



GALVmed at 10

A decade of protecting
livestock, improving
human lives

Achievements and lessons learned



Protecting Livestock – Improving Human Lives



Acknowledgments & Disclaimer

With a staff complement of around 30 people, we would achieve very little acting alone. Partnership is at the heart of our business model. In the past decade, we have worked with over 535 collaborators and partners to whom we are greatly indebted. We acknowledge, and are humbled by, our partners' professionalism and commitment.

We also acknowledge the funding and support provided by our donors – The Bill & Melinda Gates Foundation, the UK Government, the European Commission, AgResults, Biotechnology and Biological Sciences Research Council, Innovate UK and the Aga Khan Foundation. Our donors continue to be learning partners as we apply the lessons we have learned in the past decade.

We are grateful to Scriptoria for their support in preparing this report.

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Contents

Executive summary	2
The genesis of GALVmed	3
Evolution	6
GALVmed's approach	8
Key achievements	10
Lessons learned	20
The path ahead	27
Acronyms	29

GALVmed@



Protecting Livestock – Improving Human Lives

Executive summary



GALVmed has evolved over the past decade. While our raison d'être – facilitating sustainable adoption of animal health products by smallholder farmers in developing countries – remains the same, GALVmed's approach to achieving this has significantly changed over the years. This has been possible mainly due to two factors. Firstly, adopting a deliberate learning agenda has enabled us to understand the context, learn from experience and apply the lessons learned. Secondly, we have had a flexible, professional and accommodating relationship with our donors who have been, and continue to be, learning partners.

We have matured and evolved from our inception, when activities were almost solely focused on research and development, to a period that saw the implementation of pilot field projects, to test and apply our understanding of commercial development, to our current efforts at establishing large-scale market-based commercial initiatives.

Everything that we have achieved has been through our partners. We are indebted to our varied and diverse partners, local and international. Their engagement and that of stakeholders in the livestock and smallholder sectors has been, and will continue to be, instrumental to ensuring sustainable adoption of animal health products at scale. The growing interest and enthusiasm of the animal health industry in the smallholder sector holds the promise of sustainable supply and adoption

of quality animal health products at scale by smallholder farmers.

We have made great strides over the past decade. Ten products have been delivered and proof of concept achieved for a further eight products. Over 2.5 million households have been reached through commercialisation of eight products, 170 million doses of Newcastle Disease vaccine have been sold and 1.7 million cattle have been vaccinated against East Coast Fever. The estimated value of livestock disease mortalities that has been averted is USD 167 million.

We will continue to build on the achievements of the last 10 years and apply the lessons learned so that we improve the service that we, and our partners, offer, to meet the needs of smallholder farmers. Going forward, we have committed to delivering an ambitious and coherent programme of work that will make significant strides towards achieving the vision of better livestock health enabling smallholder farmers to improve their livelihoods. The major emphasis is on scale and a revised approach that reflects the reality of smallholder farming – the need for a comprehensive suite of animal health inputs that address the needs of a range of livestock species.

Among all of GALVmed's valued partners, smallholder farmers most strongly influence the direction we take. Our work begins and ends with meeting the needs of smallholder farmers in developing countries.

The genesis of GALVmed

In 2018, GALVmed marks 10 years of activities focused on bringing effective livestock vaccines, medicines and diagnostics to millions of smallholder farmers in sub-Saharan Africa and South Asia. Livestock are an intrinsic part of small-scale agriculture and of critical importance to the livelihoods of hundreds of millions of individuals and families. It is estimated that one in every five people depend on the livestock sector as a primary source of income. Livestock diseases therefore pose a significant risk to economic gains and livelihoods. At a household level, livestock are often the most valued possession for smallholder farmers. These valuable assets are also vulnerable assets: the mortality and morbidity rates of many livestock diseases in Africa and Asia are high. These diseases can lead to catastrophic loss for smallholder farmers.

GALVmed was created in 2008 from the recognition that while improved livestock health can create enormous benefits for smallholder farmers and can significantly improve productivity and livelihoods, suitable products and professional advice were not reaching smallholder farmers in developing countries. Effective livestock vaccines and medicines are valuable farming inputs that offer smallholder farmers, and donors, a return on investment that few other farming inputs can match. Our vision is to see such livestock vaccines and medicines in widespread, sustainable use by smallholder farmers.



Timeline

2005

GALVmed formally incorporated with initial seed funding of GBP 2.6 million from the UK Government's Department for International Development (DFID) to establish the organisation and seek long-term funding.

2008

GALVmed awarded USD 28 million joint funding from the Bill & Melinda Gates Foundation (BMGF) and DFID to implement the first Protecting Livestock, Saving Human Life programme (PLSHL 1).

2009

GALVmed awarded EUR 6.9 million from the European Commission via the African Union Inter-African Bureau for Animal Resources (AU-IBAR) to implement the Vaccines for the Control of Neglected Animal Diseases in Africa (VACNADA) programme aimed at improving the technical capabilities of eight national laboratories in the production of four key livestock vaccines.

2011

GALVmed awarded GBP 8 million from DFID to implement the first phase of the Animal African Trypanosomosis (Tryps) programme to develop a novel trypanocide.

2013

GALVmed awarded USD 52 million joint funding from BMGF and DFID to implement the second Protecting Livestock, Saving Human Life programme (PLSHL 2).

GALVmed awarded USD 1.5 million joint funding from BMGF and DFID via the Harbin Veterinary Research Institute to evaluate the Chinese-developed BEN-1 contagious bovine pleuropneumonia (CBPP) vaccine in Africa.

2014

GALVmed awarded USD 14.4 million by BMGF and DFID in a jointly funded programme to implement the second phase of the Tryps programme.

2016

GALVmed awarded GBP 200,000 from Innovate UK as part of a multidisciplinary collaboration to enhance the East Coast Fever Infection and Treatment Method (ECF-ITM) vaccine, particularly vaccine stability.

GALVmed awarded USD 1.7 million from AgResults, a multimillion dollar, multidonor, multilateral initiative, to implement the Brucellosis Vaccine Prize, a USD 30 million global competition to develop a vaccine against brucellosis.

2017

GALVmed awarded USD 50 million joint funding from BMGF and, subsequently in 2018, by DFID, to implement the Veterinary Innovations Transforming Animal Health & Livelihoods (VITAL) programme.

