

AgResults FMD Vaccine Challenge Project

**Insights on Technical Specifications
for FMD Vaccine Procurement**

**BADI MAULIDI, BUYER RELATIONS LEAD
22ND OCTOBER 2025**



FMD Reports from AgResults Target Countries (last 5 years approx.)



- 5 serotypes – O, A, SATs 1, 2 & 3
- At least 15 different strains/topotypes

- 2 Burundi - A - SAT2
- 10 Ethiopia - O- A- SAT1- SAT2
- 5 Kenya - O- A- SAT1- SAT2
- 2 Rwanda - O- SAT2
- 4 Tanzania - O- A- SAT1- SAT2
- 7 Uganda - O- A- SAT 1- SAT2- SAT3
(SAT3 in buffalo only)

Sources: World Reference Laboratory for Foot and Mouth Disease (WRLFMD) quarterly reports and WOA/FAO FMD Reference Laboratory Network annual reports

Fostering Development of High Quality, Regionally Relevant FMD Vaccines



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



Vaccine Development to Target Product Profile (TPP) Standards:

- Quadrivalent Vaccine at least 6PD₅₀ containing serotypes A, O, SAT1 and SAT2 that match circulating FMD viruses as demonstrated through serological testing against the Eastern African FMDV Reference Antigen Panel
- 12-month shelf life; 6-month duration of immunity
- Differentiating Infected from Vaccinated Animals (DIVA) capability
- Vial size to be appropriate for use by smallholder farmers in the region (max. 40 doses)



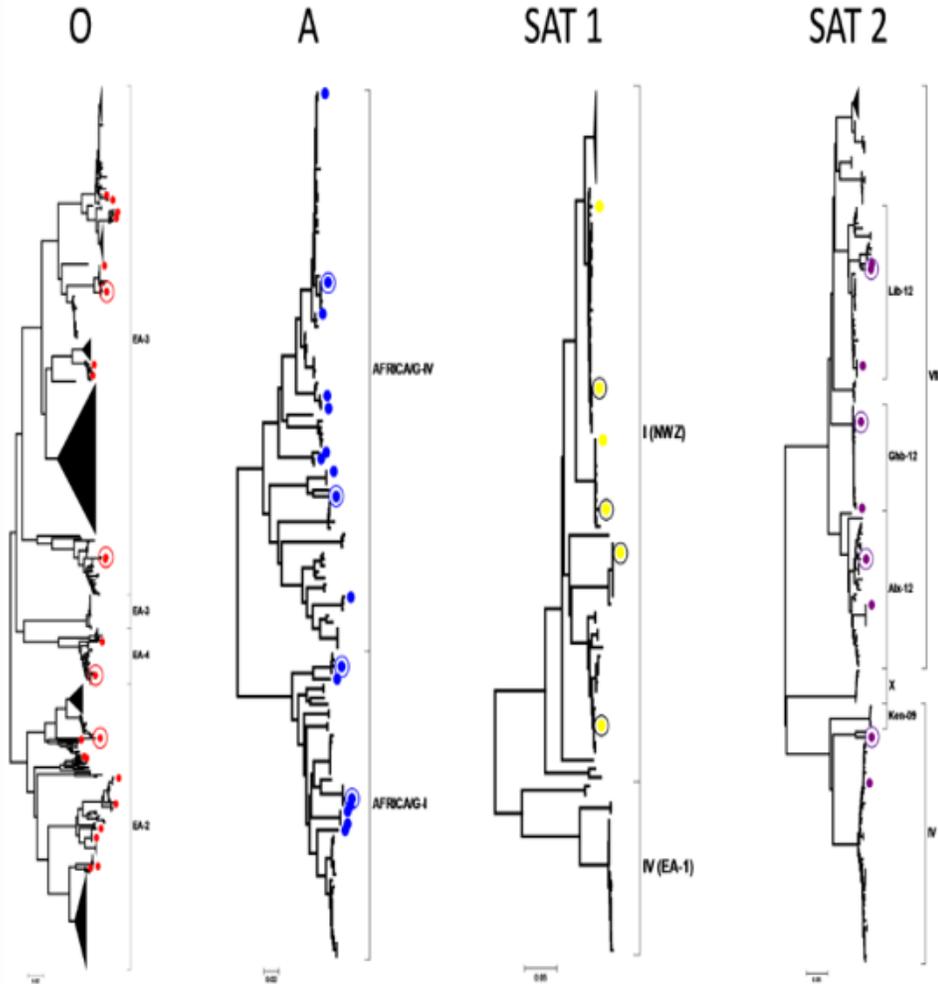
Vaccine Registration: must achieve full registration in at least 1 target country



Vaccine Approval: must be approved by AgResults Judging Panel

- Judging Panel is composed of FMD, industry and regulatory experts
- Judging Panel reviews FMD vaccine applications and grants approvals to those that meet the eligibility criteria

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.

Recommendations



1. Vaccine Quality and Efficacy

- Adopt Target Product Profile (TPP) for vaccine technical specification.
- Requirement for vaccine serological testing against the Eastern African FMDV Reference Antigen Panel.

2. Additional key specifications

- Pre-qualification of vaccine suppliers to demonstrate vaccine relevance and capacity to supply.
- Issue Multi-year Tender Framework contracts with vaccine suppliers to ensure reliable vaccine supplies.

Follow our progress by signing up for Project updates here:

www.galvmed.org/foot-and-mouth-project