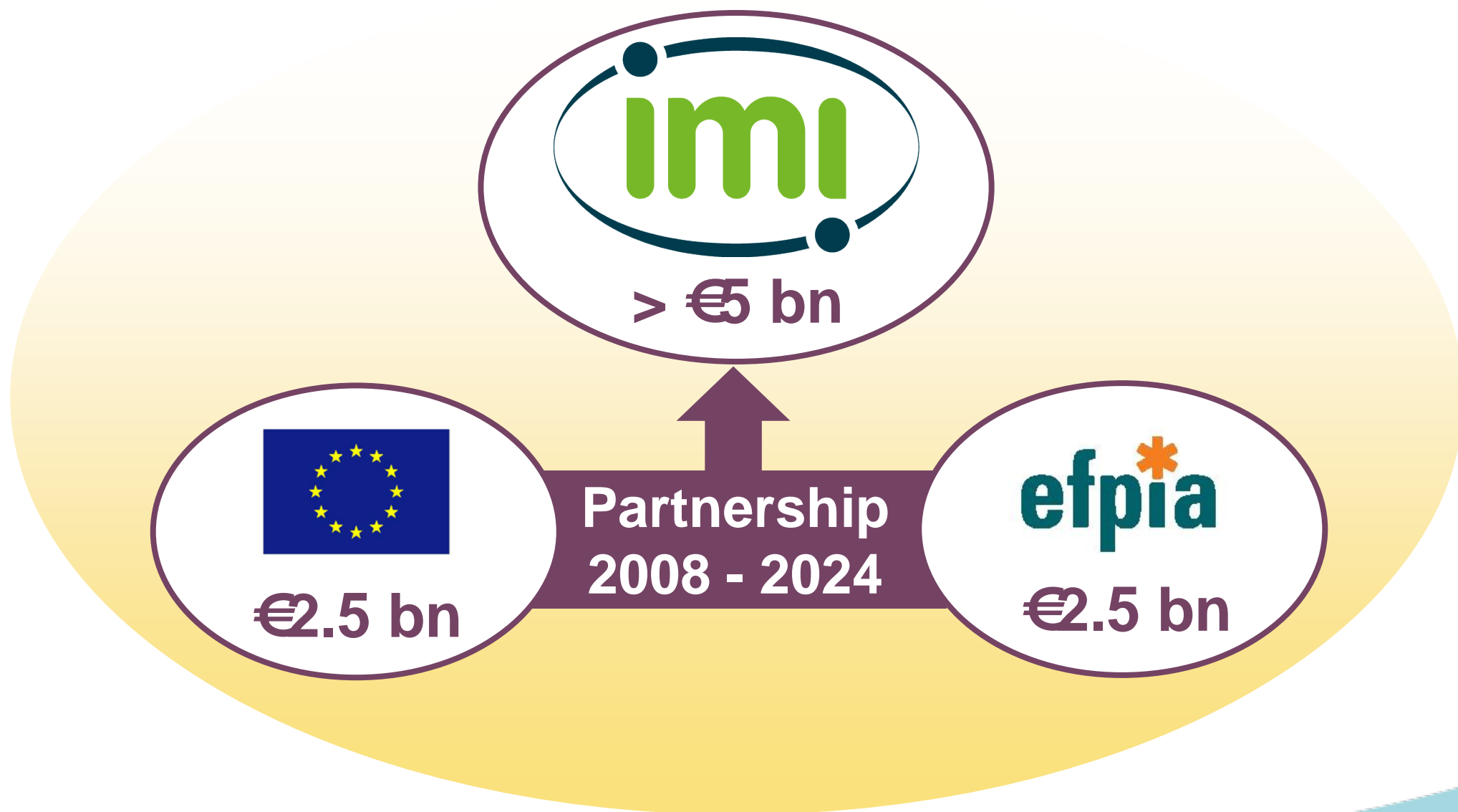


What is the Innovative Medicines Initiative?

