



SECOND CALL FOR TRANSNATIONAL RESEARCH PROJECTS WITHIN THE JOINT PROGRAMME INITIATIVE ANTIMICROBIAL RESISTANCE

JPIAMR

CALL TEXT

DEADLINES

May 12th, 2015 (17:00, CET) - SUBMISSION OF PRE-PROPOSALS

August 25th, 2015 (17:00, CET) - SUBMISSION OF INVITED FULL-PROPOSALS

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Call for translational research on repurposing of neglected antibiotics and characterizing antibiotics or antibiotic and non-antibiotic combinations to overcome bacterial antibiotic resistance

Only transnational projects will be funded. Each proposal must involve a minimum of three countries participating in this call and a maximum of six project participants. Project participants from countries not providing funding to the call may be involved in projects if they secure their own funding and if they are able to clearly demonstrate an added value to the consortium. The consortia should always consist of a majority of funded project participants. However, the maximum number of six participants may not be exceeded. Project partners from countries not providing funding to the call cannot be consortium coordinators and must accept all JPIAMR rules and guidelines just as funded members. Each consortium is encouraged to include participants from academia, clinical/public health and industry (please note the national/regional regulations section 2.5). Funding will be granted for a maximum of three years. Submissions of proposals will be in two steps: The deadline for submitting pre-proposals is **May 12th, 2015** and invited full proposals must be submitted by **August 25th, 2015**. Projects will be expected to start at the **end of 2015 or beginning of 2016**.

1 Aim of the call:

The primary aim of this second joint call of JPIAMR is to combine the resources, infrastructures, and research strengths of multiple countries in order to overcome antibiotic resistance. The goal is to foster multinational translational research collaborations that can accomplish more than individual countries working independently, and improve the control of bacterial infections.

1.1 Topic:

Sustain defense against AMR in human and animal health by:

- reviving Neglected and Disused AntiBiotics (ND-AB)
- designing combinations of ND-AB and antibiotic
- designing combinations of ND-AB and non-antibiotic

to reduce occurrence of resistance or overcome established resistance.

The activity of ND-AB and the synergy of the combinations of ND-AB with other antibiotics and non-antibiotic should be validated by testing for activity/synergy *in vitro* and in validated animal models with pharmacokinetic/pharmacodynamic (PK/PD) modelling.

1.2 Objectives

Repurposing of ND-AB and/or identify, characterize and understand interaction between ND-AB with other antibiotics and non-antibiotics already used in the medical setting, in order to find combinations avoiding selection for resistance.

The rationale must be validated through a mechanistic understanding of synergy and/or demonstration of significant improvement of antibiotic use by exploitation of PK/PD characterization.

It is mandatory that each project conclude with a head to head comparison of at least 3 to 6 different treatments in at least two validated animal models. The different *in vivo* validation

from one proposal should be comparable and it is highly recommended to perform them in the same laboratory. The *in vivo* validation should include some PK/PD analysis.

It should incorporate:

- *In vitro* demonstration of potential activity by testing ND-AB or ND-AB in combinations with other antibiotics or possibly in association with non-antibiotics, to overcome antimicrobial resistance or reduce selection for resistance.
 - Screening combinations and respective dosages of components
 - Sustaining such efficacy by understanding the mechanism involved
- Strategies to improve PK/PD
 - On earlier generation antibiotics
 - On combination of antibiotics
- Validation of the approaches
 - *in vivo*, exclusively in validated animal models of infection (preferentially pneumonia, pyelonephritis or endocarditis)
 - Validation including endpoints such as overcoming resistance of multiresistant strains and/or reduction in selection for resistance or selection of resistance strains/genes.

It would exclude:

- Studies on the resistance of *Mycobacterium tuberculosis*
- Studies with antibiotics and non-antibiotics not commercially available for a clinically use; new formulation are not eligible
- Development of new animal models

1.3 Justification:

New therapeutic approaches are urgently needed to control bacterial infections and safeguard the health of populations. The reviving of ND-AB and research on improving the efficiency of antibiotics by using them in combination with another antibiotics or a non-antibiotic can be a fast solution to overcome antimicrobial resistance.

1.4 Expected Impact:

It is expected that through international collaborations that combine complementary and synergistic research strengths, this JPIAMR call will facilitate the generation and application of new approaches to overcome antibiotic resistance. Proposals are expected to clearly define described targets and milestones to reach the objectives of the call.

