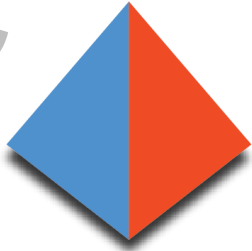


RSC  
12



GF-TADs

GLOBAL FRAMEWORK FOR THE  
PROGRESSIVE CONTROL OF  
TRANSBOUNDARY ANIMAL DISEASES



Food and Agriculture  
Organization of the  
United Nations



World Organisation  
for Animal Health  
Founded as OIE

*Africa*

African  
Union 

## Updates on progress made in availability of FMD vaccines in Eastern Africa

- ▶ Badi Maulidi, Buyer Relations Lead for AgResults FMD Vaccine Challenge Project
- ▶ GALVmed

  
AgResults  
INNOVATION IN RESEARCH  
AND DELIVERY

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# RSC 12



**\$152** million multi-donor initiative that uses Pay-for-Results (PFR) prize competitions to incentivize the private sector to invest in high-impact agricultural innovations that help achieve the following goals:



Reducing Food Insecurity



Improving Household Nutrition and Health



Increasing Livestock Productivity

AgResults' **theory of change** rests on the idea that, if appropriately incentivized, the private sector will respond by creating and/or scaling new technologies to benefit smallholder farmers:



Canada

Gates Foundation



## Overview: FMD Vaccine Challenge Project

An 8-year, US\$17.34M prize competition that supports development, registration, and uptake of high-quality FMD vaccines tailored to match the currently circulating strains in six Eastern Africa countries: Burundi, Ethiopia, Kenya, Rwanda, Tanzania, Uganda.

### Project Objectives



Develop and register high-quality FMD vaccines tailored to the needs of Eastern Africa



Create greater market stability and affordability through increased production and purchase of FMD vaccines that are regionally relevant



Build a private sector model for FMD vaccine purchase and distribution to complement public sector efforts



### Anticipated Impact



Incentivize manufacturers to support long-term efforts to control FMD in the Eastern African market with regionally appropriate vaccines

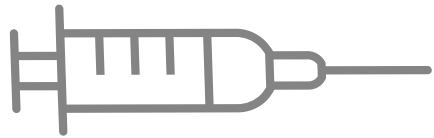


Increase access to and uptake of effective FMD vaccines



Reduce FMD-driven production losses for small-scale farmers in the region (estimated USD\$2.3 billion per year across sub-Saharan Africa)

## Fostering Development of High-Quality, Regionally Relevant Vaccines

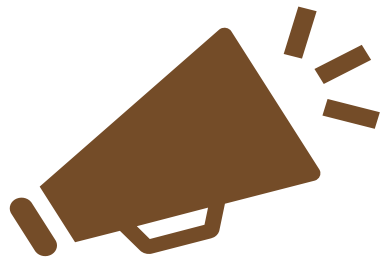


To be eligible for the AgResults FMD prize, the vaccine must meet the following conditions:

- 1 Target Product Profile**  
Quadrivalent vaccine at least 6PD50 containing serotypes A, O, SAT1, and SAT2 that match circulating FMD viruses in EA.
- 2 Vaccine Registration**  
Vaccine must achieve full registration in at least one target country (Burundi, Ethiopia, Kenya, Rwanda, Tanzania, Uganda).
- 3 Vaccine Approval**  
Judging Panel reviews applications and grant approvals to those vaccines that meet the eligibility criteria in first two columns.

**\$** The prize is structured as a **USD\$15.8M cost-share** that reduces the cost-per-dose for buyers who purchase directly from manufacturers, enabling public and private sector actors to better combat FMD through access to more effective vaccines.

## Major Project Milestone



**1st October 2024:** the Project announced Biopharma (Morocco) as the first company to register a quadrivalent FMD vaccine in Eastern Africa and meet the AgResults eligibility criteria.

Other FMD vaccine manufacturers can join the competition up to July 2027.

### The Cost-Share Phase launched on 1<sup>st</sup> October 2024.

Sales Period	# of Months	Start Date	Cost-Share %*	Total Doses Supported
1	18	1 Oct 2024	75%	3,000,000
2	14	1 Apr 2026	65%	4,250,000
3	14	1 Jun 2027	55%	5,250,000

