Agenda

- How to use GoToWebinar – Catherine Brett, IMI
- IMI rules and procedures – Elisabetta Vaudano, Fabrizio Federici, Natalia Kapetanaki, IMI
- Questions & answers
How to use GoToWebinar

- Expand / minimise control panel
- Microphone status
- Full screen
- Raise / lower your hand e.g. if you want to ask a question orally
- Send a question in writing
How to use GoToWebinar - audio

To listen via your computer, select **Computer audio**

Can’t hear us?
- Check your **speakers are switched on and not muted**
- Do a **Sound Check** to make sure GoToWebinar is picking up the right speakers
- Still not working? Select **Phone call** and dial the numbers given on your phone

To listen in via your phone, select **Phone call**, pick your country, and dial the numbers given

Can’t hear us?
- Check you have selected **Phone call** in the audio panel
- Try **another country’s** phone number
- Still not working? Select **Computer audio** and listen over your computer’s speakers
Before we start…

- This webinar is being recorded and will be published on the IMI website and/or IMI YouTube channel.
- Presentation slides will be published on the webinar web page.
- A participant list will be published on the website.
- 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.
Rules and Procedures for IMI2 JU Calls for proposals
Outline

1. Introducing IMI
2. Participation rules
3. Funding rules
4. Intellectual property rules
5. From Call to grant award
6. Writing a successful proposal
7. More information
Introducing IMI
Challenges in medicines development

Pre-clinical research
- Closed & open innovation
- Drug disc. 5000 compounds
- Pre-clinical 250 compounds
- 3 - 6 years

Clinical Trials
- Phase 1: 5 therapies
- Phase 2: 1 therapy
- Phase 3: 1 therapy
- No. patients / subjects: 20-100
- 6 - 7 years

Regulatory review
- Filing
- Approval
- HTA assessment
- Price / reimbursement
- 2 – 5 years

Pharmaco-vigilance
Real world evidence
IMI – key concepts

- Non-competitive collaborative research
- Competitive Calls for proposals
- Open collaboration in public-private consortia
  - Data sharing, dissemination of results…
- Industry contribution is in kind
IMI2 budget (2014 – 2020)

EU funding goes to:
- Universities
- SMEs
- Mid-sized companies
- Patient groups etc...

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

EU funding

€1.638 bn

Other €213 m

EFPIA

€1.425 bn
IMI2 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 life cycle

- Call topics definition
  - Scientific Research Agenda
  - Strategic Governing Groups
  - Annual Work Plan
  - Consultation Member-Associated States/Scientific Committee

- Call Launch / Evaluation / Grant award

- Project implementation
  Consortium agreement, Grant agreement, implementation and reporting
What does the typical IMI project look like?

Industrial partners align themselves around a real challenge for industry and agree to work together and commit resources.

New ideas from public sector, universities, SMEs etc. are needed to address the challenge.

Scale is a key to success and is provided by IMI funding and the outcomes should be transformative for the industry as well as having a clear “public” value.
A typical IMI consortium

- EFPIA
- Associated Partners
- Pharma 1
- Pharma 2
- Pharma 3
- Pharma 4
- Pharma 5
- Pharma 6
- ACADEMIA
- SMALL AND MEDIUM-SIZED ENTERPRISES
- PATIENTS’ ORGANISATIONS
- INDEPENDENT MID-SIZED COMPANIES (≤ €500m)
- HOSPITALS
- REGULATORS

New for IMI2
An international, cross-sector community

- 597 Universities/Academic organisations
- 33 Patient groups
- 229 SMEs
- 61 EFPIA members
- 10 EFPIA partners in research
- 29 Regulators
- 15 Associated Partners

Connecting great minds
Introduction to IMI2 JU – Calls 15 and 16
IMI2 JU Call 15 - topics

- Topic 1: Integrated research platforms enabling patient-centric drug development
- Topic 2: Blockchain enabled healthcare
- Topic 3: Microenvironment imposed signatures in tissue and liquid biopsies in immune mediated disease
- Topic 4: Emerging translational safety technologies and tools for interrogating human immuno-biology
- Topic 5: Development and validation of translational platforms in support of synaptopathy drug discovery
- Topic 6: Digital endpoints in neurodegenerative and immune-mediated diseases (part of an IMI programme on digital transformation of clinical trial endpoints)
  - Antimicrobial resistance (AMR) accelerator programme
- Topic 7 - Pillar A: Capability Building Network to accelerate and validate scientific discoveries
- Topic 8 - Pillar B: Tuberculosis drug development network to accelerate and validate scientific discoveries and advance the R&D pipeline of new and innovative agents to address the global tuberculosis epidemic
IMI 2 JU - Call 15 two stages

