

Request for Proposals for Verification Services for the AgResults Foot and Mouth Disease Vaccine Project

Date: June 3, 2024

From: AgResults Secretariat

To: Potential Offerors

Subject: Request for Proposals (RFP) to provide Verification Services for the AgResults Foot and Mouth Disease Vaccine Project

RFP Link: <https://agresults.org/news-and-blog/10-blog/request-for-proposals-for-verifier-services-for-the-fmd-vaccine-challenge-project>

The Secretariat of AgResults (“Secretariat”) invites your organization to submit a proposal (“Proposal”) to provide verification services in accordance with this Request for Proposals (“RFP”) for the AgResults Foot and Mouth Disease (FMD) Vaccine Project (“Project”).

The Project is an advance market commitment project that is part of the AgResults initiative financed by the governments of Australia, Canada, the United Kingdom and the United States, and the Bill & Melinda Gates Foundation. For more information about AgResults, please visit www.AgResults.org

The Project consists of a Pay-for-Results (PfR) prize competition in East Africa (Burundi, Ethiopia, Kenya, Rwanda, Tanzania, and Uganda) designed to encourage the development and uptake of high-quality FMD vaccines tailored to meet the needs of East Africa. The prize incentive offered by AgResults is structured as a cost-share that reduces the cost-per-dose for buyers, enabling public and private sector actors to better combat FMD through more consistent purchases of these vaccines. In this way, the Project aims to improve animal health and strengthen farmer livelihoods.

The Secretariat expects to award a Fixed Price Contract to the organization(s) hired for the services detailed in this Request for Proposals (RFP) for a period of four years and ten months:

- **Period of Performance:** November 1, 2024, to September 30, 2028

Proposal procedures and instructions follow this letter in Appendix 1 and are incorporated herein and are made a part hereof. By submitting a Proposal and the required completed and signed “Anticorruption Compliance Certification” (Appendix 5), you will have consented to the terms of this RFP, including the proposal procedures and instructions.

Please note the deadline for receipt of proposal, with all required signatures, including a completed and signed Anticorruption Compliance Certification, is due no later than 1700 Hrs. US Eastern Daylight Time (US EDT) on **July 5, 2024**. Proposal documents should be submitted in one email to info@agresults.org. Please indicate “**FMD Project Verifier RFP**” in the subject line of the email. The full timeline for this RFP is included in Appendix 1.

AgResults will review and evaluate proposal submissions using the evaluation criteria

specified in Appendix 4 of this RFP and will select the organization(s) at its sole discretion. The selected organization(s) will be notified in writing. Notwithstanding the notification by the AgResults of the contemplated award, no work shall commence prior to the issuance and signature by the AgResults Secretariat of a Project Verification Agreement. AgResults reserves the right to select any number of applying organizations or not to select any organization. The AgResults Secretariat reserves the right to award a contract for all or a portion of the work required, issue more than one contract, or to not award a contract.

We look forward to working with you on this opportunity. Should you have any questions or comments please direct them to info@agresults.org. We appreciate your responsiveness and look forward to a mutually beneficial business relationship.

Sincerely,

/s/

Parasto Hamidi
Secretariat Lead Consultant

Appendices:

1. Proposal Procedures and Instructions
2. AgResults Background
3. Terms of Reference
4. Proposal Requirements
5. Anti-Corruption Compliance Certificate
6. Pricing Template

Appendix 1 Proposal Procedures and Instructions

1. Proposal Procedures and Instructions

This section of the RFP provides the general procedures and instructions the Offeror is expected to follow in completing its response and submitting the Proposal.

1.1. Proposal Format and Content

Offerors shall submit the following clearly identified two components as separate documents, with numbered and ordered subsections in the Proposal that match those subsections detailed in Appendix 4 "Proposal Requirements":

1. Technical Proposal and
2. Price Proposal

Clarity and completeness are of the utmost importance in the Proposal, as an organization's capabilities can only be considered when properly documented within the Proposal.

1.2. RFP Schedule of Events

- a) **Deadline for Proposals**, with all required signatures, including a completed and signed Anticorruption Compliance Certification, is no later than 1700 Hrs. US Eastern Time (US ET) on **July 5, 2024**. Proposal documents should be submitted in one email to info@agresults.org. Please indicate "FMD Project Verifier RFP" in the subject line of the email.
- b) **Questions** concerning the Project, or this RFP may be submitted by Offerors at any time, but no later than 1700 Hrs. US Eastern Time (US ET) on **June 10, 2024** to info@agresults.org. Please indicate "FMD Project Verifier RFP Questions" in the subject line of the email.
- c) **Answers** to timely-received questions will be posted on the AgResults website no later than 1700 Hrs. US Eastern Time (US ET) on **June 14, 2024**. Answers to questions will be posted on <https://agresults.org/news-and-blog/10-blog/request-for-proposals-for-verifier-services-for-the-fmd-vaccine-challenge-project>.
- d) The Secretariat expects to award the FMD Project Verifier contract on or about **September 15, 2024**, with an expected contract start date of **November 1, 2024**.

Please be advised that late Proposal submissions may be considered non-responsive and may be excluded from evaluation and award consideration.

1.3. Anticipated Contract Type and Period of Performance

The Secretariat expects to award to the selected Project Verifier a Firm-Fixed-Price Contract for the Project verification services detailed in this RFP for a for a period of four years and ten months, subject to annual reauthorization in writing from AgResults:

- **Period of Performance:** November 1, 2024, to September 30, 2028

If AgResults, at its sole discretion, decides to exercise the next annual Period, the Secretariat will inform the Project Verifier no later than 30 days before the start of the annual Period to be exercised.

Payment for the Project Verifier organization's services under the contract will be made by the AgResults' Financial Trustee. The Trustee reserves the right to withhold from payments any taxes or similar fees as may be required by applicable law.

1.4. Terms of Reference

See Appendix 3.

1.5. Proposal Validity Period

The Offeror's Proposal must remain valid for one hundred and twenty (120) days after submission and the validity period of 120 days must be noted in the Offeror's Proposal cover letter.

1.6. Responsibility for Compliance with Legal Requirements

The Offeror's products, services, and facilities must be in full compliance with all applicable laws, regulation, codes, standards, and ordinances, regardless of whether or not they are referred to by the Secretariat.

1.7. Proposal-Related Incurred Costs

The Offeror will be responsible for all costs incurred in preparing or responding to this RFP. All materials and documents submitted in response to this RFP become the property of the Secretariat and will not be returned. This RFP will in no way obligate the Secretariat to compensate any Offeror for costs associated with the preparation of its Proposal.

1.8. Reservation of Rights

This RFP does not commit the Secretariat to award a contract, to pay any costs incurred in the preparation of a Proposal in response to this request, or to procure or subcontract for services or supplies. The Secretariat reserves the right to cancel this procurement at any time without prior notice. The Secretariat may require the Offeror to participate in discussions, solely at the Secretariat's discretion, and to submit such monetary, technical or other revisions of their Proposals that may result from such discussions. Offerors do not have the right to protest or seek a claim based on the Secretariat's exercise of its discretion or judgment in evaluating or awarding a contract arising from or relating to the Proposal. The Offeror expressly waives any and all rights and remedies under any civil action arising from or related to the submittal of a Proposal.

