Issue Date:	May 2, 2024
Deadline for Questions:	May 8, 2024, 04:00 PM Washington, D.C. Time
Closing Date:	June 14, 2024, 04:00 PM Washington, D.C. Time
Subject:	Notice of Funding Opportunity Number: 7200AA24RFA00015
Program Title:	**Feed the Future Innovation Lab for Veterinary Vaccine Delivery**

Catalog of Federal Domestic Assistance (CFDA) Number: 98.001

To Whom It May Concern:

The United States Agency for International Development (USAID) is seeking applications for a Leader with Associates Cooperative Agreement from qualified entities to implement the Feed the Future Innovation Lab for Veterinary Vaccine Delivery. Eligibility for this award is restricted to U.S. colleges and universities as defined under Section 296(d) of Title XII of the FAA. See Section C.I of this NOFO for eligibility requirements.

Subject to the availability of funds, an award will be made to the responsible Applicant whose application best meets the objectives of this funding opportunity and the selection criteria contained herein. The total estimated program amount for the Leader Award is $20 million. This Leader Award includes $13 million in core funding over the five years from the Bureau for Resilience, Environment and Food Security (REFS) and contingent upon funding, up to $7 million for buy-ins to the Leader Award from USAID Missions, Regional Bureaus, and other Offices. Separately, up to $15 million may be issued in the form of Associate Awards. While one award is anticipated as a result of this notice of funding opportunity (NOFO), USAID reserves the right to fund any or none of the applications submitted.

For the purposes of this NOFO the term “Grant” is synonymous with “Cooperative Agreement”; “Grantee” is synonymous with “Recipient”; and “Grant Officer” is synonymous with “Agreement Officer”.

To be eligible for award, the Applicant must provide all information as required in this NOFO and meet eligibility standards in Section C of this NOFO. This funding opportunity is posted on www.grants.gov and may be amended. It is the responsibility of the Applicant to regularly check the website to ensure they have the latest information pertaining to this notice of funding opportunity and to ensure that the NOFO has been received from the internet in its entirety. USAID bears no responsibility for data errors resulting from transmission or conversion process. If you have difficulty registering on www.grants.gov or accessing the NOFO, please contact the Grants.gov Helpdesk at

1-800-518-4726 or via email at support@grants.gov for technical assistance.

USAID may not award to an applicant unless the applicant has complied with all applicable unique entity identifier and System for Award Management (SAM) requirements detailed in Section D.IV.f. The registration process may take many weeks to complete. Therefore, Applicants are encouraged to begin registration early in the process.

Please send any questions regarding this announcement to J. Erin Baize jbaize@usaid.gov. The deadline for questions is shown above. Responses to questions received prior to the deadline will be furnished to all potential Applicants through an amendment to this notice posted to www.grants.gov.

Issuance of this notice of funding opportunity does not constitute an award commitment on the part of the Government nor does it commit the Government to pay for any costs incurred in preparation or submission of comments/suggestions or an application. Applications are submitted at the risk of the Applicant. All preparation and submission costs are at the Applicant's expense.

Thank you for your interest in USAID programs.

Sincerely,

Rachel Baltes
Digitally signed by Rachel Baltes
Date: 2024.05.02 11:52:48 -04'00'

Rachel Baltes
Agreement Officer
M/OAA/REFS

ABBREVIATIONS AND ACRONYMS USED IN THIS NOFO

ABSL	Animal Biosafety Level
ADS	Automated Directives System of USAID Policies
AIS	Agricultural Innovation Systems
AO	Agreement Officer
AOR	Agreement Officer's Representative
BEO	Bureau Environmental Officer
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BPMS	Branding Plan and Marking Strategy
BSL	Biosafety Level
CCIRs	Cross-Cutting Intermediate Results
CGIAR	Consultative Groups for International Agricultural Research
CLA	Collaboration, Learning and Adapting
DDL	Development Data Library
DEC	Development Experience Clearinghouse
DIS	Development Information Solution
EAC	External Advisory Committee
EMMP	Environmental Management and Mitigation Plan
FTFILs	Feed the Future Innovation Labs.
FAA	Foreign Assistance Act
GFSA	Global Food Security Act
GFSS	Global Food Security Strategy
GMP	Good Manufacturing Practices
IL	Innovation Lab
IEE	Initial Environmental Examination
IRs	Intermediate Results
LOE	Level of Effort
LWA	Leader with Associates
ME	Management Entity
MEL	Monitoring, Evaluation and Learning
MSIs	Minority-Serving Institutions
MTDC	Modified Total Direct Cost
NAROs	National Agricultural Research Organizations
NARS	National Agricultural Research System
NGOs	Non-Governmental Organizations
NICRA	Negotiated Indirect Cost Rate Agreement
NOFO	Notification of Funding Opportunity
OAA	Office of Acquisition and Assistance
OFAC	Office of Foreign Assets Control
OUs	Operating Units
PERSUAP	Pesticide Evaluation Report and Safer Use Action Plan
PI	Principal Investigator
PLC	Product Life Cycle
PSE	Private-Sector Engagement
R&D	Research and Development

RFA	Requests for Application
REFS	Bureau for Resilience, Environment, and Food Security
SAM	System for Award Management
SEP	Sub-awardee Engagement Plan
TEA	Total Estimated Amount
TPP	Target Product Profiles
UEI	Unique Entity Identifier Number
USAID	United States Agency for International Development
VVDIL	Feed the Future Innovation Lab for Veterinary Vaccine Delivery

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SECTION A: PROGRAM DESCRIPTION

A.I. Authority

This funding opportunity is authorized under the Foreign Assistance Act (FAA) of 1961, as amended. The resulting award will be subject to 2 CFR 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, and USAID's supplement, 2 CFR 700, as well as the additional requirements found in Section F.

In Section 103 of the Foreign Assistance Act of 1961 (FAA), as amended, Congress recognizes the value of agriculture, rural strengthening, and nutrition assistance...*to alleviate starvation, hunger, and malnutrition; to expand significantly the provision of basic services to rural poor people to enhance their capacity for self-help; and to help create productive farm and off-farm employment in rural areas to provide a more viable economic base and enhance opportunities for improved incomes, living standards, and contributions by rural poor people to the economic and social strengthening of their countries*. Congress further recognizes that agricultural research is necessary to achieve foreign assistance goals and requires that such research carried out under the Act...*shall (1) take account of the special needs of small farmers in the determination of research priorities, (2) include research on the interrelationships among technology, institutions, and economic, social, environmental, and cultural factors affecting small-farm agriculture, and (3) make extensive use of field testing to adapt basic research to local conditions* [Sec.103A.(3)]. Finally, Congress provides that *special emphasis shall be placed on disseminating research results to the farms on which they can be put to use, and especially on institutional and other arrangements needed to assure that small farmers have effective access to both new and existing improved technology*.

The U.S. Congress granted USAID the authority to direct and fund programs of international agriculture research under the FAA. Now referred to as Title XII Legislation (FAA Sect. 296a), USAID is directed to provide support for the benefit of both developing countries and the United States to mobilize the capacities of U.S. universities and public and private partners of universities for: 1) Global research on problems affecting food, agriculture, forestry, and fisheries; and 2) Improved human capacity and institutional resource strengthening for the global application of agriculture and related environmental sciences.

Demonstrating the continued importance of American leadership in international food and nutrition security efforts, including agriculture research and strengthening, in 2016 the U.S. Congress and the president passed into law the Global Food Security Act (GFSA)[1] with strong bipartisan support and in 2018 reauthorized it through 2023.

A.II. The Feed the Future Initiative, Global Food Security Act, and Research for Development

Started in 2010, the Feed the Future Initiative[2] works to sustainably reduce global poverty and hunger, recognizing the need to increase global agricultural production significantly by the year 2050 to provide sufficient nutritious food for the world's growing population. The Global Food Security Act (GFSA) builds on what we learned through Feed the Future and reflects changes in the global

[1] Pub. L. 114-195, July 20, 2016, 130 Stat. 675 (https://www.congress.gov/114/plaws/publ195/PLAW-114publ195.pdf); 22 U.S.C., Chapter 100 (http://uscode.house.gov/view.xhtml?path=/prelim@title22/chapter100&edition=prelim)
[2] http://www.feedthefuture.gov/

context since its launch. Assistance authorized under the GFSA continues to be branded as Feed the Future (FTF). The signature, top-line goal of the GFSA is to sustainably reduce global hunger, malnutrition and poverty.

In 2016, USAID submitted to Congress the Global Food Security Strategy (GFSS)[3], a new whole-of-government strategy for global food and nutritional security, on behalf of the 11 U.S. Government agencies responsible for carrying out the GFSA. The GFSS sets out how to achieve the goal of the GFSA through the primary strategy objectives of inclusive and sustainable agriculture-led economic growth (SO1), strengthened resilience among people and systems (SO2), and a well-nourished population (SO3). Technical guidance as to how the U.S. Government approaches global food and nutrition security in its strengthening activities can be found on-line at feedthefuture.gov.[4] Building off the successes and lessons of the first GFSS, the FTF interagency community updated the GFSS[5] for FY 2022-2026, a robust response to the crises that threaten to undermine global food-security progress – COVID-19, conflict, inequity, and climate. Through this strategy, we aim to contribute toward a 20% reduction in poverty and stunting in the areas where we work between 2022-2026 by partnering with foreign governments, the private sector, civil society, implementers, and the research community. Our overarching Goal is still to sustainably reduce global poverty, hunger, and malnutrition across FTF's three Objectives: Objective 1– Inclusive and Sustainable Agriculture-Led Economic Growth; Objective 2 – Strengthened Resilience Among People and Systems; and Objective 3 – A Well-Nourished Population, Especially Among Women and Children.

To meet the challenge of producing more and nutritious food with fewer natural resources while also adapting to increasingly erratic weather patterns and market price swings, the international community will need to fully harness the benefits of agricultural science and technology. Following the update of the GFSS, The U.S. Government's Global Food Security Research Strategy[6] was also updated for FY 2022-2026.[7] After a broad consultation with the global research community and interagency partners, several priority areas emerged. Feed the Future will support research activities that collectively represent three themes: a) climate-smart agricultural innovation, b) nutrition and food systems, and c) genetic improvement of crops and livestock. The strategy recognizes that research activities are most effective when they result from a sound prioritization process; directly engage community members and partners; bolster local participation and ownership; and are designed with market systems, risk reduction, and scale in mind.

This "research for development" is neither an abstract quest for fundamental knowledge and improvement of scientific theories, nor is it the straightforward delivery of goods and services associated with development work. Rather, research for development is a unique enterprise requiring the rigor, discipline, awareness of local context, and building of relationships associated with global development. Research for development generates knowledge and new or improved technologies and practices, but it does not stop there. Effective research for development puts information and innovations in the hands of stakeholders, where impacts may be achieved. Indeed, the agricultural research investments supported by USAID are designed by considering "impact pathways," which

[3] https://www.feedthefuture.gov/resource/u-s-government-global-food-security-strategy-fy-2017-2021/
[4] https://www.feedthefuture.gov/guidance-and-tools-for-global-food-security-programs/
[5] https://www.usaid.gov/what-we-do/agriculture-and-food-security/us-government-global-food- security-strategy
[6] https://www.feedthefuture.gov/the-u-s-governments-global-food-security-research-strategy/
[7] https://www.feedthefuture.gov/resource/u-s-government-global-food-security-research-strategy-fy22-26/

map out the connections between research outputs and development outcomes. This thoughtful design is not only critical for success, it is also mandated by Congress. But these impact pathways are not linear and are best considered using a systems approach. Agricultural transformation requires consideration of the interrelationships and interaction among soil fertility, agronomy, genetics, animal science, water management, the role of private sector and market access, policies, nutrition, local capacity and commitment, gender, and the specific needs of youth.

Centrally-funded research programs link national, regional, and global research partners to identify, develop, and adapt promising practices and technologies for local farming systems, and to intensify and diversify major production systems where the poor and undernourished are concentrated. As part of these programs, the USAID Bureau for Resilience, Environment, and Food Security (REFS) manages a portfolio of research activities collectively known as the Feed the Future Innovation Labs (FTF ILs). Led by U.S. Title XII Universities and intended to be collaborative research programs between U.S. universities, host-country universities, and national agriculture research organizations (NAROs), the FTF ILs are an integral component of USAID's implementation of the GFSS through their leadership and implementation of research and capacity strengthening. FTF ILs are further designed to meet Congress's demand to bring benefits to both U.S. and developing country stakeholders. Through the establishment of strong relationships with NAROs overseas, U.S. researchers gain access to international knowledge and expertise, greater awareness of the global investment landscape, and an appreciation of the challenges and technologies used in those countries. The Feed the Future Innovation Lab for Veterinary Vaccine Delivery (or Veterinary Vaccine Delivery Innovation Lab or VVDIL) will be part of this portfolio of FTF Innovation Labs.

A.III. Background and Introduction of the Veterinary Vaccine Delivery Innovation Lab (VVDIL)

A.III.a. Background of the Veterinary Vaccine Delivery Innovation Lab (VVDIL)

A.III.a.1. Livestock and Animal Source Food Market Systems

Livestock are critical to the livelihoods of over a billion people around the world. This includes 600 million livestock-keeping smallholder farmers, the majority of whom are women, and a substantial and growing number of off-farm, input, and output market participants and service providers.[8] Livestock serve multiple functions. In addition to providing sources of food and income, livestock can be a labor-saving tool, a medium to store wealth, and serve other social functions. Furthermore, efforts to improve livestock production and animal source food (ASF) market systems contribute to all three of the topline Global Food Security Strategy (GFSS) goals: 1) inclusive and sustainable agricultural-led economic growth; 2) strengthened resilience among people and systems; and, 3) a well-nourished population, especially women and children.[9]

Some experts predict that the greatest food security challenge in 2050 will be providing nutritious diets that fulfill macro- and micronutrient needs rather than adequate calories.[10] Animal source foods

[8] *Livestock pathways to 2030: One Health*. (n.d.). Why Livestock Matter. https://whylivestockmatter.org/livestock-pathways-2030-one-health#section-women-s-empowerment
[9] USAID. 2023. GFSS Activity Guidance Document: Investing in Livestock and Animal Source Food Systems. https://pdf.usaid.gov/pdf_docs/PA00ZX78.pdf
[10] Nelson, G., Bogard, J., Lividini, K. et al. Income growth and climate change effects on global nutrition security to mid-century. Nat Sustain 1, 773–781 (2018). https://doi.org/10.1038/s41893-018-0192-z

are nutrient-dense components of diversified diets, providing highly bioavailable nutrients that are critical for health, particularly for infants, children, and women of reproductive age. Access, affordability and safety of animal source foods must be increased to meet the demand that is growing in low- and middle-income countries (LMICs) as a result of increasing human populations, urbanization, and prosperity. Livestock systems in LMICs, however, suffer low productivity, relatively high greenhouse gas emission intensities, and low adaptive capacity to climatic shocks and stressors. Research innovations are needed to improve the productivity, environmental sustainability, and climate resilience of these critical agrifood systems.

A.III.a.2. Animal Health

According to the World Animal Health Organization (WOAH), about 20% of livestock production is lost as a result of animal diseases every year, which is estimated to cost the sector about $300 billion annually.[11] Livestock-disease related shocks hamper growth of the sector, reduce incentives to invest, and contribute to the continuance of poverty and poor nutritional outcomes of people. Strengthening disease control efforts can spur growth of the livestock sector, strengthen resilience of people and communities, and improve nutritional outcomes, especially for women and children. Animal health research, in particular, offers many opportunities to improve the productivity of livestock systems and ensure a sustainable supply of animal source food products to meet the demand of emerging markets. As a small number of diseases usually cause the most burden, there are opportunities for targeted disease control efforts to be transformative for global livestock production systems by making them more productive, efficient, and competitive.

Furthermore, the health of livestock is intimately linked to the health of people and ecosystems. An integrated, unifying approach such as One Health[12] is helpful for ensuring the health of people, animals, and ecosystems is sustainably balanced and optimized. In alignment with the principles of One Health, the Global Food Security Strategy promotes multi sectoral collaborations and climate smart approaches that consider natural resource management, improved health and nutrition outcomes, and social inclusion. The Global Food Security Strategy also acknowledges the potential of transdisciplinary approaches to improve the control of emerging threats from pests and disease.

Improving animal health in low- and middle-income countries is a climate-smart approach to livestock development. Drivers of low productivity, like high disease burdens, result in high rates of "unproductive emissions" in which livestock are producing greenhouse gasses without proportionally producing meat and milk at rates as high as richer countries. Increasing the efficiency of livestock systems in low- and middle-income countries by reducing production losses that result from disease will reduce greenhouse gas emission intensities and contribute to bending the trajectory of the growth of these livestock sectors toward more sustainable systems in the future. Additionally, the changes in rainfall, humidity, temperature, and wind that will accompany climate change will impact livestocks' susceptibility to diseases, the disease pathogens themselves, the vectors that transmit them as well as the environment and the behavior of livestock keepers as a result of habitat change. Decreasing the frequency and impact of animal disease outbreaks is thus seen as a key leverage point in improving climate resilience for livestock and their caretakers.

USAID's investments in animal health have included research to develop new or improved

[11] OIE/WAHO. 2005. Animal Health: A multifaceted challenge.
[12] https://www.who.int/news/item/01-12-2021-tripartite-and-unep-support-ohhlep-s-definition-of-one-health

technologies and management practices to prevent disease or improve animal nutrition; improved technologies to more readily diagnose animal diseases; and improved approaches for delivering animal health interventions. Recent examples of USAID's research investments in animal health are the Feed the Future Innovation Lab for Animal Health, the Feed the Future Innovation Lab for Livestock Systems, the Feed the Future Innovation Lab for Genomics to Improve Poultry, and the Feed the Future Innovation Lab for Rift Valley Fever Control in Agriculture. In addition to funding research or delivery of animal health interventions, many of these programs aimed to support local capacity strengthening through degree-granting training of individuals and organizational capacity strengthening including the renovation of research facilities, the provision of research equipment, and the training needed to use and maintain the equipment.

A.III.a.3. Introduction to the Feed the Future Innovation Lab for Veterinary Vaccine Delivery (VVDIL)

The updated Global Food Security Research Strategy described a set of factors that guide Feed the Future research investments including a) the likelihood of advancing practices, policies, knowledge, or technologies; b) the value to society of the outputs generated from successful research; and c) the existence of a unique and compelling need for the U.S. Government to fund the research. Subsequent to the release of the updated Global Food Security Research Strategy, the REFS Research Community of Practice partook in a research prioritization exercise to systematically identify those researchable solutions that most closely align with the updated strategy. Animal health research was identified as one of the priority areas. In response to the findings of the prioritization exercise, REFS commissioned an animal health research landscape analysis to identify research opportunities that aligned with the comparative advantage and strategic priorities of USAID. This analysis identified the enhancement of the attributes of vaccines to improve their ability to reach livestock keepers in LMIC as one of the most strategic ways for USAID to drive animal health gains in the livestock sector.

Vaccines for priority livestock diseases offer a relatively cost effective option to prevent animal disease, decrease disease impact upon an infected host, improve control of disease outbreaks, and accelerate cure of infected animals. This, in turn, strengthens household and production system resilience, increases livestock productivity, and increases community access to safe, nutrient-dense animal source foods. Although vaccines offer many benefits for smallholder livestock keepers, private sector interest in investing in upstream vaccine development for many of the diseases most important to farmers in LMIC is limited. In addition to the challenges associated with the vaccine development pipeline, the distribution and uptake of vaccines in LMICs are constrained by a number of factors including the need for proper functioning climate-smart cold chain networks from urban hubs to extremely rural areas with little other supporting infrastructure (such as electricity and roads), appropriate packaging and delivery-protocols, lack of access to veterinary services, and the need for booster doses, which require multiple animal handling events. It is also important to consider women's decreased access to agricultural extension services, markets, decision-making power, and time that can further impede their ability to use agricultural technologies such as vaccines.

Vaccine delivery and administration innovations that directly address barriers to immunization of livestock and support equitable vaccine coverage will improve animal health in low- and middle-income countries. Vaccines that do not need a cold chain for storage and transport would make them easier and cheaper to store. Additionally, public support that strategically de-risks private investment for product development, testing, targeting, and eventual transfer to vaccine manufacturers is

expected to further drive sustainable scaling of vaccine innovations.

USAID has a history of supporting animal health research that has resulted in transformative changes. In the 1980's and 1990's, USAID supported the development and field-testing of a thermostable vaccine against Rinderpest–a viral disease of cattle with a mortality rate of up to 100% in immunologically naive livestock populations. Rinderpest was subsequently eradicated from the globe in 2011,[13] resulting in the avoidance of $920 million per year of losses in the livestock sector, according to FAO estimates.[14] In alignment with the Peste des Petits Ruminant Global Eradication Programme of FAO and WAHO, USAID also supported the development and commercialization of a thermostable Pestes des Petites Ruminants (PPR) vaccine in 2020. USAID supported the first private sector firm to produce and commercialize the thermostable vaccine for this highly infectious viral disease of sheep and goats.[15] As a result of USAID support, global disease control efforts have been significantly strengthened by de-risking investment and providing technical support to catalyze private sector innovation in the veterinary vaccine development space.

More recent advances in approaches to create cold chain independent vaccine formulations hold potential to further increase the range of vaccine coverage, alleviate a significant constraint to vaccine delivery, while concomitantly decreasing the expense of vaccine application. A variety of procedures to optimize heat tolerance (or thermostability), and hence cold chain independence, are in use or under development. These include, but are not limited to: genetic engineering of proteins to increase their stability; freeze drying to prevent large ice crystal formation; spray drying; inclusion of appropriate excipients; stabilization of nucleic acid vaccines in a sugar mixture; and other agents which promote films.

In addition to thermostability, the recent advances in the means of administration of vaccines show promise in extending the application of veterinary vaccines in low- and middle-income countries. The aversion to pain and needles, the inconvenience and expense of dried vaccine reconstitution with sterile diluent, wastage related to multi-dose vials, and the need to corral livestock to give multiple vaccine types and booster doses is labor-intensive and expensive. One approach to addressing these constraints is the development of transdermal microneedle vaccine delivery systems for topical application. Microneedles can be engineered to penetrate into and release their payload into the superficial layers of the skin–above the level of pain receptors but in a region that is rich in antigen presenting dendritic cells, making this an attractive way of delivering vaccines. Microneedles can also be used to package a variety of materials including bacteria, viruses, peptides, proteins, and nucleic acids with and without protective coatings. The wide range of potential uses for microneedles accounts for the numerous publications on microneedle technologies in recent years. The development of microneedles that dissolve in the transdermal environment at different rates raises the possibility of time-delivered booster doses and combinations of vaccines including those that can not be given through a one-shot multivalent combination.

The utilization of approaches to thermostabilize vaccines and package them in novel vaccine delivery

[13] USAID's Legacy in Agricultural Development: 50 Years of Progress. 2013, 2016. https://www.usaid.gov/sites/default/files/2022-05/USAID-Legacy-in-Agricultural-Development.PDF
[14] Eradication isn't the end of the Rinderpest Story. FAO. 2018. https://www.fao.org/newsroom/detail/Eradication-isn-t-the-end-of-the-Rinderpest-story/en
[15] Feed the Future Partnering for Innovation Final Program Report. 2022. https://agrilinks.org/sites/default/files/media/file/Feed%20the%20Future%20Partnering%20for%20Innovation%20-%20Final%20Program%20Report%202012-2022.pdf

systems complements other ongoing vaccine development research such as the development of effective traditional, sub-unit, and genetic vaccines. Efforts to enhance existing vaccine products or promising vaccine candidates under development will help to ensure remote and resource-constrained livestock keepers also benefit from advances that are occurring in the wide, active space of veterinary vaccine development.

The Feed the Future Innovation Lab for Veterinary Vaccine Delivery (VVDIL) will serve as a platform for accelerating the development and deployment of veterinary vaccines that are cold-chain-independent, appropriately packaged, and time-delivered. This Feed the Future Innovation Lab will take advantage of cutting edge approaches to create and commercialize improved veterinary vaccines that will better reach remote and resource-constrained livestock keepers in LMICs. This will also involve engaging with the private and public sector vaccine manufacturers early and often, taking the needs and concerns of marginalized populations into account throughout the development process, and building the capacity of local agriculture innovation systems to continue this work beyond USAID's investment. Using sustainable and inclusive strategies to increase veterinary vaccine access will result in a "triple win" through livestock system development by preserving our environment, alleviating poverty and malnutrition, and strengthening household resilience in Feed the Future and Resilience focus countries.

A.III.b. Relevance of the Veterinary Vaccine Delivery Innovation Lab

A.III.b.1. Incorporation of GFSS Objectives

The Applicant is expected to develop a research and local capacity strengthening program that considers the program's contributions to these objectives through the activity design, implementation, and performance evaluation. The GFSS objectives aim to advance food security and improve nutrition by focusing efforts around three interrelated and interdependent objectives discussed below.

A.III.b.1.a. Agriculture-led Economic Growth

Innovations from research are seen as central to driving impact and productivity growth in agriculture. The 2019 World Bank study "Harvesting Prosperity" demonstrates that agricultural growth is up to four times more effective in reducing extreme poverty than growth in other sectors in poorer developing countries.[16] Growth in the agriculture-food sector is especially dependent on research-generated innovation, far more so than other development sectors. FTF Innovation Lab research investments often lead to outcomes that advance multiple GFSS objectives, and have an average return on investment of 237%, conservatively estimated.[17] Productivity gains drive agricultural growth through higher yields, reduced risks from pests or diseases, reduced post-harvest losses and improved quality, and overall improved value resulting from strong market demand for higher quality foods.

