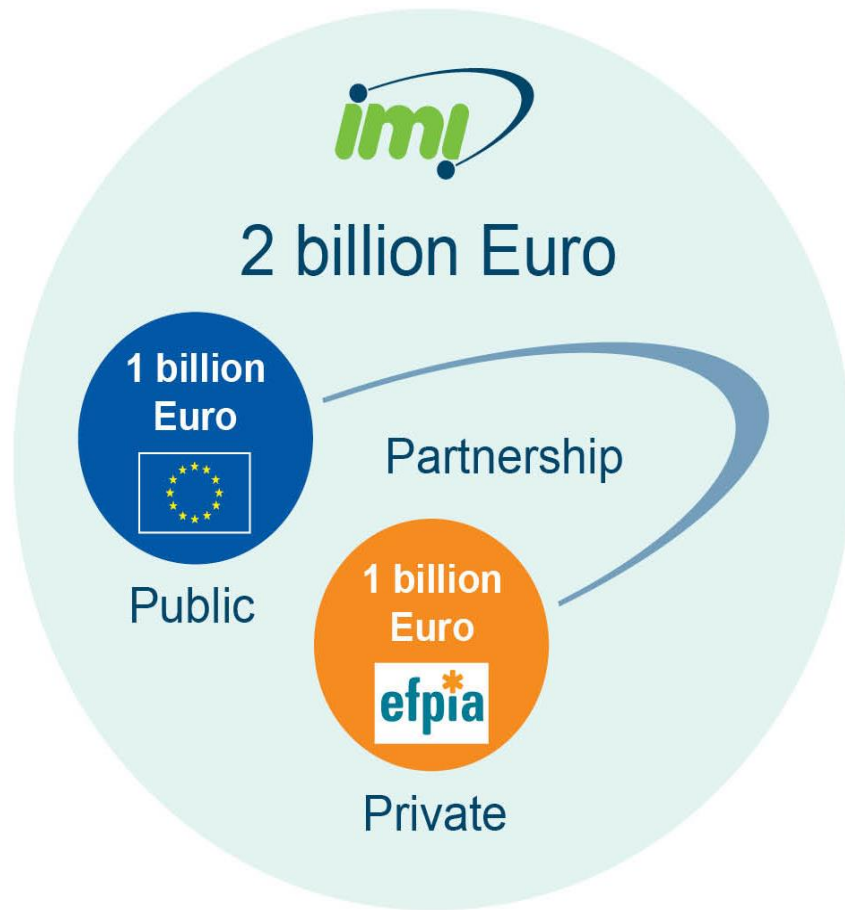


From IMI to IMI2

Hugh Lavery

20.02.2015 • PROTECT • London

Innovative Medicines Initiative: Joining forces in the healthcare sector



The biggest public/private partnership
in Life Science aiming to:

- Make drug R&D processes in Europe more **innovative** and **efficient**
- Enhance Europe's **competitiveness**
- Address key **societal challenges**

Features:

- 1:1 funding, joint decision making
- All EU funds go to SMEs, academia, patient organisations and regulatory agencies
- Large pharmaceutical industry, represented by EFPIA, contributes in-kind

