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Global Call for Research Proposals:

Innovative Veterinary Solutions for Antimicrobial Resistance (InnoVet-AMR) in Food-Producing animals: Livestock and Aquaculture

- This document is a Call for Research Proposals for funding support from Canada's International Development Research Centre and the UK Department of Health and Social Care
- The purpose of this call is to support the development of innovative veterinary solutions to reduce the use of antibiotics in food-producing animals

Deadline: September 10, 2018 at 11:00am Eastern Daylight Time (Ottawa); 3:00pm Greenwich Mean Time Click <u>here</u> to submit an application

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About the International Development Research Centre

The International Development Research Centre (IDRC), a Canadian Crown corporation, funds research in developing countries to create lasting change on a large scale. Canada's IDRC supports research that generates local solutions, bringing choice and change to those who need it most in the developing world. We achieve this by investing in knowledge and innovation, supporting the leaders of the future, and by being a partner of choice for the public and private sectors.

About the UK Department of Health and Social Care

The Department for Health and Social Care (DHSC) is the UK Government department which is responsible for helping people to live more independent, healthier lives for longer. The partnership with IDRC is part of DHSC's Global Antimicrobial Resistance Innovation Fund (GAMRIF). GAMRIF was established to support early-stage, innovative research and development, specifically targeting neglected and underinvested areas in the field of antimicrobial resistance (AMR). GAMRIF is a £50m Official Development Assistance investment, which means all projects funded must support research primarily and directly for the benefit of people living in developing countries. The Fund takes a 'One Health' approach, seeking to invest in potential solutions to reduce the threat of AMR in humans, animals, fish and the environment.

About Innovative Veterinary Solutions for Antimicrobial Resistance (InnoVet-AMR)

InnoVet-AMR is a four-year, CA\$27.9 million partnership between IDRC and DHSC. The initiative is aimed at reducing the emerging risk that AMR in animals poses to global health and food security.

Through InnoVet-AMR, IDRC and DHSC aim to achieve two main objectives:

- Support research that will identify innovative veterinary solutions, including vaccines, to reduce the use of antimicrobials in livestock and aquaculture operations in low and middle income countries;
- Build effective partnerships to better coordinate discovery, development and sustainable delivery of innovative veterinary solutions to reduce the use of antimicrobials in livestock and aquaculture operations in low and middle income countries.

About the Call

4.1 The Challenge and Opportunities

Anti-Microbial Resistance, at a global level, is a major threat to human and animal health. It endangers modern human and veterinary medicine and undermines the safety of our food and the environment. Antimicrobials (including antibiotics) play a critical role in the treatment of diseases of farm animals (aquatic and terrestrial). Their use is essential to food security, to human health, and to animal welfare. However, the misuse of antimicrobials, in both human and veterinary medicine, is associated with the emergence and spread of antimicrobial-resistant organisms (including bacteria) and has been identified as a risk factor for human infection. The risk is potentially higher in countries where legislation, regulatory surveillance and monitoring systems on the use of antimicrobials, and the prevention and control of AMR, are weak or inadequate (FAO, 2016).

Livestock provide food and income for roughly 1.4 billion farmers globally, including 800 million poor livestock keepers. With AMR on the rise, communities in developing countries are highly impacted by the increase of infectious disease outbreaks, and loss in livestock productivity, which ultimately endangers food security and disrupts international trade. In animal agriculture, antimicrobials can be used therapeutically (treating disease, preventing or controlling infection) or non-therapeutically (growth promotion). Please refer to Annex 1 for the common approach of the G7 Chief Veterinary Officers on the definitions of therapeutic, responsible and prudent use of antimicrobials in animals.