The livestock sector already represents 30 percent of the agricultural gross domestic product (GDP) in the developing world. As a fast growing sector with demand projected to grow for many Feed the Future countries, increasing productivity through sustainable pathways is becoming increasingly

[16] https://openknowledge.worldbank.org/bitstream/handle/10986/32350/9781464813931.pdf
[17] Dalton TJ, Fuglie K. Costs, Benefits, and Welfare Implications of USAID Investment in Agricultural Research through U.S. Universities. *Journal of Agricultural and Applied Economics*. 2022;54(3):461-479. doi:10.1017/aae.2022.18

important.

For more information, please see the GFSS Activity Design Guidance for Increased Sustainable Agricultural Productivity.[18]

A.III.b.1.b. Strengthen Resilience among People and Systems

Under this GFSS objective, resilience and risk are interrelated. Resilience is the ability of people, households, communities, and systems to reduce, mitigate, adapt to, and recover from shocks and stresses in a manner that reduces chronic vulnerability and facilitates inclusive growth. It is an essential condition for sustainably reducing global hunger, malnutrition, and poverty as well as to reduce reliance upon emergency food assistance.

Risk management is the set of activities, behaviors, decisions, and policies that allow individuals, households, and communities to mitigate (reduce) the likelihood or severity of a shock and to transfer or positively cope–without employing negative coping strategies, such as productive asset depletion–with shocks, stress, and risk exposure, including adaptation strategies that help individuals, households, and communities manage longer-term trends and stresses. Feed the Future Innovation Labs are an important source of risk-reducing innovations, technologies and knowledge.

FTF ILs also strengthen functional capacities of local partners and systems to adapt and respond to shocks, such as livestock diseases, to realize the potential of innovation to protect local, national, and regional production systems on which the poor depend.

Equitable access to livestock vaccines can strengthen resilience to livestock disease outbreaks, and, indirectly, to other financial shocks and stresses due to livestock often serving as a savings account for rural households. However, vaccine delivery and deployment, associated finance packages, and animal healthcare systems must be intentionally designed to provide equitable access and benefits.

For more information, please see the GFSS Activity Design Guidance for Strengthened Resilience Among People and Systems.[19]

A.III.b.1.c. A Well-Nourished Population

A well-nourished population, especially among women and children, is a high-level goal of the GFSS. In a food systems approach, FTF ILs generate technologies, methodologies and policies that contribute to improved nutrition, both directly and indirectly. FTF ILs efforts to discover, identify, create, and disseminate innovations, technologies, and methods that strengthen opportunities for smallholder farmers to sustainably and economically produce safe, nutritious foods including animal source foods.

The USAID Multi-Sectoral Nutrition Strategy also outlines how improving nutrition outcomes is critical to achieving significant gains in reducing poverty and increasing resilience among vulnerable

[18] USAID. (2022). GFSS Activity Design Guidance for Increased Sustainable Agricultural Productivity https://pdf.usaid.gov/pdf_docs/PA00ZVFH.pdf
[19] USAID. (2022). GFSS Activity Design Guidance for Strengthened Resilience Among People and Systems https://pdf.usaid.gov/pdf_docs/PA00ZVGF.pdf

communities.[20] While multiple types of activities in several sectors are needed to meet this outcome, increasing inclusive access to vaccines of priority livestock diseases is expected to increase availability of animal source foods and the potential for low-income households to adopt more nutritious diets. Due to the high density of bioavailable macro- and micronutrients, animal source foods can be an important component of a high quality diet, particularly for children and pregnant women. Decreased incidence of livestock diseases may also decrease the food safety risks related to animal source foods among low-income populations.

For more information, please see the GFSS Activity Design Guidance on Diets and Food Safety.[21]

A.III.b.2. Incorporation of Cross-Cutting Issues

The Applicant is expected to develop a coherent approach to ensure that essential cross-cutting issues are addressed at both the program level and incorporated within individual component activities as appropriate. These following cross-cutting issues can be incorporated into the Application by integrating them into objectives of the program, the approach to achieving the objectives, or the expected outcomes and impacts of the program. Applicants are encouraged to utilize external sources, such as the ones provided within this NOFO, to guide their understanding of these issues beyond the descriptions presented here.

A.III.b.2.a. Addressing Climate Change and Natural Resource Management

The updated GFSS is abundantly clear on the threat that rapidly changing climate patterns present to agricultural production. The intensifying challenges of less predictable temperature and rainfall patterns and extreme weather events such as droughts, floods, and extended periods of extreme temperatures act as significant barriers to achieving global food security goals. In addition, women and other marginalized groups are more vulnerable and less resilient to climate shocks and stresses. Thus, new food production practices, along with enhanced monitoring and response to agricultural pests and diseases are required.

USAID also seeks sustainable approaches to increasing agricultural productivity that do not exacerbate the climate crisis or cause further environmental harm. In addition to the climate crisis, continued stress on ecosystems, the land, and water, partially from inefficient and destructive agricultural practices, threatens the natural resource base on which agricultural production relies. In the face of increasing human populations and demand for animal source foods in many Feed the Future target countries, improved natural resource management will be an important component of approaches to develop sustainable food systems that can meet future needs. Responding to these challenges requires research to provide new tools and approaches for increasing sustainable agricultural productivity, monitoring and managing pests, diseases and associated risks, managing and governing natural resources related to the food supply, and adapting to the effects of a changing climate.

Veterinary vaccines increase production efficiency in livestock systems, which lead to a decrease in greenhouse gas emissions intensity from these systems. With a changing climate, livestock pests and diseases will continue to increase their ranges to affect novel populations, enhancing the need for

[20] The USAID Multi-Sectoral Nutrition Strategy addresses pathways to optimal nutrition. https://www.usaid.gov/nutrition-strategy
[21] USAID. (2022). GFSS Activity Design Guidance for Diet and Food Safety https://pdf.usaid.gov/pdf_docs/PA00ZVFF.pdf

increased availability of veterinary vaccines. Furthermore, increased temperatures and changing weather patterns threaten water and feed supplies and weaken livestock immune systems, which make them even more vulnerable to these diseases. Climate change will also increase the frequency of extreme weather events in Feed the Future target countries, which in turn can lead to livestock death, disease, physical stress, and humanitarian emergencies. For these reasons, it is critical to have veterinary vaccines that are easily accessible–physically and financially, widely distributed, and cold chain-independent to ensure that vulnerable livestock keepers have the tools to protect their animals from highly impactful diseases.

For more information, please see the GFSS Activity Design Guidance for Natural Resource Management[22] and the GFSS Activity Design Guidance for Climate-Smart Agriculture and Food Systems.[23]

A.III.b.2.b. Gender Equality, Equity, and Participation

USAID policy requires that gender equality be addressed as appropriate in all USAID-funded activities and that programming contribute to the USAID Gender Equality and Women's Empowerment Policy[24] objectives and the GFSS Cross-cutting Intermediate Result (CCIR) of advancing gender equity and female empowerment.[25] Gender-responsive agricultural research involves the identification of questions that are informed by and relevant to women's and men's roles, responsibilities, participation in, and benefits from agriculture innovation and market systems; the ability to collect and analyze data to answer those questions; and the ability to engage with and communicate findings to stakeholders. Gender analysis and integration must be implemented as a cross-cutting effort within all activities.[26]

FTF ILs must develop knowledge, recommendations, tools, and strategies that recognize and account for the needs and multi-dimensional roles of people of all genders in livestock systems and veterinary vaccine development spheres. Gender-sensitivity begins from initial product profiling and market research, and continues through the development of innovation packages and business models that ensure accessibility and usability for livestock keepers of all genders. Efforts that engage actors in marketing and distributing of vaccine products must consider factors such as access to agricultural information and cooperative membership, ability to access complementary inputs, cost, and shifts in workload, which may differentially affect gendered uptake and impact. Because men and women are not homogenous groups, FTF ILs must, to the extent possible, be sensitive to this diversity, and explicitly recognize the specific needs among different communities. Incorporating an intersectional lens to gender-sensitive technology development will be instrumental in assuring that veterinary vaccines are accessible to all livestock keepers.

For more information, please see the GFSS Activity Design Guidance for Advancing Gender

[22] USAID.(2023). GFSS Activity Design Guidance for Natural Resource Management https://pdf.usaid.gov/pdf_docs/PA00ZW1M.pdf
[23] USAID. (2023). GFSS Activity Design Guidance for Climate-Smart Agriculture and Food Systems. https://pdf.usaid.gov/pdf_docs/PA00ZX7D.pdf
[24] https://www.usaid.gov/sites/default/files/2023-03/2023_Gender%20Policy_508.pdf
[25] https://www.feedthefuture.gov/resource/global-food-security-strategy-technical-guidance-on-advancing-gender-equality-and-female-empowerment/
[26] Additional guidance on integrating gender can be found in the GFSS Gender Technical Guidance (linked above).

Equality and Women's Empowerment[27] and the Gender Good Practices In Livestock Programming.[28]

A.III.b.2.c. Youth Inclusion

Similarly, yet distinct from the gender requirements noted above, the 2012 Youth in Development Policy[29] (updated in 2022) mandates the inclusion of youth (ages 10–29) priorities across USAID's development portfolio. The GFSS has also committed itself to mainstreaming youth in agriculture, food security, and nutrition whenever and wherever possible using a Positive Youth Development approach.[30] FTF ILs should be youth-inclusive programs that develop knowledge, recommendations, tools, and strategies that recognize and account for the needs and multi-dimensional roles of youth in the diffusion, marketing and availability of innovative technologies and practices. FTF ILs must also make efforts to include youth in non-extractive and empowering ways in as many stages of the research, development, and deployment process as is reasonable.

FTF ILs should also utilize approaches that address the critical need in agricultural research of a "pipeline" of interested youth who are willing to commit their professional lives toward advancing agriculture in their home countries. Because young people are not homogenous groups, FTF ILs must, to the extent possible, be sensitive to this diversity, and explicitly recognize the specific needs and economic aspirations of various groups within the broader category of youth. Thus, it is recommended to conduct an inclusive development analysis that improves the evidence base and allows for better targeting of youth in livelihood-generating activities. An inclusive development analysis that includes youth should be integrated into all of the activities of FTF ILs (See section A.IV.c.2.b).

For more information, please see the GFSS Activity Design Guidance for Youth Empowerment and Livelihoods in Food Systems.[31]

A.III.b.2.d. Multidisciplinary Approaches: Convergence Science and One Health

The U.S. Government's FY 2022-2026 Global Food Security Research Strategy emphasizes the need for novel and creative partnerships to address the complex, interrelated challenges to food security through convergence research. The National Science Foundation described convergence research as a scientific approach that integrates knowledge, methods, and expertise from different disciplines to form novel frameworks that catalyze scientific discovery and innovation[32]. Inter-, trans-, and multidisciplinary research contributes to the achievement of the goals of the Global Food Security Strategy by developing novel technologies, practices and approaches as well as increasing the understanding of the behavior, needs, preferences, and constraints of various actors in the agriculture and food systems, including the differences facing women, men, youth, and other marginalized groups.

The One Health approach is also founded upon the recognition of the complexity of the challenges

[27] USAID. (2023). GFSS Activity Design Guidance for Advancing Gender Equality and Women's Empowerment. https://pdf.usaid.gov/pdf_docs/PA00ZVFP.pdf
[28] USAID. (2021). Gender Good Practices In Livestock Programming. https://pdf.usaid.gov/pdf_docs/PA00Z5PH.pdf
[29] https://www.usaid.gov/policy/youth
[30] https://www.youthpower.org/youthpower-our-approach
[31] USAID. (2022). GFSS Activity Design Guidance for Youth Empowerment and Livelihoods in Food Systems. https://pdf.usaid.gov/pdf_docs/PA00ZX7H.pdf
[32] National Science Foundation. Convergence Research at NSF. https://www.nsf.gov/od/oia/convergence/index.jsp

that impede optimal system operation including the need to mitigate negative externalities and ensure net-benefits that are widely shared. It is described as "an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals, and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent."[33] As livestock health impacts the health of livestock caretakers and the ecosystems in which they live, research on veterinary vaccine development should seek to utilize convergence research and One Health approaches.

Multidisciplinary, collaborative partnerships are encouraged to effectively develop and deploy vaccine product innovations through sustainable, socially-inclusive models that account for environmental, human health and nutritional outcomes. There may be opportunities to learn from the human health and environment sectors on issues to remedy logistics and other challenges such as supply chains weaknesses and lack of (climate-smart) cold chains to ensure that veterinary vaccine development and deployment are as efficient, effective, and sustainable as possible and support climate change mitigation and adaptation, economic growth and increased incomes and improved nutrition. In this way and others, a One Health approach, including involving local communities in cross-sectoral collaboration and communication, is important to success.

A.III.b.3. Agricultural Innovation Systems Approach

The long-term sustainability and success of food security and nutrition research investments are dependent on both continuous capacity strengthening for agricultural innovation and the hand off of research outputs to partners who effectively promote their widespread adoption and diffusion following a product life cycle framework (see Section A.IV.c.1.b below). Achieving scale must be planned from the start. To do so, FTF ILs must play an important role in partnering with private and public sector stakeholders to identify opportunities and barriers in innovation and market systems through their research, as well as facilitating local system capacity strengthening and relationships that are necessary to scale use of beneficial technologies and practices. Many technologies require private and public sector engagement to optimize diffusion and adoption at scale. Not every innovation will require the same set of actors or the same pathways, but discernment at the early stages of research planning and design increases the likelihood of advancing global food security, resilience and related nutrition investment.

An agricultural innovation systems (AIS) approach may be a useful lens through which capacity strengthening and scaling may be considered. This approach shifts attention away from research and the supply of science and technology as an independent operation and towards the whole process and ecosystem of innovation in which research is embedded. An AIS perspective considers the interaction of people, the knowledge, technology, infrastructure, and cultures they have created or learned, who they work with and their motivations and incentives, and what new ideas they are experimenting with. And it pays explicit attention to this interaction of individuals and organizations across the domains of research and education, the private sector and markets, agricultural extension and other bridging institutions, and the enabling environment.

Using this lens, FTF ILs strengthen the critical capacities and relationships among public research, academic, regulatory, and other governmental organizations as well as private sector entities, as

[33] USAID. 2024. One Health: A Common Facet in USAID Strategy and Policy. https://biodiversitylinks.org/library/resources/one-health-fact-sheet-usaid-strategy-policy.pdf

appropriate. In addition to the adoption of technologies and knowledge developed by the FTF ILs, local AIS entities must also have the organizational and relational capacities to create new, improved innovations that are responsive to end users such as smallholder farmers, small and medium enterprises, regulators, and policy makers. An agricultural innovation systems approach helps to ensure sustainability of results and long lasting impact.

A.III.b.4. Private Sector Engagement

Because public-private partnerships can be especially valuable for moving publicly-funded research products to the private sector for broader distribution of research outputs, the FTF ILs also work to strengthen the critical relationships among the public and private sector. Together, these actors can jointly implement effective research, technology development, and distribution activities within a virtuous cycle of an agriculture innovation and market system that is more responsive to the fast-changing local contexts. Through this process, the private sector can gain valuable knowledge and understanding on how to engage in more challenging markets and access previously unavailable market sectors. Utilizing co-creation and other collaborative approaches to develop innovations that are responsive to the demands of the private sector and the needs of other stakeholders will increase the potential of sustainable outcomes.

Scaling–or wide dissemination of innovation products–is another function with which the private sector is well-suited. Best practices to maximize the scaling potential and development impact of research outputs include:[34]

- Consider local needs, preferences, and market demand throughout activity design and implementation to ensure the resulting research outputs will ultimately achieve scale.
- Explore and identify potential scaling pathways early in activity design and implementation.
- Foster research partnerships with potential scaling partners in order to promote co-innovation, inform development of appropriate and user-oriented technologies, and facilitate downstream adoption of new knowledge and practices.
- Use participatory research methodologies that engage intended end-users, including marginalized groups, and potential scaling partners such as the private sector, in co-design development and testing of innovations.
- Solicit and respond to ongoing, iterative feedback from end-users, stakeholders, and scaling partners to inform research activities.
- Maintain research partner engagement after handoff to scaling partners with the aim of providing technical support to and building capacity of local scaling partners.

In response to these expectations for development-oriented research programming, the FTF ILs are expected not only to generate improved knowledge, technologies, and practices, but also to make

[34] https://www.usaid.gov/what-we-do/agriculture-and-food-security/us-government-global-food-security-strategy

those research outputs available for uptake by partners who will take them to scale. In addition to private sector actors, USAID may have other partners and programs that can strategically support scaling efforts. Public Private Partnerships can also be a valuable mechanism through which to take research outputs to scale by taking advantage of each partner's ability to share resources (i.e. knowledge and technological assets), industry expertise, investment support, managerial expertise, and more.

It may be useful to use the Product Life Cycle (PLC) Framework (see Section A.IV.c.1.b for more detail) to inform when and how to engage with the private sector. Private sector partners can add significant value and capacity to vaccine product commercialization and distribution efforts. They can also help to ensure that business models are inclusive and equitable.

A.IV. Program Description

A.IV.a. Program Overview

The Feed the Future Innovation Lab for Veterinary Vaccine Delivery will be a five-year Leader with Associates (LWA) Cooperative Agreement to support research and product development activities to develop and deploy veterinary vaccines for priority livestock diseases that are cold-chain-independent, appropriately packaged, and time-delivered. Research to develop improved veterinary vaccines will be combined with appropriate market, economic, social science, epidemiologic, and operational research to determine how to best disseminate or scale the envisioned end products in the defined target region(s). Additionally, the program will strengthen the capacity of local organizations to sustainably develop, deploy, and disseminate improved veterinary vaccines. The Total Estimated Amount (TEA) allows a maximum award ceiling of up to $35,000,000, structured as follows:

a) A $13,000,000 Leader Award will support the Successful Applicant to carry out the core objectives of the Veterinary Vaccine Delivery Innovation Lab.

b) $22,000,000 of potential additional funding, through buy-ins (up to $7 million) and associate awards (up to $15 million), may be awarded noncompetitively by USAID Missions or other Offices to support additional activities that fall within the technical scope of the award.

The World Health Organization estimates that about 50% of human vaccines are wasted as a result of issues such as heat exposure and inappropriate handling of multi-dose vials.[35] Similar challenges exist for veterinary vaccines. Recent advances to improve the thermostability and shelf-life of vaccines–including lyophilization, encapsulation, and coacervation–have all shown potential to create cold-chain independent vaccines. Additionally, promising approaches to encapsulate vaccines in novel polymer delivery systems as well as microneedle and rod delivery mechanisms have demonstrated potential to transform how vaccines are transported and administered.

VVDIL will capitalize on these or similar advances to transform promising vaccine candidates and already commercially-available vaccines into vaccine products that do not need a cold-chain, have a long shelf life, are packaged for individual use, and/or can deliver both priming and boosting doses over time in a single application. This will thereby expand the ability of first, second and third generation vaccines (e.g. Live Attenuated Vaccines, subunit, and DNA vaccines) to reach and be

[35] WHO. (2005). Monitoring vaccine wastage at country level.

adopted by more smallholder livestock keepers. As part of the program's efforts to identify vaccine candidates suitable for the delivery enhancement platform, VVDIL may also strategically collaborate to evaluate the efficacy and safety of vaccine candidates as well as conduct other efforts that enhance understanding of vaccine efficacy such as through genetic improvement of the host.

Guided by the principles of the USAID Product Life Cycle Framework, VVDIL will facilitate the deployment of innovative vaccine products by vaccine manufacturers that are best suited for widespread distribution across Feed the Future countries.

A.IV.b. Program Purpose and Theory of Change

A.IV.b.1. Program Purpose

The purpose of the Feed the Future Innovation Lab for Veterinary Vaccine Delivery (VVDIL) is to accelerate the development and deployment of veterinary vaccine products that are cold-chain-independent, appropriately packaged, and time-delivered.

The IL's research outputs are intended to directly contribute to achieving the Global Food Security Strategy (GFSS) Objective 1: Inclusive and sustainable agriculture-led economic growth, Objective 2: Strengthened resilience among people and systems, and Objective 3: A well-nourished population, especially women and children. They will contribute–directly and indirectly–to the following Intermediate Results (IRs) and Cross-Cutting Intermediate Results (CCIRs):

- IR1 Strengthened inclusive agriculture systems that are productive and profitable
- IR2 Strengthened and expanded access to markets and trade
- IR4 Increased sustainable productivity, particularly through climate-smart approaches
- IR5 Improved proactive risk reduction, mitigation and management
- IR6 Improved adaptation to and recovery from shocks and stresses
- IR7 Increased consumption of safe and nutritious foods
- CC IR1 Strengthened global commitment to investing in food security
- CC IR2 Increased gender equality and female empowerment
- CC IR3 Increased youth empowerment and livelihoods
- CC IR4 Enhanced climate change adaptation and mitigation
- CC IR8 Improved human, organizational, and systems performance

A.IV.b.2. Development Theory of Change

IF vaccines that target priority livestock diseases and have enhanced delivery attributes are developed and deployed equitably, THEN remote and resource-constrained livestock keepers in low- and middle-income countries will be able to strengthen their resilience to disease losses, which will lead to increased productivity, improved household nutrition, reduced greenhouse gas emissions intensity, and increased water and land use efficiencies.

The above statements are the development theory of change for USAID. Applicants are expected to articulate their own theory of change and are encouraged to consider what could reasonably be expected to be achieved during the five year program depending on where in the research process the proposed work starts. For example, where a promising vaccine candidate or enhancement process has

already been discovered and exists, the progress along the development theory of change would be faster as compared to the initial discovery of a novel target antigen.

A.IV.c. Technical and Program Management Approach

The successful applicant must provide both a **Management Approach** that effectively, efficiently ensures that all activities meet USAID requirements for international research collaborations as well as a compelling **Technical Approach** to implement the research, product development, commercialization, and capacity strengthening activities that will achieve the technical objectives.

A.IV.c.1. Technical Approach

A.IV.c.1.a Technical Objectives

The objectives of the VVDIL are to:

- Develop cold-chain-independent, appropriately packaged, and time-delivered vaccines for priority livestock diseases
- Conduct commercialization activities to align with market demand, facilitate last mile delivery, and provide practical solutions to constraints that limit widespread adoption of novel vaccine products at scale. This may include vaccine safety and effectiveness studies, regulatory affairs management, intellectual property management, technology transfer, market analyses, socio-economic research to increase access for women, youth, and other marginalized people, social behavior change research, operational research, and epidemiology to support the development of targeted, inclusive business models
- Strengthen the capacity of individuals, organizations, and systems including universities, research organizations, public and private vaccine manufacturers, and other veterinary health organizations to sustainably develop and deploy improved veterinary vaccines

The activity will target the development of innovative vaccine products for priority and economically important livestock diseases of smallholder farmers in low and middle income countries. This may also benefit domestic biosecurity if the vaccine can be used to prevent foreign animal disease spread to the US livestock sector. The activity may enhance existing vaccine products currently on the market or promising vaccine candidates that are under development.

The activity may target significant transboundary and production animal diseases such as, *but not limited to*, the causative agents of: Contagious Bovine Pleuropneumonia; Contagious Caprine Pleuropneumonia; Peste des petits ruminants; Animal African Trypanosomiasis; Theileriosis; endoparasites including helminths; and, ectoparasites. The selected animal diseases should be among those that are most significant to smallholder farmers and pastoralists in the target Feed the Future and Resilience Focus countries, so that the innovative vaccine solutions would generate impactful results that contribute to the goals of the Global Food Security Strategy.

All proposed research must follow the biosafety, biosecurity procedures, and good laboratory

practices and the appropriate biosafety level criteria for research facilities in the CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL),[36] or show a letter of exemption from the CDC or USDA for work at a BSL level if different from or not mentioned in the BMBL 6th edition, as well as following all appropriate country laws and regulations. All research outside of the United States must be able to occur in a research facility of a BSL-2 or ABSL-2 or below. USAID will not support research outside of the United States that requires BSL-3, ABSL-3, BSL-4, or ABSL-4 level facilities. All research with human and/or animal pathogens must occur in the appropriate BSL or ABSL facilities as defined in BMBL 6th edition.

A.IV.c.1.b. REFS's Product Life Cycle Framework

As described in the Global Food Security Research Strategy,[37] product development research represents one stage within a continuous, iterative process by which new food security innovations (including technologies, practices, and knowledge) are developed, validated, disseminated, and adopted in order to enhance prosperity, resilience, and nutrition. For vaccine products to yield maximum impact and result in appropriate levels of coverage in FTF countries, a facilitative approach is typically required to move a promising innovation from the discovery research stage to widespread, sustained adoption at the population level. In order to maximize the potential for research outputs to ultimately achieve development impact, USAID/REFS ensures that best practices to promote technology adoption are integrated into research activities at the earliest stages of design and implementation. This includes:

- Developing a written Target Product Profile (TPP) based upon inclusive market research and epidemiological analyses aimed at understanding and codifying the products and attributes desired by the market (e.g. farmers, manufacturers, veterinary professionals). The analyses should also help to improve understanding of the market opportunity including market size, market demand, and social inclusivity.

- During initial R&D activity design and implementation, identifying potential product delivery and dissemination pathways including the market and regulatory conditions that will ultimately be needed to support the diffusion of an innovation.

- Cultivating active and increasing collaboration between researchers and potential public-private scaling partners as innovations advance through the research and development process, beginning at the earliest phase of research design.

