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Global AMR Innovation Fund

Global Call for Research Proposals:
Innovative Veterinary Solutions for Antimicrobial Resistance (InnoVet-AMR) 2 in Food-Producing animals: Ruminants 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 improve animal health while reducing the use of antimicrobials in food-producing animals.

Deadline: October 30, 2023 at 15:00 EDT (Ottawa)

Click here to apply

Contents

Full proposal: Innovative Veterinary Solutions for Antimicrobial Resistance (InnoVet-AMR) 2.0 in Food-Producing animals: Ruminants and Aquaculture

Launch date: September 14, 2023

Full proposals must be received no later than October 30, 2023 at 15:00 Eastern Daylight Time or EDT.

The International Development Research Centre (IDRC) is pleased to announce a call for full proposals on Innovative Veterinary Solutions for Antimicrobial Resistance (InnoVet-AMR) 2.0 in Food-Producing animals: Ruminants and Aquaculture.

1. About IDRC, the program divisions and the focus area

IDRC is a Crown corporation created in 1970 by the Parliament of Canada. IDRC supports and strengthens the capacity of people and institutions in developing countries to undertake the research that they identify as most urgent. It works with researchers and research users as they confront contemporary challenges within their own countries, and contributes to global advances in their fields.

The Centre's 10-year strategy, Strategy 2030, affirms IDRC's vision for a more sustainable and inclusive world, and commits the Centre to the following mission: **IDRC will be a leader in research for development, investing in high-quality research and innovation, sharing knowledge for greater uptake and use, and mobilizing alliances for more sustainable, prosperous and inclusive societies.** (Please refer to IDRC's Strategy 2030 for more information.)

In the context of this strategy, we identified the following five programs that will shape IDRC's work over the next decade — making knowledge a tool for improving lives across the developing world:

- Climate-Resilient Food Systems
- Democratic and Inclusive Governance
- Education and Science
- Global Health
- Sustainable Inclusive Economies

Climate-Resilient Food Systems program (CRFS) funds research that helps build equitable, inclusive and sustainable food systems in developing countries. This work helps develop resilience among communities severely affected by climate change and address emerging health threats that arise from food systems. Animal Health is part of the CRFS program and funds innovative research with the aim to improve animal health and welfare, as well as food production and security. Climate, food quality and security, and gender equality and inclusion are central to our program. In the following sections you will see how we plan to address this in all our programming.

2. About the UK Department of Health and Social Care

The Department for Health and Social Care (DHSC) is the UK Government department 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 is a One Health UK aid fund that supports research and development around the world to reduce the threat of antimicrobial resistance in humans, animals and the environment for the benefit of people in low- and middle-income countries (LMICs). GAMRIF core objectives are to develop innovative One Health solutions to tackle antimicrobial

resistance (AMR); increase availability of context-specific, accessible and affordable innovations for LMICs; establish international research partnerships with industry, academia and governments; and collaborate with and leverage additional funding from other global donors.

3. About innovative veterinary solutions for antimicrobial resistance (InnoVet-AMR)

InnoVet-AMR 2.0 is a four-year, CAD26.3 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 and develop prophylactic and therapeutic innovative veterinary solutions, including vaccines, to improve health, while reducing the use of antimicrobials in ruminants and aquaculture operations in LMICs.
- Build effective, gender-balanced partnerships to better contribute to the discovery and development of innovative veterinary solutions to reduce the use of antimicrobials in ruminants and aquaculture operations in LMICs.

4. Overview of the call

Background and rationale

AMR, 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 — in particular, antibacterials — play a key role in healthy animal production systems and are critical to the treatment of diseases of farm animals, both terrestrial and aquatic. Maintaining their efficacy is essential to food security, human health, and animal health and welfare. However, the misuse and overuse of antimicrobials, in both human and veterinary medicine, is associated with the emergence and spread of antimicrobial-resistant organisms (e.g., bacteria) that threaten the ability to effectively treat infections in animals and humans. The risk posed by AMR is likely 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). The recent Global Burden of AMR study found that an estimated 4.95 million deaths in 2019 were associated with AMR, with 1.27 million deaths directly attributable to AMR (Murray et al., 2022). Food-producing animals, and the wider environment, represent an important reservoir of antimicrobial-resistant bacteria and resistance genes that may spread from animals to humans either by direct contact or indirectly, through food preparation and consumption, via contaminated water, and using animal waste as a fertilizer. While the threat of AMR in animals posed to humans is not fully known, global trends in meat consumption and antimicrobial use indicate that it is likely on the rise (Van Boeckel et al, 2019). Given the inextricable links between human, animal, plant and environmental health, AMR represents a priority One Health issue.

Ruminants and aquaculture play a pivotal role in food systems in LMICs, providing food and income for roughly 1.4 billion farmers globally, including 800 million poor ruminant keepers, whereas more than 20 million people depend on aquaculture (FAO 2020). Ruminants and aquaculture are used as safety nets in times of crisis for vulnerable households to provide essential nutrition, and ruminants especially play a central role in the cultural identities of many communities. Aquaculture, on the other hand, is currently the fastest growing animal-derived food production system and is a source for high-quality protein. Ruminants

and aquaculture keepers in LMICs are highly affected by the increase of infectious disease outbreaks and loss in productivity, which ultimately endangers food security and disrupts international trade. Research studies on climate change and AMR have shown that an increase of environmental temperatures favour multiplication and spread of both infectious microbes and AMR. This results in a higher number of outbreaks, worsened by a limited number of effective antimicrobials.

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). While vaccines are among the most promising and widely used of these alternatives (WOAH, 2015; WOAH, 2018), 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 alternatives to antimicrobials 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.

As mentioned above, vaccines are one of the most important prophylactic methods available to control infectious diseases and reduce the use of antimicrobials in farm animals. However, research on vaccines for ruminants is more prevalent than research on any other alternative to antimicrobials. Therefore, this call will fund research on the development of alternatives to antimicrobials, **excluding vaccines**, to increase the options available to prevent and treat infectious diseases that affect **ruminants**. At the same time, research on alternatives to antimicrobials, including vaccines, for fish and shellfish is not as advanced as it is for other farm animals. Therefore, this call will fund research on the development of alternatives to antimicrobials, **including vaccines**, to prevent and/or treat infectious bacterial diseases that affect **fish and shellfish**.

In 2016, the UN General Assembly recognized AMR as a global threat that disproportionally affects people in LMICs, which was confirmed by the Global Burden of AMR study, with sub-Saharan Africa and south Asia affected the most. In addition, evidence shows that, in LMICs, resistance to antimicrobials most often used for raising animals for food, including those critical to human medicine, has significantly increased in the last 20 years (Van Boeckel, et al. 2019). Given the severity and extent of the problem, failing to prevent the continued emergence of AMR will likely jeopardize progress towards achieving the United Nations Sustainable Development Goals. AMR was a priority of the health agenda of both the May 2023 G7 in Japan and the G20 in Indonesia in 2022. Both health meetings testified to the awareness of policymakers regarding the impact of the silent pandemic of AMR on the global healthcare system, with the G7 resulting in an agreement being signed that included “incentivizing the development of new antibiotics to tackle the rising threat of AMR across the G7”. Looking forward, the high-level meeting on AMR at the UN General Assembly in September 2024 will be an opportunity highlight the magnitude of the AMR threat to world leaders and policy makers to ensure continued global investment in the development of affordable innovations and products to tackle AMR.

