

AgResults Foot and Mouth Disease Vaccine Challenge Project Competitor Request for Applications Transmittal Letter
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July 1, 2020

Dear Company Representative:

On behalf of the **AgResults Foot and Mouth Disease (FMD) Vaccine Challenge Project**, the Project Manager, GALVmed, invites your organization to participate in a prize competition through which the Project aims to test a Pay-for-Results mechanism to increase the adoption of FMD vaccines tailored to the needs of Eastern Africa, specifically Burundi, Ethiopia, Kenya, Rwanda, Tanzania, and Uganda.

GALVmed is calling for applications from potential Competitors who are established animal health companies with experience and expertise in FMD vaccines.

The below Request for Applications outlines the competition background, objectives, and rules, and includes an application form. In submitting an application, your organization consents to the Request For Applications terms, including the Competition rules, application procedures and instructions.

Please note that an online portal for submitting applications, with all required signatures and certifications, is available on the Project website (<https://www.galvmed.org/foot-and-mouth-project/>). We encourage you to submit an application and join us for a chance to contribute to the control of FMD in Eastern Africa.

Should you have any questions or comments please direct them to the AgResults FMD Vaccine Challenge Project team at: FMDchallenge@galvmed.org. We look forward to cooperating with you on this important project.

Sincerely,

Nina Henning
Project Manager Team Lead
AgResults FMD Vaccine Challenge Project

Request for Applications

Foot and Mouth Disease Vaccine Challenge Project

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Point of Contact:

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This is a Request for Applications (“RFA”) from qualified and eligible organizations to participate as competitors (“Competitors”) in the AgResults Foot and Mouth Disease Vaccine Challenge Project (“Project”). This is an eight-year, US \$17.68 million prize competition (“Competition”) that supports the development and uptake of high-quality FMD vaccines tailored to meet the needs of Eastern Africa, targeting in particular: Burundi, Ethiopia, Kenya, Rwanda, Tanzania and Uganda.

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 that uses Pay-for-Results prize competitions to incentivize, or “pull”, the private sector to overcome agricultural market barriers by investing in innovative research and delivery solutions that improve the lives of smallholder farmers. In doing so, AgResults goes beyond traditional “push”, or upfront grant funding by harnessing private sector competition and innovation in spurring sustained market improvement. AgResults is implementing its first livestock vaccine project for Eastern Africa, the “AgResults FMD Vaccine Challenge Project”.

The objectives of AgResults are to:

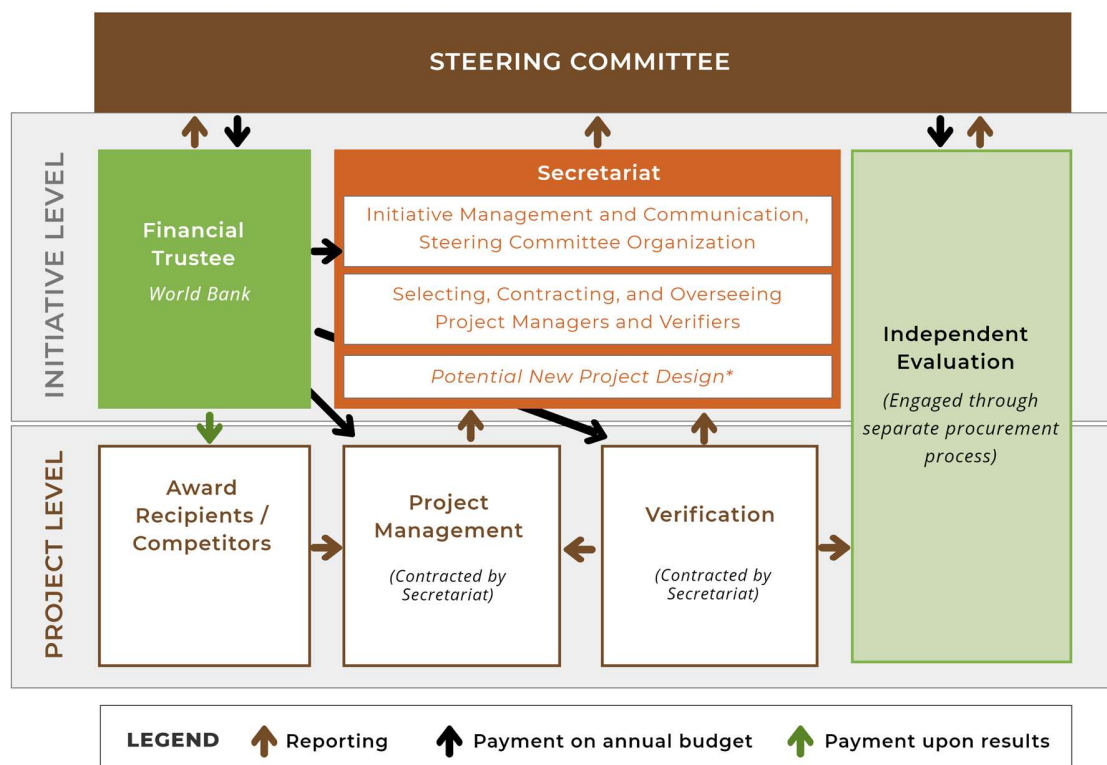
- (1) **Overcome market failures impeding agricultural innovations** by offering results-based economic incentives (known as Pay-for-Results mechanisms) to competing private actors for the adoption of new agricultural technologies; and
- (2) **Test the effectiveness and efficiency of Pay-for-Results financing** in comparison with traditional approaches to the promotion and adoption of innovative agricultural technologies.

Several different bodies are involved in implementing AgResults:

- AgResults **Steering Committee**, comprising donor organization representatives and the Trustee, makes strategic decisions.
- The International Bank for Reconstruction and Development (IBRD, “The World Bank”) serves as the **Financial Trustee** of the AgResults initiative, manages Donor contributions in a trust fund, and manages disbursement of the prizes to the Competitors in accordance with the respective project terms, and contracts with the AgResults Secretariat and an Independent Evaluator.
- 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.
- The Global Alliance for Livestock Veterinary Medicines (GALVmed) manages the implementation of the Project (referred to as the “Project Manager”).
- **Competitors** are organizations/companies that participate in the sales of input bundles and receive performance-based prizes if the results are achieved and verified.
- A **Sales Verifier** verifies, determines, and certifies for the Project Manager whether the Competitors have achieved the reported sales, which is required before any prize payments can be disbursed.

- 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 these parties is illustrated below:



2. AgResults FMD Vaccine Challenge Project Objectives

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

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

To achieve this, the Project will utilize a cost-share mechanism that reduces 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.

3. AgResults FMD Vaccine Challenge Project Overview

There are two Project phases: (a) development and (b) cost-share.

3.1 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 attached as Annex 1 (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 January 31, 2028 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: • TPP details the specific elements required, including valency and efficacy testing.
✓	Vaccine Registration: must achieve full registration in at least 1 target country • Target countries: Burundi, Ethiopia, Kenya, Rwanda, Uganda and Tanzania • Registration can be achieved either through the Mutual Recognition Procedure (MRP) or through individual country registration (Ethiopia must be done individually). • Manufacturers must notify the Project Manager (GALVmed) when they are submitting an FMD vaccine dossier for Marketing Authorization to at least one target country to prevent termination of the project.
✓	Vaccine Approval: must be approved by AgResults Judging Panel • 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

3.2 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 January 31, 2028. The

Cost-Share Phase commenced on October 1, 2024 and will end on July 31, 2028. The Cost-Share Phase is 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.

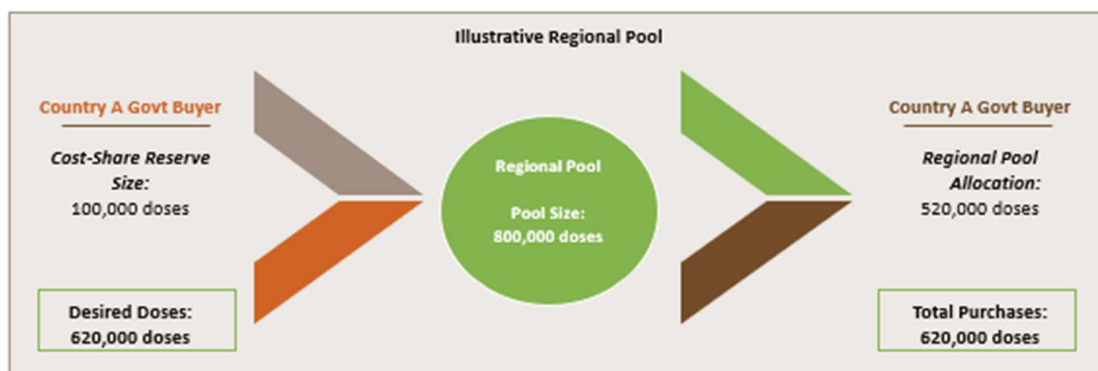
The Regional Pool will be available to public and private sector buyers (as described more fully in the Competition Rules) and has two main components:

- 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.

4. Competitor Application for Participation in the Project

4.1 Interested Organizations

All interested animal health companies should notify the Project Manager.