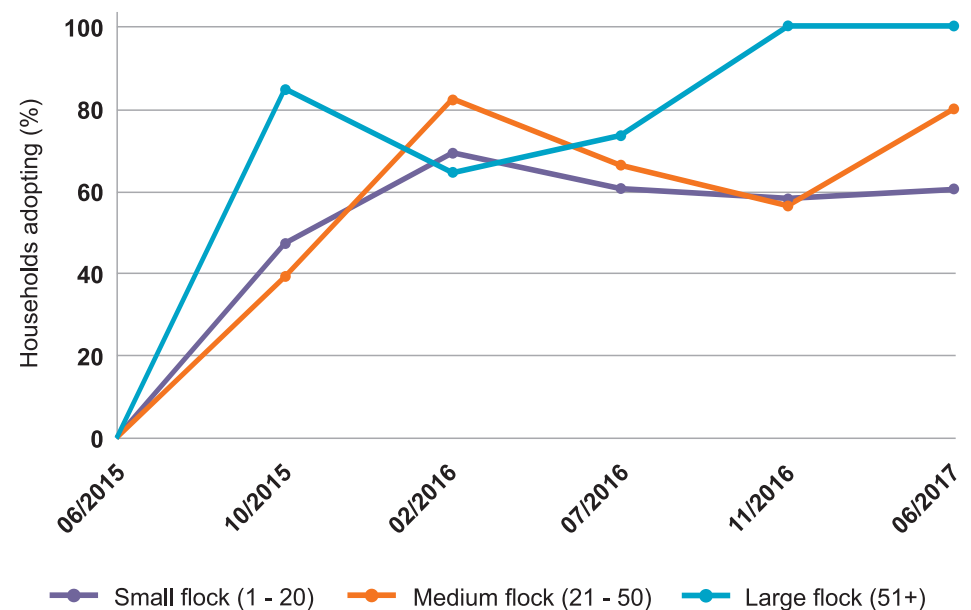
GALVmed awarded USD 3 million from BMGF to oversee and support a programme of activity to develop a viable business model for providing quality veterinary healthcare to smallholder farmers in Africa.

GALVmed awarded a further USD 4.3 million supplementary funding for the Tryps programme by BMGF and DFID.

Insight

Smallholders with larger flock sizes adopt vaccines earlier and at higher rates than those with smaller flock sizes.

ND vaccine uptake in Uganda (zero vaccine available at baseline)



Evolution



In the early years, 'low hanging fruit' was the initial focus for product development rather than a long-term, high-impact product development portfolio. There was considerable emphasis on high-level advocacy and promoting the livestock agenda, while commercial development was not considered an area of great focus. With the recognition that product uptake presented a significant challenge, GALVmed's strategy evolved over the course of earlier programmes.

Our work can now be best understood in two strands: product development – where a new or improved product is developed to meet the specific needs of smallholder farmers – and commercial development – using the inherent commercial value of products to make them widely and sustainably available to smallholder farmers. A broad range of support functions, such as policy and monitoring and evaluation, underpin these two strands. Functions such as finance and legal, project management and human resource management, continue to be the backbone supporting project delivery.

Over the years, the strategic approach to implementing product development and commercial development activities has evolved. Our product development work is more than 'just' product development. We use innovative approaches to develop new products and conduct product process improvement. These include facilitating complex consortia, such as our

work on the Tryps programme. We often facilitate public–private, north–south partnerships, leverage intellectual property and technology transfer and use innovative mechanisms for increasing investment in product development, such as the AgResults-led Brucellosis Vaccine Prize – a USD 30 million prize competition inviting vaccine developers to develop a suitable vaccine for use against *Brucella melitensis* in small ruminants in developing countries.

In commercial development, our work began with small-scale pilot projects to test and understand models for the delivery of key vaccines and vaccination services to livestock smallholders. As a result, our understanding of the smallholder sector developed significantly. We are still learning, but now have a broad base of experience from which to start scaling up from the earlier pilots to commercial market initiatives. Our commercial development work is not only about increasing adoption of GALVmed-supported products, it is crucially also about demonstrating that the smallholder sector is a financially viable market segment.

Underwriting all aspects of commercial development is the willingness of smallholder farmers to pay the market price for essential livestock health products. This willingness is driven by the recognition that appropriate animal health products represent a profitable investment through reduced mortality rates and increased productivity.

Economics of a vaccine

Average value of a goat



Typical PPR mortality rate



Typical cost of PPR vaccine



Insight

Very few livestock-owning smallholders operate on a purely subsistence basis. Most smallholder farmers overwhelmingly participate in the cash economy. Because we rely on smallholders paying the market price for animal health inputs, this is a fundamental cornerstone of our market understanding.

Livestock sales and investments



GALVmed's approach



Our vision of success is a world where markets supplying smallholder farmers function well and GALVmed's funding and support is no longer needed. This makes us unique and different from many NGOs and charities. We aim to make targeted interventions that result in lasting and sustainable outcomes. These interventions also need to be replicable and scalable. Thus, sustainability and scalability inform our strategy and are key criteria in our choice of partners.

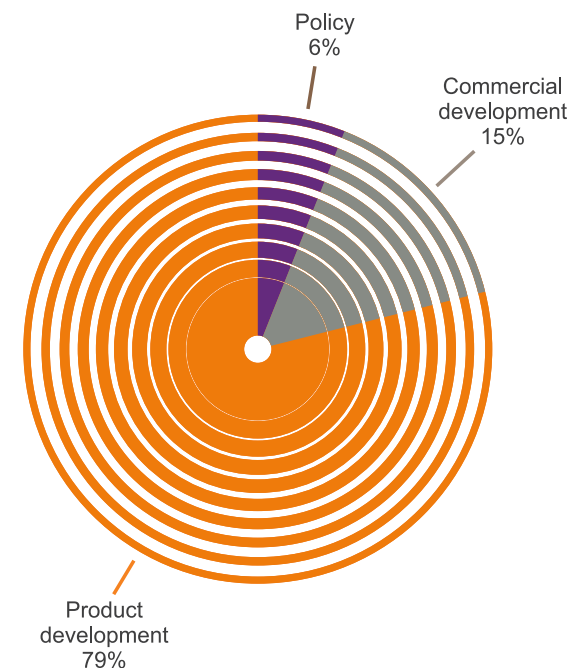
Our experience in commercial development has led us to an increased emphasis on collaborating with private sector partners who recognise the value in the smallholder market segment and wish to develop sustainable mechanisms for accessing this opportunity. In markets where the private sector is underdeveloped, we have, in the past, worked with other proven, credible and delivery-focused partners.

In product development, we go to where the best science is. This typically involves forming and facilitating partnerships with universities, research institutes and the private sector, including biotechnology companies.

The impact of our work in product and commercial development can sometimes be limited by policy and regulatory environments that present barriers to project delivery. We have established good links with policy makers and continually seek to build the right strategic

Project expenditure by area, 2008–2018

GALVmed projects have involved mutually supporting activities to develop products and commercial markets, with product development demanding the largest share of expenditure.



partnerships to support our efforts to address policy bottlenecks. This often includes working with national medicines registration agencies to increase the efficiency of registration of veterinary products, government livestock departments, veterinary boards and councils and other global and regional

organisations, such as the World Organisation for Animal Health (OIE), Food and Agriculture Organization (FAO) and AU-IBAR, that have a mandate in addressing policy-related matters.

