

Innovative Medicines Initiative (IMI) Current & future funding opportunities

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Outline

What is IMI and why do we need it?

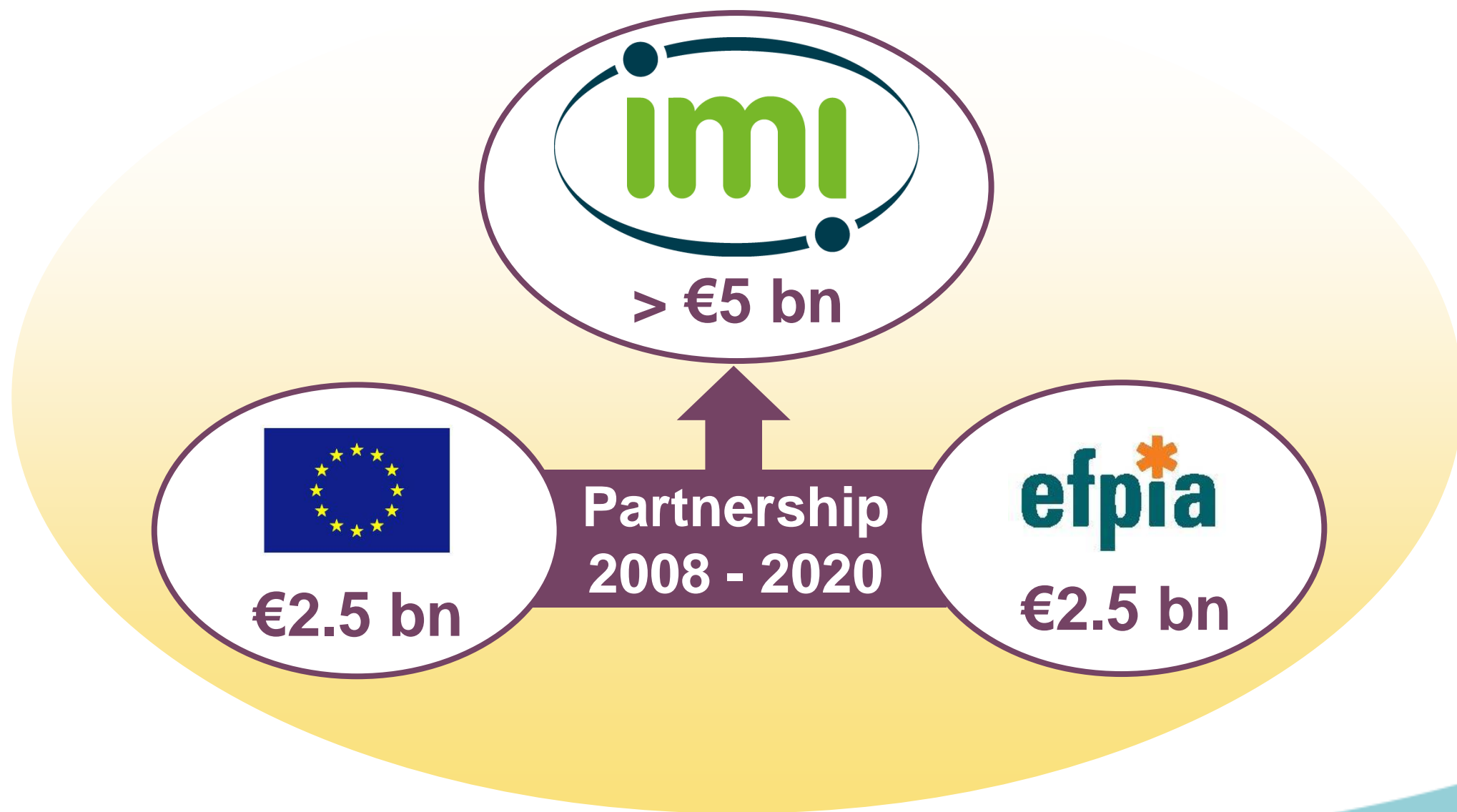
How does IMI work?

What's in it for me?

Current / future funding opportunities

What is IMI and why do we need it?

