Brucellosis Vaccine Pilot

**Brucellosis Overview**

Brucellosis is a costly, highly contagious disease that affects cattle, sheep, goats, pigs, and other productive animals worldwide. Symptoms for infected animals include abortions, decreased milk production, weight loss, infertility, and lameness. Brucellosis is also the most common type of disease that is transmitted from animals to humans, with approximately 500,000 new human cases each year. In humans, the disease presents symptoms similar to influenza or malaria, and can be severely debilitating.

Brucellosis is endemic in a number of developing countries, where livestock management is less advanced, and has significant economic and public health consequences. The toll on smallholder farmers (SHFs) is particularly devastating, since cattle and small ruminants, such as goats and sheep, are a crucial source of income, food, and fiber for this population. While the true prevalence of the disease in livestock is not well known, the annual impact of Brucellosis to SHFs in South Asia and Sub-Saharan Africa is estimated at USD $641 million per year.

Wholesale vaccination of livestock can be a cost-effective way of controlling the disease and limiting its impact on both human and animal health. However, the existing Brucellosis vaccines are not safe or efficacious enough to use in developing countries. Current vaccines do not provide protection across different species of animal hosts, are unsafe for use in pregnant animals, can harm humans, and make it difficult to effectively differentiate infected animals from vaccinated ones. A new vaccine that addresses these shortcomings would deliver lasting benefits to SHFs’ health and livelihoods.

**Pilot Pull Mechanism Structure**

Through results-based milestone payments, the Brucellosis Vaccine Pilot aims to encourage the development of an improved, safe, low-cost, and efficacious registered vaccine for *B. melitensis*, a bacterial strain of the disease found in goats and sheep that accounts for 90% of human cases.

There are three broad stages of vaccine development: research, product development, and commercialization. The development of an improved Brucellosis vaccine rests heavily on success in the high-risk and high-cost stage of basic research. With an estimated 90-95% failure rate, successful progression through this phase is critical to the eventual development and commercialization of a vaccine. The Brucellosis Pilot will focus on the research stage of vaccine development, aiming to promote the development of a vaccine that is safe and efficacious in host animals, as well as the product development phase, to ensure vaccines are properly registered.

The pull mechanism for the Brucellosis Pilot will include three milestone payments for solvers during the vaccine development process: one for successful submission of an application to AgResults and subsequent selection by an expert review panel, the second for completion of an “Efficacy Study” phase, and the third for the successful submission and registration of a *B. melitensis* vaccine that meets Minimum Viable Product (MVP) and / or Best-in-Class requirements laid out in the Target Product Profile (TPP).

At a minimum, a registered vaccine should be safer, lower cost, and more efficacious than vaccines that exist today. The first solver who achieves these improvements and submits their product for registration will receive the final prize award of USD $20 million after they officially register their vaccine. The first solver (including the final prize winner) can receive USD $5 million for registering a
A product that hits both the MVP and one of the Best-in-Class elements. A Best-in-Class vaccine, in addition to meeting MVP requirements, will also be cross-protective against multiple strains of Brucellosis and inactivated for maximum human and animal safety.

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<thead>
<tr>
<th>Milestone 1: Application</th>
<th>Milestone 2: Efficacy Study</th>
<th>Milestone 3: Final Prize</th>
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<tr>
<td>Solvers can receive the first milestone payment based on their application submissions. Applications must meet established criteria and will be reviewed by an expert panel. This prize will be capped at 10 solvers, total.</td>
<td>Solvers who demonstrate they have successfully completed the Efficacy Study phase of product development are eligible for a milestone payment of USD $1 million. For this milestone, solvers must test a scaled-up version of the vaccine and meet TPP efficacy requirements.</td>
<td>The first solver that successfully submits their product for registration in an EU country that meets the MVP requirements set out by AgResults will receive $20M after they officially register their product. If the same—or a different—solver meets any of the Best-in-Class elements within one year of the USD $20 million prize award, they can also receive a USD $5 million prize.</td>
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**Duration**

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<th>Milestone 1: Application</th>
<th>Milestone 2: Efficacy Study</th>
<th>Milestone 3: Final Prize</th>
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<tr>
<td>Up to 1 year</td>
<td>~5-7 years</td>
<td>1-2 years</td>
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**Prize Value**

<table>
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<tr>
<th>Milestone 1: Application</th>
<th>Milestone 2: Efficacy Study</th>
<th>Milestone 3: Final Prize</th>
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<tr>
<td>$100,00 per solver to 10 solvers max</td>
<td>$1 million per solver to 3 solvers max</td>
<td>$20 million final prize for 1 solver $5 million for Best-in-Class</td>
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**Anticipated Results**

The development of a safe, low-cost, and efficacious vaccine through the Brucellosis Vaccine Pilot will have significant impact on populations affected by the disease—particularly SHFs—within the developing world. Anticipated results include:

- Improved livelihood for SHFs through the mitigation of costs associated with animal sickness from Brucellosis (abortions, lameness, compromised milk production). In India, the cost of Brucellosis in goats and sheep has been estimated at approximately USD $21 and USD $38 per infected animal.
- Economic and health benefits through the mitigation of costly human infections. Economic losses from human infection encompass the cost of hospitalization, drugs and other treatment expenses, and loss of work or income due to illness.
- Prevention of future Brucellosis outbreaks, which can put millions of humans at risk and compromise livestock industries as well as international trade. In 2012, a Brucellosis outbreak in China put 350 million humans at risk of becoming infected.

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