- Using participatory research methodologies to engage intended end-users and potential public-private sector scaling entities in co-design and validation, ensuring that characteristics preferred by target market segments (e.g. smallholder farmers, manufacturers, veterinary professionals) guide product selection during the upstream research process. It is a best practice to share research results with the communities that participated in this research.

- Conducting field trials to validate vaccine products including packaging, application, instructions and economic costs for the user.

[36] BMBL 6th edition
[37] https://www.usaid.gov/documents/1867/us-governments-global-food-security-research-strategy

- Soliciting and responding to ongoing, iterative feedback from end-users, stakeholders and market system actors to inform upstream research activities throughout the product research and development process.
- Thoughtful consideration and timely management of intellectual property issues to ensure they enable the uptake of innovations along the dissemination pathways most appropriate for widespread impact on the target geographies.
- Appraising and planning for commercial regulatory requirements very early in a vaccine's development to avoid actions that can render the vaccine unfit for registration in target markets
- Facilitating successful technology scaling through implementing USAID/REFS agricultural development approaches that consider the structure and function of local product supply and distribution systems in order to promote effective, equitable dissemination of agricultural inputs and other technologies to their intended users.

The Product Life Cycle (PLC) is a standardized process that every product undergoes as it matures, from inception through disposal. A PLC framework typically captures three main features: a) the development of a Target Product Profile (TPP) drawing on market segmentation research, b) the Product Life Cycle stages that characterize the development of an innovation from definition, to research and development, to commercialization, adoption and eventual phase out, and c) the specific stage gate criteria, established in advance in accordance with the TPP and regulatory requirements, that must be met at each stage in order to advance. The product life cycle tracks a product as it advances from one stage to the next, using established criteria at each stage to determine whether the product can advance through the "gate" and progress to the next stage. Stage gate criteria include matching key characteristics defined in the TPP as well as other conditions that must be satisfied in order to launch activities required in the next stage.

A life-cycle approach to product development is critical for the long-term success of VVDIL activities and partners because it strengthens coherence and alignment between the various activities and actors involved in development, manufacturing, and dissemination of a vaccine product based on target market demands within a product's full life cycle. A significant amount of complementary work in veterinary vaccine development by public and private sector actors is ongoing. Forging a strong partnership with appropriate public-private research, development and scaling partners is preferred in the earliest phase of research prioritization and design. Therefore, an integral part of the VVDIL will be the utilization of market-oriented, disease- and geography-specific target product profiles, which will guide and coordinate generation of demand-driven research outputs from the Innovation Lab. All research must be undertaken with the insights about in-demand attributes as described in the target product profiles to increase the ability of researchers to meet farmer and veterinary provider demands. Care should be taken to ensure that the demands of marginalized end-users are taken into account during this research process. To accelerate development and promote sustained investment, well developed target product profiles also articulate the assessed value of the product and follow the market segment specific to each geography and context.

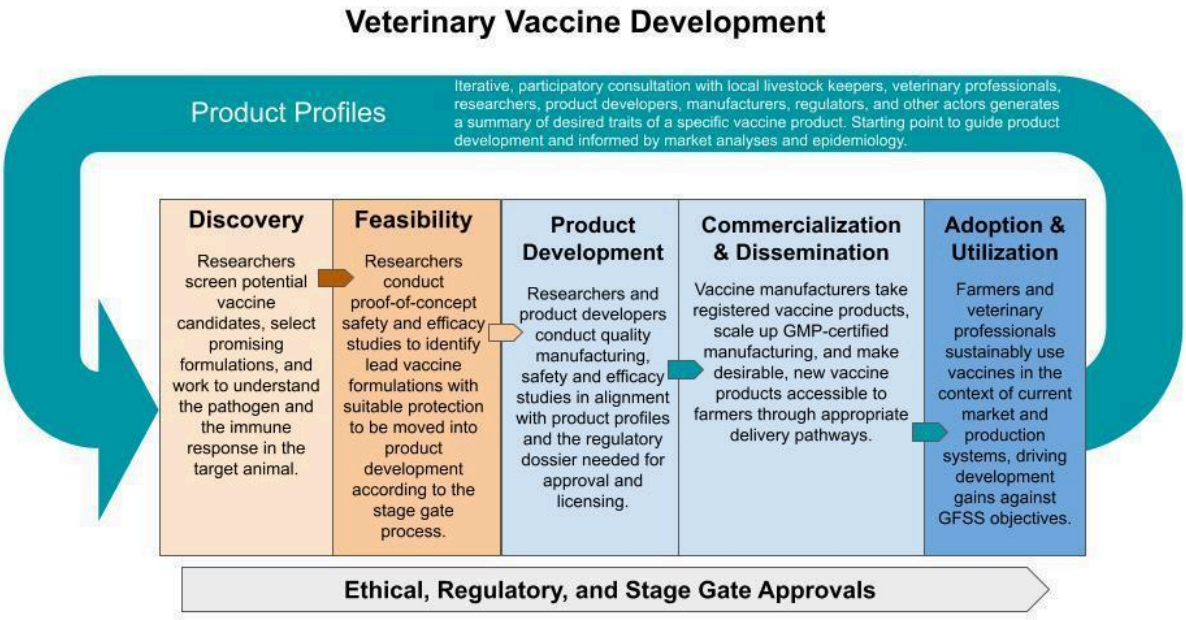

Figure 1 – Illustration of the Veterinary Vaccine Development Process, which includes the key elements necessary to generate a commercially-viable vaccine. The simplified model does not show all of the elements, actions, or stakeholders necessary for such a system to be fully functional.

Managing research utilizing a product life cycle approach further encourages researchers to consider the work beyond discovery, development, field testing, and piloting that is necessary to achieve adoption at scale. To assist researchers in implementing a product life cycle approach to research, USAID supported the development of the Innovation to Impact (i2i) platform[38]. I2i is both a learning platform and innovation management system.

Applicants must propose a life-cycle approach to vaccine research and product development that will guide the management of the program as well as the development and deployment of the improved vaccine products, with consideration of the key activities and actors that will be involved in each step. In addition to a clear process to develop and use TPPs to guide the research activities, the applicant should propose initial ideas for the stage-gate decision making process as well as a potential set of criteria that will be used.

A.IV.c.1.c. Integrative Research

Integrative research is one of ten core Feed the Future research principles and relates to the concepts of convergence science and the One Health Approach described in section A.III.b.2.d. Outputs from biophysical research such as vaccine development should be designed with an understanding of the social, behavioral, environmental and economic factors of the target food and agriculture systems. Innovations developed in conjunction with socioeconomic information increase their potential to be

[38] The i2i platform, including an informative introductory video, can be accessed at https://usaid.s4prod.com/.

responsive to demand and most appropriate for the target production systems. Integrative research also provides information needed by public and private sector organizations to adapt and adopt the technology, design implementation strategies, and strengthen relevant aspects of the enabling environment.

Socioeconomic and behavior change research increases understanding of the incentives and constraints facing key local market system actors. In addition to the geographical, biological, and physical compatibility of the solutions with actors in the target market, consideration of their socioeconomic interests such as compatibility with local culture, political systems, knowledge, and potential for net-positive benefits is essential for the sustainable adoption of effective innovations. Socioeconomic research, such as behavioral economics, social impact assessments, political economy assessments or analysis, ethnographic research and more, can also generate evidence that increases understanding of the potential impacts on target populations and production systems including social-, economic-, environmental- and health-related impacts. Market system research helps identify market opportunities and market failures based on relevant regulatory, political, social, and economic factors of the enabling environment. Evidence from market systems research can inform the development of targeted business models and identify the market and regulatory factors that must be addressed to enable sustainable scaling including policies, regulations, and the capacity of veterinary health systems, supply chains, and climate-smart cold chain networks. Epidemiology improves understanding of how disease is spread and informs the development of effective control strategies including the use of tools such as vaccines. It will be important to also actively disseminate evidence to inform key stakeholders, policy-makers, and potential investors.

Applicants must demonstrate a clear understanding of integrative research and propose how they will utilize multidisciplinary, collaborative partnerships to accomplish the goals of the program.

A.IV.c.1.d. Plan for Local Capacity Strengthening

The development and adaptation of innovations suited to local contexts require a strong and empowered cadre of researchers and practitioners with advanced competencies and professional skills who are embedded within high-performing organizations and institutional networks. Integrating local capacity strengthening into the design and implementation of the VVDIL will be vital to sustaining and innovating research for accelerating veterinary vaccine development.

Capacity strengthening in the GFSS Results Framework is represented as the cross-cutting result of "improved human, organizational, and system performance." Under the GFSS, USAID's approach to improving human, organizational, and system performance is rooted in local capacity strengthening. Local capacity strengthening, according to USAID's Local Capacity Strengthening Policy, is a "strategic and intentional investment in the process of partnering with local actors—individuals, organizations, and networks—to jointly improve the performance of a local system to produce locally valued and sustainable development outcomes."

USAID recognizes that local leadership and ownership are essential for fostering sustainable results across our development and humanitarian assistance work and emphasizes the importance of local capacity strengthening approaches that recognize, understand, and build upon the existing strengths of local actors and systems. Consequently, VVDIL will be responsible for developing a local capacity strengthening approach that aligns with the priorities of host-country and/or regional partners,

ensuring that opportunities are in alignment with local research priorities and strategically targeted to contribute to a strengthened local Agricultural Innovation System as described in Section A.III.b.3. Such an approach must listen to and reflect local actor input. It also should consider the alignment of capacity strengthening activities across the IL portfolio, so that IL capacity strengthening efforts are not duplicative but reinforcing.

Overall "capacity" is a function of capacities at three interconnected levels that are parts of a whole: individuals, organizations, and an enabling environment. While capacity strengthening at each level needs to be dealt with in its own right, it is pertinent to stress the crucial importance of partnerships and networks to create interconnectedness across the three levels to create new knowledge to spur innovation. A capacity strengthening for Agricultural Innovation Systems perspective may help frame an approach that integrates more traditional interventions, such as strengthening technical skills through training, with more contemporary interventions – facilitative approaches that support individuals and organizations to develop and manage their own capacity strengthening and learning plans through continuous improvement processes.

- Local capacity strengthening efforts must be designed to primarily benefit host-country individuals and/or host country and/or regional organizations.
- While recognizing the varied roles of men and women in animal health research and of men and women as producers, consumers, and marketers of livestock-related products, efforts must be made to ensure balance among men and women in access to capacity strengthening opportunities and to promote equal participation of men and women in all activities.
- USAID values a proactively inclusive approach in all development work.

The following documents can provide additional insights on USAID's overarching approach to transforming innovations and reforms into sustained strengthening: USAID Local Systems Framework,[39] the USAID ADS 201 Additional Help Document,[40] Local Capacity strengthening Suggested Approaches,[41] and the USAID Technical Note on the 5Rs Framework.[42] Technical guidance for capacity strengthening in the framework of the GFSS can be found at the GFSS Technical Guidance for Capacity strengthening webpage.[43]

VVDIL will ensure that Local Capacity Strengthening is a fundamental design consideration, both across the overarching program and within individual program activities as appropriate. To the extent possible, Local Capacity Strengthening efforts must be integrated into research activities as support for trainings, workshops, conferences, and meetings for the purpose of professional strengthening of students and researchers associated with the IL.

Local capacity strengthening must not be restricted only to local research institutions. An important facet of a system of organizational strengthening includes the incorporation of the private sector to enable technologies to be implemented at scale during and after the life of the VVDIL; therefore the local capacity strengthening approach must necessarily include a plan to improve the capacity of local private sector stakeholders.

[39] https://www.usaid.gov/policy/local-systems-framework
[40] https://www.usaid.gov/sites/default/files/2023-10/USAID-ID-Hub_ADS-201-AH-Document_Oct-2023_1.pdf
[41] https://usaidlearninglab.org/sites/default/files/resource/files/ads_additional_help_lcd_1.13.2017.pdf
[42] https://usaidlearninglab.org/library/5rs-framework-program-cycle
[43] https://www.feedthefuture.gov/resource/global-food-security-strategy-technical-guidance-on-capacity-strengthening/

Applicants must propose a process and initial ideas for a Local Capacity Strengthening approach that aligns with USAID's interests in Local Capacity Strengthening as described in this section; the successful applicant will design a more detailed strategy after the IL award. Applicants must propose a Local Capacity Strengthening approach that describes which individuals or groups will benefit, how they will benefit, and how the benefits will help achieve development outcomes.

Applicants must also consider how the proposed local capacity strengthening program can complement other USAID investments, including the work of other FTF ILs and/or USAID local capacity strengthening efforts and strive to collaborate where possible in activities, especially those aimed at organizational and institutional relationship strengthening.

A.IV.c.2. Program Management

The management approach including the prime award and subaward engagement process should be one that is suitable for developing, selecting, and managing veterinary vaccine improvement research, commercialization, and capacity strengthening activities. The sub-awards may include a mix of competitively procured activities and commissioned (i.e. non-competed) activities. The management approach should also be appropriate for a program that may improve more than one promising vaccine candidate or existing vaccine in alignment with the objectives of the program. The full application should describe the management structure, organizational arrangements, and staffing which the applicant will establish for implementation of the program to ensure strong and effective management, administration, technical performance, clerical support, and efficient use of resources.

A.IV.c.2.a. Appropriate Partnerships with Private Sector and Public Sector Entities and Appropriate Linkages to Mission(s) Bilateral Programming

The Veterinary Vaccine Delivery Innovation Lab must include at a minimum 1) An eligible US university partner as defined in Section A.II, and 2) at least one local university partner in a Feed the Future or Resilience country. Additional consortium partners are encouraged and may include private sector, public sector, Consultative Group on International Agricultural Research (CGIAR), National Agricultural Research Organizations (NAROs), and Non-Government Organizations (NGOs). Private sector partners and Minority Serving Institutions are highly encouraged. Federal agencies can not formally participate as a consortium partner. Applicants may propose collaborations or opportunities for synergy with USDA scientists, or other federal employees working directly with the school or university lab involved in agriculture research; however, Innovation Lab funding cannot be used to directly pay federal employees.

In order to ensure program relevance, widespread adoption of technologies and information, and subsequent development impact, the applicants should engage with policy-makers, Mission implementing partners, private sector representatives, and other stakeholders as appropriate, even in the early stages of research design and implementation, to ensure that program activities are inclusive and contribute to a pathway of significant development impact. The Veterinary Vaccine Delivery Innovation Lab will be encouraged to collaborate with veterinary vaccine sector stakeholders to plan for future events, outcomes, and market dynamics in the sector, and to promote adoption of research outcomes generated by the Veterinary Vaccine Delivery Innovation Lab as well as past USG supported animal health research activities, if any. These collaborations should help to define research activities that support outreach to stakeholders throughout the sector including policy

makers.

Applicants are encouraged to include private sector partners in their applications. Applicants must discuss how linkages with the private sector, local public veterinary health, other global or regional public research organizations, not-for-profit organizations (local or international), and other entities will facilitate research and development and must include a plan for ensuring that these linkages do not solely remain on paper. Applicants must discuss what strengths in these organizations will be sought after and leveraged and what strengths the VVDIL will contribute.

A.IV.c.2.b. Plan for Inclusive Development

USAID promotes a nondiscriminatory, inclusive, equitable, and integrated development approach that ensures that all people have access to a country's services, opportunities, and legal protections, and are able to take part in their societies. This approach requires a concerted effort to include those who face discrimination, marginalization, underrepresentation, and/or have been made vulnerable.[44] Specific groups of interest can and should vary and intersect depending on context, including the extreme poor; women;[45] youth;[46] people with disabilities;[47] ethnic and religious minorities; indigenous peoples;[48] LGBTQI+ (lesbian, gay, bisexual, transgender, queer, and intersex) persons;[49] widows and orphans; and other often-marginalized groups. USAID acknowledges that engagement with marginalized groups may take various forms. In some instances, direct engagement is necessary, while in others, inclusion impacts may be generated indirectly. It is crucial to monitor actual results with care.

VVDIL will be intentional about including, and not excluding, all persons–including the most marginalized–from benefiting from the associated research and activities.[50] Whether building on prior women's economic empowerment theory and evidence or engaging youth or persons with disabilities in meaningful and creative ways, the technical products generated by the VVDIL will reflect considerations for inclusive agricultural development. In addition, VVDIL's operations and methods on the ground will incorporate the capacity and tools to identify and address the factors that underlie marginalization related to the VVDIL's activities.

As noted in USAID's Gender Equality and Women's Empowerment Policy, all activities are required to conduct a context-specific gender analysis and incorporate findings into the design and implementation of those activities.[51] For this reason, the Applicant is expected to outline key research processes or questions to support gender integration in each objective. Applications must demonstrate a clear understanding of gendered challenges and opportunities: 1) among low-income livestock keepers that can be addressed through improved veterinary vaccines, 2) in engagement of women

[44] Please also see USAID's additional guidance for ADS 201 (https://www.usaid.gov/inclusivedevelopment/additional-help-ads-201), which includes helpful definitions, policy links, and resources.
[45] Please also see the GFSS Activity Design Guidance for Advancing Gender Equality and Female Empowerment. https://agrilinks.org/activities/guidance-and-tools-global-food-security-programs-fy-2022-2026
[46] Please also see USAID's Youth in Development Policy. https://www.usaid.gov/policy/youth
[47] Please also see USAID's Disability Programming landing page for additional resources. https://www.usaid.gov/inclusivedevelopment/disability-rights/disability
[48] Please also see USAID's Policy on Promoting the Rights of Indigenous Peoples. https://www.usaid.gov/policy/indigenous-peoples
[49] Please also see UDAID's LGBTQI+ Inclusive Development Policy. https://www.usaid.gov/policy/lgbtqi
[50] Please also see Frequently Asked Questions on nondiscrimination for beneficiaries. https://www.usaid.gov/inclusivedevelopment/nondiscrimination-faq
[51] USAID's Gender Equality & Women's Empowerment Policy. https://www.usaid.gov/sites/default/files/2023-03/2023_Gender%20Policy_508.pdf

along the full length of veterinary vaccine value chains, 3) among researchers to realize the potential of agriculture innovation and market systems, and 4) to reduce barriers to entry and advancement in research for women as scientists, entrepreneurs and as farmers. Where this information is unavailable, Applicants must address knowledge gaps to ensure that outputs and outcomes of research conducted under the VVDIL are beneficial to people of all genders. Further guidance and information on the importance of gender to livestock systems and veterinary vaccine development and deployment can be found in the Veterinary Vaccine Delivery Innovation Lab Gender Analysis (Annex 2)**.**

An Inclusive Development Plan, which may include an Inclusive Development Analysis,[52] is recommended to guide VVDIL's research efforts, and should be based on the local context and technical approach. An Inclusive Development Analysis should build on the completed Gender Analysis (Annex 2) to incorporate both gender and social inclusion integration into VVDIL's work. This Plan must also include a discussion on how the Applicant will ensure that the IL's local capacity strengthening activities promote inclusivity and follow the principle of 'Do No Harm.' Applicants must demonstrate a clear understanding of how VVDIL's research efforts will lead to improved or new technologies and enabling environment systems that will be utilized to create agricultural transformation and create innovative market systems that are inclusive of all groups. This will include creating inclusive business models, scaling plans, and communicating with private sector partners about the importance of taking an inclusive approach throughout the product life cycle and when conducting market research. It will also be important for applicants to incorporate inclusive development approaches into the MEL and staffing plans.

A.IV.c.2.c Plan for Sustainability Beyond the Life of Project and Potential for Impact

Applicants should describe plans for sustainability through the transfer of research outputs and technical know-how to local private or public sector entities capable of continuing the research, advancing product development or deploying the innovation. The majority of the impact from VVDIL will come from the adoption and application of technology and knowledge outputs that the research activities generate. Applicants should adequately describe how the proposed project will increase impact, reach and efficiency by mobilizing significant new resources, ideas, technologies and partners to address critical food security challenges.

For research investments to contribute to achieving development gains in nutrition, resilience, or agriculture-led economic growth in focus countries, research programs must play an important role in ensuring that research outputs are ultimately handed off to entities who effectively promote their widespread, sustained adoption and use in a manner that enhances food security. The process by which research outputs undergo progressive dissemination, adoption and impact across expanding geographies and populations is referred to as scaling. Scaling can occur via a variety of different delivery pathways, ranging from commercialization by the private sector to dissemination by public-sector or civil-society partners (or a combination thereof).

Broad food security impacts can only happen when new approaches and technologies are adopted and deliver benefits at scale, by the millions. This requires an understanding of market needs, including those of policy makers, producers, processors and end users. It also requires an understanding of

[52] For guidance please see USAID's Guide to Inclusive Development Analysis. https://www.usaid.gov/inclusivedevelopment/guide-inclusive-development-analysis

specific challenges that limit expansion and adoption at scale. Local partners can be critical to identifying challenges and testing real timely and practical solutions to pressing problems. To leverage this experience, applicants should engage local public and private sector scaling partners early and throughout the research process, working backwards from the needs of local private and public sector scaling organizations toward a shared vision of practical solutions. Through close collaboration across the PLC stages, these collaborators would then become local adopters of the innovation.

Therefore, USAID requires that research partners actively address issues of downstream handoff and eventual scaling of outputs throughout all stages of research activity design, selection, and implementation, as an essential element of a research program's technical and management approach. The promotion of innovation handoff, or technology transfer, is critical for sustainable scaling and eventual impact of USAID's development-oriented research programming. Partners are encouraged to keep in mind the timeline of research and technology development, and how that may influence when and to whom that handoff will occur, as well as which research topics to pursue. The Product Life Cycle framework and subsequent approach can be used as a guide to thinking through these timelines. Moreover, it is important to understand and address demand across different target population groups, including marginalized groups, who may have different information channels and specific constraints. The Applicant should develop a coherent technical approach to how vaccines and inclusive business models are developed, and ensure that essential cross-cutting issues are incorporated to increase sustainable scaling and impact as appropriate.

A.IV.c.2.d. Geographic Focus

As a key component of the proposed program description, applicants must select target countries in which to conduct research and capacity-strengthening activities funded under the Leader Award. Additionally, VVDIL must be able to expand activities into other countries in which USAID invests agriculture and nutrition resources in response to additional buy-in or Associate Award funding opportunities that may arise. The VVDIL is encouraged to engage with private sector representatives, and other local stakeholders as appropriate, including in the early stages of research design and implementation, to ensure that program activities will contribute to a pathway of significant development impact. Please note: Applicants **must NOT** contact any USAID Mission or Office staff, other than the contact person identified in this NOFO, during the application phase.

This NOFO primarily aims to conduct research, capacity strengthening, and the promotion of the application of innovations in vaccine development specifically in the Feed the Future target countries (Bangladesh, Democratic Republic of the Congo, Ethiopia, Ghana, Guatemala, Honduras, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Nigeria, Rwanda, Senegal, Tanzania, Uganda and Zimbabwe) or Resilience countries (Burkina Faso, Democratic Republic of the Congo, Ethiopia, Haiti, Kenya, Madagascar, Malawi, Mali, Mozambique, Niger, Nigeria, Somalia, South Sudan, Uganda, and Zimbabwe).

To be successful under this NOFO, relevant local partners must play an active role in any research or capacity strengthening activity or approach proposed for USAID investment. All activities must comply with the CDC Biosafety in Microbiological and Biomedical Laboratories (as noted in the BMBL 6th edition), international OIE guidelines, and applicable local partner country laws and regulations pertaining to research, biosafety, and work with live animals.

Additional information on GFSS country strategies and programs can be accessed from the Feed the Future information hub[53] and the Mission websites.[54]

A.IV.d. Approach to Ensure Accountability

A.IV.d.1. Staffing Plan

To ensure successful implementation of core technical and management functions, applicants must clearly define the roles and responsibilities of proposed staff, proposed staff positions, other university departments, and external advisory bodies. USAID discourages exclusivity agreements between the Applicant and any candidates that will be proposed for Key Personnel (i.e., a person could be proposed by multiple Applicants). “Key Personnel " of the VVDIL will be the Veterinary Vaccine Delivery Innovation Lab (VVDIL) Director, the Associate Veterinary Vaccine Delivery Innovation Lab (VVDIL) Director, and the Technology Commercialization Specialist. The proposed team, which may include Technical Specialists, must collectively demonstrate strong technical and managerial capacity such that the VVDIL will effectively and efficiently achieve its objectives in alignment with Section A.III.b. Relevance of the Veterinary Vaccine Delivery Innovation Lab and its subsections.

Applicants must describe in detail the specific staffing plan, including an organizational chart, to ensure efficient use of resources and strong and effective management, administration, technical implementation/performance, and clerical support. The staffing plan must outline the roles and responsibilities of proposed staff positions, proposed lines of responsibility, authority and communication, and procedures to ensure productivity as well as cost and quality control and to ensure that all USAID programmatic requirements are assigned to at least one proposed position. If more than one staff member will be assigned responsibility for an area, functional supervision must be defined for that area.

A.IV.d.1.a. Veterinary Vaccine Delivery Innovation Lab (VVDIL) Director

The Veterinary Vaccine Delivery Innovation Lab (VVDIL) Director has overall responsibility for the management and implementation of the VVDIL, and serves as USAID’s principal point of contact for all issues regarding the IL. The VVDIL Director publicly represents the VVDIL to the U.S. Government, the public, the global research community, and other diverse stakeholders, and is ultimately responsible for activity coordination, planning, work plan strengthening, program reporting, and overall program monitoring and evaluation. The VVDIL Director ensures that cross-cutting themes are properly addressed throughout the program. The VVDIL Director also ensures coordination, communication, and cross-learning between both internal and external partners and stakeholders of the project. The VVDIL Director is the primary point of contact for the strengthening of Associate Awards and buy-ins and is responsible for integrating Associate Awards and buy-ins into the overall IL program.