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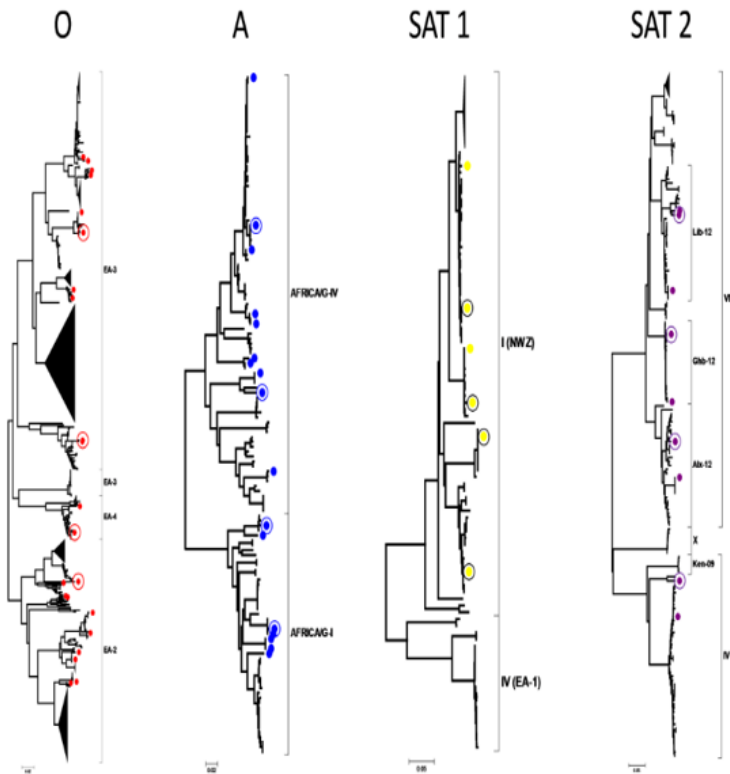
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## Vaccine Valency: Demonstrating the Regional Relevance



Phylogenetic representation (based on VP1 sequences) of FMDV lineages circulating in Eastern Africa. Candidate reference antigens are indicated by the coloured dots, from which the 16 reference antigens (highlighted by circles) in the Eastern Africa panel were selected. These trees also include sequences for FMD viruses from other African regions which were excluded from the selection process. Source: <https://www.wrlfmd.org/node/2096/>

- ▶ The Eastern Africa Foot and Mouth Disease Virus Reference Antigen Panel comprises 16 FMDV strains clustered into 4 serotype sets: O, A, SATs 1&2. Strains are selected to encompass the greatest extent of genetic diversity within the FMDV lineages that circulate in Eastern African countries.

— 4x Serotype O      4x Serotype SAT1  
— 4x Serotype A      4x Serotype SAT2

- ▶ For each vaccine submitted to the competition, cattle sera generated by vaccination (either one or two dose sera) will be subject to a Virus Neutralization Test for relevance to the Eastern African region. Current approved testing labs are Pirbright (UK) and Sciensano (France). It is expected that AU-PANVAC will establish testing capability during the lifetime of the AgResults Project.
- ▶ A threshold titre, pre-defined by Pirbright, provides a pass or fail for the vaccine's suitability for the AgResults competition. Minimum 70% pass rate is required for each serotype set.



## Impacts of the Eastern African FMDV Reference Antigen Panel



This is the first time that the independent approach of an antigen panel test has been applied to vaccine assessment before commercialization. In the lifetime of the AgResults FMD Vaccine Challenge Project we have seen the following impacts:

- ▶ Regulators unanimously agreed to authorize vaccines that do not contain local strains.
- ▶ Because of the AgResults requirement for testing against the FMDV antigen panel, potential buyers have expressed more confidence in vaccine efficacy.
- ▶ Promotion of the Eastern African FMDV antigen panel has generated interest in development of similar antigen panels for other regions, an initiative that is currently being undertaken by Pirbright. These future panels have the potential to demonstrate the efficacy of the vaccines being developed for Eastern Africa in other parts of Africa.

## Regulatory Authority Capacity Building to Support Harmonised Registration of Regionally-Relevant Vaccines

- ▶ Memorandum of Understanding (MOU) signed (2017) between EAC and GALVmed on the harmonisation of registration of veterinary medicines and mutual recognition procedures (MRP).
- ▶ Cooperation since 2020 between EAC, GALVmed, and UK Veterinary Medicines Directorate (VMD) on harmonisation of registration of FMD vaccines in the form of:
  - ▶ Training Workshops / Meetings, including 3-day training with senior assessors from Eastern African NRA (Nov 2020)
  - ▶ Development/ adoption of annotated EAC Guideline 2 (GL2) on technical requirements for marketing authorization to support the National Regulatory Authorities (NRA), provides the basis for harmonization of authorisations in line with at least the minimum international standards for FMD vaccines defined in the WOAH Terrestrial Manual.
- ▶ EAC Technical Working Group agreed that:
  - ▶ FMD vaccines may be approved as conventional multi-valent authorisations or by using the multi-strain dossier approach, in which a range of strains are included on a single authorisation to allow different combinations of strains in final product, subject to regulatory controls and limits.
  - ▶ Close cooperation between the NRA and CVO/DVS is key as both are involved in authorization of FMD vaccines.
  - ▶ The EA FMDV Reference Antigen Panel provides a valuable tool to assist the selection of vaccine strains.

