Increase your chances for participation: IMI rules & Practical advice

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Participation and Funding Rules

Who can participate?

- Any entity carrying out work relevant to the IMI in a Member State or Associated Country
- Anyone else with the agreement of the IMI JU

BUT

Not all participating entities are eligible for funding

- Stage 1 : at least two independent legal entities eligible for funding
- Stage 2: + at least 2 EFPIA companies

Who is eligible for IMI funding?

- Academic institutions
- Non-profit research organizations
- Small & medium-size enterprises
- Non-profit patient organizations
- Non-profit public bodies and intergovernmental organizations including specialized agencies

carrying out activities in a Member State or a country associated to FP7

Main categories of eligible costs

- Personnel
- Other direct costs

  (Equipment, Consumables, Travel…)
- Subcontracting
- Overheads

Eligible vs. Ineligible costs

- Actual
- Incurred by the participant during the project
- Determined according to usual accounting and management principles and practices
- Recorded in the accounts of the participant
- Incurred for work carried out in a Member State or associated country
- Incurred for the sole purpose of achieving the project objectives related to an activity accordingly described

- Identifiable indirect taxes including value added tax
- Duties
- Interest owed
- Provisions for possible future losses or charges
- Exchange losses, cost related to return on capital
- Costs declared or incurred, or reimbursed in respect of another Union project
- Debt and debt service charges, excessive or reckless expenditure

Funding Rates

- **Research activities**
  - up to75% of total eligible costs
- **Other activities -> management, training, communication, IP, etc.**
  - up to 100% of total eligible costs
- **Indirect costs -> overheads**
  - Actual or flat rate 20%

No impact for beneficiaries changing their status

EFPIA in-kind contribution

- Actual direct and indirect costs or average FTE
- Based on the usual management principles and accounting practices
- Contribution from EFPIA affiliated entities as part of EFPIA in-kind

