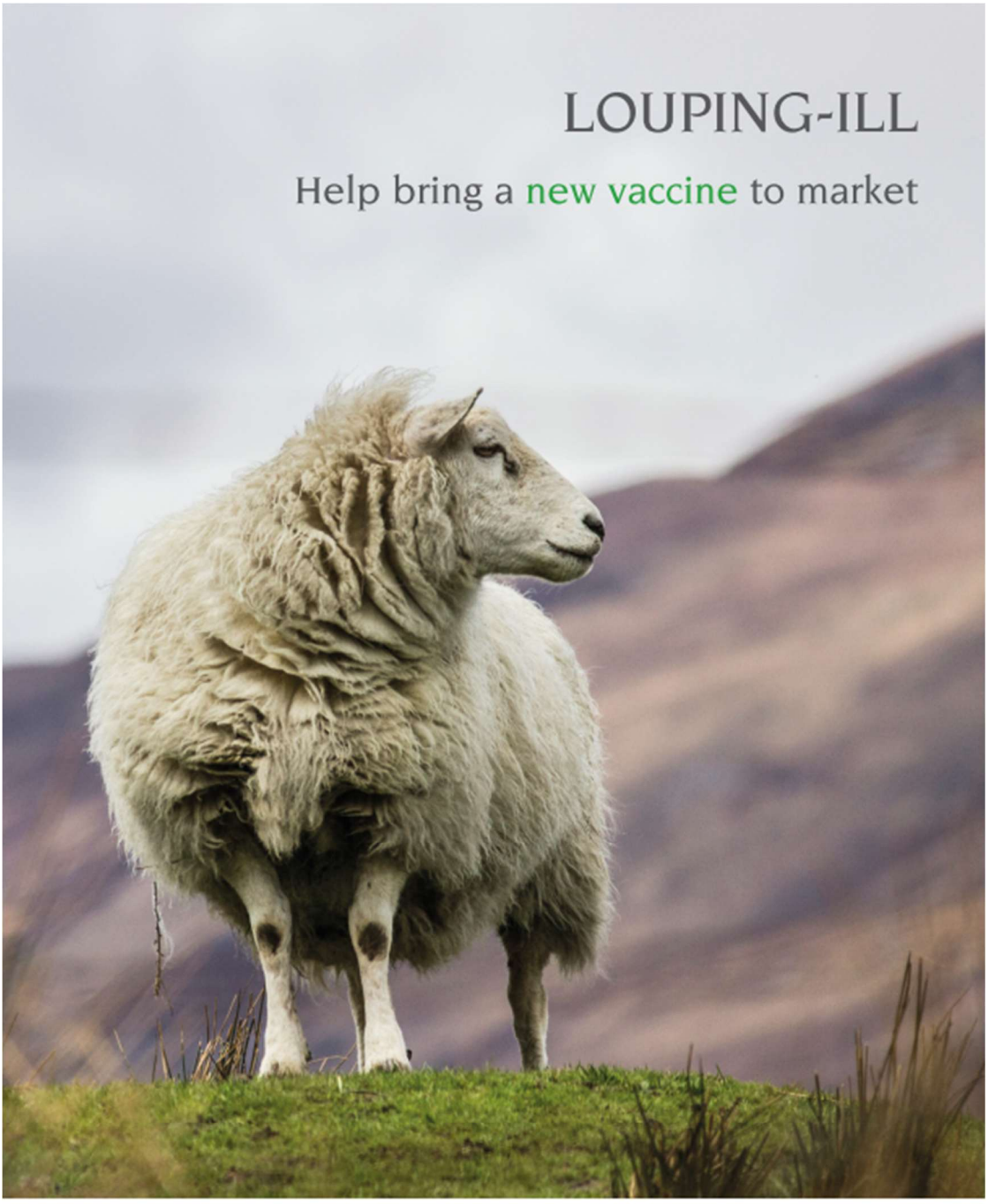
LOUPING-ILL

Help bring a new vaccine to market



Moredun Research Institute

Kernfarm LIVESTOCK PHARMA

Louping-ill

The Moredun Research Institute (MRI) is committed to promoting livestock health and welfare through research and education, so it was natural that moorland organisations and the GWCT should support its work to find a new vaccine to fight the scourge of Louping-ill (LIV).