An international, cross-sector community



Over 7 000 researchers
55 public-private consortia

The IMI portfolio

■ Corporate contribution

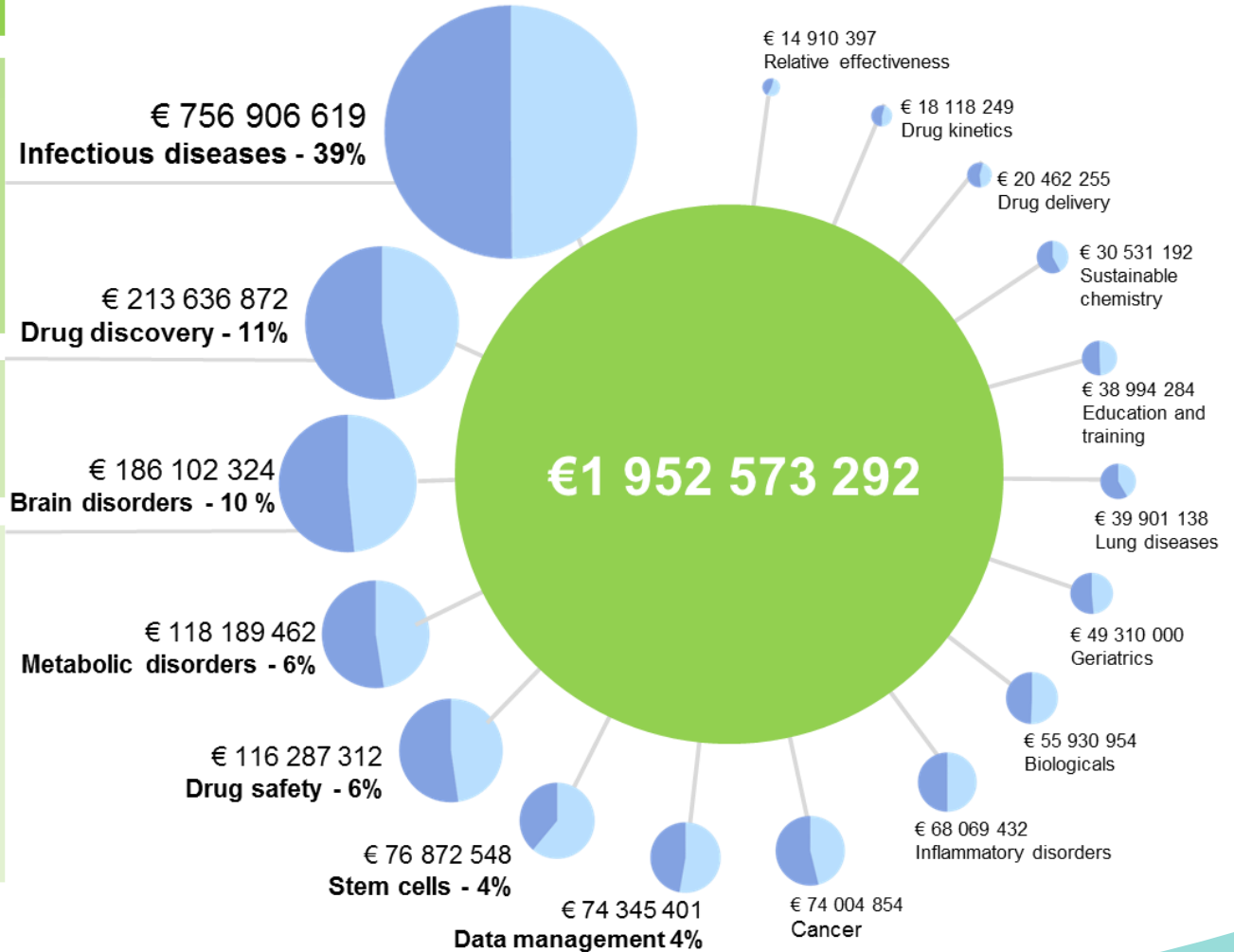
■ IMI funding

Partners

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

AstraZeneca	Novartis
Bayer	Pfizer