IMI – Europe's partnership for health



Why do we need IMI?

Because drug development is very...

risky

inefficient

complex

time
consuming

expensive

Because...

Not enough
science
throughout
development

Clinical trial
designs not
always optimal

Regulatory
pathways not
always optimised

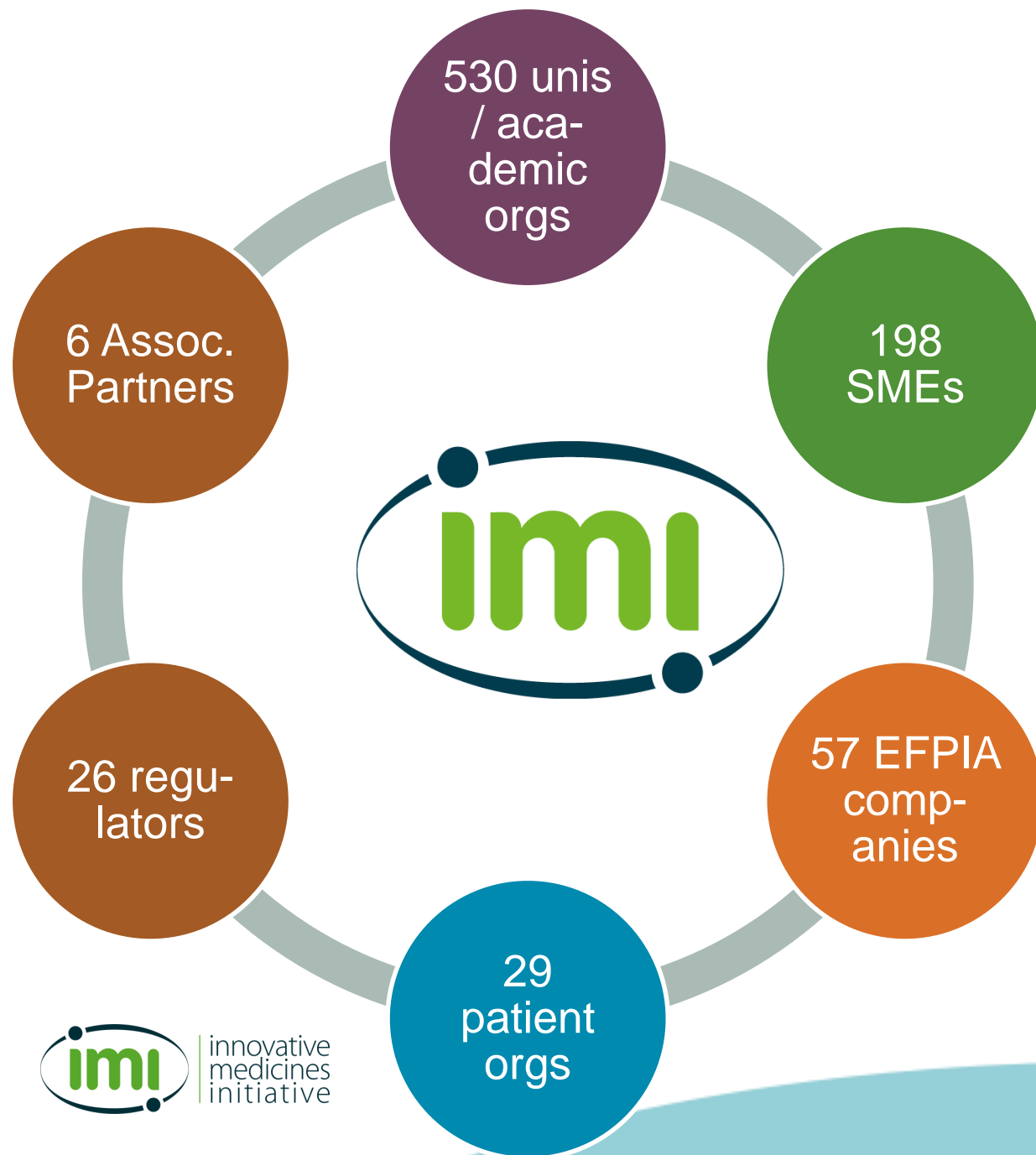
How is IMI addressing the challenges in drug development?