Background

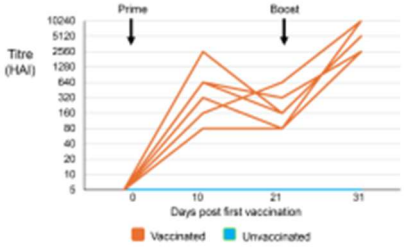
An effective LIV vaccine was commercially available for use in sheep up until 2018, when production and sale was discontinued. Previous use of the vaccine to control LIV in sheep also reduced the incidence of LIV disease in other, co-habiting, species including red grouse. Since withdrawal of the vaccine, reports clearly indicate that there has been further significant increase in the number of cases of LIV disease in sheep and grouse across the UK. Therefore, the need for an alternative LIV vaccine is urgent.

Successful research trials

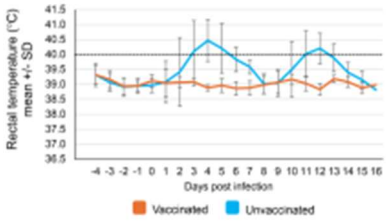
GWCT helped raise funds to enable MRI to develop a recombinant vaccine based on LIV sub-viral particles and to use it to conduct immunity and efficacy trials in sheep. This novel vaccine is non-infectious and therefore easier to produce. MRI remains extremely grateful for the funds raised by all grouse moor interests who contributed to the trials, as the work could not have been conducted without this assistance. Recognising the significance of this initiative for the upland management community, the leading moorland conservation organisations are committed to ongoing support.

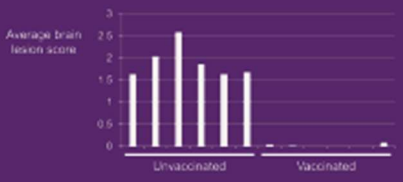
This initial research phase has been a resounding success. Through proof-of-concept studies, MRI has shown that the new vaccine reproducibly stimulated a strong antibody response to LIV in sheep.

Antibody response in vaccinated sheep



Temperature response in infected sheep





Importantly, in experimental infection studies using live LIV virus, vaccinated sheep had none of the typical brain lesions that are characteristic of LIV.

These results indicate that the trial vaccine can prevent or reduce infection of the brain by LIV, and therefore provides a high degree of protection against the disease.

Bridging from successful research to manufacture

As progress became evident towards conclusion of the research trials, MRI began to determine how a new vaccine could be brought to market. Key to this was finding the right players for contract manufacturing, marketing and distribution.

It rapidly became apparent that KernFarm *(www.kernfarm.com/uk.html)* had the credentials to solve these challenges as a well-established European veterinary medicines partner.

It develops its own products as a pharmaceutical manufacturer, but also plays a significant role as a network and collaboration organisation, and as an administration and registration office. It has developed sound distribution capacity in the UK and as such, it was well positioned to play a critical part in the next steps towards delivery of a new LIV vaccine, particularly regarding commercial-scale testing and production, as well as completion of a regulatory registration dossier.

Kernfarm
LIVESTOCK PHARMA

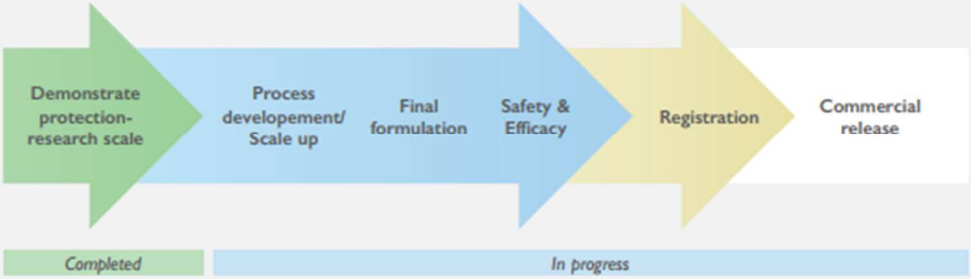
What needs to happen now?