Janssen	Sanofi
Lundbeck	UCB
Merck	

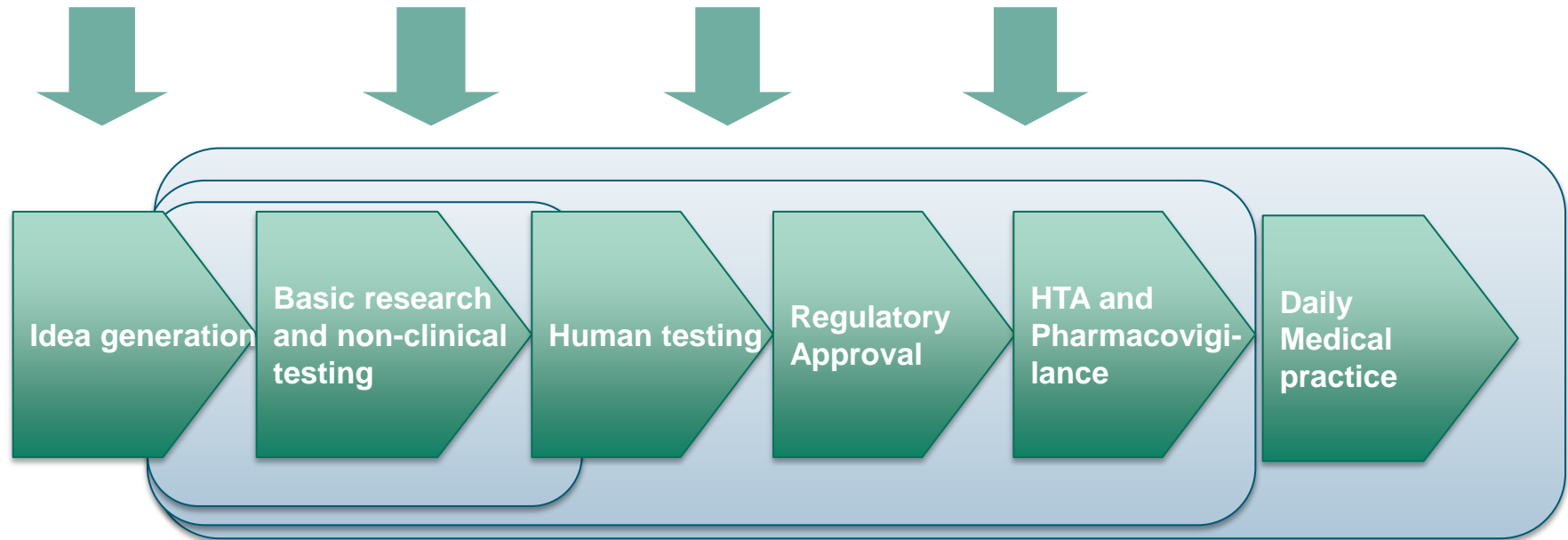
Abbott	Janssen
AbbVie	Lundbeck
AC IMMUNE	Merck
Amgen	Novartis
Astellas	NOVO NORDISK
AstraZeneca	Orion Corporation
BIOMEDIC	Pfizer
BoehringerIngelheim	Roche
Eisai	Sanofi
Eli Lilly	SERVIER
ESTEVE	UCB
Grunenthal	Vifor
GSK	



IMI2

The 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**

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

efpia
European Federation of Pharmaceutical
Industries and Associations

ve Vaccines Europe
An industry for healthy lives

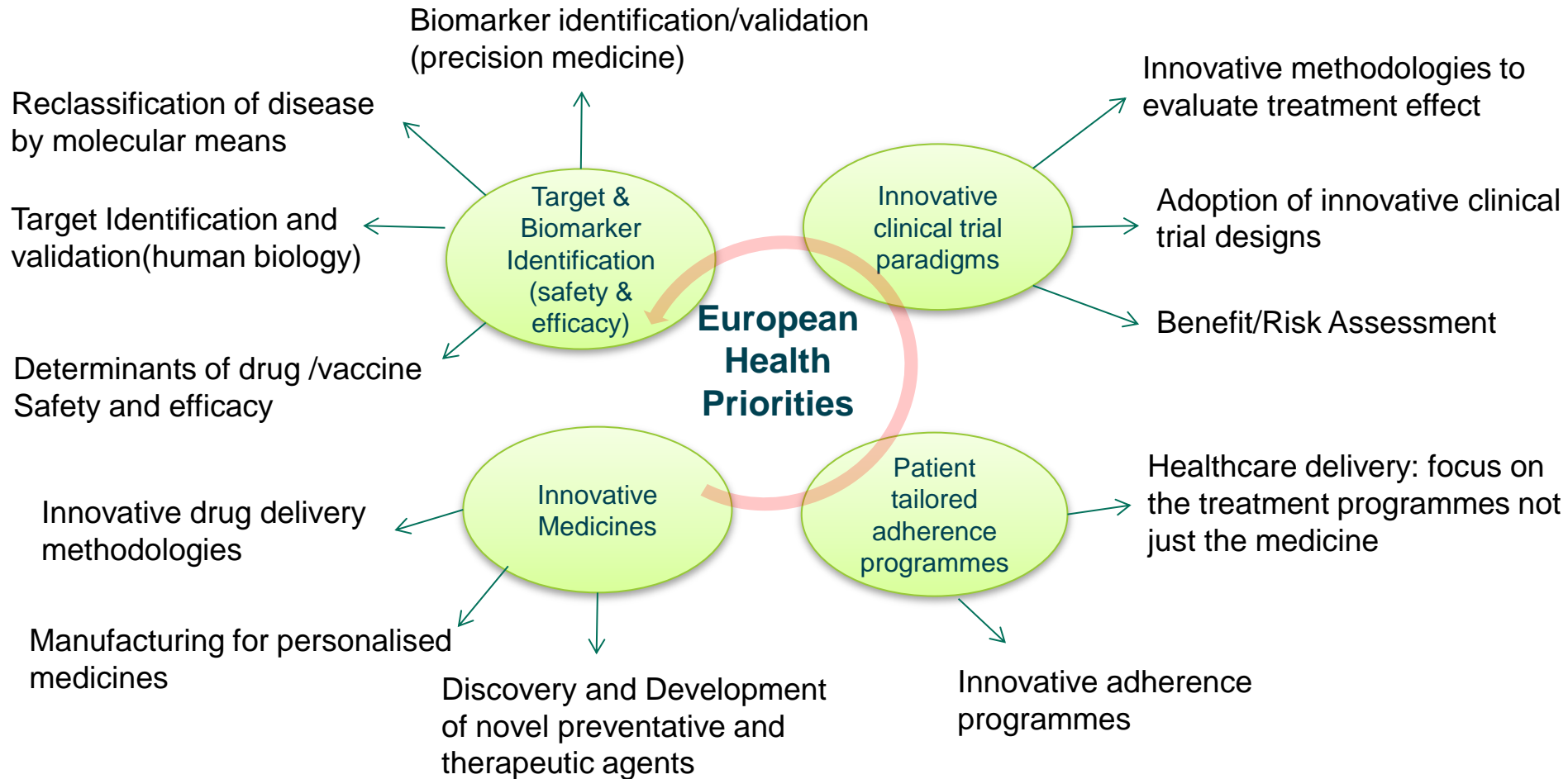
ebe
European
Biopharmaceutical
Enterprises

imi
Innovative Medicines Initiative

The premises

- Alignment with **Horizon 2020** objectives of the Health challenge
- Addressing healthcare priorities identified by the WHO 2013 report on priority medicines for Europe and the world
- Strategic Research Agenda aimed at progressing the vision of personalised medicines, for both prevention and treatment
- Collaboration across sectors to harness all knowledge and technologies which can contribute to IMI2 vision - diagnostics, imaging, IT, medical devices, ...