For research costs incurred in Europe

unless expressly foreseen *(e.g. AMR programme)*

Intellectual Property Rules

Strengths of the IMI policy

ONE policy for MULTIPLE interests

TRUSTED THIRD PARTY

Guiding principles

Support to
EU industry

Incentive to
participate

Freedom of
Access

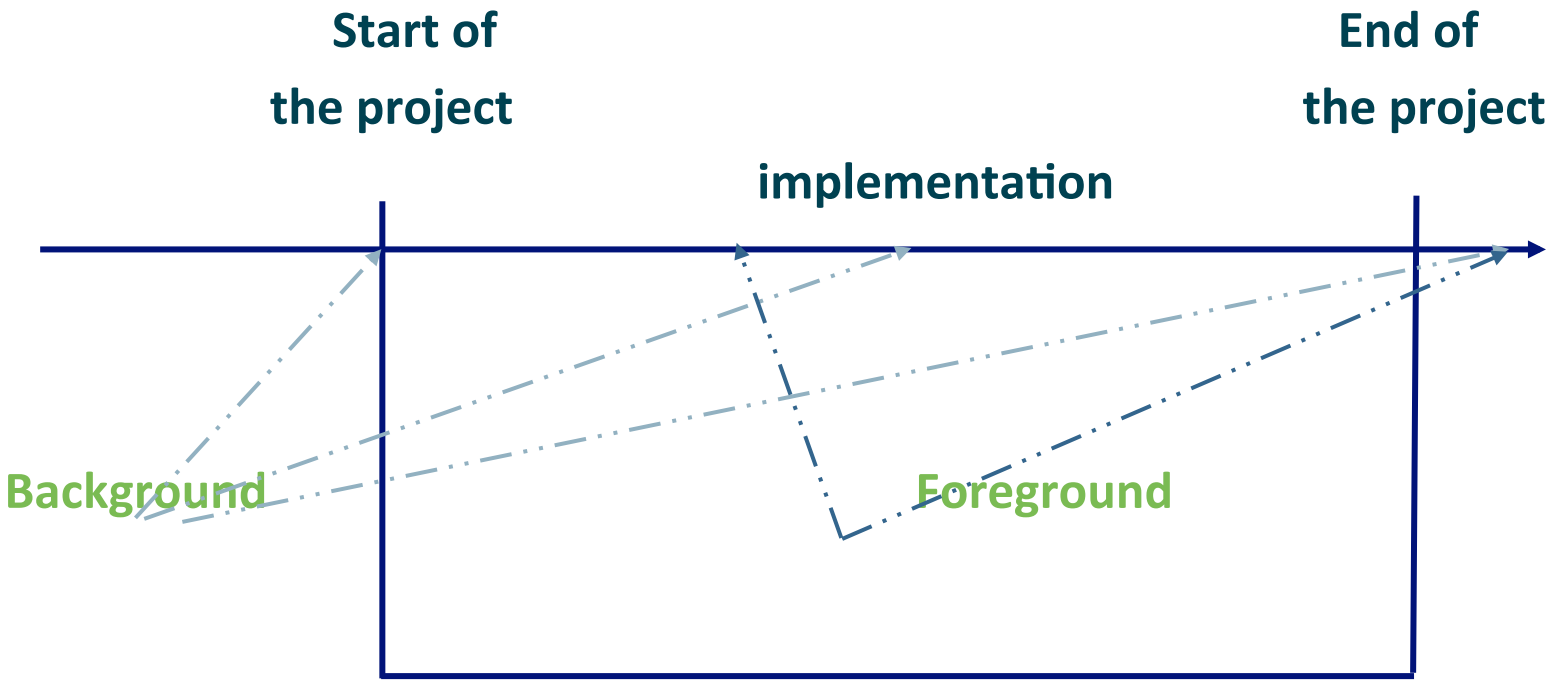
Dissemination
of information

Compensation
for IP

Project Agreement

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

Background vs. Foreground



// Sideground //

(generated during the Project but outside the Project Objectives and not needed for implementation or Research Use)

access rights

Ownership of Foreground and Sideground

Foreground and Sideground belongs to the participant who generated it

unless otherwise agreed

- European Lead Factory
- Antibiotic Clinical Trials
- iP Stem Cells Bank

Jointly owned Foreground

Individual use of joint Foreground is possible

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

all IMI projects

Transfer of Foreground

Foreground may be transferred to affiliates and subcontractors

without prior notification

all IMI projects

Unprotected valuable Foreground

may be transferred

not used yet

Protection of Foreground

- **Common practices (not mandatory):**
  - lies with the owner(s) in adequate and effective manner -> relevant (national) legal provisions, project's peculiarities, legitimate interests
  - if valuable Foreground left unprotected -> to be discussed within the consortium

Research Use vs. Exploitation

- **Research Use**
  - **use of Foreground or Background necessary to use Foreground for all purposes other than for completing the Project or for Direct Exploitation**

- **Direct Exploitation**
  - **to develop for commercialisation or to commercialise Foreground itself**

Access Rights: conditions

Access rights granted by a Participant to/on	**Background** (necessary and identified)	**Foreground**	**Sideground**
Participants for completion of the Project	**Royalty-free**	**Royalty-free**	N.A.
Participants and affiliates for Research Use	**Royalty-free OR Fair & reasonable terms** for Background needed for using Foreground as determined in Project Agreement	**Royalty-free OR Fair & reasonable terms** as determined in Project Agreement	N.A.
Third Parties for Research Use after the Project	**Fair & reasonable terms** for Background needed for using Foreground as determined in Project Agreement	**Fair & reasonable terms** as determined in Project Agreement	N.A.
Participants and affiliates or Third Parties for Direct Exploitation	To be negotiated	To be negotiated	N.A.

