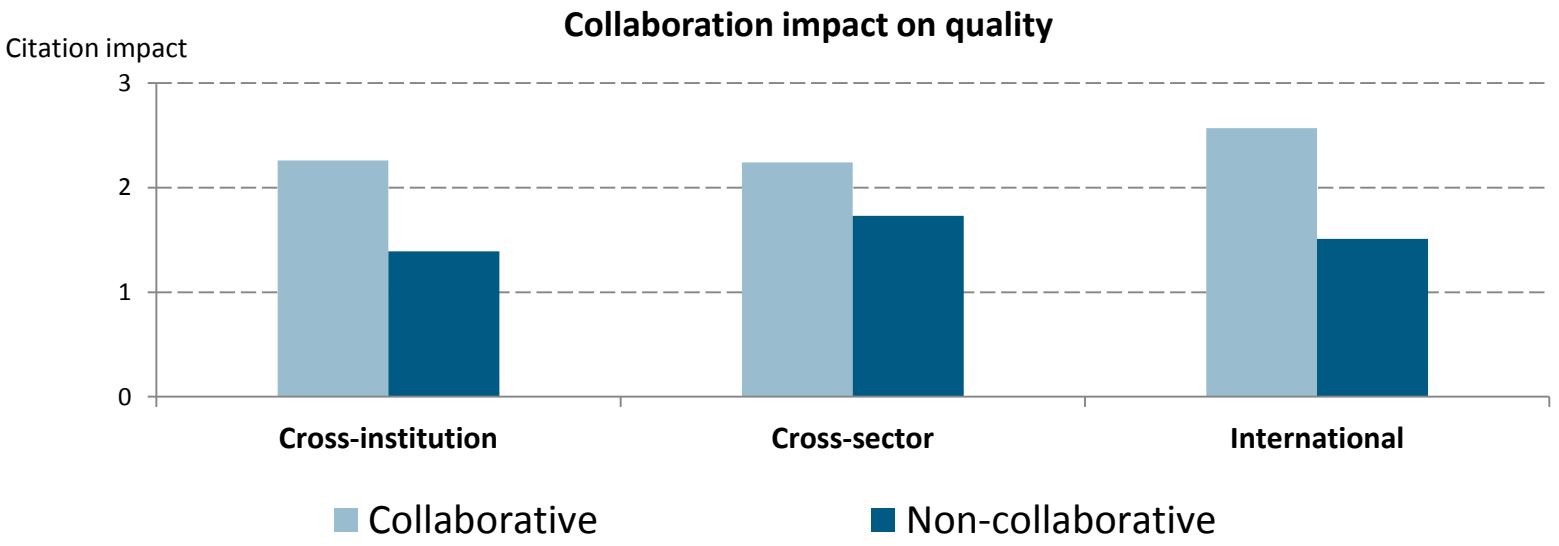
75%

of IMI publications

INTERNATIONAL collaboration

50%

of IMI publications



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Making a difference

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Implementation of project results inside industry

Project	Area	Results description
IMIDIA	**diabetes**	The human beta cell line EndoC BetaH1 has been validated by Endocells and 3 pharma partners confirming their initial insulin secretion capacity. These cells have been **successfully transferred as a research tool for drug discovery to industrial partners.**
DDMORE	**knowledge management**	Several drug/disease models identified by DDMORE are **adopted or further developed inside the industry.**
eTRIKS	**knowledge management**	Adoption of the eTRIKS results, **TransMART system deployments in 5 pharmaceutical companies.**
EUROPAIN	**Chronic pain**	Preclinical model of spontaneous pain in rodents has been developed, standardized, validated, and is already **used for internal decision making in the drug development process**. The ultraviolet B (UVB) pain model has also started to be **used for in house R&D**.