To ensure strong engagement among the VVDIL, other international research institutions, NAROS, and the private sector, USAID is seeking a VVDIL director who is a prominent member of the global agricultural research community–a person highly experienced in producing valued global agricultural

[53] https://www.feedthefuture.gov/about/
[54] Additional information on Feed the Future mission strategies and programs can be accessed from https://feedthefuture.gov/countries and the mission websites at https://www.usaid.gov/where-we-work.

research goods. The VVDIL Director must be a thought leader in the area of animal health research and/or commercialization of biomedical research products in low-income country contexts with an actionable vision for leading a global research community and capable of interfacing well at high levels of international organizations, national governments, and the private sector including existing consortia. One of the responsibilities of the Director will be to catalyze additional international investments and resources to increase impact beyond what USAID is solely able to fund.

Applicants may transfer some of the VVDIL Director's responsibilities to the Associate VVDIL Director at the time of application, but must clearly describe this transfer of responsibilities and provide a justification as to why this would benefit the VVDIL (e.g., to free the VVDIL Director to spend more time coordinating with relevant stakeholders) and the impact to Level of Effort (LOE) for both the VVDIL Director and the Associate VVDIL Director. After the start of the IL, the VVDIL Director may decide to transfer some of these responsibilities to other staff contingent upon approval by USAID.

The VVDIL Director is envisioned as a full-time position (0.80 to 0.95 LOE [Full Time Equivalent]); however, if the VVDIL Director meets the subject matter expertise qualifications but cannot commit to full-time management responsibilities, a lower level of LOE (but no less than 50%) may be proposed with justification of such an arrangement and a staffing plan that supports theVVDIL Director's management responsibilities within other staff members. The VVDIL Director must hold at minimum a Ph.D. (or equivalent advanced degree) in a subject relevant to international animal health research as described by this NOFO, a minimum of 5 years (10 years preferred) relevant technical expertise, and demonstrated competency in international agricultural research program management. Experience in managing research partnerships between international, national, and local partners is preferred. Experience integrating gender, social sciences, environmental, and nutritional considerations into research programs is preferred.

Applicants must identify the person proposed to serve as the VVDIL Director with a complete description including (1) role and responsibilities for IL leadership and implementation; (2) proposed LOE; and (3) qualifications for this position. Higher consideration will be given to applicants who propose a candidate with experience most closely matching the requirements described above. A CV (limited to 5 pages) and a letter of commitment from the proposed candidate must be included in an annex to the technical application that will not count toward the page limit. (Note: USAID discourages exclusivity for these candidate positions, i.e. the same candidate may be proposed in more than one application.)

A.IV.d.1.b. Associate Veterinary Vaccine Delivery Innovation Lab (VVDIL) Director

The Associate Veterinary Vaccine Delivery Innovation Lab (VVDIL) Director supports the VVDIL Director. The Associate VVDIL Director must hold at least a Masters or equivalent advanced university degree in a subject relevant to animal health research, a minimum of 5 years relevant technical expertise, and demonstrated program management competency.

Applicants must identify the person proposed to serve as the Associate VVDIL Director with a complete description including (1) role and responsibilities for IL leadership and implementation, including any that are to be transferred from the VVDIL Director; (2) proposed LOE; and (3) qualifications for this position, including qualifications for any responsibilities to be transferred from the VVDIL Director. Higher consideration will be given to Applicants who propose a candidate with

experience most closely matching the requirements described above. A CV (limited to 5 pages) and a letter of commitment from the proposed candidate must be included in an annex to the technical application that will not count toward the page limit. (Note: USAID discourages exclusivity for these candidate positions, i.e. the same candidate may be proposed in more than one application.)

A.IV.d.1.c. Technology Commercialization Specialist

The Technology Commercialization Specialist supports the processes involved in bringing a product to market through private, public, or public-private partnership pathways. They will strategically engage with researchers, VVDIL partners, and other public and private sector actors throughout the vaccine product life cycle to drive the commercialization of vaccine products according to the demands and needs of the target markets. The Specialist will establish, expand, and deepen partnerships that accelerate the commercialization of vaccine innovations, which may include partnership brokering and facilitation, the development of institutional agreements, the facilitation of collaboration and co-creation, and the identification of constraints that may impede market entry or expansion. The Specialist will facilitate and advise relevant actors on intellectual property management processes including patents, technology transfer agreements, and licenses according to relevant regulations and laws. They will strengthen the capacity of researchers and other relevant actors to craft business models and identify market opportunities for the research output, thereby strengthening their commercial mindsets. They will help to incorporate the consideration of viable delivery pathways that have the financial, talent, market insights, relationships, and infrastructural resources needed to move a technology from the research phase to commercialization and impact throughout all activities of the VVDIL. They will also work to ensure regulatory requirements for market entry are met including support for the preparation of regulatory submissions and Good Manufacturing Practices (GMP) compliance. The Technology Commercialization Specialist must hold a university degree in a subject relevant to business, law, or biology, and a minimum of 3 years relevant technical expertise.

Applicants must identify the person proposed to serve as the Technology Commercialization Specialist with a complete description including (1) proposed LOE; and (2) qualifications for this position, including qualifications for any responsibilities to be transferred from the VVDIL Director. Higher consideration will be given to Applicants who propose a candidate with experience most closely matching the requirements described above. A CV (limited to 5 pages) and a letter of commitment from the proposed candidate must be included in an annex to the technical application that will not count toward the page limit. (Note: USAID discourages exclusivity for these candidate positions, i.e. the same candidate may be proposed in more than one application.)

A.IV.d.1.d. Other Personnel

Proposal of any additional management positions, position descriptions, and accompanying LOE, rests with the Applicant and will depend on the nature of the proposed IL. The proposed team of personnel must be sufficient to effectively and efficiently execute all technical and management functions. Various responsibilities that need to be filled within a successful program include:

- Effective management of all financial tasks, including timely and accurate financial statements and reports according to USAID guidelines and generally accepted accounting principles (GAAP).

- Creation and management of sub-contracts or sub-grants to other responsible institutions to conduct research activities, including international institutions and the private sector. The financial and contract and grant offices of the successful Applicant institution must have the demonstrated capacity to issue and manage such sub-contracts or sub-grants using financial and contract mechanisms appropriate for the expected range of sub-awardees. The accounting system must be able to account for funds allocated to each country, including through sub-sub-awards, and by funding origination year.

- In-country coordination to ensure that decisions and analyses are consistent with on-the-ground realities, that activities are aligned with USAID country and regional priorities and geographies, research and capacity strengthening activities are implemented effectively, and that critical partners are engaged from the beginning of the project.

- Creation of materials to increase awareness and to promote productivity including maintaining a positive image of the IL to all parties, including research and development communities, policy makers and government stakeholders, users of generated technologies, and the general public.

- Monitoring, evaluation, and learning of the IL activities including planning and reporting in line with USAID requirements (see section A.IV.d.2.).

- Integrates gender equality and social inclusion (GESI) into the VVDIL's activities from research and implementation to monitoring, evaluation and learning

A.IV.d.1.e. Advisory Committee

Applicants must describe the accountability mechanism to guide technical and strategic progress of research and product development activities along the defined product life cycles including a means to select, correct, cancel, or terminate under-performing activities. Typically, ILs accomplish this partly through the oversight of an Advisory Committee (variously called an External Advisory Panel, External Advisory Committee, etc.). Applicants must describe the mandate and oversight to be ascribed to any such committee and the desired composition of the members.

A.IV.d.2. Monitoring, Evaluation, and Learning

Applicants must submit a preliminary Activity Monitoring, Evaluation, and Learning (MEL) plan[55] with the application. The successfully selected applicant must submit a comprehensive Activity MEL Plan within 60 days after the award is made. The MEL plan should include a relevant theory of change describing impact pathways, an accompanying logic model, results framework, or results chain; illustrative Feed the Future and custom performance indicators; preliminary plans for interim and/or final evaluation and illustrative evaluation questions; preliminary learning agenda questions; and a description of how learning and adaptive management will be incorporated. The plan must specify how indicators, and other qualitative and quantitative data will be used to measure progress and how cross-cutting issues are incorporated and measured throughout the impact pathways.

Impacts denote change from one condition, status, or behavior to another as a consequence of using

[55] See ADS 201.3.4.10 (https://www.usaid.gov/ads/policy/200/201) for USAID requirements on Activity MEL Plans. Note that "Activity" in this sense means the entire Veterinary Vaccine Delivery Innovation Lab.

research results; they must not be confused with research program outputs or deliverables. The theory of change or "development hypothesis" outlines how, why, and under what conditions the proposed program—based on the given parameters and best available information—will be successful in achieving the stated objectives and contribute to wider impacts related to Feed the Future goals. The theory of change for the program should support the monitoring, evaluation and learning plan, the indicators used to measure progress, and how gender, youth, and inclusive development considerations are incorporated and measured. The theory of change must also acknowledge what is and isn't within the spheres of control and influence of the VVDIL as well as critical assumptions. Impact pathways must also consider knowledge sharing and transfer of research outputs to relevant downstream users. Such users may be local organizations, researchers, government decision-makers, regulatory officials, development professionals, and the private sector. A theory of change can be presented in both graphical and narrative form.

The preliminary MEL plan illustrates how evidence will be collected, analyzed, used and disseminated to determine if the proposed technical approach is meeting the objectives and results and what should be adjusted. The Applicant's approach for ensuring that research activities will be oriented to development impact must be clearly articulated throughout the Technical Application.

Performance management requires access to useful and timely information on a broad range of factors throughout the life of a program. Without planning how and when this information will be obtained, it will be difficult or impossible, once activities start, to put systems in place to ensure adequate information flow to enable ongoing decision-making and to meet performance reporting requirements (see Section F.III). VVDIL must take adequate steps to plan and institutionalize a process for collecting performance information as part of everyday work. This performance information consists of the indicators that will measure progress toward intermediate and final results and includes baseline data and periodic and final performance targets.

A "Collaboration, Learning and Adapting" (CLA) approach[56] is a primary precept for USAID work and should be included in the MEL plan. The VVDIL's incorporation of CLA is expected to strengthen the technical knowledge base for new strategies and programs, contribute to continuous alignment of programs with dynamic contexts, encourage adaptability and accountability, and support early recognition and application of new trends and findings to strategically influence outcomes within and beyond animal health research.

The Successful Applicant will adaptively manage the portfolio of sub-awards (contracts or grants) to ensure optimal implementation of all activities. VVDIL will institute procedures that provide partners with appropriate technical guidance and feedback, to ensure that planned research and local capacity strengthening benchmarks are met, to assure compliance and accountability, and to address unexpected challenges and opportunities. VVDIL will also ensure that partners are accountable for progress along their impact pathway. Furthermore, an approach to achieving development impacts must also address opportunities for the VVDIL to implement or support technology-scaling activities, where applicable. The Applicant must ensure that structures and opportunities are in place to facilitate cross-project learning, disseminate lessons learned and regularly curate and disseminate the data that is generated by the program. The program must utilize approaches, including partnerships and platforms, to reach both internal (among target and partner countries and among the IL participants) and external stakeholders, including technology end users, public and private sector and

[56] https://usaidlearninglab.org/cla/cla-toolkit/understanding-cla

civil society. This includes supporting a cycle of learning and feedback between downstream technology users (e.g. marginalized groups), regarding their preferences and willingness-to-pay, and upstream researchers to be integrated into the product profiles. The VVDIL must also ensure that knowledge and understanding gained from the cross-cutting issues are incorporated into the rest of the program in addition to being shared with other FTF stakeholders as relevant. The VVDIL must engage and leverage existing knowledge-sharing platforms and resources to further their reach and impact. For insights on and some examples of knowledge management under FTF programs, please visit Agrilinks[57] and the USAID Learning Lab.[58]

The preliminary Activity MEL Plan must include the following:

- Performance indicators that will measure progress toward achieving the desired results and account for gender and youth dimensions and cross-cutting issues, as relevant. The Activity MEL Plan must use appropriate FTF indicators, custom indicators, and/or context indicators as appropriate. Indicators can include quantitative data (e.g., individuals receiving training) and qualitative information (e.g., description of technology adoption and reported barriers). Indicator definitions and required disaggregation categories can change from year to year. At times, FTF may designate additional mandatory indicators or drop mandatory designations. All people-level indicators must be disaggregated by sex and age cohort (youth [15-29]/non-youth [30+]) .
    - FTF indicators are defined under the Standard Program Structure (SPS) indicator categories in the most recent version of the FTF Indicators Handbook: Definition Sheets.[59] All FTF indicators are considered "required as applicable", which means any indicator is required if the activity is making progress toward the outcome on which that indicator covers. VVDIL should review the list of FTF indicators that are at the Implementing Mechanism level to see which are applicable according to expected objectives and results.
    - Custom indicators are performance indicators that are used in combination with standard indicators to monitor progress toward intended results. At the activity-level, they may be useful for filling in gaps where standard indicators don't fully provide the needed information on specific activity-level implementation or outcomes.
    - Context indicators are a means to monitor factors outside the control of the Activity that have the potential to affect the achievement of results.

- A baseline and targets for standard and custom indicators, with appropriate benchmarks and milestones of progress.

- Documentation of data collection methods and data sources, frequency, data security procedures, analysis, aggregation and storage plans, as well as known data limitations of each performance indicator by explaining potential data quality limitations and what steps will be taken to address them.

- Description of the data quality assessment procedures that will be used to verify and validate the measured values of actual performance of all the performance information.

[57] http://agrilinks.org/
[58] http://usaidlearninglab.org/
[59] https://agrilinks.org/post/feed-future-indicator-handbook

- Schedule and timeline of the performance monitoring and evaluation activities and designation of the individuals or contractors responsible, including reviewing performance reports, conducting site visits, updating and revising the Activity MEL Plan as will be necessary, data collection, aggregation, review, approval, and entry into the Development Information Solution (DIS) see Section F.III, that must be conducted over the expected duration of the IL. Include approximate timeline for the completion of each task, recognizing there will be modifications necessary based on the sub-award portfolio.
- An Evaluation Plan that includes possible evaluation questions, ideas for evaluation design, and methodologies to be used. This plan will be utilized by the external evaluation team to design the external evaluation that may take place in year 4. Also see Section F.III.
- The estimated budget for collecting, analyzing, and reporting performance data and carrying out any planned evaluations.
- Note: All of the aforementioned items will be refined after award and again after selection of the portfolio of activities.

A.IV.d.3. Open Data Management Plan

USAID is committed to making U.S. Government funded data accessible, discoverable, and usable by our partners and is proactively releasing Agency-funded data to the public as a member of the Open Government Partnership,[60] USAID's policy of sharing data in machine readable formats for public benefit is in adherence with the Office of Management and Budget's Open Data Policy[61]. The Successful Applicant is responsible for developing a Data Management Plan in accordance with USAID strengthening Data ADS Chapter 579[62] and storing and maintaining data in such a way as to deliver the data to the USAID Development Data Library (DDL).[63] Applicants must describe the kinds of data expected to be generated and how the VVDIL will adhere to the Open Data Policy with each type of data, including whether data will be entered into the DDL, another data platform that meets the standards of the policy, or both.

A.IV.d.4. Buy-ins and Management of Associate Awards

The VVDIL will be implemented under a Leader with Associates (LWA) mechanism, as described in the cover letter, Section A.IV.a, and Section B.I. Funding will be obligated under the Leader Award to support the core program focused on veterinary vaccine research for development. The Innovation Lab may also accept up to $22 million of additional funds, through buy-ins (up to $7 million) and Associate Awards (up to $15 million) from USAID Missions or other Operating Units (OUs) in USAID, to support additional activities related to its core research mission. Buy-ins and Associate Awards permit USAID Missions or OUs to address country-specific needs or respond to dynamically changing programmatic requirements by tapping into a competitively awarded program that offers global expertise that can be put into place quickly and efficiently. Depending on the nature of the request, buy-ins and Associate Awards may consist of commissioned activities, competitively

[60] http://www.opengovpartnership.org/
[61] https://project-open-data.cio.gov/
[62] http://www.usaid.gov/ads/policy/500/579
[63] https://www.usaid.gov/data

awarded sub-awards, or both. Therefore, the Applicant must be prepared to identify and seek out partners to address a broad array of research questions regarding veterinary vaccine research. **However, these additional activities and associated funding are not guaranteed.**

Buy-ins to the Leader Award are particularly valuable tools for Missions to access a global research program such as the VVDIL. Buy-ins are generally used to fund small activities ($1,000,000 or less) that are already part of the approved Leader Award technical program. For example, an Innovation Lab conducting market or epidemiological research in one country might receive a buy-in from the USAID Mission in another country to conduct similar research there. Buy-ins are managed under the Leader Award (i.e., financial and activity reporting are incorporated into the core program documentation and submitted to the Operating Unit funding the Leader Award). Buy-ins also allow for increased flexibility of the VVDIL program as a whole, and can be used to facilitate rapid responses to emerging or re-emerging threats to livestock.

Associate Awards are frequently used to scale up technological innovations proven to be successful by ILs, are generally larger than $1,000,000, and often have a timeline longer than one year. Associate Awards require an agreement separate from the Leader Award, and financial and activity reporting may be overseen from the Operating Unit funding the Associate Award. An Associate Award has its own timeline apart from the Leader Award and may extend beyond the duration of the Leader Award program. For these reasons, OUs that prefer to maintain direct management of an activity may instead choose to issue an Associate Award to an IL.

Applicants must describe how the VVDIL will manage potential buy-ins and Associate Awards, including potential staffing changes and the engagement of additional experts required to fulfill potential research or scale-up objectives.

A.IV.d.5. Subawardee Engagement Plan

Applicants are required to submit a Sub-awardee Engagement Plan (SEP) to be reviewed as part of the Management Approach of the Technical Application evaluation. The SEP will describe the plan for identifying, managing, and partnering with sub-awardees that provides sufficient detail for USAID to review alternative approaches among applicants as well as sufficient detail to guide interaction with, support to, and management of subawards and sub-awardees. In addition, this section provides the opportunity for applicants to address the Title XII legislative mandate that implementing Title XII institutions partner with non-traditional partners, including MSIs, civil society, the private sector and local partners. USAID is also committed to localization, which includes locally-led development, local systems practice, and local capacity strengthening[64]. The SEP must include letters of support and commitment for those partners already identified as well as the process they intend to undertake following the award to continue to seek out these types of partners. USAID discourages exclusivity agreements between the Applicant and proposed partners.

It is possible that applicants will have three or more different kinds of partners including:

- Possible consortium members, if one or more U.S. universities or research entities come together to bid to provide overall leadership on global research and on capacity strengthening, potentially including the private sector and MSIs;

[64] https://www.usaid.gov/localization

- Sub-awardees (local and/or international) providing specific services necessary to project success; and
- Country or regional research institutions that will be in some sense the direct "beneficiaries" of the work of the prior two categories, and also the primary implementers of country and regional research under this activity.

The SEP may also set out how the Applicant will have deeper and fuller relationships with the country or regional partner policy research organizations with which it plans to partner.

Please note that a consortium approach is one possible approach to engagement, partnership, and subawards since any consortium would be led by a prime awardee to interface with USAID.

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SECTION B: FEDERAL AWARD INFORMATION

B.I. Estimate of Funds Available and Number of Awards Contemplated

USAID intends to award one (1) Leader with Associates (LWA) Award pursuant to this notice of funding opportunity. Subject to funding availability and at the discretion of the Agency, the Bureau for Resilience, Environment and Food Security (REFS) intends to provide $13 million in total USAID core funding over a five (5) year period. The ceiling for this program is up to $35 million. It is estimated that up to $2.6 million will be obligated to the Leader Award in the first year as core funding from REFS, and up to $2.6 million per year thereafter, for a total of up to $13 million in core funding from REFS. Actual funding amounts are subject to availability of funds.

Furthermore, pending demand and funds availability from USAID Missions and other Bureaus or OUs, USAID will allow up to an additional $22 million as a pool for potential Associate Awards and buy-ins during the life of the project to the holder of the Leader Award. The competition under this NOFO covers both the Leader Award and all subsequent Associate Awards and buy-ins. USAID reserves the right to fund any one or none of the applications submitted.

For the purposes of this NOFO, applicants must prepare a budget for the $13 million core funding from REFS.

B.II. Start Date and Period of Performance for Federal Awards

The anticipated period of performance is five (5) years. The estimated start date will be on or about September 2024. The estimated end date will be on or about September 2029.

B.III. Substantial Involvement

USAID intends to award one (1) cooperative agreement for the Leader Award. A cooperative agreement is distinguished from a grant by virtue of USAID having substantial involvement (beyond that which is permitted under a grant) in the implementation of the program.

B.III.a. Leader Award

USAID will be substantially involved in the implementation of the core program of this NOFO under the Leader Award described in Section A. The intended purpose of the Agreement Officer's Representative (AOR) involvement during the implementation of the program is to assist the recipient in achieving the supported objectives. These approvals must be made by the Agreement Officer except where explicitly delegated to the AOR.

Substantial involvement will include:

1. Approval of Specified Key Personnel (i.e. Veterinary Vaccine Delivery Innovation Lab Director and Associate Veterinary Vaccine Delivery Innovation Lab Director).

2. Approval of the Recipient's overall Activity MEL Plan, including impact pathway and theory of change documentation, performance evaluation, indicator selection, and annual indicator reporting. This will be delegated to the AOR.
3. Approval of the Recipient's Data Management Plan. This will be delegated to the AOR.
4. Approval of the Recipient's IEE modifications, PURSUAPs, and Environmental Mitigation & Monitoring Plan. This will be delegated to the AOR.
5. Approval of Annual Implementation Plans, work plans, budgets, and semi-annual and annual reports. The work-plan must include a travel matrix of proposed international trips. This will be delegated to the AOR.
6. Concurrence and approval of the recipients of sub-awards. This will be reviewed and coordinated with the AOR. However, the AO will have final approval for sub-awards.
7. Concurrence on the substantive provisions of sub-award RFAs and contracts for research and capacity development activities.
8. Collaborative involvement in selection of members for any advisory body or bodies for oversight, such as oversight of the program's research and capacity development portfolio, and membership on such body/bodies. This will be delegated to the AOR.
9. Review and approval of Program Descriptions and Budgets for proposed Associate Awards and Buy-Ins. This will be reviewed and coordinated with the AOR. However, the AO will have final approval by issuing amendments to the Award to incorporate buy-ins or issuing new Associate Awards.

B.III.b. Associate Awards

An Associate Award may be a grant or a cooperative agreement. If an Associate Award will be a cooperative agreement, specific substantial involvement provisions will be identified for that Associate Award.

B.IV. Authorized Geographic Code

The geographic code for the procurement of commodities and services under this program is 937 (the United States, the recipient country, and developing countries other than advanced developing countries, but excluding any country that is a prohibited source). Geographic Codes are described in 22 CFR 228.03 and the Internal Mandatory References to Chapter 310 of USAID's Automated Directives System (ADS 310) entitled "List of Developing Countries," "List of Advanced Developing Countries," and "List of Prohibited Source Countries."

B.V. Nature of the Relationship between USAID and the Recipient

The principal purpose of the relationship with the Recipient and under the subject program is to transfer funds to accomplish a public purpose of support or stimulation of the Feed the Future Innovation Lab for Veterinary Vaccine Delivery which is authorized by Federal statute. The successful Recipient will be responsible for ensuring the achievement of the program objectives and the efficient and effective administration of the award through the application of sound management practices. The Recipient will assume responsibility for administering Federal funds in a manner consistent with underlying agreements, program objectives, and the terms and conditions of the Federal award.

SECTION C: ELIGIBILITY INFORMATION

C.I. Eligible Applicants

Eligibility is restricted. The eligibility requirements below apply only to the principal Applicant.

This program is authorized under Title XII of the Foreign Assistance Act of 1961, as amended. Applications must only be submitted by eligible U.S. colleges and universities as defined under Section 296(d) of Title XII of the Foreign Assistance Act, as amended:

"... those colleges or universities in each State, territory, or possession of the United States, or the District of Columbia, now receiving, or which must hereafter receive, benefits under the Act of July 2, 1862 (known as the First Morrill Act) or the Act of August 30, 1890 (known as the Second Morrill Act), which are commonly known as 'land-grant' universities; institutions now designated or which must hereafter be designated as sea-grant colleges under the Act of October 5, 1966 (known as the National Sea Grant College and Program Act), which are commonly known as sea-grant colleges; Native American land-grant colleges as authorized under the Equity in Educational Land-Grant Status Act of 1994 (7 U.S.C. 301 note); and other United States colleges and universities which— (1) have demonstrable capacity in teaching, research, and extension (including outreach) activities in the agricultural sciences; and (2) can contribute effectively to the attainment of the objectives of this title."

The Title XII university-led FTF IL programs involve multiple partners, principal of which are U.S. universities, working in collaboration with scientists in developing country universities, national and international research centers, the private sector, and non-governmental organizations (NGOs), to jointly pursue scientific investigations to overcome critical agricultural constraints facing today's global food systems. All types of U.S. and non-U.S. entities are eligible as collaborating partners (i.e. sub-recipients or contractors at various tiers), provided that they are not excluded from U.S. Government acquisition and assistance awards (this may be verified through SAM.gov). In preparing the application, it is the Applicant's responsibility to ensure that no individuals or organizations proposed for participation in the program are excluded by the U.S. Government. After award, it is the Recipient's responsibility to ensure that no transactions are conducted with excluded parties. USAID encourages Applicants to include qualified Minority-Serving Institutions (MSIs) including, but not limited to, Historically Black Colleges and Universities, Predominantly Black Institutions, Hispanic-Serving Institutions, Tribal Colleges and Universities, and Asian American Native Alaskan and Pacific Islander Serving Institutions.

