Addressing Neglected Animal Diseases through Pay-for-Results Incentives: Lessons from Marketing a Global Brucellosis Vaccine Competition

Introduction: Why Brucellosis?

Brucellosis is a contagious and costly bacterial disease that causes abortions, decreased milk production, weight loss, infertility, and lameness in cattle, sheep, goats, and other ruminants. Brucellosis is also the most common zoonotic disease worldwide with around 500,000 new human cases annually.[1] Brucella melitensis, the strain that affects sheep and goats, is the most virulent strain of the disease and causes the majority of human Brucellosis cases. Few countries have eradicated the disease, which remains endemic in many regions of the world, including Latin America, Middle East, Africa, and Asia. Successfully controlling Brucellosis requires an integrated approach involving slaughter of infected animals and vaccination among other measures.[2] However, existing vaccines are unsafe for pregnant animals and can cause infection in humans.[3] Culling of infected animals is also difficult in the developing world, making the creation of a safer vaccine a priority in the fight against this costly disease.

However, despite the critical need for an improved vaccine against B. melitensis, there is little economic incentive to develop one. Large commercial entities are unlikely to invest in developing vaccine candidates because of limited market potential. Similarly, smaller companies will avoid the risk associated with large, upfront costs for research and development. A third potential group, research and academic institutions, often take on development of new vaccines, but face barriers in undertaking expensive safety and efficacy testing in large animals.[4]

1   Pappas, G., Papadimitriou, P., Akritidis, N., Christou, L., Tsianos, E.V. "The new global map of human Brucellosis". Lancet Infectious Diseases. 2006, 6 (2): 91–99.
2   "Facts about Brucellosis." United States Department of Agriculture Animal and Plant Health Inspection Service.
3   Yang, X., Skyberg, J.A., Cao, L., Clapp, B., Thornburg, T., Pascual, D.W. "Progress in Brucella vaccine development". Front Biol (Beijing). 2013, 8 (1): 60-77.
4   AgResults Brucellosis Vaccine Development Business Plan.

Initial Lessons Learned

- The right PM with industry trust is key to encourage participation in a prize Challenge.

- Challenges should have rules that allow for consistent evaluation of submissions while spurring interest.

- The initial understanding of what would incent industry to address the Challenge may have been misaligned.

- An expert judging panel with complementary skills is vital to the success of the project.

The AgResults Brucellosis Vaccine Development Challenge Project ("Challenge") works to overcome these market barriers by providing three phases of results-based incentive prizes to commercial and/or academic actors ("competitors") that develop solutions to the Challenge. This Lessons Learned article explores the experience of AgResults during the Brucellosis Challenge design, launch, and Year 1 implementation phases. Lessons are presented in full at the end of the article, including insights into industry engagement and marketing, contest rule formulation, and the judging process.

Project Design: Tapping into the Global Animal Health Industry

Importance of Technical Insight and Global Connections

From the start, we envisaged marketing as crucial to encouraging competitor participation and generating excitement and publicity for the challenge. However, unique among AgResults projects is the Brucellosis

Project's scope, which is research-focused and global to provide the possibility for the best possible vaccine candidate to emerge. Therefore, we needed to engage the global animal health community, primarily through a Project Manager (PM) that not only had the technical capacity to understand vaccine R&D and the developing world context, but also has a global reach to encourage participation from competitors.

First, the Project required considerable technical expertise in vaccine R&D, commercialization and registration of veterinary vaccines, and experience in developing countries, so the Brucellosis PM's role would extend beyond the normal AgResults project management activities (work planning, competitor sign-up, stakeholder engagement, and marketing). The Brucellosis PM would also provide technical input into a number of critical tasks, such as developing technical Challenge rules, defining technical requirements of animal safety and efficacy studies, recruiting specialized experts to judge each round of competitor submissions, and promoting the Challenge at highly technical industry and research events. Facilitating the development of an improved Brucellosis vaccine that can be more effective in emerging markets also requires experience and knowledge of developing country contexts. The PM would need a deep working knowledge of the realities of animal health in developing countries to achieve the ends of the AgResults program.

Second, the Brucellosis Project Manager would need to tap into global animal health industry networks to encourage a broad set of pharmaceutical companies and research institutions to act as Competitors. Importantly, we would need to develop high trust in this novel pay-for-results process, as most pharmaceutical industry actors might hesitate to engage with external actors like AgResults due to intellectual property concerns Given the unique nature of the Brucellosis Challenge Project, AgResults identified GALVmed as the Project Manager ("PM").

GALVmed: A Project Manager at the Nexus of Industry and Development

GALVmed, a not-for-profit organization based in the United Kingdom, works with the private sector to develop new animal health products, primarily vaccines, for distribution on a commercial basis to smallholder livestock farmers in low-income countries. Much of its work consists of convening experts along with networking and facilitating partnerships, including in the private sector. GALVmed's network gives it deep and meaningful reach

Brucellosis Prize Background

The Brucellosis Vaccine Development Project is a $30 million Pay-for-Results prize contest aiming to incentivize animal health companies to develop a vaccine against Brucella melitensis. Eligible companies can receive up to three performance-based milestone payments totalling $26.1 million for one entrant.