Key objectives and intended outcome

InnoVet-AMR 2.0 will support scientific research that will target:

1. therapeutic and prophylactic alternatives to antimicrobials for aquaculture (CAN include vaccines)

2. therapeutic and prophylactic alternatives to antimicrobials for ruminants (must NOT include vaccines)

The ultimate intended outcome of InnoVet-AMR 2.0:
To minimise the development of AMR in ruminants and aquaculture — and the threat it poses to human health — through the prudent and reduced use of antimicrobials in LMICs by supporting the development and uptake of innovative veterinary products.

Thematic focus areas

Research proposals should focus on veterinary solutions, where new product-oriented solutions would significantly reduce the therapeutic and/or non-therapeutic use of antimicrobials in LMICs in ruminants and/or aquaculture production. These solutions should **target the prevention and control of bacterial infectious diseases of importance in LMICs and the reduction of the use of antimicrobials** while considering **gender equity and inclusion** and demonstrating commitment to **climate change mitigation.**

Ruminants

Ruminants are extremely important and frequently consumed in many LMICs. Small-scale production systems have been part of human livelihoods for many years, enhancing diet and nutrition as well as income. Animal diseases have major impacts on food production and food security; AMR increases those risks. The misuse of antimicrobials in agriculture contributes to the spread of AMR and undermines the effectiveness of veterinary and human medicines. Making sure that these treatments remain effective and available to the agricultural and medical sector is critical. The effectiveness of vaccines in preventing diseases has been considerable and could significantly reduce the need and use of antimicrobials in animal agriculture. However, vaccine research is more common in ruminants and, therefore, the focus will be on developing alternatives to antimicrobials for bacterial diseases. The prevention and reduction of disease in ruminants has the potential to improve efficiency of production and reduce animal losses. Additionally, alternatives used as prophylactics and growth promoters might influence ruminants' gas emissions, which could reduce any negative effect on climate.

There is evidence that AMR in farm animals is rising fast in LMICs (FAO 2017). Due to a rise in intensive farming practices, antimicrobials are widely used to treat infections, prevent diseases and promote growth. This extensive misuse of antimicrobials impacts food security directly. There is evidence that foods from many animal sources contain a high number of resistant bacteria. There is political and consumer pressure to reduce the use of antimicrobials as growth promoters and, therefore, the identification of alternatives is an important approach.

Aquaculture

Aquaculture (fish and shellfish) is a significant industry for many LMICs, particularly in Asia. Moreover, the aquaculture sector has seen tremendous growth in the last 50 years and is an essential source of protein and micronutrients, as well as providing an income for billions of people worldwide. This sector is expected to grow even further to support growing global food demands. The aquaculture sector has unique features that makes it especially prone to the emergence and spread of antimicrobial-resistant pathogens. Like in other farm systems, fish and shellfish (e.g., shrimp) are grown in high density to increase productivity while

reducing costs. However, water is essential for life and a great vehicle for the transmission of microbes and AMR. These production conditions may favour the development of multi-drug resistant pathogens.

Furthermore, aquatic environments are effective reservoirs of AMR bacteria from different sources, including human wastewater, hospital effluents and animal and crop agricultural run-off, but the direct contribution of aquaculture to these AMR sources remains unknown. Additionally, climate change is affecting aquaculture. It is important to note that fish are poikilotherm, which means that they cannot control their own temperature. Therefore, changes in environmental temperature, such as an increase in water temperature, causes stress on fish, making them more susceptible to infectious diseases. For example, research has shown that an increase of 1°C in water temperature could lead to higher fish mortality by infectious diseases (Combe et al 2023).

It is important to focus on development of both vaccines and alternatives to antimicrobials for fish and shellfish production systems. However, while vaccines have proven to be effective in preventing teleost diseases, they do not work in shellfish (e.g., shrimp) due to their primitive immune system. Therefore, alternatives to antimicrobials (excluding vaccines) are of extreme importance in shellfish production farms where antimicrobial use can be high.

5. Funding scope and duration

As a result of this call, a series of grants of up to CAD1.6 million will be issued. The project duration will not exceed 32 months, including the time required for project set-up (e.g., set up contracts and hire personnel), research activities and final reporting. The inclusion of project set-up (buffer time) is important because projects will not be extended beyond the 32 months.

Proposals should demonstrate how **gender equality and inclusion** will be promoted and adopted using an intersectional approach with respect to both of the following the following:

1. team composition and organizations comprising the research team
2. the design and implementation of the proposed research

Proposals need to:

- demonstrate that they have considered the potential **environmental impacts** of their activities
- detail potential benefits
- describe how any potential harmful effects will be mitigated

Special consideration will be given to products that, in addition to their prophylactic or therapeutic effect, contribute to reducing the use of antimicrobials and the carbon footprint of farm animals.

InnoVet-AMR will only consider veterinary solutions that address:

- infectious diseases of importance to LMICs
- the reduction of use and/or misuse of antimicrobials

IDRC reserves the right to fund additional proposals from this call if/when more funding becomes available.

IDRC is under no obligation to issue any funds prior to the applicant returning a fully executed Grant Agreement to IDRC.

All grants are subject to sufficient funds being made available to IDRC by the Parliament of Canada and the Global AMR Innovation Fund (GAMRIF), part of UK Government's Department of Health and Social Care (DHSC).

The DHSC contribution's primary purpose must be for use in LMICs. The Development Assistance Committee list of Official Development Assistance Recipients (DAC list of ODA) eligible countries is reviewed periodically and thus subject to change. UK and DHSC policy on countries eligible for UK or DHSC funding is also subject to change.

IDRC reserves the right to cancel this call at any time without prior notice and/or to not issue any grants under this process.

IDRC offers a training and support package from third-party experts. It is expected that at least the principal investigators (PIs) involved in the projects participate in these events, particularly for evaluation of projects and program. The support events are organized to help grantees move their products through the product-development pipeline (see Annex 2).

6. Eligibility criteria

Only proposals that meet the eligibility criteria will be considered.

Proposals that will NOT be considered are those that:

- focus on projects and products funded by InnoVet-AMR 1.0
- focus on vaccines for ruminants
- focus on new antibiotic drug discovery of commercially existing antimicrobial families
- focus on enhancing commercially available antimicrobials
- focus on improving animal husbandry and farm management
- focus on development of diagnostic devices
- focus on the development of surveillance platforms
- focus on pilot test new biomarkers or combinations of biomarkers
- focus on development of alternatives solutions to antimicrobials not relevant to LMICs
- focus on enhancing commercially available vaccines
- focus on strictly ready-to-market products and field trials
- are related only to registration or commercialization issues
- comprise consortia (research teams from diverse funded institutions involved in each project) without an LMIC partner

The following eligibility criteria also apply:

- This call is purposely encouraging gender-balanced consortia without compromising the expertise needed to accomplish the objectives of each proposal.
- The proposed veterinary solution must focus on ruminants or aquaculture animals.
- The research team must include at least one researcher from an institution based in a LMIC as principal investigator or co-applicant (see Frequently Asked Questions for more details).
- Applicants from academia, private and public sector organisations with strong research focus are eligible for this global call.