- Date of Call launch: 18 July 2018
- Calls text and documents are published on the: IMI2 JU website and H2020 Participant Portal
- **Deadline for Short Proposal submission:** 24 October 2018
- **Deadline for Full Proposal submission:** 15 May 2019
- Webinar topic presentations and recordings: http://bit.ly/1RSPiTC
Call 15 – two stages

- At stage 1 evaluation the **budget** is evaluated under criterion 3 ‘Quality and Efficiency of the Implementation’
- Applicants will need to provide a breakdown of costs (and not only the overall amount, as previously the case), by filling in the budget table in Part A of the proposal.
IMI2 JU Call 16 - topics

- Topic 1: Progress new assets (One pre new molecular entity (preNME) and one first-time-in-human (FTIH)) for tuberculosis that act synergistically with bedaquiline, cytochrome bc or cytochrome bd inhibitors
- Topic 2: Progress novel assets (One first-time-in-human (FTIH)) for non-tubercular mycobacteria (NTM) that may act synergistically with bedaquiline, and cytochrome bc drugs
- Topic 3: Discover and progress novel assets with new mechanisms of action (1 pre-new molecular entity (NME) for tuberculosis (TB) and 1-pre- new molecular entity (NME) for non-tubercular mycobacteria (NTM) and biomarkers for TB and NTM infection
- Topic 4: Determination of gepotidacin levels in tonsils and prostatic tissue
- Topic 5: Infection site targeting, antibiotic encapsulated in nanoparticles for treating extracellular bacterial infections
- Topic 7: Intravenous treatments of serious infections (urinary tract infections (UTI), intra-addominal infections (IAI) & hospital-acquired pneumonia/ventilator associated pneumonia (HAP/VAP)) caused by Gram(-) bacteria (Enterobacteriaceae +/- Pseudomonas and/or Acinetobacter
IMI 2 JU - Call 16 single stage

- Date of Call launch: 18 July 2018

- Calls text and documents are published on the: IMI2 JU website and H2020 Participant Portal

- **Deadline for Proposal submission:** 24 October 2018

- Webinar topic presentations and recordings: http://bit.ly/1RSPiTC
Call 15 – Call 16

- As of IMI2 JU Call 10, use of the electronic submission service of the Horizon 2020 Participant Portal:

- To access the portal and submit a proposal, applicants must have:
  - An EU Login account (previously, ‘ECAS’ account)
  - Their organisation registered on the Participant Portal Beneficiary Register, with a 9-digit Participant Identification Code (PIC) number

If you do not have an EU Login account yet, you can create an EU Login account on the Participant Portal, and register your organisation.

Participation rules
A single set of rules

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

etc.
Conditions for Call 15 two-stages

H2020 Rules for participation apply to IMI2 JU Call for Proposals and Actions except where specifically derogated

- **Minimum conditions**
  - **RIA**: at least three independent legal entities, each established in a different EU Member State or H2020 associated country

- **Two-stages - C15**
  - Stage 1 SPs from applicants requesting JU funding
  - Stage 2 merging 1st-ranked SPs with industry consortia

- **Evaluation criteria**
  - At stage 1, all 3 criteria are evaluated *(including budget)*
Conditions for Call 15 two-stages

- **Submission tool**
  (As of Call10) SPs/FPs to be submitted through the Electronic Submission Service of the H2020 Participant Portal

- **Submission deadlines**
  Established in the Call topic text both for stage 1 and 2

- **Indicative contribution**
  For each topic, the maximum JU contribution and the estimated industry contributions are set in the call text

- **Hearings**
  Panels may decide at stage 1 to held hearings with applicants during panel meetings. After submission deadline, coordinators will be informed about the possible date for the hearing (check SP details!)
Conditions for Call 15 two-stages

- **Information on the outcome of the evaluation:**
  Information to the applicants - max 5 months from submission deadline

- **Financial Support to Third Parties**
  Where relevant, applicants should develop in FPs open, transparent, objective processes and criteria for the allocation of financial support in accordance to Annex K of the H2020 WP, and article 15 of the IMI2 MGA