Alternative products to antimicrobials can play a crucial role in reducing the need, and hence misuse, of antimicrobials in animal agriculture (e.g. preventing infectious diseases altogether). Vaccines are among the most promising and widely used of these alternatives. However, other innovative products are in use or currently being investigated and offer additional options to producers (e.g. pre- and pro-biotics or the use of products to enhance the innate immune system). While alternative products have great potential to reduce the emergence and spread of AMR, it should be noted that these solutions reach their full potential when considered as one part of a comprehensive animal management program aimed at ensuring healthy and disease-free animals.

The last two decades have witnessed major advances in biotechnology and vaccinology which now provide an unparalleled opportunity for the development of new generation livestock and aquaculture animal vaccines and alternative products. Innovations in delivery and administration mechanisms provide opportunities to enhance the ease of use and uptake of these products by large numbers of producers in the livestock and aquaculture sectors globally.

Despite scientific advances, many new products or innovations have failed to respond to the realities of the needs of farmers and livestock keepers and the aquaculture sector in low and middle income countries where they are most needed. Strong involvement of researchers, manufacturers and other organizations, as well as early involvement of regulatory authorities, in developing countries is critical when working towards accelerating the registration of veterinary

products. This will ensure a deep understanding of local issues faced by farmers and other endusers, and will further contribute positively to the sustainability of the innovations.

In addition, gender equity is a fundamental component of social sustainability. Ensuring gender responsive innovations for farmers is key to ensuring uptake and sustainability of these innovations.

Finally, awareness of the environmental impact of research activities is of great importance. AMR encompasses the interface between humans, animals and the environment. The fact that human and veterinary health, food and feed production systems and agro-ecological environments all contribute to, and are affected by, AMR indicates the need for a multisectoral and multidimensional approach to tackle its emergence and spread.

For more background information, please refer to the Frequently Asked Questions.

4.2 Research Themes

The ultimate intended outcome of InnoVet-AMR:

To reduce the threat of antibiotic resistance to human health by minimising the misuse of antibiotics and the development and spread of antibiotics resistance in developing countries, through the development and uptake of innovative veterinary products.

The InnoVet-AMR initiative addresses antibiotic resistance and is divided into two themes focused on reducing the use of antibiotics in the livestock (poultry and swine) and aquaculture (fish and shellfish) sectors in **low and middle income countries**¹. The main goal of both themes is to develop innovative veterinary solutions, focusing on product development, to reduce the therapeutic (prevention and control) and non-therapeutic (growth promotion) use of antibiotics, while still protecting animal health and welfare.

Research supported in this fund will be expected to understand and address the local contexts and realities which drive antibiotic-usage patterns on farms in developing countries, in order to ensure that innovations are relevant, feasible, practical and appropriate for the ultimate uptake and use by farmers, veterinarians and paraveterinarians in developing countries.

Research proposals must focus on veterinary solutions, where new or improved product oriented-solutions would significantly reduce the therapeutic and/or non-therapeutic use of antibiotics in low and middle income countries in poultry, swine, and/or aquaculture (fish and shellfish) production. These solutions must target the prevention and control of infectious diseases of importance in low and middle income countries and the reduction of the use of antibiotics as growth promoters.

¹ http://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/daclist.htm

These product-oriented solutions include:

- the development of vaccines, vaccine administration/delivery methods; or
- the development of alternatives to antibiotics, including but not limited to pro- and prebiotics, immunomodulators and bacteriophages.

We will only consider veterinary solutions that address:

- infectious diseases of importance to low and middle income countries;
- the reduction of use and/or misuse of antibiotics;
- antibiotic resistance (research projects can target any pathogen as long as a relevant link can be made to minimising the development and spread of antibiotic resistance and/or use/misuse of antibiotics).