Informal notification of a company's intention to participate in the Competition ("Expression of Interest") is encouraged at any time and should be indicated by signing up to the Project's mailing list on the website (<https://www.galvmed.org/foot-and-mouth-project/how-to-engage/>) which will allow interested companies to be kept informed about important Project developments and milestones.

The first formal notification required for participation in the Competition is to advise the Project Manager of the submission of an FMD vaccine dossier for Product Registration in at least one of the target countries.

Eligible organizations interested in participating in the Project as Competitors must complete and submit the **application, required supporting documentation and Anticorruption Compliance Certification via the secure online portal (<https://fmdapp.galvmed.org/>)**. This submission should be made once a vaccine meets all of the Eligibility Criteria set out in the Competition Rules (Annex 1). Applications may be submitted from February 7, 2021 for consideration by the Project's Judging Panel. Organizations may apply to join the Project until January 31, 2028.

4.2 Cost of Participation

Applying organizations will bear all their costs associated with applying for and participating in the Project.

4.3 Confidentiality

Non-public information in the applications submitted by the interested organizations shall be marked as proprietary or confidential. Such information will be treated as confidential in accordance with Section 7 of the Competition Rules.

4.4 Selection and Participation in the Project

Selected Competitors will be expected to sign a contractual agreement (Competitor Agreement) to confirm their participation in the Project and agreement with the Competition Rules.

The Project Manager reserves the right to terminate participation of any selected Competitor if the Project Manager, in its sole discretion, determines that the Competitor:

1. has engaged in corrupt, fraudulent, collusive, or coercive practices in the performance of the Competition,
2. if the performance of the Competition by such Competitor would be in conflict with law or
3. if the Competitor's activity or conduct in relation to the Competition may adversely affect the integrity of the Competition or the name or reputation of the other Competitors, GALVmed and/or other AgResults Entities.

4.5 Associations, Joint Ventures or Consortiums for Project Purposes

Organizations may formally associate or form consortia or joint ventures for the purpose of participating in the Project as a Competitor. Competitors may only participate in the Project independently or in one association, joint venture or consortium for the purposes of the Project and cannot concurrently apply as a member of other participating groups. The association, joint venture or consortium members shall

designate a lead member who will be authorized to bind the association, joint venture or consortium and who shall submit the Competitor application on their behalf and together with duly signed and notarized authorization (submitted in hard copy) granted by all other members authorizing the lead organization to represent them in all matters related to the Project, including signature of the Competitor Agreement and receipt of any prize. The named lead member will be the sole point of contact with respect to any communications or actions by or concerning AgResults entities, including the Project Manager, Secretariat, Steering Committee, Trustee and Sales Verifier organization(s). The composition or the constitution of the association, joint venture, or consortium shall not be altered without the prior consent of the AgResults Secretariat. Any legal services or fees involved in partnerships or litigation will be solely the responsibility of the Competitors involved.

5. Application Instructions and Evaluation

5.1 Application Instructions

Interested organizations must complete and submit an **application, required supporting documentation and Anticorruption Compliance Certification via the secure online portal (<https://fmdapp.galvmed.org/>)**. Questions concerning the Project or this RFA may be submitted to the Project Manager Team Lead at FMDchallenge@galvmed.org.

- Applications will be reviewed by the Judging Panel, composed of FMD, industry and regulatory experts. The Judging Panel reserves the right to request additional information from applicants as necessary to make an informed final decision.
- The Judging Panel will review applications quarterly to determine whether the applicable applicants' FMD vaccine(s) meet the Eligibility Criteria.

In order to be accepted for evaluation, applications must include the following information, all of which shall be submitted via the secure online portal (<https://fmdapp.galvmed.org/>):

- An online **application form**. It must be fully completed in the English language with all compulsory questions answered and all relevant information included.
- **All documents that demonstrate compliance with the Eligibility Criteria**, as specified in Section 3.1 of the Competition Rules (Annex 1), and as requested as part of the application form. This must include a copy of the applicable Product Registration approval documents (marketing authorisation, product license or certificate of registration), all related documentation received from the applicable regulatory authority (including, but not limited to, the summary of product characteristics, product literature and labelling), a copy of relevant manufacturing authorisation(s) as evidence of compliance with the principles of GMP throughout the process of manufacture, and any other data the Competitor determines is relevant to provide evidence that the product as registered meets the requirements of the Target Product Profile. For clarity, as set forth in the Target Product Profile, with respect to testing for vaccine valency, data demonstrating compliance must be generated by an approved laboratory using batches of product shown to comply with the terms of the marketing authorisation. An approved laboratory is one that: (a) has the capabilities to test against the full approved Eastern African FMDV Reference Antigen Panel set forth in the Target Product Profile and (b) is neutral,

independent, impartial and conflicts-free (including that such laboratory may not have any financial interest in the applicable Competitor or vaccine and may not hold any intellectual property with respect to such vaccine). As of October 1, 2022, the following AgResults-approved laboratories have indicated that they can provide the capability and capacity required, and are willing to participate in the testing against the Eastern African FMDV Reference Antigen Panel:

- World Reference Laboratory for FMD (WRL-FMD), Pirbright,
- OIE Collaborating Center for Validation, Quality Assessment and Quality Control of Diagnostic Assays and Vaccine for Vesicular Diseases in Europe, Sciensano, Belgium

Approval for inclusion of additional laboratories for the provision of testing services against the Eastern African FMD panel will be at the discretion of the AgResults FMD Project Technical Committee. Laboratories approved for this testing will be identified on the Project website: <https://www.galvmed.org/foot-and-mouth-project/resources-potential-competitors/>

- A completed **Anticorruption Compliance Certification** as provided in the application form.
- Any additional documentation deemed necessary by the Judging Panel.

Upon receipt of an application, GALVmed will review the application to determine its completeness in accordance with the above and will notify the applicant of their determination within thirty (30) days of submission.

5.2 Application Evaluation

Once GALVmed deems an application to be complete, the Judging Panel will be convened to review the application and determine whether the FMD vaccine meets the Eligibility Criteria as described in Section 3.1 of the Competition Rules (Annex 1) and as follows:

- All research, development and manufacturing for the FMD vaccine has been conducted rigorously and safely in compliance with the general and FMD-specific guidance provided in the 9th Edition of the World Organization of Animal Health (WOAH) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2024 (as may be updated or amended), and all biosafety, biosecurity and legal requirements that are applicable to the locations where any of these activities take place.
- The FMD vaccine has received full product registration in at least one of the target countries (Burundi, Ethiopia, Kenya, Rwanda, Tanzania and Uganda). Product registration may be obtained through (a) the MRP and/or (b) individual country registration(s). In recognition of the fact that the Government of Burundi is a signatory of 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 Competitor receives Product Registration for the FMD vaccine via MRP in other East African Community countries.
- The FMD vaccine satisfies the Target Product Profile set forth on Schedule 1 of the Competition Rules.

Applicants must have no contact with the Judging Panel prior to or during the application review process. The Judging Panel may request additional information from the applicant to assist with their

evaluation. If the information is not provided within thirty (30) days of the Judging Panel's request, GALVmed will reject the application.

The Judging Panel will approve applications for FMD vaccines that it determines, in its sole discretion, meet the Eligibility Criteria, and GALVmed will promptly notify each applicant of the Judging Panel's decision.

If the Judging Panel determines that an applicant's FMD vaccine does not meet the Eligibility Criteria, the applicant can re-submit an application to the Competition.

6. Conflicts

In the event of a conflict between the terms of this RFA and the Competition Rules, the Competition Rules shall govern.

Annex 1: AgResults FMD Vaccine Challenge Project Competition Rules

AgResults Foot and Mouth Disease (FMD) Vaccine Challenge Project Competition Rules

1. Introduction and Background

- 1.1. These terms and conditions (the “**Rules**”) govern eligibility for and the rules of the AgResults Foot and Mouth Disease (“**FMD**”) Vaccine Challenge Project (the “**Competition**”) pursuant to which AgResults (a collaborative multi-donor initiative between the Australian, Canadian, UK and USA governments and the Bill & Melinda Gates Foundation) (“**AgResults**”) has made available fifteen million eight hundred thousand dollars (\$15,800,000) (to be administered as Awards (as defined in Section 6.1.1)) to share the cost of certain sales of FMD vaccines that meet all of the requirements set forth in Section 3.1 (such requirements, the “**Eligibility Criteria**,” and such vaccines that meet such Eligibility Criteria, “**Qualified FMD Vaccines**”) in Burundi, Ethiopia, Kenya, Rwanda, Tanzania, and Uganda (collectively, the “**Region**”) all as more fully described in these Rules.
- 1.2. The Competition is managed by the Global Alliance for Livestock Veterinary Medicines (a charity registered in Scotland under number SC039197) with offices at Doherty Building, Pentlands Science Park, Bush Loan, Edinburgh, EH26 0PZ, UK (“**GALVmed**”).
- 1.3. The Competition launched on February 7, 2020 (“**Launch**”).
- 1.4. Organizations wishing to be eligible to receive the Awards (“**Competitors**”) must comply with these Rules.
- 1.5. For the purposes of the Rules, the “**AgResults Entities**” means GALVmed’s partner organizations and governmental bodies working with and/or providing funding for GALVmed or Competitors in relation to the Competition during the period of the Competition (including without limitation AgResults, the Bill & Melinda Gates Foundation, the governments of Australia, Canada, the UK, the USA, and the organization acting as the Secretariat for AgResults from time to time).
- 1.6. GALVmed and the AgResults Entities, as well as their respective affiliates, personnel/employees and family members, are excluded from participating in the Competition without prior written approval of the AgResults’ steering committee. None of the above-mentioned entities or individuals are eligible to provide Competition-related technical support or consultancy to Competitor applicants or selected Competitors. Each Competitor shall immediately disclose to GALVmed in writing any potential conflict of interests in connection with its participation in the Competition. Failure to do so could result in rejection of applications or early termination of participation in the Competition. All current or potential conflicts of interest will be evaluated by GALVmed and the AgResults’ Secretariat to determine eligibility.