- **Plan for exploitation and dissemination**
  It must be included in 2nd stage Full proposals

**NB:** Contacts/discussions about a given topic between potential applicant consortia and members of the industry consortium are prohibited throughout the procedure until the results of the first stage evaluation.
Conditions for Call 16 single stage

H2020 Rules for participation apply to IMI2 JU Call for Proposals and Actions except where specifically derogated

- **Minimum conditions for this call**
  Each applicant consortium must include at least two independent legal entities, each established in a different EU Member State or H2020 associated country. *At least one* them must be an EFPIA constituent or affiliated entity, i.e. EFPIA company.

- **Single stage**
  Proposals will be evaluated and ranked under the topic they have been submitted to.
Conditions for Call 16 single stage

- **Submission tool**
  (As of Call10) Proposals to be submitted through the Electronic Submission Service of the H2020 Participant Portal

- **Submission deadlines**
  Established in the Call topic text

- **Indicative contribution**
  For each topic, the maximum JU contribution is set in the call text

- **Information on the outcome of the evaluation:**
  Information to the applicants - max 5 months from submission deadline

- **Plan for exploitation and dissemination**
  It must be included in the submitted proposal
Attracting stakeholders

Any legal entity, regardless its place of establishment, carrying out work relevant to the Call objectives may be part of applicant consortia.

But… not all participating entities are eligible for funding.
Who is eligible for funding?

- Academic institutions
- Small & medium-sized enterprises (SMEs)
- Mid-sized enterprises (≤ €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 IMI2 JU for carrying out the action

Art.1 Commission Delegated Regulation (EU) No 622/2014
Expected consortia – Call 15

Stage 1 of two stage - Short Proposals

- Consortia consisting of:
  - IMI2 JU fundable legal entities carrying out activities relevant for achieving the project objectives
  - additional legal entities carrying out activities relevant for achieving the project objectives.
Expected consortia Call 15

Stage 2 of two stage – Full Proposals

- One Full Consortium per topic consisting of:
  - 1st ranked SP consortium - IMI2 JU fundable legal entities/additional legal entities
  - Industry consortium (EFPIA companies and IMI2 JU Associated Partners) associated to the relevant topics
Expected consortia Call 16

Single stage – Proposals

- Consortia consisting of:
  - IMI2 JU fundable legal entities (and any other legal entities if necessary) carrying out activities relevant for achieving the project objectives, and
  - At least one EFPIA affiliates (i.e. EFPIA companies)
Funding rules
IMI2 Funding model

- IMI2 JU is a PPP, actions are normally co-funded by:
  - JU funding to BRFs (beneficiaries receiving funding = legal entities eligible for funding)
  - In-kind/cash contribution from BNRFs (beneficiaries not receiving funding):
    - EFPIA constituents and affiliates
    - IMI2 JU Associated Partner
    - (future other IMI2 members)

Other legal entities may also participate as BNRFs at their own cost
One single funding rate per project - BRFs

One project = One rate
For all beneficiaries and all activities

- 100% of the direct eligible costs
- Indirect costs: 25% flat rate
JU contribution to BRFs covers:

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

- **Equipment, consumables, travels…**

- **Subcontracting**

Considering BRFs accounting and management principles

- **BRFs (only) may also receive Financial contribution from EFPIA/APs**
  - to be reported as receipts
Third party is a *legal entity which carries out work of the action, supplies goods or provide services for the action, but which did not sign the grant agreement*

**Types of third parties:**

1. Third parties directly carrying out part of the work described in Annex 1

2. Other third parties: providing resources, goods or services to beneficiaries carrying out the work described in Annex 1