- Applicants from United Nations (UN) systems are not eligible to apply to this call as lead or co-applicant organizations. UN organizations may participate as collaborating organizations.
- Applicants from the Consultative Group on International Agricultural Research Centres are not eligible as lead organization but are eligible as co-applicants or collaborating organizations.
- At least one institution from an LMIC country should be involved with a maximum of three institutions per proposal.
- Only institutions of LMIC origin that are not private or for-profit organizations, excluding private universities (national non-profit research organizations) and small and medium biotech companies, will be considered as part of the consortium.
- At most, one person can apply as the principal investigator for one project.

Applicants must have independent legal status (or "legal personality") and be capable of contracting in their own right and name, receiving and administering funds, and have authority to direct proposed project activities. Applicants must be able to demonstrate legal status through written documentation. Legal status will be reviewed only if and when applicants are selected for funding.

7. Expectations of projects

Proposals will also be evaluated by an external scientific review panel based on the following criteria:

A) High-quality research for impact

Assessed against the following four quality dimensions (refer to IDRC's Research Quality Plus (RQ+) framework for more details):

1. **Scientific rigour** — extent to which the research design demonstrates accepted standards of technical merit for its domain and discipline. This involves an assessment of the structural quality of the research protocol, including the following: the study is framed by examination of current knowledge on the issue, clear presentation of research questions and data-collection strategies (that would enable reproduction), adherence to methodological standards for the type of research, identification of relevant analytical frameworks, and well-considered reporting and sharing.
2. **Research legitimacy** — extent to which the research proposal accounts for the concerns and insights of relevant stakeholders and addresses potential environmental consequences. IDRC has defined three sub-dimensions for assessing the legitimacy of the proposed research:
    - **Addressing potentially negative consequences** — appropriateness of proposed strategies to address the risk of negative consequences of the research process or expected outcomes.
    - **Gender equality and inclusion** (see B, below)
    - **Engagement with local knowledge** — extent to which the research proposal is contextually grounded relative to the appropriate scale (community-level, national, regional or global) at which the research is designed.
3. **Research importance** — is the value of the research questions for intended users and uses. IDRC has defined two sub-dimensions for assessing research importance:
    - **Originality** — potential to contribute to theory and/or practice in terms of innovation in generating new knowledge relative to current state of the research field or context.
    - **Relevance** — extent to which the proposed research design and expected outputs and outcomes address existing social and/or environmental problems.

4. **Positioning for use** — extent to which the research design has a **knowledge-sharing plan** that will enhance the probability of use and impact. IDRC has defined two sub-dimensions for assessing positioning for use:
    - **User engagement** — degree to which the research proposal has incorporated plans to build meaningful, two-way connections with intended knowledge users at appropriate stages of the research process.
    - **Openness and actionability** — appropriateness and feasibility of the plans in the proposal for sharing research data and results. This includes the extent to which the knowledge-sharing plan has considered tailoring products to be timely, useful, comprehensible and attractive to knowledge users, as well as following guidance on whether a data-management plan is required.

Additionally, IDRC has developed guidelines to assist with product development (Target Product Profile, see Annex 3). IDRC recognizes this may vary depending on the technology, target pathogen and regulatory guidelines for each country. However, we require applicants to consult these guidelines and include this information in their application as needed.

B) IDRC gender-equality and inclusion considerations

IDRC strives for equality in all aspects of its work. We support the generation of knowledge — including by individuals from diverse genders, communities, histories and experiences — that tackles the systems that perpetuate inequalities based on identity. Inequalities exist across multiple and intersecting categories of identity, including, but not limited to, the following: gender, sexuality, age, class, race, caste, ethnicity, citizenship status, religion and ability. Taking an intersectional approach to gender equality recognizes these differences and understands diversity as central to advancing equality. Given that gender inequality is a significant barrier across all dimensions of diversity, IDRC invests specific efforts in ensuring its work promotes gender equality and inclusion (see Annex 5).

For additional background, please see IDRC's Equality Statement.

Accordingly, proposals should demonstrate how gender equality and inclusion will be promoted and adopted using an intersectional approach, both with respect to the following:

1. team composition and organizations comprising the research team
2. the design and implementation of the proposed research

More specifically:

- consideration of gender for the formation of the research consortium
- consideration of gender during the hiring process
- gender-specific commitments will include training provided by IDRC

C) Southern leadership

IDRC's mandate is to promote inclusive development in the Global South. Projects that are led by researchers from the Global South will be given greater preference.

More specifically, scientists working for institutions of origin and located in LMICs are strongly encouraged to apply as leads of the scientific consortium. InnoVet-AMR will provide training on topics related to product

development to strengthen southern leadership. InnoVet-AMR will accept only proposals that include at least one lead scientist for an LMIC in the consortium to ensure capacity building, international collaboration and cultural diversity. Additionally, principal investigators from a high income country (HIC) are encouraged to hire LMIC students.

Other complementary criteria:

- Level of leadership in the research area.
- The proposed research adopts a **systems approach** to strengthen, rather than create silos of information or action.
- Existing **capacity of participating institution**(s) to carry out the research, including financial and administrative capacity.
- **Feasibility** of achieving project goals and objectives, as well as appropriateness of proposed human and financial resources.
- **Support from other agencies** or institutions (formal letters of support are required as proof).
- Where relevant, strength of the **project monitoring, evaluation and learning plan**.
- Attention to **ethical considerations** and potential risks.
- Potential for, or commitment of, **local contribution** and in-kind resources.

D) Climate-change considerations

Under the 2030 strategy, IDRC will invest in knowledge, innovation and solutions for equitable, sustainable and diverse food systems. The overarching goal is to build the resilience of communities most vulnerable to climate change and to the emerging health threats that arise from food systems. Work under this theme will address the gap in adaptation practice, identify limits to adaptation, help avoid maladaptation, and harness synergies and reduce trade-offs between adaptation and mitigation and interaction with other major development risks to advance sustainable development. Results under this theme will help people and societies pursue climate-resilient development pathways and seize opportunities for transformative change.

Proposals need to:

- demonstrate that they have considered the potential environmental impacts of their activities
- detail potential benefits
- describe how any potential harmful effects will be mitigated

The proposed research should consider:

- the impact of product research and development on the global carbon footprint, such as in waste reduction, lowering animal mortalities and inefficient livestock production
- combining AMR solutions with climate-change mitigation strategies or outputs
- combining research with technologies that are accessible to vulnerable populations who are most affected by climate change

8. Submission process

Call for proposals

IDRC invites eligible applicants to submit **research proposals**. Proposals will be submitted through SurveyMonkey for this call before the deadline.

- Applications must be received no later than October 30, **2023 at 15:00 EDT.** Applications received after the deadline will not be considered.
- Applications can be submitted in either English or French.
- An acknowledgement of receipt of your submission will be sent to all applicants whose application was received before the closing date and time.

9. Format and requirements for proposals

Applications should be concise and present in single-spaced, 12-point Arial font text, with a maximum length of 20 pages (not including abstract and annexes).

The application form for this call for proposals includes five fields that applicants will need to complete. Note the budget template included in the application form is the general template. This call will use a specific InnoVet-AMR budget template.