2. Phases of the Competition; Technical Committee; Termination

2.1. Phases. The Competition will be conducted in two phases: the Development Phase and the Cost-Share Phase.

2.2. Development Phase.

2.2.1. The Development Phase will commence immediately upon Launch of the Competition and, unless the Competition is earlier terminated pursuant to Section 2.5, will end on January 31, 2028.

2.2.2. During the Development Phase, each Competitor will develop and seek Product Registration of a Qualified FMD Vaccine in the Region. For purposes of these Rules, “**Product Registration**” means, for each country in the Region, receipt of approval from the competent regulatory authority(ies) in such country to market, sell and distribute an FMD vaccine in such country in the form of a marketing authorisation, product license or certificate of registration, as applicable.

2.2.3. The Competitors are encouraged, but not required, to notify GALVmed in writing that they wish to participate in the Competition and to provide periodic updates to GALVmed regarding the status of development of their FMD vaccines. Notwithstanding the foregoing, within four (4) weeks of submission of an application for Product Registration for an FMD vaccine in a country in the Region, a Competitor is required to notify GALVmed in writing thereof. If a Competitor fails to notify GALVmed of such a submission, GALVmed and AgResults reserve the right to prohibit such Competitor from accessing the Awards for the applicable FMD vaccine in the applicable country for up to twelve (12) months after the later of the date of such notice and the date such FMD vaccine receives Product Registration in such country, which determination will be made at GALVmed’s and AgResults’ sole discretion, taking into account the impact of such Competitor’s failure to notify GALVmed on the Competition and other Competitors. All such updates and notifications will remain confidential and will not be disseminated outside of the AgResults Entities and the Technical Committee.

2.3. Cost-Share Phase.

2.3.1. The Cost-Share Phase will commence on the first (1st) day of the first (1st) full month after the first Competitor Agreement is signed between a Competitor and GALVmed, as set forth in Section 5.1.

For clarity, the Development Phase may continue after the commencement of the Cost-Share Phase.

- 2.3.2. The Cost-Share Phase will end on July 31, 2028. The Cost-Share Phase will be split into three (3) or more “sales periods” to be defined by GALVmed (each, a “**Sales Period**”).
 - 2.3.3. GALVmed will publish the Cost-Share Phase commencement date on its website located at <https://www.galvmed.org/foot-and-mouth-project> (or such other website as may be published by GALVmed) (the “**Website**”) and will notify all Competitors that signed up on the Website to the Competition’s mailing list of such date. At the same time, GALVmed will publish on the Website the timing and duration of the Cost-Share Phase Sales Periods, including percentage of cost-share support per Sales Period and volume of doses eligible for cost-share support per Sales Period.
 - 2.3.4. Once the Cost-Share Phase commences, Competitors may continue to submit applications to the Competition for Qualified FMD Vaccines until January 31, 2028 and, upon final approval by the Judging Panel and execution of a Competitor Agreement, the Qualified FMD Vaccines sold in accordance with these Rules will be eligible for the Awards. No application submitted after January 31, 2028 will be eligible to enter into the Competition.
- 2.4. Technical Committee.
- 2.4.1. GALVmed has convened a Technical Committee to assist with the design and implementation of the Competition. The Technical Committee assisted with developing these Rules and the Target Product Profile (TPP) and will continue to advise GALVmed and AgResults in connection with the implementation of the Competition.
 - 2.4.2. The Technical Committee is composed of industry, regional, and academic experts. GALVmed reserves the right to remove or replace any member of the Technical Committee at any time.
- 2.5. Termination; Competitor Misconduct.
- 2.5.1. Termination of Competition. AgResults reserves the right to terminate the Competition (a) three and one-half (3.5) years after the Launch, or any time thereafter if at that time GALVmed has not received written notice from a Competitor that such Competitor has submitted an application for Product Registration with the applicable regulatory authorities in one (1) or more countries in the Region for an FMD vaccine that, if approved, would satisfy the Target Product Profile, (b) at any time after the fourth (4th) anniversary of Launch, if at that time no Qualified FMD Vaccine has been (or continues to be) approved by the Judging Panel or (c) if at any time during the Cost-Share Phase, fewer than one

hundred fifty thousand (150,000) doses have been the subject of Awards during the prior twelve (12) months.

2.5.2. Termination of Competitor; Competitor Misconduct.

- (a) Without limiting Section 2.5.1, AgResults reserves the right to terminate any Competitor from the Competition immediately if (i) it or GALVmed determines that the Competitor has failed to adhere to the Rules or engaged in corrupt, fraudulent, collusive or coercive practices in the performance of the Competition (including any breach of the requirements of Section 2.5.2(b)), if the performance of the Competition by such Competitor would be in conflict with law or if the Competitor's activity or conduct in relation to the Competition may adversely affect the integrity of the Competition or the name or reputation of the other Competitors, GALVmed and/or other AgResults Entities or (ii) Competitor (A) files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of Competitor or of its assets, (B) proposes a written agreement of composition or extension of its debts, (C) is served with an involuntary petition against it, filed in any insolvency proceeding that is not dismissed within 60 days after the filing thereof, (D) proposes or is a party to any dissolution or liquidation, or (E) makes an assignment for the benefit of its creditors. Without limiting the foregoing, if AgResults or GALVmed determines that a Competitor has engaged in corrupt, fraudulent, collusive or coercive practices in connection with the Competition, in addition to its right to terminate the Competitor, AgResults reserves the right to suspend such Competitor from the Competition for a period of time and/or exclude such Competitor from participating in future GALVmed competitions. If AgResults terminates or suspends a Competitor in accordance with the foregoing, for purposes of the first sentence of Section 2.5.1, such Competitor's FMD vaccine will not be considered a Judging Panel-approved Qualified FMD Vaccine and any notification from such Competitor regarding submission of a Product Registration shall not be considered. If a Competitor disputes AgResults' or GALVmed's determination that it engaged in corrupt, fraudulent, collusive or coercive practices, it may notify the AgResults' Secretariat of such dispute in accordance with Section 8.13.1(b). For the purposes of this Section 2.5.2, fraudulent practices include, but are not limited to, forgery of any documents required for participation in the Competition; lack of authority or consent from applicable persons required for execution of any documents required for entry into and participation in the Competition; bribery or coercion; forging sales records and/or tampering with the digital

sales tracking system; and defaming or unfairly reporting of fellow Competitors.

- (b) Without limiting the foregoing, in connection with the Competition and the Awards, the Competitors will not offer to make, promise, authorize, or accept any payment or anything of value, including bribes, either directly or indirectly, to or from any public official, governmental authority, regulatory authority, or any other person for the purpose of influencing, inducing, or rewarding any act, omission, or decision in order to secure an improper advantage, or obtain or retain business. The Competitors will comply with all anti-corruption laws in connection with the Competition and the Awards, including the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism. A Competitor will immediately notify GALVmed upon becoming aware of any breach of the requirements of this Section 2.5.2(b).

2.5.3. Consequences of Termination. In the event of a termination of the Competition pursuant to Section 2.5.1 or the Competitor from the Competition pursuant to Section 2.5.2, (a) for purposes of Section 2.5.1, Competitor's FMD vaccine will not be considered a Judging Panel-approved Qualified FMD Vaccine and any notification from such Competitor regarding submission of a Product Registration shall not be considered, and (b) any request for Awards from such Competitor shall not be considered. Any Awards previously received by Competitor shall remain the property of Competitor. For clarification, Competitor shall not be entitled to Awards for sales Completed after the date of termination. For the purposes of these Rules, "**Completed**" means, with respect to the sale of a Qualified FMD Vaccine in an Approved Country, that: (a) such sale constitutes a bona-fide arm's length transaction; (b) all applicable quantities of such Qualified FMD Vaccine that are subject to such transaction have been delivered to the buyer or buyer's designee; and (c) in the case of private buyers, the buyer or the buyer's designee have paid Competitor in full for such sale.