3. Third parties receiving financial support (money) from the beneficiary as part of the action, subject to specific conditions, i.e. Annex K H2020 WP
<table>
<thead>
<tr>
<th>TYPE</th>
<th>Works on action tasks?</th>
<th>Provides resources or services for action?</th>
<th>What is eligible?</th>
<th>Must be indicated in Annex 1?</th>
<th>Indirect costs?</th>
<th>Selecting the third party</th>
<th>GA articles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linked third party</td>
<td>YES</td>
<td>NO</td>
<td>Costs</td>
<td>YES</td>
<td>YES</td>
<td>Must be affiliated or have a legal link</td>
<td>Article 14</td>
</tr>
<tr>
<td>Int. Partners</td>
<td>YES</td>
<td>NO</td>
<td>N/A</td>
<td>YES</td>
<td>N/A</td>
<td>Must not be eligible for funding</td>
<td>Article 14a</td>
</tr>
<tr>
<td>Subcontractor</td>
<td>YES</td>
<td>NO</td>
<td>Price</td>
<td>YES</td>
<td>NO</td>
<td>Must be best value for money, avoid conflict of interest</td>
<td>Article 13</td>
</tr>
<tr>
<td>Third party providing in-kind contribution</td>
<td>NO</td>
<td>YES</td>
<td>Costs</td>
<td>YES</td>
<td>YES</td>
<td>May not be used to circumvent the rules</td>
<td>Articles 11 and 12</td>
</tr>
<tr>
<td>Contractor (selling, equipment, good or service)</td>
<td>NO</td>
<td>YES</td>
<td>Price</td>
<td>NO</td>
<td>YES</td>
<td>Must be best value for money, avoid conflict of interest</td>
<td>Article 10</td>
</tr>
<tr>
<td>Third parties receiving financial support</td>
<td>The third parties participate in the action as recipients.</td>
<td>Amount of support given</td>
<td>YES</td>
<td>NO</td>
<td>According to the conditions in Annex 1</td>
<td>Article 15</td>
<td></td>
</tr>
</tbody>
</table>
EFPIA and Associated Partners contribution - BNRFs

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

* Recipient of FC must be BRFs, i.e. eligible for JU funding

When relevant to IMI2 JU objectives: non-EU in-kind contribution (up to 30% at programme level)

Annual financial reporting is disconnected from GA periodic reports
Deadlines for reporting

- Scientific reporting (full consortium) due at project deadlines (i.e. GA),
  duration reporting period: 12 months
- Financial reporting for:
  - Beneficiaries receiving JU funding, due at project deadlines (i.e. GA)
  - CFS: >EUR 325k at project end
  - Beneficiaries Not receiving funding (e.g. EFPIA companies and APs),
    due by 31 Jan - certification by 30 April - covering previous calendar year
IMI2 JU’s Intellectual Property (IP) rules
One set of rules for multiple interests

Support to industry

Incentive to participate

Flexibility + trusted party

Dissemination of information

Freedom of access

Compensation for IP
Background vs. Results

Background identification

Implementation of the action
- Results
- Access rights

End

Sideground
Generated during the action but **outside of its objectives** and not needed for implementation or Research Use
Background vs. Results

Background
- Any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
  - is held by the beneficiaries before they acceded to the Agreement,
  - is needed to implement the action or exploit the results, and
  - which is identified and agreed by the Beneficiaries.

All conditions have to be met to be considered background and be subject to specific rights & obligations

Results
- Any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not
  - that is generated in the action, as well as any rights attached to it, including intellectual property rights
  - excluded Sideground - output generated by a beneficiary under the action but outside of the action objectives as defined in the Grant Agreement

=> Importance of Action objectives
Ownership of results

Results are owned by the beneficiary that generates them

Possible transfer of ownership
- within the consortium to affiliates and purchasers without prior notification
- on case-by-case basis
Research Use vs. Direct 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

- **Direct exploitation**
  - to develop for commercialisation or to commercialise the results
## Access Rights conditions

<table>
<thead>
<tr>
<th>Access rights granted by a beneficiary to/on</th>
<th>Background (necessary and identified)</th>
<th>Results</th>
<th>Sideground</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beneficiaries for completion of the action</td>
<td>Royalty-free</td>
<td>Royalty-free</td>
<td>N.A.</td>
</tr>
<tr>
<td>Beneficiaries and affiliates for Research Use</td>
<td>Fair &amp; reasonable conditions (e.g. Royalty-free conditions)</td>
<td>Fair &amp; reasonable conditions (e.g. Royalty-free conditions)</td>
<td>N.A.</td>
</tr>
<tr>
<td>Third Parties for Research Use after the action</td>
<td>Appropriate conditions</td>
<td>Appropriate conditions</td>
<td>N.A.</td>
</tr>
<tr>
<td>Beneficiaries and affiliates or Third Parties for Direct Exploitation</td>
<td>To be negotiated</td>
<td>To be negotiated</td>
<td>N.A.</td>
</tr>
</tbody>
</table>