As part of the application process, applicants will also be required to submit the following individual/institutional documents:

- Tentative schedule and estimated budget in local currency:
  - To be prepared and submitted based on the InnoVet-AMR budget template.
  - Complete all the tabs except the Summary tab, which will be generated automatically.
  - Save the completed and duly signed budget as a PDF document and attach this to your application. The Excel template should also be included.
  - For a list of eligible expenses, please refer to the IDRC Guidelines for Acceptable Project Expenditures.
  - For general information, refer to the General IDRC Funding Guidelines.
  - Note that due to the nature of the funding for this call, specific expenditure and funding guidelines can be found in the InnoVet-AMR budget template category descriptions.
  - Please add information on any matched funding, or additional leveraged resources, that are relevant to this proposal under the “Donor contributions” and “Local contributions” tabs.
- Target product profile (see Annex 3)
- Gantt chart with the proposed activities and timelines with 32 months of research activities. Please consider buffer time (one month) to set up the project, including signing of the research agreement, country clearance (if needed), hiring of personnel, etc.
- Data Management Plan (see Developing a data management plan: guidance for applicants and grantees | IDRC - International Development Research Centre). The plan can be submitted in MS Word or PDF formats.
- Institutions and personnel:
  - A copy of the legal or corporate registration of the organization with whom the applicant is affiliated.
  - Institutional documents as outlined in Annex 1.
  - An attestation of your organization's capacity to manage a grant of this size and complexity (largest grants managed to date, compliance with other donor reporting and legal requirements, ability to manage third parties, foreign funds and disbursements).
  - Names of proposed principal investigator (PI), research institutions and study team.

  - For each member of the core research team, this should include information on their respective expertise and previous work in this area.
  - As an annex, letters of commitment from the leading and collaborating institutions interested in participating, and a description on how the different partners, key stakeholders and institutions will collaborate in the initiative.
- The CVs (in an annex) of the principal investigator and proposed team members.
- Letters of other institutions willing to collaborate or supporting the study should be attached.
- IDRC's institutional profile questionnaire must be completed, signed, and submitted along with the proposal.
- Statement by the applicant acknowledging the requirement to sign IDRC's Intellectual Property agreement in the first 6 months of the project. This can be included within the letter of support from the institution.
- An IP Strategy which includes the components listed in Annex 4

IDRC reserves the right to rescind its selection of a project if it is deemed that the information provided in the application is false or misleading.

10. Evaluation criteria

Proposal for InnoVet-AMR 2.0		
Topics	**Content**	**Scores**
High-quality research	• Scientific rigour • Importance • Technology • Provides a detailed justification of the selected innovative veterinary solution and clearly describes how this approach will reduce the use of antimicrobials and decrease development of antimicrobial resistance in Ruminants and animal aquaculture sectors in LMICs. • Demonstrates well-defined objectives, clearly described methodology and scientific soundness of innovation. • Addresses all ethical issues in relation to the use of animals and genetically modified organisms.	45%

Feasibility to achieve project objectives (including appropriateness of proposed human and financial resources)	• Describes how the proposed results will be achieved within the 32 months of research activities and the allocated budget. • Provides clear and achievable milestones within the 32-month funding period. • Provides clear and well-defined steps to characterize the product prototype to achieve proof-of-concept (safety and efficacy) in target species with a fully defined candidate (e.g., Master seed, working seed, dose response or optimum dose determination, sterility, toxicity and/or immunogenicity, etc). • Provide a realistic product-development plan for the veterinary solutions from discovery to proof-of-concept in target species for use in LMICs. • Positioning for use, including the appropriateness and feasibility of a knowledge-sharing plan.	30%
Team composition and strength	• The research team has the necessary partners and expertise to complete the proposal and demonstrates strong expertise and track record in AMR 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). • Legitimacy, including special attention to gender equality and inclusion through an intersectional lens. • Clearly includes and describes effective partnerships with organizations in LMICs.	15%
Cross-cutting considerations: Gender equity, Environmental safety, climate-change, LMIC participation	• Demonstrates how the project will include and empower women throughout the research process and specifically contribute to narrowing of gender gaps in the vaccine or alternatives development process. • Presents an environmental management plan that ensures compliance with existing laws. • Demonstrates commitment to climate-change mitigation (e.g., decrease mortalities or reduce carbon footprint). • Demonstrates awareness of the specific LMIC disease context under study and identifies and includes local disease expertise.	10%
Total score		100%

11. Selection process

Responding to this call is the step in the application process for potentially securing funding for your proposal.

Applications will first be screened for eligibility using the eligibility criteria outlined in section 6. Those applications that do not fulfill the eligibility criteria will be removed. IDRC staff will first conduct an assessment to determine which proposals will proceed to a full technical review. Research proposals are then assessed by an external scientific advisory committee who will evaluate and rank research proposals according to the review criteria outlined above. This committee comprises IDRC program staff and external reviewers from different related disciplines, including those with expertise in scientific research and technology. Other areas of expertise may include regulatory and scientific industry experience, as well as gender, diversity and inclusion, environment assessment, knowledge translation and/or knowledge users, who will assess the applications according to the evaluation criteria outlined above.

Proposals will be graded in accordance with the evaluation criteria. However, recommendations will not be made solely based on the technical evaluation score. The scientific advisory committee will provide the ranked proposals with their evaluations to the IDRC InnoVet-AMR team, which will then present recommendations to the Governance Steering Committee (GSC). The GSC will select the proposals for funding based on the evaluations and recommendations, and direct the InnoVet-AMR team to follow up with selected proposals. The GSC reserves the right to take a portfolio approach in its selection of projects.

Following selection by the GSC, successful and non-successful applicants will receive notification of the results within a week.

Successful proposals may receive specific comments from the reviewers to be addressed, including suggested budgetary adjustments. Applicants will be required to satisfactorily address the reviewers' comments before receiving any grant.

The technical selection of a proposal does not constitute a formal commitment by IDRC to fund the project. Applicants whose proposals are selected for a recommendation for funding will undergo an institutional assessment. This step assesses the potential risk of material loss of IDRC funds due to weaknesses in the capacity of an applicant's institution to manage or report on the financial aspects of project activities, or because of economic and political conditions relating to the institution's operating environment. IDRC needs to review three broad areas in its assessment of what measures should be applied to minimize such risk:

- the materiality of the investment
- the management capacity of the applicant's institution
- the wider environment within which the organization operates

IDRC will have no obligation to deliver funds to the applicant until the applicant returns an executed **Grant Agreement – InnoVet-AMR Terms and Conditions**, which IDRC will issue to them. See "Selection process" for further information.

Table 1: Application Process	
1.	The call is launched.
2.	Full proposals are submitted by the deadline.
3.	Late applications are eliminated.
4.	Incomplete and ineligible applications are eliminated.
5.	Based on the proposal scores, the InnoVet-AMR team will recommend projects to the Governance Steering Committee for consideration (this may include a portfolio approach, consideration for regional and geographic balance, and thematic balance of the proposals, etc.).
6.	The Governance Steering Committee of InnoVet-AMR 2.0 makes the final decision based on the recommendations of the review committee, based on the evaluation criteria.
7.	A slate of applicants is prepared, and those selected are asked to finalize their proposal. (Please note that the technical selection of a proposal at this stage does not guarantee that it will be funded by IDRC.)
8.	Successful applicants are asked to make any necessary amendments to the proposal, budget and administrative documentation.
9.	IDRC conducts an institutional assessment of each applicant invited to finalize a proposal.
10.	Applicant completes any applicable country approval procedures.
11.	IDRC and the applicant enter into a Grant Agreement.