3. Application and Eligibility

3.1. Eligibility. Application to the Competition is open to organizations that are able to manufacture and supply a Qualified FMD Vaccine to one (1) or more countries in the Region in sufficient quantities to meet market demand in such countries. To be eligible for the Awards, a Competitor must comply with these Rules and must submit to GALVmed for review by the Judging Panel an application demonstrating that its FMD vaccine meets all of the following Eligibility Criteria:

- 3.1.1. All research, development and manufacturing for the FMD vaccine has been conducted rigorously and safely in compliance with the general and FMD-specific

guidance provided in the 9th Edition of the World Organization of Animal Health (WOAH) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2023 (as may be updated or amended) (the “**WOAH Terrestrial Manual**”), and all biosafety, biosecurity and legal requirements that are applicable to the locations where any of these activities take place.

3.1.2. The FMD vaccine has received Product Registration in at least one (1) country in the Region. Product Registration may be obtained through (a) the East African Community Mutual Recognition Procedure (MRP) or (b) individual country registration(s); provided that unless and until Ethiopia participates in the MRP, Competitors must obtain individual country registration in Ethiopia in order to be eligible for Awards for sales of Qualified FMD Vaccine in Ethiopia. In recognition of the fact that the government of Burundi is a signatory of 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 Competitor receives Product Registration for the FMD vaccine via MRP in at least one (1) other country in the Region.

3.1.3. The FMD vaccine satisfies the Target Product Profile set forth on **Schedule 1**.

3.1.4. **Submissions.** Applications should be submitted to GALVmed via a secure online portal available on the Website. Applications must include the following:

- (a) The application form, with the mandatory information filled and submitted online via the secure portal.
- (b) The application must include supporting documentation sufficient to demonstrate satisfaction of the Eligibility Criteria (Section 3.1), including:
 - a copy of the applicable Product Registration approval documents (marketing authorisation, product license or certificate of registration, as applicable),
 - all related documentation received from the applicable regulatory authority (including, but not limited to, the summary of product characteristics, product literature and labelling),
 - a copy of relevant manufacturing authorisation(s) as evidence of compliance with the principles of GMP¹ throughout the process of manufacture,

¹ In line with Chapter 2.3.3 of the WOAH Terrestrial Manual ‘Minimum standards for the organization and management of a vaccine manufacturing facility’ as a minimum.

- any other data the Competitor determines is relevant to provide evidence that the product as registered meets the requirements of the Target Product Profile. For clarity, as set forth in the Target Product Profile, with respect to testing for vaccine valency, data demonstrating compliance must be generated by a laboratory that (i) has the capabilities to test against the full approved Eastern African FMDV Reference Antigen Panel set forth in the Target Product Profile and (ii) is neutral, independent, impartial and conflicts-free (including that such laboratory may not have any financial interest in the applicable Competitor or vaccine and may not hold any intellectual property with respect to such vaccine) (an “**Approved Lab**”)², using batches of product shown to comply with the terms of the Product Registration. If, in a Competitor’s Product Registration submission, the data to support vaccine valency was not conducted by an Approved Lab, the Competitor must submit additional data conducted by an Approved Lab to AgResults to satisfy the vaccine valency element of the Eligibility Criteria,
- a completed Anticorruption Compliance Certification as provided in the application form, and
- any additional documentation deemed necessary by the Judging Panel.

3.1.5. GALVmed may require any applicant to participate in discussions related to application submission and to submit such technical or other revisions of their applications that may result from such discussions.

3.1.6. Each Competitor waives any and all rights and remedies under any civil action arising from or related to the submission of an application.

3.2. Procedures.

3.2.1. The application must be submitted in the English language. The application must be complete, with all compulsory questions in the application form filled out and all relevant information included.

3.2.2. Applications may be submitted at any time after the first (1st) anniversary of the Launch. Competitors may continue to submit applications to the Competition for Qualified FMD Vaccines until January 31, 2028.

4. **Judging Panel**

4.1. Composition. The Judging Panel will be composed of FMD, industry and regulatory experts. Members of the Judging Panel will be distinct from members of the Technical

² The Approved Laboratories are available on the Website on the “Competitor Resources” page.

Committee. GALVmed reserves the right to remove or replace any member of the Judging Panel at any time without notice.

- 4.2. No Contact with Judging Panel. Without limiting the foregoing, Competitors will not contact any person that they know to be a member of the Judging Panel directly regarding the Competition and any/all correspondence and communication regarding the Competition must be directed to GALVmed. GALVmed reserves the right to disqualify a Competitor from the Competition in the event the Competitor does not comply with this section.

4.3. Submission and Review Process.

- 4.3.1. Each Competitor must submit an application to GALVmed in accordance with Section 3.1.4.
- 4.3.2. Upon receipt of an application, GALVmed will review the application to determine if, on its face, it appears to be complete in accordance with Section 3.1.4 and will notify the applicable Competitor of its determination within thirty (30) days of submission.
- 4.3.3. The Judging Panel will review applications quarterly to determine whether the applicable Competitors' FMD vaccine(s) meet the Eligibility Criteria.
- 4.3.4. The Judging Panel may request additional information from each Competitor to assist with its evaluation of the Competitor's application prior to finalizing its review of the application. If any such information is not provided within thirty (30) days of the Judging Panel's request, GALVmed reserves the right to reject the application.
- 4.3.5. If a Competitor has complied with all of these Rules, the Judging Panel will approve any application submitted by that Competitor for an FMD vaccine that it determines, at its sole discretion, meets the Eligibility Criteria, and GALVmed will promptly notify each Competitor of the Judging Panel's decision. In the event that the Judging Panel determines that a Competitor's FMD vaccine does not meet the Eligibility Criteria or rejects the application in accordance with Section 4.3.4, such Competitor will have the right to re-submit an application to the Competition.

- 4.4. No Limit on Number of Competitors. There is no maximum number of Competitors that may be approved for the Awards.

5. Ongoing Competitor Requirements

- 5.1. Ongoing Eligibility. Once a Competitor's application has received final approval from the Judging Panel, the Competitor will be required to enter into a written agreement with GALVmed, which agreement will obligate the Competitor to abide by these Rules, as well

as other related terms and conditions (the “**Competitor Agreement**”). Upon signing the Competitor Agreement, the Competitor’s Qualified FMD Vaccine sold in accordance with these Rules will be eligible for the Awards set forth in Section 6, provided that, to maintain such eligibility, (a) the Qualified FMD Vaccine must continue to meet the Eligibility Criteria (as demonstrated through the testing set forth in Section 5.3.2) and the ongoing Competitor requirements set forth in this Section 5 (including successfully completing annual quality verifications pursuant to this Section 5) and (b) the Qualified FMD Vaccine is sold in bona fide arm’s-length transactions that conform to these Rules, the Competitor Agreement and applicable law in the relevant Region (such sales that satisfy these requirements, “**Eligible Sales**”). If at any time the Qualified FMD Vaccine fails to meet the Eligibility Criteria, the Competitor will be ineligible to receive further Awards until the Competitor is able to establish to the Judging Panel’s satisfaction that its FMD vaccine meets the Eligibility Criteria. Notwithstanding the foregoing, any sale by Competitor in a country in the Region for which Competitor has received Product Registration for a Qualified FMD Vaccine in accordance with Section 3.1.2 and has received approval by the Judging Panel for such Qualified FMD Vaccine in such country (each such country, an “**Approved Country**”) that would have been an Eligible Sale but for non-compliance with the Eligibility Criteria, that was Completed prior to the earlier of the date that (x) GALVmed first notifies Competitor of such non-compliance and (y) Competitor knew, or reasonably should have known, of such non-compliance, shall continue to be eligible for the Awards in accordance with Section 6.

- 5.2. Competitor Notification Requirements. After a Competitor’s application has received final approval from the Judging Panel, the Competitor will promptly notify GALVmed if at any time (a) the Competitor has any reason to believe that its Qualified FMD Vaccine no longer satisfies the Eligibility Criteria, (b) the Competitor determines that any event, incident or circumstance has occurred that may result in the need for a recall, corrective action, market suspension or market withdrawal of its Qualified FMD Vaccine in any country in the Region or (c) a regulatory authority in the Region will or has conduct(ed) an inspection or audit of the Competitor or its facilities with regard to its Qualified FMD Vaccine, and, in each case ((a), (b) and (c)), such notice shall include the reasoning behind such belief, determination or inspection and any supporting information (including, with respect to clause (c), the findings from such inspection or audit, once available).

- 5.3. Quality Verification.

- 5.3.1. For verification purposes, AgResults reserves the right to conduct unannounced sampling and testing, at AgResults’ cost, to verify the quality of any Competitor’s Qualified FMD Vaccine. Testing will be performed by appropriately qualified laboratory(ies) appointed by AgResults in consultation with the Technical Committee (such appointed laboratory(ies), the “**Quality Verifier(s)**”). Upon receipt of a written request from GALVmed, a Competitor will submit to the Quality Verifiers, in accordance with the specifications on the World Reference Laboratory for FMD website: <https://www.wrlfmd.org/au-panvac-pirbright->

twinning-project/FMD-vaccine-evaluation, the Day 0 and Day 21 sera generated from five (5) individual cattle that were inoculated within three (3) months of production of the specified batch of Qualified FMD Vaccine. Competitor will send a verified summary of batch release data from the tested batch to GALVmed as soon as such verified summary is available. The verified summary of batch release data should contain at least the minimum of data provided in Schedule 2 to these Rules. Competitor will store a vial of Qualified FMD Vaccine from the tested batch in a refrigerated sealed container with a temperature logger on their premises, in case of a need for re-testing. In addition, within six (6) months of the approval of a Qualified FMD Vaccine by the Judging Panel, the Competitor will share the following with GALVmed: Standard Operating Procedures for the sera generation and collection process; and a relevant Good Manufacturing Practices inspection report.