Research Use of Foreground

Access to Foreground for further developments - except commercialisation - granted on royalty-free basis or under fair & reasonable conditions*

- European Lead Factory
- Antibiotic Clinical Trials
- Antibiotic Discovery Platform

*may include financial terms and/or other conditions

Access rights to Foreground for third parties

Possibility to exclude specific elements of Background

- Europain
- European Lead Factory
- Real Effectiveness

Granting modalities

Granted on written request

unless otherwise agreed

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

Time-limits for requesting access

along the most appropriate needs

1/5 of the existing consortia have agreed on restricted time-limits based on projects' purposes

Dissemination modalities

Obligation to disseminate the Foreground

as soon as reasonably practicable

- European Lead Factory
- Antibiotic Clinical Trials instead of COMBACTE
- Antibiotic Discovery Platform instead of ENABLE

- Mandatory mention to IMI support & EFPIA in-kind contribution in patent applications / publications
- Promotion of open access publications

Conclusions of KU Leuven study (Oct. 2013)

- IMI projects reflect **successful partnerships** towards innovative scientific research build upon trust
  - Unique dynamics, openness, transparency, constructive, constant peer-review
  - Need for business plans
- IMI portrays the important **paradigm shift** in business models at companies and academia (e.g. IP strategy)
  - Timing of patenting and value consideration
  - Honest broker model as basis for sharing (non-) confidential data
- **Sharing** resources and outcomes create a multiplication effect in terms of scientific and business outcomes
  - Open EFPIA-Academia collaboration
  - Standardization and harmonization of scientific tools and protocols
- Value of IMI projects for **SMEs** is high, feasibility to participate could be improved

Writing a successful proposal

Common Mistakes

- **Eligibility criteria not met**:
  - submission deadline missed
  - **a single legal entity is not a consortium**
  - parts of the EoI not uploaded (this should not be a problem anymore with SOFIA)
  - submitted text does not respect the EoI template (sometimes received even slides!)
  - **EoI out of scope** (if you have doubts on how to respond to the call contact IMI)

Common Mistakes

- Applicants are not eligible for funding
- Unclear legal status of applicants
- Applicant consortia do not have the capabilities to address all of the objectives (e.g. redundancy between partners)
- Submitted text so concise that it **does not clearly state what is proposed** in practice
- The EoI **does not address all the objectives** (in some cases EoIs have nothing to do with the topic!)
- **Ethical issues** not addressed

Tips

- **Read all the Call-relevant material that is provided on the IMI website – www.imi.europa.eu**
- Understand **IMI's Rules** and respect them
- **If in doubt ask** a member of the IMI Executive Office
- Your EoI should provide **reviewers** with all the information requested to allow them to evaluate it