We will give highest priority to projects that:

- Present a compelling justification for the proposed innovative veterinary solution, are scientifically sound and clearly describe how this approach will curb antibiotic use and the development of antibiotic resistance in the livestock and aquaculture sectors in **low and middle income countries**
- Demonstrate clear plans for sustainability of the proposed solution
- Support innovations at the **technology readiness level (TRL) 3 to 6** (see Annex 2 for further information), that is early-stage product development, excluding fundamental research
- Demonstrate **strong capacity** to generate timely results based on specific milestones and within the allocated budget
- Include and describe a future **'Commercialization and Adoption plan'** for the veterinary solutions to be developed and ready for use in developing countries
- Include and describe effective partnerships with organizations in low and middle income countries (refer to Frequently Asked Questions)
- Show an awareness of medicines regulation and/or the intent to engage with a Government Regulatory Body for veterinary medicines in low and middle income countries.

Cross-cutting Considerations

Applications must describe how gender equity and environmental considerations will be integrated into the design and implementation of the proposed research. While it may not be possible to address all considerations at the same level of depth, these will be taken into account in the selection process.

• Gender equity: Proposals need to demonstrate how the project will involve women from all participating organizations comprising the research team and throughout the research process. In addition, the Commercialization and Adoption Plan of the innovation should also demonstrate how women will be involved; including a strategy that explains how gender implication will be considered.

• Environment: Proposals need to demonstrate that they have considered the potential environmental impacts of their activities, detailing potential benefits and describing how any potential harmful effects will be mitigated. See Annex 3 for more information.

Examples of what we are looking for (but not exclusively):

- Novel vaccine design/formulation that present significant improvements over current vaccines
- New vaccine administration methods and delivery systems
- Exploration and development of **new multivalent vaccines**
- New alternative products to antibiotics that targets **improved infection prevention and control**
- New alternative products to antibiotics that promote animal productivity and growth.

It is important to emphasize that approaches or examples mentioned are only meant to be illustrative, and not a comprehensive list of appropriate approaches/examples or exclusive of others.

We will NOT consider funding proposals that:

- Do not consider antibiotic resistance
- Do not consider swine, poultry or aquaculture (fish or shellfish)
- Are focused on new antibiotic drug discovery
- Are focused on improving animal husbandry and farm management
- Are to develop diagnostic devices
- Are focused on the development of surveillance platforms
- Are to pilot test new biomarkers or combinations of biomarkers
- Are to develop alternatives solutions to antibiotics not relevant to low and middle income countries
- Are to carry out field trials only
- Are designed for fundamental research, corresponding to TRL 1 and 2 (See Annex 2)
- Are related only to registration or commercialization issues.

InnoVet-AMR Budget Contribution and Duration

Projects must be between CA\$1 to 3 million each for up to 33 months. Projects should plan for 1.5 months start-up, 30 months to conduct research, and 1.5 months to close. Projects are expected to begin in either March or April of 2019.

The project should ensure that it has the necessary team in place to effectively manage a research project of this size, including, but not limited to project coordination (e.g., project managers, thematic leads in each organization, language capabilities, etc.), monitoring and evaluation, and communication activities.

Contribution in the form of co-funding and mobilization of third party resources (public or private sector, other donor or stakeholder funding, etc.) to support and expand the research is encouraged.

Eligibility

- The purpose of the project must be primarily and directly relevant to people in low and middle income countries (Official Development Assistance eligible).
- The proposed veterinary solution must focus on poultry, swine or aquaculture animals (including either fish and shellfish).
- The research team must include at least one researcher from an institution based in a low and middle income country as principle investigator or co-applicant (see Frequently Asked Questions for more details).
- Applicants from academia, private and public sector organisations with a strong research focus are eligible for this global Call.
- Applicants from the United Nations (UN) system are not eligible to apply to this Call as lead or co-applicant organizations. UN organizations may participate as collaborating organizations.
- Applicants from Consultative Group on International Agricultural Research Centres are not eligible as lead organization, but are eligible as co-applicants or collaborating organizations.
- The lead applicant and co-applicants may negotiate and develop funding arrangements directly with third-party organizations for specific services. IDRC will not contract directly with third-party organizations. Applications that involve third-party organizations must clearly justify their involvement and explain their role(s). The total third-party participation in a project is set at a maximum of 30% of the budget.
- At most, a person can apply as the principle investigator for one project and be a coapplicant for one additional project.