2 Application:

2.1 Eligibility

Applicants must adhere to the specific regulations of the national funding organizations. Each transnational consortium submitting a proposal must involve:

- A minimum of three eligible partners from countries participating in the call
- A maximum of six countries/project participants
- A maximum of two partners of the same country per consortium
- Project participants not eligible to be funded (e.g. from non-funding countries or not fundable according to national/regional regulations of the participating funding countries) may be involved in projects if they secure their own funding and if they are able to clearly demonstrate an added value to the consortium. Each consortium can include only one partner which is not fundable by the funding organizations.
- Project participants not eligible for funds cannot be consortium coordinators and must accept all JPIAMR rules and guidelines just as funded members.

2.2 Submission of joint transnational proposal

Submissions of proposals will be in two steps. In both cases, one joint proposal document (in English) shall be prepared by the project participants of a joint transnational proposal, and must be submitted to the Joint Call Secretariat (JCS) by the coordinator.

JCS Contact:

Dr. Serena Battaglia, French National Research Agency

Phone: +33 1 78 09 80 14

Email: JCSAMR@agencerecherche.fr

A submission tool will be implemented in the JPIAMR website (<https://submission2015.jpiamr.eu>). For details see also the **Guidelines for Applicants**.

The two-steps application process (pre-proposal, full proposal) will have the following timetable:

17th of February 2015	Pre-announcement of the second joint transnational call
17th of March, 2015	Publication of the second joint transnational call
12th of May, 2015 (17:00, CET)	Deadline for pre-proposal submission
End of June, 2015	Communication of the results of the pre-proposal assessment (invitation for full proposal)
25th of August, 2015 (17:00, CET)	Deadline for full proposal submission
October 2015	Peer Review Panel Meeting and funding recommendation to national funding agencies
November 2015	Communication of the funding decisions to the applicants
End of 2015, beginning 2016	Expected projects start (also subject to national procedures)

2.3 Financial modalities and funding prerequisites

Funding is granted for a maximum of three years in accordance with national regulations. **Applicants must refer and adhere to their own specific national regulations and scientific remits as detailed in the National Announcements.** Clarification may be obtained from the individual funding organizations (see contact details in section 2.4).

The funds provided by the Parties are listed in the table below. The “virtual common pot model” shall apply for this transnational call. As such, each country will fund its own approved project partners. The proposals will be funded, as far as possible, following the ranking list recommended by the Peer Review Panel.

Anticipated funding provided by each party

Name of Organisation	Country	Contribution in million €
Ministry of science, technology and productive innovation (MINCYT)	Argentina	0,1
The research Foundation - Flanders (FWO)	Belgium	0,2
The National Fund for Scientific Research – French speaking community (FNRS)	Belgium	0,2
French Agency National of the Research (ANR)	France	1,0
The Federal Ministry of Education and Research (BMBF)	Germany	1,0
The Ministry of Health (MoH)	Italy	0,7
The Netherlands Organisation for Health Research and Development (ZonMw)	Netherlands	0,75
The Research Council of Norway (RCN)	Norway	1,5
National Centre for Research and Development (NCBR)	Poland	0,5
Swedish Research Council (SRC)	Sweden	3,7
TOTAL		9,65

Each consortium should provide a consortium agreement (CA) signed by all participants. The project consortium is strongly encouraged to sign this CA before the start of the project to clarify the potential IP matters (such as licensing in, licensing out, patent and exploitation strategy), and in any case no later than six months after the official project start date. The points that must be addressed in the CA are detailed in the Annex C.

2.4 Contact persons

The only official communication line of the proposal is between the Joint Call Secretariat and the project coordinator. The project coordinator will be the person contacted by the Joint Call

Secretariat during the application procedure, so he/she must forward this information to the other participants. Each funding organisation has national contact persons who can be contacted for information about the specific national requirements (see table below).

Country	Funding organisation	Contact person	Email
Argentina	MINCYT	Dr. Monica Silenzi	msilenzi@mincyt.gob.ar
Belgium	FWO	Dr. Olivier Boehme Toon Monbaliu	jpi@fwo.be
Belgium	FNRS	Dr. Arnaud Goolaerts Dr. Freia Van Hee	arnaud.goolaerts@frs-fnrs.be freia.vanhee@frs-fnrs.be
France	ANR	Dr. Serena Battaglia Dr. Martine Batoux	JCSAMR@agencerecherche.fr
Germany	BMBF/Ptj	Dr. Henrike Knizia	h.knizia@fz-juelich.de
Italy	MoH	Dr. Gaetano Guglielmi	g.guglielmi@sanita.it
The Netherlands	ZonMw	Dunja Dreesens	dreesens@zonmw.nl
Norway	RCN	Sonja Prehn Dyveke Hetland	sp@forskningsradet.no dhe@forskningsradet.no
Poland	NCBR	Aleksandra Moscicka- Studzińska	aleksandra.moscicka@ncbr.gov.pl
Sweden	SRC	Dr. Maria Starborg	maria.starborg@vr.se

2.5 National Regulation Overview

Please note that this is only a summary. Refer to the national websites and contact the respective national contact person for full details.