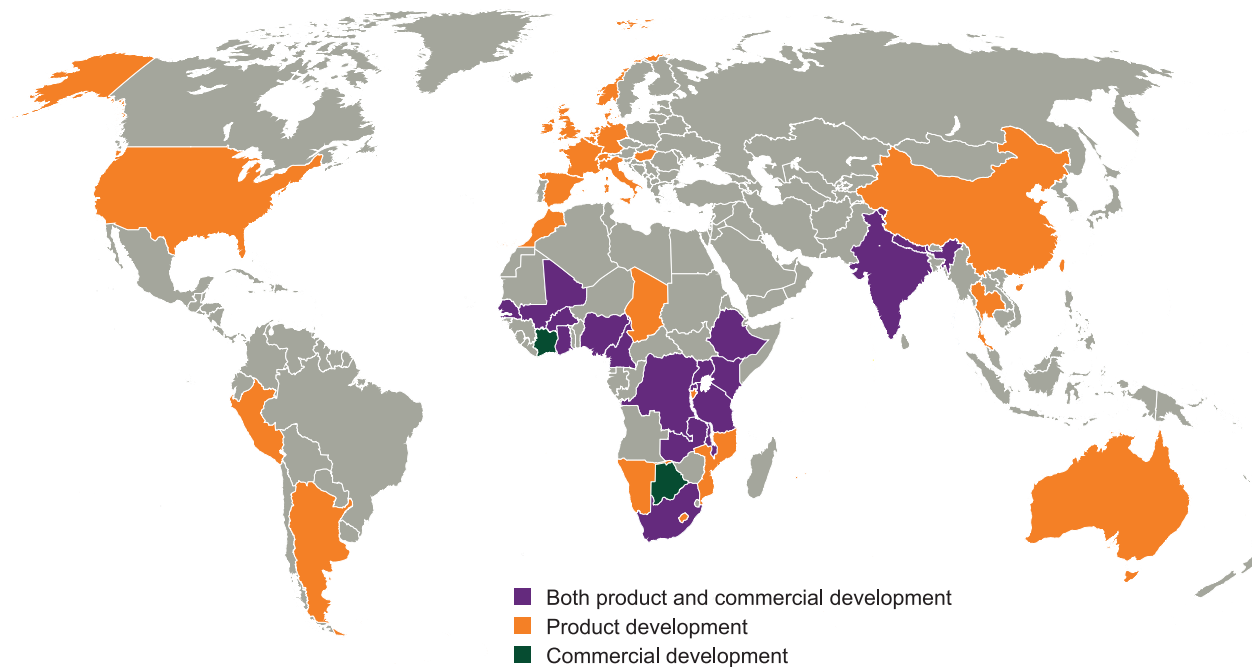
Our achievements are attributable to a long list of collaborators and partners, from governments

to the private sector, the research community, vaccinators and livestock owners themselves. Our interventions continually aim to produce outcomes, through working in partnership, that are replicable, scalable and will carry on long after our involvement. Ultimately, our vision of success is a world where smallholder farmers

in developing countries routinely use a suite of effective veterinary products to protect their livestock and, in turn, improve their livelihoods. Everything our partners accomplish is a step towards this.

Location of product and commercial development partners, 2008–2018

Our product and commercial development activities involve partners in 45 countries across six continents.



Key achievements

1

Scale and reach of commercial development initiatives

During the first phase of GALVmed, the commercial development projects were reaching 10,000 to 20,000 smallholder households. By the end of 2017, this figure had risen to well over 2.5 million households benefiting during the past decade. This is a significant increase in scope and scale over a relatively short period. Furthermore, it points towards the viability and sustainability of these business initiatives that provide valued farming inputs actively sought after by the majority of smallholders who are willing to pay the market price for these products.

2

Engaging the animal health industry in product and commercial development initiatives

During the early years of GALVmed's existence, there was little appetite from the animal health industry in specifically targeting the smallholder sector. A decade later, we are either directly partnering with, or planning activities with, a wide representation of the animal health industry, covering both product and commercial development activities. This emerging engagement reflects, in large part, our sustained focus and effort in highlighting the opportunities in the smallholder sector.

3

An expanded and innovative product development pipeline

When GALVmed was created, it was, in part, based on the assessment that, while a lot of good research into livestock diseases impacting on smallholder farmers had been undertaken, few products had been taken through to development and registration. By the end of the decade, 25 product development projects were completed or are currently underway. This expansion reflects a judicious and dynamic portfolio approach whereby development projects with little likelihood of success are stopped early and the funding channelled into new opportunities with good potential for impact.

Key achievements

4

Mutual recognition of vaccine registration

Over the past eight years, substantial effort has been devoted to facilitating the standardisation of registration requirements across six countries in the East African Community (EAC) leading to mutual recognition of veterinary vaccine registration. The highest level of political and legal endorsement was obtained in 2016 when the EAC Council of Ministers issued a directive to EAC partner states to implement the Mutual Recognition Procedure (MRP) developed with GALVmed support. MRP will make the system of registration of veterinary products more efficient through simultaneous granting of marketing authorisations by participating countries. The first product, submitted by a multinational company, has been registered and two more products are in the process of registration.

5

Leveraging organisational capability for other development projects

The significant scope and scale of the two main PLSHL programmes necessitated a good degree of organisational support and effectiveness. This support infrastructure has enabled us to support a range of other animal health development programmes. These include a programme to develop a novel trypanocide (the Tryps programme), the Brucellosis Vaccine Prize (focusing on development of improved vaccines to control brucellosis in small ruminants) and a number of smaller projects. Over the course of the past five years, GALVmed has refined its support functions so that these form a lean and effective foundation for the delivery of product and commercial development projects.

6

Products delivered

In addition to substantially expanding the pipeline of new products in development, the original target to develop three to five and five to seven new products during the PLSHL 1 and PLSHL 2 programmes, respectively, was achieved. Ten products have been delivered in the past decade.



The following are developments and achievements in addressing smallholder needs in each disease area.



East Coast Fever (ECF)

The only immunological approach that protects cattle against ECF is the ECF-ITM (or Muguga Cocktail) vaccine, which is relatively complicated to manufacture, yet highly effective. ECF-ITM involves injecting a preparation of live *Theileria parva* parasite, which takes more than a year to produce, at the same time as a long-acting antibiotic. We supported work to improve the production process – reducing the vaccine production time by three months – while transferring the technology from the International Livestock Research Institute, where it was originally developed, to larger-scale production at the African Union Centre for Ticks and Tick-borne Diseases (CTTBD) in Malawi. This vaccine is now registered in Malawi and Rwanda and is in the process of registration in three other countries. Development work has also been conducted to produce 10-dose vials of the ECF-ITM vaccine, which would be preferable for the smallholder dairy sector than the current 40-dose vials. A novel diluent, which will significantly reduce the production and storage costs of the ECF-ITM vaccine, has been identified and is ready to be field-tested before commercial implementation. Despite the complex process of producing and administering this vaccine, an unprecedented 1.7 million cattle have been vaccinated so far.

Newcastle Disease (ND)

Two thermotolerant ND vaccines, which are easy to transport and administer to poultry, were among the most successful product development outputs funded during the first years of GALVmed. A LaSota strain vaccine, manufactured in India, and an I-2 strain vaccine, made in Morocco for the African market, are already in widespread use in both regions. The relative thermotolerance of these vaccines means that they are suitable for the rural environment, where maintaining a cold chain is particularly challenging; their delivery as ocular drops means that they can easily be administered by village-based vaccinators or farmers themselves. Through our partners, about 170 million doses have been sold. We have also funded the development of a fast-dissolving tablet form of the vaccine, and are facilitating transfer of the technology to commercial partners, which could make this much-needed vaccine even easier to deliver to smallholder farmers in remote areas.



