

## Work leading up to the EGS vaccine trial

Over the past three years, a huge amount of work has gone in to preparing for the EGS vaccine trial.

### Preliminary Safety Study

In 2011 – 2012, a small study was conducted to determine that the vaccine was safe to use in horses. The same *Clostridium botulinum* type C vaccine is actually used routinely for the prevention of classic botulism in mink, with a very low occurrence of adverse reactions following vaccination. The safety study showed that the *Clostridium botulinum* type C vaccine was safe in horses as young as 3 months of age when administered by intramuscular injection. Only 1 of the 15 young horses enrolled in the safety study developed a slight swelling at the injection site after the second vaccination; however this horse was needle shy and had to have two injections in order to receive the full dose of vaccine. No other swellings or adverse reactions were observed during the study in any of the horses.

### Feasibility Study

In 2013, the Animal Health Trust undertook a feasibility study for the EGS vaccine trial. This type of survey is commonly used in the study design phase for clinical trials in human medicine. This study involved two parallel questionnaire surveys – one for veterinary surgeons and one for horse owners who had reported EGS cases to our surveillance scheme. These questionnaires were design to help us to identify EGS-affected premises that might be eligible to take part in the vaccine trial, and to explore the opinions and attitudes of vets and owners about the vaccine trial. The feasibility study has been very useful in identifying what concerns owners might have about enrolling their horse or pony in the vaccine trial, and we have included helpful information covering many of these topics in the [FAQs section](#). A summary of the horse owner feasibility survey can be [found here](#).

### Pilot Vaccine Trial

From 2012 – 2013, in collaboration with the University of Edinburgh, the Animal Health Trust conducted a 12 month pilot field vaccine trial, enrolling 95 horses and ponies in Scotland. The pilot trial used a very similar study design and protocol to the full nationwide vaccine trial, except that horses and ponies received a booster at six months instead of the usual recommendation of annual booster injections – this ensured we were able to measure the immune response to the booster injections ahead of starting the full trial.

The pilot trial enrolled only a small number of horses and ponies, and was designed to test the methods used for recruitment and vaccine administration, rather than to test the effect of vaccination. Very few horses and ponies in the pilot study had local reactions to the vaccine or placebo injections – these included a small number of horses and ponies who showed mild swelling or heat following injection, which all resolved completely without any treatment in 1 or 2 days. These minor reactions at the site of injection are common following other routinely used vaccinations, such as the equine influenza and tetanus vaccines. We are exceptionally grateful to the veterinary practices and horse owners who volunteered to participate in the pilot trial, as they have contributed invaluable information which has helped us to improve upon many aspects of the EGS vaccine trial protocol. Results of the pilot study can be [found here](#).

In collaboration with the Universities of Edinburgh and Liverpool, the Animal Health Trust have developed blood tests to allow us to measure antibody levels to *Clostridium botulinum* type C. Using these blood tests, we have been able to demonstrate that the majority of horses and ponies given the *Clostridium botulinum* type C vaccine have a significant increase in their antibody levels following the primary vaccination course, indicating an immune response to the vaccine.