

# Introduction to the AgResults Foot and Mouth Disease Vaccine Challenge Project

Presented by Jeremy Salt at GFRA 2019  
30 October 2019



The AgResults initiative is a partnership between:

**\$145** 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:



# GALVmed Vision & Mission

GALVmed was selected by AgResults as Project Manager for the FMD Challenge Project

**Our vision** is transformational improvement in the wellbeing and economic progression of smallholder livestock farmers

**Our mission** is to contribute to the transformation of smallholder farmers' lives by:

- Understanding the constraints to animal health and how to overcome them
- Engaging the animal health industry
- Ensuring awareness, availability and adoption of effective animal health interventions.



# GALVmed's Fit & Interest

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## Why GALVmed?

1. GALVmed has strong in-house expertise related to FMD and market commercialization of vaccines.
2. The Project fits GALVmed's integrated approach -- facilitating development and adoption of livestock vaccines in SSA.

## GALVmed's Interest

1. Recognition that there is still an unmet demand for FMD vaccine at smallholder and government level in the region.
2. The Project offers a long-term investment using a regional approach to achieve a common goal -- a safe, effective and affordable FMD vaccine.

# The Challenge: FMD in East Africa - Summary

FMD control in East Africa is hindered by two interconnected challenges: lack of vaccine that addresses all regional risks, and suboptimal distribution.

# 1

## Currently no available vaccine that addresses all East African regional risks.

- FMD is a complex disease with high variation in its strains which increases the difficulty of developing an appropriate vaccine for the region.
- Vaccines currently available in East Africa are costly and/or not completely efficacious against all local strains.
- Current vaccines could be improved by better matching East African strains and/or increasing antigen levels.



# 2

## Even with an improved vaccine developed, the private sector is challenged to distribute in the region given current market conditions.

- In most countries in the region, governments control FMD vaccine purchases and consider the vaccine to be a public good.
- No FMD vaccine has been formally registered in the region because they are procured through specialized processes or tenders.
- Government purchases are often reactive to outbreaks, leading to unreliable market demand.
- Government purchases and distribution do not sufficiently meet the addressable market due to constrained budgets and political priorities.



# FMD Vaccine Challenge Project Overview

The AgResults FMD Vaccine Challenge Project is a \$17.7 million cost-share mechanism that aims to meet both the technical and market requirements for an FMD vaccine in East Africa.

## Mechanism Overview

1. The Project will aim to incentivize vaccine manufacturers to develop and produce an improved FMD vaccine tailored to East Africa.
2. It will support government and private sector actors to consistently purchase high volumes of FMD vaccines by **reducing the cost-per-dose**, enabling public and private actors to better combat FMD through higher purchase volumes.
3. The Project will also support the liberalization of the FMD vaccine markets in East Africa by setting aside a minimum volume of vaccines available for purchase by only private sector actors.

## Overview of Product Eligibility

To be eligible for inclusion in the Project, each manufacturer must meet the following conditions.



### **Vaccine Development to Target Product Profile (TPP) Standards:**

- The TPP will detail the specific elements for an improved FMD vaccine for East Africa



### **Vaccine Registration: must achieve registration in at least 3 of the countries that are in-scope for the Project and pass PANVAC tests for FMD vaccine quality**

- Registration can be achieved either through the Mutual Recognition Procedure (MRP) or through individual country registrations
- Ethiopia is not currently part of the MRP, so if a company would like to access the Cost-Share in Ethiopia, this will have to be done as an individual country registration
- PANVAC testing includes vaccine matching, sterility, identification, and potency tests, providing an independent assessment of the quality of each vaccine

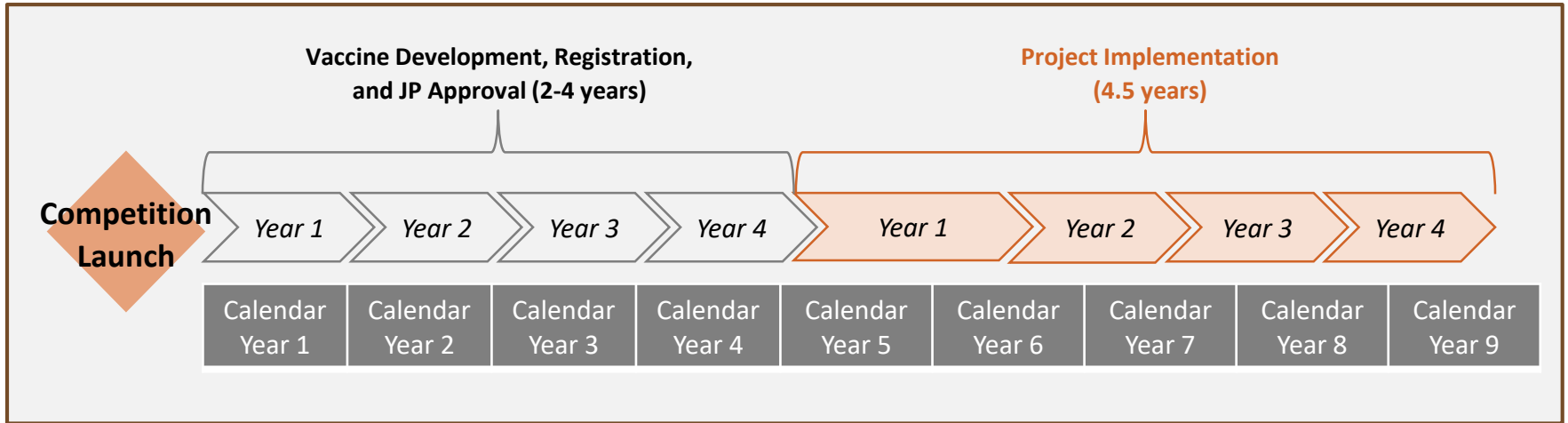


### **Vaccine Approval: must achieve approval by AgResults Judging Panel**

- The AgResults Judging Panel will be composed of industry, regional, and academic FMD experts (e.g. OIE, FAO, PANVAC representatives)
- It will review and approve applications to participate in the Project, determine if the TPP has been met, validate the registration dossier, and review outputs of PANVAC testing

# Project Timeline

The FMD project is allocating a significant time commitment (6.5-8 years) over two phases: Vaccine Development, Registration, and Judging Panel Approval (2-4 years) and Implementation (4.5 years).



## High-Level Overview of Timeline

- Launch expected in Jan 2020 and competition rules will be announced at this time.
- Vaccine Development, Registration, and Judging Panel Approval phase is expected to take a minimum of two years, and may require up to four years. If no manufacturer has communicated that they have begun the registration process by the end of Year 3, AgResults has the right to cancel the project.
- Project Implementation phase begins after successful vaccine registration and Judging Panel approval.
- During Project Implementation, the project will support government and private sector buyers through a cost-share at decreasing levels of support over the course of the four years.



**Save the Date**  
for the OFFICIAL LAUNCH of the

**AgResults Foot & Mouth Disease  
Vaccine Challenge Project**  
alongside the EuFMD Vaccine Security Meeting

**Wednesday, January 22, 2020  
Rome, Italy**

**Interested FMD vaccine manufacturers can RSVP to:  
[fmdchallenge@galvmed.org](mailto:fmdchallenge@galvmed.org)**