Collaborating partners may be contractors or sub-recipients, and Applicants must be aware of the distinction between procurement contracts (acquisition) and sub-awards (assistance). Contracts are subject to 2 CFR 200.318-326 and the USAID standard provision entitled "USAID Eligibility Rules for Goods and Services". Sub-awards are subject to 2 CFR 200, 2 CFR 700 and the USAID standard provision entitled "Applicability of 2 CFR 200 and 2 CFR 700." The recipient's and sub-recipients' contractors and subcontractors at all tiers must also meet USAID's supplier nationality requirements described in Section D.IV. below.

USAID welcomes applications from organizations that have not previously received financial assistance from USAID.

C.II. Cost Sharing or Matching

C.II.a. Leader Award

There is no mandatory level of cost-sharing (matching) for this program, but USAID nevertheless encourages cost sharing to the maximum practicable extent. A cost-share or match is that portion of project or program costs not borne by the U.S. Government. Cost sharing includes cash and in-kind contributions, and for U.S. organizations is subject to 2 CFR 200.306 and the USAID standard provision for U.S. NGOs entitled "Cost- Sharing (Matching)", which, among other things, requires that cost sharing be verifiable from the Recipient's records. Cost sharing or matching is normally associated with contributions from the same prime and sub-recipient sources that also receive USAID funds under an award but can include contributions from third parties. Failure to meet a cost-sharing requirement can result in the Recipient having to make refunds to USAID or a reduction in future funding. Cost sharing will not have an impact on evaluation.

C.II.b. Associate Awards

Cost sharing requirements, if any, will be established for each Associate Award by the USAID Mission or Office that finances the Associate Award.

C.III. Other

There is a limit of one application per eligible institution. If two eligible institutions propose to share leadership of the Veterinary Vaccine Delivery Innovation Lab, only one of the two institutions can submit an application. The Applicant must include a letter of support and commitment from the partner institution that will not count toward the Application page limit. USAID does not require and does not encourage exclusivity contracts between proposed key personnel and the applying institution. As such, the proposed key personnel may be listed on more than one application.

C.IV. Risk Assessment

In order for an award to be made, the USAID AO must evaluate the risks posed by Applicants as outlined in 2 CFR 200.205 and ADS 303.3.9. This means that the Applicant must possess, or must have the ability to obtain, the necessary management and technical competence to conduct the proposed program and must agree to practice mutually agreed-upon methods of accountability for funds and other assets provided or funded by USAID.

In evaluating the risks posed by Applicants, the Federal Awarding Agency uses a risk-based approach and must consider:

1. Financial stability;
2. Quality of management systems and ability to meet the management standards prescribed in this part;

3. History of performance. The Applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
4. Reports and findings from audits performed under Subpart F—Audit Requirements of this part or the reports and findings of any other available audits;
5. The Applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities; and
6. That Applicant is otherwise qualified to receive an award under applicable laws and regulations (i.e. Nondiscrimination, Lobbying, Debarment/Suspension, Terrorist Financing, etc.).

In the absence of a positive risk assessment, an award can ordinarily not be made. Awards to potential new partners may be significantly delayed if USAID must undertake necessary pre-award reviews of these organizations to make an adequate risk assessment. These organizations must take this into account and plan their implementation dates and activities accordingly.

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SECTION D: APPLICATION AND SUBMISSION INFORMATION

D.I. Agency Point of Contact

Name: J. Erin Baize
Title: Agreement Specialist
Email: jbaize@usaid.gov

D.II. Questions and Answers

Questions regarding this NOFO should be submitted in writing to the Agency Point of Contact at the email address above no later than the date and time indicated on the cover letter, as amended. Any information given to a prospective applicant concerning this NOFO will be furnished promptly to all other prospective applicants as an amendment to this NOFO, if that information is necessary in submitting applications or if the lack of it would be prejudicial to any other prospective applicant. In order to maintain the integrity of the competitive process, USAID staff, to include Mission staff, will be unable to advise or provide information to potential Applicants that would be used in preparation of the application. Therefore, Applicants are advised not to contact USAID Missions or any other USAID staff members regarding this NOFO. Information on Mission strategies and programs can be accessed from http://feedthefuture.gov/ and Mission websites (http://www.usaid.gov/where-we-work).

D.III. Amendments to the NOFO

If this NOFO is amended, all terms and conditions that are not amended remain unchanged. The AO will do their best to alert Applicants that have already submitted applications that an amendment to the NOFO has been published; however, it is ultimately the responsibility of the Applicants to be aware of published amendments to the NOFO through Grants.gov.

D.IV. General Content and Form of Application

D.IV.a. Preparation of Applications

Each applicant submitting a Full Application must furnish the information required by this NOFO. Applications must be submitted in two separate parts: the Technical Application and the Business (Cost) Application. This subsection addresses general content requirements applying to the full application. Please see subsections 5 and 6, below, for information on the content specific to the Technical and Business (Cost) applications. The Technical application must address technical aspects only while the Business (Cost) Application must present the costs, and address risk and other related issues.

Both the Technical and Business (Cost) Applications must include a cover page containing the following information:

- Name of the organization(s) submitting the application;

- Identification and signature of the primary contact person (by name, title, organization, mailing address, telephone number and email address) and the identification of the alternate contact person (by name, title, organization, mailing address, telephone number and email address);
- Program name;
- Notice of Funding Opportunity number;
- Name of any proposed sub-recipients or partnerships (identify if any of the organizations are local organizations, per USAID's definition of 'local entity' under ADS 303; and
- A Unique Entity Identifier (UEI) number shall be included for each organization listed on the cover page.

Any erasures or other changes to the application must be initialed by the person signing the application. Applications signed by an agent on behalf of the applicant must be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

Applications must comply with the following:

- USAID will not review any pages in excess of the page limits noted in the subsequent sections. Please ensure that applications comply with the page limitations.
- Applications must be written in English.
- Use standard 8 ½" x 11", single sided, single-spaced, 12 point Times New Roman font, 1" margins, left justification and headers and/or footers on each page including consecutive page numbers, date of submission, and applicant's name.
- 10 point font can be used for graphs and charts. Tables however, must comply with the 12 point Times New Roman requirement.
- Applications must be submitted via Microsoft Word or PDF formats, except budget files which must be submitted in Microsoft Excel.
- The estimated start date identified in Section B of this NOFO must be used in the cost application.
- The technical application must be a searchable and editable Word or PDF format as appropriate.
- The Cost Schedule must include an Excel spreadsheet with all cells unlocked and no hidden formulas or sheets. A PDF version of the Excel spreadsheet may be submitted in addition to the Excel version at the applicant's discretion, however, the official cost application submission is the unlocked Excel version.

Applicants must review, understand, and comply with all aspects of this NOFO. Failure to do so may be considered as being non-responsive and may be evaluated accordingly. Applicants should retain a copy of the application and all enclosures for their records.

D.IV.b. Application Submission Procedures

It is the Applicant's responsibility to ensure that all necessary documentation is complete and received on time no later than the closing date and time indicated on the cover letter, as amended.

Late applications may be considered at the discretion of the Agreement Officer. Applicants must retain proof of timely delivery in the form of a system generated document (i.e. delivery receipt). Applications **must** be submitted by email to jbaize@usaid.gov. Applications **must not** be submitted through www.grants.gov. USAID cannot accept emails over 25MB in size. If Application attachments are in excess of that size, then the Applicant must submit over multiple emails. For an application sent by multiple emails, please indicate in the subject line of the email whether the email relates to the 1) technical application or 2) cost/business application. For example, if your cost application is being sent in two emails, the first email should have the subject line which says: "[organization name], Cost/Business Application, Part 1 of 2".

USAID's preference is that the Technical Application and the Business (Cost) Application be submitted as single email attachments, e.g., that the Applicant consolidates the various parts of a Technical Application into a single document before sending. If this is not possible, please provide instructions on how to collate the attachments. USAID will not be responsible for errors in compiling electronic applications if instructions are not provided or are unclear. All applications received by the submission deadline will be reviewed for responsiveness to the NOFO and the application format. No additions or modifications will be accepted after the submission date.

After submitting applications electronically, the Applicant should immediately check for email confirmation that the attachments sent were indeed sent. If there is an error in transmission, please send the material again and note in the subject line of the email that it is a "corrected" submission. Do not send the same email more than once unless there has been a change, and if so, please note that it is a "corrected" email.

D.IV.c. Technical Application Format

The Technical Application should be specific, complete, and concise. The application must demonstrate the Applicant's capabilities and expertise with respect to achieving the goals of this program. The application should take into account the requirements of the program and merit review criteria found in this NOFO.

The Technical Application must not exceed 30 pages, excluding table of contents, attachments, and annexes. Only information specifically requested to be included as an annex will be considered during review for technical merit. Unless otherwise indicated, a page in the Technical Application that contains a table, chart, graph, etc. will be counted as a page within the page limitation. Information that exceeds page limitations will not be furnished to the USAID Merit Review Committee.

All material and information necessary to support the application must be submitted within or annexed to the application. Hyperlinks and references to websites will not be considered part of the submission. Applicants must only reference information on the internet that is of general background knowledge, publicly available, and considered a reliable source of research information; USAID does not guarantee that reviewers on the Merit Review Committee will review such information.

All information that the Applicant thinks is necessary for a reviewer to accurately understand the proposal must be submitted with the application and submitted through the appropriate process as

directed in Section E. In addition, the Technical Application must be divided into sections corresponding to, and following the order of, the evaluation criteria set forth in Section E of this NOFO and as described below. Each section of the Technical Application must be clearly identified, using the title of the appropriate merit review criterion and divided by sub-criteria. This requirement is not intended to prohibit or discourage applicants from submitting technical data in addition to what is required herein and by the evaluation criteria.

1. Cover Page (See Section E.I.a. above for requirements)
2. Table of Contents that follows the Technical Application format outlined herein.
3. Executive Summary (one page) must provide a high-level overview of key elements of the Technical Application.
4. Technical Application that follows the outline below:
    a. **Background and Context** which includes a discussion of the following:
        i. How cold chain independent and appropriately packaged veterinary vaccine research outputs contribute to the objectives of the GFSS;
        ii. The role that the proposed research, commercialization and capacity strengthening activities have in supporting food security and One Health at the global, regional and national levels.
    b. **Technical Approach**
        i. This section will describe the applicant's proposed Technical Approach to implement a successful, high-quality research, commercialization, and capacity strengthening program. The application must address the overall strategy, proposed approaches and planning processes, development goals and objectives including the use of the product life-cycle approach and multidisciplinary research
            1. Vaccine Development - Approach to developing vaccines that are cold chain independent and appropriately packaged including the selection of candidate vaccines
            2. REFS's Product Life Cycle Framework - Approach to a) develop target product profiles (TPPs) drawing on market segmentation research, b) show product life cycle (PLC) stages from initial stage of research to commercialization, adoption and eventual phase out, and c) specify stage gate criteria in advancing innovations from one stage to the next in the PLC.
            3. Integrative Research - Approach to integrating socioeconomic research that complements vaccine development to inform business models and improve understanding of development related impacts
            4. Agricultural Innovation Systems Approach (including Private Sector Engagement and Local Capacity Strengthening) - This should include a plan for a) strengthening critical capacities and relationships among veterinary research, academic, pharmaceutical, regulatory, and service provider organizations, using market-based approaches and target product profiles (see A.III.b.3.), and b) engaging private and public sector actors, and end users throughout the program to strengthen relevance, commercialization, adoption, scaling as well as sustainable and equitable benefits. c) Applicants are highly encouraged to include

private sector partners in their applications. Applicants must discuss how linkages with the private sector will facilitate research and development and must include a plan for ensuring that these linkages do not solely remain on paper. Applicants must discuss what strengths in the private sector will be sought after and leveraged and what strengths the IL will contribute.

ii. *Approach to ensure relevance of the program portfolio* - This includes linkages with other donors, research institutions, producer representatives and the private sector to ensure the relevance of the activity to USAID and global priorities.

1. Global Engagement of the Veterinary Vaccine Delivery Innovation Lab (VVDIL) Director - This should discuss the extent to which the qualifications of the proposed Innovation Lab Director, or its designate, meet the requirements of the position described in Section A.IV.d.1 and the Applicant's proposed approach to engage global donors, research organizations, and the private sector (e.g. international and national research centers, research oversight and coordination bodies, regulatory bodies, and industry groups).
2. Incorporation of Cross-Cutting Issues - This should discuss the Applicant's approach to integrating meaningful attention to climate change, natural resource management, gender, youth and social inclusion into the research program.
3. Geographic Focus - This should outline how target countries will be selected and justified as well as plans to engage USAID Missions and implementing partners.

c. **Management Approach**

i. *Results Framework and Theory of Change* - This section must include a theory of change and results framework with impact pathways that acknowledge what is and is not within the spheres of control and influence of the Veterinary Vaccine Delivery Innovation Lab as well as critical assumptions.

ii. *Appropriate Partnerships and Sub-awardee Engagement Plan (SEP)* - The SEP, as described in Section A.IV.d.5, should address steps, procedures, and approaches to identify and partner with a diverse range of institutions, with attention to the Title XII interest, including MSIs, civil society, the private sector and local partners as described in Section A.IV.c.2.a. Selection approaches for both competitively selected and commissioned activities should be described and include a description of the process to identify quality partners.

iii. *Approach to Ensure Accountability* - This section should outline how the Applicant will provide program accountability and financial oversight.

1. Staffing Plan - This should include the qualifications and capabilities of proposed Key Personnel. An organizational chart is required as part of the main body of the application. Applicants must discuss the various types of financial oversight as part of the duties of the appropriate staff member(s) and the composition and responsibilities of the External Advisory Committee.

2. Monitoring, Evaluation and Learning - This should outline plans for program monitoring and evaluation, knowledge sharing and learning, communications and outreach, and integrating a CLA approach.
3. Management of Associate Awards - This should discuss how the Applicant will be able to accommodate additional funding through Associate Awards and include a plan for expansion of the Veterinary Vaccine Delivery Innovation Lab to adequately monitor and manage such potential new activities.

iv. *Plan for Sustainability Beyond the Life of Project and Potential for Impact* - This includes approaches and considerations that will be addressed to ensure sustainable outcomes including the hand off of technologies and technical know-how to local public and private sector organizations that have the capacity and motivation to carry on the work and scale the innovations generated by the program.

(i) General Instructions for the Technical Application

It is anticipated that the successful application (as may be revised) will become the Program Description for the award resulting from this NOFO. Thus, applications submitted in response to this NOFO must, in addition to being responsive hereto, be written in the active voice and in results-oriented terms in order to address what is proposed to be done, why it is proposed to be done, how it is proposed to be done, who will do it, where it will be done, when it will be done, and the anticipated results and impact.

The Program Description set forth in Section A.IV. of this NOFO describes a range of issues that must be addressed in technical applications which includes both the Applicant's Management Approach and Technical Approach to the Veterinary Vaccine Delivery Innovation Lab. It is not meant to describe how those issues must be addressed because USAID seeks the expertise of the Applicant, who must describe in their technical applications how they propose to address such issues. In addition, the Program Description should not be interpreted as restrictive. Applicants are encouraged to raise and justify other technical issues that may not appear in the Program Description but are, nevertheless, related. As FTF ILs are mandated to benefit both host countries and U.S. agriculture, applicants are urged to link potential benefits to U.S. agriculture with any proposed research activities and Areas of Inquiry.

The Technical Application must have a definitive strategy and plan, and must set forth in detail the Applicant's approach, methodology, procedures, and techniques for design, management, implementation, and monitoring of the proposed program. The application must also demonstrate the Applicant's capabilities and expertise to successfully implement, manage, and monitor the proposed program. The application must define technical resources, capabilities, and expertise of the applicant's organization and other institution(s) involved, and of the professional personnel proposed. The information presenting capabilities of the implementing organization(s) and of individuals to be assigned must spell-out clearly the pertinent work experience and accomplishments in developing and conducting activities of the type being proposed, as well as the specialized skills, professional competence, academic training, and relevant achievements of the personnel. It is important that the Technical Application furnish verifiable, objective supporting evidence of successful program

management, implementation, and monitoring. The Technical Application must be specific, detailed, and include appropriate benchmarks or milestones.

(ii) Business (Cost) Application Format

The Business (Cost) Application must be submitted separately from the Technical Application. While no page limit exists for the full cost application, applicants are encouraged to be as concise as possible while still providing necessary details. The business (cost) application must illustrate the entire period of performance, using the budget format shown in the SF-424A.

Prior to award, applicants may be required to submit additional documentation deemed necessary for the Agreement Officer to assess the applicant's risk in accordance with 2 CFR 200.206. Applicants should not submit any additional information with their initial application.

The Cost Application must contain the following sections (which are further elaborated below this listing with the letters for each requirement):

1. Cover Page (See Section E.I.a. above for requirements)
2. SF 424 Form(s) The Applicant must sign and submit the cost application using the SF-424 series Standard Forms (SF) listed below. They can be accessed electronically through https://www.grants.gov/web/grants/forms/sf-424-family.html.

    - Instructions and Application for Federal Assistance (SF-424)
    - Instructions and Budget Information for Non-Construction Programs (SF-424A)
    - Instructions and Assurances for Non-Construction Programs (SF-424B)

Failure to accurately complete these forms could result in the rejection of the application.

D.IV.d. Required Certifications and Assurances

The applicant must complete the following documents and submit a signed copy with their application:

a) "Certifications, Assurances, Representations, and Other Statements of the Recipient" document found at https://www.usaid.gov/about-us/agency-policy/series-300/references-chapter/303mav
b) Assurances for Non-Construction Programs (SF-424B)
c) Certificate of Compliance: Please submit a copy of your Certificate of Compliance if your organization's systems have been certified by USAID/Washington's Office of Acquisition and Assistance (M/OAA)

D.IV.e. Budget and Budget Narrative

The Budget must be submitted as one unprotected Excel file (MS Office 2000 or later versions) with visible formulas and references and must be broken out by project year, including itemization of the federal and non-federal (cost share) amount. Files must not contain any hidden or otherwise

inaccessible cells. Budgets with hidden cells lengthen the cost analysis time required to make an award and may result in a rejection of the cost application. The Budget Narrative must contain sufficient detail to allow USAID to understand proposed costs. The Applicant must ensure budgeted costs address any additional requirements identified in Section F, such as Branding and Marking. The Budget Narrative must be thorough, including sources for costs to support USAID's determination that proposed costs are fair and reasonable.

The Budget must include the following worksheets or tabs, and contents, at a minimum:

- Summary Budget, inclusive of all program costs (federal and non-federal), broken out by major budget category and by year for activities implemented by the applicant and any potential sub-applicants for the entire period of the program.
- Detailed Budget, including a breakdown by year, sufficient to allow the Agency to determine that the costs represent a realistic and efficient use of funding to implement the applicant's program and are allowable in accordance with the cost principles found in 2 CFR 200 Subpart E.
- Detailed Budgets for each sub-recipient, for all federal funding and cost share, broken out by budget category and by year, for the entire implementation period of the project.

The Detailed Budget must contain the following budget categories and information, at a minimum:

1. **Salaries and Allowances** – Must be proposed consistent with 2 CFR 200.430 Compensation - Personal Services. The applicant's budget must include position title, salary rate, level of effort, and salary escalation factors for each position. Allowances, when proposed, must be broken down by specific type and by position. Applicants must explain all assumptions in the Budget Narrative. The Budget Narrative must demonstrate that the proposed compensation is reasonable for the services rendered and consistent with what is paid for similar work in other activities of the applicant. Applicants must provide their established written policies on personnel compensation. If the Applicant's written policies do not address a specific element of compensation that is being proposed, the Budget Narrative must describe the rationale used and supporting market research.
2. **Fringe Benefits** – (if applicable) If the Applicant has a fringe benefit rate approved by an agency of the U.S. Government, the Applicant must use such rate and provide evidence of its approval. If an Applicant does not have a fringe benefit rate approved, the Applicant must propose a rate and explain how the Applicant determined the rate. In this case, the Budget Narrative must include a detailed breakdown comprised of all items of fringe benefits (e.g., superannuation, gratuity, etc.) and the costs of each, expressed in U.S. dollars and as a percentage of salaries.
3. **Travel and Transportation** – Provide details to explain the purpose of the trips, the number of trips, the origin and destination, the number of individuals traveling, and the duration of the trips. Per Diem and associated travel costs must be based on the applicant's normal travel policies. When appropriate please provide supporting documentation as an attachment, such as company travel policy, and explain assumptions in the Budget Narrative.
4. **Procurement or Rental of Goods (Equipment & Supplies), Services, and Real Property** – Must include information on estimated types of equipment, models, supplies and the cost per unit and quantity. The Budget Narrative must include the purpose of the equipment and

supplies and the basis for the estimates. The Budget Narrative must support the necessity of any rental costs and reasonableness in light of such factors as: rental costs of comparable property, if any; market conditions in the area; alternatives available; and the type, life expectancy, condition, and value of the property leased.

5. **Subawards** – Specify the budget for the portion of the program to be passed through to any subrecipients. See 2 CFR 200.331 for assistance in determining whether the sub-tier entity is a subrecipient or contractor. The subrecipient budgets must align with the same requirements as the applicant's budget, including those related to fringe and indirect costs.
6. **Other Direct Costs** – This may include other costs not elsewhere specified, such as report preparation costs, passports and visas fees, medical exams and inoculations, as well as any other miscellaneous costs which directly benefit the program proposed by the applicant. The Applicant should indicate the subject, venue and duration of any proposed conferences and seminars, and their relationship to the objectives of the program, along with estimates of costs. Otherwise, the narrative should be minimal.
7. **Indirect Costs** – Applicants must indicate whether they are proposing indirect costs or will charge all costs directly. In order to better understand indirect costs please see Subpart E of 2 CFR 200.414. The application must identify which approach they are requesting and provide the applicable supporting information. Below are the most commonly used Indirect Cost Rate methods:

   Method 1 - Direct Charge Only
   Eligibility: Any Applicant. Initial Application Requirements: See above on direct costs.

   Method 2 - Negotiated Indirect Cost Rate Agreement (NICRA)
   Eligibility: Any Applicant with a NICRA issued by a USG Agency must use that NICRA. Initial Application Requirements: If the Applicant has a current NICRA, submit your approved NICRA and the associated disclosed practices. If your NICRA was issued by an Agency other than USAID, provide the contact information for the approving Agency. Additionally, at the Agency's discretion, a provisional rate may be set forth in the award subject to audit and finalization. See USAID's Indirect Cost Rate Guide for Non Profit Organizations for further guidance.

   Method 3 - De minimis rate of 10% of modified total direct costs (MTDC)
   Eligibility: Any Applicant that has never received a NICRA. Initial Application Requirements: Costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate an indirect rate, which the non-Federal entity may apply to do at any time. The Applicant must describe which cost elements it charges indirectly vs. directly. See 2 CFR 200.414(f) for further information.

   Method 4 - Indirect Costs Charged As A Fixed Amount
   Eligibility: Non U.S. non-profit organizations without a NICRA may request, but approval is at the discretion of the AO.

Initial Application Requirements: Provide the proposed fixed amount and a worksheet that includes the following:

- Total costs incurred by the organization for the previous fiscal year and estimates for the current year.
- Indirect costs (common costs that benefit the day-to-day operations of the organization, including categories such as salaries and expenses of executive officers, personnel administration, and accounting, or that benefit and are identifiable to more than one program or activity, such as depreciation, rental costs, operations and maintenance of facilities, and telephone expenses) for the previous fiscal year and estimates for the current year.
- Proposed method for prorating the indirect costs equitably and consistently across all programs and activities of using a base that measures the benefits of that particular cost to each program or activity to which the cost applies.

If the Applicant does not have an approved NICRA and does not elect to utilize the 10% de minimis rate, the Agreement Officer will provide further instructions and may request additional supporting information, including financial statements and audits, should the application still be under consideration after the merit review. USAID is under no obligation to approve the Applicant's requested method.

8. **Prior Approvals in accordance with 2 CFR 200.407 -** Inclusion of an item of cost in the detailed application budget does not satisfy any requirements for prior approval by the Agency. If the Applicant would like the award to reflect approval of any cost elements for which prior written approval is specifically required for allowability, the Applicant must specify and justify that cost. See 2 CFR 200.407 for information regarding which cost elements require prior written approval.

9. **Approval of Subawards** - The Applicant must submit information for all subawards that it wishes to have approved at the time of award. For each proposed subaward, the Applicant must provide the following:

    - Name of organization,
    - Unique Entity Identifier (UEI) Number,
    - Confirmation that the subrecipient does not appear on the Treasury Department's Office of Foreign Assets Control (OFAC) list,
    - Confirmation that the subrecipient does not have active exclusions in the System for Award Management (SAM),
    - Confirmation that the subrecipient is not listed in the United Nations Security designation list,
    - Confirmation that the subrecipient is not suspended or debarred,
    - Confirmation that the Applicant has completed a risk assessment of the subrecipient, in accordance with 2 CFR 200.332, and
    - Any negative findings as a result of the risk assessment and the applicant's plan for mitigation.