1.9. Rejection of Solicitation Response

The Secretariat reserves the right to reject any or all responses received or any part thereof, on any basis or for any reason to accept any response or any part thereof, or to waive any informalities when deemed to be in the Secretariat's best interest.

1.10. Taxes

Any applicable taxes that may be levied in connection with the Services in any jurisdiction will be the responsibility of the selected Project Verifier and are deemed to be included in the Offeror's proposed fixed price or fixed unit prices. The Secretariat

cannot confer any special tax- or duty-free status to the Project Verifier and the work is not exempt from any taxes or duties.

1.11. Evaluation Criteria

Proposals will be evaluated and ranked by the Secretariat in the order in which they represent, in the Secretariat's sole discretion, the best value for AgResults. Greater weight will be given to the technical services than to price, but price (value for money) remains an important determinant for selection. Evaluation of the Proposals may include the following criteria (not in any particular order):

- a) The Offeror's demonstrated ability to perform the requested services.
- b) The management team proposed to carry out the scope of work.
- c) Past performance of similar or relevant services in the region.
- d) The price and value for money of the requested services.
- e) Compliance with the terms set forth in this RFP.

1.12. Compliance with Anticorruption Laws

By submission of the Proposal, the Offeror represents and warrants that, in connection with this solicitation, the Offeror and any person or entity acting on its behalf has complied, and will continue to comply, with the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.) as amended ("FCPA"), and all other applicable anticorruption laws, rules and regulations. As a general description, the FCPA prohibits corruptly offering or providing money, gifts or anything of value, to foreign (i.e., non-U.S.) officials for the purpose of obtaining or retaining business, or to secure an improper advantage. Other applicable anticorruption laws may also prohibit bribery of foreign officials or commercial counterparties. The Offeror, if awarded the Project Verification contract, must notify the Secretariat immediately of any suspected or known violation of this warranty.

1.13. Anticorruption Compliance Certification

The Offeror is required to submit a completed and signed Anticorruption Compliance Certification (see Appendix 5).

1.14. Confidential Information

Notwithstanding any agreements, including any separate nondisclosure agreements, already in place between the parties, the Secretariat assumes no obligation regarding confidentiality of all or any portion of a Proposal or any other material **except** that the Secretariat may not disclose any portion, which the Offeror clearly designates as containing proprietary information by affixing the following paragraph **on the title page**:

"This proposal, where explicitly marked, includes data that shall not be disclosed outside of the AgResults Initiative and its respective advisors, consultants and contractors, and shall not be used or disclosed—in whole or in part—for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this Offeror as a result of—or in connection with—the submission of this proposal, the Secretariat shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Secretariat's right to use information contained in this data if it is obtained from another source without restriction."

The Offeror will 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 proposal.”*

Notwithstanding the foregoing, the Offeror agrees that its Proposal, including any portion containing confidential information, may be shared by the Secretariat with AgResults’ Financial Trustee, the AgResults’ Steering Committee and any or all Contributors to the AgResults Trust Fund. The Offeror’s Proposal may also be disclosed to third parties if required by order of a court, administrative agency or governmental body, or by any law, rule or regulation, or by subpoena, or any other administrative or legal process, or by applicable regulatory or professional standards; provided, however, that, to the extent permitted by applicable law, the Secretariat would use reasonable efforts prior to such disclosure to notify the Offeror and allow the Offeror to seek a protective order to restrict or narrow the disclosure in accordance with applicable law.

Appendix 2 AgResults Background

1. AgResults Background

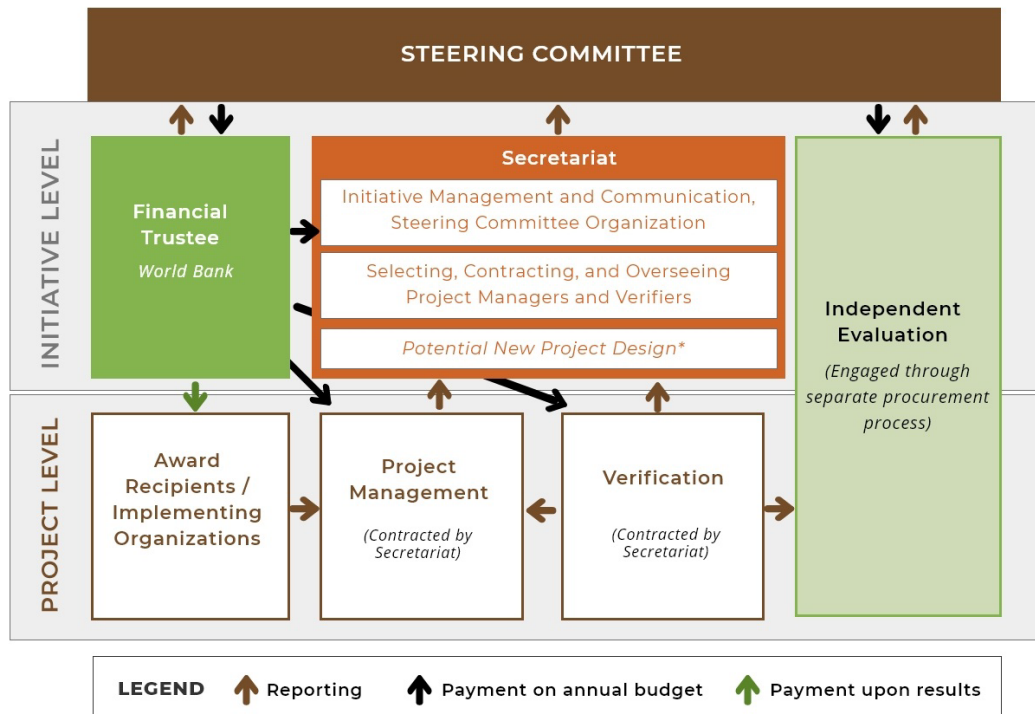
The AgResults initiative (“AgResults”) is a US\$152 million multilateral initiative financed jointly by the governments of Australia, Canada, the United Kingdom, the United States, and the Bill & Melinda Gates Foundation (each, a “Contributor”). AgResults seeks to increase private sector investment in food security and agriculture globally. AgResults establishes “pay-for-results” - economic incentives, or grants, that are provided to implementing organizations after achieving specific outcomes, where private sector investment is absent or hindered due to market uncertainties. In doing so, AgResults goes beyond traditional aid “push mechanisms” that provide funding, technical assistance, or other inputs to create development impacts. Instead, AgResults finances pay-for-results projects that define a development problem and pay only for development outcomes achieved. AgResults is currently implementing projects in East Africa, Tanzania, Indonesia, Senegal, as well as a global Brucellosis project.