Funding Body/ Country	ANR (France)
Funding of industrial partners eligible?	Yes
Participation of industry required?	No
Maximum funding per partner/ per project	Maximum funding per partner: 250 k€.
Eligible costs	Personnel, Consumables, Animals, Subcontracts (if costs < 50% eligible costs), Equipment, Travel See French Annex for details at http://www.agence-nationale-recherche.fr/JPIAMR2015
Additional documents required	No
Other national restrictions	For projects selected for funding: a copy of the signed consortium agreement established between the partners of the consortium must be provided to ANR before the first payment to the French researchers involved in the project.

Funding Body/ Country	FNRS (Belgium)
Funding of industrial partners eligible?	No
Participation of industry required?	No
Maximum funding per partner/ per project	200 k€
Eligible costs	See: http://www.ncp.frs-fnrs.be/index.php/17-appels/144-zerzerz
Additional documents required	No
Other national restrictions	See: http://www.ncp.frs-fnrs.be/index.php/17-appels/144-zerzerz

Funding Body/ Country	FWO (Belgium)
Funding of industrial partners eligible?	No
Participation of industry required?	
Maximum funding per partner/ per project	Only top-up money for existing FWO projects will be provided € 10.000 /year per partner; € 30.000 in total
Eligible costs	The same as in the regulation for the existing FWO projects
Additional documents required	No
Other national restrictions	No

Funding Body/ Country	MINCYT (Argentina)
Funding of industrial partners eligible?	SMEs, (max funding 70%)
Participation of industry required?	SMEs participation is not mandatory
Maximum funding per partner/ per project	€ 30.000 per project
Eligible costs	<ul style="list-style-type: none"> • Mobility (travel + accommodation) • Short-term exchange visits • Meeting, workshops and events organization • Publication, dissemination • Consumables/ Small equipment • Other costs (administration)
Additional documents required	NO
Other national restrictions	NO

Funding Body/ Country	MoH (Italy)
Funding of industrial partners eligible?	NO
Participation of industry required?	NO
Maximum funding per partner/ per project	YES max 200.000€ per Projects with max 200.000€ per partner
Eligible costs	<p>Only costs generated during the lifetime of the project can be eligible.</p> <p>Personnel (only ad hoc contracts/consultants/fellowship, max 50% of the requested fund); travel costs and subsistence allowances (max 10% of the requested fund); equipment (rent/leasing only), consumables, dissemination of results (publications, meetings/workshops etc.) (max 1% of the requested fund); data handling and analysis; overhead (maximum 10% of the requested fund). (All according to national regulations).</p> <p>Travel expenses and subsistence allowances associated with training activities linked to the project</p>
Additional documents required	<p>In order to expedite the eligibility check process, the Ministry of Health will grant an eligibility clearance to the applicants prior to the submission of the pre-proposals. To this end, it is mandatory that the applicants fill out and return a pre-eligibility check form through IRCCS Scientific Directorate using WFR System before submitting their pre-proposals to the Joint Call Secretariat. It is strongly recommended that the form, completed and duly signed, is returned at least 10 working days before the pre-proposal submission deadline. Applicants will be sent a written notification of their eligibility status.</p> <p>After the JTC peer review has been completed and the final (scientific) ranking list has been performed and endorsed by the Call Steering Committee, the Ministry of Health will invite the principal investigators of the projects approved for funding to enter the formal national negotiations (according to national regulations).</p>
Other national restrictions	<p>Funded only Scientific Institutes for Research, Hospitalization and Health Care (Istituti di Ricovero e Cura a Carattere Scientifico pubblici e privati, IRCCS).</p> <p>The simultaneous participation in proposals submitted in 2015 to different transnational research calls, funded by the Ministero della Salute, is not allowed to Italian Principal Investigators or other research team members.</p>