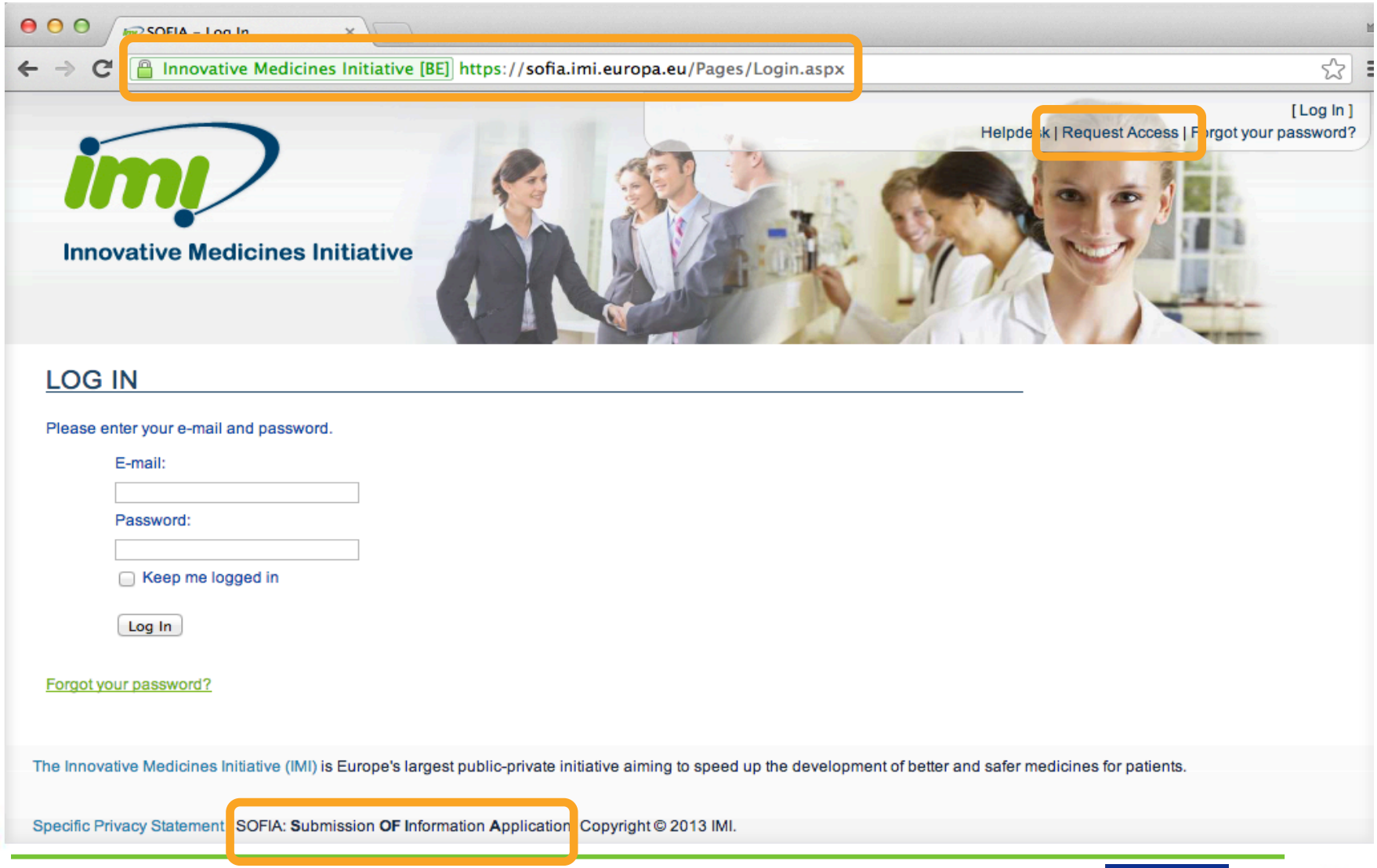
Evaluation Criteria

- Scientific and/or technological excellence
- Excellence of Partnership
- Work-plan outline
- Ethical Issues