Several different bodies are involved in implementing the AgResults Initiative:

- A **Steering Committee**, comprised of donor organization representatives and the Trustee, makes strategic decisions.
- The International Bank for Reconstruction and Development serves as the **Financial Trustee** of the AgResults initiative and, among other things, manages donor contributions in a trust fund, makes payments of the grants or prizes to the Competitors, and contracts with the AgResults Secretariat.
- Deloitte Consulting is the current AgResults **Secretariat** and during its appointment is responsible for designing new projects as well as oversight, monitoring, and coordination of implementation of the approved AgResults projects.
- **Competitors** are organizations that participate or compete in each AgResults project and receive performance-based grants or prizes based on achieved and verified results. In case of the FMD Vaccine Project, the Competitors are pharmaceutical companies that develop, register and commercialize vaccines for FMD in East Africa and that will participate in the Project.
- The Global Alliance for Livestock Veterinary Medicines (GALVmed) manages the implementation of the Project (referred to as the “Project Manager”).
- A Sales **Verifier** verifies, determines and certifies if Competitors have achieved the reported sales, which is required before any prize payments can be disbursed.
- In the case of the FMD Vaccine Project, a panel of 5 scientific, commercial, and animal health registration technical experts serve as “**The Judging Panel**”. They provide technical expertise at the end of the vaccine development stage of the Project to:
 - a. Verify Competitor registration compliance with the Project competition Rules,
 - b. Verify results of periodic vaccine quality testing conducted by appointed qualified laboratories.
 - c. Interpret the contest rules in the case of disputes.
- The Steering Committee will also contract an **Independent Evaluator** to measure impacts and to compare AgResults projects to traditional “push mechanism” development approaches.

The relationship among the key parties is illustrated below:

Figure 1: AgResults Initiative Structure



Appendix 3 Terms of Reference

1. Project Verifier Period of Performance

The Secretariat expects to award to the selected Project Verifier a Firm-Fixed-Price Contract for the Project verification services detailed in this RFP for a period of four years and ten months, subject to annual reauthorization in writing from AgResults:

- **Period of Performance:** November 1, 2024, to September 30, 2028

If AgResults, at its sole discretion, decides to exercise the next annual Period, the Secretariat will inform the Project Verifier no later than 30 days before the start of the annual Period to be exercised.

Payment of the Project Verifier's services under the contract will be made by the AgResults' Financial Trustee. The Trustee reserves the right to withhold from payment any taxes or similar fees as may be required by applicable law.

2. Project Overview

2.1 Project Background

FMD control in Eastern Africa is hindered by two interconnected challenges: a need for a high-quality vaccine and for stronger distribution networks.

Eastern Africa's FMD control challenge: Africa loses about US\$2.3bn annually due to FMD, with most of the economic burden falling on sub-Saharan Africa. In Eastern Africa, where FMD is endemic, outbreaks typically strike as waves of infection one to two years apart with outbreaks exacerbated when multiple serotypes or strains circulate concurrently. A suitable FMD vaccine does not exist for Eastern Africa because strains vary significantly in the region, making it difficult to develop an appropriate vaccine. Vaccines currently in use do not contain representative strains from all four serotypes circulating in the region, limiting their ability to provide protection against FMD.

The distribution challenge: The private sector across Eastern Africa has struggled to establish effective vaccine distribution networks. National governments currently control FMD vaccine purchases and are often reactive, creating unreliable market demand and hinging on political priorities. These factors combine to limit profitability and discourage investment among potential private sector players to manufacture and distribute vaccines.

Through a pay-for-results cost-share mechanism the Project aims to address these challenges by encouraging the development and uptake of high-quality vaccines tailored to meet the needs of Eastern Africa. The cost-share mechanism will reduce the cost-per-dose for FMD vaccine buyers, enabling public and private sector actors to better combat FMD through more consistent purchases of the new vaccines. This will also increase the market potential for vaccines in the region. Each sales period, the Project will commit to funding a portion of the purchase price of the vaccine for a specified volume of vaccine doses. The amount of funding will decrease each sales period to encourage the development of a sustainable market for FMD vaccines in Eastern Africa beyond the life of the Project.

2.2 Project Goals and Theory of Change

Through a pay-for-results mechanism the Project aims to achieve three objectives:

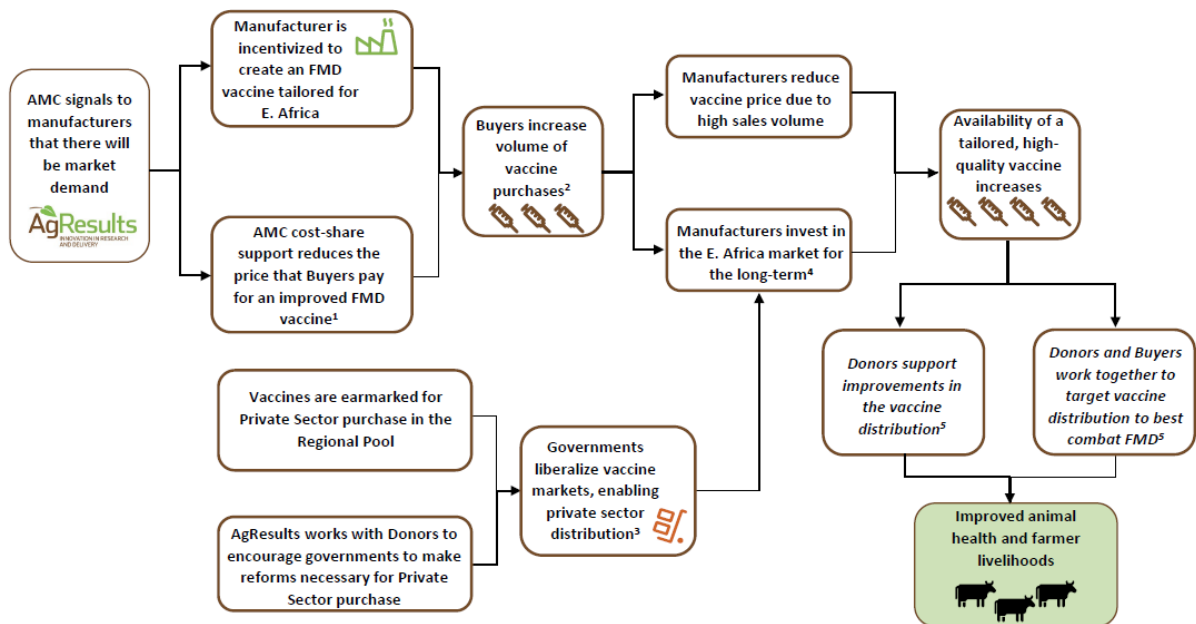
- i. Develop high-quality FMD vaccines, tailored for the needs of Eastern Africa
- ii. Increase vaccine production and regional purchases to create greater market stability and affordability
- iii. Encourage the development of a private sector model for buying and distributing FMD vaccines

The project's Theory of Change hypothesizes that by creating an attractive market for FMD vaccines tailored to Eastern Africa, vaccine manufacturers will be encouraged to develop a regionally relevant FMD vaccine. AgResults will work with private and public sector buyers to increase regional purchases and work towards a stable FMD vaccine market.