A growing flock

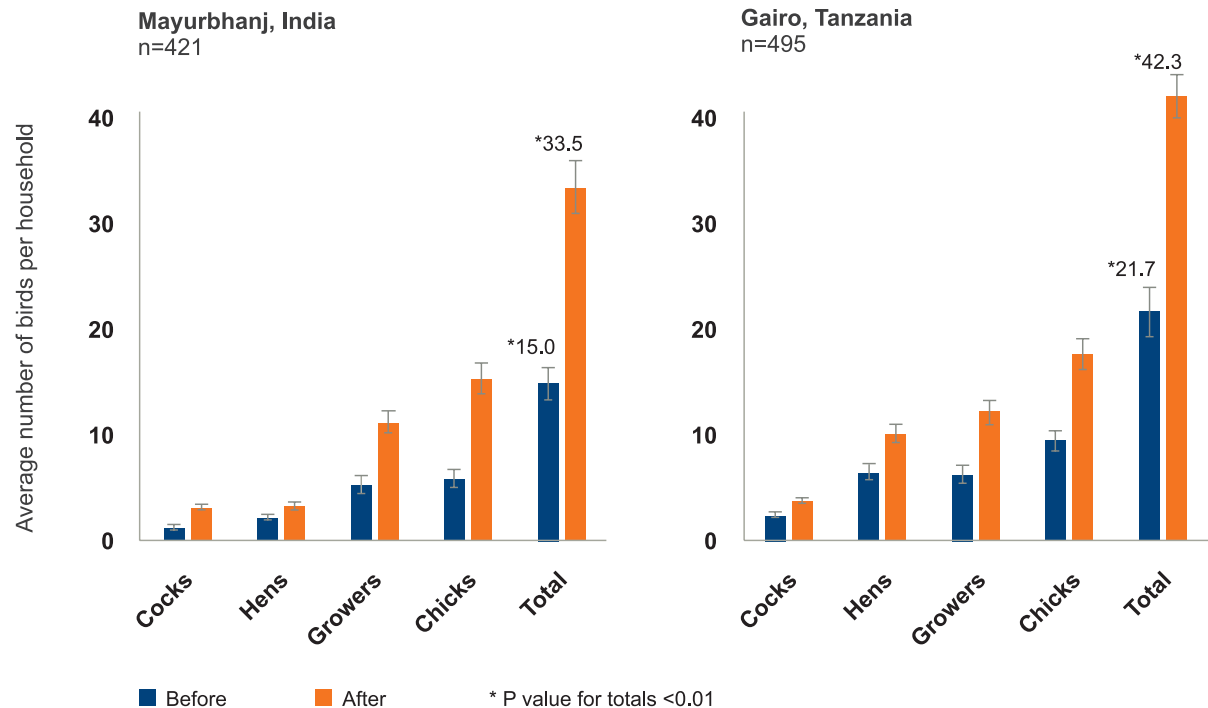
Silanti Linda, a mother of one in the Indian state of Jharkhand, used to keep three or four backyard chickens at a time. In a region of falling land productivity, deforestation and rising living costs, every household like Linda's is on the lookout for new income opportunities – but she could not treat her little flock as an opportunity when it was regularly wiped out by Newcastle Disease.

The LaSota vaccine has helped change this. A year after learning about the vaccine, Linda owns 40 to 45 chickens, selling birds to bring in extra money and supplement her husband's income. This helps meet increasing food costs, take care of medical expenses and support her child's education. "As we can get some income from chicken sales now, we can even save some money," she says.

Insight

Our field projects demonstrate that significant increases in livestock productivity can occur when diseases are controlled through effective vaccines. Within 16 months in a project site in India, the average household flock size increased by 123% when farmers used the ND vaccine. In Tanzania, an increase of 95% was observed over a period of 24 months.

Average flock size before and after introduction of ND vaccine





The power of diagnosis

In 2012, Aboubakary Hamadou, a cattle farmer in northern Cameroon, lost more than 50 of his animals to AAT. In 2015, he lost another 26. The reason for these economically catastrophic deaths was ineffective treatment based on misdiagnosis.

In 2016, a rapid diagnostic test developed by GALVmed's partners in the Tryps project came on the market in Cameroon. With just a drop of blood, the test reveals the presence of one of two different strains of the *Trypanosoma* parasite, informing farmers to begin the right course of treatment. Across Cameroon, rapid diagnosis has led to correct treatment of cattle leading to increased productivity. "This innovation has given farmers a plus, it is like health security for our cattle," says Hamadou. Since he has started administering treatment based on the test, he has not lost a single animal.

Animal African Trypanosomosis (AAT)

Since 2011, we have successfully collaborated with a large group of partners to develop a better product for reducing the impact of this major African cattle disease. More than 20 such research partnerships have comprised a global mix of private pharmaceutical companies, universities and public research institutes. The collaborations originally included a search for an effective vaccine but the focus changed to discovery and development of a new class of trypanocides, a pen-side diagnostic test, improved integrated control methods and better quality control of the various drugs sold across Africa. The pen-side diagnostic test is now marketed by a commercial animal health company while the trypanocide is close to moving into full development with a private sector partner.

Rift Valley Fever (RVF)

Together with our partners, we have focused on a cattle vaccine for RVF known as Clone 13. This vaccine was known to be effective but did not have a long shelf life. Stability improvements have extended its shelf life beyond 12 months, opening up the possibility of establishing a strategic reserve of the vaccine that can be quickly deployed across Southern Africa to prevent epidemics. Parallel work developing a pen-side diagnostic test to track the disease in the field easily was completed. The technology is being transferred to a partner. Clone 13 has the potential for use in combination vaccines for other cattle, sheep and goat diseases.





Capacity building at national labs

Many African countries have national laboratories for producing veterinary vaccines. In 2009 and 2010, through VACNADA, a special capacity building programme, GALVmed supported improvement of the technical capabilities of laboratories in Botswana, Cameroon, DRC, Ethiopia, Ghana, Kenya, Mali and Senegal. In Ethiopia, the establishment of a new Process Development Laboratory at the African Union Pan-African Veterinary Vaccine Centre (AU-PANVAC) led to this facility becoming a key partner in later product development activities.

Contagious bovine and caprine pleuropneumonia (CBPP and CCPP)

There are existing vaccines available in Africa against CBPP, but there is great scope to develop a more effective, accessible system of integrated disease control. Our first work towards this was to test the BEN-1 cattle vaccine, used to eradicate CBPP in China, in an African context. From 2014 to 2017, we coordinated a consortium led by the Harbin Veterinary Research Institute, which originally developed the vaccine in the 1960s. Three batches of BEN-1 vaccine were produced and trialled in Africa, and found to be effective, but no more effective than the existing vaccine. Work is now proceeding to improve the performance and production processes of the existing vaccine. The product development effort for CCPP has focused on a novel live vaccine approach, which could eventually be included in a combination vaccine for other goat diseases.