12. Additional requirements

A) Research ethics and safeguarding

Research work must be carried out in accordance with high ethical standards, in keeping with IDRC's Corporate Principles on Research Ethics. The InnoVet-AMR specific Terms and Conditions further outlines applicable ethics standards. Grantees are expected to follow their own institutions' guidelines for ethical principles.

Prior to commencing research, applicants may need to obtain approval from an official institutional or national research ethics body. In contexts where there is no official institutional or national research ethics body, the applications will need to propose how they plan on setting up an ethics committee for the project.

After approval of the project by IDRC, successful organizations are expected to submit the ethics and security protocols to IDRC, and monitor and report on ethical risks and their management as the research is implemented. It is expected that the funded institutions have safeguarding policies in place. After projects are approved, IDRC will provide to all selected projects training on safeguarding to ensure it is well understood.

B) Intellectual property

i. The project must demonstrate how existing and future intellectual property (IP) protections applicable to the project's subject matter product have been considered and will be managed to enable the program objective to advance prophylactic and therapeutic alternatives to antimicrobials to improve health, while reducing the use of antimicrobials in ruminants and aquaculture (fish and shellfish) operations in LMICs. This includes securing the rights to carry out the research and the rights necessary for the product to be available at a reasonable cost in LMIC markets.

ii. Applicants must submit an IP Strategy that sets out all relevant IP considerations relative to Inno-Vet AMR 2.0's objectives. This strategy will be used to anticipate risks to the project's success.

iii. Applicants must sign an Intellectual Property Rights Agreement with IDRC in relation to IP rights related to project inventions made in the course of the project. In addition to other requirements, this agreement will require the grantee to:

- retain ownership if the invention remains with the grantee unless assigned in accordance with the agreement
- be responsible for any patent expenses for all patent application(s) for the project IP rights filed by the grant
- provide IDRC with advance notice of any application for IP protection, assignment or licence in the invention
- provide march-in rights for IDRC to proceed with patent protection in specified circumstances
- licence to IDRC the ability to use and sub-licence the right to use the invention and related IP rights for research purposes
- licence the invention for use in LMICs on reasonable terms as approved by IDRC

iv. In addition to the minimum requirements in the IP Strategy, IDRC encourages consideration of the following:

- IDRC encourages the signing of a consortium agreement so that all rights and obligations are established within the research consortium from the beginning. The consortium agreement must be led by the lead institution and involve all funded institutions for each project.
- It is important for scientists to realize, even in the early stages of research, that many of the reagents/materials used are for research purposes only and not available for commercialization if the product achieves full development. If the project does receive full development, a licence for commercialization may be required to continue using the reagents/materials..
- It is strongly recommended that the consortium have material transfer agreements and non-disclosure agreements in place to protect the invention, particularly if third parties are paid to do some of the work.

C) Capacity strengthening

Projects that combine research with capacity strengthening of researchers, civil society organizations, research users and community members are strongly encouraged.

Examples of capacity-strengthening activities include training, mentoring, networking, opportunities for publishing, presenting or engaging with researcher users, and opportunities to take on new roles and responsibilities, among others.

Capacity strengthening can focus on a range of research-related skills, such as the ability to identify and analyze development challenges; conceive, conduct, manage and communicate high-quality research; and/or share and use the knowledge and innovation generated by research to address challenges over time and in a sustainable manner. Strengthening leadership skills, particularly for marginalized or underrepresented students, early-career researchers or emerging community leaders, is also an important capacity-strengthening consideration.

Projects that have a mix of experienced and early-career researchers are also encouraged.

More specifically, IDRC will provide training and/or support to guide grantees in the development of their products with high quality standards. It is expected that the institutions involved in each consortium share knowledge and help build capacity for those in need.

D) Open access and data-management plan

Applicants funded through this program will be expected to comply with IDRC' Open Access Policy and IDRC Open Data Statement of Principles.

IDRC recognizes the importance of maintaining confidential all the information pertaining to an IP before an application is submitted and a license is granted. However, IDRC encourages applicants to publish information according to IDRC's Open Access Policies when possible.

IDRC encourages the use of data management plans (DMP) in our programming. We have two templates: Stage 1 and 2 DMPs. Stage 1 DMPs requires less detailed information and a Stage 2 DMPs assume applicants have a good understanding of their data-collection and management plans. The DMP templates can be found here.

E) Required network collaboration

To foster deeper shared learning and collaboration across countries and projects, project teams will be expected to participate in a series of joint activities, with all projects across regions. The InnoVet-AMR team will coordinate shared learning efforts and will organize joint activities with project teams at key points in the research process. These activities will include an inception workshop, mid-term workshops to share findings, and a closing workshop. The InnoVet-AMR team will also interact with individual teams and groups of teams, through virtual platforms, to provide support and coaching on research activities, and to stimulate peer-to-peer exchanges and learning across the project cohorts.

F) Multidisciplinary and multisectoral collaboration

The applicant is required to show identified themes and areas of work that reflect the interconnectedness of veterinary alternatives to antimicrobials and engagement with different disciplines. The applicant should also indicate any levels of collaboration being developed among sectors.

G) Knowledge sharing and scaling

Knowledge sharing

A key objective of IDRC's Strategy 2030 is to share knowledge for greater uptake and use, increasing the reach and impact that IDRC-supported research has in driving solutions and in influencing national, regional and global development agendas, including through synthesizing and communicating results.

Applicants must explain how their expression of interest/concept note/proposal responds to an emerging need, knowledge gap or demand, and they must demonstrate intentionality and identify opportunities to move knowledge (research evidence) into action (policy, social and behavioural change, etc.).

Applications must include a knowledge-sharing strategy that identifies key knowledge users and that describes the anticipated approach to engage these strategic stakeholders (ideally throughout the research process) to support research uptake and use and/or scale impact (by optimizing impact beyond original project boundaries). Note that IDRC anticipates supporting the implementation of knowledge-sharing plans integrated into project proposals — provided the resources required are clearly described, appropriate and incorporated as part of the overall project budget.

Scaling impact

IDRC recognizes that this call is for discovery projects. Therefore, the scaling impact is at the scientific research level, including scientists, students and other possible important stakeholders, such as farmers.

Please note as you develop a scaling-impact strategy that IDRC's scaling science approach focuses on scaling impact rather than scaling specific actions or innovation. This means that scaling is not necessarily about pushing up or out, because bigger outputs or more actions do not always lead to better impact. Aiming for impact at optimal scale requires balancing multiple dimensions of impact, including equity, sustainability, variety and magnitude. You can refer to the **The Scaling Playbook: A Practical Guide for Researchers** for guidance on this approach.

While it may not be possible to address all these considerations to the same degree, their integration and inclusion into the applications will be a **key** component in the evaluation process.

13. Post-selection requirements

Proposal and budget finalization

Prior to finalizing a Grant Agreement, IDRC reserves the right to request any revisions to the submitted proposal and budget. A revised proposal with the necessary revisions must be returned in a timely manner to IDRC.

Country clearance requirements

In some cases, IDRC has scientific and technical cooperation agreements with the governments of the countries where we support projects. Where such agreements exist, IDRC may require additional or alternative approval processes that comply. Otherwise, grantees must follow a government authority's prevailing approval procedure. This is often administered by a coordinating or nodal agency of the government and varies by jurisdiction.