- 5.3.2. The Quality Verifier(s) will test batch samples in accordance with the Vaccine Quality Verification Protocol, attached to these Rules as Schedule 2, as such protocol may be amended or supplemented by GALVmed from time to time.
- 5.3.3. If the results of any of the tests set forth in Section 5.3.2 demonstrate that a Qualified FMD Vaccine fails to meet the quality standards set forth in the Target Product Profile, then GALVmed will promptly notify the applicable Competitor thereof, and the Competitor will be ineligible for further Awards until the Competitor provides to GALVmed a remedial action plan (if applicable) and is able to establish to the Judging Panel's satisfaction, in the Judging Panel's sole discretion, that batches of its FMD vaccine being sold in the Region meet the quality standards set forth in the Target Product Profile. If a Competitor disagrees in good faith with the results of such testing, the Competitor may notify GALVmed thereof, and the Competitor will have an opportunity to discuss such disagreement with the Quality Verifier(s) to attempt to resolve any technical or other issues. The Quality Verifier(s) and the Competitor will provide GALVmed with a summary of such discussions and the outcome(s) thereof, and the Judging Panel will re-examine whether the applicable FMD vaccine fails to meet the quality standards set forth in the Target Product Profile. If the Judging Panel determines that the FMD vaccine still fails to meet the quality standards set forth in the Target Product Profile, the Competitor will have the right, at its own cost, to have the remaining batch sample retested at the Quality Verifier(s) or another Approved Lab, as determined by GALVmed. The Judging Panel will review the results of any such retesting and re-examine whether or not the applicable FMD vaccine meets the quality standards set forth in the Target Product Profile, which the Judging Panel will determine at its sole discretion. Notwithstanding the foregoing, any sale by a Competitor of any FMD vaccine that would have been an Eligible Sale but for this Section 5.3.3, that was Completed prior to the earlier of the date that (a) GALVmed first notifies such Competitor of such non-compliance as set forth in the first sentence of this Section

5.3.3 and (b) such Competitor knew, or reasonably should have known, of such non-compliance, will continue to be eligible for the Awards in accordance with Section 6.

6. Awards and Administration

6.1. Overview.

- 6.1.1. Each Sales Period during the Cost-Share Phase, AgResults commits to share the cost of Qualified FMD Vaccine doses (up to a cap on total cost-share doses per Sales Period) sold for the Region in bona fide arm's-length transactions that conform to the Rules, the Competitor Agreement and applicable law and regulations in the Region (such cost-share, the "**Awards**").
- 6.1.2. The cap on cost-share doses and the portion of the Qualified FMD Vaccine selling price funded by the Awards in each Sales Period of the Cost-Share Phase will be announced on the GALVmed Website at the same time that the Cost-Share Phase commencement date is published. To encourage buyer participation, AgResults' level of cost-share support during the first Sales Period will be seventy-five percent (75%). AgResults will gradually reduce the cost-share amount during each subsequent Sales Period of the Cost-Share Phase to help buyers prepare for price adjustments that will occur after the Cost-Share Phase has closed.
- 6.1.3. Total cost-share doses in the Region will be split between two categories: the country-specific cost-share reserves ("**Country Reserves**") and the regional pool ("**Regional Pool**"). The Country Reserves will provide an allotment of doses for specific countries in the Region in a given Sales Period, and the Regional Pool will provide additional doses beyond what is allocated through the Country Reserves that would be available for any country in the Region. 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.

6.2. Country Reserves.

- 6.2.1. In each Sales Period of the Cost-Share Phase, cost-share doses will be allocated to Country Reserves in countries that have issued or are anticipated to issue Product Registration(s) for a Qualified FMD Vaccine prior to or during such Sales Period (which anticipated Product Registrations will be determined based on notifications from Competitors regarding submitted applications for Product Registrations for FMD vaccines in a country in the Region as set forth in Section 2.2.3), taking into account such country(ies)' share of the Region's cattle population and discussions with such country(ies)' government(s). For any country that has issued or is anticipated to issue Product Registration(s) for a Qualified FMD Vaccine prior to or during a Sales Period of the Cost-Share Phase, a minimum of twenty-five thousand

(25,000) doses will be allocated to such country for such Sales Period. If, with respect to any Sales Period of the Cost-Share Phase, (a) doses are allocated to Country Reserves in a country that has not issued, but is anticipated to issue during such Sales Period, Product Registration(s) for a Qualified FMD Vaccine and (b) six (6) months after the commencement of such Sales Period, such Product Registration(s) have not been issued or are not anticipated to be issued during such Sales Period, AgResults reserves the right to re-allocate such doses to another country or to the Regional Pool (provided that, for clarity, AgResults will not decrease the amount of doses allocated to any country in which a Product Registration has issued to a Qualified FMD Vaccine).

6.2.2. The allocation of total cost-share doses to the Country Reserves for each country in the Region in a given Sales Period of the Cost-Share Phase will be disclosed quarterly or upon request to Competitors with Qualified FMD Vaccines that are approved by the Judging Panel for such country.

6.2.3. If the doses allocated to a country's Country Reserves are not fully used in a given Sales Period, one hundred percent (100%) of such excess doses will roll-over to the following Sales Period and will be added to the following Sales Period's Country Reserves for such country during the Cost-Share Phase. For clarity, the Cost-Share Phase will not be extended and the per-unit cost-share shall not be increased as a result of such rollover. The cap on total cost-share doses for the Region for that Sales Period will be increased accordingly.

6.3. Regional Pool.

6.3.1. The Regional Pool will provide additional doses for Awards in the Region beyond the Country Reserves.

6.3.2. Thirty-five percent (35%) of the Regional Pool will be reserved for private sector sales. This thirty-five percent (35%) may not be used for government sales, even if private sector sales do not use such allotment in any given Sales Period. If the doses allocated to the Regional Pool are not fully used in a given Sales Period, one hundred percent (100%) of such excess doses will roll-over to the following Sales Period and will be added to the following Sales Period's Regional Pool during the Cost-Share Phase (provided that unused doses that were part of the thirty-five percent (35%) of the Regional Pool reserved for private sector doses will be allocated to such thirty-five percent (35%) of the Regional Pool in the following Sales Period and will continue to be reserved for private sector sales in the following Sales Period), and the cap on total cost-share doses for the Region for that Sales Period will be increased accordingly. For clarity, the Cost-Share Phase will not be extended and the per-unit cost-share shall not be increased as a result of such rollover.

6.4. Allocation of Sales.

- 6.4.1. For purposes of the Competition and these Rules, government sales will mean any sale made in a country in the Region in connection with a government tender or directly to a government buyer. All other sales will be considered private sector sales.
- 6.4.2. Requests for Awards received from Competitors will be pulled from the Country Reserves or Regional Pool as follows:
- (a) Government sales and sales made in a country in the Region in which the government does not directly purchase vaccines for distribution (e.g., as of the date of the Launch, Tanzania) will first be pulled from the applicable Country Reserves, if any. If the doses in the applicable Country Reserves are exhausted in any given Sales Period of the Cost-Share Phase, additional sales will then be pulled from the Regional Pool; provided that government sales will not be pulled from the thirty-five percent (35%) of the Regional Pool reserved for private sector sales, even if the other sixty-five percent (65%) of the Regional Pool and the applicable Country Reserves are exhausted in the applicable Sales Period.
 - (b) Except in a country in the Region in which the government does not directly purchase vaccines for distribution, private sector sales will first be pulled from the Regional Pool. If the doses in the Regional Pool are exhausted in any given Sales Period of the Cost-Share Phase, additional private sector sales will then be pulled from the applicable Country Reserves, if any.

6.5. Administration of Awards and Sales Verification.

- 6.5.1. If a Competitor wishes to access the Awards for a prospective sale in a given country in the Region in which its Qualified FMD Vaccine has received Product Registration, the Competitor must notify GALVmed thereof via email to FMDchallenge@galvmed.org (or such other email address as may be published by GALVmed on the Website), which email shall specify the number of requested cost-share doses, the country for which such cost-share doses are requested, the identity of the buyer, whether such sale is a private sector sale or government sale and, if it is a government sale, whether it is made in connection with a government tender or direct purchase. GALVmed will promptly notify the Competitor whether Awards are available for the applicable Eligible Sale in the applicable Sales Period in the Country Reserves or Regional Pool (as such doses are accessible/allocated to the applicable sale as set forth in Section 6.4).
- (a) With respect to a request submitted by a Competitor for a sale in connection with a government tender, if GALVmed notifies the

Competitor that cost-share doses are available for such sale, GALVmed will reserve such doses for such sale once GALVmed has received a copy of the authorized government tender document from the Competitor. Such doses will be reserved for the applicable government sale (but will not be reserved for any specific Competitor) and may be awarded to any Competitor to the extent such Competitor is selected by the applicable government for such sale in connection with such tender. When the tender is awarded, the applicable Competitor must promptly send GALVmed a copy of the executed tender award agreement, and the number of doses required to fulfill the tender for each Sales Period. If the Competitor is not selected, the Competitor must also notify GALVmed.