Once vaccines are developed and registered, the focus will shift to supporting the adoption of the approved vaccines in the region. AgResults has established a cost-share mechanism that will reduce the cost-per-dose for both public and private sector vaccine purchases. A subset of these vaccines will be earmarked for private sector purchase; at the same time, the project will work via donors to encourage government reform to liberalize the vaccine market. The combinations of these actions will further enable private sector distribution, driving the sales and reach of effective FMD vaccines, particularly among smallholder farmers. As sales volumes rise and prices fall, access will continue to climb, improving animal health and strengthening farmer livelihoods.

The project's Theory of Change is presented below as Figure 2.

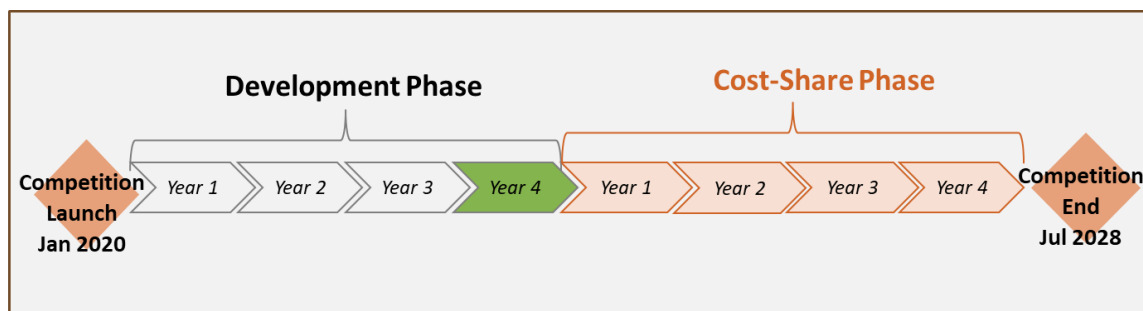
Figure 2: Project Theory of Change



2.3 Competition Timing and Stages

The Competition has two phases: (1) development and (2) cost-share. The overall Competition timeline is presented in Figure 3.

Figure 3: Competition Timeline



Phase 1: Development Phase

During the Development Phase, which began on February 7, 2020, animal health companies (potential Competitors) will work on the development of FMD vaccines tailored to the needs of Eastern Africa. The Target Product Profile (TPP), set out in the competition rules, defines the characteristics that a vaccine must meet, including standards related to safety, efficacy and utility in the smallholder farmer setting, to be eligible for the cost-share.

The Competition requires vaccines to be registered in at least one of the Project's target countries (Burundi, Ethiopia, Kenya, Rwanda, Tanzania, and Uganda), either through the East African Community Mutual Recognition Procedure (MRP) or individual country registration procedures. A vaccine developed by a Competitor that has complied with the Competition Rules and has been granted full product registration, defined as approval from the competent regulatory authority to market, sell and distribute an FMD vaccine in such country in the form of a marketing authorisation, product license or certificate of registration ("Product Registration"), in at least one of the target countries, and demonstrates compliance with all the Eligibility Requirements defined in the Competition Rules, as assessed by the Project's Judging Panel, will then be approved as eligible for the Cost-Share Phase of the Competition. Companies may submit an application from February 7, 2021 onwards. The first vaccine is expected to be approved by the Judging Panel within three to four years of the start of the Development Phase. This approval and the execution of the first Competitor Agreement between the applicable Competitor and GALVmed will trigger the start of the Cost-Share Phase. Additional Competitors may submit vaccine applications until July 31, 2027 and the Cost-Share Phase will end on July 31, 2028. All Competitors and their vaccines are required to adhere to the Eligibility Requirements throughout the life of the Project.

Summary of Vaccine Eligibility

✓	Vaccine Development to Target Product Profile (TPP) Standards: <ul style="list-style-type: none">• <u>Quadrivalent Vaccine</u> at least 6PD₅₀ containing serotypes A, O, SAT1 and SAT2 that match circulating Eastern African Foot and Mouth Disease Viruses• 12-month shelf life• 6-month duration of immunity• Differentiating Infected from Vaccinated Animals (DIVA) capability• Vial size to be appropriate for use by smallholder farmers in the region
✓	Vaccine Registration: must achieve full registration in at least 1 target country <ul style="list-style-type: none">• Target countries: Burundi, Ethiopia, Kenya, Rwanda, Tanzania, and Uganda• First vaccine was submitted for registration in Q4 2022
✓	Vaccine Approval: must be approved by AgResults Judging Panel <ul style="list-style-type: none">• Judging Panel is composed of FMD, industry and regulatory experts.• Judging Panel will review FMD vaccine applications and grant approvals to those that meet the eligibility criteria above.

Phase 2: Cost-Share Phase

Once the Judging Panel has approved the first vaccine and the applicable Competitor has signed a Competitor Agreement, the Cost-Share Phase of the Competition will commence. Other Competitors can submit applications for consideration by the Project's Judging Panel until July 31, 2027. The Cost-Share Phase is expected to begin three to four years after the start date of the Development Phase (February 7, 2020) and will end on July 31, 2028. The commencement of this phase will be announced via the Project's website (<https://www.galvmed.org/foot-and-mouth-project>), press releases and directly to those organizations that have signed up to the Project's mailing list. The Cost-Share Phase will be split into three (3) or more "sales periods," to be defined by GALVmed, which sales periods will also be announced via the Project's website at the same time as the commencement of the Cost-Share Phase is announced.

To support the adoption of new high-quality vaccines in the region, AgResults has established a cost-share mechanism to reduce the cost-per-dose, in accordance with the Competition Rules, for certain sales to both public and private sector buyers. During the Cost-Share Phase, AgResults commits to funding a portion of the purchase price of the vaccine for a specified volume of vaccine doses and will provide funding directly to vaccine manufacturers. Competitors will only be eligible to access the cost-share awards in countries where their vaccine has been granted full Product Registration. In recognition of the fact that the Government of Burundi is a signatory to the MRP but does not have a national regulatory authority, unless and until the Government of Burundi establishes a national regulatory authority for purposes of administering the MRP, sales of the FMD vaccine in Burundi will be considered to be made under a valid Product Registration if the manufacturer receives Product Registration for the FMD vaccine via MRP in other East African Community countries.

Quantifying the Cost- Share Support

The total value of cost-share support available through the Competition is \$15.8M.

During the Cost-Share Phase, the level of cost-share support will start at seventy-five percent

(75%) and gradually decrease each sales period, to help buyers prepare for price adjustments that will occur after the Project has closed. The Project will fund a portion (e.g., seventy-five percent (75%) in sales period 1) of the price of the vaccine up to a selling price of USD\$2.00 per dose. If the vaccine has a selling price above USD\$2.00, the buyer will pay the difference. The volume of doses eligible for the cost-share benefit will gradually increase over the Cost-Share Phase, up to five million in the final sales period.

As noted above, the timing and duration of the sales periods will be announced together with the start of the Cost-Share Phase, including the following information for each sales period: percentage of cost-share support (e.g., portion of sales price reimbursed through the Project) and volume of doses eligible for cost-share support.