D.IV.f. Unique Entity Identifier (UEI) Number and SAM Requirements

USAID may not award to an applicant unless the applicant has complied with all applicable unique entity identifier (UEI number) and System for Award Management (SAM) requirements. Each applicant (unless the applicant is an individual or Federal awarding agency that is exempted from requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)) is required to:

1. Provide a valid Unique Entity Identifier (UEI) number for the applicant and all proposed sub-recipients;
2. Be registered in SAM before submitting its application. SAM is streamlining processes, eliminating the need to enter the same data multiple times, and consolidating hosting to make the process of doing business with the government more efficient (www.sam.gov).
3. Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency.

The registration process may take many weeks to complete. Therefore, applicants are encouraged to begin the process early. If an applicant has not fully complied with the requirements above by the time USAID is ready to make an award, USAID may determine that the applicant is not qualified to receive an award and use that determination as a basis for making an award to another applicant.

UEI Number & SAM registration: http://www.sam.gov

Non-U.S. applicants can find additional resources for registering in SAM, including a Quick Start Guide and a video on how to obtain an NCAGE code, on www.sam.gov, navigate to Help, then to International Registrants.

D.IV.g. History of Performance and Evidence of Positive Risk Assessment

The Applicant must provide information in order to permit the Agreement Officer to make a risk assessment. Specifically, the Applicant must provide statements and evidence in support of the categories outlined in Section C.IV.

Additionally, the Applicant must provide information regarding its recent history of performance for all its cost-reimbursement contracts, grants, or cooperative agreements involving similar or related programs, not to exceed five projects as follows:

- Name of the awarding organization;
- Award number;
- Activity title;
- A brief description of the activity;
- Period of performance;
- Award amount;
- Reports and findings from any audits performed in the last three years; and

- Name of at least two (2) updated professional contacts who most directly observed the work at the organization for which the service was performed with complete current contact information including telephone number, and e-mail address for each proposed individual.

If the Applicant encountered problems on any of the referenced Awards, they may provide a short explanation and the corrective action taken. The Applicant should not provide general information on its performance. USAID reserves the right to obtain relevant information concerning an Applicant's history of performance from any sources and may consider such information in its review of the applicant's risk. The Agency may request additional information and conduct a pre-award survey if it determines that it is necessary to inform the risk assessment.

D.IV.h. Branding Strategy and Marking Plan

The applicant is required to comply (and ensure compliance by partners) with USAID's branding and marking requirements set forth in 2 CFR 700.16 with Feed the Future specific guidance located at https://www.feedthefuture.gov/branding/.

D.IV.i. Funding Restrictions

USAID policy is not to award profit under assistance instruments. In accordance with 2 CFR 200.400(g) and 2 CFR 700.13, no funds under the award resulting from this NOFO will be paid as profit to any recipient or sub recipient. Profit is any amount in excess of allowable direct and indirect costs. This does not preclude payment of profit to the recipient's or sub-recipients' vendors (contractors) under procurement contracts and subcontracts for the acquisition of goods and services, which are subject to 2 CFR 200 and 2 CFR 700, as well as the USAID standard provision entitled "USAID Eligibility Rules for Goods and Services." Also see http://www.usaid.gov/ads/policy/300/303sai.

However, all reasonable, allocable and allowable expenses, both direct and indirect, which are related to the agreement program and are in accordance with applicable cost principle under 2 CFR 200 Subpart E of the Uniform Administrative Requirements must be paid under the anticipated award. Construction is not authorized under this award.

USAID will not allow the reimbursement of pre-award costs under this award without the explicit written approval of the Agreement Officer.

At the time of award and throughout implementation, funding restrictions may be placed on particular types of work and/or in particular geographies.

Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in Section B.IV. of this NOFO and must meet the source and nationality requirements set forth in 22 CFR 228.

D.IV.j. Conflict of Interest Pre-Award Term

Personal Conflict of Interest

An actual or appearance of a conflict of interest exists when an applicant organization or an employee of the organization has a relationship with an Agency official involved in the competitive award decision-making process that could affect that Agency official's impartiality. The term "conflict of interest" includes situations in which financial or other personal considerations may compromise, or have the appearance of compromising, the obligations and duties of a USAID employee or recipient employee.

The applicant must provide conflict of interest disclosures when it submits an SF-424. Should the applicant discover a previously undisclosed conflict of interest after submitting the application, the applicant must disclose the conflict of interest to the AO no later than ten (10) calendar days following discovery.

Organizational Conflict of Interest

The applicant must notify USAID of any actual or potential conflict of interest that they are aware of that may provide the applicant with an unfair competitive advantage in competing for this financial assistance award. Examples of an unfair competitive advantage include but are not limited to situations in which an applicant or the applicant's employee gained access to non-public information regarding a federal assistance funding opportunity, or an applicant or applicant's employee was substantially involved in the preparation of a federal assistance funding opportunity. USAID will promptly take appropriate action upon receiving any such notification from the applicant.

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SECTION E: APPLICATION REVIEW INFORMATION

E.I. Review and Selection Process

E.I.a. Merit Review

Applications will be evaluated in accordance with the criteria set forth in Section E.II. After evaluation of the full applications, either: (1) award(s) will be made without negotiations; or (2) if deemed necessary or desirable by USAID, co-creation through written and/or verbal negotiations will be conducted with applicants that submit the most highly rated applications. Applicants invited to co-creation will be evaluated based on the evaluation criteria stated in section E.II, with all weights established for each factor and sub-elements remaining unchanged. USAID hopes to evaluate full applications and award a grant(s) or cooperative agreement(s) without negotiations with applicants. Therefore, the Applicant's initial application should contain the Applicant's best terms. After the conclusion of any such negotiations, Applicants with whom negotiations were conducted will, unless otherwise advised, be required to submit a revised application or addendum to the initial application, which will be re-evaluated against the criteria set forth in Section E.II. It is expected that award will ordinarily be made after the first round of any such discussions and revised applications/addenda; however, USAID reserves the right to conduct subsequent rounds of discussions and revised applications/addenda, and to further limit the number of Applicants with which such subsequent discussions would be conducted and from which a subsequent round of revised applications/addenda would be requested.

USAID intends to award a cooperative agreement(s) resulting from this NOFO to the responsible Applicant whose application, application modification(s), and/or revised application(s)/addendum(s) represents the greatest value to USAID based on the evaluation of applications in accordance with the evaluation criteria set forth in Section E.II.

The AO will make the final decision as to which institution(s), if any, will be awarded a cooperative agreement based on the determination of the Selection Committee, the cost/management evaluation, and whether the applying institutions are eligible to receive the award.

E.I.b. Business/Cost Review

The Agency will evaluate the cost application of the applicant(s) under consideration for an award as a result of the merit criteria review to determine whether the costs are allowable in accordance with the cost principles found in 2 CFR 200 Subpart E.

The Agency will also consider (1) the extent of the applicant's understanding of the financial aspects of the program and the applicant's ability to perform the activities within the amount requested; (2) whether the applicant's plans will achieve the program objectives with reasonable economy and efficiency; and (3) whether any special conditions relating to costs should be included in the award. Proposed cost share, if provided, will be reviewed for compliance with the standards set forth in 2 CFR 200.306, 2 CFR 700.10, and the Standard Provision "Cost Sharing (Matching)" for U.S. entities, or the Standard Provision "Cost Share" for non-U.S. entities.

The AO will perform a risk assessment (2 CFR 200.206). The AO may determine that a pre-award survey is required to inform the risk assessment in determining whether the prospective recipient has the necessary organizational, experience, accounting and operational controls, financial resources, and technical skills – or ability to obtain them – in order to achieve the objectives of the program and comply with the terms and conditions of the award. Depending on the result of the risk assessment, the AO will decide to execute the award, not execute the award, or award with "specific conditions" (2 CFR 200.207).

E.II. Review Criteria

USAID will conduct a merit review of all submissions received that comply with the instructions of this NOFO. Submissions will be reviewed and evaluated in accordance with the following criteria. The technical evaluation criteria have been tailored to the requirements of this particular NOFO. Applicants must note that these criteria serve to: (a) identify the significant matters which applicants must address in their submissions (also see Section A.III and Section A.IV above); and (b) set the standard against which all submissions will be evaluated. For purposes of weighting, the below factors are by order of importance.

E.II.a. Evaluation Factor Descriptions

The Applicant's Technical Application will be evaluated on the effectiveness of addressing the following Factors, as described below.

Factor 1: Technical Approach - The extent to which the Applicant's technical approach demonstrates a clear understanding of the objectives of the Program Description and a convincing, feasible, and technically sound approach to achieve them including the goals and problems to be addressed. The Applicant should ensure that any proposed highly technical approaches are clearly explained with appropriate background information and citations. The Applicant should also discuss current assumptions including the potential technical challenges and realistic timeframes to meet stated results based on previous and related work to the proposed approach. The Application should articulate how they will use a Product Life Cycle (PLC) approach to guide the progression of the research activities to ensure the generation of quality, appropriate, and demanded vaccine innovations including a stage-gate process with an appropriate level of stakeholder involvement. The Applicant should also articulate their approach to integrative research that consists of a complementary set of both biophysical and socioeconomic work to develop innovation packages that are prime for adoption in the target context(s). The information provided must be specific, complete, and presented concisely.

Factor 2: Program Management Approach - The extent to which the Applicant clearly describes the organizational structure of the activity including appropriate partnerships with the public and private sector (e.g. vaccine manufacturers, local public sector research institutions, non-governmental organizations, and international research organizations) as well as a clear articulation of their roles and responsibilities including why the proposed partners are best placed to achieve the proposed objectives. The extent to which the Sub-awardee Engagement Plan demonstrates sufficient steps, procedures, and approaches to successfully identify and partner with a diverse range of institutions across the life of the project. Successful plans will indicate meaningful outreach to the non-traditional

partner community. The Applicant should also demonstrate the capacity to manage buy-ins and Associate Awards. For any country where activities are proposed to take place, the Applicant should demonstrate evidence of having researched the respective bilateral Mission's programming to make appropriate linkages.

Factor 3: Approach to Ensure Accountability - The extent to which the Applicant demonstrates sufficient management capacity to comply with USAID policies, regulations, and requirements. Proposes key and other personnel who possess outstanding knowledge, skills, and experience relevant to the proposed activity as well as a clear articulation of their roles, responsibilities, and the reasons why they are best placed to carry out the proposed approaches. The extent to which the Applicant lays out a rational Theory of Change and associated approaches to monitoring, evaluation and learning (MEL), knowledge management, and stakeholder communications that will contribute to the successful achievement of objectives including how they will integrate the principles of collaborating, learning and adapting (CLA). Graphical illustrations of the Theory of Change are preferred to further explain the proposed approach, expected outputs, outcomes and impacts as well as provide additional context for the key indicators that will be used to monitor progress.

Factor 4: Local Capacity Strengthening, Inclusive Development and Relevance to other Key USAID Strategies and Priorities - The extent to which the Applicant's local capacity strengthening plan clearly articulates an approach aligned with the values of USAID's Localization agenda, ensures sustainable outcomes, and complements the proposed technical and program management approaches. The extent to which the proposal demonstrates an evidence-based plan and partner capacity for ensuring gender and social inclusion integration in programming, and fostering female and youth empowerment. The proposed plan should ideally utilize an inclusive development analysis, seek to integrate gender, youth, and other marginalized group considerations into all facets of the program including research, capacity strengthening, and program management, and demonstrate sufficient gender expertise to identify and address gender issues. The extent to which the Applicant describes how they will ensure relevance to key USAID strategies and priorities.

Factor 5: Plan for Sustainability Beyond the Life of Project and Potential for Impact - The extent to which the proposed program has plans for sustainability and handing over of technologies and technical know-how to local private or public sector entities capable of achieving Feed the Future goals and to track progress of such adoption. The extent to which the proposed program increases the impact, reach, efficiency and effectiveness of USAID's development assistance investments by mobilizing significant new resources, ideas, technologies and/or partners to address critical food security challenges. The Applicant should discuss potential challenges and the viability of the proposed implementation timeline for the research activities, deliverables and objectives based on previous experience or similar work in that field. The application should be concise, clearly and professionally written, and contain appropriate logical linkages throughout including the benefits and rationale of the proposed approaches.

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SECTION F: FEDERAL AWARD ADMINISTRATION INFORMATION

F.I. Federal Award Notices

The Leader Award is anticipated to be made on or by September 2024.

Award of the agreement contemplated by this NOFO cannot be made until funds have been appropriated, allocated and committed through internal USAID procedures. While USAID anticipates that these procedures will be successfully completed, potential applicants are hereby notified of these requirements and conditions for the award. The AO is the only individual who may legally commit the U.S. Government to the expenditure of public funds. No costs chargeable to the proposed Agreement may be incurred before receipt of either a fully executed Agreement or a specific, written authorization from the AO.

Although an earlier notification may be provided to Applicants regarding their recommended selection for an award, only an award signed by the USAID AO will constitute the USAID commitment of the selection of the Applicant. USAID may, at its sole discretion, provide the award to the Successful Applicant's designated point of contact in hardcopy originals, by fax, or electronically. The signed award will authorize the selected Applicant to begin implementation of the activities described in their Technical Applications or revised Technical Applications/Addenda and will obligate funds for payment to the recipient of the award for costs incurred in such implementation. The AO may authorize the selected Applicant(s), at its sole risk, to begin implementation and the incurrence of costs prior to a signed award as of a specified date, with no commitment to reimburse costs in the event that the award is not subsequently signed.

Unsuccessful Applicants will be notified of their non-selection after the award has been made. Within 10 working days after an Applicant receives notice that USAID will not fund its application, the unsuccessful Applicant may send a written request for additional information to the AO. This information may be provided at the discretion of the AO orally or in writing. To the maximum extent practicable, the AO will respond to the request within 30 days or inform the Applicant that more time is necessary. If a response is granted, it will be limited to the Agency’s interest in supporting the Applicant’s program as described in the application without comparison of one Applicant to another. Only additional information that would be useful to the Applicant in future application preparation must be provided.

F.II. Administrative and National Policy Requirements

The resulting award from this NOFO will be administered in accordance with the following policies and regulations.

For US organizations: ADS 303, 2 CFR 700, 2 CFR 200, and Standard Provisions for U.S. Non-governmental organizations.

For Non US organizations: Standard Provisions for Non-U.S. Non-governmental Organizations. See Annex 1, for a list of the Standard Provisions that will be applicable to any awards resulting from this NOFO.

F.III. Reporting Requirements

F.III.a. Financial Reporting

Financial reporting requirements will depend on the method of payment. In accordance with 2 CFR 700, advance payments will be provided if the recipient meets the standards for financial management systems in 2 CFR 700. Recipients will comply with the financial reporting requirements set forth in 2 CFR 200 and 2 CFR 700. If advance payments are provided, reporting periods are calendar quarters or parts thereof. Quarterly financial reports are due not later than 30 days after the end of each calendar quarter. The final financial report is due not later than 90 days after the estimated completion date of the award. If payment is on a reimbursement basis, financial reports may be submitted monthly, but not less frequently than 30 days after the end of each calendar quarter. The final financial report is due not later than 90 days after the estimated completion date of the award. The Recipient shall also comply with the USAID standard provision entitled "Reporting Host Government Taxes." For more information, please see ADS 303.

The Recipient must submit to the AOR an estimate of quarterly accruals at least 2 weeks prior to the end of each financial quarter. The Recipient must submit a completed Standard Form SF-425 to the AOR no later than 30 days after the end of each financial quarter.

In the additional comments section of the SF-425, the Recipient must include the total funds to date distributed to non-US institutions, including to private contractors in foreign countries, by country. This will allow the AOR to inform any requests on funding provided to beneficiary countries. These amounts should not include funds used for temporary travel of US-based staff to foreign countries. Often, U.S. Government funding has different restricted countries for each year of funding; the Recipient's accounting system should be able to keep each year's funding obligation separate and allocable based upon any such restrictions.

F.III.b. Performance Reporting

The Recipient must electronically submit all performance reports to the AOR. Once approved by the AOR, all reports must be submitted to the USAID Development Experience Clearinghouse (DEC) at http://dec.usaid.gov. Occasionally, a report will contain sensitive information such as data not yet ready for release to the general public or otherwise embargoed information. In such an event, the AOR will work with the Recipient to either 1) approve an interim, edited version that can be submitted to the DEC until the full report can be released publicly or 2) approve a delay of a reasonable amount of time for submission to the DEC. Evaluations, whether conducted by the Recipient, USAID, or other entity contracted to perform the evaluation, must also be submitted to the DEC.

All research activities implemented under the Leader Award, including those activities at the country and global levels, must be included in the performance reports. The AOR will send a draft template of the performance reports near the end of each designated reporting period, but in general, the performance reports will consist of Semi-Annual Reports, Annual Reports, the Final Report, data entry of reported results into the Development Information Solution[65] (DIS) portal, and more detailed

[65] https://www.usaid.gov/work-usaid/resources-for-partners/development-information-solution

reporting on FTF EG. 3.2-7 indicator in the Research Rack Up. Regardless of the program start date, the program is requested to align to reporting periods in the sections below unless the period is less than two months in which case the first required report is waived and the information added to the following report.

(i) Semi-Annual Reports
Semi-Annual Reports covering the period October 1 through March 31 must be submitted not later than 30 days after the end of the reporting period. The reports are to follow the draft template sent by the AOR but generally include the following sections: Research Progress Summary, Local Capacity Development, Innovation Transfer and Scaling Partnerships, and Future Work.

In accordance with 2 CFR 200.328, the semi-annual reports must be concise and also present the following information:

- A comparison of actual accomplishments with the goals and objectives established for the period, the findings of the investigator, or both. Whenever appropriate, and when the output of programs or projects can be readily quantified, such quantitative data must be related to cost data for computation of unit costs.
- Progress made toward established benchmarks and result indicators of development impact, as discussed in the program description of this NOFO and detailed in the Recipient's Activity MEL Plan.
- Progress made on each discrete research activity.
- Reasons why established goals were not met, if appropriate.
- Other pertinent information including, when appropriate, analysis and explanation of cost overruns or high unit costs.
- In addition, qualitative descriptions of success stories and achievements to illustrate impacts of the program must be included when possible. At the conclusion of each research activity, at least one success story and achievements must be submitted for that activity. Efforts must be made to continue following the results of the achievements each reporting period until the end of the IL.
- Summary information on capacity training investments to include, but not limited to, number of Ph.D. candidates and M.Sc. candidates, candidates' countries of origin, and institutional affiliations during training (U.S. host institution and host country partner institution(s) involved in student training).
- A list of all peer reviewed journal articles published during the reporting period.

(ii) Annual Reports
Annual Reports covering the period October 1 through September 30 must be submitted not later than 60 days after the end of the reporting period. The reports are to follow the draft outline sent by the AOR but generally will include the following sections: Title Page, Management Entity (ME) Information, Technical and/or Advisory Committee Information, Map or List of Countries Where the Lab Works, List of Program Partners, Acronyms, Glossary, Table of Contents, Executive Summary, Program Activities and Highlights, Focus Country(ies) Key Accomplishments, Research Program Overview and Structure, Theory of Change and Impact Pathways(s), Research Project Reports, Associate Award Research Project Reports, Human and Institutional Capacity Development,

Innovation Transfer and Scaling Partnerships, Environmental Management and Mitigation Plan (EMMP), Open Data Management Plan, Governance and ME Activities, Other Topics, Issues, three Success Stories, and any required Appendices. A copy of the Annual Report shall also be submitted to the USAID Development Experience Clearinghouse. Please reference the web site https://dec.usaid.gov/dec/home/Default.aspx for instructions on submission and any questions your organization may have on the reporting requirements. Ensure that the AOR receives a copy of any reports submitted to the DEC.

(iii) Research Rack Up

Research Rack Up data covering the period October 1 through September 30, or the equivalent time period as per the award date, shall be submitted via the Research Rack Up data collection tool. The Research Rack Up provides more detailed data on the Feed the Future indicator EG.3.2-7 (Technologies and Practices under Research, Development, and Dissemination)[66] and curates descriptive information on research outputs to: a) report progress an(d impact; b) facilitate uptake by key technology scaling partners; and, c) create the evidence needed to inform innovation-related strategies and priorities in alignment with the goals of the Global Food Security Strategy. Data counts reported into the Research Rack Up[67] should align with data reported into DIS.

(iv) Notifications

The Recipient will be required to immediately notify the AOR and the Agreement Officer of developments that have a significant impact on the award-supported activities. Also, notification shall be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

(v) Final Report

The final performance report, which does not replace the last annual report, shall cover the life of award or the first five years, whichever is shorter. In the event the award is extended for up to two years, the final report shall cover the additional time period and shall be due following the end of the extension unless specified otherwise, in writing, by the AOR. If the award is extended for more than two years, a second final report is required that covers only the extension time period. The final report shall include the following sections: Title Page, Executive Summary, Program Partners, Program Goals and Objectives, Overview of Activities, Accomplishments, Utilization of Research Outputs, Further Challenges and Opportunities. The exact format and page limit will be determined by the AOR. The final report shall incorporate the findings and results that were included in previous annual reports and is due no later than 90 days after the completion, extension, expiration, or termination of the award. The final report shall be submitted to the AOR for approval. Once approved, a copy of the final report shall also be submitted to the USAID Development Experience Clearinghouse.

[66] Feed the Future Indicator Handbook, https://www.agrilinks.org/sites/default/files/ftf-indicator-handbook-march-2018-508.pdf
[67] Feed the Future Research Rack Up Data Collection Tool Manual, https://drive.google.com/file/d/1eeDSu7PPoWsq76gt2l-aPaDFc0vgosAq/view

(vi) Associate Awards

Reporting requirements and evaluation plans for Associate Awards will be specified in such awards. The Recipient will be required to provide an electronic copy of all reports produced under Associate Awards to the AOR with the Leader Award.

F.III.c. Other Reports and Required Submissions

F.III.c.1. Branding Strategy and Marking Plan

The Applicant is required to comply (and ensure compliance by partners) with USAID's branding and marking requirements set forth in 2 CFR 700.16 with Feed the Future specific guidance located at https://www.feedthefuture.gov/.

Applicants are encouraged, but are not required, to submit their Branding Strategy and Marking Plan with their initial Cost/Management Applications. Applicants who choose not to include their Branding Strategy and Marking Plan with their initial Cost/Management Application will not be penalized during the evaluation process but must be aware that, if the Applicant is the Apparently Successful Applicant, the Applicant will be required to submit an acceptable Branding Strategy and Marking Plan as a prerequisite for any resulting award. This would delay any such award, pending receipt, review, and, if necessary, negotiation of the Applicant's Branding Strategy and Marking Plan, with failure to submit or negotiate a Branding Strategy and Marking Plan within the time specified by the AO making the Apparently Successful Applicant ineligible for award. Moreover, because USAID's branding and marking requirements have cost implications, such costs must be included in the detailed budget (see Section E.I.e.), even if the applicant does not submit its Branding Strategy and Marking Plan with the initial cost/management application.

Failure to submit or negotiate a Branding Strategy and Marking Plan within the time specified by the AO will make the Apparently Successful Applicant ineligible for award.

The proposed Branding Strategy and Marking Plan will not be evaluated competitively. The AO will review for adequacy the proposed Branding Strategy and Marking Plan, and will negotiate, approve, and include the Branding Strategy and Marking Plan in the award.

F.III.c.2. Annual Work Plans

The Recipient will be required to submit annual work plans, covering the period October 1 through September 30 (or parts thereof), which describe all activities planned for the year, including activities planned under Associate Awards to the extent known at the time; the site(s) where they will be conducted, benchmarks/milestones and annual performance targets; the outputs/outcomes which the Recipient expects to achieve; and the input/support planned to be provided by the Recipient, during the work plan period. Included must be an explanation of how those inputs are expected to achieve the outputs/outcomes and benchmarks/milestones. The Recipient must describe and use appropriate methodologies to integrate and address all cross-cutting issues, local capacity development, and private sector engagement. The work plans must include geographic data collection, geographic analysis, and data submission methods as a separate section.

The first-year work plan will include the environmental documentation that must be required by the approved Regulation 216 environmental documentation (see Section F.V. Environmental Compliance). An Environmental Mitigation and Monitoring Plan (EMMP), Pesticide Evaluation Report and Safer Use Action Plan (PERSUAP), or other document which is approved by USAID as a requirement of the approved Regulation 216 environmental documentation will be integrated into subsequent-year annual work plans, making any necessary adjustments to activity implementation in order to minimize adverse impacts to the environment.

The annual work plan for the first year will be submitted no later than 60 days after the effective date of the award. Annual work plans for subsequent years must be submitted no later than 60 days prior to the start of that year. As indicated in Section B.III. of this NOFO annual work plans and significant revisions thereto are subject to USAID approval.

A first year Data Management Plan is also required at the time of the submission of the first year work plan. The work plans will describe activities to be conducted at a greater level of detail than the Program Description of the award but must be cross-referenced with the applicable sections in the Program Description. All work plan activities must be within the scope and objectives of the award. Work plans must not change such scope and objectives or any other terms and conditions of the award in any way; such changes must only be approved by the AO, in advance and in writing. Thereafter, if there are inconsistencies between the work plan and the Program Description or other terms and conditions of the award, the latter will take precedence over the work plan.

Additional information on the annual work plans, Activity MEL Plan, and periodic reports will be provided to the Recipient after award.