For more information about eligibility please refer to the Frequently Asked Questions.

Research Ethics

- It is the policy of IDRC that research involving human participants or animals must be carried out in accordance with high ethical standards (please consult <u>here</u>), including the following:
 - Prior to commencing research, applicants will need to obtain approval from an official institutional or national research ethics body and will need to comply with the terms and conditions of the Grant Agreement.
 - Any research involving animals will need to obtain explicit approval from an appropriate body for oversight of the use of animals in research. All research will need to comply with local regulations.
 - Any research involving the use of genetically modified organisms must demonstrate adherence to all applicable international standards including the Nagoya protocol and procedures and meet local regulations.

- Research projects must demonstrate the Freedom to Operate in order to avoid the commercial use of a technology that is suspected to infringe on existing intellectual property rights.
- Applications must explicitly address intellectual property rights and must detail any potential issues identified (e.g. patents emerging from the research).
- There may be intellectual property rights considerations that flow from a patentable invention generated during the course of a project funded by InnoVet-AMR. The intellectual property guidelines followed by InnoVet-AMR recognize rights to patentable inventions and copyright. In order to ensure that intellectual property generated during this project is made available to those persons or areas of the world that most need it and at a cost that can be afforded, IDRC reserves the right to discuss intellectual property issues with accepted proposals, to request clarification pertaining to intellectual property issues from applicants, or to require agreement on certain licensing conditions.

Submission and Review Process

10.1 Timeline

IDRC invites eligible applicants to submit an electronic application through IDRC's grant application submission system to this Call for Research Proposals before the deadline: Monday September 10, 2018 at 11:00am Eastern Daylight Time (Ottawa); 3:00pm Greenwich Mean Time. Acknowledgements of receipt will be sent to all applicants whose application was received before the closing date and time.

Successful applicants will be notified by **mid to late December, 2018.** Due to the high number of anticipated proposals, unsuccessful applicants will not be notified.

10.2 Selection Process

An external Scientific Advisory Committee will evaluate and rank research proposals received according to the review criteria outlined below and make recommendations to a Governance Steering Committee on funding decisions.

Proposals will be either accepted or rejected for funding. Accepted proposals may receive specific comments from the reviewers, including budgetary adjustments, which applicants will be required to satisfactorily address before receiving any grant. Applicants with accepted proposals will be required to sign a Grant Agreement with IDRC that details the terms and conditions for the grant.

Review Criteria

Proposals will be assessed against the following review criteria:

Review criteria	Percentage of score (%)
Innovative approach & Justification	
The proposal:	
 Provides a detailed justification of the selected innovative veterinary solution and clearly describes how this approach will reduce use of antibiotics and the development and spread of antibiotic resistance in the livestock and aquaculture sectors in low and middle income countries (25%) Demonstrates well-defined objectives, clearly described methodology and scientific soundness of innovation. (15%) Addresses all ethical issues in relation to the use of animals and genetically modified organisms. (5%) 	45
Feasibility	
The proposal:	30
• Describes how the proposed results will be achieved within the 33-	
month funding period and the allocated budget. (10%)	
 Provides clear and achievable milestones within the 33-month funding period. (5%) 	
 Provide a realistic commercialization and adoption plan for the 	
veterinary solutions to be developed and ready for use in low and middle income countries. (7.5%)	
Clearly includes and describes effective partnerships with	
organizations in low and middle income countries. (7.5%)	
Expertise and composition of research team	
 The research team has the necessary partners and expertise to 	15
complete the proposal and demonstrates strong expertise and	
track record, as appropriate, in antimicrobial resistance research,	
vaccine research, research in the field of alternatives to	
antimicrobials other than vaccines, animal health and/or	
veterinary science (in relation to the research proposed). (15%)	
Cross-cutting considerations	
• Gender equity (5%)	10
 Environment (please refer to Cross-cutting Considerations section) (5%) 	

How to Apply

All applications must be submitted through an online application system by September 10, 2018 at September 10, 2018 at 11:00am Eastern Daylight Time (Ottawa); 3:00pm Greenwich Mean Time. **Proposals received after the submission deadline WILL NOT be considered.**

Please visit <u>https://innovet-amr-ram.fluidreview.com/</u> to access the online application system and all the documents related to this Call. Applications can be submitted in either English or French.