Dose Allocations

Each sales period, AgResults will allocate a portion of the total available vaccine doses for individual target countries to use (**Country Reserves**) based on:

- a) countries which have or will have achieved Product Registration for the new vaccine(s),
- b) the individual country's share of the Region's cattle population, and
- c) discussions with each country's government.

There will also be a **Regional Pool**, available to buyers from countries with the registered vaccine(s), that provides access to additional cost-share doses beyond the Country Reserves. Forty percent (40%) of the total cost-share doses available in each sales period will be allocated to the Regional Pool and sixty percent (60%) will be allocated to the Country Reserves.

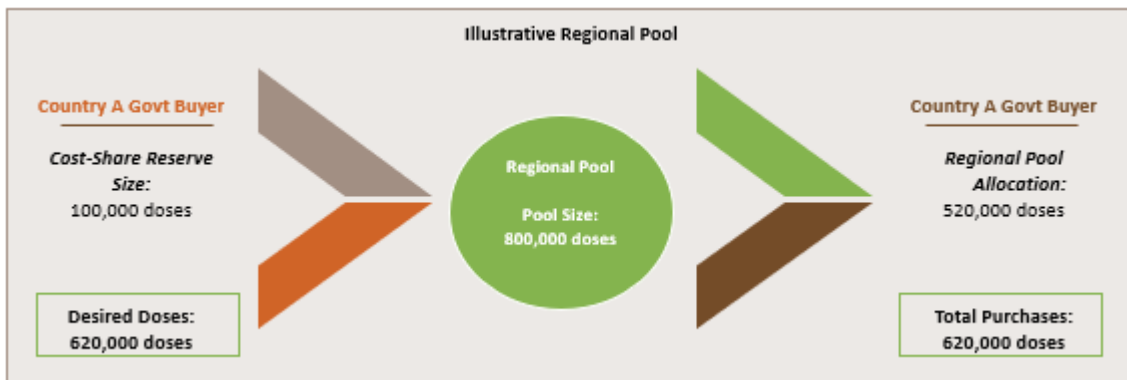
The Regional Pool will be available to public and private sector buyers (as described more fully in the Competition Rules) and has two main components:

- a) **Sector Agnostic Component:**
A portion of the pool available to any buyer (65%)
- b) **Private Sector Component:**
A portion of the pool available only to private sector buyers (35%)

The majority of the Regional Pool is available for use by any buyer; however, to encourage governments to create a regulatory environment that supports private sector involvement in vaccine distribution, thirty-five percent (35%) of the Regional Pool will be set aside for private sector purchase only, as described more fully in the Competition Rules.

Illustrative Regional Pool

If a country in the region wants to purchase more than the amount allocated in its Country Reserve, it may request additional vaccines from the Regional Pool, as detailed below.



During the Cost-Share Phase, the Project Manager will keep Competitors updated on the total number of doses available within the cost-share mechanism, together with the status of the Country Reserve and Regional Pool dose allocations.

2.4 Verification

Verification begins at the Cost-Share Phase. At this point the competition's Judging Panel reviews the manufacturer's application and provides a high-level decision on whether to allow the prospective manufacturer to proceed to the Cost-Share Phase as a Competitor. For example, the Judging Panel may determine that certain manufacturers have not met the competition requirements, such as achieving vaccine registration in one of the target countries or having a vaccine that satisfies the Project's TPP. Once the Judging Panel approves a manufacturer for participation in the Cost-Share Phase, the manufacturer will sign a competitor agreement to join the competition and be eligible for the cost-share. Once the competitor agreement is signed, they can begin selling vaccines to public and private sector purchasers in the Project's target countries. The Competitor will be eligible for quarterly cost-share payments upon verification of their vaccine sales.

AgResults will engage a competition Verifier that will provide comprehensive verification services to AgResults. The verification will be in place prior to the start of the Cost-Share Phase so that clear and transparent verification protocols can be communicated to competitors. Specifically, the Verifier will employ **Competitor Sales Audits** utilizing traditional financial audits to confirm the reported sales of vaccines. Sales auditing will occur on a quarterly basis.

After analysing the results of the sales audits, the Verifier will submit results, indicating which manufacturers distributed vaccines in what quantities, to what countries, and what payment amounts they should receive based on the price of the vaccine.

3. Project Verifier Responsibilities and Tasks

The Verifier Team will be responsible for carrying out the scope of work described in this section, utilizing the guidance given by the Secretariat and Project Manager, exercising the duty of care and professional skill expected of a professional firm.

3.1 Overall Responsibilities of Verifier

AgResults will engage a competition Verifier that will provide comprehensive verification services to AgResults. Specifically, the Verifier will develop a reporting and auditing procedure to track competitor sales of FMD vaccines to public and private purchasers in the Project's target countries.

The Verifier will develop a verification system that covers the following high-level tasks below:

- Obtain and review the following documentation for each sale made by a competitor during the verification period:

Buyer Category	Documentation Required from Manufacturer
Public Sector (Government) 1. Tender 2. Direct	1. tender award 2. purchase order 3. proof of fulfilment (invoice) 4. proof of delivery (delivery note) 1. purchase order 2. proof of fulfilment (invoice) 3. proof of delivery (delivery note)
Private Sector	1. proof of fulfilment (invoice) 2. proof of delivery (delivery note) 3. proof of payment

- Analyze the sale trends from one quarter to the next to detect abnormal activities.
- Determine total competitor sales to public and private sector purchasers during the verification period and tabulate potential competitor prizes based on the competition rules.
- Conduct periodic interviews with the Competitor and the competitors' LTRs to detect any inappropriate collusion or coordination during the competition.
- Once a year, review the annual order forecast forms for each competitor (requested by the manufacturer from the LTR and provided to the Project Manager) to confirm that the amount produced is consistent with the forecasted demand.
- After analyzing reported results, the Verifier will submit results, indicating which competitors sold vaccines in what quantities, to which countries, and the prize payment amounts they should receive.

The specific verification components are described in more detail below.

Sales Audits. For sales of vaccines, the Verifier will conduct sales audits to confirm that competitors' reported sales information is accurate. The Verifier will also obtain annual order forecast forms from the competitors' LTR(s) to confirm that reported sales figures are

reasonably aligned with the demand for vaccines. Irregularities between sales information and annual order form will be further investigated by the Verifier to prevent against competitor gaming or fraud.

Determination of Results. The Verifier will run progress reports, tabulate results and recommend awards on an ongoing basis, with reporting due to the Secretariat and Project Manager every three months during the competition period. This will enable the Verifier to monitor the sale of vaccines and identify any sales abnormalities on a periodic basis. The Verifier will tabulate results and recommend awards based on the corresponding cost-share benefit outlined in section 2.3.