IMI – Europe's partnership for health

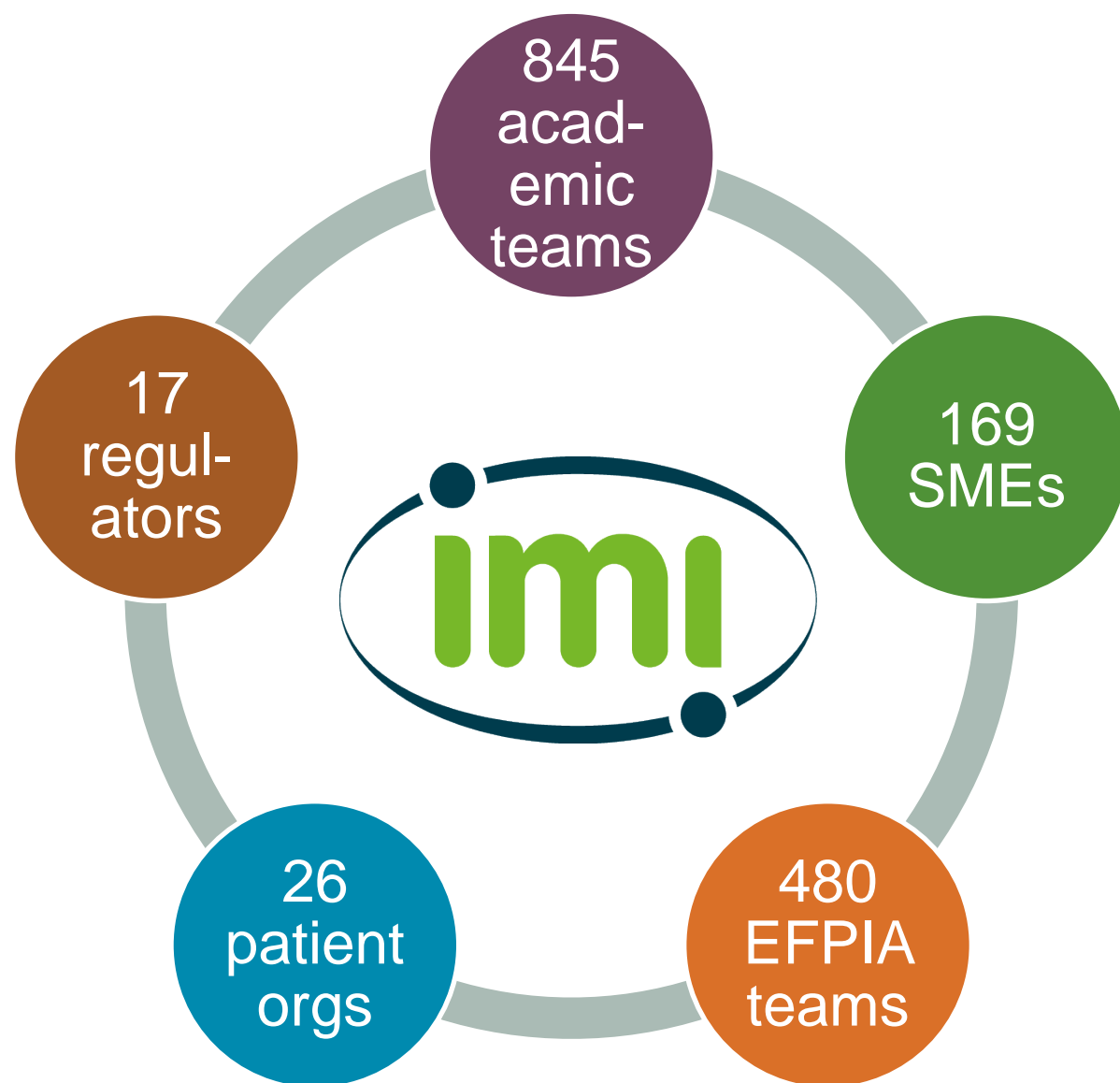


IMI – key concepts

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



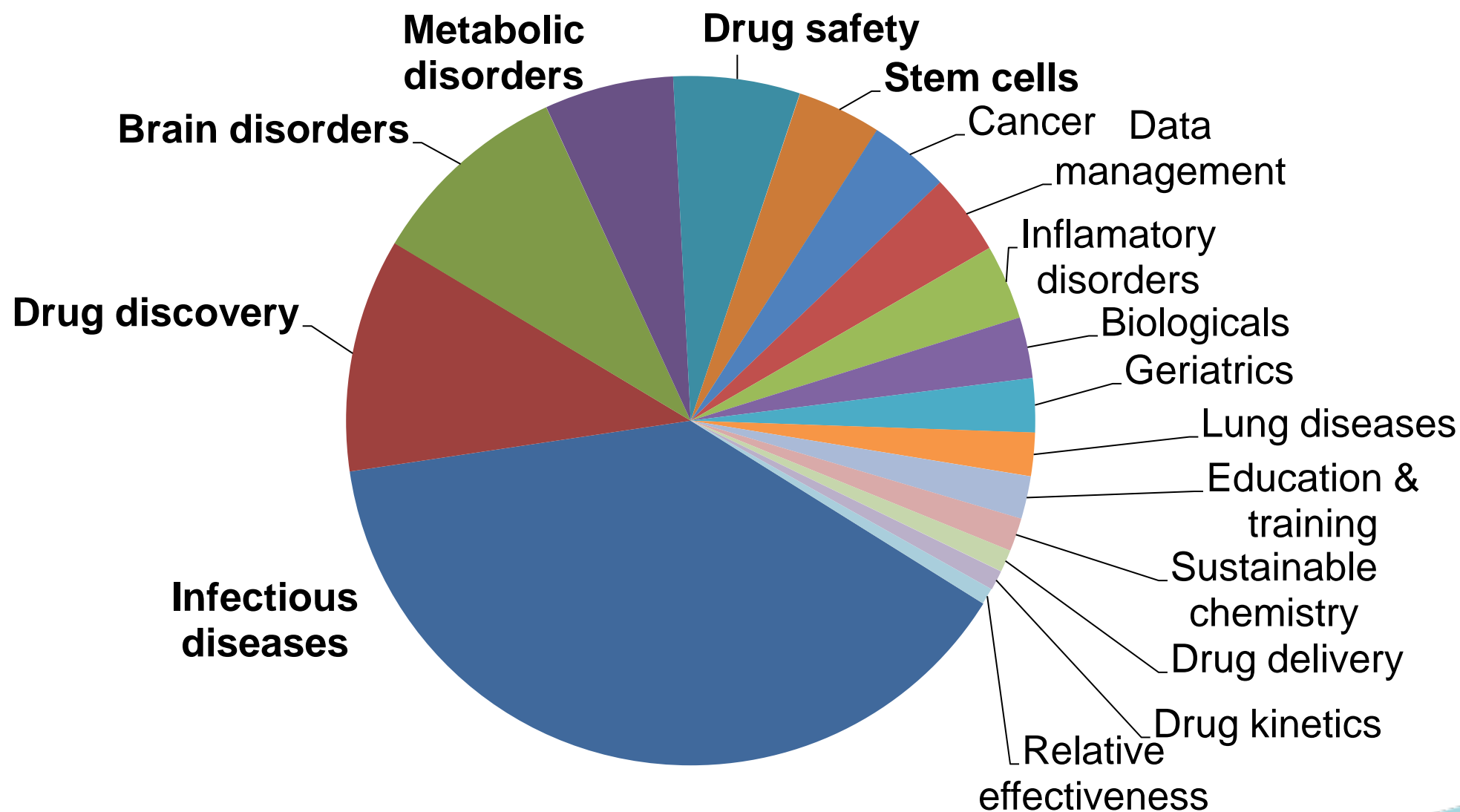
An international, cross-sector community



Over 7 000 researchers working for:

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

IMI 1 – €2 bn budget breakdown

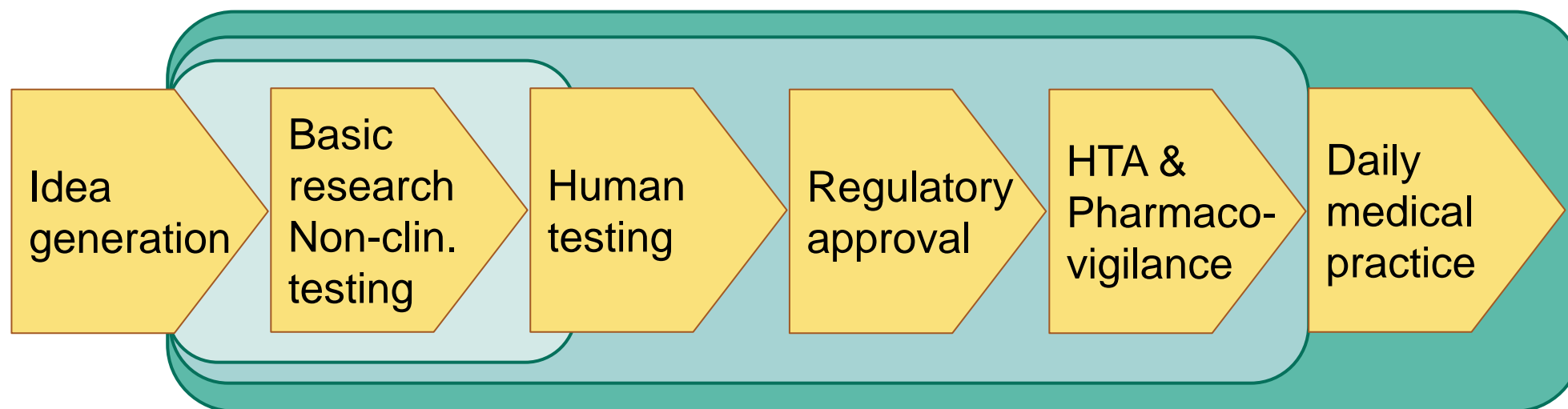


What is IMI 2?

Evolution of IMI

From bottlenecks in industry to bottlenecks in industry & society

- Make drug R&D in Europe more efficient & effective
- Enhance Europe's competitiveness in pharmaceutical sector



**Focus of early
IMI Calls
(2008 SRA)**

**Inclusion of society /
healthcare challenges
(2011 SRA)**

**Inclusion of real life
medical practice
(2014 SRA – IMI 2)**

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

What's new in IMI 2?