The next steps in vaccine commercialisation are to develop a method for large-scale production, and to confirm its protective activity in a further round of efficacy and safety studies. These steps are described in this section to explain what needs to happen, the timescales involved, regulatory requirements and how much funding is now needed to support the project through to vaccine availability.

Timeline: 3-phase approach

For manufacture and registration of the vaccine, a method of large-scale production of the vaccine will be developed (sub-contracted to a Contract Development and Manufacturing Organisation (CDMO)) followed by confirmation of its protective activity in a further round of infection studies at MRI. In addition, dose determination trials and safety studies will be required for the vaccine registration dossier, for submission to the Veterinary Medicines Directorate (VMD) to allow the vaccine to progress towards market authorisation.

Development phases



Phase 1
Manufacturing Transfer

9 months – starting as soon as there is sufficient funding support

- Proof of concept - large-scale production at the CDMO and determination of the optimum dose required for the vaccine at MRI.

This phase is estimated to require **£720,000** to complete. It is anticipated that it will be funded by donations to MRI, which has charitable status.

Phase 2
Completion of Regulatory Dossier

16 months to complete

- Safety studies and challenge trials at MRI, using material supplied by the CDMO
- Dossier development for vaccine registration by KernFarm and MRI

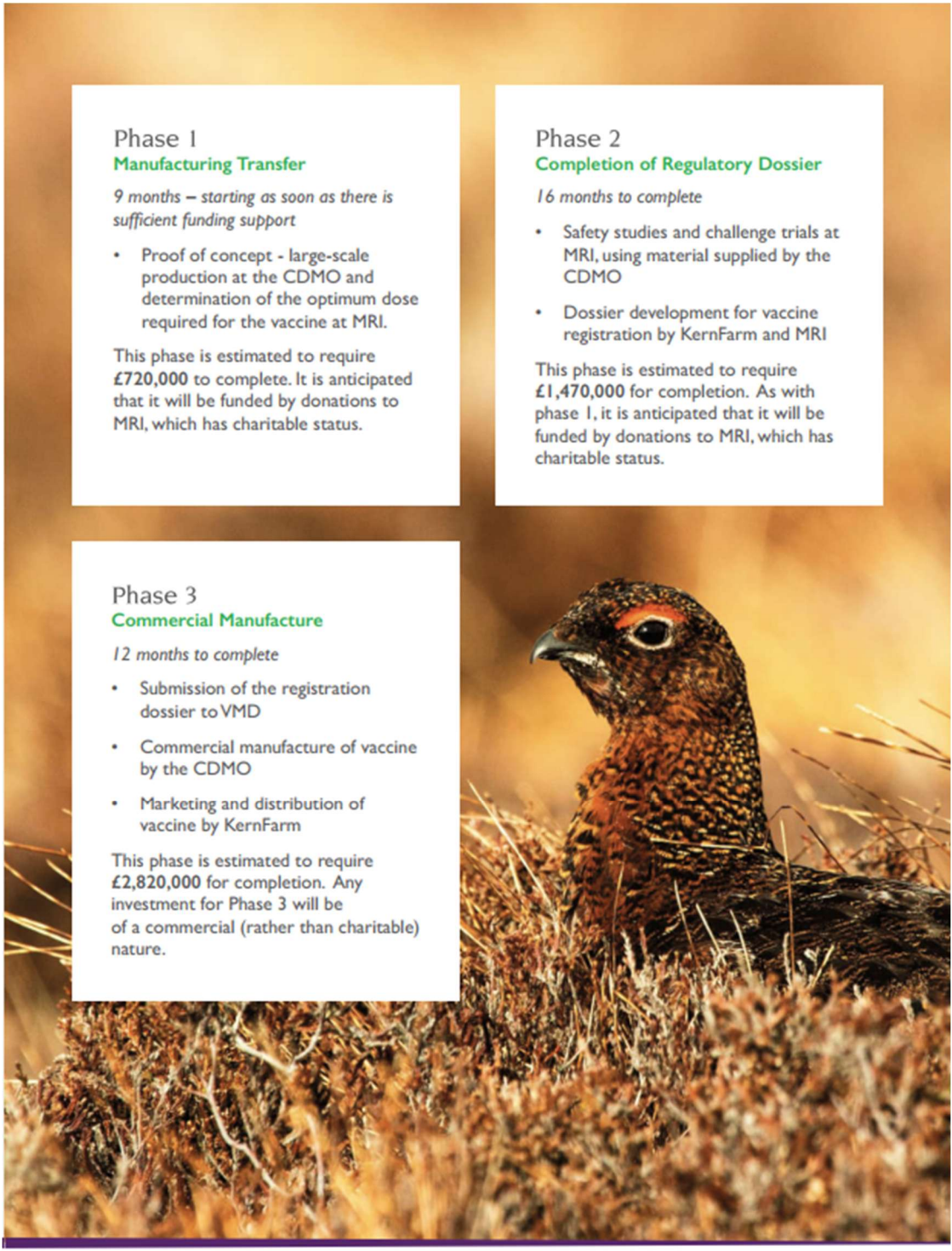
This phase is estimated to require **£1,470,000** for completion. As with phase 1, it is anticipated that it will be funded by donations to MRI, which has charitable status.