Enquiries

Any enquiries related to the Call and application process must be sent by e-mail to <u>innovetamr@idrc.ca</u>. All enquiries must be received on or before 17:00 Eastern Daylight Time on August 24, 2018 in order to receive a response prior to the deadline date.

Any enquiries, which affect all applicants, received on or before the above-mentioned deadline will be added to the Frequently Asked Questions with InnoVet-AMR's responses to those inquiries, without revealing the source of the enquiries.

Additional Important Considerations

- 1. Although there is no limit on the number of co-applicants in one application, IDRC will only negotiate Grant Agreements with the lead applicant's organization and up to two co-applicant organizations (i.e. up to three Grant Agreements per research project).
- 2. If equipment is needed, InnoVet-AMR expects that key equipment will be procured and purchased within the first 6 to 12 months of the project. Please state how the project will ensure that this occurs. Also, clarify who will own any purchased equipment during and after the project. Unless justified, this should be one of the eligible country partners.
- 3. As a Canadian Crown corporation, IDRC is subject to Canada's Access to Information Act. Consequently, any submissions in response to this Call for Research Proposals will be held by IDRC in a manner consistent with the Access to Information Act, including IDRC's obligations to disclose documents requested by members of the public.
- 4. By way of submitting an application under this Call, the applicants consent to the disclosure of the documents submitted by the applicant to IDRC, DHSC, and external reviewers who are involved in the assessment and selection processes of proposals. If selected for funding, the applicants further consent to the disclosure of their name and the title of the proposed project in any announcement of selected projects. Unsuccessful proposals will be destroyed within 180 days after the close of the application period.
- 5. Applicants must publish research findings in the public domain in accordance with IDRC's <u>Open Access Policy</u>.
- 6. IDRC reserves the right to reject proposals based on the geographical location of the applicant's organization or based on relevant policy or legislative considerations. Please refer to Frequently Asked Questions for further details.

7. After an institutional assessment of an applicant's organization is performed, IDRC reserves the right to require the applicant's organization to partner with another institution, for administrative reasons, as a condition of receiving the grant.

Annex 1

Schematic for distinguishing between the concept of using antimicrobials for reasons relating to disease and using them for production reasons.



Ref: Common approach of the G7 CVOs on the definitions of the therapeutic, responsible and prudent use of antimicrobials in animals (G7 CVOs second Forum, Rome – October 2017)

http://www.salute.gov.it/imgs/C_17_notizie_3118_listaFile_itemName_0_file.pdf

Annex 2

Technology readiness levels (TRL)

There are 9 technology readiness levels, with 1 being the least ready and 9 being already used in real-life conditions.

Levels 1 through 6 represent the early stages of research and development for innovations. InnoVet-AMR will support innovations at **TRL 3 to 6.**

