Topic: AMR Accelerator programme Pillar A: Capability Building Network to accelerate and validate scientific discoveries

Part of IMI2 JU AMR Accelerator programme

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.

Topic details

Action type	Research and Innovation Action (RIA)
Submission and evaluation process	2 stages

Specific challenges to be addressed

The Capability Building Network (CBN), Pillar A of the IMI2 JU AMR Accelerator programme, will work to address the innovation gap in the AMR space by enabling pre-competitive research in the treatment and prevention of multi-drug resistant infections.

The success of the overall Accelerator relies on a coordinated approach to ensure efficient implementation, management, and strategic alignment across a broad range of topics, partners, and stakeholders. Expert support for the programme, via a centralised operational group will address this need and will allow all Accelerator projects to focus on delivering scientific advancements for the field and progressing medicines and therapies to patients. This operational group will also provide a unique opportunity to coordinate large scale efforts in the AMR space in collaboration with industry and public partners and will be part of the first project in the CBN.

Scope

The dual aim of this first call for the CBN will be to:

- create an operational group to support the delivery of projects across the Accelerator, specifically:
  - support the project coordinators in horizontal administration of projects, including project and alliance management;
  - centrally source and implement IT infrastructures for projects in the Accelerator (e.g. information sharing portals or databases, such as the framework created for the ND4BB Information Centre, electronic notebooks);
  - act as an interface with stakeholders in the AMR field to explore synergies and collaboration with other initiatives and contribute to coordinating the broader AMR strategy on a global scale.
- conduct pre-competitive research aimed to:
  - provide learnings derived from shared vaccine and/or antibacterial clinical trial data;
  - improve understanding of variability and translatability of animal models of bacterial infection.

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An advisory and communications board, (containing independent external experts to be selected by the CBN consortium and representatives from all the projects running in the AMR Accelerator) will be created as part of the operations group within the CBN. This group will meet regularly to share summary level, non-confidential progress reports on projects and where appropriate make recommendations to the AMR Accelerator overall including on potential future call topics.

Expected key deliverables

Deliverable 1: Operationalisation of the entire AMR Accelerator portfolio of projects, including

- framework established for rigorous programme management and coordination of support of all projects in the Accelerator;
- secretariat role established for Accelerator committees as needed;
- interactions between the Accelerator and IMI2 Infection Control Strategic Governing Group, EFPIA, and other key stakeholders supported;
- interactions between Accelerator projects and IMI2 JU streamlined, facilitated, and supported, including support with financial and scientific reporting;
- ethical guidance and data governance and privacy standards facilitated across Accelerator as appropriate;
- sustainability of results of projects within the Accelerator ensured.

Deliverable 2: Guidelines and tools for collection, integration, and dissemination of knowledge from Accelerator projects

- IT infrastructure (e.g. information sharing portals or databases, such as the framework created for the ND4BB Information Centre, electronic notebooks) to be used across projects in the Accelerator; for example datasets could include:
  - Clinical trial data;
  - Microbiology data;
  - Preclinical screening / profiling data;
  - Chemical structures and descriptors;
  - Animal infection model data;
- streamlined and appropriate processes for aggregation and sharing of AMR data established;
- historical AMR data to be fed into other Accelerator projects collected as needed;
- plan for distillation of findings and synthesis of key learnings across the Accelerator programme established.

Deliverable 3: Communication and collaboration across AMR funding landscape

- mechanism for sharing information and strategies across the global AMR funding community to maximize awareness and synergy and minimize redundancy;
- plans for networking and communications across the Accelerator;
- assistance delivered in the implementation of the EU AMR agenda;
- coordination with other stakeholders on the broader AMR strategy on a global scale.

Deliverable 4: Learnings derived from shared AMR clinical trial data (e.g. Phase 1-3 vaccines trials, and antibacterial trials) and associated enabling studies

- generation and collation of clinical trial data allow for analysis and the translation of preclinical to clinical data with respect to, for example, safety, tolerability, dose prediction, animal models of infection and efficacy, and

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greater disease understanding (note: the data for these studies will not be available immediately and we foresee future calls in 2019-2020 for additional partners to address this deliverable based on the data available.

Deliverable 5: Improved understanding of animal infection model reproducibility and translation to clinical efficacy

- establishment of a collection new and/or "control" bacterial strains to demonstrate virulence and growth in vivo;
- validation of rodent pneumonia and pyelonephritis models using benchmarked control compounds;
- more standardized methods of conducting these studies as "best practices" identified by comparing data, sharing common practices and experiences between different investigators;
- a data set of benchmark control compounds and bacterial isolates to determine, for example:
  - reproducibility (study-to-study and lab-to-lab);
  - improve / optimize translation to clinical efficacy;
  - predictability of PK/PD targets;
  - identify optimal study conditions and practices for minimizing variability.

Expected impact

The expected impact of the CBN will be to:

- contribute to the development of a vibrant AMR research environment in the EU and strengthening the competitiveness and industrial leadership of Europe;
- contribute to EU's ambition of being a 'best practice region' for addressing AMR;
- with other elements of the AMR Accelerator, enhance the overall pipeline of medicines for patients with AMR infections;
- strengthen interaction of AMR stakeholders from across EU and globally;
- strengthen the scientific basis on AMR research.

Applicants should indicate how their proposals will impact and strengthen the competitiveness and industrial leadership of Europe by, for example, engaging suitable SMEs.

Potential synergies with existing consortia

Applicants should take into consideration, while preparing their short proposal, relevant national, European (both research projects as well as research infrastructure initiatives), and non-European initiatives. Synergies and complementarities should be considered in order to incorporate past achievements, available data and lessons learnt where possible, thus avoiding unnecessary overlap and duplication of efforts and funding.