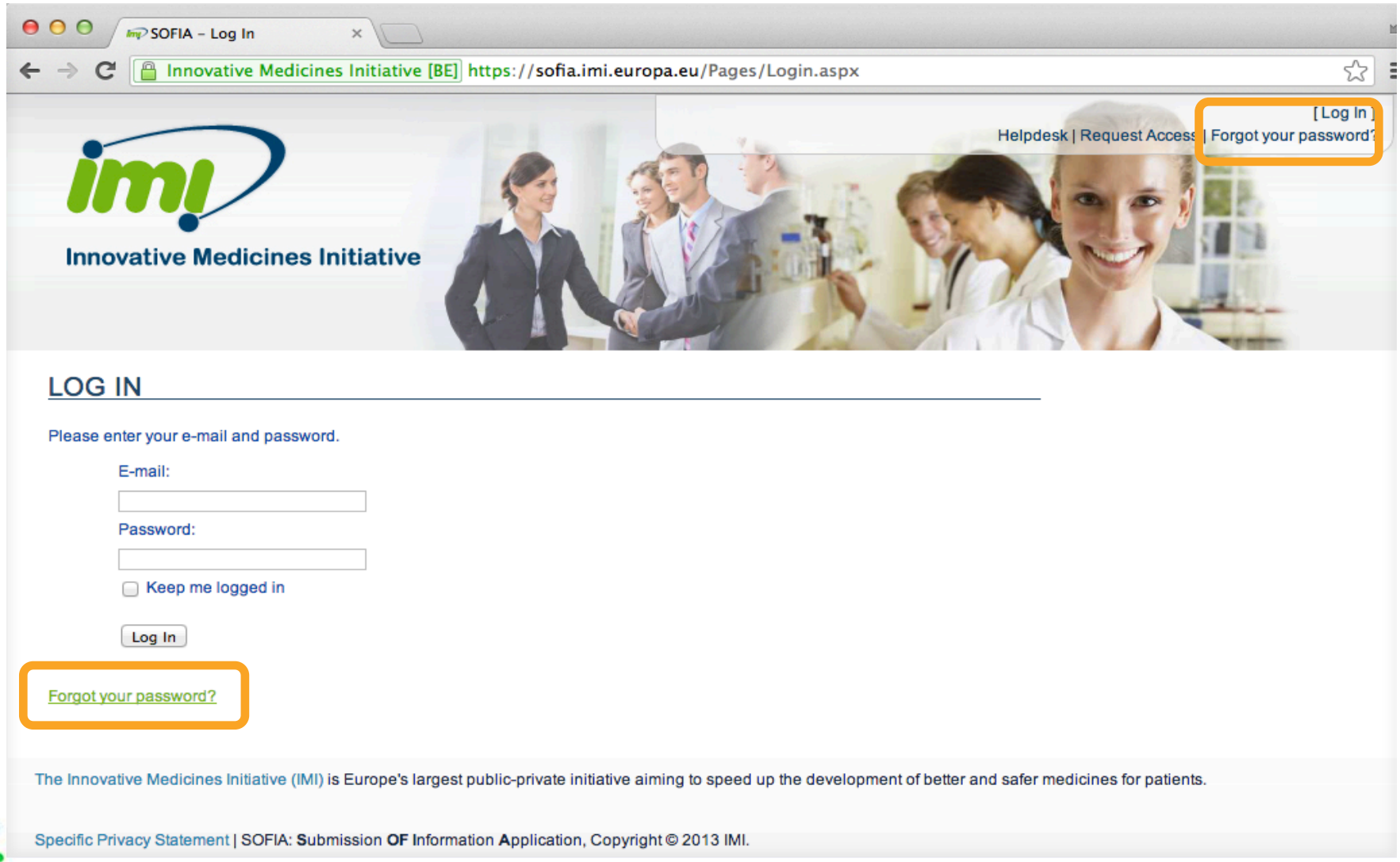
Tips

- **Finalise** your submission
- If invited to a hearing **answer the questions** as precisely and concisely as possible
- **Exchange with existing Polish participants**
- Contact **key players** of the topic area