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Impact on regulatory framework

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Project	Area	Results description
PROactive	COPD	**Qualification Advice completed** at the EMA
EU-AIMS	autism	Started EMA formal scientific advice procedure for **qualification of 5 biomarkers in ASD**
eTOX	drug safety	Provided an update on the eTOX database and the prediction system to the CHMP Safety Working Party (SWP) at EMA. **Scientific Advice Procedure was initiated**.
MARCAR	cancer	Has developed new biomarkers, technologies, and alternative test systems that help explain or predict animal and/or human carcinogenic pathways and mechanisms for non-genotoxic carcinogenesis. This will provide enhanced scientific rationale for Carcinogenicity Assessment Document (CAD) submissions, with **potential impact for ICH S1 carcinogenicity testing guideline revisions**.
Safe-T	drug safety	Developed and now **progressed towards an aligned EMA/FDA qualification** a set of novel safety biomarkers for drug-induced kidney, liver, and vascular injury.
DDMORE	knowledge management	In May 2012 an advisory meeting with EMA and FDA representatives was held. Through a Modelling Review Group , DDMoRe is in regular contact with both the EMA and FDA regarding the qualification of the content of the project's Model Library.

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SME participation in IMI projects (up to 8th Call)

Total IMI commitment	€ 723 million
Total received by SMEs	€ 133 million
% SME	18.4%
Total IMI participations	886
Total SME participations	135
% SME	15%

SME success stories

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SME involved in **SAFE-T** project
"Thanks to IMI our company went from **6 to 50 employees.**
Now we are ready to go to further expand."

SME involved in **IMIDIA** project –
"1st product released to the market in 2013 – **IMI was instrumental in validation of the first cell line product**, 2nd product release planned this year, 3rd diagnostic product in development.

In preparation: **a new patent filing** to protect technologies for the creation of third generation human beta cell lines.

SME involved in **PharmaCog** project
"We are developing a blood panel for AD for diagnosis, stratification and companion diagnostics in AD. **The Panel was tested on 300 patients in IMI project**"

SME involved in **eTOX** project
"We have developed in silico models for predicting toxicity, which were validated by pharmas in eTOX. Now **we have signed a contract with one of the companies to use our models in house**."

Promoting patient involvement

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- ✓ IMI makes efforts to enhance **patient centric approach**
  - **Patient dedicated workshops**
  - Involving **patients at all levels**
  - Providing **forum for discussion**
- ✓ IMI best practice examples:

EUPATI

U-BIOPRED

PROactive

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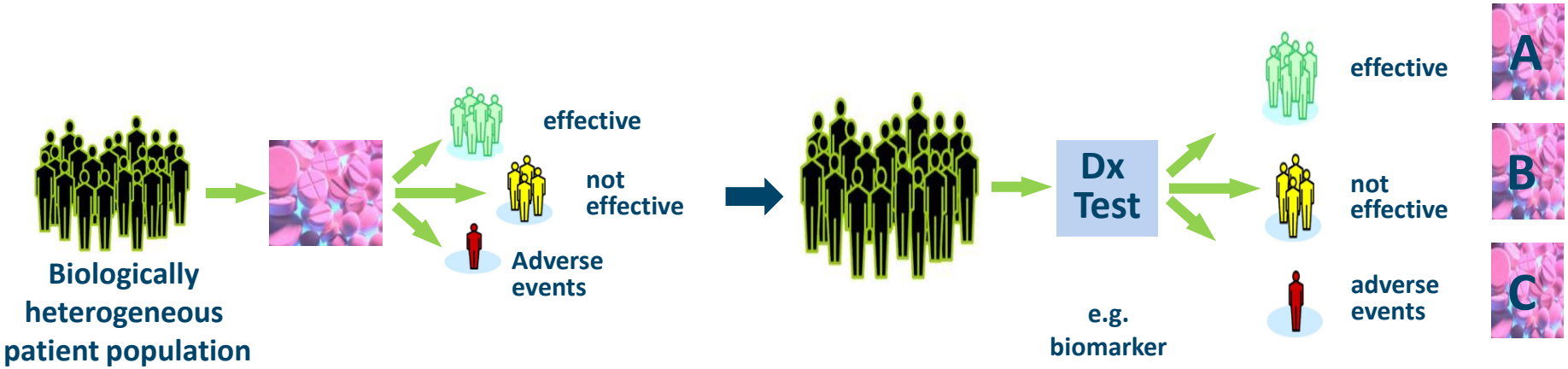
Towards IMI2

The Vision for IMI2 – The right prevention and treatment for the right patient at the right time



Trial and Error vs **Information based treatment decisions**

*Graphic adapted from C. Carini, C. Fratazzi, Eur. Pharm. Rev. **2008**, 2, 39-45*

Goals of the IMI2 programme

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- ✓ 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

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IMI2 focuses on the needs of society

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines

IMI is evolving – what's new?

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Scientific focus

- Stronger focus on **needs of patients and society**
- Research Agenda aligned with **WHO priorities**
- Increased emphasis on **improving patient access to innovative medicines** (in addition to medicines development)
- Focus on **personalised medicine**

Rules & procedures

- **More** entities eligible for funding
- Simpler funding rules (100% of direct costs for research + 25% flat rate for indirect costs)
- Open for other industries / companies (**associated partners**)
- **Open to** projects with **other sectors** (ICT, diagnostics, imaging, animal health, etc.)
- **Simpler reporting** procedures

Taking part to IMI activities

Why take part in IMI projects?

- Scientific excellence
- Impact on drug development, regulatory procedures, patients' lives
- Access to expertise of scientists from universities, industry, biotechs, regulators, patient groups…
- New business opportunities
- Under IMI 2 – improved funding rates
- Flexible intellectual property policy protects partners while promoting use of knowledge

How to take part in IMI projects

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Apply for funding

- Look out for new IMI Calls
  - www.imi.europa.eu
  - IMI newsletter
  - Twitter, LinkedIn
- Link up with other experts
- Read and understand the Call documents
  - Info sessions / webinars
  - Contact the IMI Programme Office
- Submit your proposal

Contribute to IMI as an Associated Partner

Your contribution is matched by the EU

- Read the IMI Strategic Research Agenda
- Identify points that match your priorities
- Contact the IMI Programme Office

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IMI2: The First Call

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Translational approaches to disease modifying therapy of type 1 diabetes mellitus (T1DM)

Magda.Gunn@imi.europa.eu

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

Nathalie.Seigneuret@imi.europa.eu

Submission date: 12 November 2014

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Participating to IMI evaluations

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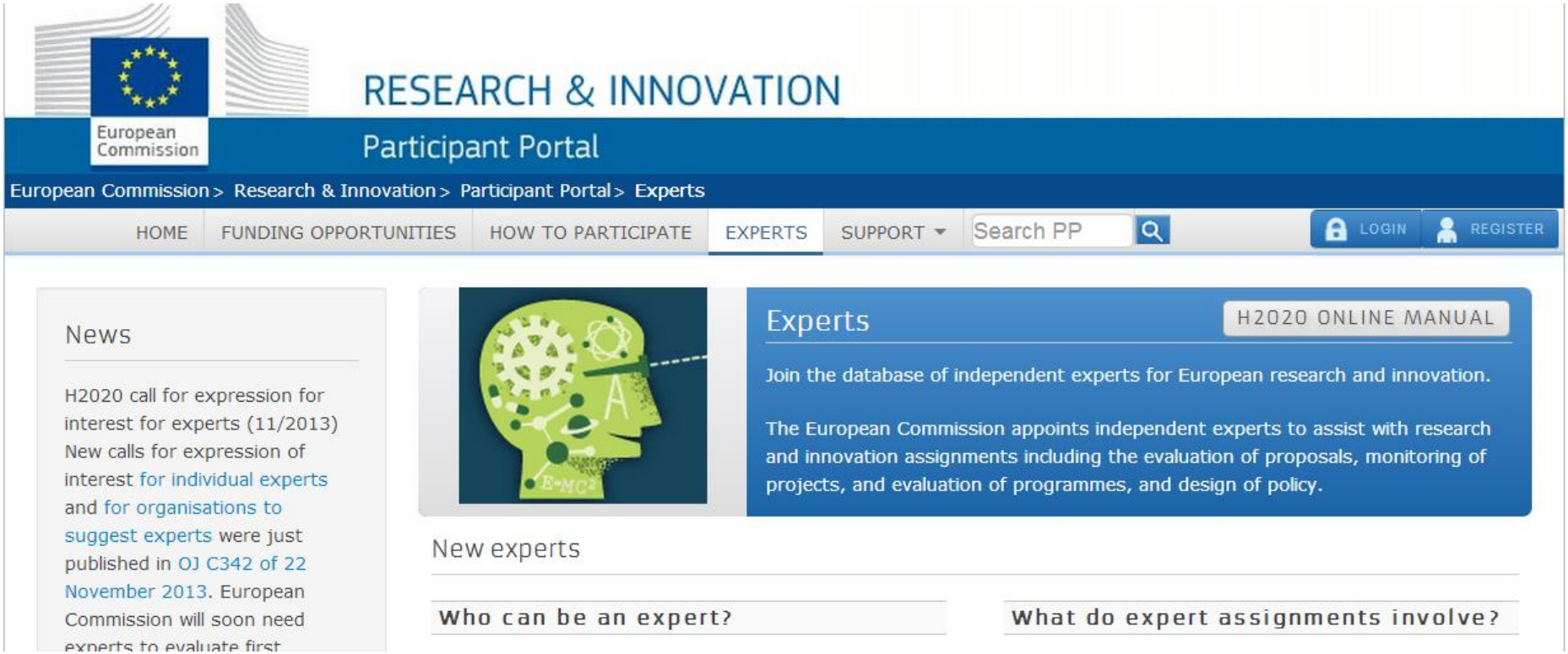