Risk Management. The Verifier's work will confirm whether each competitor's self-reported sales are accurate so that incentive payments to the competitors are calculated and paid correctly per the contest rules. Therefore, it is critical that the Verifier develop appropriate checks to prevent potential abuse of the project by competitors, including:

- *Misstated quantities or sales values:* the risk that reported quantities and/or sales values are inflated by the Competitor, increasing their prize payment amount.
- *Risk of incomplete delivery:* the risk that reported sales of vaccines were only partially met. For a sale to be eligible, the vaccines must be paid for and received by the purchaser (in some cases, it could take several months for an order to be received by the purchaser depending on customs delays and other distribution issues).
- *Sales of counterfeit products:* the risk that reported sales were generated from sale of counterfeit products like vaccines that were not approved by the Judging Panel.
- *LTR collusion:* the risk that competitors and LTRs are placing higher sales than demanded within a certain country.

3.2 Verifier Detailed Tasks

The following are the proposed tasks that the Verifier will perform.

3.2.1 Verifier Orientation and Start-Up (within two weeks of signing of contract)

Activities to be carried out include:

- a) Hold an orientation meeting with the Project Manager to do the following:
 - i. Review verification objectives, the scope of work, approach, timelines and expected outputs.
 - ii. During this meeting, develop communication and feedback protocols for use during the assignment, including how to manage any significant issues or challenges that might arise during the assignment.
- b) Develop an overall detailed design of the assignment including a comprehensive work plan. The design shall describe the verification procedures to be employed, including:
 - i. Methodology for conducting sales audits.
 - ii. Quality control mechanisms to be employed by the Verifier in carrying out the assignment.
 - iii. Any verification reporting templates to be used.
 - iv. The design and work plan will be reviewed and approved by the Project Manager and the Secretariat.

3.2.2 Competitor Verification Planning (corresponding with the period prior to the first sales period; to be determined once a competitor application is submitted and on an ongoing basis thereafter based on competitor acceptance into the competition)

Activities to be carried out include:

- a) After competitors have been accepted into the competition, work with Project Manager to inform competitors of sales reporting responsibilities, including dissemination of any preferred data reporting tools and templates. This will be repeated with each new competitor entering the competition.
- b) Based on each competitor's registered and Judging Panel-approved vaccine, hold a virtual meeting with each competitor to review and document operations, management, and accountability systems and controls, including:
 - i. Review competitors' pricing strategies and distribution supply chains.
 - ii. Document competitor controls and accountability measures to avoid fraud and gaming that could imperil the verification objectives in Section 3.1.
 - iii. As per the International Standard on Auditing (ISA) 550, identify the related party's relationships and transactions in relation to risks of material misstatement associated with related party relationships and transactions.
 - iv. Identify potential risks inherent in the operations systems for each competitor as they relate to the Project.
 - v. Develop a detailed verification program for each competitor. This will include the plan for documentation review and LTR interviews.

3.2.3 Detailed Competitor Sales Verification Activities -corresponding with each sales period; Sales Period 1 is 18 months and all subsequent Sales Periods are 12 months or less. The actual dates for the sales period will be determined based when the project approves its first competitor.

Activities to be carried out include:

- a) Oversee submission of sales data by each competitor through regular reporting, to include the following:
 - i. Purchaser information, including name, phone number, geographic location, sector (public or private sector), and other information to be defined prior to competition start.
 - ii. The volume and price of vaccines sold, as well as the country they were sold to.
- b) Obtain signed competitor self-reported sales reports for the verification period and validate against the documents and activities below. Each sales report for each competitor to include the following:
 - i. The volume and price of vaccines sold, as well as the country and buyer they were sold to.
- c) Test internal control systems for initiation, review, approval and processing of payments. Activities to be carried out include:
 - i. Obtain and review written competitor policies or management representations on specific controls.
 - ii. Conduct interviews with operational staff to ensure that competitor policies are understood by the staff.
- d) Verify customer validity (the customer will usually be the LTR but in some cases the sale may be direct to a government or private buyer):

- i. Review the competitors' customer sales documents – purchase order forms and corresponding shipping documents, requisition forms, emails, letters etc. to confirm that customers are valid entities and not fictitious.
- ii. Flag and investigate any suspicious sales that are initiated by the competitor and/or their project partners.
- e) Verify and reconcile billing documents:
 - i. Reconcile sales recorded via billing documents such as invoices, bank transfer forms, or similar documents with the originating customer sales order.
 - ii. Flag and specifically investigate completed sales forms that are not supported by customer sales documentation.
 - iii. Verify that all competitor's customer billing documents for the reported sales are supported with proper shipping and delivery documentation including a stamped invoice and a Goods Received Note.
- f) Sales book/ledger audit:
 - i. Check that sales ledger entries are referenced to valid invoices if possible.
 - ii. Flag and specifically investigate sales ledger entries that are not supported by valid invoices.
- g) Reconciliations:
 - i. Reconcile sales back to the bank records and report any un-reconciled sales.
- h) Inquire into overdue Credit Sales and Bad Debts:
 - i. Obtain a debtor listing, aged as per the competitor's policy.
 - ii. Determine the reason for delinquency and retrace the delinquent sale to its initiation.
 - iii. Obtain a list of bad debts and determine the reason for non-collectability, re-tracing the sale to its initiation.
 - iv. Check for any provision for bad debts and query the reasonability of the assumptions behind such provision, and the adequacy of the provision.
 - v. Remove overdue credit sales from Implementer sales reports.
- i) Analyse the trend of sales from one reporting period to the next and point out instances of unusual activity.
- j) Obtain a listing of, and investigate reasons for, any payments made by the competitor to the LTR or any other customers.
- k) Conduct periodic phone call spot checks to vaccine purchasers, such as the LTRs, to cross-check the volume and sale price of vaccines recorded by the competitor in their sales report.
- l) Gather any other relevant and sufficient evidence to substantiate in all material aspects the accuracy of each competitor's sales documentation.

3.2.4 Sales Verification Reporting and Dispute Resolution

Upon verification of each competitors' sales reports for each sales period, the Verifier will undertake the following tasks:

- a) Every three months during the competition period, prepare a draft verification report for each competitor showing the results of the sales verification in the following format:
 - i. The total number of vaccines that were verified differentiated by country, sector (public or private) and price.
 - ii. The total amount of sales deemed by the Verifier, based on the applied verification method, to have met the Project's criteria for valid sales.
 - iii. The total amount of ineligible sales and reason(s) for such ineligibility.
 - iv. Specifically highlight the number of ineligible sales suspected to be fraudulent.
 - v. Recommendation for awards payments based on the verified sales in accordance with the Project's competition rules.
- b) Present and discuss the draft reports with the Project Manager and Secretariat.

- c) After approval by the Secretariat, present the individual draft reports to each competitor, and provide an opportunity for the competitor to explain any discrepancies as needed.
- d) At the end of each competition sales period, present a consolidated Verification Report for each competitor to the Project Manager and the Secretariat summarizing the total number of valid sales, broken out by country, sector (public or private) and price, the total prize payments recommended throughout the year, and the total number of ineligible sales.
- e) Be available to answer verification-related queries and help to resolve verification-related disputes arising from the competitors:
 - i. Disputed Verifier findings will be reviewed by the Secretariat.
 - ii. Per the dispute mechanism in competitor agreements, the Secretariat may request the Verifier to re-examine their results.
- f) Hold weekly calls with Project Manager to provide updates of:
 - i. Summary of ongoing verification work;
 - ii. Any significant issues and challenges experienced with the competitors, how the challenges were resolved or are proposed to be resolved;
 - iii. Any anticipated delays in completion of the verification and plans for mitigating such delays.