Submitting an Expression of Interest



Submission OF Information Application



IT Applications

Participant Portal

Unique **R**egistration **F**acility

Managed by **EC**

- PIC Number
- Legal statutes
- SME Validation

SOFIA

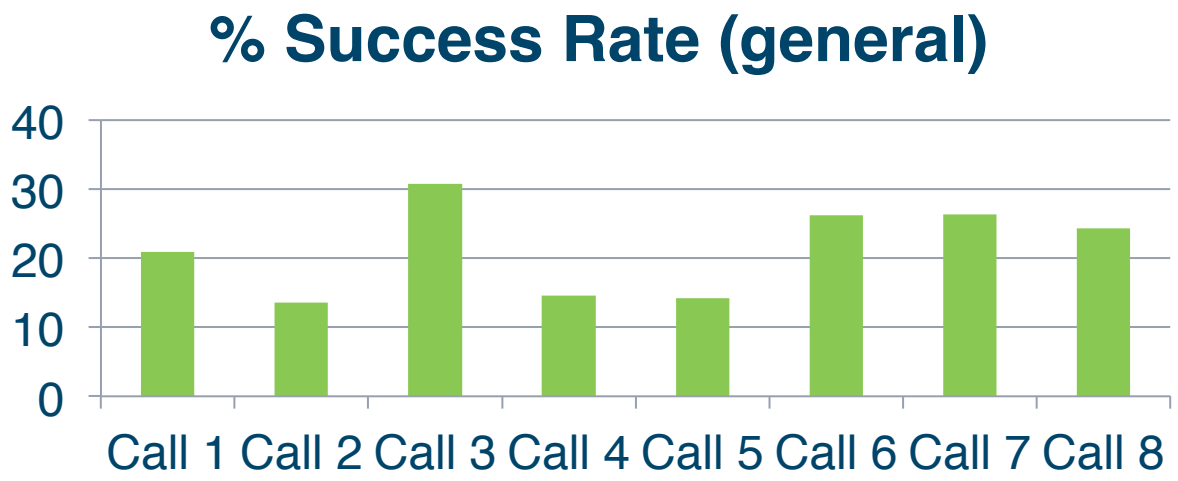
Managed by **IMI**

- Proposal Application
- Project Amendment
  - Participants Admin Data
  - Budget
  - DoW
- Reporting Form C

Polish participations and some general figures

IMI – Applications

- 22 applications from Polish organisations (Calls 1-8)
- 11 applications from Polish organisations (Call 9)



IMI – Polish participation

PROJECT NAME	SUBJECT	POLISH PARTICIPANT
PROTECT	Pharmacovigilance	Uniwersytet Medyczny im. Karola Marcinkowskiego w Poznaniu
U-BIOPRED	Athsma	Uniwersytet Jagiellonski
EHR4CR	Exploitation of electronic health records	Warszawski Universytet Medyczny
EUPATI	European Patient Academy on Therapeutic Innovation	INFARMA - Związek Pracodawców Innowacyjnych Firm Farmaceutycznych
ENABLE	ND4BB: Discovery & development of new drugs combatting Gram–negative infections	Narodowy Instytut Lekow
EMTRAIN	European Medicines Research Training Network	Medical University of Warsaw
COMBACTE	ND4BB: Enabling Clinical Collaboration and refining clinical trial design	Uczestnice sieci centrow do badan klinicznych

Participation in on-going projects

- **Top 10 research organisations/academics**

Research Organisation Name	Country	# Projects
Institut National de la Santé et de la Recherche Médicale	France	15
Uppsala Universitet	Sweden	8
University of Dundee	United Kingdom	6
The Chancellor, Masters and Scholars of the University of Oxford	United Kingdom	10
Universitair Medisch Centrum Utrecht	Netherlands	3
King's College London	United Kingdom	9
Karolinska Institutet	Sweden	14
Centre Hospitalier Universitaire de LIMOGES	France	1
Max-Planck-Gesellschaft zur Foerderung der Wissenschaften e.V.	Germany	6

N°13 -> LATVIJAS ORGANISKAS SINTEZES INSTITUTS — Latvia

Participation in on-going projects

- **20,7% of SME participation**
- **Top 10 SMEs**

SME Name	Country	# Projects
Pivot Park Screening Centre BV	Netherlands	1
MPS Hamburg GmbH	Germany	1
BioCity Scotland Ltd	United Kingdom	1
Julius Clinical Research BV	Netherlands	1
Taros Chemicals GmbH & Co KG	Germany	1
Roslin Cells Ltd.	United Kingdom	1
Alacris Theranostics GmbH	Germany	1
MERCACHEM B.V.	Netherlands	1
OncoTargeting AB	Sweden	1
EDELRIS S.A.S	France	1