Example of relevant IMI/IMI2 JU and non-IMI projects include:

- aspects of the research of ND4BB TRANSLOCATION (http://www.nd4bb.eu/) (e.g. the ND4BB Information Centre as a possible framework for data sharing);
- ND4BB ENABLE project (http://nd4bb-enable.eu/);
- ND4BB COMBACTE projects, (https://www.combacte.com) in particular, in relation to networks (CLIN-NET, LAB-NET, STAT-NET and EPI-NET);
- Projects funded by other organisations/programmes supporting AMR R&D e.g. the EU Framework Programmes for Research and Innovation FP7 and Horizon 2020, the Joint Programming Initiative AMR, Wellcome Trust, BARDA, MRC, CARB-X, GARDP, NIAID, TB Alliance and TB Drug Accelerator etc. to ensure synergy and avoid duplication of research.

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Industry consortium

The industry consortium will provide knowledge and expertise in:

- best practices on resourcing, setting milestones, and project/portfolio management;
- setting up and maintaining active and nimble governance processes;
- data and knowledge management (e.g. potential mechanisms for collection and pooling relevant data sets);
- ethical guidance and data governance and privacy standards as appropriate;
- networking and communication across large programmes such as the Accelerator.

The industry consortium will also:

- generate and share data, samples, and information from industry-sponsored clinical trials (Phases 1-3) in the AMR space (e.g. resources associated with vaccine R&D for drug resistant bacteria causing major burden of disease in developing world, e.g. pathogen A-D, including but not limited to clinical trials and enabling studies, manufacturing, toxicology studies, etc. and for antibacterial R&D, e.g. Phase 3 gepotidacin clinical trials and associated enabling studies such as but not limited to CMC activities, clinical operations);
- assist in the analysis of the output of clinical trials in the AMR space, e.g. efficacy, safety, translation of preclinical data with respect to safety, tolerability, dose prediction, animal models of infection and efficacy;
- conduct, share data, and analyse results from animal infection studies.

Indicative duration of the action

The indicative duration of the action is 72 months.

Future project expansion

Potential applicants must be aware that the Innovative Medicines Initiative 2 (IMI2) Joint Undertaking may, if exceptionally needed, publish at a later stage another call for proposals restricted to the consortium already selected under this topic, in order to enhance and progress the results and achievements by extending the duration and funding by means of another grant agreement. The consortium will be entitled to open to other beneficiaries as it sees fit. One of the purposes of pillar A is to collate data on antibiotic attrition and effectiveness. The analyses that are carried out will generate further knowledge and understanding and will generate further workstreams as yet to be identified. The additional workplans will be addressed via a call for proposals restricted or not to the consortium already selected, depending on the resources required.

Applicant consortium

The applicant consortium will be selected on the basis of the submitted short proposals. The applicant consortium is expected to address all the research objectives and make key contributions to the defined deliverables in synergy with the industry consortium which will join the selected applicant consortium in preparation of the full proposal for stage 2. The applicant consortium is expected to mobilise expertise and proven track record in, for the operational group:

- conducting, and capacity for supporting, grant funded research, preferably with respect to working within projects established by the IMI / IMI2 JU or H2020;
- coordinating multiple discovery AMR projects;
- rigorous project and programme management and alliance management for projects of the complexity and scale of the overall AMR Accelerator, preferably with respect to working within projects established by the IMI / IMI2 JU or H2020 (including management of scientific and financial reporting, legal agreements including IP arrangements, meeting facilitation / secretariat role);

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- ethics and data governance and privacy in relation to AMR;
- communications and outreach to the scientific community and public;
- collection, collation and curation of data sets and identifying, implementing, maintaining IT systems across large collaborative projects or PPPs,
- business development as applied to large collaborative projects or PPPs;

and in, for the scientific group:

- analysis of preclinical and clinical trial data in the AMR space in relation to e.g. efficacy, safety, translation of preclinical data with respect to safety, tolerability, dose prediction, animal models of infection and efficacy;
- conducting and analysing animal infection models to generate reference data of benchmarked control compounds and bacterial isolates.

Note that the number of participants directly related to the operational objectives is expected to be limited in size to minimise complexity.

Suggested architecture of the full proposal

The applicant consortium should submit a short proposal which includes their suggestions for creating a full proposal architecture, taking into consideration the industry contributions and expertise.

The final architecture of the full proposal will be defined by the participants in compliance with the IMI2 rules and with a view to the achievement of the project objectives.

In the spirit of the partnership, and to reflect how IMI2 Call topics are built on identified scientific priorities agreed together with EFPIA beneficiaries/large industrial beneficiaries, it is envisaged that IMI2 proposals and projects may allocate a leading role within the consortium to an EFPIA beneficiary/large industrial beneficiary. Within an applicant consortium discussing the full proposal to be submitted at stage 2, it is expected that one of the EFPIA beneficiaries/large industrial beneficiaries may elect to become the coordinator or the project leader. Therefore to facilitate the formation of the final consortium, all beneficiaries are encouraged to discuss the weighting of responsibilities and priorities therein. Until the roles are formally appointed through a Consortium Agreement the proposed project leader shall facilitate an efficient negotiation of project content and required agreements.

Sustainability

A plan for aspects related to sustainability, facilitating continuation beyond the duration of the project should also be proposed.

Applicants to Calls launched as part of the Accelerator should consult the IMI2 JU Model Grant Agreement and IMI2 JU Annotated Model Grant Agreement.

Indicative text