An IDRC grant administration representative will advise the selected applicant if any country procedures need to be followed. A grant agreement will be issued only if and once country clearance(s) is/are obtained. IDRC reserves the right not to pursue the funding of a selected project if the country approval is not secured within six months after IDRC officially announces approval of the project, as this would jeopardize the timely completion of the initiative.

After an institutional assessment of an applicant's organization is performed, IDRC may identify operational or financial weaknesses that could pose some administrative risks to the proposed project. In such cases, IDRC reserves the right to request the applicant's organization to partner with another institution as a condition of receiving the grant.

Sub recipients

In cases where the recipient will manage sub-grantees, the country requirements that apply to sub-grantees are also documented in the grant agreement. It becomes the responsibility of the grantee to ensure that sub-grantees meet these requirements.

Country risk

IDRC funds research in locations that respond to the corporate and programmatic plans and objectives approved by IDRC's Board of Governors. Project proposals and risk-mitigation measures may need to be revised where:

- project activities may be affected by legal restrictions on transferring funds or other resources to specific entities
- due to physical remoteness, physical risks to IDRC employees in particular regions (or other inaccessibility factors) prevent IDRC from properly monitoring and supporting the project
- applicable laws and regulations prevent institutions from accessing funds

Grant agreement

By submitting this proposal, the applicant confirms that their acknowledgement of the InnoVet-AMR Terms and Conditions for a Grant Agreement | IDRC – International Development Research Centre (idrc-crdi.ca), acknowledged and accepted, form an integral part of the funding application. The Applicant also agrees to abide by the IDRC's Corporate Principles on Research Ethics, IDRC's Intellectual Property Rights Agreement | IDRC (IP), IDRC's Open Access Policy and IDRC's Open Data Statement of Principles to proceed. Any failure to abide by or accept any of the stated conditions may cause IDRC to consider the application null and void. Any selected proponents must sign IDRC's standard Grant Agreement to receive funds. The grant agreement will provide a schedule for submitting interim and final technical and financial reports. Although there is no limit on the number of co-applicants in one application, IDRC will only negotiate Grant Agreements with the organization of the lead applicant.

14. Timeline and communication of results

Submission process

Call launch: September 11, 2023

Information session/webinar: October 2, 2023

Deadline for submitting proposals; receipt of proposals acknowledged: October 30, 2023

Selection process

External review by committee: week of November 26, 2023

Successful proposals informed they have been selected for potential funding contingent on meeting any specific conditions: mid-December 2023

Applicants submit full proposals/applicants resubmit amended final proposals: no later than February 2024

Award

Approval of proposals and project start date: April 2024

15. Information session, inquiries and FAQs

Following the launch of the call for proposals, IDRC will organize an information session to address any queries from potential applicants. This will take place on October 2, 2023, at 9:00 EDT. An invitation via MS Teams will be sent with a link to join the session.

Any additional inquiries related to the call and application process should be sent by email to the InnoVet-AMR 2.0 team on SurveyMonkey. All inquiries should be received on or before October 23, 2023, at 14:00 EDT to receive a response prior to the deadline date.

Any inquiries that affect all applicants received on or before the above-mentioned deadline will be added to the FAQs with IDRC's responses to those inquiries, and without revealing the source of the inquiries.

16. Permission for use and disclosure of information

As a Canadian Crown corporation, IDRC is subject to Canada's Access to Information Act and the Privacy Act. Consequently, any submissions in response to this call for proposals will be managed by IDRC in a manner consistent with applicable legislation and IDRC's Privacy Policy, including IDRC's obligations to disclose documents requested by members of the public or requests for personal information. More information on how IDRC manages information in accordance with this legislation can be accessed here: Access to Information and Privacy | IDRC - International Development Research Centre (idrc-crdi.ca).

By submitting an application under this call, the applicant will consent to the use of the documents and information as well as the disclosure of the documents submitted by the applicant to the reviewers involved in the selection process, both within IDRC and externally for the purposes of evaluating the proposal for funding by IDRC. To the extent that the application contains personal information, the applicant is responsible for obtaining informed consent from the individuals whose personal information is being shared. The applicant further consents to the disclosure of the name of the applicant, the name of the lead researcher and the name of the proposed project in any announcement of selected proposals. All personal

information collected by IDRC about grant, scholarship and fellowship applicants is used to review applications, to administer and monitor awards, and to promote and support international development research in Canada and in the regions where IDRC operates.

17. ANNEX 1 — Institutional assessment documentation

Applicants must provide the following documents to allow IDRC to undertake an institutional assessment prior to confirmation of funding:

1. Most recent audited financial statements,* including but not limited to:
   - balance sheet, statement of income and expenses or profit and loss, and statement of cash flow
   - notes to the financial statements
   - audit report
   - any management or internal control letters, and related follow-up response

   **The latest financial statements duly authorized by a financial officer if audited statement is not available.*

2. current organizational chart
3. human resources manuals
4. finance and administration manuals
5. policy/procedure for procurement
6. list of active external donors and their current contributions
7. latest annual report

18. ANNEX 2 — InnoVet-AMR general guidelines

These general guidelines do not include all the regulatory requirements needed to develop and register a product. However, they provide a good reference of the processes and requirements needed to advance a product through the product-development pipeline.

Know the market

Define the product type and its potential markets before any development takes place, as this will determine the registration pathway and illuminate the limitations for commercialization.

Technology transfer and intellectual property:

8. Facilitate exchange of proprietary materials and information needed to advance techniques and tools to improve health. Important to consider signing agreements to protect materials, knowledge, technologies and others.

- Efficiently establish collaborations with a gender lens that enhance research programs and promote technology transfer with the scientific community — including industry, academia, non-profit organizations and government collaborators — to develop research partnerships and commercialize inventions that are products of the grants.
- Increase visibility of technology transfer opportunities by engaging in different outreach venues, including workshops and trade meetings.

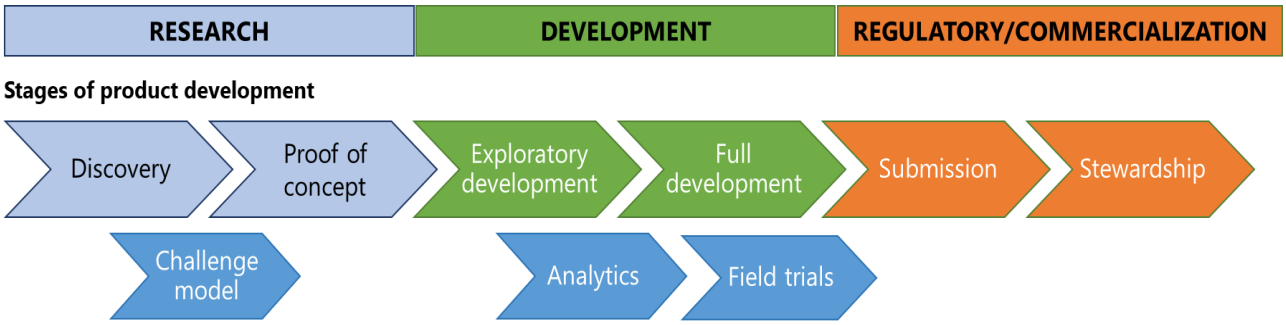
Quality assurance systems:

- Quality assurance is the systematic process of oversight and controls based on established guidelines to ensure that a product meets quality standards. Quality assurance systems are used to measure results at each stage of a process to ensure consistency.
- Standard operating procedures (SOPs) are developed for every activity performed. Some examples of SOPs include preparation of SOPs to perform all activities in good manufacturing practice environment, preparation of reagents, development and validation of assays and testing and maintenance of equipment. Records are kept according to regulatory guidelines.
- Record all the information, methods, experiments and results as per quality assurance guidelines, such as good laboratory practices (GLP), good clinical practices (GCP), and good manufacturing practices (GMP).
- Determine the GMP standards for the target countries as they are not harmonised globally.