Through IMI's projects we are trying to...

- **put patients at the centre**
- **share risk** (among public & private players)
- **increase efficiency** (by developing common tools)
- **reduce duplication of effort** (esp. at early stages)
- **reduce timelines** (by using a personalised medicine approach)
- **integrate the latest science** into drug development
- **use data and knowledge management** to work more effectively

We do this by creating a **neutral platform** where **all involved** in drug development – academics, industry, SMEs, patients, regulators, others – can engage in **open collaboration** on **shared challenges**.

An international, cross-sector community



Over 11 500 researchers working for:

- open collaboration
- improved R&D productivity
- innovative approaches to unmet medical needs

Figures as of end 2016

How does IMI work?

Goals of IMI2 programme

- ✓ **Improve the drug development process** by creating tools to assess the efficacy, safety and quality of medicines
- ✓ **Develop biological markers to diagnose** diseases and **assess** treatments
- ✓ **Speed up the earlier stages** of drug development
- ✓ **Increase the success rate of clinical trials** of priority medicines
- ✓ **Develop new therapies** for diseases with a high unmet need / limited market incentives
- ✓ Reduce the failure rate of **vaccine candidates** in clinical trials



Official Journal of the European Union
COUNCIL REGULATION (EU) No 557/2014
of 6 May 2014
establishing the Innovative Medicines Initiative 2 Joint Undertaking
(Text with EEA relevance)

IMI 2 Strategic Research Agenda

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



The right prevention and treatment
for the right patient at the right time

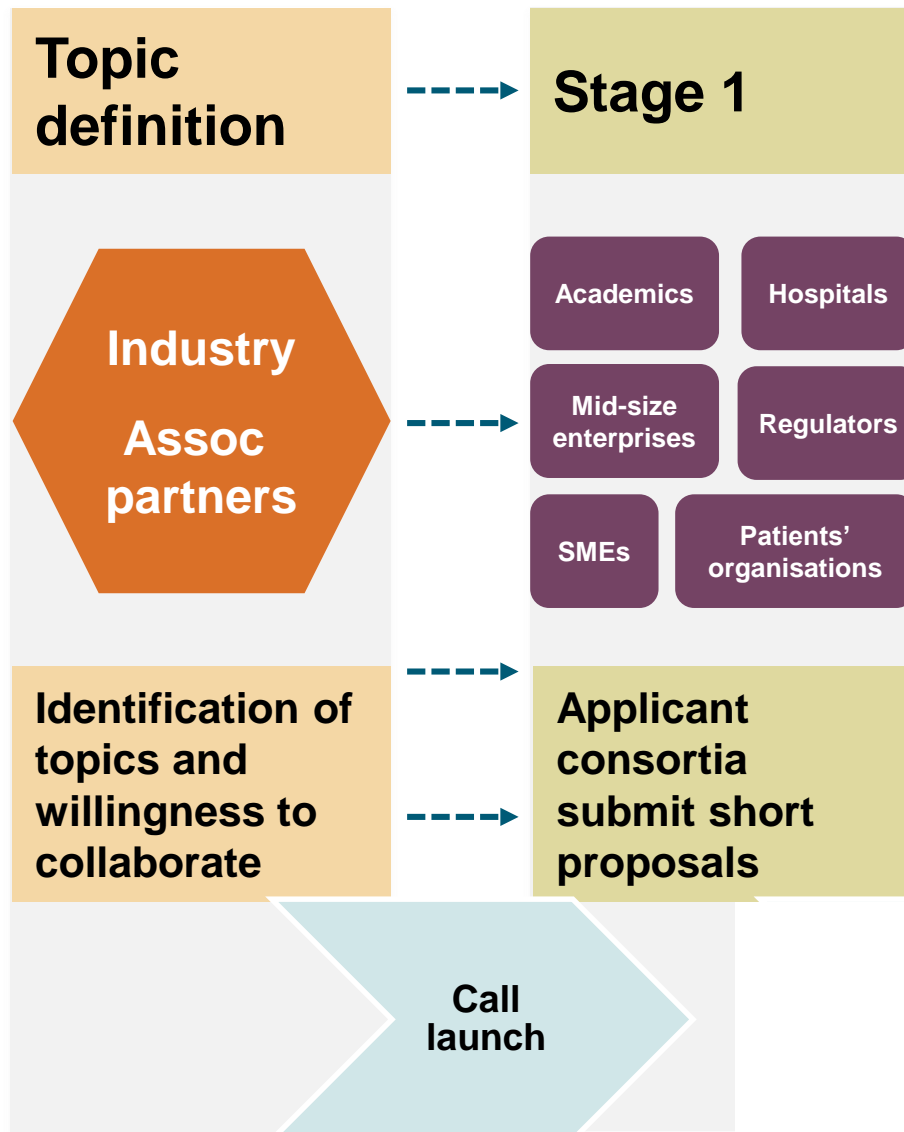
Strategic Research Agenda for
Innovative Medicines Initiative 2

**Aligned with
WHO priorities**

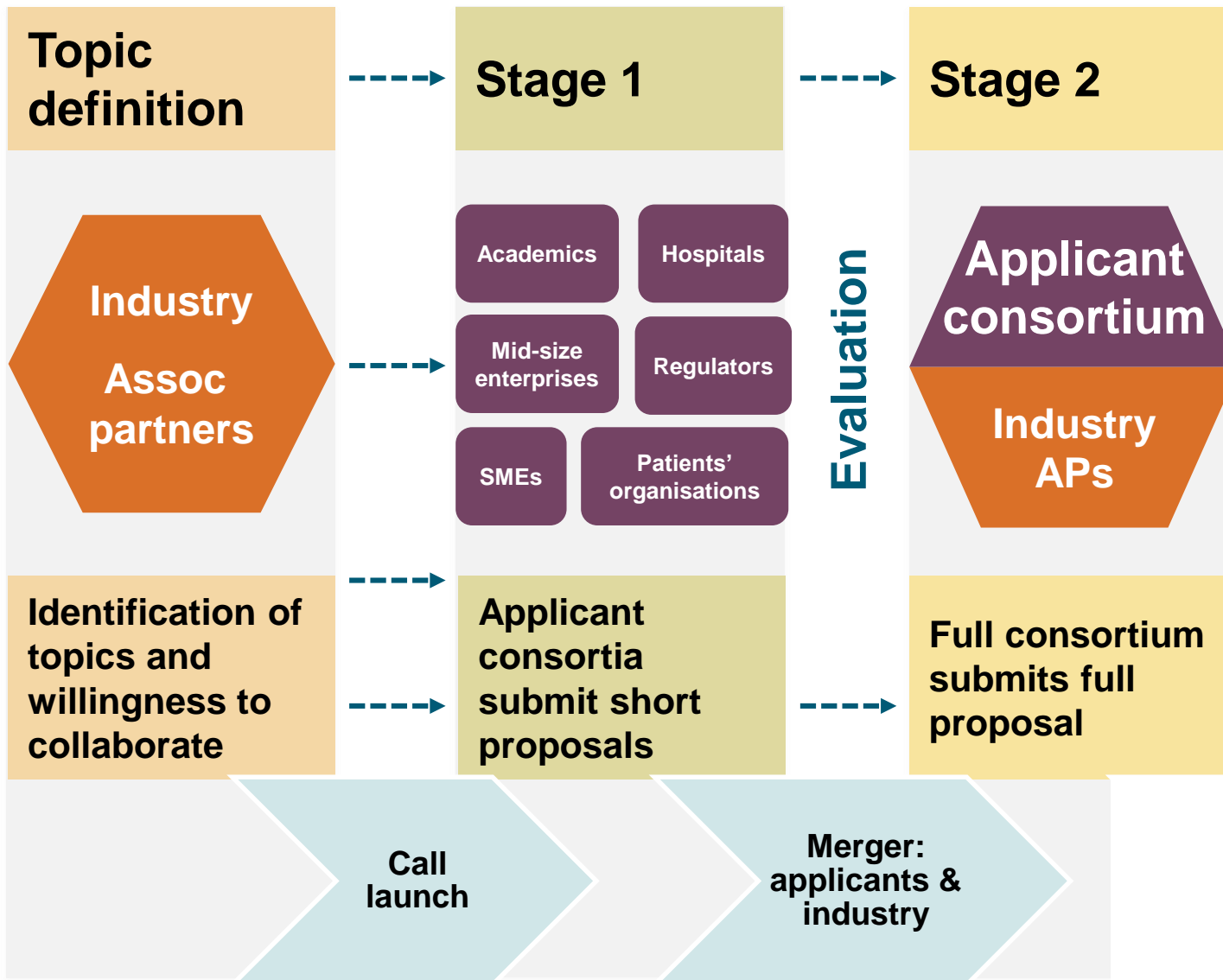
Typical IMI project life cycle



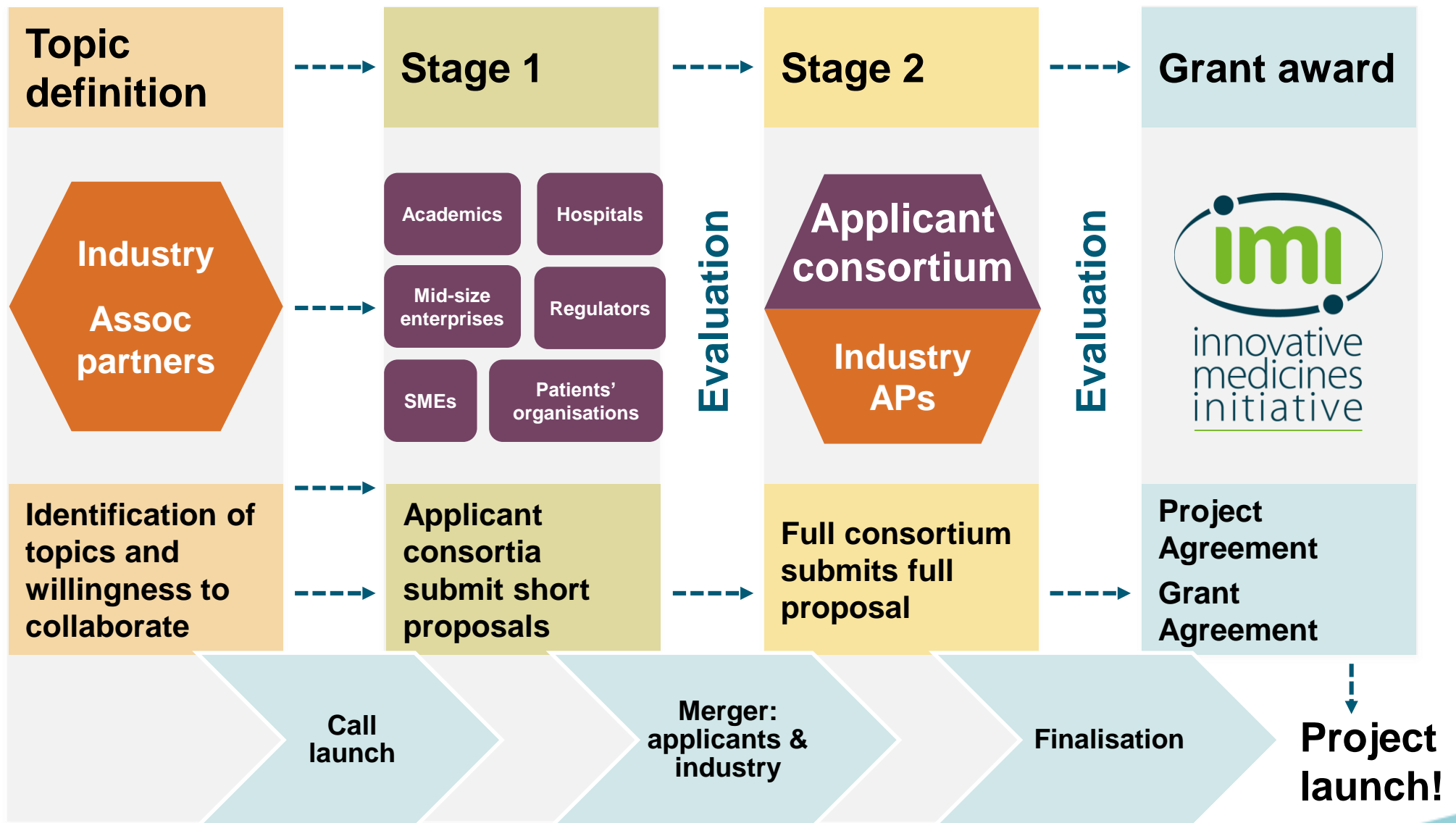
Typical IMI project life cycle



Typical IMI project life cycle



Typical IMI project life cycle



What's in it for me?

Benefits of participating in IMI projects include...

- Form new networks and partnerships with top teams from industry, academia, SMEs, patients and regulators
- Build reputation and visibility. IMI research has a citation impact of 2.03 - nearly twice the EU average
- Access to infrastructure, technology and resources
- Learn about industry standards
- Learn new ways of working from project partners
- Access to funding

Why should SME and biotechs consider participating in an IMI project?

- By engaging with all stakeholders, sectors, initiatives and funders across Europe, IMI provides a dynamic ecosystem for research and business networks
- Collaboration with large pharmaceutical companies allows access to whole value chain of drug discovery
- IMI ecosystem creates opportunities for further development and validation of assets while protecting background IP
- 100% funding for EU-based entities

Some observations from IMI first phase regarding SME involvement

- SMEs who are founder funded (rather than VC funded) seem to fit better with IMI
- SMEs that are platform technology driven rather than new product development driven seem to find a good match with IMI projects
- Scale is key to success
- Administrative resources and IP should be allowed for

IMI IP policy to support innovation

- Opportunity of further development and/or validation of background assets
- Background and sideground assets protected (no transfer)
- New results owned by the generator(s) and right to transfer ownership / for non-exclusive license
- Result owner to design on the best protection modalities
- Access to expertise from the other partners on equal basis
- Access rights for exploitation purposes to be negotiated on a case-by-case basis
- Dissemination subject to conditions, such as respect of the legitimate interests

ABIRISK unpicks risks of reactions to MS treatments

Analysed data from 20 000 MS patients in 4 countries
(with help from IMI's eTRIKS project)

Interferon beta

Higher risk: males, older people, starting treatment in April

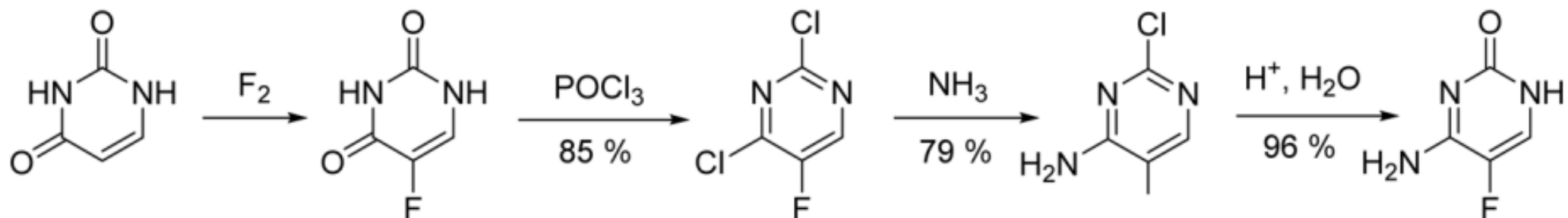
Natalizumab

Higher risk: women, older people

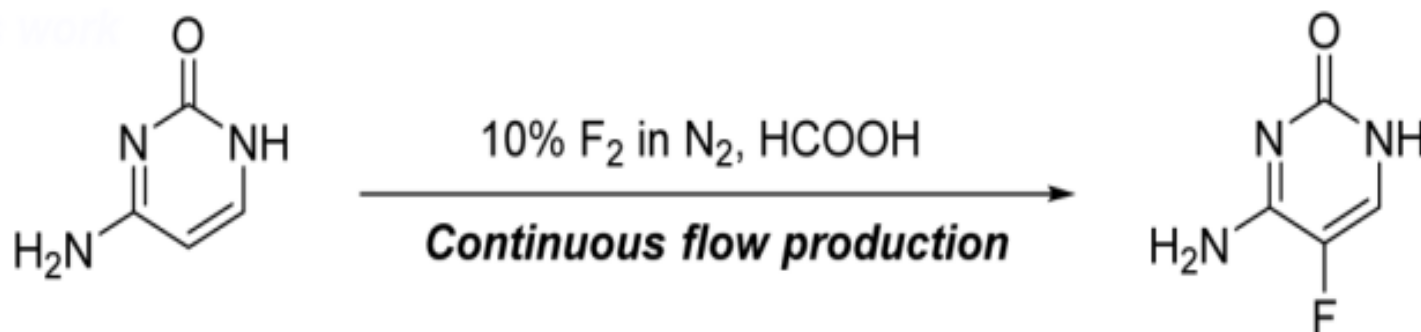
Implications: could improve monitoring of at-risk patients, develop interventions...

CHEM21 method could dramatically cut production costs of essential anti-fungal medicine

Current manufacturing process for flucytosine (4 reactions)



The CHEM21 process (1 reaction)



Medicines safety – an IMI success

What eTOX did

Pharma data

+

Public data

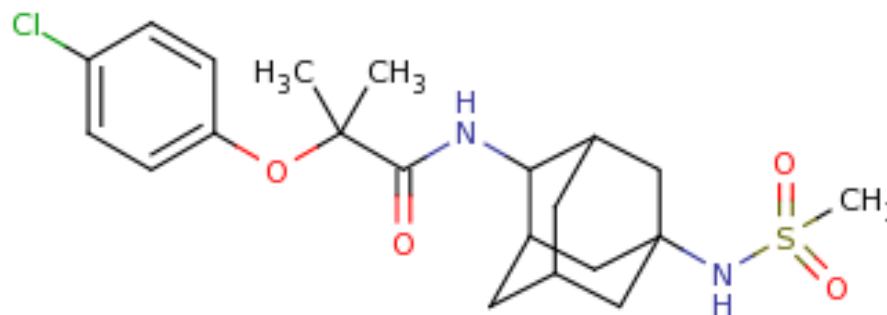
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One big database
underlying multiple
computer-based tools

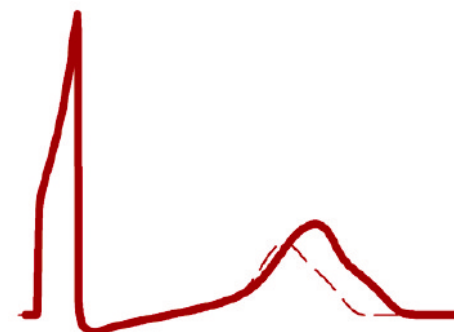
- ✓ Project partners using tools
- ✓ Reducing animal testing

Example: Will this be toxic to the heart?

Input = 2D
structure of a
possible drug



Output =
possible effect
on heart – ECG
result!



Current / future funding opportunities

IMI2 – Call 8

Open Call on Ebola & related diseases

Call launched December 2015, will remain open for two years.

- Opportunity to capture emerging scientific advances and progress those rapidly into healthcare interventions.
- Deliverables of projects funded must increase our preparedness to react to future outbreaks of Ebola and other filoviral haemorrhagic fevers.
- Projects can address vaccines, diagnostics, treatments, etc.
- Indicative IMI budget: **€25.85 million** (remaining)
- Cut-off dates: ~~16 March 2016, 15 September 2016,~~
~~16 March 2017, 14 September 2017,~~ **15 March 2018.**