Porcine cysticercosis (PC)

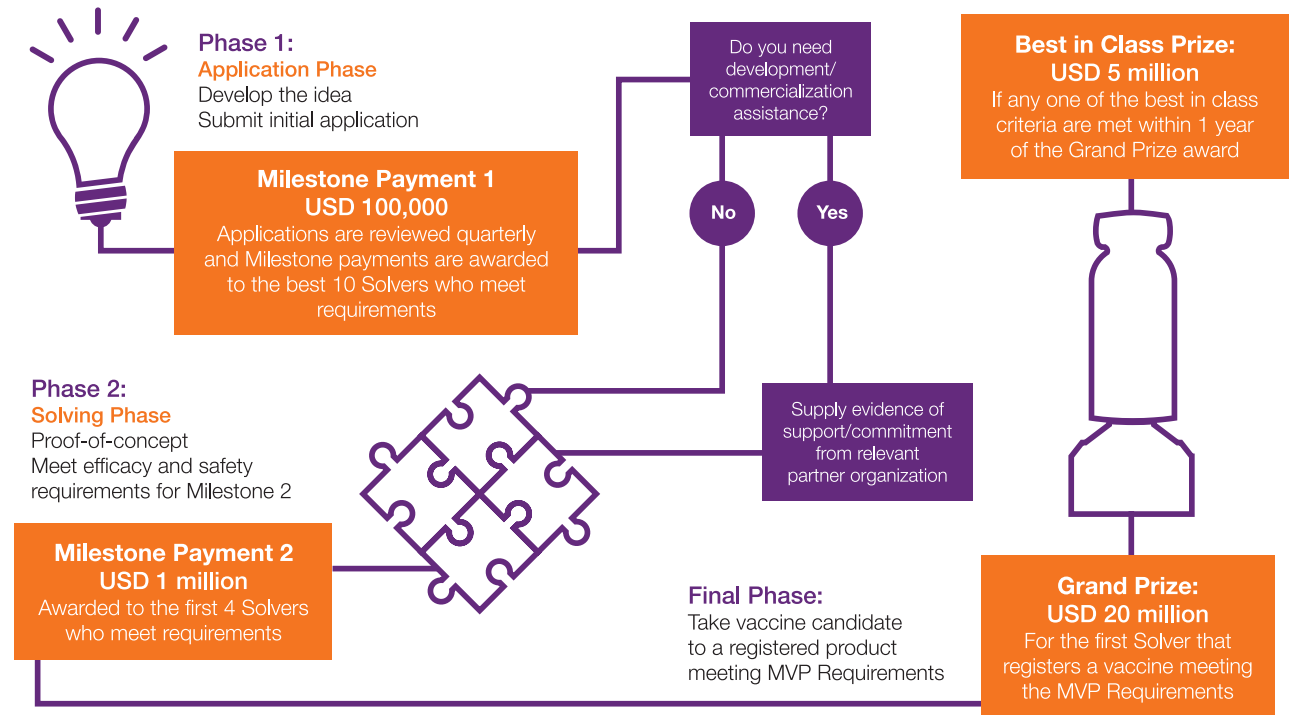
We have supported the testing and commercial development of a dual approach to break the zoonotic cycle of this parasite between pigs and humans. A new vaccine, based on technology from the University of Melbourne, became the first licensed cysticercosis vaccine for pigs. It was launched in India through our manufacturing and distributing partner Indian Immunologicals Ltd. Another partner based in Morocco, MCI Santé Animale, has developed a therapeutic drug to eliminate parasite larvae. As a combined therapeutic-prevention approach, these products were successfully field tested in Nepal, Tanzania, Uganda and Zambia from 2016 to 2017. They are now in various stages of the registration process in African countries.



Brucellosis

Launched in 2016, the Brucellosis Vaccine Prize competition is an entirely new approach providing monetary prizes as incentives for product development. The USD 30 million competition is funded by AgResults, a collaboration between the Australian, Canadian, UK and US governments, as well as BMGF and is implemented by GALVmed. It is the first competition of its kind in animal health research and will reward researchers who can develop and register a vaccine for *Brucella melitensis* that is safe and effective for use in sheep or goats across the developing world. Milestone 1 of the 10-year vaccine development competition resulted in a total of USD 1 million being awarded to 10 organisations across four continents.

Brucellosis vaccine prize journey



Peste des petits ruminants (PPR) and sheep and goat pox (SGP)


The multivalent vaccine for PPR and SGP in sheep and goats, developed by our commercial partner MCI Santé Animale in Morocco, is a convincing example of the advantages of combining protection. The two diseases affect many of the same animals in the same regions, and are not, in fact, easy to distinguish. Many farmers vaccinate against the more frequently occurring SGP, but not against the less common, but more deadly, PPR. By organising market priming and acceptability trials in three African countries, we have been able to show that smallholders are willing to purchase a combination vaccine that is cheaper than vaccinating against each disease separately. Commercial sales of the multivalent vaccine during these licensed trials – which were almost 7 million doses – are a promising step towards the long-sought control and eradication of both diseases. Our work with a British biotechnology company, Arecor – which specialises in vaccine diluent technologies to enhance vaccine thermostability – has identified a novel diluent that will significantly reduce the production and storage costs of the ECF-ITM vaccine. This approach is being used to prepare a potentially thermotolerant PPR vaccine, currently in long-term stability studies, with possible extension for use in other vaccine targets. This development is timely given the expected global eradication scheme for PPR where thermotolerance will have real benefit.




Achievements

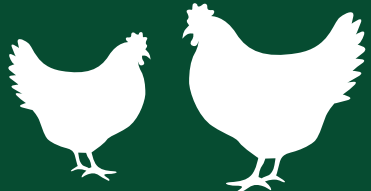
10 
PRODUCTS
DELIVERED

PROOF OF
CONCEPT
ACHIEVED FOR **8**
 PRODUCTS

OVER **6,000** COMPOUNDS
SCREENED AGAINST
TRYPANOSOMOSIS:
1 POTENTIAL TRYPANOCIDE
AND SEVERAL
BACKUP
CANDIDATES
IDENTIFIED 

 **8**
PRODUCTS
COMMERCIALISED

1.7 MILLION
CATTLE VACCINATED
AGAINST
**EAST
COAST
FEVER** 

170 MILLION

NEWCASTLE DISEASE
VACCINES SOLD

2008–2018

**OVER 2.5 MILLION
HOUSEHOLDS
REACHED**



**USD
167
MILLION**

ESTIMATED VALUE OF
LIVESTOCK DISEASE
MORTALITIES AVERTED



**OVER
12,400
VACCINATORS
TRAINED**

EAC MUTUAL
RECOGNITION
PROCEDURE
SYSTEM
ESTABLISHED:
1 PRODUCT
REGISTERED
2 UNDER
REVIEW



FARM AFRICA BUSINESS PLAN
DEVELOPED LEADING TO
ESTABLISHMENT OF LIVESTOCK
SOCIAL ENTERPRISE **SIDAI**



MANUFACTURING
CAPABILITY
OF 8
**AFRICAN
LABORATORIES
ENHANCED**



Lessons learned



As we move into our second decade, we build on our experience to accelerate delivery and increase our impact. We have always sought to learn from our successes and failures to improve our effectiveness and efficiency in making products sustainably available to smallholder farmers. The critical insights that have informed and continue to shape our approach include the following.

1. Broader portfolio offerings

Our initial strategy of seeking 'low hanging fruit' obscured the obvious but longer-term requirement of focusing on what products were needed most by smallholder farmers. Recently, substantial efforts have been made to address this through market and field assessments. Whereas in the past we used a single product/disease approach, our commercial development initiatives now focus on a broader range of animal health products than just essential vaccines. For example, over 10 million doses of de-wormer have been sold to smallholder poultry farmers alongside the ND vaccine. A de-wormer does not affect mortality rates but it improves smallholder productivity. Going forward, the 'offer' to smallholder farmers will no longer be a sole vaccine/product but a portfolio of products.



2. The need for a strong smallholder field focus

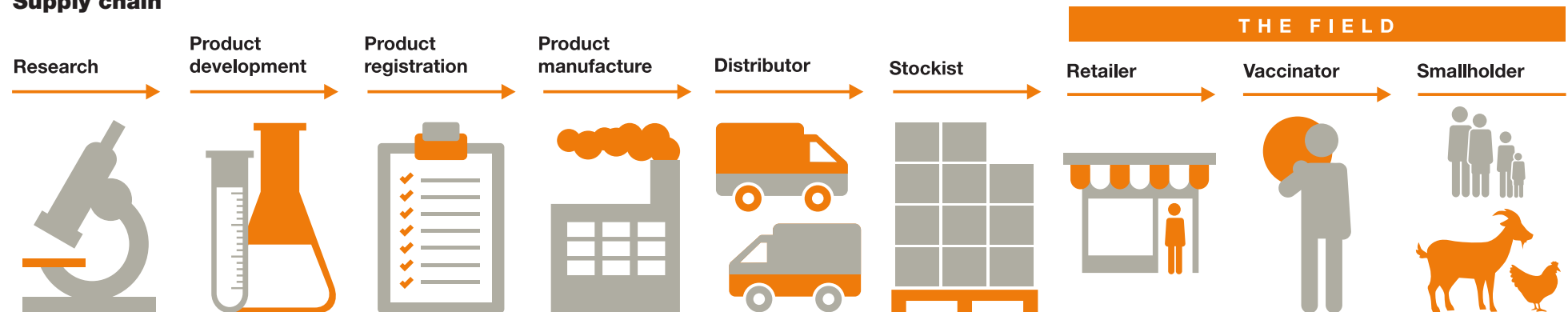
GALVmed works across a very broad landscape that spans a diverse range of disciplines and activities as illustrated in the figure below.

While each of these areas requires specific knowledge and expertise they must all be informed by the ultimate, and arguably greatest, barrier within this landscape – the ‘smallholder field’. This is the final interplay between rural

retailers, veterinarians, vaccinators/paravets and smallholders. It is here that the critical product demand and supply factors are at play and ultimately determine the success or failure of our efforts. In the early stages, we were slow to develop an adequate learning agenda around the smallholder field. The lack of existing available data meant that general perceptions and anecdotal evidence frequently held sway and there was little effort to build a better understanding systematically based on evidence from the field.

More recently, we have commenced a substantial and ongoing programme of field studies to build the necessary understanding. Information on these and many other aspects of the smallholder field now actively underpins our strategy. This detailed understanding is also increasingly sought after by commercial partners in the animal health industry to enable them to invest in the smallholder sector.

Supply chain



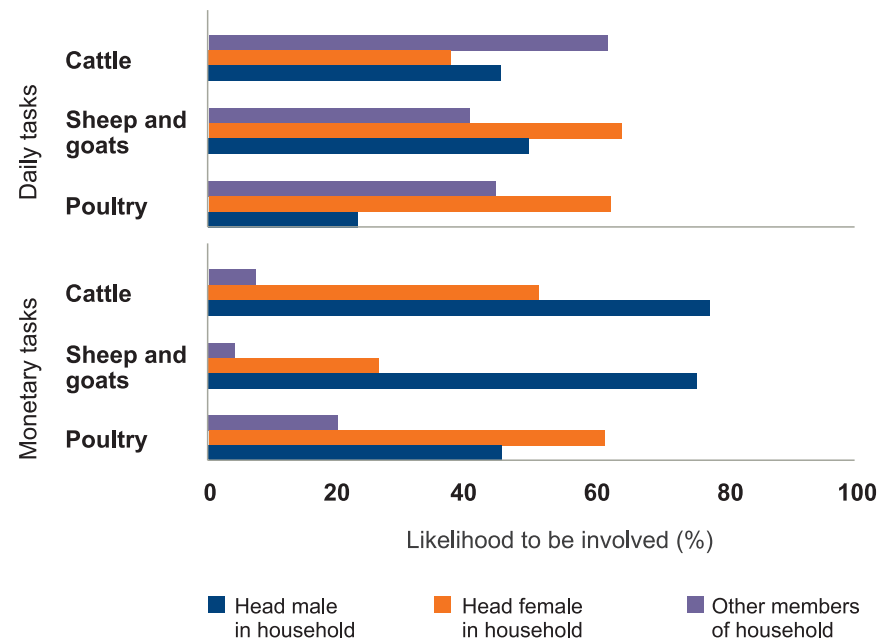


Insight

We collect data from field studies to increase understanding of the distribution of benefit and impact of our work on smallholder households. These data are useful to commercial partners as they promote better understanding of the customer/beneficiary base. There is a clear division between monetary and care-giving tasks.