During Phase 1, which ran from November 2017 to November 2018, we accepted applications to the Challenge, with a payout of $100,000 for those judged among the best 10 submissions. Phase 2 prizes will be awarded on evidence of successful proof of concept vaccine safety and efficacy trials. Phase 3 prizes will be awarded after successful registration of a vaccine that meets minimum requirements set forth by the Challenge. Details may be found at www.agresults.org.

into the traditional pharmaceutical industry as well as the development sector. Furthermore, GALVmed's status as a not-for-profit organization lessens private sector partners' hesitation in partnering, as pipeline confidentiality and intellectual property are of critical concern in the pharmaceutical industry.

During the Brucellosis Project design phase, the AgResults Secretariat had first-hand experience with the difficulty of accessing this particular industry, as industry actors were hesitant to engage or share information due to our status as outsiders running an unheard-of Challenge. In response, we engaged a GALVmed expert and industry insider to help establish contact and engender trust among pharmaceutical companies. That consultant's industry knowledge helped companies more openly engage the Secretariat design team and facilitate information exchange, highlighting the need for a fully linked in PM like GALVmed.

A Challenging Timeline to Launch

GALVmed formally joined AgResults as PM in April 2016, just before the official launch of the Project in Brussels in June 2016 at the International Federation for Animal Health conference. This short window required GALVmed to work quickly to facilitate the launch, which provided important initial publicity, and then prepare the Challenge for a Phase 1 start date of September 1, 2016. This window proved far too short. GALVmed had little time to convene the technical experts needed to finalize the competition rules, let alone to allow for legal review necessary for a

project with a prize structure as large and complex as this one. There was also not enough time to engage a suitable marketing firm that would be present at the launch and after to amplify the Project's message.

As a compromise, the Project's application portal opened on September 1, 2016, but only allowed prospective competitors to register interest, not apply. It would take another two months for AgResults to finalize and publicize the official Challenge rules, relaunch the project at the Brucellosis 2016 International Conference in New Delhi in November, and officially start accepting applications on November 18, 2016.

Engaging the Challenge's Judging Panel and Technical Committee

Simultaneous to the launch of the Challenge, GALVmed recruited the five-person panel who would serve as the Project's independent judges and determine the awardees in all three phases of the Challenge. Judges were recruited based on experience in animal health as well as technical vaccine research and development, Brucellosis and its impacts, regulatory affairs, marketing authorization for veterinary vaccines, and vaccine marketing and commercialization.[5] The panel was selected for its balance of industry, academic, and regulatory backgrounds. The balance has proved crucial in AgResults' ability to fully consider all aspects of the 39 applications received during Phase 1 to award prizes.

GALVmed recruited additional experts to serve on the Technical Committee, which established the technical requirements and finalized rules or the Challenge. The Committee has also been called upon to provide expert feedback on competitor questions regarding the rules.

Marketing at a Global Scale

The Need to Market the Project

In the original business plan, we identified three groups of potential competitors: large commercial firms, small commercial firms, and academic/ research institutions. We knew large firms would probably not go for a Challenge focused on Brucellosis due to the limited profitability of a new vaccine. However, the last two groups were prime targets, and they became the focus of outreach. To that end, GALVmed developed a "target competitor" priority contact list built from AgResults and GALVmed contacts.

Although GALVmed had the ability to target many of these known industry players through direct communications and industry events, we also set aside specific funding for GALVmed to engage in specialized marketing activities to amplify its reach through general and targeted communications.

For the global campaign, GALVmed conducted an open procurement and selected Garnet Keeler (GK), a UK-based firm with extensive animal health marketing and global media experience, to lead the strategy. GALVmed also hired a China-based consultant who focused on outreach to prospective competitors there, resulting in several applications received from Chinese organizations.

Targeted and Broad Outreach: A Multi-Faceted Approach

Under the oversight of GALVmed and the Secretariat, GK conducted a multi-faceted media campaign that focused on targeted communications. Press releases covering competition news, such as at the Phase 1 launch in India and upon award of Milestone 1 prizewinners provided broad coverage with more focused material being disseminated through important animal health publications, such as coverage in Animal Pharm and an article in the International Animal Health Journal. Other publications in which the competition was promoted were Vet Practice Magazine, The Sheep Site, Drug Discovery Today, and Philanthropy News Digest.

Building on GALVmed's industry presence, support was secured from events including IFAH Europe, the Animal Health Investment Forum (AHIF), the World Association of Veterinary Laboratory Diagnosticians symposium and the Vet Health Global conference: this ranged from negotiating preferential entrance rates, to providing banners and flyers for display and distribution to delegates. At several events, GALVmed speakers including Peter Jeffries, Jeremy Salt, Gwynneth Clay, and Amy Tranzillo presented in part on the Brucellosis Project. Engagement with a major organization, Health for Animals, resulted in materials being displayed at their Brussels event and sent information to their associate members around the world.