Register at: http://ec.europa.eu/research/participants/portal/desktop/en/experts/

Send us an email with your CV at: infodesk@imi.europa.eu

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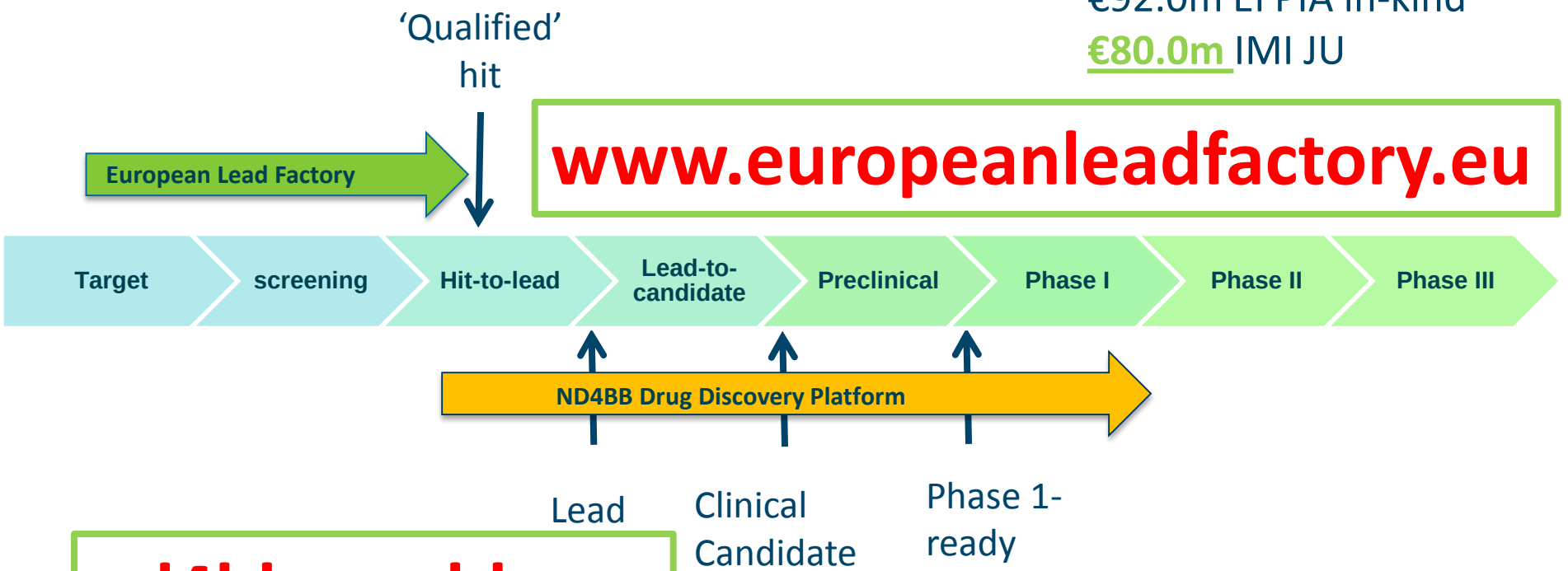
IMI's drug discovery platforms

European Lead Factory Focus: identification of new hits

ELF Budget:

€92.0m EFPIA in-kind

€80.0m IMI JU



nd4bb-enable.eu

ENABLE Focus: to move promising hits into early clinical development

ENABLE Budget:

€26.0m EFPIA in-kind

€58.9m IMI JU

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Thank you

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