*IMI Innovative Medicines Initiative*
Access rights and third parties

- Only after the end of the action for research use purposes
- Time-limits to be agreed
- Possibility to exclude specific elements of background (only for existing background) under exceptional circumstances and after a reasoned request

Based on IMI1 experience
Open Access in IMI2 Projects

**Open Access to Publications**
(Article 29.2 GA)
Deposit in repositories and publishing in Open Access (OA) both encouraged.
Processing charges can be considered eligible costs but:
- Must be budgeted before project start
- Publications must be placed in repository
- Provision of OA is a requirement

**Open Research Data (ORDP)**
(Article 29.3 GA)
From Call 11, all IMI2 projects are automatically part of the ORDP.
The ORDP covers ‘underlying data’ generated in the project, but can be extended to other types of data.
The ORD balances openness with protection of scientific information, commercialisation and IPR and embraces a flexible approach; allowing projects varying degrees of engagement with the ORDP.

**Data Management Plan (DMP)**
(AWP)
All projects need to:
- Develop and update a DMP*.
- Deposit their data.
DMPs should aim to produce ‘FAIR’ data:
  - Findable
  - Accessible
  - Interoperable
  - Re-usable

*Note: All IMI Projects are required to provide a Data Management Plan (DMP) regardless of the project’s engagement with the ORDP.*
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 November 2017)
  - IPR section: Articles 23a to 31

- **IMI2 annotated Grant Agreement**

From Call to grant award
IMI2 JU Call 15 two-stages (typical)

**Topic definition**

- Industry Assoc partners
- Identification of topics and willingness to collaborate

**Stage 1**

- Applicant consortia submit short proposals
- Evaluation

**Stage 2**

- Full consortium submits full proposal
- Applicant consortium
- Industry APs

**Grant award**

- Consortium Agreement
- Grant Agreement
- Finalisation
- Project launch!

**Evaluation**

- Call launch
- Merger: applicants & industry
IMI2 JU Call 16 Single-stage

- Call launch
- Single stage
  - Applicant consortium including 1 EFPIA company
  - Submitted proposals evaluated by independent experts/ethics panel
- Granting phase
  - Signature of Consortium Agreement and Grant Agreement
- Project launch!
A single set of evaluation criteria

- Two-stage evaluation: all three criteria considered at both stages
- Thresholds and weighting in the **Call documents** depending two-stages/single stage
- Minimum of **3 independent experts**

Each proposal **evaluated ‘as it is’**, not as ‘what could be’
Keeping the momentum

Maximum Time To Grant: 8 months from submission of full proposal

5 months for informing applicants of scientific evaluation

3 months for signature of grant agreement

NEW Legal entity validated in parallel
IMI2 Grant Agreement

- The new IMI2 JU MGA (v.5) will apply to Call 15 and 16
- It follows H2020 Model Grant Agreement (v.5) with IMI2 specificities.
- **NEW** IMI2 JU Annotated Model Grant Agreement (v1 based upon H2020 AGA v4.1, while H2020 AGA v.5 already published)
- It is e-signed between IMI2 JU and Coordinator only. Other beneficiaries e-sign Accession Forms
- EFPIA and Associated Partners are beneficiaries not receiving funding (BNRFs, Art.9) - their financial report occurs outside the GA, for more info please consult ‘IMI2 JU guidelines for reporting in kind and financial contributions by Members other than the Union and Associated Partners’ **NEW**
Article 41.3 - Consortium agreement *may cover*:

- *internal organisation of the consortium, including allocation of scientific tasks among beneficiaries*

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**Scientific Project Leadership**

Scientific Project Leader may be different from Coordinator to:

- reflect the *spirit of industrial co-leadership* in call topics built upon EFPIA/industry scientific priorities

- address the need for strong scientific coordination and collaboration between BRFs (JU funded) and BNRFs (industry)

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*IMI2 specificities are presented in the IMI2 JU AGA*
Consortium agreement

- Contractual arrangement **between all participants** to set out their rights and obligations, especially governance, liability and IPR
- Shall comply with the **IMI2 JU Model Grant Agreement**
- To be agreed before the signature of the GA, IMI2 JU is not a party
- **To be adapted to the specific needs of each IMI action!**
- A template prepared by EFPIA shows what a consortium agreement might look like:
  