Phase 3
Commercial Manufacture

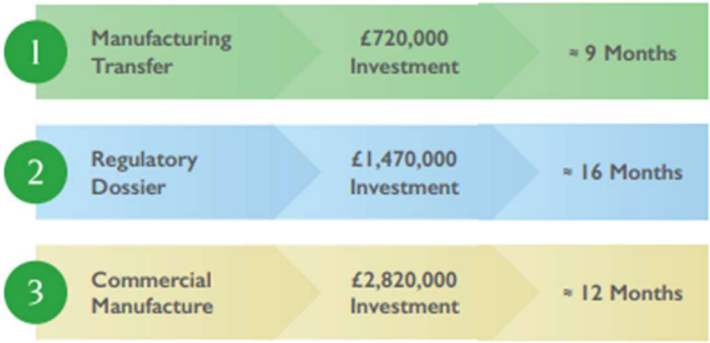
12 months to complete

- Submission of the registration dossier to VMD
- Commercial manufacture of vaccine by the CDMO
- Marketing and distribution of vaccine by KernFarm

This phase is estimated to require **£2,820,000** for completion. Any investment for Phase 3 will be of a commercial (rather than charitable) nature.



The development plan for bringing the recombinant subunit vaccine to market will be carried out in three phases



With funding and investment support, the aim is to have the LIV Vaccine on the market by 2027-2028, but this timescale is dependent on progress with fundraising, all technical aspects working as expected, the success of the previous phase and on the regulatory process. While this timescale may appear rather lengthy, it is necessary to pass the rigorous assessment required for new vaccines. However, once complete, the project should ensure continuous stable supply for at least 20 years and likely longer.

What will this enable?

- Fundamentally, it will provide the ability to bear down on LIV infections and lessen the impact of ticks, placing upland landowners and managers back in the position that existed before the previous vaccine was withdrawn.
- It will assist the economic return on upland management.
- A recombinant subunit vaccine is entirely safe to manufacture and administer when used in accordance with manufacturer instructions.
- Although the vaccine will protect against LIV, acaricide treatments will still be required to control tick bites. These treatments have been the only option in the absence of a vaccine, so in combination with the new vaccine, there may be less reliance on acaricide usage. This may help to reduce animal welfare impacts from regular, intrusive treatments and mitigate potential risks to invertebrates from acaricides through detriment to upland food chains, including grouse broods.

How you can help make this vaccine available for upland managers

Please consider supporting Moredun Research Institute, KernFarm and veterinary product manufacturing partners to deliver this extremely important and innovative project.

Initially MRI is looking for donations, from multiple sources, of **£720,000** to allow completion of Phase 1 of this project. Please note that any donations raised above the original target will be used to further progress work on the Louping Ill vaccine programme.

All donations of any size are welcomed and to donate please use the bank details:

Moredun Research Institute
Bank of Scotland
Sort Code: 80-02-24
Account Number: 00127731

If you would prefer to donate by another method or would like further information on the project, please contact us.

Moredun
Research Institute

Contact us

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