Emails and newsletters distributed to target audiences including existing vaccine developers, registered competitors, and event attendees via a database of GALVmed and event contacts, including a conference in Latin America helped broaden yet target appropriate dissemination of competition information. The targeted

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5   The same requirements were included in the final Brucellosis Challenge Rules.

communications generated high levels of engagement: Emails averaged a 46% open rate and 15% click rate, while newsletters averaged a 39% open rate and 9% click rate. For comparison, recent average results for UK email marketing campaigns are a 24.79% open rate and a 4.19% click rate.[6]

The targeted campaign ran alongside a general communications platform, which used Twitter and LinkedIn to amplify the reach of press releases and conference participation along with a News and Media section on the Brucellosis Prize Competition website that includes blogs, newsletters, graphics, and press releases.[7] Since launch, the News and Media section has attracted more than 2,400 pageviews (1,900 unique pageviews).

Results of Phase 1

The response to Phase 1 of the Challenge has been significantly greater than what AgResults expected at the onset. Instead of ten applications, we received 39. Out of those 39 applications, the independent judging panel recommended 20 to move on to Phase 2, with the top 10 receiving a $100,000 milestone award. Before the launch of Phase 1, we had developed a target competitor database built from AgResults and GALVmed contacts. From that list, we received 13 applications, of which six received a milestone award and six more moved on to Phase 2 with no award. This high pass rate highlights the success of the direct outreach strategy.

The large number of applications did present a situation that was somewhat at odds with the spirit of the Challenge rules, which allowed for prizes to the best 10 applications, but which the judging panel reviewed on a quarterly basis. The panel therefore had to take an extremely conservative approach to reviewing applications, and delayed a final prize decision on a number of applications until later quarters when the overall quality of certain applications vis-à-vis the others became clearer. In retrospect, it may

"Ten applicants to the Challenge is a high bar. More realistically there will be five to seven applicants."
- AgResults Steering Committee Meeting, September 30, 2015

Figure 1: Spring 2017 Newsletter

have been easier to render judgement on all applications only at the end of the first phase of the competition. However, the prizes that AgResults awarded at the ends of the 2nd and 3rd quarters, along with the associated publicity, may have prompted other competitors to apply.

We had considered additional outreach after Phase 1 to continue to encourage Challenge applications, which competitors can submit at any point before the final prize award. However, due to the high number of applications, we modified our focus to promote the competition and its progress rather than to encourage new competitors to join.

Another important component to address is how to encourage partnerships between competitors and other organizations who may have complementary skills and thereby increase the chances of a successful development, without explicitly prescribing partners. The prize website includes an open access partnering portal, but additional opportunities may be sought by AgResults to facilitate further partnering opportunities.

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6   Estimates provided by Smart Insights, www.smartinsights.com.
7   Accessible at www.brucellosisvaccine.org.

Conclusion and Lessons Learned

Though design, launch, and Year 1, we have gathered compelling evidence that this type of Challenge can help overcome market failures in the development of an improved vaccine. Initial insights include the following:

- **The right PM with industry trust is key to encourage participation.** During project design, AgResults had difficulties in accessing important information from potential competitors due to concerns about confidential information. Our initial experience with a GALVmed consultant, and later with GALVmed, highlighted the importance of engaging an organization as PM that has existing industry links and built-in trust.

- **Challenges should allow for consistent evaluation of submissions and use prize awards to generate interest.** The independent judging panel has provided a fair and balanced review of all submissions. However, the panel had to reconcile a quarterly review process in which they chose the best 10 applications for award with the high number of applications received overall. It may have been easier for judges to review all submissions at once. However, the early awards may have incentivized other competitors to apply in later quarters.

- **The initial understanding of what would incent industry to address the challenge may have been misaligned.** AgResults' expectations of application volume did not match with what we received, which raises questions that the AgResults External Evaluator will work towards answering. It could be that we set incentives that did not align with the amount of work towards an improved Brucellosis vaccine that many industry players were pursuing. AgResults' External Evaluator, in its ongoing evaluation, may be able to discern any specific assumptions from the initial design that proved misaligned once the Challenge began.

- **An expert judging panel is crucial to the success of the Challenge.** The science involved in the verification of this Challenge is arguably the most complex of any in AgResults. The judging panel's combination of Brucellosis research background, animal health industry experience, and developing world context allows for a thorough and fair review of all submissions. Having a five-member panel also increases cross-checking of findings and eliminates potential bias in decisions.

About AgResults

AgResults is a $147 million collaborative initiative between the governments of Australia, Canada, the United Kingdom, the United States, and the Bill & Melinda Gates Foundation to incentivize the private sector to overcome market barriers and develop solutions to food security and agricultural challenges that disproportionately affect people living in poverty. The initiative designs and implements agriculture-focused prize competitions, also referred to as pay-for-results or pull mechanisms, which are innovative development finance programs that incentivize the private sector to work towards a defined goal to receive a monetary award.

About AgResults Lessons Learned Series

One of the primary objectives of AgResults is to better understand how well pay-for-results prize competitions work to overcome market failures in agricultural development. The lessons learned series explores AgResults' experience designing and implementing agricultural-focused pay-for-results prize competitions, with the goal of providing key lessons and recommendations that development practitioners should take into account when designing similar programs.

AgResults
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