



Innovative Medicines Initiative

IMI's 6th Call for proposals Procedures & Practicalities

Nathalie Seigneuret, Senior Scientific Project Manager, IMI
Maria Teresa De Magistris, Principal Scientific Manager, IMI



efpia*

Call 6: Key steps and timelines



Stage 1

Launch of the Call

24 May

Submission of Expressions of Interest

9 July

1 st peer review: (remote + panel meeting)	evaluation + ranking
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Panel meeting 25-27 July

Ethical screening of 1st
ranked consortia
by ethical experts

Approval of the
1st ranked consortia
by IMI Governing Board

End July – early August

Invitation to submit
Full Project Proposal

Early August

Stage 2

Submission of Full Project Proposal
by Full Consortium

10 October

Preparation
of the
Project
Agreement

by Full
Consortium

Administrative &
financial
negotiations
Full Consortium
+ IMI Executive
Office

2nd peer review
(remote + panel meeting)
including ethical evaluation

Panel meeting 29-30 October

Go / no-go decision on the Full
Project Proposal by IMI Gov. Board

Early November

Description of Work
(Annex I to Grant Agreement)
by Full Consortium
+ IMI Executive Office

Approval of Budget
by IMI Governing Board

Contract negotiation

Signature
Project
Agreement

by Full
Consortium

Signature of Grant Agreement
by Full Consortium and IMI Executive Office

End December



Submission of Expressions of Interest



Submission of separate Expressions of Interest (EoI) for each of the following (sub)topics:

- **Subtopic 1A:** Establishment of clinical investigator network, surveillance and epidemiology programs & innovative trials design
- **Subtopic 1B:** Conduct of clinical trials supporting the development of GSK 1322322
- **Topic 2:** Creating new knowledge and sharing data to boost antibiotic R&D



Subtopic 1A EoI: key points to consider



- Indicative budget for IMI-JU beneficiaries: € 5 M
- WP1: - will be in charge of open calls to include additional beneficiaries as needed
 - will work with similar WPs in other ND4BB topics to ensure cross-topic collaboration and dissemination
- Attention to be paid to expectations from investigators and sites forming the investigators network (GCP and high-quality clinical microbiology lab)
- Merge with subtopic 1B for the preparation of Topic 1 FPP