- (b) With respect to all other requests by a Competitor (i.e., private sales and direct government sales), once GALVmed notifies the Competitor of available cost-share doses, GALVmed will reserve such doses for thirty (30) days. The applicable Competitor must promptly notify GALVmed in writing when a purchase order for the applicable Eligible Sale is received (or if the Eligible Sale is cancelled). If the purchase order for the applicable Eligible Sale is not received within such thirty (30)-day period, the Competitor may request an extension, and GALVmed will consider such extension in good faith while taking into account any competing requests received from other Competitors during such period. The Competitor shall also notify GALVmed of the expected delivery date and GALVmed will allocate cost-share doses in the Sales Period that aligns with such expected delivery date. If the Competitor fails to deliver during the expected Sales Period, GALVmed will, subject to availability, move the allocation of cost-share doses to the following Sales Period at the prevailing level of support.
- (c) With respect to any sale described in Section 6.5.1(a) or Section 6.5.1(b), if the applicable Competitor has produced, but has not yet delivered to the applicable buyer or such buyer's designee, all quantities of Qualified FMD Vaccine subject to such sale as of the last day of the applicable Sales Period and, notwithstanding such non-delivery, the Competitor desires that such Eligible Sale be attributed to the applicable Sales Period, the Competitor shall (i) provide GALVmed with an Invoice for such Eligible Sale no later than the last day of the applicable Sales Period confirming that all quantities of Qualified FMD Vaccine subject to such sale have been produced by the Competitor and (ii) Complete such Eligible Sale within thirty (30) days of the last day of the applicable Sales Period, in which case (notwithstanding Section 6.5.1(a) or Section 6.5.1(b)) GALVmed will allocate cost-share doses in such applicable Sales Period and not the Sales Period that aligns with the expected delivery date. If the

Competitor fails to Complete such Eligible Sale during such thirty (30)-day period after the last day of the applicable Sales Period, GALVmed will, subject to availability, move the allocation of cost-share doses to the following Sales Period at the prevailing level of support. For the purposes of these Rules, “**Invoice**” means, with respect to an Eligible Sale, a written, formal and itemized commercial document issued by the applicable Competitor to the applicable buyer or buyer’s designee for such Eligible Sale that indicates (x) all quantities of Qualified FMD Vaccine subject to such Eligible Sale and (y) the cost thereof to be charged to buyer or buyer’s designee.

- (d) If the Competitor fails to notify GALVmed of the applicable Eligible Sale as required by this Section 6.5.1, any payment or grant of Award for such sale will be made at GALVmed’s sole discretion, taking into account the impact of the Competitor’s failure to notify GALVmed on the Competition and other Competitors.

6.5.2. At least once per month, Competitors will be required to provide to GALVmed statements of Qualified FMD Vaccine sales that have been Completed within the prior one (1)-month period in the Region, allocated by Approved Country and by private sector sales and government sales broken down between tenders and direct sales, as well as the selling price per dose, buyer of each such sale and all applicable Required Documentation with respect to such sale. For the purposes of these Rules, “**Required Documentation**” means: (a) for a government tender purchase, the executed tender award agreement, purchase order, proof of fulfilment (Invoice) and proof of delivery (Delivery Note); (b) for a government direct purchase, the purchase order, proof of fulfilment (Invoice) and proof of delivery (Delivery Note); and (c) for private sector buyers, proof of fulfilment (Invoice), proof of delivery (Delivery Note) and proof of payment (bank transfer receipt). If the Competitor fails to notify GALVmed of the applicable Eligible Sales as required by this Section 6.5.2, any payment or grant of Award for such sale will be made at GALVmed’s sole discretion, taking into account the impact of the Competitor’s failure to notify GALVmed on the Competition and other Competitors. For the purposes of these Rules, “**Delivery Note**” means a document issued by the Competitor and included with a shipment of goods sent to a buyer, that lists the description and amounts of goods enclosed in such shipment.

6.5.3. A third party sales verification and audit company (the “**Sales Verifier**”) designated by AgResults will be responsible for verifying sales for purposes of the Awards.

6.5.4. At least once every three (3) months, each Competitor will permit the Sales Verifier to audit its Eligible Sales and will provide copies of all necessary documents in connection therewith, including the Required Documentation, financial statements, invoices and payment and delivery receipts on an Approved Country-by-Approved

Country basis. Each Competitor will and will cause its buyers in the Approved Countries in the Region in which it applies for Awards to, assist and cooperate in good faith with GALVmed and the Sales Verifier, as may be reasonably requested by GALVmed or the Sales Verifier, in connection with the verification of Eligible Sales of its Qualified FMD Vaccine. Without limiting the foregoing, each Competitor will cause such buyers to provide any information required to verify the Competitor's sales and, if applicable, the characterization thereof as a government sale, including any of the buyer's receipts or tender documentation.

- 6.5.5. The Sales Verifier will verify sales as follows: (a) with respect to sales made in connection with a government sale (tender or direct), the Sales Verifier will confirm the selling price and that the Competitor delivered the applicable quantity of Qualified FMD Vaccine in accordance therewith (though payment from the applicable government need not be received by the Competitor (or its distributor) in order for the sale to be verified) and (b) with respect to private sector sales, the Sales Verifier will confirm the selling price and that the Competitor has Completed such sale. Once a sale is verified by the Sales Verifier, the Sales Verifier will submit confirmation of such sale to AgResults indicating the amount of payment required to be made to the applicable Competitor.
- 6.5.6. GALVmed will cause payments to be made to Competitors once every calendar quarter for sales verified by the Sales Verifier in the prior calendar quarter. For clarity, no payments shall be owed unless sales are verified by the Sales Verifier in accordance with the Rules and the Competitor Agreement).
- 6.5.7. Subject to meeting the other provisions of these Rules, an Eligible Sale to a private buyer that has satisfied clauses (a) and (b), but not clause (c), of the definition of "Completed" within a Sales Period of the Cost-Share Phase is eligible for an Award in such Sales Period, even if not verified in such Sales Period, provided that payment for the applicable Eligible Sale is received by Competitor no later than thirty (30) business days after the date of receipt of goods by the buyer, as indicated in the Required Documentation provided to GALVmed pursuant to Section 6.5.2, and such sale is then verified as provided in this Section 6.5.
- 6.5.8. If, with respect to an Eligible Sale, a Competitor has produced, but has not yet delivered to the applicable buyer or such buyer's designee, all applicable quantities of Qualified FMD Vaccine subject to such sale as of the last day of the applicable Sales Period, but subsequently delivers all applicable quantities of Qualified FMD Vaccine subject to such sale to such buyer or buyer's designee within thirty (30) days of the last day such Sales Period, as indicated in the Required Documentation provided to GALVmed pursuant to Section 6.5.2, and such Eligible Sale otherwise meets the other provisions of the Rules and the Competitor Agreement, then such Eligible Sale is eligible for an Award in such Sales Period, provided that (a) with respect to a government sale (tender or direct), the Competitor has submitted an

Invoice with respect to such Eligible Sale pursuant to Section 6.5.1(c) and (b) with respect to a private sale, the Competitor has submitted an Invoice with respect to such Eligible Sale pursuant to Section 6.5.1(c) and payment for the applicable Eligible Sale is received by the Competitor no later than thirty (30) days after the last day of such Sales Period, as indicated in the Required Documentation provided to GALVmed pursuant to Section 6.5.2, and, in each case ((a) and (b)), such sale is then verified as provided in this Section 6.5.

6.5.9. Taxes. Competitor shall be solely responsible for paying any taxes or fees due, in accordance with applicable law or otherwise, in connection with its activities with respect to the Competition and the receipt of Awards.

7. Confidentiality, Questions and Information Sharing

- 7.1. Throughout the Competition, Competitors may submit questions and inquiries to GALVmed via email to FMDchallenge@galvmed.org (or such other email address as may be published by GALVmed).
- 7.2. GALVmed will not provide technical assistance to Competitors, but may instead share general, non-proprietary/non-confidential information, as appropriate, equally with all Competitors. GALVmed may, for example, publish information in writing to all Competitors regarding regulatory requirements or market demand.
- 7.3. GALVmed and AgResults will not publish any information that is marked confidential or proprietary by a Competitor or that would otherwise identify a confidential innovation of a Competitor (including the applications submitted by Competitors to the Competition and any Product Registration documentation or data submitted in connection therewith). However, each Competitor acknowledges and agrees that, subject to the foregoing, (a) the Competitor's application and related information may be shared with the AgResults' Secretariat, AgResults' steering committee for the Competition, and the members of the Technical Committee and Judging Panel and (b) AgResults may publish information about the Competition, including high-level details on the results of the FMD vaccine efficacy studies and any approval by the Judging Panel of an FMD vaccine.