- Builds on **successes** of IMI 1
- Greater focus on speeding up **patient access** to new medicines (regulatory, HTA, etc.)
- SRA aligned with **WHO priorities**
- Creation of **Associated Partners** (3 and counting...)
- Involvement of **other sectors** (animal health, diagnostics, imaging...)
- Improved, simpler **funding** system
- More flexible **procedures**

IMI 2 budget (2014 – 2024)

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc...



€1.638 bn



€1.425 bn

Other

€213 m

IMI 2 total budget

€3.276 billion

EFPIA companies

receive no funding

contribute to projects 'in kind'

Associated Partners e.g. charities, non-EFPIA companies

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**



IMI 2 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 & interpretation
- Prevention, disease interception
- Patient adherence
- Health disease management
- Regulatory framework
- Reimbursement/patient access

IMI 2 Call 5

IMI 2 – Call 5 current indicative topics

- **Patient perspective** elicitation on **benefits and risks** of medicinal products from development through the entire life cycle, for integration into benefit risk assessments by **regulators** and **health technology assessment** bodies
- **Diabetic kidney disease** biomarkers
- **Inflammation and Alzheimer's disease** (AD): modulating microglia function – focussing on TREM2 and CD33
- Understanding the role of **amyloid biomarkers** in the current and future diagnosis and management of patients across the spectrum of **cognitive impairment** (from pre-dementia to dementia)
- Evolving models of **patient engagement** and access for earlier identification of **Alzheimer's disease**: phased expansion study
- **Apolipoprotein E** (ApoE) biology to validated **Alzheimer's disease** targets

IMI 2 – Call 5 current indicative budget

IMI 2 -2015-05-01	<p>The indicative contribution from EFPIA companies is EUR 6 000 000.</p> <p>The financial contribution from IMI 2 is a maximum of EUR 6 000 000.</p>	<p>Research and Innovation action.</p> <p>Two stage submission and evaluation process.</p> <p>Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.</p>
IMI 2 -2015-05-02	<p>The indicative contribution from EFPIA companies is EUR 13 235 000.</p> <p>The indicative contribution of IMI 2 Associated Partners is EUR 1 851 000.</p> <p>The financial contribution from IMI 2 is a maximum of EUR 15 086 000.</p>	<p>Research and Innovation action.</p> <p>Two stage submission and evaluation process.</p> <p>Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.</p>
IMI 2 -2015-05-03	<p>The indicative contribution from EFPIA companies is EUR 8 838 000.</p> <p>The financial contribution from IMI 2 is a maximum of EUR 8 838 000.</p>	<p>Research and Innovation action.</p> <p>Two stage submission and evaluation process.</p> <p>Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.</p>

IMI 2 – Call 5 current indicative budget

IMI 2 -2015-05-04	<p>The indicative contribution from EFPIA companies is EUR 12 000 000.</p> <p>The financial contribution from IMI 2 is a maximum of EUR 12 000 000.</p>	<p>Research and Innovation action.</p> <p>Two stage submission and evaluation process.</p> <p>Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.</p>
IMI 2 -2015-05-05	<p>The indicative contribution from EFPIA companies is EUR 2 043 000.</p> <p>The financial contribution from IMI 2 is a maximum of EUR 2 043 000.</p>	<p>Research and Innovation action.</p> <p>Two stage submission and evaluation process.</p> <p>Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.</p>
IMI 2 -2015-05-06	<p>The indicative contribution from EFPIA companies is EUR 3 510 000.</p> <p>The financial contribution from IMI 2 is a maximum of EUR 3 510 000.</p>	<p>Research and Innovation action.</p> <p>Two stage submission and evaluation process.</p> <p>Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.</p>

Expected consortia at Stage 1 (Short Proposals)

- **Consortia consisting of:**
 - IMI fundable legal entities carrying out activities relevant for achieving the project objectives
 - additional legal entities carrying out activities relevant for achieving the project objectives.
 - Stage 2 – Full proposals industry companies (in-kind and direct financial contributions)

Partner Search Tool



The screenshot shows the IMI Partner Search Tool website. The header includes the IMI logo (Innovative Medicines Initiative) and a navigation bar with links for Contact, Newsletter, and Links. A search bar is visible on the right. The main content area is titled 'Partner search' and describes the tool's purpose: to facilitate the search for potential partners for an Expression of Interest in response to an IMI Call for proposals. It lists several key features and updates, including accessibility through a link, inclusion of key words for IMI 2 Call 1, and improvements to the tool's functionality. A sidebar on the left contains a navigation menu with links to Home, About IMI, Ongoing projects, Calls for proposals, News, Events & Media, and Reference documents. Below the menu are sections for 'LATEST NEWS' and 'UPCOMING EVENTS', each with a list of recent updates and dates.

Partner search

IMI provides an online **partner search tool** for people, organisations and enterprises interested in participating in future IMI projects.