3.2.5 Data Quality Control

The Verifier team will be responsible for data quality control of the competitor verification reviews. In particular:

- i. The Verifier must demonstrate independence, integrity, ethics and objectivity
- ii. All verification working papers prepared by members of the Verifier team should be reviewed and approved by a senior member of the team other than the preparer.
- iii. A checklist should be prepared by the Verifier's Team Leader in advance to guide field staff in identifying significant matters (including potentially fraudulent competitor practices) and escalating them to the Team Leader.
- iv. The Verifier must create and retain complete and well referenced verification documentation and records.

4. Verifier Deliverables and Reporting

The table below lists the deliverables and minimum reporting requirements. This list is not intended to be exhaustive or restrictive but provide the Verifier with reporting expectations. Before submitting the reports and deliverables, the Verifier will submit reporting templates for approval.

Table 1: Deliverables and Reporting Requirements

Corresponding Task	Deliverables Required	Due Date
Verifier Orientation and Start-up (3.2.1)	<p>Detailed design of the assignment including a comprehensive work plan. The design shall describe the verification procedures including:</p> <ul style="list-style-type: none"> • Methodology for conducting sales audits. • Quality control mechanisms to be employed by the Verifier in carrying out the assignment. • Any verification reporting templates to be used. 	Two weeks after date of fully executed contract

Competitor Verification Planning (3.2.2)	<ul style="list-style-type: none"> Detailed verification program for competition based on competitors and where they plan to sell their vaccines. This will include the plan for obtaining the necessary sales data and conducting documentation review. 	Before start of Sales Period 1 and ongoing basis thereafter
Periodic Competitor Sales Verification Activities and Reporting (3.2.3/ 3.2.4)	<p>Verification report for each Competitor showing the results of the sales verification in the following format:</p> <ul style="list-style-type: none"> The total number of sales that were verified differentiated by country and sale price. The total amount of sales deemed eligible based on the applied verification method to have met the Project's criteria for valid sales. The total amount of ineligible sales and reason(s) for such ineligibility. Specifically highlight that number of ineligible sales suspected to be fraudulent. Recommendation for awards payments based on the verified sales in accordance with the Project's competition rules. 	Every three months during competition period
Consolidated Sales Period Verification Report (3.2.4)	Consolidated Verification Report for each Competitor to the Project Manager and the Secretariat. This report will include verification results for each sales period including the total number of valid sales, broken out by country and price, the total prize payments recommended throughout the year, and the total number of ineligible sales.	30 days after end of each sales period

5. Illustrative Timeline

The following is an illustrative timeline of activities for the first 18 months of the Project. This is presented as an illustrative example. Offers may modify this timeline according to the proposed solution. Please note, these timelines will be superseded by the work plans submitted by and agreed with the Verifier.

Illustrative Timeline	2024				2025				2026									
	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A
Verifier Orientation and Start-Up (3.2.1)																		
Orientation by PM Team																		
Develop overall design for the assignment, including work plan																		
Competitor Verification Planning (3.2.2)																		
Support competitor training on verification																		
Meet with competitors to review systems and identify risks																		
Finalize competitor verification plans																		
Detailed Competitor Sales Verification Activities (3.2.3)																		
Review competitor self-reported sales reports																		

- Ensure all audit papers are well organized and preserved
- Kenyan nationals preferred.

Appendix 4 Proposal Requirements

Proposal Requirements

1. Technical Proposal

Offerors are required to address the components below in a response limited to fifteen (15) pages, notwithstanding the separate annexes outlined below that will not count towards the page limit. Any specific additional page limits for annexes are noted below.

1.1 Technical Approach and Methodology

- A) The offeror shall present their overall approach to implementing the AgResults FMD Project Verifier role. In particular, the offeror shall demonstrate the following:
- a. Technical understanding of the project and Terms of Reference;
 - b. A clear, logical approach to implementing the project Terms of Reference, particularly with balancing the different verification methods required.
 - c. Sound, objective, and transparent methodology for verifying results and proposing prize awards.

1.2 Corporate Capability and Past Experience

- A) The offeror shall provide a statement of Corporate Capabilities included as part of the technical proposal response. Included in this statement, **the offeror must provide evidence of an existing presence and registration in Kenya.**
- B) In an annex, the offeror shall also provide three past performance references related to the efforts identified in the Terms of Reference. Each reference in the annex should be no more than two pages. These references should identify the specific role the offeror played in each project, particularly if they were part of a larger team.
- Please provide a description of the services, name(s), e-mail addresses, and phone numbers of the client(s)/customer(s) to whom the services were provided, dates and periods during which the indicated services were provided, and the extent and nature of services provided. (The Offeror consents to the AgResults Secretariat contacting and verifying these references at its discretion.)
- C) In an annex, the Offeror shall also provide a one-page list of relevant ongoing and past projects or activities, with budget amounts, duration and total level of effort provided for the past five (5) years or more if relevant.

1.3 Personnel and Management

The Offeror should provide the information indicated below about the proposed staffing and management structure required for executing the Verifier activities. All key personnel should be indicated in the Proposal and their commitment confirmed (future substitution of such personnel will be subject to the Secretariat's written approval). The Secretariat or its designee reserves the right to interview the Lead Verifier and other individuals as part of the selection process.

1.3.1 Key Personnel – Position Requirements

- a) The Offeror shall provide as an annex to the technical proposal a list of any proposed key staff by specialty and include CVs recently signed by the proposed professional staff and authorized representatives submitting the proposal. The key information should include number of years working for the firm/entity and degree of responsibility held in various assignments and relevance of their experience with respect to the requirements set forth in Section 3. The Offeror should list the tasks that will be assigned to each proposed key staff team member.
- b) The minimum list of key positions and their qualifications are listed in Section 3.

The Offeror will include an explanation of the structure of the performing team (the key personnel and Support staff – see 1.3.2). If the Offeror proposes a different configuration, it should be included in the personnel section and justified.

1.3.2 Support Staff

Key Personnel are accountable for all verification tasks described in the Scope of Work. The Offeror must provide a summary of other staff, if any, that will have a role in the work and/or in supporting any of the Key Personnel. Please state the role, for which the individual is being proposed, how his or her qualifications correspond to that role, and provide a summary description of the individual and attach detailed CVs. Staff named in the proposal will be expected to be available to start performing the work upon contract award.

It is expected that for the purposes of verification field work, the Offeror would appoint Verification Assistants (equivalent of Audit Assistants), who would be persons with at least bachelor's degree and 1-3 years of experience in audit or work similar to this assignment.

1.4 Illustrative Year 1 Work Plan

Building off the proposed Project Timeline in Figure 3 as well as the details provided throughout the RFP, the Offeror must propose an illustrative Work Plan for Year 1, with activities defined monthly, for the activities described in the Terms of Reference in Appendix 3. Offerors must include an estimated timing of major activities, deliverables, and interaction with other entities. Upon award, a definitive Year 1 Work Plan will be required within 30 days for discussion and approval by the Secretariat.