4 participations -> Islensk Erfdagreining ehf Iceland

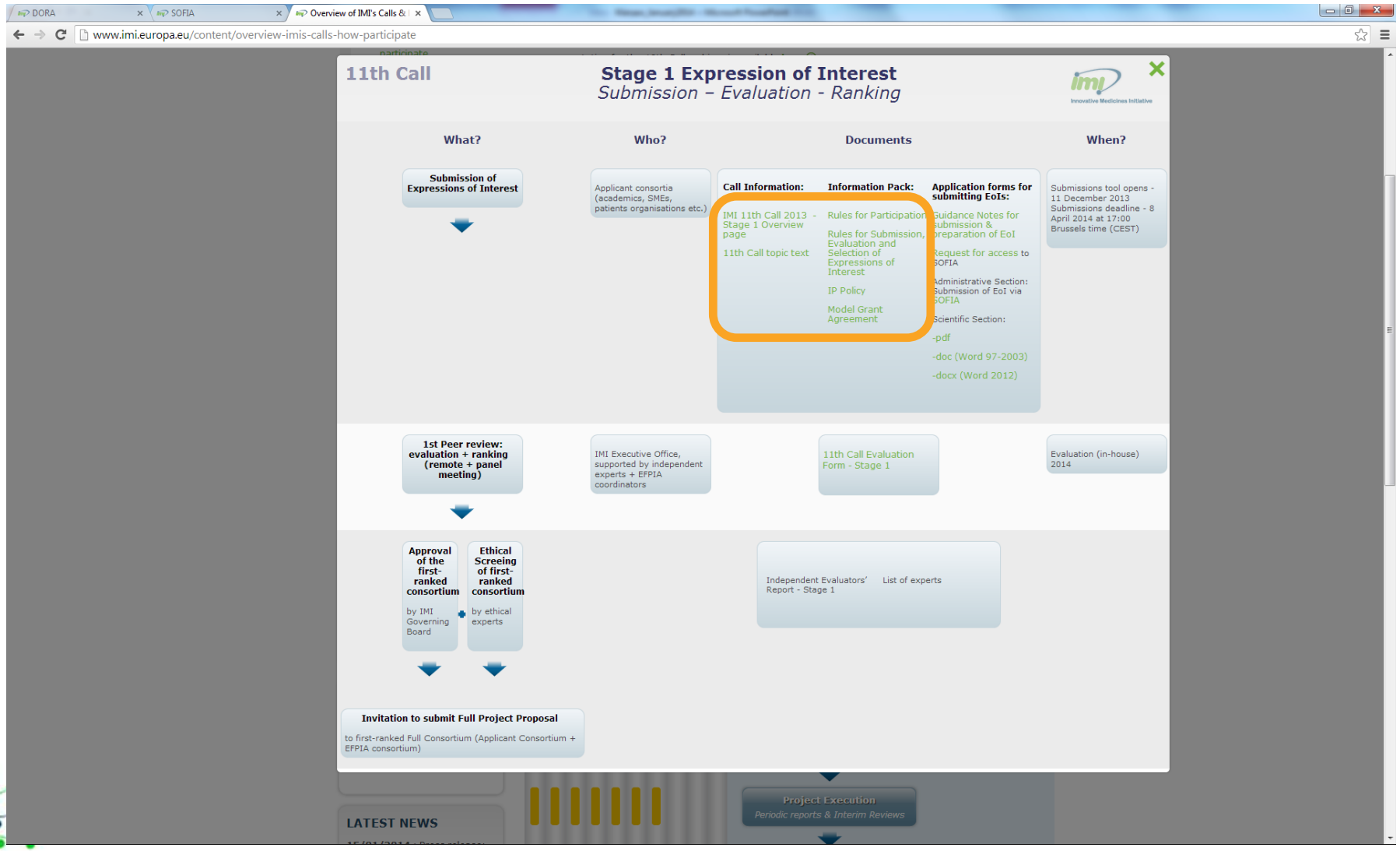
More information

Useful documents

- **Rules for Participation** (part of the Call Documents)
- **IMI model Grant Agreement**
- **IMI Financial Guidelines**
- **IMI Reporting Templates and Guidelines**
- **IP Guidance Note**

www.imi.europa.eu/content/documents

Useful documents



Your contact points

- Contact the IMI Executive Office

  infodesk@imi.europa.eu

  Magda.Gunn@imi.europa.eu

  Magali.Poinot@imi.europa.eu

- Get in touch with your **local IMI contact point** www.imi.europa.eu/content/states-representatives-groups

- Talk to your **Health National Contact Point** (NCP)

The role of the IMI Executive 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

Thank You

Questions?