F.III.c.3. Evaluation

The Veterinary Vaccine Delivery Innovation Lab will be subject to a performance evaluation, typically during the fourth year of the program, per USAID's evaluation policy. USAID will arrange for and support the cost of the external evaluation outside of the award resulting from this NOFO. The Recipient and individual sub-award activities must support the evaluation efforts by coordinating access to project researchers and facilities, arranging (but not paying for) local transportation and hotels for external evaluators (if needed), continued salary support of researchers and staff during the evaluation, and travel and per diem costs of activity researchers and staff during the evaluation. If any sub-award activity to be evaluated has already closed, the Recipient must arrange logistics associated with a site visit, and as agreed by the evaluation team, the Recipient must support the participation of the Primary Investigator and any appropriate collaborators to participate in the evaluation, such as covering the cost of transportation. Similarly, if any staff member from the Recipient is a part of the evaluation team, the Recipient must support the travel and per diem costs from the Recipient budget. The evaluation will assess the following: (1) the research program performance, (2) the capacity strengthening efforts, and (3) overall management.

The performance evaluation will evaluate the implementation of the global research program, including incorporation of the core program components; the quality and progress of the research; the achievement of development targets; the degree to which the research activities achieve integration and are relevant to development in the host countries and more broadly; and overall progress on

agreed-upon measurable research, training, outreach/dissemination, knowledge and technology hand-off, and institutional strengthening results of the program.

It will also evaluate the administrative and management effectiveness of the Recipient, including the relationship between the Recipient and sub-recipients/partners; the relationship and communication with USAID Washington and Missions; and the outreach and intellectual leadership activities undertaken by the Recipient.

The performance evaluation is distinct from, but will complement, any impact assessment activities undertaken by USAID that examine the Veterinary Vaccine Delivery Innovation Lab's impact.

F.III.c.4. Comprehensive Activity Monitoring Evaluation and Learning Plan

The Recipient will be required to submit a comprehensive Activity MEL Plan within 60 days after the award is made. The Activity MEL Plan, which describes the program over the life of the project, will be submitted at the same time as the first-year work plan. As indicated in Section B.III., the Activity MEL Plan and significant revisions thereto are subject to USAID approval. More detail on the Activity MEL Plan is available in Section A.IV.d.2.

F.IV. Program Income

Any program income generated under the award will be added to USAID funding (and any cost sharing that will be provided) and used for program purposes. Program income will be subject to 2 CFR 200.307.

F.V. Environmental Compliance

Section 117 of the Foreign Assistance Act of 1961, as amended, requires that the impact of USAID's activities on the environment be considered and that USAID include environmental sustainability as a central consideration in designing and carrying out its development programs. This mandate is codified in 22 CFR 216 (sometimes referred to as "Reg 216") and in USAID's Automated Directives System (ADS) Parts 201.5.10g and 204, which, in part, require that the potential environmental impacts of USAID-financed activities are identified prior to a final decision to proceed and that appropriate environmental safeguards are adopted for all activities. The environmental compliance obligations of the Recipient of the award resulting from this NOFO under these regulations and procedures are specified in the following paragraphs.

1) In addition to following U.S. federal environmental regulations and restrictions, the Recipient must comply with host country environmental regulations unless otherwise directed in writing by USAID. In case of conflict between host country and USAID regulations, the latter will govern.
2) No activity funded under the award resulting from this NOFO must be implemented unless an environmental threshold determination, as defined by 22 CFR 216, has been reached for that activity, as documented in a Request for Categorical Exclusion (RCE), Initial Environmental Examination (IEE), or Environmental Assessment (EA) duly signed by the Bureau

Environmental Officer (BEO). (Such documents are hereinafter described as "approved Regulation 216 environmental documentation.")

3) To this end, the Technical Application and any environmental analysis therein will be reviewed by USAID for the purpose of conducting an IEE of the proposed program. Depending on the results of the IEE, USAID may:

    a) Approve a Request for Categorical Exclusion.
    b) Determine that a Negative Determination with Conditions applies to one or more of the proposed activities. This indicates that if these activities are implemented subject to the specified conditions, they are expected to have no significant adverse effect on the environment. Such conditions must be stipulated in the award, and the Recipient will be responsible for implementing all IEE conditions pertaining to activities to be funded under the award. Because the exact nature and location of many activities will only be fully known after sub-awardees are selected, which will take place after award, the initial IEE may require further environmental review and an IEE amendment to be completed post-award, before sub-award activities may proceed.
    c) Determine that a Positive Determination applies to one or more of the proposed activities. This indicates that these activities have the potential for significant adverse effects on the environment. In such cases, the Recipient must be required to prepare and submit an EA addressing the environmental concerns raised by such activities. No activity identified under a Positive Determination can proceed until Scoping (as described in 22 CFR 216.3[a][4]) and an EA (as described in 22 CFR 216.6) are completed and approved by USAID. (Note: The completed Scoping Statement is normally submitted by the Mission Environmental Office [MEO] to the BEO when the project originates in a Mission. The Statement must be circulated outside the Agency by the BEO with a request for written comments within 30 days and approved by the BEO subsequently. Approval of the Scoping Statement must be provided by the BEO before the EA can be initiated.) Accordingly, the Technical and Cost Applications would need to reflect IEE or EA preparation costs and approaches.

4) As part of its annual work plans, the Recipient, in collaboration with the AOR and MEO/BEO, will review all ongoing and planned activities under the award to determine if they are within the scope of the approved Regulation 216 environmental documentation. If the Recipient plans any new activities outside the scope of the approved Regulation 216 environmental documentation, it must prepare an amendment to the documentation for USAID review and approval. No such new activities will be undertaken prior to receiving written USAID approval of environmental documentation amendments. Any activities found to be outside the scope of the approved Regulation 216 environmental documentation will be halted until an amendment to the documentation is submitted and written approval is received.

5) Unless the approved Regulation 216 documentation contains a complete Environmental Mitigation and Monitoring Plan (EMMP) or a Project Mitigation and Monitoring (M&M) Plan, the Recipient will need to prepare and submit an EMMP or M&M Plan for USAID approval. The EMMP or Project M&M Plan will describe how the Recipient will, in specific terms, implement all IEE and/or EA conditions that apply to proposed project activities within the scope of the award. The EMMP or M&M Plan must include monitoring the implementation of the conditions and their effectiveness. Unless included in the successful

Technical Application or revisions/addenda thereto, the completed EMMP or M&M Plan will be integrated into the initial work plan. The approved EMMP or M&M Plan will be integrated into subsequent annual work plans, making any necessary adjustments to activity implementation in order to minimize adverse impacts to the environment.

6) The Recipient will be required to use an Environmental Review Form (ERF) or Environmental Review (ER) checklist using impact assessment tools to screen sub-award and contract proposals to ensure the funded proposals will result in no adverse environmental impact, to develop mitigation measures, as necessary, and to specify monitoring and reporting. Use of the ERF or ER checklist is required when the nature of the proposals to be funded is not well enough known to make an informed decision about their potential environmental impacts; yet, due to the type and extent of activities to be funded, any adverse impacts are expected to be easily mitigated. Implementation of these activities cannot proceed until the ERF or ER checklist is completed and approved by USAID. The Recipient is responsible for ensuring that mitigation measures specified by the ERF or ER checklist process are implemented. The Recipient will also be responsible for periodic reporting to the AOR, as specified in the award.
7) The costs of environmental compliance will be reimbursable under the award resulting from this NOFO provided that they are otherwise in accordance with the terms and conditions of the award.

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SECTION G: FEDERAL AWARDING AGENCY CONTACT

All questions and application submissions regarding this NOFO must reference "7200AA24RFA00015" in the subject line when directed to:

J. Erin Baize
Agreement Specialist
USAID M/OAA/REFS
Email: jbaize@usaid.gov

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SECTION H: OTHER INFORMATION

USAID reserves the right to fund any or none of the applications submitted. The Agreement Officer is the only individual who may legally commit the Government to the expenditure of public funds. Any award and subsequent incremental funding will be subject to the availability of funds and continued relevance to Agency programming.

H.I. Applications with Proprietary Data

Applicants who include data that they do not want disclosed to the public for any purpose or used by the U.S. Government except for evaluation purpose, should mark the cover page with the following:

> "This application includes data that must not be disclosed, duplicated, used, or disclosed – in whole or in part – for any purpose other than to evaluate this application. If, however, an award is made as a result of – or in connection with – the submission of this data, the U.S. Government will have the right to duplicate, use, or disclose the data to the extent provided in the resulting award. This restriction does not limit the U.S. Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets {insert sheet numbers}."

Additionally, the applicant must mark each sheet of data it wishes to restrict with the following:

> "Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this application."

H.II. Demonstration of Eligibility

Applicants that are not "land-grant universities," "sea-grant colleges," or "Native American land-grant colleges" under the statutory definition of Title XII "universities" must submit with their application an additional statement relating to their eligibility under the statutory definition of Title XII institutions. This statement must contain references to other parts of the Technical and/or Cost Application and to references readily available on the Internet and must not exceed two pages in length.

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ANNEX 1 - STANDARD PROVISIONS

(Note: the full text of these provisions may be found at: https://www.usaid.gov/ads/policy/300/303maa and https://www.usaid.gov/ads/policy/300/303mab). The actual Standard Provisions included in the award will be dependent on the organization that is selected. The award will include the latest Mandatory Provisions for either U.S. or non-U.S. Nongovernmental organizations**.** The award will also contain the following "required as applicable" Standard Provisions:

Please note that the resulting award will include all standard provisions (both mandatory and required as applicable) in full text.

REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

Required	Not Required	Standard Provision
		M1. APPLICABILITY OF 2 CFR 200 AND 2 CFR 700 (NOVEMBER 2020)
		M2. INELIGIBLE COUNTRIES (May 1986)
		M3. NONDISCRIMINATION (JUNE 2012)
		M4. AMENDMENT OF AWARD (JUNE 2012)
		M5. NOTICES (JUNE 2012)
		M6. SUBAWARDS AND CONTRACTS (DECEMBER 2022)
		M7. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (OCTOBER 2023)
		M8. USAID ELIGIBILITY RULES FOR GOODS AND SERVICES (MAY 2020)
		M9. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS (JUNE 2012)
		M10. DRUG-FREE WORKPLACE (JUNE 2012)
		M11. EQUAL PARTICIPATION BY FAITH-BASED ORGANIZATIONS (JUNE 2016)
		M12. PREVENTING TRANSACTIONS WITH, OR THE PROVISION OF RESOURCES OR SUPPORT TO, SANCTIONED GROUPS AND INDIVIDUALS (MAY 2020)
		M13. MARKING AND PUBLIC COMMUNICATIONS UNDER USAID-FUNDED ASSISTANCE (DECEMBER 2014)
		M14. REGULATIONS GOVERNING EMPLOYEES (OCTOBER 2023)
		M15. CONVERSION OF UNITED STATES DOLLARS TO LOCAL CURRENCY (NOVEMBER 1985)
		M16. USE OF POUCH FACILITIES (AUGUST 1992)
		M17. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (DECEMBER 2014)

		M18. OCEAN SHIPMENT OF GOODS (JUNE 2012)
		M19. VOLUNTARY POPULATION PLANNING ACTIVITIES - MANDATORY REQUIREMENTS (MAY 2006)
		M20. TRAFFICKING IN PERSONS (APRIL 2016)
		M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)
		M22. LIMITING CONSTRUCTION ACTIVITIES (AUGUST 2023)
		M23. USAID IMPLEMENTING PARTNER NOTICES (IPN) PORTAL FOR ASSISTANCE (JULY 2014)
		M24. ENHANCEMENT OF RECIPIENT EMPLOYEE WHISTLEBLOWER PROTECTIONS (DECEMBER 2022)
		M25. SUBMISSION OF DATASETS TO THE DEVELOPMENT DATA LIBRARY (OCTOBER 2014)
		M26. PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS (MAY 2017)
		M27. SAFEGUARDING AGAINST EPLOITATION, SEXUAL ABUSE, CHILD ABUSE, AND CHILD NEGLECT (OCTOBER 2023)
		M28. MANDATORY DISCLOSURES (JUNE 2023)
		M29. NONDISCRIMINATION AGAINST BENEFICIARIES (NOVEMBER 2016)
		M30. CONFLICT OF INTEREST (AUGUST 2018)
		M31. PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (DECEMBER 2022)
		M32. USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2022)
		M33. AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (DECEMBER 2022)
		M34. EXCHANGE VISITORS VISA REQUIREMENTS (DECEMBER 2022)
TBD		RAA1. NEGOTIATED INDIRECT COST RATES - PREDETERMINED (NOVEMBER 2020)
		RAA2. NEGOTIATED INDIRECT COST RATES - PROVISIONAL (NONPROFIT) (NOVEMBER 2020)
		RAA3. NEGOTIATED INDIRECT COST RATE - PROVISIONAL (FOR-PROFIT) (DECEMBER 2022)
		RAA4. INDIRECT COSTS - DE MINIMIS RATE (NOVEMBER 2020)
		RAA5. (RESERVED)
		RAA6. VOLUNTARY POPULATION PLANNING ACTIVITIES - SUPPLEMENTAL REQUIREMENTS (JANUARY 2009)
		RAA7. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)
		RAA8. CARE OF LABORATORY ANIMALS (MARCH 2004)

		RAA9. TITLE TO AND CARE OF PROPERTY (COOPERATING COUNTRY TITLE) (DECEMBER 2022)
		RAA10. COST SHARING (MATCHING) (FEBRUARY 2012)
		RAA11. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)
		RAA12. INVESTMENT PROMOTION (DECEMBER 2022)
		RAA13. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2022)
		RAA14. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)
		RAA15. CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) (FEBRUARY 2012)
		RAA16. CONDOMS (ASSISTANCE) (SEPTEMBER 2014)
		RAA17. PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEC TRAFFICKING (ASSISTANCE) (SEPTEMBER 2014)
		RAA18 [RESERVED]
		RAA19. STANDARDS FOR ACCESSIBILITY FOR THE DISABLED IN USAID ASSISTANCE AWARDS INVOLVING CONSTRUCTION (SEPTEMBER 2004)
		RAA20. STATEMENT FOR IMPLEMENTERS OF ANTI-TRAFFICKING ACTIVITIES ON LACK OF SUPPORT FOR PROSTITUTION (JUNE 2012)
		RAA21. ELIGIBILITY OF SUBRECIPIENTS OF ANTI-TRAFFICKING FUNDS (JUNE 2012)
		RAA22. PROHIBITION ON THE USE OF ANTI-TRAFFICKING FUNDS TO PROMOTE, SUPPORT, OR ADVOCATE FOR THE LEGALIZATION OR PRACTICE OF PROSTITUTION (JUNE 2012)
		RAA23. UNIVERSAL ENTITY IDENTIFIER 9UEI) AND SYSTEM FOR AWARD MANAGEMENT (SAM) (DECEMBER 2022)
		RAA24. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION (DECEMBER 2022)
		RAA25. PATENT REPORTING PROCEDURES (DECEMBER 2022)
		RAA26. ACCESS TO USAID FACILITIES AND USAID'S INFORMATION SYSTEMS (AUGUST 2013)
		RAA27. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2022)
		RAA28. [RESERVED]
		RAA29. RESERVED
		RAA30. PROGRAM INCOME (AUGUST 2020)
		RAA31. NEVER CONTRACT WITH THE ENEMY (NOVEMBER 2020)

REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR NON-U.S. NONGOVERNMENTAL ORGANIZATIONS

Required	Not Required	Standard Provision
		M1. ALLOWABLE COSTS (NOVEMBER 2020)
		M2. ACCOUNTING, AUDIT, AND RECORDS (MARCH 2021)
		M3. AMENDMENT OF AWARD AND REVISION OF BUDGET (AUGUST 2013)
		M4. NOTICES (JUNE 2012)
		M5. PROCUREMENT POLICIES (JUNE 2012)
		M6. USAID ELIGIBILITY RULES FOR PROCUREMENT OF COMMODITIES AND SERVICES (MAY 2020)
		M7. TITLE TO AND USE OF PROPERTY (DECEMBER 2014)
		M8. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND DATA RIGHTS (JUNE 2012)
		M9. MARKING AND PUBLIC COMMUNICATIONS UNDER USAID-FUNDED ASSISTANCE (DECEMBER 2014)
		M10. AWARD TERMINATION AND SUSPENSION (DECEMBER 2014)
		M11. RECIPIENT AND EMPLOYEE CONDUCT (OCTOBER 2023)
		M12. DEBARMENT AND SUSPENSION (JUNE 2012)
		M13. DISPUTES AND APPEALS (DECEMBER 2022)
		M14. PREVENTING TRANSACTIONS WITH, OR THE PROVISION OF RESOURCES OR SUPPORT TO, SANCTIONED GROUPS AND INDIVIDUALS (MAY 2020)
		M15. TRAFFICKING IN PERSONS (APRIL 2016)
		M16. VOLUNTARY POPULATION PLANNING ACTIVITIES - MANDATORY REQUIREMENTS (MAY 2006)
		M17. EQUAL PARTICIPATION BY FAITH-BASED ORGANIZATIONS (JUNE 2016)
		M18. NONDISCRIMINATION (JUNE 2012)
		M19. USAID DISABILITY POLICY - ASSISTANCE (JUNE 2012)
		M20. LIMITING CONSTRUCTION ACTIVITIES (AUGUST 2023)
		M21. USAID IMPLEMENTING PARTNERS NOTICES (IPN) PORTAL FOR ASSISTANCE (JULY 2014)
		M22. ENHANCEMENT OF GRANTEE EMPLOYEE WHISTLEBLOWER PROTECTIONS (DECEMBER 2022)

		M23. SUBMISSION OF DATASETS TO THE DEVELOPMENT DATA LIBRARY (OCTOBER 2014)
		M24. PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS (MAY 2017)
		M25. SAFEGUARDING AGAINST EXPLOITATION, SEXUAL ABUSE, CHILD ABUSE, AND CHILD NEGLECT (OCTOBER 2023)
		M26. MANDATORY DISCLOSURES (JUNE 2023)
		M27. NONDISCRIMINATION AGAINST BENEFICIARIES (NOVEMBER 2016)
		M28. CONFLICT OF INTEREST (AUGUST 2018)
		M29. PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (JULY 2022)
		M30. EXCHANGE VISITORS VISA REQUIREMENTS (DECEMBER 2022)
		M31. CONTRACT AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (DECEMBER 2022)
		M32. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (OCTOBER 2023)
TBD		RAA1. ADVANCE PAYMENT AND REFUNDS (NOVEMBER 2020)
		RAA2. REIMBURSEMENT PAYMENT AND REFUNDS (DECEMBER 2014)
TBD		4AA3. INDIRECT COSTS - NEGOTIATED INDIRECT COST RATE AGREEMENT (NICRA) (nOVEMBER 2020)
		RAA4. INDIRECT COSTS - CHARGED AS A FIXED AMOUNT (NONPROFIT) (JUNE 2012)
		RAA5. INDIRECT COSTS - DE MINIMIS RATE (NOVEMBER 2020)
		RAA6. UNIVERSAL ENTITY IDENTIFIER (UEI) AND SYSTEM FOR AWARD MANAGEMENT (SAM) (DECEMBER 2022)
		RAA7. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION (DECEMBER 2022)
		RAA8. SUBAWARDS (DECEMBER 2014)
		RAA9. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (DECEMBER 2014)
		RAA10. OCEAN SHIPMENT OF GOODS (JUNE 2012)
		RAA11. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2022)
		RAA12. PATENT RIGHTS (DECEMBER 2022)
		RAA13. [RESERVED]
		RAA14. INVESTMENT PROMOTION (DECEMBER 2022)
		RAA15. COST SHARE (JUNE 2012)
		RAA16. PROGRAM INCOME (AUGUST 2020)

		RAA17. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)
		RAA18. STANDARDS FOR ACCESSIBILITY FOR THE DISABLED IN USAID ASSISTANCE AWARDS INVOLVING CONSTRUCTION (SEPTEMBER 2004)
		RAA19. PROTECTION OF HUMAN RESEARCH SUBJECTS (JUNE 2012)
		RAA20. STATEMENT FOR IMPLEMENTERS OF ANTI-TRAFFICKING ACTIVITIES ON LACK OF SUPPORT FOR PROSTITUTION (JUNE 2012)
		RAA21. ELIGIBILITY OF SUBRECIPIENTS OF ANTI-TRAFFICKING FUNDS (JUNE 2012)
		RAA22. PROHIBITION ON THE USE OF ANTI-TRAFFICKING FUNDS TO PROMOTE, SUPPORT, OR ADVOCATE FOR THE LEGALIZATION OR PRACTICE OF PROSTITUTION (JUNE 2012)
		RAA23. VOLUNTARY POPULATION PLANNING ACTIVITIES - SUPPLEMENTAL REQUIREMENTS (JANUARY 2009)
		RAA24. CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) (FEBRUARY 2012)
		RAA25. CONDOMS (ASSISTANCE) (SEPTEMBER 2014)
		RAA26. PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEX TRAFFICKING (ASSISTANCE (SEPTEMBER 2014)
		RAA27. LIMITATION ON SUBAWARDS TO NON-LOCAL ENTITIES (jULY 2014)
		RAA28. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2022)
		RAA29. [RESERVED]
		RAA30. RESERVED
		RAA31. NEVER CONTRACT WITH THE ENEMY (NOVEMBER 2020)

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ANNEX 2 - GENDER ANALYSIS

SECTION 1: Activity Background

The primary objectives of the Feed the Future Innovation Lab for Veterinary Vaccine Delivery (VVDIL) activity are to:

1. Develop cold-chain-independent, appropriately packaged, and time-delivered vaccines for priority livestock diseases
2. Conduct product development and commercialization activities to support the deployment of vaccines including the development of targeted, inclusive business models
3. Strengthen the capacity of individuals and organizations such as academic and research organizations, public and private vaccine manufacturers, and government and regulatory agencies to accelerate the development and distribution of improved veterinary vaccines

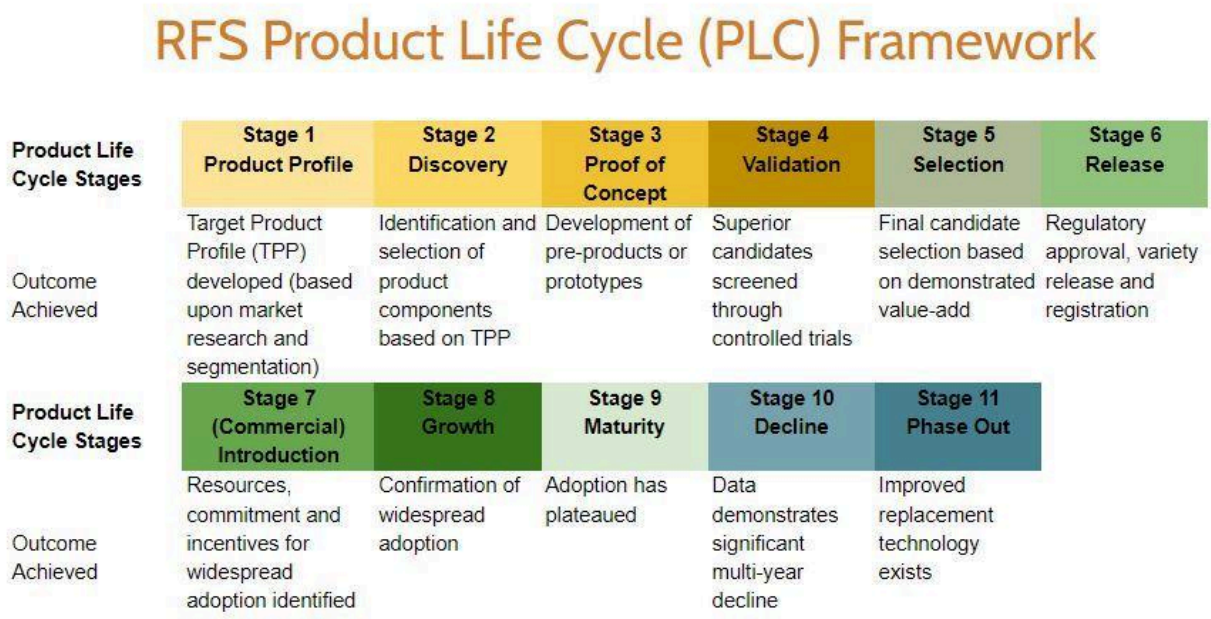
The underlying theory of change is that IF vaccines that target priority livestock diseases and have enhanced delivery attributes are developed and deployed, THEN livestock keepers in low- and middle-income countries will be able to strengthen their resilience to disease losses, which will lead to increased productivity, improved household nutrition, reduced greenhouse gas emissions intensity, and increased water and land use efficiencies.

Guided by the USAID Product Life Cycle Framework (see Figure 1), VVDIL will facilitate the deployment of enhanced vaccines by de-risking private investment for product development, testing, targeting, and eventual transfer to vaccine manufacturers that are best suited for widespread distribution. The proposed activity aligns with REFS functional priorities[68] of driving innovation and scale of global goods that enhance implementation in the field as well as influencing and shaping enabling environments for private sector investment through engagement and collaboration.