8. Other Terms

- 8.1. Ownership Change. Each Competitor agrees to notify GALVmed of any change in control of such Competitor within thirty (30) days of such change. For the purpose of this provision, "control" means (a) the legal or beneficial ownership of the Competitor, including, without limitation, as a result of acquisition, merger or sale; or (b) the power to

direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, through membership, by contract or otherwise.

- 8.2. Taxes. Each Competitor will be solely responsible for paying any taxes or fees due in accordance with the applicable laws or otherwise, in connection with Competitor's activities with respect to the Competition and/or the receipt of any Awards.
- 8.3. Reservation of Rights.
- 8.3.1. These Rules do not commit GALVmed or AgResults to distribute Awards to any Competitor.
- 8.3.2. GALVmed reserves the right to correct clerical or typographical errors in these Rules, the Competitor Agreement or any other Competition materials. GALVmed also reserves the right to unilaterally and without liability to Competitors amend the Rules or other terms of the Competition. GALVmed would not issue such amendments lightly and only if it believes that it is necessary or helpful, for example, in order to clarify any terms or to accomplish the Competition's objectives. Competitors should note that any amendments of these Rules would be only made based on specific direction from the AgResults Entities (or their designee) and subject to approval by the AgResults Entities (or their designee).
- 8.4. Independent Evaluator. Each Competitor that has an approved Qualified FMD Vaccine will, upon AgResults' or GALVmed's request, meet with an independent evaluator to discuss the Competition and the Competitor's participation in the Competition (subject to appropriate confidentiality obligations), which independent evaluator will measure the impact of the Competition.
- 8.5. Intellectual Property. All improvements, inventions, discoveries, know-how, materials, general intangibles, formulae, processes, techniques, data, graphics, trade secrets, technology, algorithms, computer programs, audio, video or other files or other content, and all other intellectual property rights, whether or not patentable, generated, conceived, developed or provided by a Competitor in connection with the Competition, including with respect to the Competitor's FMD vaccine, will, as between the Competitor and GALVmed and the other AgResults Entities, remain the sole and exclusive property of the Competitor.
- 8.6. Use of Name.
- 8.6.1. Each Competitor agrees that nothing in these Rules grants the Competitor a right or license to, and each Competitor will not, use the name, trademark or logo of GALVmed or any of the AgResults Entities in any public material, advertisement, press release or in the media (including on the internet), without prior written approval. In the event that a Competitor receives such approval to use the name, trademark or logo of GALVmed or any of the AgResults Entities, the Competitor shall do so in a manner consistent with branding guidelines provided by AgResults.

- 8.6.2. If AgResults or GALVmed wishes to use a Competitor's name, trademark, logo or any related images in any public material, advertisement, press release or in the media (including on the internet) in connection with the Competition, AgResults or GALVmed, as applicable, will notify the applicable Competitor thereof, and AgResults and GALVmed will not use such Competitor's name, trademark, logo or any related images without such Competitor's prior written consent. The Competitors agree to consider any such request in good faith and not to unreasonably withhold, condition or delay their consent to such request. Any use by AgResults or GALVmed of a Competitor's name, trademark, logo or any related image will be in accordance with the Competitor's standard usage guidelines (to the extent such guidelines are provided to AgResults and GALVmed in writing).
- 8.7. Records. Competitors shall maintain, during the term of the Competition and for three (3) years after its termination or expiration, complete records of all information and materials related to its participation in the Competition (both with respect to ongoing eligibility and sales) and shall make such records available to AgResults, GALVmed, or any of their representatives or agents for review and audit upon request.
- 8.8. Compliance with Law. Without limiting Section 2.5, Competitors shall comply with any and all applicable laws and regulations in connection with their Competition activities, including, without limitation, any laws and regulations related to medical or pharmaceutical research and testing, animal testing, and safety and security of its personnel.
- 8.9. Release and Indemnity.
- 8.9.1. In consideration for making the Awards available and as a condition to participate in the Competition, each Competitor, on behalf of itself, its affiliates, and its and their predecessors, successors and assigns, knowingly and voluntarily fully and forever releases and discharges GALVmed and each of the AgResults Entities (and their affiliates and their respective predecessors, successors and assigns), as well as the members of the Technical Committee and Judging Panel, from any and all past, present and future claims, demands, liens, actions, suits, causes of action, obligations, controversies, debts, costs, legal fees, expenses, damages, judgments, orders, and liabilities of whatever kind or nature in law, equity or otherwise, whether known or unknown, that are based in whole or in part upon, arise out of, or relate to, conduct (or omissions) under or in connection with such Competitor's participation in the Competition, including in connection with (a) termination of a Competitor Agreement, (b) termination of the Competition by AgResults in accordance with Section 2.5 or (c) GALVmed's determination that a Competitor is ineligible for further Awards, suspension of a Competitor from the Competition for a period of time or exclusion of a Competitor from participating in further GALVmed competitions, in each case, in accordance with the Rules and the Competition Agreement.

- 8.9.2. GALVmed and AgResults are not responsible for typographical, printing or other inadvertent errors in these Rules or in any other materials relating to the Competition.
- 8.9.3. In consideration for making the Awards available and as a condition to participate in the Competition, each Competitor will indemnify and hold harmless GALVmed and each of the AgResults Entities (and their respective directors, officers, representatives, employees and agents) and the members of the Technical Committee and Judging Panel (collectively, the “**Indemnified Parties**”) from and against any and all losses, damages, costs, expenses, rights, claims, demands and actions (including legal fees and expenses for litigation and settlement) that may be brought against any one or more of them relating to or arising out of the Competitor’s participation in the Competition. If any third party makes a claim, or notifies an intention to make a claim, against an Indemnified Party that may reasonably be expected to give rise to a liability under this Section 8.9.3, (a) unless otherwise agreed in writing by the Parties, GALVmed (or the applicable Indemnified Party) shall have the right to control the defense of such claim and (b) the Competitor shall: (a) cooperate with GALVmed and the Indemnified Party in the defense of such claim as may be requested by GALVmed or the Indemnified Party, including by giving access at reasonable times (on reasonable prior notice) to its premises and its officers, directors, employees, agents, representatives or advisers, and to any relevant assets, accounts, documents and records within the power or control of the Competitor and (b) not make any admission of liability, agreement or compromise in relation to the claim without the prior written consent of GALVmed. The provisions of this Section 8.9 shall survive the expiration or termination of the Competition.
- 8.10. Limitation of Liability. (a) Any and all disputes, claims, and causes of action arising out of or in connection with the Competition, including, without limitation, those concerning any payments of Awards pursuant to these Rules, shall be resolved individually without resort to any form of class action; (b) to the maximum extent permitted by applicable law, the liability of GALVmed and any of the AgResults Entities (and their respective directors, officers, representatives, employees and agents) and the members of the Technical Committee and Judging Panel, individually or collectively, for any claims, actions, damages, liabilities, costs, expenses or losses in any way arising out of or in relation to the Competition shall in no event exceed in the aggregate ten thousand U.S. dollars (\$10,000); and (c) in no event shall GALVmed or any of the AgResults Entities (or their respective directors, officers, representatives, employees and agents) or the members of the Technical Committee and Judging Panel, be liable for (i) indirect, punitive, incidental, special, exemplary or consequential damages or (ii) loss of profits, turnover, business opportunities, damage to goodwill or other opportunity costs. The provisions of this Section 8.10 shall apply regardless of the form of action, damage, claim, liability, cost, expense, or loss, whether in contract, statute, tort (including, without limitation,

negligence). The provisions of this Section 8.10 shall survive the expiration or termination of the Competition.

- 8.11. Governing Law. All issues and questions concerning the construction, validity, interpretation and enforceability of these Rules shall be governed by and construed in accordance with the law of England and Wales.
- 8.12. Severability. If any provision of these Rules is held to be illegal, invalid or unenforceable under any present or future applicable law, (a) such provision shall be fully severable, and (b) in lieu of such illegal, invalid or unenforceable provision, GALVmed shall use good faith efforts to add as a part of these Rules a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible (and, to the extent GALVmed includes a replacement provision, (i) these Rules shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, and (ii) the remaining provisions of these Rules shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom). To the fullest extent permitted by applicable law, each Competitor hereby waives any provision of applicable law that would render any provision hereof illegal, invalid or unenforceable in any respect.
- 8.13. Dispute Resolution.
- 8.13.1. With respect to any concern or complaint of a Competitor, GALVmed shall facilitate the resolution process with oversight from the AgResults' Secretariat, except in the event that GALVmed is the subject of the concern or complaint, in which case the AgResults' Secretariat will be responsible for facilitating the resolution process.
- (a) If a Competitor has evidence or believes that another Competitor is behaving in a way that contradicts these Rules, the Competitor Agreement or otherwise has a concern or dispute related to the Competition, the Competitor should submit an email to GALVmed at FMDchallenge@galvmed.org (or such other email address as may be published by GALVmed) and detail in writing what is being challenged and submit documentary evidence, if any, to support its claim.
 - (b) If a Competitor has evidence or believes that GALVmed is behaving in a way that contradicts these Rules or the Competitor Agreement, the Competitor should submit an email to the AgResults' Secretariat at info@agresults.org and detail in writing the possible issue. The email should list the practices the Competitor believes are contradicting the Rules or the Competitor Agreement, along with dates and any documentary evidence, if any, to support its claim.