Regulatory framework:

- Regulations are not harmonised globally. Some regulatory authorities accept phased submissions, but others require all parts of the registration dossier to be submitted together.
- Ensure open communication with the regulatory authorities.
- Track the status of the application as it progresses through the registration process.
- Recompile all the information required for the dossier.
- Submit the dossier to the regulatory authorities.

Industry standard phases of product development



DiscoveryDevelop a target product profile (see template in Annex 4)

Determine the steps, activities and stages needed for the development of the product to remain focussed. Design a project starting from the end or desired final product and walking backwards.

Identification and selection of vaccine or alternative candidates

This refers to characterization of the selected active ingredient as a candidate — in the case of vaccines, inactivation, attenuation or modification of pathogen. In the case of alternatives, type of molecule or bacteriophage. The type of molecule may affect the pharmacodynamics and pharmacokinetics as well as the prophylactic and/or therapeutic effects.

Production of research grade active ingredient:

- Research grade active ingredients do not follow strict quality assurance systems required under GLP/GMP and may need not be applicable when scaling up. Results using research grade active ingredients are not generally accepted by regulatory agencies.
- Basic testing of candidates for yield, purification and sterility

Working prototype/experimental model (studies to support proof of concept). Preliminary animal testing for safety and immunogenicity or efficacy of alternatives in animal models and/or target species:

- Selection of adjuvant or diluent or vehicle
- Laboratory evaluation of prototype alternative; development of assays to test for safety and immunogenicity
- Identification of optimum dose (e.g., dose response) and number of immunizations or treatments required

Pharmacokinetics, pharmacodynamics and pharmacotoxicity studies:

- Development of assays to test for safety
- Development of assays to test pharmacokinetics, pharmacodynamics and pharmacotoxicity in target species

Development of challenge model:

- In vitro culture of pathogen. Determination of dose and route of infection. Determination of end point.
- Development and characterization of master and working seeds. Testing for exclusion of other pathogens or microorganisms.
- Determination of clinical signs. Development of assays to evaluate the clinical signs and pathology of disease.
- Standardization and validation of the challenge model.

Proof of concept (target species)

Proof of concept studies are small control experiments with enough statistical power to demonstrate safety, efficacy and effectiveness of the candidate active ingredient in the target species. Preliminary studies can be performed in animal models in preparation for studies in target species. These studies may or may not be used to support registrations, which will depend on whether they are pilot or confirmatory. While pilot proof of concept studies are not required to be performed under a GLP/GCP environment, confirmatory studies are performed within GLP and GCP guidelines and may require approval from a regulatory authority. Consider including a number of animals in the study that will demonstrate statistical power of the study. To reduce bias, it is important to ensure blinding and randomization.

Proof of safety:

- Development of parameters to measure safety. The number of animals and observation period varies depending on the characteristics of the product, target species and end points. It can be performed first in laboratory and then in target species. Dose titration is many times used to

determine the optimal dose and any side effects. It is important to demonstrate safety using the optimal dose as the bases. Many countries rely on quality systems, seed lot systems and pharmacovigilance.
    - Animal safety — Earliest age for vaccination or administration of active ingredient. Administration of active ingredient to pregnant animals (extension of safety). Consider including a number of animals in the study that will demonstrate statistical power of the study.
    - Environmental safety (e.g., shedding or excretion)
    - Human safety (health care professionals or animal keepers)
    - The consumers for human food safety, such as residues

- Pharmacodynamics, pharmacokinetics and pharmacotoxicity should be evaluated. Pharmacotoxicity is the evaluation of clinical signs or tissue pathology after the administration of the active ingredient.
- Target animal safety test varies depends on regulatory requirements. When safety test is required, it may include higher doses (1x to 10x depending on the type of vaccine and the target species and the country), particularly for attenuated vaccines and nucleic acid vaccines, to determine if there are side effects. The number of animals included in the study must have proper statistical power to demonstrate safety.

Proof of efficacy

This is the ability of a product (active ingredient) to produce the desired effect. In the case of vaccines, demonstrating immunogenicity and protection against homologous and heterologous challenge is crucial. Often, it is critical to demonstrate efficacy against several strains or serotypes of the same pathogen. The active ingredient has to be effective in preventing or treating a disease in animals. However, the product can also prevent infection and dissemination of the pathogen.

- Development of assays and parameters to prove immunogenicity and protection or treatment efficacy of most susceptible animals against challenge with each pathogen.
- Non-clinical trials are in vitro assays used as an aid in the demonstration of efficacy.
- Clinical studies in animal models — Although the use of animal models is important at the beginning of discovery studies, most times they do not mirror the effects on other species, particularly from outbred populations.
- Clinical trial in target species — Prioritize the use of target species to obtain more accurate results and to establish the optimum dose:
    - Use of standardized and validated challenge model
    - Verification that the pathogen used for the challenge was the only one causing the disease
- Duration of immunity; duration of treatment
- Comparison with commercial products is not generally important for regulatory purposes. However, it is frequently done for marketing.

Exploratory development:

- Upstream processing
- Creation and characterization of master seed and working seed. Process optimization on a small scale (for example, use of bioreactors). Tests on master seeds, master cell seeds (stocks), working seeds and cells, ingredients of animal origin.

Assays for quality control during the production process and at the end (e.g. batch testing), such as potency, purity, and stability:

- Potency — The final product has the right concentration of active ingredient to work properly and obtain the desire effects.
- Purity — Assurance that the product does not contain anything that might adversely affect potency, safety or efficacy. Veterinary biologics are tested for purity at each step of the manufacturing process and are then tested again before release.
- Stability — The biologic needs to work even on the day it expires.
- Sterility tests (e.g., mycoplasma)

Downstream processing:

- Removal of insoluble
- Product isolation
- Product purification
- Sterility tests
- Testing of residuals, such as moisture, DNA, LPS, formaldehyde

Full development

Upstream processing:

- Process optimization (bioreactors) large scale
- Process confirmation, validation and scale-up

Downstream processing:

- Validation of quality control tests
- Removal of insoluble
- Sterility tests
- Testing of residuals, such as moisture, DNA, LPS, formaldehyde
- Product isolation
- Product purification
- Product polishing
- Process validation

Consistency batches

This is the production of three batches where quality tests are applied to prove that all three batches are produced within the established parameters.

Analytics

This is not considered a phase, but it is part of diverse phases of product development. Analytics in this case refers to the development of assays and tests that will be used to measure diverse parameters of a product (e.g., immunoassays) and that might be used for the quality control of the final product (e.g., potency tests). This is different from data analytics, which is related to data management and analysis used to make predictions with the end goal of accelerating and optimizing production, as well as improving decision-making throughout the drug development and marketing processes. The standardization and validation of the assays is of extreme importance to obtain reliable and consistent results.