The tool facilitates the search for potential partners for an Expression of Interest in response to an IMI Call for proposals.

- The Partner Search Tool is accessible through [this link](#)
- Full lists of **key words** has been included for the **IMI 2 Call 1** Call for proposals.
- The Partner Search Tool was improved, updated and moved to a new location in June 2012. If you were already registered in the previous version of the tool, your profile is automatically included in the new tool, but you will need to **reset your password**, by going to 'Login with an existing account' on the login page.
- People who used the partner search tool for IMI's previous Calls for proposals are advised to update their profiles to reflect the new topics that they are interested in.

If you have any difficulties using the partner search tool, contact [pst\[at\]imi.europa.eu](mailto:pst[at]imi.europa.eu)

LATEST NEWS

11/07/2014 : RT @EFPIA: Friday means a FRESH EFPIA Newsletter! Highlight of the week @IMI_JU @innovationunion #horizon2020 #JTICalls2014 READ <http://t.c...>

10/07/2014 : RT @MichelGoldman: @IMI_JU future:we are very proud to welcome @JDRF to co-drive the type1 #diabetes topic of IMI2:#patients will be at the...

UPCOMING EVENTS

- **30/09/2014** - **IMI 2 Open Info Day 2014** IMI will hold an Open Info Day on its

www.imi.europa.eu/content/partner-search

<http://www.fitforhealth.eu/>

Consortia at Stage 2 (Full Proposals)

- **Consortia consisting of:**
 - Partners of the 1st ranked proposal
 - Industry consortium (contributing with in-kind/cash contributions)

IMI-2 Call 5 – Draft Timelines

- **Consultation launch:** 17 April 2015
- **Call launch:** 30 June 2015
- **SP submission deadline:** 29 September 2015
- **SP in-house evaluation:** early November 2015
- **FP submission deadline:** End February 2015
- **Project launch:** Summer 2016

Future IMI Calls - timelines & info

- Download the **indicative Call text**:
<http://bit.ly/futuretopics>
- Sign up for the **webinars** – info coming soon!

Disclaimer

All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

Keep up to date with Call launches

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



Submitting a proposal

LOG IN

Please enter your e-mail and password.

E-mail:

Password:

☐ Keep me logged in

[Forgot your password?](#)

The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of

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RESEARCH & INNOVATION
Participant Portal

European Commission > Research & Innovation > Participant Portal > Home

[HOME](#) [FUNDING OPPORTUNITIES](#) [HOW TO PARTICIPATE](#) [EXPERTS](#) [SUPPORT](#) [LOGIN](#) [REGISTER](#)

Welcome to the Research and Innovation Participant Portal

About the Participant Portal:

The Participant Portal is your entry point for the electronic administration of EU-funded research and innovation projects. It hosts services for managing proposals and projects throughout their lifecycle.

The Participant Portal supports activities funded mainly by the following EU programmes:

- 7th Framework Programme for Research and Technological Development (FP7)
- Competitiveness and Innovation Framework Programme (CIP)

Using the Participant Portal:

As a guest user, browse the public pages to:

- search for funding opportunities
- download guidance and legal documents
- search for the participant identification code (PIC) of an organisation
- contact the FP7 support services and browse the FAQ for guidance on the Participant Portal tools

As a registered user, benefit from personalised services for proposal submission, negotiation, and project management.

WHAT'S NEW **FUNDING OPPORTUNITIES** **HOW TO PARTICIPATE?** **WORK AS AN EXPERT** **ACCESS MY PERSONAL AREA** **INFORMATION AND SUPPORT**

Funding rules

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

One single funding rate per project

NEW 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
- but limited to a maximum of 70% for innovation projects (exception for non-profit organisations - maximum of 100%)

Considering accounting and management principles

- **Personnel**

- Wider acceptance of average personnel costs
- Acceptance of supplementary payments
- *New For* non-profit organisations of up to 8000 euros / year / person
- Less requirements for time records

- **Equipment, consumables, travels...**

- **Subcontracting**

One single indirect cost model (*new*)

**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

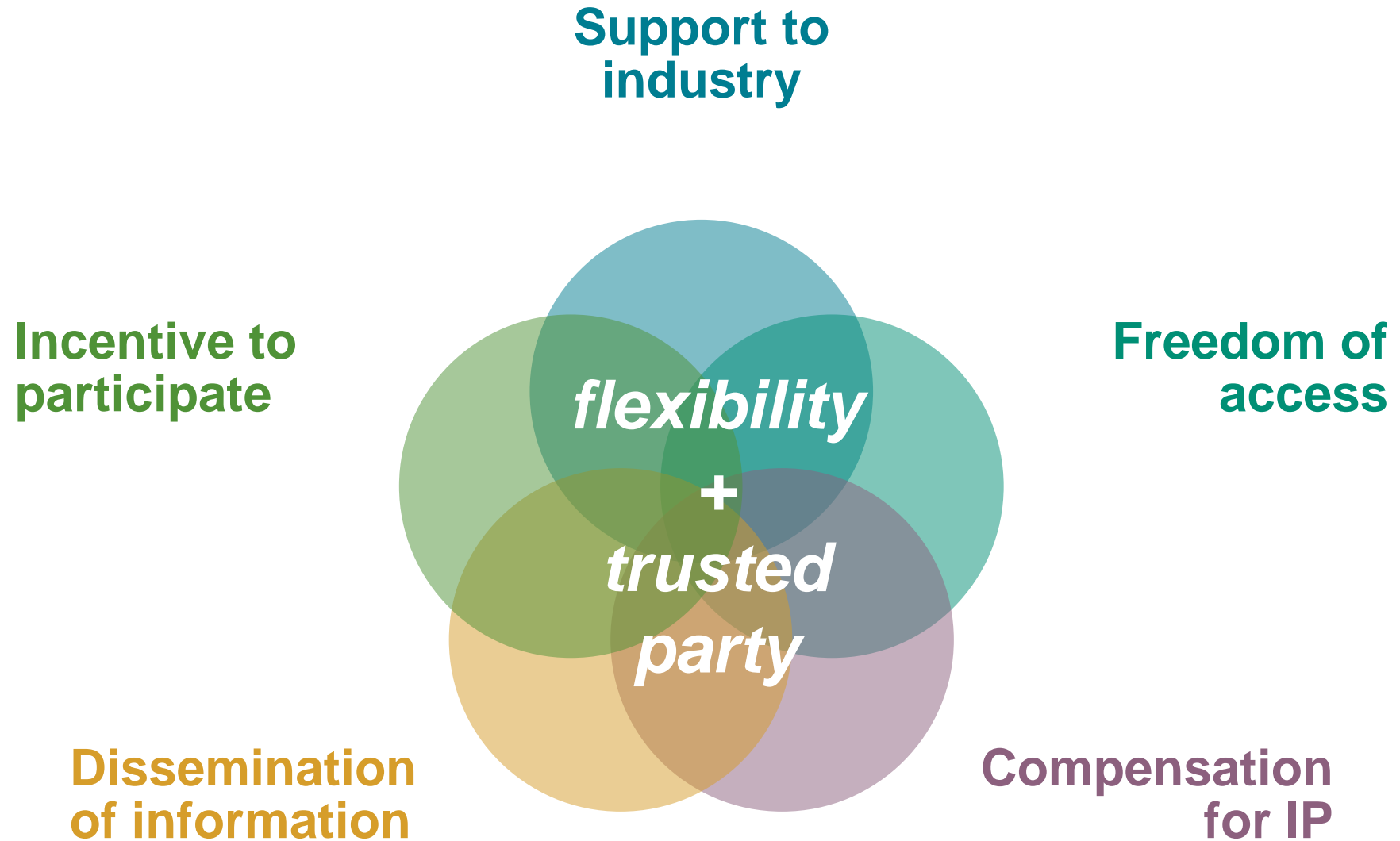
EFPIA and Associated Partners contribution

- 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

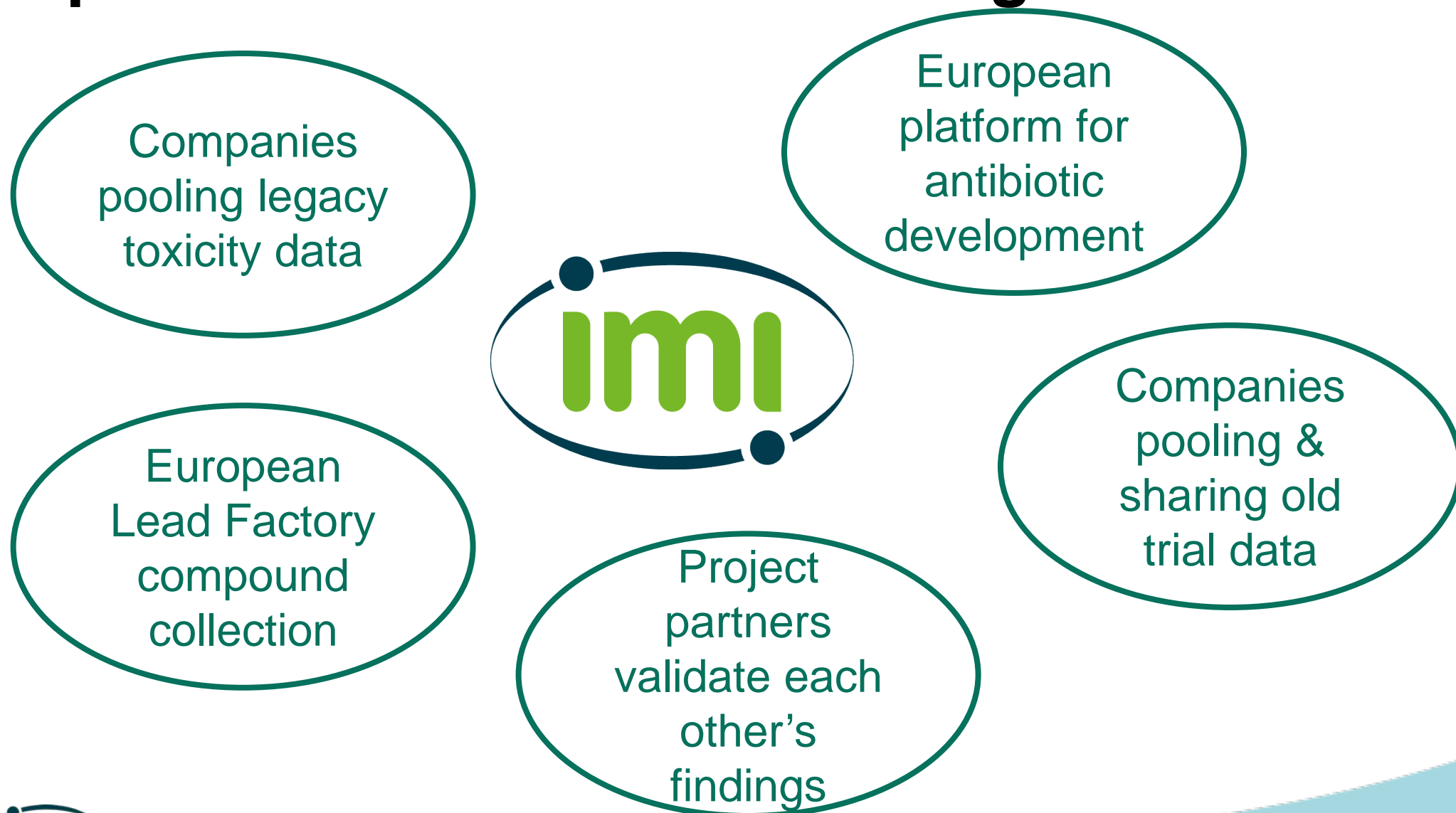
When relevant to IMI2 objectives: up to 30% non-EU in-kind contribution

IMI's Intellectual Property (IP) rules

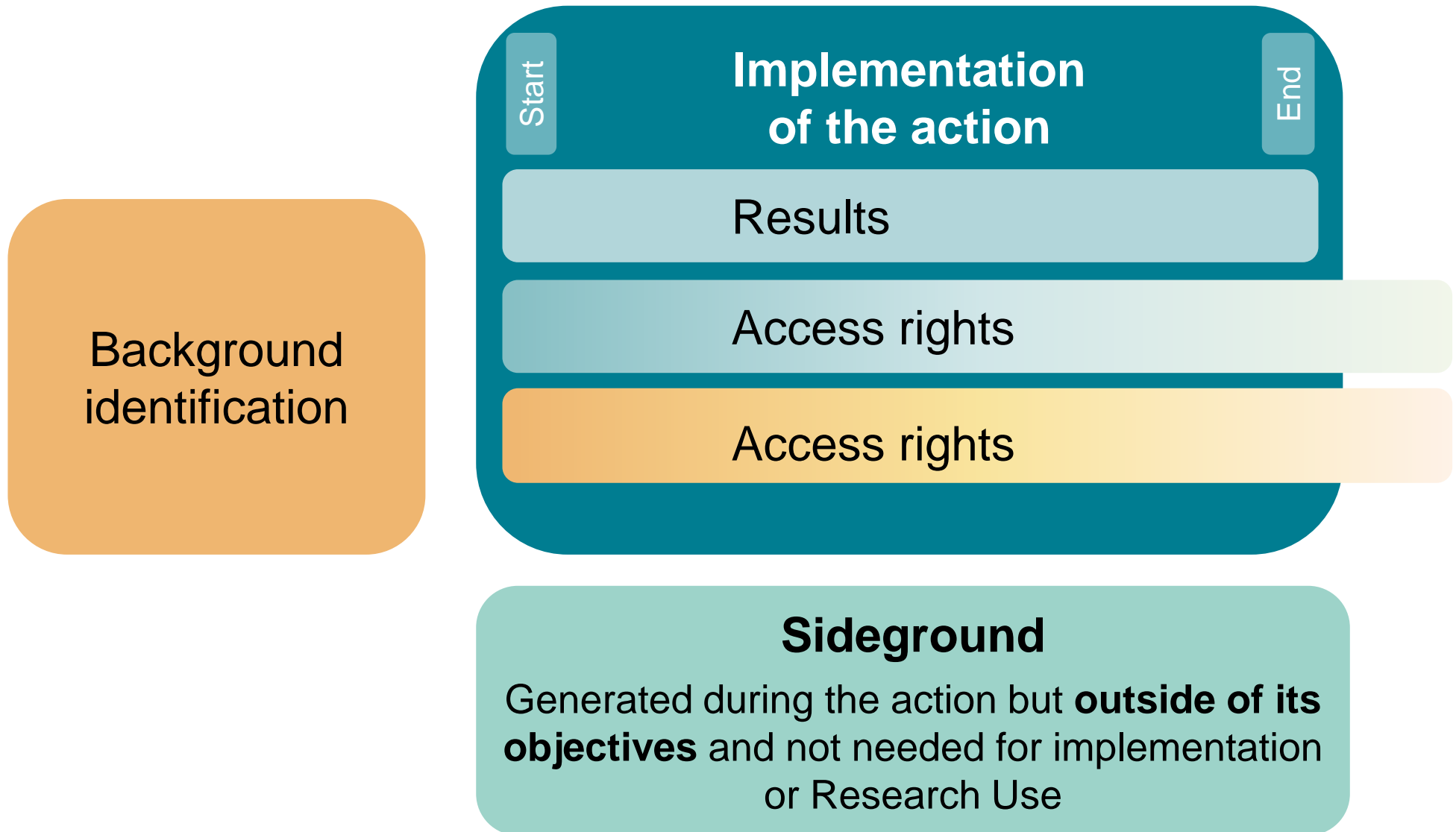
One policy for multiple interests



IMI IP policy has already allowed unprecedented levels of sharing



Background vs. Results



Ownership of results

Results belong to the beneficiary who generated it

- Possible transfer of ownership
- within the consortium to affiliates and purchasers without prior notification
 - on case-by-case basis

Joint ownership of results

Individual use of jointly owned results

provided prior notice and fair & reasonable compensation to the other joint owners

Based on previous experience

Protection of results

Mandatory for beneficiaries receiving funding *NEW*

Common practice

- lies with the owner(s) in adequate and effective manner → relevant (national) legal provisions, action peculiarities, legitimate interests
- if valuable results left unprotected → to be discussed within the consortium

Research Use vs. Exploitation

- **Research Use**

- Use of results or background necessary to use the results for all purposes other than for completing the action or for direct exploitation

Based on previous experience

- **Direct exploitation**

- to develop for commercialisation or to commercialise the results

Access Rights conditions

Access rights granted by a beneficiary to/on	Background (necessary and identified)	Results	Sideground
Beneficiaries for completion of the action	Royalty-free	Royalty-free	N.A.
Beneficiaries and affiliates for Research Use	Fair & reasonable terms for background needed for using the results	Fair & reasonable terms	N.A.
Third Parties for Research Use after the action	Fair & reasonable terms for background needed for using the results	Fair & reasonable terms	N.A.
Beneficiaries and affiliates or Third Parties for Direct Exploitation	To be negotiated	To be negotiated	N.A.

Based on previous experience

Access rights to results for third parties

- Only after the end of the action
- Possibility to exclude specific elements of background (**NEW** only for existing background)

Based on previous experience

- Time-limits to be agreed **NEW**

Granting modalities

Granted on written request unless otherwise agreed

Almost all ongoing IMI projects agreed that access rights to background are granted without any additional administrative step

Time-limits for requesting access **NEW**

To be agreed in the consortium agreement

Dissemination modalities

Each beneficiary has the obligation to disseminate its own results:

- As soon as reasonably practicable
- **NEW** for publications: Open access is mandatory

Mandatory mention to IMI support & Partners' in-kind contribution
in patent applications / all communications

Consortium agreement

- Contractual arrangement **between all participants** to set out their rights and obligations, especially governance, liability and IPR
- Shall comply with the IMI2 model **Grant Agreement**
- Generally before the signature of the Grant Agreement with the IMI Office
- **To be adapted to the specific needs of each IMI action!**

More information

Reference documents

- **H2020 Rules for Participation**
 - IPR section: Article 1.3.c and Articles 41 to 49
- **IMI2 Delegated Regulation**
 - IPR section: Articles 2 to 7
- **IMI2 model Grant Agreement** (revised January 2015)
 - IPR section: Articles 23a to 31
- **IMI2 annotated Grant Agreement** (soon)

www.imi.europa.eu/content/documents

Simplified model Grant Agreement



Core text

Special
clauses

General
conditions

Annex II

Specific
provisions

Annex III

Your contact points

At the IMI Programme Office

- General queries: infodesk@imi.europa.eu
- IP queries: IMI-IP-Helpdesk@imi.europa.eu

Local contacts

- IMI States Representatives Group: bit.ly/IMISRG
- Horizon 2020 Health National Contact Points: bit.ly/H2020_NCPs

Thank you!

Magali.Poinot@imi.europa.eu

www.imi.europa.eu

 @IMI_JU