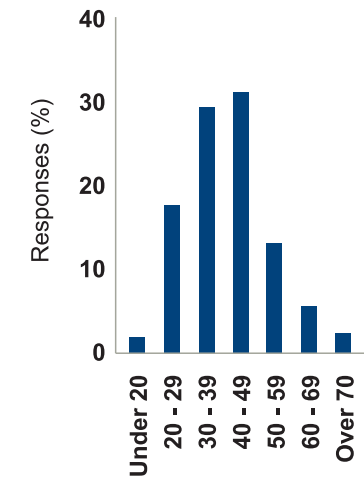
Division of tasks – Ethiopia

n=635



Age distribution – Ethiopia

n=635

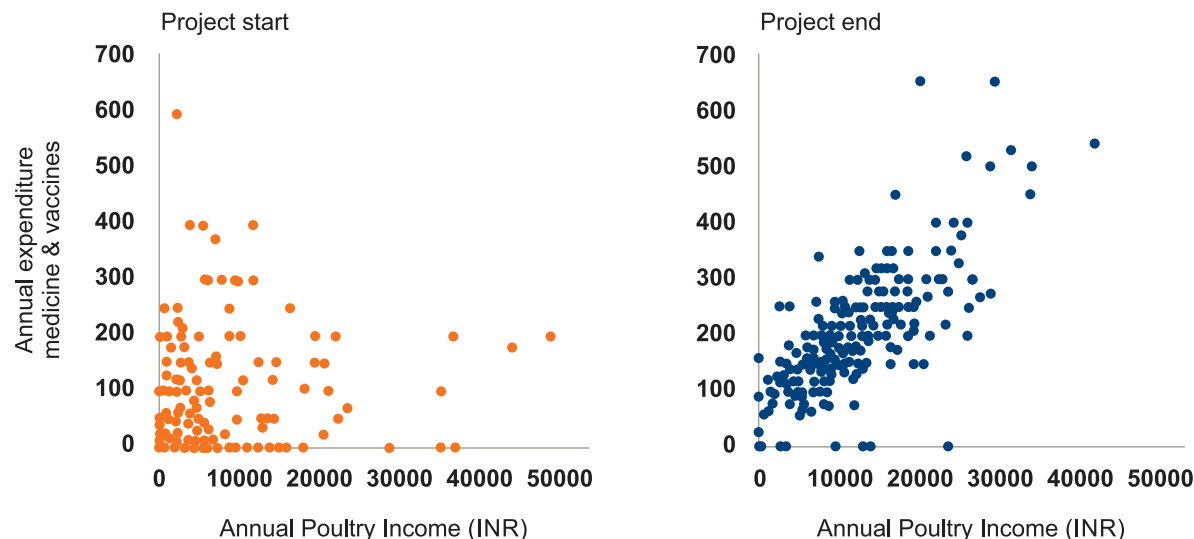


Insight

We have also been conducting market characterisation studies. These are primarily aimed at demonstrating the underlying principles of commercial viability and sustainability of our work. Such studies are of great value in positively engaging the animal health industry and demonstrating the potential of the smallholder market segment. In 16 months in an ND vaccine project in Odisha, India, the average household poultry income almost doubled and expenditure on animal health products nearly quadrupled.

Poultry income and vaccine expenditure – Odisha, India

n=282



3. Optimising vaccination through combination vaccines

In product development, we have recognised the benefit of moving from monovalent to combination vaccines because these can cover a wider range of diseases without the need for accurate diagnosis, which is widely lacking. Our product development work in the next decade will incorporate a wider range of diseases that have a significantly detrimental impact through the development of vaccine combinations. This broadening of disease scope reflects the need for a syndromic approach to disease control in the absence of reliable diagnostic capabilities.

4. Sustainability through bundling of services

Pilot projects implemented at the start of the decade have provided us with an opportunity to go back years after a project's end to assess the long-term commercial sustainability. Not having received any further form of assistance in the intervening period, three project areas have showed a surprising degree of commercial durability with continued strong demand from smallholders and an active supply chain through retailers and vaccinators. With commercial sustainability at the heart of GALVmed's commercial development work, these results are most encouraging and have increased our understanding of what drives sustainability. We have learned that all players in the supply chain need to make a meaningful profit to remain engaged, particularly vaccinators, and that this is best achieved through offering the farmer a suite of products and bundling services at the 'last mile'. Profitability increases the likelihood of sustainability.

5. The need for appropriate partner selection

A fundamental requirement for success in any GALVmed project is a strong implementing partner. Our modus operandi is delivery through partners and a critical success factor common to all projects is the quality, capability and commitment of the implementing partner.

In the formative stages of GALVmed, there was a strong focus on smaller, local partners in both product and commercial development projects. This was partly a natural response to the limited number of potential partners in certain disciplines, but also a desire to build capacity in the countries where we operate. The results achieved with these partners were mixed. In response to this, our strategy has evolved towards partners with a proven track record in delivery. This does not mean just the global multinational companies but also the regional companies that are often based in emerging market countries. These regional companies are often highly motivated to target the smallholder segment seriously as part of their ongoing corporate growth strategies. The latter part of the decade has therefore seen a gradual evolution in the type of GALVmed partner and these changes have been mirrored internally with our personnel capable of steering, guiding and influencing these commercial entities.

6. The need for focused policy and advocacy work in support of market needs

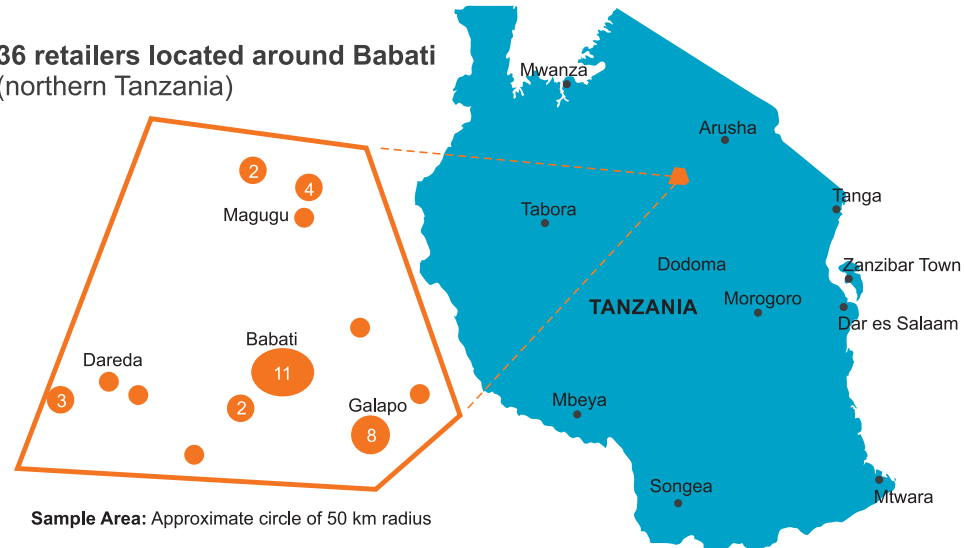
In the first half of the past decade, our policy and advocacy objectives were broad and wide-ranging. Originally, some of these encompassed livestock as a whole and not just animal health-related issues. However, the ability of an organisation like GALVmed to influence these broader livestock policies and issues was felt to be somewhat limited. Progress has been made in some areas (notably mutual recognition in regional registration of livestock vaccines) and it was felt that the best prospects for success lay in a focused approach towards a few specific elements of policy and advocacy. This narrow policy and advocacy focus will continue to serve product and commercial development projects in the next decade. We now believe that we can achieve localised success in some policy activities but long-term success requires wider and sustained engagement by appropriate policy-focused organisations. GALVmed's role in this area is therefore to catalyse, stimulate and advocate for wider regulatory initiatives to be undertaken by appropriate organisations.

Insight

While the penetration of cold chain facilities into rural areas is not ideal, it is far from non-existent. The majority of animal health inputs are sold to smallholder farmers in sub-Saharan Africa and South Asia through rural retailers (agrovets) of which there are considerable numbers. Some of these have a relatively comprehensive product offering and have cold chain facilities for vaccine storage. Future commercial development initiatives will focus on such retailers and work with them to improve the level of information and service provided to smallholder customers.