IMI2: Major Axes of Research



Drive change in delivery of medical practice

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

IMI – Europe's partnership for health

IMI1 programme 2008-2013

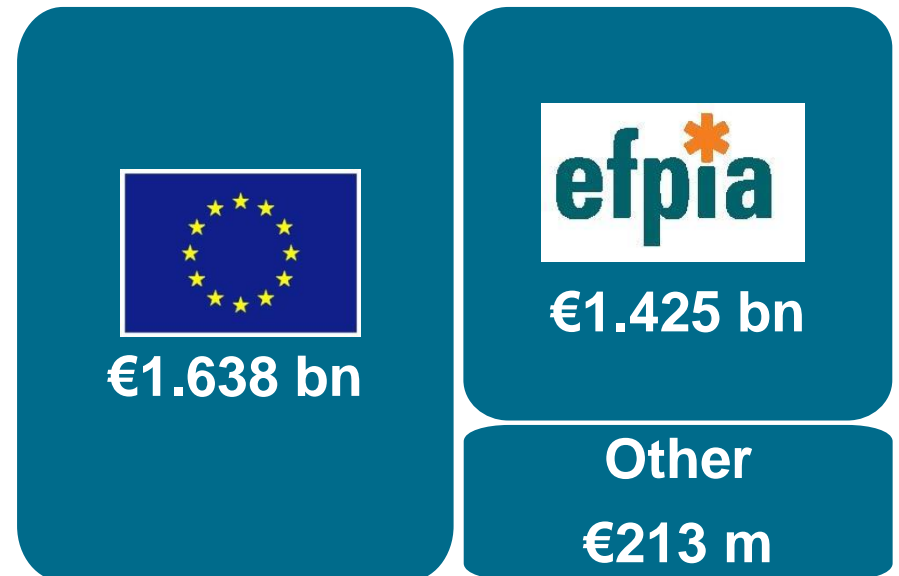
- €2bn budget
- 11 Calls for proposals
- 59 projects

IMI2 programme 2014-2024

- Larger budget
- Ambitious Strategic Research Agenda
- Open to other industries

IMI2 total budget

€3.28 bn



IMI2 - Broad participation to be able to set ambitious goals

IMI is evolving, with a stronger focus on the needs of patients and society and with simpler rules and procedures

Evolution in scientific focus

- Stronger focus on needs of patients and society, including unmet needs
- Increased emphasis on improving patient access to innovative medicines (in addition to medicines development)
- Focus on personalised medicine (**the right treatment for the right patient at the right time**)

IMI rules and procedures

A single set of rules



EU Financial
Regulation

Specific rules
for
participation

- **Covering all H2020 research and innovation actions**
- **Adaptability where needed:**
 - Entities eligible for funding
 - IP

Who is eligible for funding?

- Academic institutions
- Small & medium-sized enterprises (SMEs)
- Mid-sized enterprises (\leq €500m)
- Non-profit organisations e.g. research organisations, patient organisations, NGOs, public bodies, intergovernmental organisations etc.

Established in:

- **EU Member State**
- **Associated Country**

Other countries:

No funding unless

- participation deemed essential by IMI for carrying out the action

- foreseen in the **Annual Work Plan**

Simplified conditions for participation

- **Minimum conditions for standard collaborative actions**

Research and Innovation Actions: At least **three** legal entities

Coordination and Support Actions: At least **one** legal entity
each established in a different Member State or
an associated country

- **Additional conditions**

In the annual work plan (and Call documents)

One single funding rate per project

One project = One rate

For all beneficiaries and all activities

Defined in the annual work plan/Call documents:


- Up to 100% of the eligible costs
- Limited to a maximum of 70% for innovation projects (exception for non-profit organisations - maximum of 100%)

One single indirect cost model

**Single
model:
25 % Flat
Rate**

A more attractive funding model

An example

 <i>Majority of beneficiaries</i>	Direct costs	Indirect costs	Total costs	% EU contribution	EU contribution
Flat-rate (20%) (or actual)	100	20	120	75%	€ 90

HORIZON 2020	Direct costs	Indirect costs	Total costs	% IMI2 contribution	IMI2 contribution
100/25 Funding	100	25	125	100%	€ 125

EFPIA and Associated Partners

- EFPIA companies
- Other industries and partners (= Associated Partners to IMI2)
New!
 - In-kind (actual direct and indirect costs or average FTE) + cash contributions
 - Based on the usual management principles and accounting practices
 - Contributions from affiliated entities as part of in-kind

Proposals accepted from third parties

When relevant to IMI2 objectives: up to 30% non-EU in-kind contribution

The 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

IMI2 – Calls

IMI2 - Call1

Launch date: **09 July 2014**

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

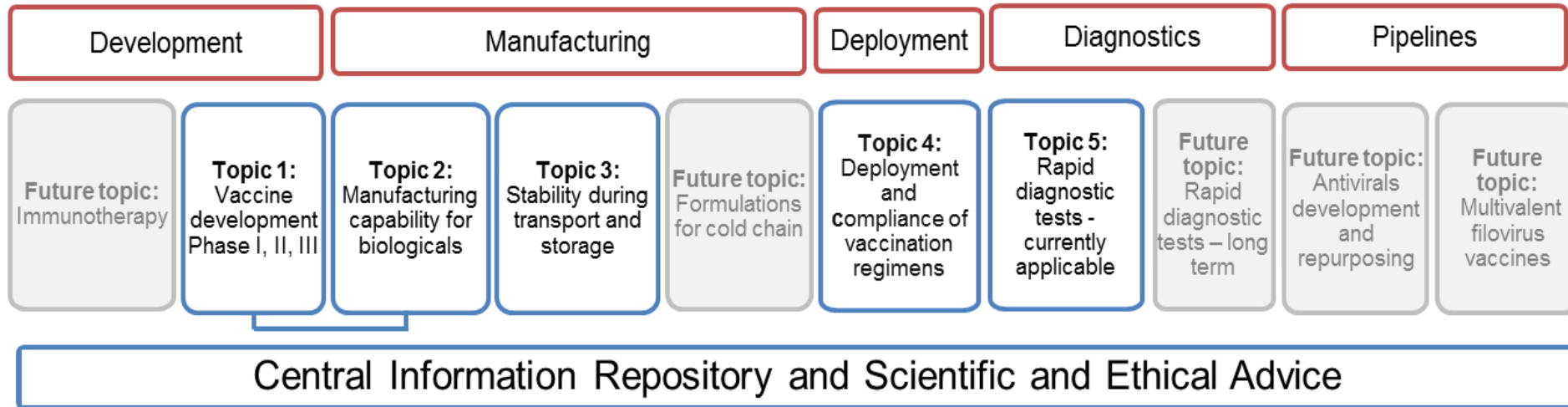
Nathalie.Seigneuret@imi.europa.eu

Submission date: **12 November 2014**

IMI2 - Call2: Ebola+ programme overview

Launch date: **06 Nov 2014**

IMI2 Ebola and other Filoviral Haemorrhagic Fevers (Ebola+) Programme



Submission date: **01 December 2014**

‘Single stage fast track process’

IMI 2 – Calls 3 & 4

Research and innovation topics (Call 3)

- Remote assessment of disease & relapse (RADAR): CNS
- Assessing risk & progression of prediabetes & type 2 diabetes
- Linking clinical neuropsychiatry & quantitative neurobiology
- Quality control in vaccine manufacture
- Pertussis vaccination research
- Knowledge repository for patient focused medicine development

Submission deadline: **24 March 2015**

Coordination and Support Action (Call 4)

- Enabling platform on medicines adaptive pathway to patients

Submission deadline: **11 February 2015**

Reference documents

- **H2020 Rules for Participation**
- **IMI2 Delegated Regulation**
- **IMI2 Call Documents**
- **IMI2 model Grant Agreement (revised)**
- **IMI2 annotated Grant Agreement (soon)**

[**www.imi.europa.eu/content/documents**](http://www.imi.europa.eu/content/documents)

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Thank you

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