19. ANNEX 3 — Target product profile

Below is a template for the target product profile. The first column "Category" lists all categories of a product to be developed. The second column "Target product profile" refers to the optimum characteristics of the product. This is what the PIs aim to achieve with their product. The third column "Minimum product profile" refers to the minimum acceptable characteristics of a product to achieve market.

Target product profile

Project number	
Product	
Product type	
Mechanism of action	
Indication	
Phase of development	

Business strategy

1. **Most important indication:**	
2. Key target audience:	
3. **Basic approach to marketplace:** Place an "X" for the appropriate category, choose one only	
____ Gain market share ____ Defend market share	____ Create/expand the market ____ Occupy a niche

Product specifications

Category	Target (maximum) product profile	Minimum product profile
Primary/secondary species		

Target population / target age group		
Target pathogen		
Active ingredient included		
Formulation /adjuvant system		
Mechanism of action		
Clinical description of effects		
Comparative efficacy		
Safety profile /side effects/contraindications		
Route of administration		
Site of action		
Dosage & dosage schedule		
Onset of action/immunity		
Duration of action or Immunity		
Interference and co-administration with other vaccines or products		
Slaughter withdrawal		
Epidemiological relevance (e.g., regional or global)		
Shelf life & storage		

Manufacturability		
Patentability		
Target countries		

20. ANNEX 4 — IP strategy

IP Strategy components:

1. Existing IP ("Background IP") and parameters of the same, including:
    - List of all background IP
    - What is applicable to research/applicable to commercialization
    - Who owns the background IP
    - Applicable licences
2. Anticipated IP ("Foreground IP") development:
    - Anticipated development
    - Jurisdictions to file
    - Who will own the IP
3. Strategic considerations:
    - The ultimate objective of the Inno-Vet AMR 2.0 program is to advance prophylactic and therapeutic alternatives to antimicrobials to improve health, while reducing the use of antimicrobials in ruminants and aquaculture (fish and shellfish) operations in LMICs.
    - Describe how the project will ensure that intellectual property parameters identified in section 1, above ,will not prohibit the program objective.
    - Describe how the project will leverage IP protections to advance the program objective.
    - Describe how the rights of different inventors will be managed (i.e. consortia agreements, etc.).

21. ANNEX 5 — Resources for gender equality and inclusion (GEI)

Here is a **selection of resources** applicants may wish to consult for further information, guidance and examples:

ASSAR. (n.d.). Infographic: Gender is one of the many factors that influence how we are impacted by and respond to climate change. Adaptation at Scale in Semi-Arid Regions.

CARE. (n.d.). Gender and Inclusion Toolbox. https://careclimatechange.org/gender-inclusion-toolbox/

Chaplin, D., Twigg, J., & Lovell, E. (2019). *Intersectional approaches to vulnerability reduction and resilience-building* (Resilience Intel, Issue 12). BRACED. https://cdn.odi.org/media/documents/12651.pdf

Dupar, M. and P. Velasco. (2021). Advancing gender equality and climate action: A practical guide to setting targets and monitoring progress. Cape Town: Climate and Development Knowledge Network.

Kratzer, S. & Le Masson, V. (n.d.). *10 things to know: Gender equality and climate goals*. Climate Development Knowledge Network.

Monjurul Kabir, A. H. et al. (2021) Intersectionality Resource Guide and Toolkit. UN Women.

Mullinax, M., Hart, J., & Vargas Garcia, A. (2018). Using Research for Gender-Transformative Change: Principles and practice.

Glossary of terms

Note that the following definitions have been compiled to strive for a shared and consistent use and understanding of key terms related to gender equality and inclusion for the purposes of this call for concept notes. Definitions have been drawn from multiple sources and adapted to reflect the InnoVet-AMR context and principles. We encourage proponents that prefer to use alternative definitions to those offered below to be explicit about the particular definition they employ.

Diversity* consists of the conditions, expressions and experiences of different groups identified by age, culture, ethnicity, education, gender, disability, sexual orientation, migration status, geography, language, religious beliefs and other factors.

Genderˆ£ ǂ refers to the roles, behaviours, activities and attributes that a given society at a given time considers appropriate for men, boys, women, girls and people with diverse gender identities. Gender is socially constructed, learned through socialization processes and plays out through relationships. It is context/time-specific and changeable. In most societies there are differences and inequalities between women, men and people of diverse genders in responsibilities assigned, activities undertaken, access to and control over resources, as well as decision-making opportunities. Gender is often conceptualized as a binary (girl/woman and boy/man), but there is considerable diversity in how individuals and groups understand, experience and express it, including nongendered, non-binary and transgendered. Gender is one of many factors that influence how people are impacted by climate change and natural hazards.

Gender analysisˆ is a critical examination of how differences in gender roles, activities, needs, opportunities and rights/entitlements affect men, women, girls, boys and non-binary people in certain situations or contexts. Gender analysis examines the relationships between females, males and non-binary people and their access to and control of resources and the constraints they face relative to each other. Integrating a gender analysis into research helps to ensure that gender-based injustices and inequalities are not exacerbated by interventions, and that, where possible, greater equality and justice in gender relations are promoted.

Gender equalityˆ refers to the equal rights, responsibilities and opportunities of women and men, girls and boys, and non-binary people. Equality does not mean that women, men and non-binary people will become the same, but that people's rights, responsibilities and opportunities will not depend on whether they are born male or female. Gender equality implies that the interests, needs and priorities of women, men and non-binary people are taken into consideration, recognizing the diversity of different groups.

Inclusion£ǂ refers to the practice of ensuring that all individuals are valued and respected for their contributions and are equally supported. Research into inclusion aims to understand why some people are

more at risk to changes in climate, and how their social positions influence their vulnerability and capacity to respond to climate signals in particular contexts. Advancing inclusion has two interrelated dimensions:

1. improving the terms on which individuals and groups take part in social, political and economic development processes
2. enhancing the agency of those who are excluded on the basis of social positions

Intersectionality°‡ recognises that people's lives are shaped by their identities, relationships and social factors. These interact to create intersecting forms of privilege and oppression depending on a person's context and existing power structures such as patriarchy, ableism, colonialism, imperialism, homophobia and racism. We use the concept of intersectionality to emphasize that inequalities experienced in relation to climate change and adaptation are seldom the result of a single social category, but result from the intersections of multiple social positions (e.g., gender, race, ethnicity, class, sexuality, age, disability, etc.) and depend on existing systems and structures of power.

Intersectional analysis° looks beyond gender to examine multiple identity factors and root causes that produce vulnerability, oppression and privilege in certain situations or contexts.

Marginalised groups₹ are those who have been systematically or historically excluded from participation or influence in society and/or who frequently experience exclusion from exercising rights and freedoms.

Sex* refers to the genotypic and phenotypic attributes of an individual, which are manifested in a person's biological and physiological traits. It is most often determined by a medical assessment at the moment of birth. This is also referred to as birth-assigned sex.

Transformational change‡ refers to change that addresses the root causes of social and gender inequality and exclusion. It moves beyond the individual and entails change at the level of structures. It implies using transformative approaches that focus on institutional structures and norms as key barriers to equality and inclusion, as opposed to accommodating approaches that focus on closing gender and social exclusion gaps through improving availability of resources and services within a given institutional context. This also requires a deliberate effort to sustainably increase the life choices of individuals and groups, rather than a temporary increase in opportunities.

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