36 retailers located around Babati
(northern Tanzania)





7. Strengthening project management capacity and increasing programmatic flexibility

Over the past two years, substantial efforts have been made to improve the efficiency with which projects are managed. The initial absence of product development plans and general lack of visibility had previously made for an ambiguous environment where real progress was difficult to monitor. The creation of a portfolio function within GALVmed's organisational structure and the incorporation of industry-based work practices are successfully addressing this shortcoming.

By being flexible, we are able to recognise failure early and shut down projects while adapting to new opportunities by channelling funding into other areas of opportunity. Our approach to budgeting, particularly for product development activities, reflects our appreciation that projects do not always succeed and that we can learn from these failures as much as we can learn from successes.

8. Managing expectations in regulatory matters

Initial expectations for project development timelines proved to be over-optimistic, a recurrent theme being delays in achieving regulatory approvals. This was, in part, due to a limited understanding of the complexities and inherent inefficiencies of national regulatory processes. With an increased focus on registering products, we are now factoring in timelines that are more realistic. Through our interaction with regulatory agencies, we have a better understanding of how they work and the main causes of delays and inefficiencies in regulatory matters. Our work on mutual recognition in particular seeks to address this challenge in the EAC.

Many of the lessons learned over the course of the years have informed our thinking and have resulted in new and revised work streams and projects. Our donors' flexibility has allowed us to continue adjusting our approach as we seek the most effective ways to deliver our mission.

The path ahead



The founding rationale for GALVmed was the substantial unrealised potential for translating global progress in research technologies into tangible livestock health products for the developing world. In bridging this gap, we use donor funding to de-risk product and commercial development costs that constrain the development of these much-needed products. This rationale remains equally valid today.

As a Product Development Partnership, we will continue to build our product development pipeline and will work on the development of 25 products and product-related technologies – processes or platforms that will increase access to products. We will maintain a global perspective on the livestock diseases affecting smallholder farmers and the potential for product development work to meet the needs of the smallholder sector. In addition to our 13 priority diseases,¹ we will continue to consider the inclusion of additional diseases based on evidence of need and the potential for benefiting smallholders.

Our vision is that effective and affordable vaccines and medicines are made widely available and used by smallholders in the developing world. For this to happen, our initiatives need to achieve substantial levels of sales and market support that signify viable levels of market activity. These are the ‘tipping points’, after which GALVmed and

donor funding is no longer required and where continued growth and expansion will come from market momentum. Our activities will be focused on the substantial scale up necessary to reach these tipping points. Achieving the desired level of scale will require a partnership approach with relevant organisations and a series of structured, market-based initiatives taking place.

The policy and regulatory environment can promote or hinder the sustainability and scalability of our activities. The objective of our policy work is to continue supporting the specific needs of product and commercial development activities. Although there is a broad spectrum of potential policy constraints from product development to ‘last mile’ delivery at the household level, we will focus on those areas that specifically affect project delivery.

For the next five years, we have committed to developing seven new high-impact livestock vaccines ready for commercial production and suitable for widespread use by smallholder farmers. We will also establish five large-scale product distribution networks in Africa and Asia and support other partners in establishing sustainable animal health delivery systems. We will continue to work on the Brucellosis Vaccine Prize initiative and the Tryps programme. The organisation and management of GALVmed, and

¹ African swine fever, porcine cysticercosis, AAT, brucellosis, RVF, haemorrhagic septicaemia, ECF, CBPP, CCPP, SGP, PPR, fowlpox and ND.

the way our projects are designed, has been informed by the key learnings from the past decade. In particular, there will be:

- Greater emphasis on working with private sector partners in the animal health industry in both product and commercial development.
- In product development, greater focus on multivalent vaccine development. This reflects a syndromic approach, where appropriate, by offering pragmatic and cost-effective disease control tools for the smallholder.
- In commercial development, a greater focus on demonstrating and proving the underlying business case of distribution networks. Ensuring

smallholder-focused business models are subsequently capable of autonomous replication and scale up by private sector partners, i.e., continued growth can be achieved without further donor funding.

- In policy and advocacy, continued focus on activities that directly support project delivery as opposed to stand-alone initiatives.
- Through our monitoring and evaluation activities, continued effort to monitor impact, document learnings on what makes initiatives sustainable and contribute to increased understanding of the drivers of adoption, including aspects such as gender. We will use the improved understanding to inform our strategy and

operations and to demonstrate the overall value of our work.

- Continued commitment to improve organisational efficiency by maintaining a lean organisational structure that functions effectively within the large and diverse network of our partner organisations and stakeholders.

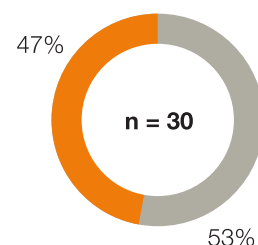
Effective products can have a major impact on the lives of smallholder farmers. Few agricultural inputs can deliver the benefits that vaccines and veterinary medicines can. We remain committed to continuing success as we move into the next decade. It has been, and continues to be, a great privilege to contribute to protecting livestock and improving human lives.

Insight

Five years after a ND vaccine market pilot project ended, a survey of one pilot area in Jhapa District, Nepal, and two pilot areas in Odisha State, India, showed that village retailers were still stocking the vaccine, vaccinators were delivering it, and smallholders were benefiting, with higher income from their poultry, driving sustainable demand.

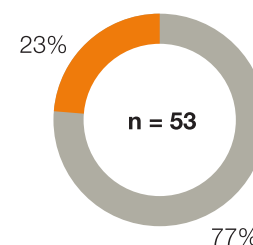
Impact five years later

Retail outlets



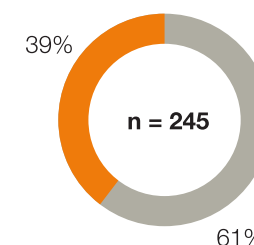
- Stocking
- Not stocking

Vaccinators



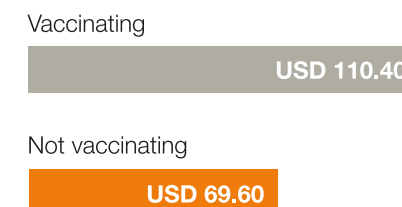
- Actively vaccinating
- Not actively vaccinating

Smallholders



- Vaccinating
- Not vaccinating

Smallholder annual poultry income



Acronyms

AAT	Animal African Trypanosomosis
AU-IBAR	African Union – Inter-African Bureau for Animal Resources
BMGF	Bill & Melinda Gates Foundation
CBPP	Contagious bovine pleuropneumonia
CCPP	Contagious caprine pleuropneumonia
DFID	UK Department for International Development
EAC	East African Community
ECF	East Coast Fever
ECF-ITM	East Coast Fever Infection and Treatment Method
MRP	Mutual Recognition Procedure
ND	Newcastle Disease
PLSHL	Protecting Livestock, Saving Human Life
PPR	Peste des petits ruminants
RVF	Rift Valley Fever
SGP	Sheep and goat pox
VACNADA	Vaccines for the Control of Neglected Animal Diseases in Africa

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