Technology readiness levels	Definitions
Level 1: Basic principles of concept are	Scientific research begins to be translated into applied
observed and reported	research and development. Activities might include paper
	studies of a technology's basic properties.
Level 2: Technology concept and/or	Invention begins. Once basic principles are observed,
application formulated	practical applications can be invented. Activities are
	limited to analytic studies.
Level 3: Analytical and experimental	Active research and development is initiated. This
critical function and/or proof of concept	Includes analytical studies and/or laboratory studies.
	integrated or representative
Lovel 4: Component and/or validation in	Basic technological components are integrated to
a laboratory environment	establish that they will work together Activities include
	integration of "ad hoc" hardware in the laboratory.
Level 5: Component and/or validation in	The basic technological components are integrated for
a simulated environment	testing in a simulated environment. Activities include
	laboratory integration of components.
Level 6: System/subsystem model or	A model or prototype that represents a near desired
prototype demonstration in a simulated	configuration. Activities include testing in a simulated
environment	operational environment or laboratory.
Level 7: Prototype ready for	Prototype at planned operational level and is ready for
demonstration in an appropriate	demonstration in an operational environment. Activities
operational environment	include prototype field testing.
Level 8: Actual technology completed and	lechnology has been proven to work in its final form and
demonstrations	developmental testing and evaluation of whether it will
demonstrations	meet operational requirements
Level 9: Actual technology proven through	Actual application of the technology in its final form and
successful deployment in an operational	under real-life conditions, such as those encountered in
setting	operational tests and evaluations. Activities include using
Setting	the innovation under operational conditions
	the innevation under operational conditions.

Government of Canada (2015). Annex 2—Technology Readiness Level (TRL) Scale - Technology Demonstration Program (TDP). <u>https://ito.ic.qc.ca/eic/site/ito-oti.nsf/eng/00849.html</u>

Annex 3

Environmental Safety Guidelines of Innovative Veterinary Solutions for Antimicrobial Resistance (InnoVet-AMR)

The research, development and manufacturing of veterinary vaccines and other biological veterinary products is the subject of several national and international legislations and standards. The basic criteria that must be met are those of safety, efficacy, quality, purity and potency. Environmental safety is one of the aspects that must be considered at all stages, and must be demonstrated within the research and development process. The World Organisation for Animal Health (OIE) is the reference for laboratory methods and requirements for the production and control of vaccines and other biological veterinary products. Overall, Good Manufacturing Practices, Good Laboratory Practices and Good Clinical Practices should be applied throughout all stages of veterinary vaccine research, development and manufacture.

For this call for research proposals, the projects that will be funded should at the very least comply with their national or relevant international legislations related to veterinary vaccine and other biological veterinary products research and development. In addition, research teams must comply with the Terms and Conditions of the Grant Agreement, including those related to environmental safety guidelines.

Potential risks related to research conducted under this call, but not limited to, include contamination, pollution, virus shedding, infection of non-target species, recombination with naturally occurring virus relatives, reversion to virulence and integration of genetically modified virus DNA into host cell chromosomes. All research teams must identify potential environmental risks and indicate how each will be mitigated through the use of proper infrastructure and adequate processes. Research teams are required to conduct self-assessment and classify their proposed research into one of the following categories:

 \Box X – Very High Environmental Risk: Projects with high probability of medium or high environmental impact that would be hardly manageable.

A - High Environmental Risk: Projects with low or moderate probability of high environmental impact or high probability of low or moderate environmental impact;

□ B - Low or Moderate Environmental Risk: Projects with low or moderate probability of low to moderate environmental impact; and

□ C - Negligible Environmental Risk: Projects with negligible probability of environmental impact

Please note that the IDRC reserves the right to subject the self-assessment to an independent environmental safety expert prior to project selection and funding. Depending on the classification category above, some proposed research projects may be asked to conduct a full environmental impact assessment of their proposed research. Some useful links addressing Canadian and International Environmental Safety Standards are provided below.

- 1. World Organisation for Animal Health (OIE): <u>http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/</u>
- 2. Canadian Environmental Assessment Agency, 2012: https://www.ceaa-acee.gc.ca/default.asp?lang=En&n=A4C57835-1
- 3. World Health Organization (WHO) http://www.who.int/biologicals/vaccines/good_manufacturing_practice/en/
- 4. Organisation for Economic Co-operation and Development (OECD) <u>http://www.oecd.org/chemicalsafety/testing/goodlaboratorypracticeglp.htm</u>
- 5. European Commission http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm