AgResults FMD Vaccine Challenge Project

Targeting FMD Vaccines for Eastern Africa: Lessons and opportunities

BADI MAULIDI, BUYER RELATIONS LEAD
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Progress of the AgResults FMD Vaccine Challenge Project

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INNOVATION IN RESEARCH AND DELIVERY

$152 million multi-donor initiative that uses Pay-for-Results (PfR) prize competitions to incentivize the private sector to develop or distribute high-impact agricultural innovations that achieve the following goals:

- Reduce Food Insecurity
- Improve Household Nutrition and Health
- Increase Livestock Productivity

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

1. Identify or source new technology
2. Incentivize the private sector to overcome market barriers
3. Achieve wide-scale adoption and scaling
4. Create sustainable markets

Australian Government
Department of Foreign Affairs and Trade

Canada

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from the British people

WORLD BANK GROUP

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)

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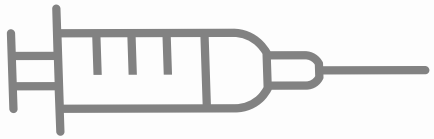
Fostering Development of High-Quality, Regionally Relevant Vaccines



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.

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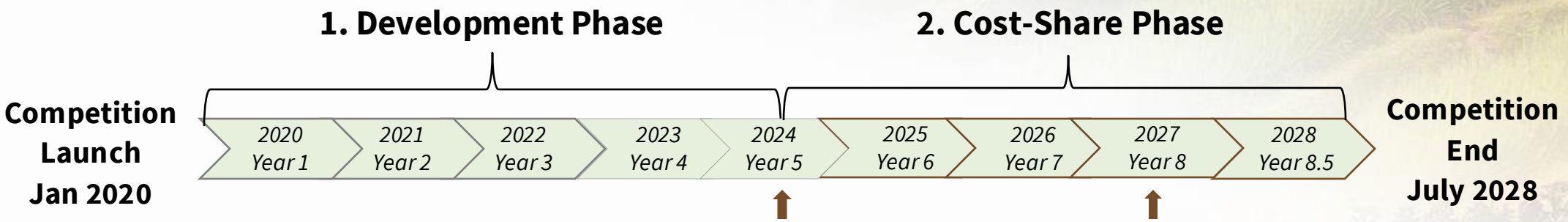
Cost-Share Phase Launch



Sep 2024: Biopharma (Morocco) was the first company to register a quadrivalent FMD vaccine in Eastern Africa and meet the AgResults eligibility criteria.

Oct 2024: Launch of the Cost-Share Phase.

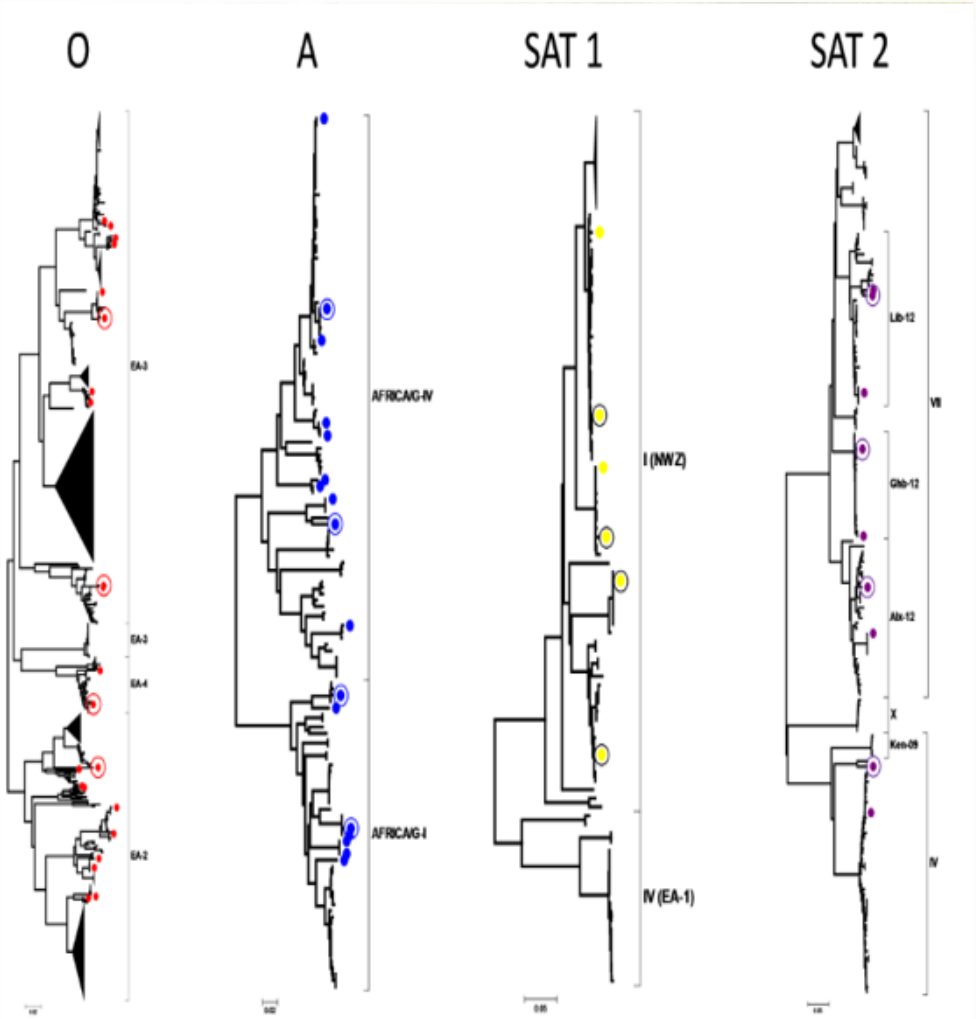
Other manufacturers can join **up to July 2027**.

The Cost-Share Phase launched on 1st October 2024 and eligible vaccines have been delivered to Eastern Africa.

Cost-Share 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

Harmonised Authorisation of Regionally-Relevant FMD Vaccines

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. The current list of testing labs approved for the competition are available on the Project website: https://www.galvmed.org/foot-and-mouth-project/
- A threshold titre, pre-defined by WRLFMD, 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 and thus far 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 Western and Southern African regions. These future panels could demonstrate the efficacy of the vaccines being developed for Eastern Africa in other regions of Africa.

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Capacity Building of Regulatory Authorities to Support Harmonised Registration

- Memorandum of Understanding (MOU) signed (2017) between EAC and GALVmed on the harmonisation of registration of veterinary medicines and mutual recognition procedures.
- 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.
  - The EA FMDV Reference Antigen Panel provides a valuable tool to assist the selection of vaccine strains.

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Proposed Way Forward

Call to Action: Proposed Way Forward

1. **Improve/Maintain FMD Vaccine Quality and Performance**
   - FMD Manufacturers to demonstrate vaccine efficacy against circulating strains in the region.*
   - Encourage vaccine registration and testing by reference laboratories.*
   - Improve FMD surveillance systems and Post Vaccination Monitoring (PVM).
   - Investments in cold chain, vaccine handling and vaccination campaigns.

2. **Increase Vaccination Coverage for Effective Control**
   - Regionally-coordinated FMD control approach led by key institutions (EAC, IGAD, AU-IBAR, WOAH, FAO-ECTAD)
   - Secure supply of high-quality, regionally-relevant FMD vaccines to meet WOAH-recommended vaccination rates (80% or higher).
   - Budgetary allocation for vaccines and vaccinations to meet WOAH-recommended vaccination rates.
   - Online platform(s) to support information transparency on vaccine access, surveillance, PCP-FMD, etc.

**Part of the mandate of the AgResults FMD Vaccine Challenge Project*

Follow our progress by signing up for Project updates here:
www.galvmed.org/foot-and-mouth-project

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