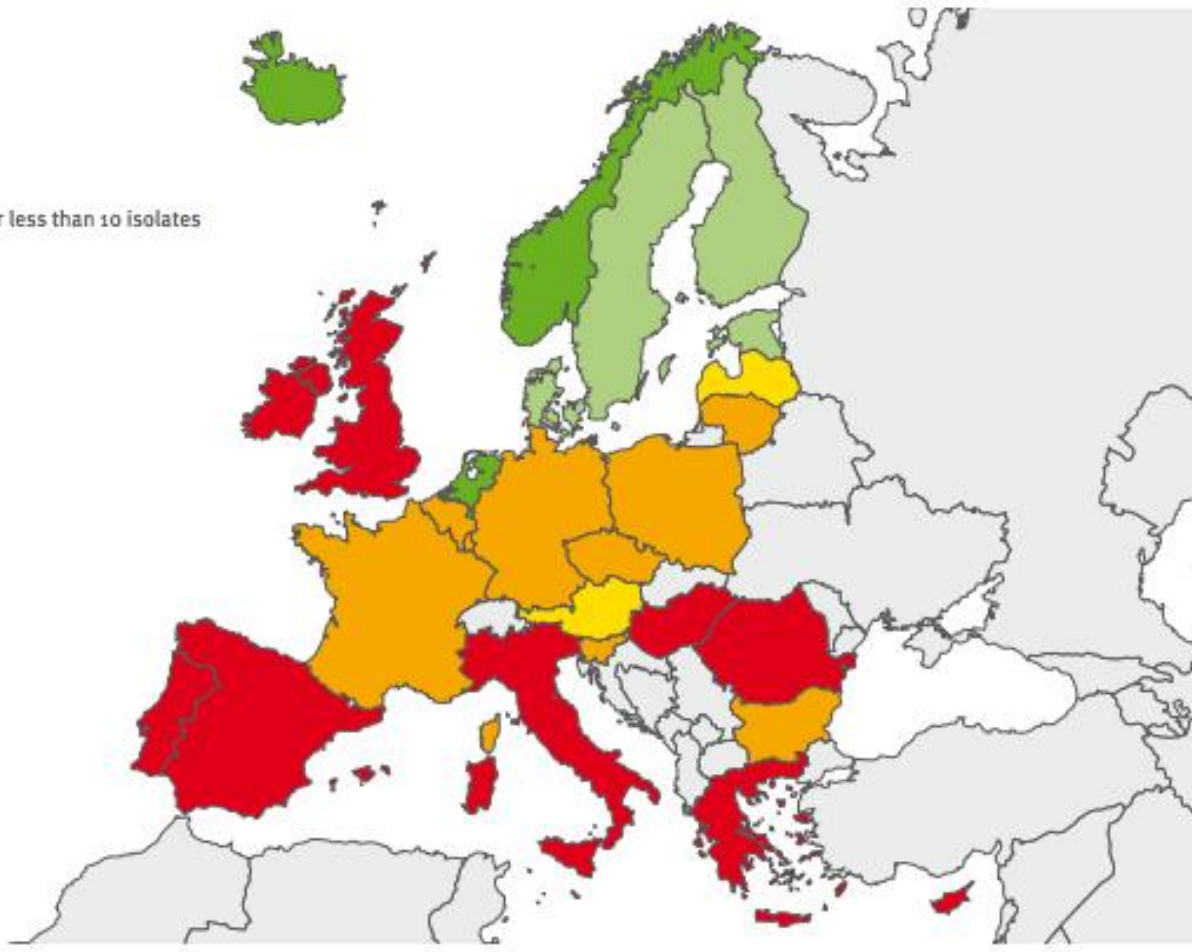
Subtopic 1B EoI: key points to consider



- Indicative budget for IMI-JU beneficiaries (€ 88 M)
 - clinical studies: € 48-53 M
 - *CRO subcontracting*: € 20 M
 - *Biomarkers/endpoints*: € 15-20 M
- 2 trials at the initiation of the project (WP5A and WP5C)
- 2 additional trials (WP5B and WP5D):
 - to be defined later according to milestones completion
 - might include additional partners selected by open calls handled by the consortium with IMI JU guidance
- Sites/investigators must fulfill specified requirements
- **Geographic distribution of MRSA**

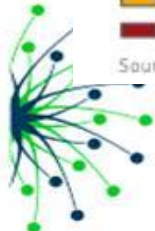


Subtopic 1B: Geographical distribution of multiresistant Staphylococcus aureus



Non-visible countries
Liechtenstein
Luxembourg
Malta

Source: EARS-Net. Only data from countries reporting more than 10 isolates are shown.

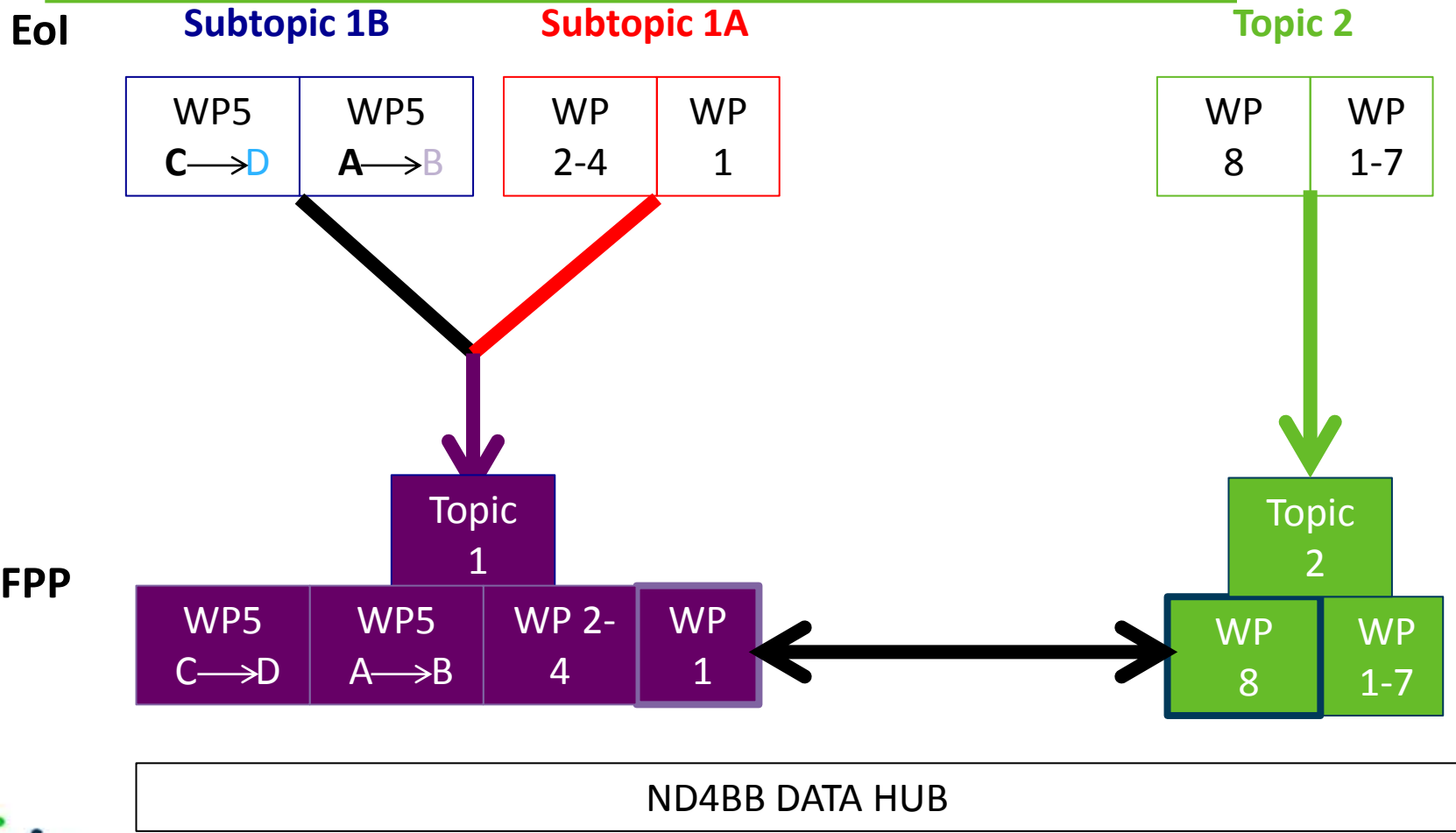


Topic 2: key points to consider

- Indicative budget for IMI-JU beneficiaries: € 16 M
- 8 workpackages
- WP8: will lead ND4BB cross-topic collaboration and dissemination



Links between (sub) topics of Call 6



Evaluation and ranking of Expressions of Interest



- Peer-review evaluation and ranking using the same peer-review process as for Call 5
- New EoI Guidance/Template and Evaluation form to accommodate the specific case of clinical trial centres (*re section partnership – individual participants*)
- The evaluation panel may recommend to merge the first-ranked consortium with other applicants' consortium(a) for the preparation of the Full Project Proposal (FPP)
- The first-ranked EoIs are screened by ethical experts to provide guidance on key ethical questions to be addressed in the FPP



Preparation and evaluation of Full Project Proposals



- The first-ranked consortia for subtopic 1A and subtopic 1B are merged and invited to prepare the Topic 1 FPP together with the EFPIA consortium
- The first-ranked consortium for Topic 2 is invited to prepare the topic 2 FPP together with the EFPIA consortium
- The FPPs of Topic 1 and Topic 2 are evaluated by experts' panels including ethical experts for go/no-go recommendation to the IMI Governing Board (GB) (same procedure as for Call 5)
- Following the GB decision, successful consortia are invited to finalize negotiations and to sign project agreements and grant agreements



Questions?



Contact us

Nathalie Seigneuret
Maria Teresa De Magistris

nathalie.seigneuret@imi.europa.eu
MariaTeresa.DeMagistris@imi.europa.eu
infodesk@imi.europa.eu

Visit the IMI website

www.imi.europa.eu



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