In addition to the Global Food Security Strategy,[69] the Veterinary Vaccine Delivery Innovation Lab will contribute to the goals of the strategies for Resilience, Multi-sectoral Nutrition, and Private Sector Engagement. As a research activity, it will directly align with the Global Food Security Research Strategy.[70]

[68] Bureau for Resilience and Food Security Functional Strategy
[69] US Government Global Food Security Strategy, 2022-2026
[70] US Government Global Food Security Research Strategy

Figure 1 - REFS Product Life Cycle Framework



Resilience

Increasing *equitable* access to livestock vaccines will increase resilience to livestock disease outbreaks, and, indirectly, to other financial shocks and stresses due to livestock often serving as a savings account for rural households. However, vaccine delivery and deployment, associated finance packages, and animal healthcare systems must be intentionally designed to provide equitable access and benefits. This activity will study those innovations and systems and seek to improve our understanding of how to improve them to intentionally benefit women, including women who are members of other marginalized groups. This activity will improve our understanding of how veterinary vaccine delivery can be harnessed to improve the resilience of women.

Multi-Sectoral Nutrition Strategy (MSNS)

This activity will contribute secondarily to the MSNS through the pathway of increased availability and access to sufficient, safe and nutritious animal source foods. This, however, is a higher order projected outcome of the Innovation Lab (IL) via improved availability of vaccines for prioritized livestock diseases leading to increased livestock populations, which in turn will lead to increased availability of animal source foods to local communities.

Private Sector Engagement Strategy

Private sector engagement is critical to the success of VVDIL. The private sector will thus be engaged early and often to ensure that veterinary vaccines are developed and distributed in a cost effective and equitable manner. This will involve leveraging existing vaccine distribution networks to ensure these vaccines are marketable, and that those in need of these vaccines have access to these markets.

Localization

Finally, this activity will directly increase local capacity through supporting students and researchers in local universities, as well as building local institutional capacity to develop and distribute improved veterinary vaccines. The activity will provide an equal amount of support to women students as men and will be deliberate in choosing women as lead researchers where possible. The activity will also intentionally engage with women-owned businesses where possible to improve veterinary vaccine delivery.

SECTION 2: Why Gender?

Promoting gender equality and advancing the status of all women and girls globally is vital to achieving U.S. foreign policy and development objectives.[71] "President Biden and Vice President Harris believe that advancing gender equity and equality is fundamental to every individual's economic security, safety, health, and ability to exercise their most basic rights. It is also essential to economic growth and development, democracy and political stability, and the security of nations across the globe. Ensuring that all people, regardless of gender, have the opportunity to realize their full potential is, therefore, both a moral and strategic imperative."[72]

This is particularly important in the agriculture sector in developing countries. Women often play a major role in agricultural activities, producing 60-80% of food, yet they have limited access to, and control of, productive resources such as land, labor, credit, and capital. Women comprise 43% of the agricultural labor force globally and in the least developed countries, two in three women are employed in farming.[73] They play critical roles across food systems — as farmers, service providers and entrepreneurs. While women own just one-third of small, medium, and large businesses globally, this number is growing.[74] In Africa, women make up 58% of the continent's self-employed population.[75] In the agriculture sector, urbanization, changing diets, and transformation of the agri-food systems are creating more opportunities for women. Gender intersects with other spheres of disadvantage — age, caste, ethnicity and socio-economic status and identity — further impacting how women and men engage in agriculture and food systems and reap benefits. Therefore, agriculture sector activities should address equity issues, including access to resources; access to financial services, extension, training, technologies, tools, and inputs; and access to markets, including information and business-development services. Empowering women and girls, in all their diversity, and the recognition and respect of their rights, lead to more inclusive growth, better nutrition and health, and less hunger — all of which build resilience and self-reliance.

In the 2022-2026 US Global Food Security Strategy (GFSS), equity and equality are elevated to priority areas of emphasis and action. Despite having prioritized gender previously, "USAID must do better to fully achieve its potential for addressing hunger and poverty, nutrition, and resilience by

[71] USAID ADS 205, https://www.usaid.gov/ads/policy/200/205
[72] National Strategy on Gender Equity and Equality, https://www.whitehouse.gov/briefing-room/statements-releases/2021/10/22/fact-sheet-national-strategy-on-gender-equity-and-equality/
[73] CERES 2030. 2020. Ending Hunger Sustainably: The Role of Gender
[74] https://blogs.worldbank.org/opendata/women-entrepreneurs-needed-stat
[75] https://blogs.worldbank.org/africacan/supporting-african-women-through-economic-consequences-covid-19

intentionally addressing inclusion, especially of women and youth, both on farm and off".[76] Gender equality and female empowerment are also included as an explicit Cross-Cutting Intermediate Result (CCIR 2) of the GFSS and there is a deliberate effort to impact all programming through the project cycle to ensure more equitable gender outcomes. USAID will "apply evidence from the Women's Empowerment in Agricultural Index and the Gender Integration Framework, developed under FTF, to effectively address the greatest constraints ... under the following domains: decision making in agriculture, improving women's and men's access to and control over resources, income, social capital and leadership, workload, human capital, and access to technologies."[77]

There are a range of gender-related obstacles such as discriminatory norms, power hierarchies, unconscious biases and other institutional structures and social arrangements that may limit access to and adoption of innovations by women.[78] USAID needs to support the participatory design of gender-sensitive and inclusive agriculture activities in order to have the greatest impact.[79] Building evidence of gendered roles, resources, needs, and preferences creates opportunities not only to improve the relevance and adoption of improved agricultural technologies and practices but also to advance gender equity and women's empowerment.

Gender equality is not just a good in itself, it is also critical to achieving our goals related to reducing poverty, hunger, and malnutrition. If women had the same access to productive resources like land as men, they could increase farm yields by 20-30 percent. This increase in agricultural output could reduce the number of hungry people in the world by up to 150 million.[80] Recent case studies conducted in five sub-Saharan African countries further support the argument that once access to agricultural inputs such as labor, machinery and fertilizer is equalized, women can be as productive as men.[81] Furthermore, closing the gender gap in farm productivity and the wage gap in agriculture would increase global GDP by 1%, which is nearly $1 trillion.[82]

The Importance of Intersectionality: Many aspects of a person's identity affect how they experience the world. Women and girls, men and boys, and gender-diverse individuals are shaped by their sex and gender identity as well as a range of other characteristics including age, marital status, class, ethnicity, race, disability status, geographic location, and sexual orientation. This is particularly relevant for individuals who experience overlapping marginalized identities, and therefore experience overlapping inequalities. Incorporating an intersectional gender lens improves our programming by identifying—and strategically addressing—the ways in which gender and other inequalities can limit certain people's access to, participation in, and benefit from development interventions.

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[76] 2022-2026 Global Food Security Strategy, https://www.usaid.gov/sites/default/files/documents/Global-Food-Security-Strategy-FY22-26_508C.pdf

[77] Ibid

[78] "Innovating to Address Gender-Based Violence" via the International Development Innovation Alliance (IDIA), September 2020

[79] Ibid

[80] Food and Agriculture Organization of the United Nations. (2011). The State of Food Insecurity in the World – Women in agriculture: Closing the gender gap for development. Rome, Italy. http://www.fao.org/docrep/013/i2050e/i2050e.pdf

[81] UN Women. 2021. The gender gap in agricultural productivity in sub-Saharan Africa: Causes, costs and solutions. Policy Brief No.11. UN Women: New York

[82] FAO. 2023. *The status of women in agrifood systems*. Rome. https://doi.org/10.4060/cc5343en

SECTION 3: Gender Constraints in Livestock Systems

Across the globe, men and women play specific, often highly gendered, roles in agriculture and food systems. Specifically, while women contribute significantly to the sector—as farmers, agricultural laborers, and entrepreneurs—deeply rooted norms and perceptions shape the nature and terms of their work; assigning roles and responsibilities as "male" or "female", jointly shared or not gendered. For example, across developing countries women commonly play primary roles as caregivers, providers and custodians of household food preparation, food security and nutrition.

These gender norms also apply to livestock caretaking, where women are more likely to own fewer, less valuable animals such as chickens, goats, and sheep.[83] Livestock keeping is often the sole option for women to generate income and support their families, yet women face greater constraints in accessing income-generating roles along the livestock value chain, and often take up more labor-intensive roles such as feeding, milking, and caring for sick animals. Women also have decreased access to resources (e.g. land, feed, labor, technical advice), markets, infrastructures, and related information and services in livestock systems. Generally, women also tend to have less access to financial capital and more limited mobility, making it difficult to access privatized veterinary and extension services as well as the markets that are at a greater distance from their homes.[84] Women also tend to have less control over productive resources and spending choices than men, which means they often struggle to operate profitable livestock-related businesses.

These context-specific and varied roles men and women play in livestock systems influence their access to, and willingness to adopt, new agricultural technologies such as veterinary vaccines. Not only that, but it is important to also use an intersectional lens to analyze vaccine value chains as other factors such as age, ethnicity, education level, or cultural norms can have a significant effect on vaccine access. For example, being of low caste, belonging to a certain ethnic group or living in remote regions are additional factors that can make women less visible and less likely to be reached by livestock development programs.[85] One study in northeastern Uganda found that widows, the elderly, and people with disabilities, in addition to women generally, also had limited access to vaccines and animal health information.[86] Therefore, it is important to consider intersecting systems of oppression that may limit program end users' ability to access new vaccines or the associated innovation package.

In addition to informal gender norms, formal policies, governance, and institutions can either exacerbate barriers to women's full participation in resilient agriculture and food systems or catalyze fundamental improvements in women's status. Disparities can be addressed through gender-responsive policy and governance, budgeting in institutions, and identification of policies that have different implications for women and men, along with addressing social and cultural norms.

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[83] Staal, S., Wanyoike, F. and Ballantyne, P. 2020. *Impacts of livestock development investment. Documented positive impacts of livestock-related interventions in Africa, Asia and Latin America*. Nairobi, Kenya: ILRI.

[84] USAID. (2021). Gender Good Practices in Livestock Programming. Available at https://pdf.usaid.gov/pdf_docs/PA00Z5PH.pdf

[85] McKune, S., Serra, R. & Touré, A. 2021. Gender and intersectional analysis of livestock vaccine value chains in Kaffrine, Senegal. PLoS ONE, 16(7): e0252045. https://doi.org/10.1371/journal.pone.0252045

[86] Acosta, D., Ludgate, N., McKune, S.L. & Russo, S. 2022. Who Has Access to Livestock Vaccines? Using the social-ecological model and intersectionality frameworks to identify the social barriers to Peste des Petits ruminants vaccines in Karamoja, Uganda. Frontiers in Veterinary Science, 160.

When considering developing and deploying livestock vaccines with updated delivery methods, it's important to consider women's decreased access to information–including agricultural extension services, markets, decision-making power, and time that can affect their access to these agricultural innovations.

Access to Information: How and where men and women receive information vary by country and community and often follow gendered patterns. Women commonly have lower education levels and higher rates of illiteracy than men, which limits their access to written and complex information. The gender digital divide means women are less likely to access information through mobile phones or other digital tools and technologies compared to men. Women and men's informational needs also diverge due to gender-based differences, including their differing roles and responsibilities in the social, health and economic spheres. Due to household responsibilities and childcare needs, women often have less availability to attend training or meetings and especially to travel overnight.

In the context of livestock systems, both men and women need information on good husbandry practices, technologies for improved production (e.g. vaccines), biosecurity, nutrition, breeding, animal health services, market demand and pricing, and weather data. While agricultural technical assistance often provides access to information and technologies as well as training, services and technologies, they are often tailored for and targeted to male-dominated value chains.[87] Thus, women remain severely underserved by extension and advisory services across the globe. A study in Ethiopia found that both female heads of households and female plot-managers are 10 percent less likely to benefit from agricultural extension services than their male counterparts.[88] Stereotypical perceptions of women as carers or helpers can translate into agricultural extension and advisory services being disproportionately delivered to the male heads of households, who are considered the main farmers.[89] In some conservative contexts, prevailing social norms mean that male extension officers only engage with male farmers,[90] and extension officers are predominantly male in many regions.[91] Women's ability to attend and benefit from training sessions or demonstration plots may be limited by several factors, such as social norms around mobility, literacy levels, work burden or asymmetric power dynamics.[92] Similarly, some government extension programs may require beneficiaries to be the owners or managers of certain assets (e.g. fishponds, land), thus potentially discriminating against women who are less likely to own these assets.[93] Other factors, such as religious or ethnic group,

[87] Okonkwo, Nkiruka Stella."Special Highlight on Youth & Women Economic Empowerment Through Agriculture in West Africa". A Review of Agriculture Sector Performance in West Africa. September 2020

[88]Ragasa, C., Berhane, G., Tadesse, F. & Taffesse, A.S. 2013. Gender differences in access to extension services and agricultural productivity. The Journal of Agricultural Education and Extension, 19(5): 437–468.

[89] Mudege, N.N., Mdege, N., Abidin, P.E. & Bhatasara, S. 2017. The role of gender norms in access to agricultural training in Chikwawa and Phalombe, Malawi. Gender, Place & Culture, 24(12): 1689–1710.

[90] Galiè, A. 2013. Empowering women farmers: The case of participatory plant breeding in ten Syrian households. Frontiers: A Journal of Women Studies, 34(1): 58–92.

[91] Huyer, S., Gumucio, T., Tavenner, K., Acosta, M., Chanana, N., Khatri-Chhetri, A., Mungai, C. et al. 2021. From vulnerability to agency in climate adaptation and mitigation. In: R. Pyburn & A.H.J.M. van Eerdewijk, eds. Advancing gender equality through agricultural and environmental research: Past, present, and future, pp. 261–294. Washington, DC, International Food Policy Research Institute.

[92] Kosec, K. & Wantchekon, L. 2020. Can information improve rural governance and service delivery? World Development, 125: 104376. https://doi.org/10.1016/j.worlddev.2018.07.017

[93] Malapit, H., Heckert, J., Scott, J., Padmaja, R. & Quisumbing, A. 2021. Nutrition-sensitive agriculture for gender equality. In: R. Pyburn & A.H.J.M. van Eerdewijk, eds. Advancing gender equality through agricultural and environmental research: Past, present, and future, pp. 189–218. Washington, DC, International Food Policy Research Institute.

physical and mental ability, and age can also influence a woman's mobility, literacy level, and intrahousehold power dynamics that can thus influence her access to agricultural extension services.

Agricultural extension services are key to livestock disease control, not only related to the delivery of the vaccines themselves, but also to inform livestock keepers of all genders about the importance of vaccinations and other biosecurity measures to control priority livestock diseases in their herds and flocks. Thus it will be crucial to consider how agricultural extension services can be delivered in a way that is inclusive and accessible to all livestock keepers as part of this activity.

Access to Markets: A number of factors underscore the differences in male and female farmers' and processors' market access and the types of markets they sell into. These include participation in producer organizations such as cooperatives, farmer's groups, or other groups that provide for economies of scale and bargaining power; the scale and quality of production; mobility and transport constraints to list a few. Though unreliable transportation and lack of infrastructure influence everyone's ability to get to and from the market, women face additional challenges. Women are less likely to have their own means of transport, have limited cash to pay for transport, and may face higher risk to personal security. Moreover, market infrastructure is frequently not tailored to women's needs.[94] Typically female responsibilities such as cooking meals, childcare and fetching water are necessary on a daily basis. As a result, women may have limited control over their schedules and are often tied to an inflexible home routine that may leave insufficient time to go to markets and search for better prices and terms. Furthermore, women are often bound by gender restrictive norms that may not allow them to interact with men and businesspeople, particularly in public spaces. Men on the other hand are more likely to own their own means of transportation, have greater access to cash for transportation, and not be constrained by cultural norms restricting their mobility. Men are also more likely to have more freedom to negotiate publicly, and they often do not have household obligations that limit their time traveling and finding or negotiating for better terms for their products. In this way, female livestock keepers are disadvantaged in not being able to sell their livestock to all potential buyers, or in getting a fair price for their animals. This also means female livestock keepers tend to have less money to invest in innovations that could help improve the health and wellbeing of their livestock, e.g. vaccines.

When looking at vaccine value chains, it is also important to consider the different roles that men and women play along each entire value chain. For example, one study found that there was a lack of female representation in higher nodes of the vaccine value chain in Kaffrine, Senegal.[95] This lack of representation can influence how different groups interact with various actors along each value chain, including decisions around vaccine markets and how accessible and inclusive they are to women and other marginalized groups. Thus when analyzing vaccine value chains, it will be important to consider how existing norms and power structures influence these value chains and market systems, including how access may be limited for women and other marginalized groups.

Decision-making: Power relations in terms of roles and responsibilities in production, use of technology, resource management, access to markets, and income control are often gendered within households, communities and associations and across cultures and countries. Gender norms also

[94] "Gender in Agriculture Sourcebook" The World Bank, 2009 https://openknowledge.worldbank.org/handle/10986/6603

[95] McKune, S., Serra, R. & Touré, A. 2021. Gender and intersectional analysis of livestock vaccine value chains in Kaffrine, Senegal. PLoS ONE, 16(7): e0252045. https://doi.org/10.1371/journal.pone.0252045.

shape women's and men's abilities to participate in, be represented in and have leadership roles in agriculture and food system institutions from research to extension to markets.

Studies across various contexts demonstrate that when women can exert more influence on household decisions regarding production and income use, this can lead to increased access to food and health care and eventually improved nutrition.[96] There is also some evidence that women's control over land, cash, other assets, and related decision-making reduces the prevalence of child malnutrition.[97, 98] In many contexts however, discriminatory social institutions, including norms and legal frameworks, limit women's critical access to these assets and their ability to make decisions regarding their use. Increasing women's control over the income generated from livestock production can thus have a net positive impact on household nutrition and, potentially, increase the uptake of veterinary vaccines among women livestock keepers.

Time use: In many settings, particularly where infrastructure is weak and market substitutes are unavailable or unaffordable, women often face significant time constraints as they work to meet their productive, domestic and care responsibilities; a pattern that became even more visible during the COVID-19 pandemic. The time poverty women experience have impacts on their health and well-being and the trade-offs they face in allocating their time lead to lost economic opportunity and gain and can compromise feeding and caregiving practices that require women's time.[99] These constraints on women's time are also compounded by women's relatively less command over household labor and their inability to use hired labor. This means that women's unique time constraints must be taken into account when deciding how and when agricultural extension, training, and other interventions should be delivered. Additionally, it is crucial to consider if new agricultural technologies will lighten women's time burden or not, and consider this during the technology design process.

As summarized above, women play many important and varied roles in production systems yet commonly face additional inclusion issues that men do not face. Furthermore, women are not a monolithic group and age, ethnicity, disability, race and socio-economic status are a few of the factors that can shape their capabilities and agency and ability to take advantage of economic opportunities. Building evidence of gendered roles, resources, needs, and preferences creates opportunities not only to improve the relevance and adoptions of improved agricultural technologies and practices but also advance gender equity and women's empowerment. Research can play a key role in identifying where, how, what and when interventions would be most beneficial.

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[96] Ruel, M. T., & Alderman, H. (2013). Nutrition-sensitive interventions and programmes: how can they help to accelerate progress in improving maternal and child nutrition? The Lancet 382 (9891): 536–51. doi:10.1016/S0140-6736(13)60843-0.

[97] Allendorf, Keera, (2007), Do Women's Land Rights Promote Empowerment and Child Health in Nepal?, *World Development*, 35, issue 11, p. 1975-1988, https://EconPapers.repec.org/RePEc:eee:wdevel:v:35:y:2007:i:11:p:1975-1988.

[98] Quisumbing, A., & Maluccio, J. (2003). Resources at marriage and intrahousehold allocation: Evidence from Bangladesh, Ethiopia, Indonesia and South Africa. Oxford Bulletin of Economics and Statistics, 65(3), 283-327.

[99] Johnston, Deborah and Stevano, Sara and Malapit, Hazel Jean and Hull, Elizabeth and Kadiyala, Suneetha, Agriculture, Gendered Time Use, and Nutritional Outcomes: A Systematic Review (August 28, 2015). IFPRI Discussion Paper 1456, Available at SSRN: https://ssrn.com/abstract=2685291

SECTION 4: Gender Recommendations for VVDIL

Despite the potential benefits, the adoption and impact of veterinary vaccines within livestock systems in low- and middle-income countries can be limited by lack of awareness of their benefits; limited knowledge of appropriate vaccine storage, administration, or dose timing; age and gender dynamics of research programs; lack of input availability and resources; labor requirements; lack of a robust animal healthcare system in rural areas; and a host of other constraints. Research and associated capacity building to address these challenges can improve the adoption of such innovations leading to accelerated gains in livestock production and farming household income.

Research from the VVDIL must seek to improve the systems supporting adoption of improved veterinary vaccines through the lens of improving women's equality and gender empowerment.[100] Women may control or share in the control of income from the livestock systems in Feed the Future countries[101] and thus selected research must also be viewed through the lens of gender impacts. Improved veterinary vaccines that are cold chain-independent and time-delivered have the potential to increase livestock productivity without increasing opportunity costs to women's time and labor. These vaccines can thus increase household income to which women have access and women's empowerment, and thus have the potential for positive impact on the health and nutrition of children.[102]

The main focus of the VVDIL is to develop and deliver cold-chain-independent and time-delivered veterinary vaccines using inclusive business models. However, for this research to contribute to gender equality in a longer term perspective, appropriate consideration of context specific gender dynamics and careful measures are likely to be required. This IL contributes to this process as part of its activities, by 1) considering the preferences of women and other marginalized groups in product profiles of veterinary vaccines; 2) actively recruiting women for key positions and training opportunities; 3) ensuring business models for vaccine deployment are inclusive; 4) including gender equality and social inclusion (GESI) experts among the implementing team; and 5) supporting local capacity strengthening in inclusive agricultural research and veterinary vaccine deployment.

The VVDIL must be a gender-sensitive program that will develop knowledge, recommendations, tools, and strategies that recognize and account for the needs and multi-dimensional roles of women and other marginalized groups in livestock systems, including the vaccine value chains that support those systems. Gender and inclusive development analysis and integration must be implemented as a cross-cutting effort within all activities. This analysis must reflect the (a) laws, policies, regulations, and institutional practices that influence the context in which different social groups act and make decisions; (b) cultural norms and beliefs; (c) gender roles, responsibilities, and time use; (d) differences in access to and control over assets and resources for different social groups; (e) patterns of power and decision-making; as well as explicitly mentioning any of these GESI considerations in the program description.

In the Application, Applicants must discuss the needs of women researchers and engagement of women and other marginalized groups in livestock systems and vaccine value chains in the countries

[100] For USAID's definition of gender equality see the Gender Equality and Women's Empowerment Policy.
[101] See the Feed the Future Initiative homepage for an up to date list of target countries. https://www.feedthefuture.gov/about/.
[102] FAO. 2023. *The status of women in agrifood systems*. Rome. https://doi.org/10.4060/cc5343en

in which the IL operates. The Management Entity of this IL is expected to outline key research processes or questions to support gender and social inclusion integration in descriptions of each proposed Area of Inquiry. Through gender and inclusive development analysis, research activities must demonstrate a clear understanding of men's and women's distinctive roles in the research process and the barriers to entry in the research fields for women. Applicants must also demonstrate a clear understanding of what challenges among marginalized livestock keepers can be overcome through improved veterinary vaccines. Where this information is unavailable, Applicants must address knowledge gaps to ensure that outputs and outcomes of research conducted under the program are beneficial to all relevant marginalized groups.[103] Because men and women are not homogenous groups, the program must be sensitive to this diversity, and explicitly recognize the specific needs among different marginalized communities, including those with intersectional identities.

The Recipient will ensure that local capacity strengthening is a fundamental design consideration; both across the overarching technical program and within individual program activities as appropriate. The successful applicant's approach to local capacity strengthening as a cross-cutting issue will identify the anticipated recipients of capacity strengthening efforts under the VVDIL, provide a rationale and process for how recipients are selected, describe what types of capacity-strengthening efforts and approaches will be applied, and explain how these efforts will contribute to sustainable achievement of the program's Strategic Objectives and Areas of Inquiry. The local capacity strengthening approach must pursue gender balance and social inclusion in access to capacity development opportunities and promote equal participation in capacity development activities.

This activity will also involve a co-creation process that integrates GESI dimensions. All partners in the consortium will participate in a collaborative co-creation process among USAID Bureau for Resilience, Environment and Food Security, relevant USAID Missions, and the applicants. This will occur before awards are finalized. The co-creation process will intentionally plan for discussions about the integration of GESI considerations in the activity proposal and subsequent implementation.

Because of the importance of GESI within the VVDIL, the proposed technical team must demonstrate strong technical capacity in gendered agricultural research, social inclusion, and local capacity strengthening—either within the key personnel or through technical specialists. Among approaches to ensure proper attention to GESI within the program, a comprehensive Activity Monitoring Evaluation and Learning Plan will serve as a tool to plan and manage the process of monitoring, evaluating, and reporting progress toward achieving the desired results. Appropriate gender-sensitive and youth-inclusive methodologies (including sex and age disaggregation) must be used, along with performance indicators that will measure progress toward achieving the desired results and account for GESI dimensions, as relevant.

The VVDIL conforms to USAID policy requirements[104] that gender issues be considered across the program cycle, such as during activity planning, implementation, and MEL. The VVDIL will be required to provide systematic consideration of gender issues and impacts and report on sex-disaggregated data for persons directly engaged in the IL and assisted. Each focus area work will assess gender issues relevant to the sub-sector and identify measures the IL will take to enhance

[103] Note that this is dependent on the specific context of the countries in which this IL will operate.
[104] USAID ADS 205. https://www.usaid.gov/ads/policy/200/205

positive gender impacts. USAID will monitor gender participation levels in annual performance reporting and, in the event that a focus area falls substantially behind in women's participation, will require corrective action be taken in subsequent Annual Work Plans. The IL is expected to assist with reviews of gender equity and participation during the course of the five-year program.

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