IMI2 – Call 13 topics 1/2

- Assessment of the uniqueness of **diabetic cardiomyopathy** relative to other forms of heart failure using unbiased phenomapping approaches
- Genome-environment interactions in **inflammatory skin disease**
- The value of **diagnostics** to combat **antimicrobial resistance** by optimising antibiotic use
- **Mitochondrial** dysfunction in **neurodegeneration**
- **Support and coordination action** for the projects of the **neurodegeneration** area of the Innovative Medicines Initiative
- A sustainable European **induced pluripotent stem cell platform**
- Linking **digital assessment of mobility** to clinical endpoints to drive regulatory acceptance and clinical practice

IMI2 – Call 13 topics 2/2

- Human **tumour** microenvironment **immunoprofiling**
- CONCEPTION – continuum of evidence from **pregnancy** exposures, reproductive toxicology and **breastfeeding** to improve outcomes now
- Improving the **preclinical prediction of adverse effects** of pharmaceuticals on the **nervous system**
- **Translational safety biomarker pipeline** (TRANSBIOLINE): enabling development and implementation of novel safety biomarkers in clinical trials and diagnosis of disease

Pilot programme on a clinical compound bank for repurposing

- **4 topics:** cardiovascular diseases and diabetes; respiratory diseases; neurodegenerative diseases; rare/orphan diseases

IMI2 – Call 13 key information

Deadline for short proposals: 28 February 2018

- Budget from IMI/H2020: **EUR 116 421 000**
EFPIA / Associated Partner contributions: **EUR 106 629 000**
- Call web page: bit.ly/IMI2Call13
- Sign up for / catch up on the webinars: bit.ly/Call13webinars
 - 11/12: Induced pluripotent stem cell platform
 - 11/12: Pregnancy, reproductive toxicology & breastfeeding
 - 12/12: Adverse effects of drugs on nervous system
 - 14/12: Digital assessment of mobility & clinical endpoints
 - 14/12: Diabetic cardiomyopathy
 - 15/12: Diagnostics and antimicrobial resistance
 - 15/12: Inflammatory skin disease

Future plans for 2018 and beyond

'Think big'

Immunology

Antimicrobial
resistance

Digital health /
big data

Modernisation
of clinical trials
& regulatory
pathways

Tips for applicants

- Start working early
- Get informed
- Find partners
- Read and understand the Call documents
- Ask questions
- Make sure you address the requirements of the topic
- Don't forget to address any ethical issues
- Don't forget the basics (eligibility criteria, deadlines, format)
- The evaluators aren't psychic

Good luck!

Stay in touch

- Visit our new website www.imi.europa.eu
- Sign up to our newsletter [via the website](#)
- Follow us on Twitter [@IMI_JU](https://twitter.com/IMI_JU)
- Join our LinkedIn group bit.ly/LinkedInIMI
- E-mail us infodesk@imi.europa.eu



The screenshot shows the IMI website homepage. At the top left is the IMI logo (innovative medicines initiative). To the right is the tagline "Europe's partnership for health". Below this is a navigation bar with links: Home, About IMI, Get involved, Apply for funding, Projects & results, News & events, and Reference documents. The main content area features a large image of a petri dish with colorful bacterial colonies. A text box in the center reads: "We are an EU public-private partnership funding health research and innovation". At the bottom, a teal bar displays key statistics: €5.3bn BUDGET, 90 PROJECTS, 864 PARTICIPANTS, 6 995 PROJECT OUTPUTS, and 2 686 PUBLICATIONS.

The screenshot shows the IMI Twitter profile page. The header includes the IMI logo and the text "innovative medicines initiative" and "#InvestEUresearch". Below the header are statistics: Tweets (5,476), Following (2,229), Followers (6,393), Likes (751), Lists (3), and Moments (0). The main content area shows a pinned tweet from October 24: "Commissioner @Moedas gets the Sierra Leone #Ebola vaccine trial experience with an iris scan at #JU4Innovation". The tweet includes a photo of Commissioner Carlos Moedas and others at a booth. Below the tweet are engagement icons (reply, retweet, like) and a count of 4 replies and 12 likes. Another tweet from 38 minutes ago is partially visible: "Next week we'll be at #BJOEUROPE in Berlin! Visit us at booth #111 and don't miss our SME session on Tue 7 Nov: bit.ly/2gOsDyS".



Thank you!

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