Funding Body/ Country	NCBR (Poland)
Funding of industrial partners eligible?	Yes
Participation of industry required?	No
Maximum funding per partner/ per project	No; not more than €500 000
Eligible costs	<p>The eligible costs shall be the following:</p> <ol style="list-style-type: none"> personnel costs (researchers, technicians and other supporting staff to the extent employed on the research project); costs of instruments and equipment, technical knowledge and patents to the extent and for the period used for the research project; if such instruments and equipment are not used for their full life for the research project, only the depreciation costs corresponding to the life of the research project, as calculated on the basis of good accounting practice, shall be considered eligible; costs for buildings and land, to the extent and for the duration used for the research project; with regard to buildings, only the depreciation costs corresponding to the life of the research project, as calculated on the basis of good accounting practice shall be considered eligible; for land, costs of commercial transfer or actually incurred capital costs shall be eligible; cost of contractual research, costs of consultancy and equivalent services used exclusively for the research activity; this cost type cannot account for more than 70% of all eligible costs of a project; the subcontracting can be obtained from consortium partner only in justified case, this need will be verified by a national experts panel; other operating costs including costs of materials, supplies and similar products incurred directly as a result of the research activity; additional overheads incurred indirectly as a result of the research project; that costs cannot account for more than 25% of eligible project costs; That costs (6) are counted as a multiplication by percentage given above (called x%) and the rest of direct costs, excluding subcontracting (4); It means $6=(1+2+3+5)*x\%$. <p>Other type of activities (e.g. coordination, dissemination, management) is not eligible for funding as separate research tasks in the project schedule.</p>
Additional documents required	For the projects selected for funding, a national proposal submission to the NCBR by Polish partners is required.
Other national restrictions	<p>Funding of Polish partners can be started from January 2016.</p> <p>All proposals must be aligned with National regulations, inter alia:</p> <ul style="list-style-type: none"> The Act of 30 April 2010 on the Principles of Financing Science, published in Journal of Laws No. 96 item 615, 2010; The Act of 30 April 2010 on the National Centre for Research and Development, published in Journal of Laws No. 96 item 616, 2010; <p>The Regulation of the Minister of Science and Higher Education on criteria and rules on granting state aid and “de minimis” aid by the National Centre for Research and Development.</p>

Funding Body/ Country	PTJuelich (Germany)
Funding of industrial partners eligible? Participation of industry required?	Funding of industrial partners eligible. Participation of industry is preferred.
Maximum funding per partner/ per project	Up to 350 K€ per part project.
Eligible costs	See national guidelines
Additional documents required	National application forms after funding recommendation
Other national restrictions	no

Funding Body/ Country	RCN (Norway)
Funding of industrial partners eligible? Participation of industry required?	Yes, funding for industrial partners is possible No, participation from the industry is not required
Maximum funding per partner/ per project	A maximum of 750 000 € for Norwegian partners per project for a 3 year period
Eligible costs	Relevant project expenses such as payroll expenses, grants/fellowships, procurement of R&D services, network measures, depreciation of equipment used under project. Consult the Norwegian information on The Research Council of Norway's website, for details.
Additional documents required	
Other national restrictions	Consult the Norwegian information on The Research Council of Norway's website.

Funding Body/ Country	SRC (Sweden)
Funding of industrial partners eligible?	Yes
Participation of industry required?	No
Maximum funding per partner/ per project	No, however, the anticipated maximum number of funded projects will be 5.
Eligible costs	The grant can be used to cover any type of project-related costs, for example salaries (including salary of principal investigator, corresponding to the level of activity in the project), travel (including visits to, and stays at, research facilities), publication costs, minor equipment and depreciations, etc. The grant may not be used for scholarships.
Additional documents required	No
Other national restrictions	<p>Total budget for industrial partners is 1,6 million € Total budget for Academia, public research institutes and hospital is 2,1 million €</p> <p>The principal investigator needs to hold a PhD at the time of application submission. Grants distributed by the Swedish Research Council must be administrated by a Swedish university, higher education institution (HEI) or other public organization that fulfils the Swedish Research Councils criteria for an administrating organization. A list of eligible organizations is found at: http://www.vr.se/inenglish/researchfunding/applyforgrants/generalconditionsforgrantapplications/approvedadministratingorganisations.4.4b1cd22413cb479b80537a9.html</p> <p>Further general conditions for grant applications is found at: http://www.vr.se/inenglish/researchfunding/applyforgrants/generalconditionsforgrantapplications.4.5adac704126af4b4be280007743.html</p>

Funding Body/ Country	ZonMw (the Netherlands)
Funding of industrial partners eligible?	Yes, contact your national contact person for specific industry funding conditions
Participation of industry required?	No
Maximum funding per partner/ per project	No, however, the anticipated maximum number of funded projects will be 2 or 3.
Eligible costs	Please consult http://www.zonmw.nl/nl/subsidies/voorwaarden- en-financien/ or your national contact person
Additional documents required	No
Other national restrictions	Dutch part of the project needs to start in 2015, for further details please consult http://www.zonmw.nl/nl/subsidies/voorwaarden- en-financien/ or your national contact person