  Consortia may also use alternative templates if they wish.
Call 16 – internal decision making process

- Each applicant consortium must agree on a fair and robust go/no-go decision making process to ensure that only the most promising compounds/approaches are pursued.
- Go/no go milestones need to be clear in each proposal.
- A committee including at least one project-independent expert tracks progress against milestones and makes recommendations for progression/stop.
- Final decision about project continuation or termination will be taken in line provisions of the IMI2 JU Grant Agreement.
Tips for success
Common Mistakes

- Admissibility/Eligibility criteria not met:
  - submission **deadline** missed
  - proposal **out of scope**
    (if you have doubts on how to respond to the Call contact us)
  - Not involving at least **three independent legal entities** (RIA) from **three** different **MS/AC**
Common Mistakes

- The proposal does not address all the **objectives** (in some cases proposals have nothing to do with the topic!)
- Submitted text does not respect the proposal template (sometimes received even slides!)
- Applicants do not have the **capabilities** to address all of the objectives or there is redundancy between partners
- A proposal is scientifically excellent but will have **limited impact**
- **Budget**, either over-estimated or not fully justified
- **Ethical issues** not addressed
Tips

- Read all the Call-relevant material that is provided on the IMI website – www.imi.europa.eu
- Understand IMI2 JU rules and respect them
- Consider the PPP dimension of the action (e.g. Governance, industry contribution vs IMI2 JU funding)
- If in doubt, ask a member of the Programme Office
- Your proposal should provide reviewers with all the information requested to allow them to evaluate it
- Start working early (pre-materials available before)
- Dedicate sufficient time to submit the proposal: create an EU login account, obtain a PIC number - don’t wait until the last day to start the submission process
- More tips: www.imi.europa.eu/content/tips-applicants
Submitting a proposal

- The links to start the submission of a proposal are available on the Participant Portal.
Proposal Submission Form - Part A

Please indicate only one of the following options if applicable to your organisation:

- Companies (including micro enterprises and SMEs) with an annual turnover up to EUR 500 millions which are not affiliated entities of companies with an annual turnover of more than EUR 500 millions
- Patients Organisation
- Regulatory Agency
- Member of EFPIA not requesting funding
- IMI2 Associated Partners to this topic not requesting funding
- Any other organisation not requesting funding

Certain type of organisations are not covered by the above options, in that case none should be selected

- Where applicable, the organisation type has to be indicated (see above):
  - Applies to the 6 types of organisations identified in the form;
  - If none of the options is selected, the system generates a warning;
  - The warning is not blocking the submission of the proposal.
Proposal Submission Form - Part A

- When validating the forms, different warnings appear (see above):
  - The yellow warnings don’t block the submission of the proposal;
  - Only the warnings flagged in red will block the submission of the proposal.
Proposal Submission Form - Part A

4 - Call specific questions

**Essential information to be provided for proposals including clinical Trials / studies / investigations**

**Applies to proposals including clinical trials / studies / investigations**

- Are clinical studies / trials / investigations included in the work plan of this project?  
  - Yes  
  - No

Please upload the dedicated annex 'Essential information for clinical studies / trials / investigations' (a Word template is provided under 'download templates' in the upload section for Part B and Annexes).

This document should include the relevant information of each clinical study / trial / investigation included in the work plan of this project.

- Please give a short title, an acronym or a unique identifier to each clinical study / trial / investigation, to be used as a reference/identifier in the other parts of the proposal.

<table>
<thead>
<tr>
<th>Give short title/acronym/unique identifier</th>
</tr>
</thead>
</table>

- If the proposal includes clinical trials/studies/investigations, in stage one of two-stages calls, the specific annex is not requested (see above the section):
  - In stage one relevant aspects should be integrated in part B of the proposal template;
  - The dedicated annex is compulsory in stage two (see *Clinical trial template*).
More information
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
- Join our LinkedIn group bit.ly/LinkedInIMI
- E-mail us infodesk@imi.europa.eu
Your contact points

At the IMI Programme Office

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

Local contacts

- IMI2 JU States Representatives Group: bit.ly/IMISRG
- Horizon 2020 Health National Contact Points: bit.ly/H2020_NCPs
Questions
Questions?

Raise your hand if you want to ask a question orally

Send a question in writing

After the webinar, send any questions to the **IMI Programme Office**

applicants@imi.europa.eu