Upon receipt of the information from the Competitor, GALVmed or the AgResults' Secretariat, as applicable, will acknowledge receipt and respond to the Competitor as soon as practical about next steps. Any unresolved issues will be resolved in accordance with Section 8.13.2 below.

- 8.13.2. Any dispute between the Competitor and GALVmed or any of the AgResults Entities relating to the interpretation or application of these Rules, the Competitor Agreement or otherwise arising in connection with the Competition shall be finally settled by a binding arbitration; provided that with respect to any dispute arising from a concern or complain of a Competitor, the Competitor must first follow the procedures set forth in Section 8.13.1. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties to the dispute, or in the absence of such agreement, in accordance with the Rules of Arbitration of the International Chamber of Commerce (ICC Emergency Arbitrator Provisions shall not apply). The arbitration shall take place in location(s) agreed-upon by the parties, or in the absence of such agreement, in London, United Kingdom. The arbitrator(s) shall have no power to award damages inconsistent with these Rules, including the limitation on liability provisions contained herein. All aspects of the arbitration shall be treated as confidential. Each party shall bear its own costs of the arbitration; however, the parties shall share the fees and expenses of the arbitrators equally. The arbitral award shall be final and binding. The provisions of this Section 8.13 shall survive the expiration or termination of the Competition.
- 8.13.3. The Competitor and GALVmed irrevocably waive, to the fullest extent permitted by law, all right to trial by jury in any action, proceeding or counterclaim (whether in contract, statute, tort (including, without limitation, negligence)) relating to the Competition.

Schedule 1
Target Product Profile (TPP)

	Characteristic	Target Product Profile
1	Vaccine Valency	Quadrivalent: A, O, SAT1, SAT2 serotypes that match > 70%* (each serotype) of circulating Eastern African Foot and Mouth Disease Viruses (FMDV), as defined by the Eastern African FMDV Reference Antigen Panel** • Vaccine testing against the Eastern African FMDV Reference Antigen Panel to be done at an AgResults-approved laboratory***, which has demonstrated it has (i) the capability to test against the full approved Eastern African FMD panel according to the agreed methodology (ii) no IP / financial conflict of interest with the vaccine development company, and (iii) accreditation to international standards for the specified testing • Data to be included in the registration dossier
2	Host Animal	Cattle from 3 months of age
3	Efficacy	Contains a minimum 6PD₅₀ per strain per dose • For registration: ○ Efficacy requirements as described in the WOAHA Manual, FMDV chapter 3.1.8 (point 5.3), efficacy testing using challenge virus appropriate to the virus types in the vaccine ○ PD₅₀ test to be conducted on monovalent component(s) of the vaccines • For batch testing: ○ Indirect potency tests (serology) allowed ○ Batch potency test to be conducted using sera from animals vaccinated with quadrivalent vaccine ○ Pre-requisite that to qualify for cost-share payments each batch considered as ordered / sold is shown to meet this potency requirement
4	Duration of Immunity (DoI)	Minimum 6 months, with maximum of 2 doses****
5	Shelf Life	12 months
6	Differentiating Infected from Vaccinated	(i) Purified vaccine; does not induce antibodies to NSP or (ii) the response to vaccination in the target species can be differentiated

	Animals (DIVA)	from natural infection in another way (WOAH Manual, FMDV chapter 3.1.8, point 5.4)
7	Animal Safety	Compliant with WOAH safety and innocuity standards described in the WOAH Manual, FMDV chapter 3.1.8, point 4.1
8	Vial Size	1 or more vial sizes, at least one of which to be a maximum of 40 doses per vial to be appropriate for use with smallholder farmers in the Region

Footnotes

* The 70% refers to the percentage of isolates per serotype for which heterologous titers in post-vaccinal sera are above the quality threshold. The panels for each serotype will contain a number of isolates representative of FMDV topotypes currently circulating in Eastern Africa. The post-vaccinal sera to be used, and testing against the Eastern African FMDV Reference Antigen Panel, should be in full accordance with the guidelines of the World Reference Laboratory for FMD (WRL-FMD), Pirbright issued February 2020 (<http://www.wrlfmd.org/au-panvac-pirbright-twinning-project/FMD-vaccine-evaluation>), and in accordance with the associated guidance on virus neutralization test methods published in the WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2024 (WOAH Manual), and with the guidance in the latter on use of alternative serological tests. The rationale and evidence for the heterologous titers pass criteria (quality threshold) has been provided by the WRL-FMD, following consultation with the WOAH reference laboratory network and the AgResults FMD Project Technical Committee (https://www.wrlfmd.org/sites/world/files/quick_media/Cross-neutralisation%20measure%20AgResults%20Final%20v2.1.pdf).

**The Eastern African FMDV Reference Antigen Panel includes reference viruses representative of the viruses circulating in 10 countries in Eastern Africa: Burundi, Democratic Republic of Congo, Eritrea, Ethiopia, Kenya, Somalia, South Sudan, Tanzania, Uganda, Rwanda. The panel is available here: <https://www.wrlfmd.org/node/2096/>

*** As of October 1, 2022, the following Approved Labs indicated that they can provide the capability and capacity required, and are willing to participate in the testing against the Eastern African FMDV Reference Antigen Panel:

1. World Reference Laboratory for FMD (WRL-FMD), Pirbright,
2. OIE Collaborating Center for Validation, Quality Assessment and Quality Control of Diagnostic Assays and Vaccine for Vesicular Diseases in Europe, Sciensano, Belgium

Approval for inclusion of additional laboratories for the provision of testing services against the Eastern African FMDV Reference Antigen Panel will be at the discretion of the AgResults FMD Project Technical Committee. Laboratories approved for this testing will be identified on the Website: <https://www.galvmed.org/foot-and-mouth-project/resources-potential-competitors/>

**** First vaccination should consist of primary vaccination followed by a boost vaccination 4-6 weeks later. Thereafter, Duration of Immunity should be at least 6 months. Re-vaccination after Duration of Immunity should be by a single boost vaccination.

Schedule 2

Vaccine Quality Verification Protocol, May 2024

An FMD vaccine that is approved by the AgResults FMD Judging Panel must continue to meet the Eligibility Criteria, as demonstrated by successful completion of annual quality verifications. If at any time the FMD vaccine fails to meet the Eligibility Criteria, the Competitor will be ineligible for further Awards until the Competitor is able to establish to the Judging Panel's satisfaction that its FMD vaccine meets the Eligibility Criteria. Notwithstanding the foregoing, any sale by Competitor in an Approved Country that would have been an Eligible Sale but for non-compliance with the Eligibility Criteria, that was Completed prior to the earlier of the date that (i) GALVmed first notifies Competitor of such non-compliance and (ii) Competitor knew, or reasonably should have known, of such non-compliance, shall continue to be eligible for the Awards in accordance with Section 6 of the Rules.

The vaccine quality verification protocol is as follows:

Testing

- One vaccine batch per Competitor will be tested annually, starting the year after the vaccine's approval into the Competition and ending in 2027.
- Virus Neutralization Test (VNT) will be conducted by the Quality Verifier, against the full Eastern African FMDV Reference Antigen Panel, with Day 0 and Day 21 sera generated in cattle that were inoculated with a field dose of a defined vaccine batch within three months of vaccine production. The pass criteria will be the same as used for approval into the Competition.
- Competitor will send a verified summary of batch release data to GALVmed as soon as it is available. Verified summary batch release data should contain at least the minimum of data shown in the "Batch Release Data" section below.

Sera Generation/Collection/Shipment

- VNT will be conducted on sera generated by the Competitor as part of their batch release protocol.
- Competitor to ship sera to Pirbright Institute and store a vial of vaccine from the same batch in a sealed container in their refrigerator (with a temperature logger), in case of a need to re-test.
 - Pirbright Institute to manage shipping logistics and payment.
 - AgResults to pay Pirbright Institute for shipping and testing costs.

Independent Review of Sera Generation and Collection Process

- Within six months of the approval of a vaccine by the AgResults FMD Judging Panel, the Competitor will share the following with GALVmed:
 - SOPs for the sera generation and collection process
 - relevant GMP inspection report
- GALVmed will review these documents and assure compliance with international standards.

Batch Release Data

The verified summary of batch release data should contain the following information, at minimum:

1. Product Name / Code

2. Batch Details

- a. Batch Number
- b. Batch Size
 - i. Volume
 - ii. Quantity of vials
- c. Production Date
- d. Expiration Date

3. Place of Manufacture

4. Antigen Strains

Serotype	Details of Strain(s)*	Potency (PD50)**
O		
A		
SAT1		
SAT2		

*If the vaccine contains multiple strains per serotype, include details of all strains.

**PD50 – 50% protective dose in cattle as described in Ph. Eur. monograph 0063.

5. Adjuvant

6. List of Excipients

7. Test Results

Information to confirm that the batch meets Competition and WOAHP standards:

Test	Description of Process	Status/Outcome	Date
Inactivation Kinetics			
Innocuity Test			
Sterility Test			
Appearance			
Potency Test			
Mycoplasma test			
PH			