2. Cost Proposal

The Offeror shall submit a separate file containing a full Cost Proposal on a **firm-fixed-price basis**, using the provided fixed-price cost template along with any information to support and justify the proposed costs. The cost response should include all fees and expenses, including any taxes, for the entire contract period, as well as on a per-year basis, as per the Terms of Reference and following the cost template.

The Price Proposal should cover all activities detailed in the Scope of Work in Appendix 3.

The price proposal should - at a minimum - include a breakdown of anticipated costs as follows:

- a) Labor costs based on fixed daily rates for each labor category, utilizing the Verifier Pricing Template in Appendix 5.
- b) Any other additional expenses related to the assignment fully broken down

Notes:

- Proposed payments will be made quarterly and tied to deliverables proposed by the Project Verifier in the submitted illustrative Work Plan.
- All expenses should be listed separately, with sufficient detail to allow for evaluation as to the reasonableness of the items proposed.
- In budgeting for this project, assume two competitors in Sales Period 1, three in Sales Period 2, four in Sales Periods 3 and 4.
- Offerors should include notes on labor and other direct cost assumptions to justify the expenses.
- All prices shall be quoted in US dollars.
- Offeror is responsible for any applicable taxes and similar fees (those are deemed included in the proposed fixed price). Deloitte Consulting cannot confer any special tax- or duty-free status.
- Payments to the selected Offeror will be made after receipt of the deliverables by the AgResults Secretariat and will come from the World Bank-administered Trust Fund.

3. RFP Schedule of Events

1. **Deadline for Proposals**, with all required signatures, including a completed and signed Anticorruption Compliance Certification, is no later than 1700 Hrs. US Eastern Time (US ET) on **July 5, 2024**. Proposal documents should be submitted in one email to info@agresults.org. Please indicate “FMD Project Verifier RFP” in the subject line of the email.
2. **Questions** concerning the Project, or this RFP may be submitted by vendors at any time, but no later than 1700 Hrs. US Eastern Time (US ET) on **June 10, 2024** to info@agresults.org. Please indicate “FMD Project Verifier RFP Questions” in the subject line of the email.
3. **Answers** to timely-received questions will be posted on the AgResults website no later than 1700 Hrs. US Eastern Time (US ET) on **June 14, 2024**. Answers to questions will be posted on <https://agresults.org/news-and-blog/10-blog/request-for-proposals-for-verifier-services-for-the-fmd-vaccine-challenge-project>.
4. The Secretariat expects to award the FMD Project Verifier’s contract by **September 15, 2024** with an expected contract start date of **November 1, 2024**.

Appendix 5

Anticorruption Compliance Certification

AgResults requires full compliance by the Offeror with the U. S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.) as amended (“FCPA”), and all other applicable Anti-Corruption laws, rules and regulations.

The anti-bribery provisions of the FCPA make it illegal to offer, promise, authorize, or provide anything of value, either directly or indirectly (e.g., through third parties), to a Foreign Official (as defined below) for the corrupt purpose of (1) influencing an official act or decision; (2) inducing the Foreign Official to do or omit to do anything in violation of his lawful duty; or (3) securing an improper advantage; in each case in order to assist in obtaining, retaining, or directing business to anyone.

Under the FCPA, a Foreign Official includes not only a person who performs traditional governmental or administrative functions, but also any member of a royal family or an employee of an entity in which a governmental body has an ownership interest (even a minority interest). Such employee could still qualify as a Foreign Official even if he or she performs business-related functions as an employee of such entity engaged in commercial, rather than governmental, activities.

To facilitate the Offeror’s understanding and compliance with obligations set forth in this clause, ‘Foreign Official’ is hereby defined for the purposes of this clause to include:

- Any officer or employee of a non-U.S. government (including any non-U.S. military personnel) or any of its departments or agencies or incorporated entities (including state-owned enterprises);
- Any director, officer, or employee of any legal entity or joint venture that is controlled or significantly owned by a non-U.S. government (including any non-U.S. military personnel) or any of its departments or agencies or incorporated entities (including state-owned enterprises);
- Any officer or employee of any public international organization (e.g., the United Nations or World Bank);
- Any person that represents or acts on behalf of, or in an official capacity for, any non-U.S. government or any of its departments or agencies or incorporated entities (including state-owned enterprises), even if honorary;
- Any non-U.S. political party or party official or candidate for non-U.S. political office;
- Any member of a royal family; and
- Any member of a non-U.S. legislative body.

The Offeror understands that prohibited payments or offerings under the FCPA need not take the form of cash or cash equivalents. For the purposes of this clause, and in line with the FCPA, the reference to ‘anything of value’ is construed broadly and covers any tangible benefit of any kind, including, without limitation, cash or cash equivalents, gifts (including, but not limited to, gifts or courtesies of local custom, wedding and personal gifts, jewellery), political contributions, donations to charities at the behest of a Foreign Official or his/her family, entertainment (including, but not limited to, meals and tickets to events), travel and travel-related expenses, hospitalities (including, but not limited to, accommodation), ownership rights in joint ventures or other entities, inflated or excessive contract prices, loans and employment (whether long-term or temporary). Even if any payments or gifts are a customary part of the culture of a particular country, they may be prohibited under the FCPA. In addition, providing

or offering gifts, payments or other benefits to another person for an improper or corrupt purpose may violate not only the FCPA but also other similar anti-bribery laws and regulations.

Moreover, certain laws and regulations, that may be also applicable in connection to the Project Verifier’s activities, prohibit bribes or kickbacks in the private sector and regulate, among other things, whether gifts, entertainment or employment may be provided to U.S. government officials. Offeror shall comply with all such applicable laws and regulations.

Therefore, in connection with the submission of this proposal for participation in the AgResults FMD Vaccine Project, the Offeror shall not cause the Secretariat, or any other entity associated with the AgResults Initiative to be in violation of the FCPA or any other applicable anticorruption laws or regulations. The Offeror must refrain from either directly or through others, making or offering to make bribes, kickbacks or other corrupt payments or provide anything of value to a Foreign Official or anyone else for purposes of influencing them to benefit the Secretariat or any other entities associated with AgResults Initiatives, the Offeror, or any other party.

The Offeror shall notify the Secretariat immediately if it learns of any violations of the FCPA or any other anticorruption laws in connection with the Offeror’s involvement in the AgResults FMD Vaccine Project. Notifications can be made to Secretariat through email: info@agresults.org. Notifications can be also made anonymously through the website www.integrityhelp.com, or by calling +1 866 850 1485 (within the U.S.) or +1 503 748 0570 (outside the U.S.).

Compliance Certification

By my signature, I certify as an authorized representative of Offeror, that in connection with the preparation and submission of this proposal, the Offeror has complied with and will comply with the U. S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.) as amended (“FCPA”), and all other applicable anticorruption laws, rules and regulations.

For and on Behalf of Offeror:

Name _____

Title _____

Organization _____

Signature _____

Date _____

Appendix 6 Pricing Template

See attached.