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## Encouraging Public-Private Partnerships to Address Challenges in the FMD Vaccine Value Chain

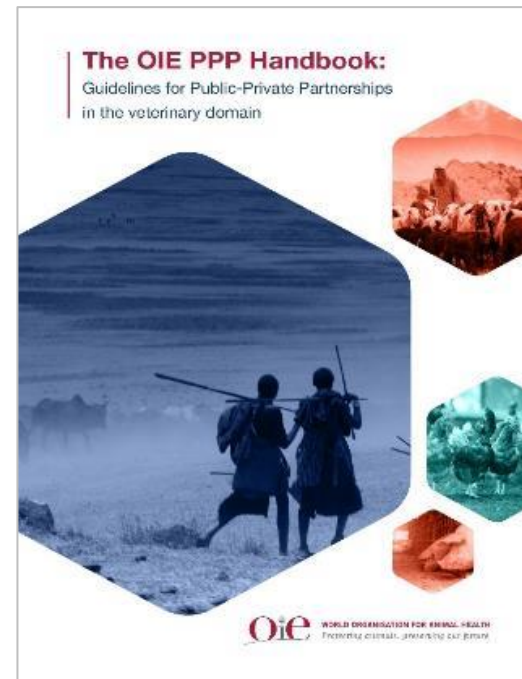
### ► PPP Framework Objective and Value

The AgResults FMD Project Team developed this framework to create awareness about the benefits that PPPs could bring to the Foot and Mouth Disease Vaccine Value Chain (FMD VVC) in Eastern Africa - from production, purchasing, distribution, delivery, and vaccinations to post-vaccination monitoring - that would complement current public sector efforts, resulting in improved vaccine accessibility for farmers, greater market stability and increased vaccination coverage.

### ► Scope of the PPP Framework

It customizes aspects of the WOAHP PPP Handbook into a practical framework that can be further developed into appropriate commitments between partners.

It addresses the challenges of the FMD VVC and is relevant to the unique FMD control situation in each of the Project's target countries. It can also be applied more broadly to other livestock VVCs and other geographies.



## Key PPP Challenges for FMD Vaccine Value Chain

The project conducted outreach to more than 140 stakeholders in Eastern Africa and beyond. Public (47%) and private (53%) sectors contributed.

The biggest challenges identified through stakeholder feedback were:

1. High costs of vaccination
2. Limited capacity in vaccine supply chains
3. Long vaccine supply lead times
4. Challenge in current vaccine to address all the regional FMD risks
5. Challenges with serotyping and vaccine matching
6. Limited post-vaccination monitoring

*Note:* Challenges 1-3 apply to all AgResults target countries, and challenges 4-6 apply to a subset of target countries.

## Promoting PPPs in the Eastern African Region

- ▶ The Project has engaged with WOA, EuFMD, USDA-TRASE Project and others on PPP activities related to the FMD vaccine value chain in the Eastern African region.
- ▶ The Project has created awareness on PPPs in various Eastern African regional and national platforms and association meetings (EA-RAHN, TVA, KVA, APSK, etc.)



***The AgResults FMD Vaccine Challenge Project continues to identify opportunities to encourage initiation and scale-up of PPP opportunities that can strengthen the FMD vaccine value chain in Eastern Africa and thereby increase the impact of the Project.***

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## Recommendations for Adoption by The 12<sup>th</sup> GF-TADs Conference

### ► Improve/Maintain FMD Vaccine Quality and Performance

#### *Continuing workstreams (inside/outside Project scope):*

- FMD Manufacturers/Suppliers must demonstrate vaccine efficacy to circulating strains in the region.
- Encouragement of vaccine registration and testing by AU PANVAC/WRL Pirbright.
- Pre-qualification of approved vaccines relevant for the region.
- Improvement of FMD surveillance systems and post-vaccination monitoring (PVM).
- More investments in cold chain, vaccine handling, and vaccination campaigns.

### ► Increase Vaccination Coverage for Effective Control

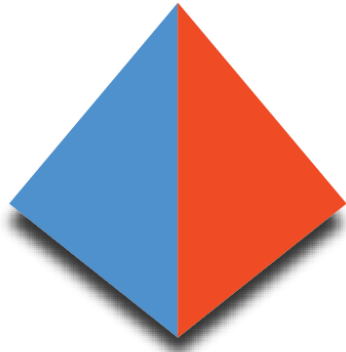
#### *Proposed future initiatives (outside Project scope):*

- Establishment of **regional FMD antigen banks** for emergency and prophylactic vaccinations.
- Development and implementation of an **information portal to connect vaccine manufacturers and buyers**.
- Policy reviews and budgetary allocation to promote pro-active vaccination and increase vaccination coverage.
- Regional coordinated approach to FMD control between key institutions: AU IBAR, WOA, FAO, IGAD, EAC, etc.

Follow our progress by signing up for Project updates here:

[www.galvmed.org/foot-and-mouth-project](http://www.galvmed.org/foot-and-mouth-project)





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