



The combination of the skills and expertise of our best academic organisations and industry leads to positive and practical outcomes. A good example of this type of collaboration was when Dechra, and the Biotechnology and Biological Sciences Research Council (BBSRC) funded a four year iCASE PhD programme at the Royal Veterinary College, University of London supervised by Prof. Ross Bond and Dr Anette Loeffler. Siân-Marie Frosini (née Clark) undertook the studies to support the use of topical therapy (medication that is applied directly on to the skin like a cream or gel rather than given as a tablet or injection) in the treatment of bacterial skin infections in dogs. In this era of growing awareness of antibiotic resistance, topical treatments are being seen as a better means for treating certain infections. This project generated three publications, five meeting abstracts at international conferences and resulted in the award of three prizes, with a number of manuscripts still in the pipeline for publication. Alongside traditional research, Siân-Marie undertook a six month placement at the DVP EU UK office where she worked alongside the dermatology product group, most notably creating a new Dechra Academy CPD module.

Overall, this collaboration has provided compelling evidence in support of topical therapy, and specifically fusidic acid, as an alternative to systemic antimicrobials, such as an injection or tablet, for the treatment of bacterial skin infections in dogs. Fusidic acid is one of the active ingredients contained in three of Dechra's leading products: Isaderm, Isathal, and Canaural.

Current guidelines encourage treatment using topical therapy in an effort to limit the spread of antimicrobial resistant bacteria and promote good antimicrobial stewardship. However, behaviour changes in veterinary practice are slow, and this project provides timely confirmation that concentrations of topically applied fusidic acid on the skin far exceed clinical resistance breakpoints, in other words the point at which the antibiotic defeats the bacteria. This excellent evidence helps to encourage veterinarians to change their prescribing habits and follow current recognised treatment guidelines for canine superficial pyoderma (bacterial skin infection).

Most strikingly, the novel methods developed during this project could help the microbiologists to determine resistance breakpoints specifically for topical therapies such as the fusidic acid contained in Isaderm gel. Currently, these breakpoints are based on systemic therapies, and are often misinterpreted for topical-only antimicrobials. Development of this novel method into a system to determine clinical breakpoints based on topical application of a drug would be a significant leap forward in the appropriate use of antimicrobials.

This project is an excellent example of science and academia working with industry to develop veterinary medicine for the benefit of pet health. Siân-Marie is also continuing to build on her collaborative start with Dechra and we are all grateful for the unique opportunity this project has given.

The University of Kansas has also collaborated with industry and the FDA Center for Veterinary Medicine (CVM) to offer an ongoing seminar series covering topics that are key to veterinary drug development. Members of the Dechra Clinical Operations team have been speakers at two of these seminars. Karen Bond, Senior Clinical Trial Manager, presented on Data Quality from a study monitor's standpoint and Lisa Andreas, Senior Clinical Data Manager, presented on the importance of Data Management Plans in the conduct of clinical studies. Both presentations were extremely well received and sparked discussions within the industry on best practices.



Three of the members of the Clinical Operations team are actively involved in a cross functional working group that consists of a collaboration of three industry associations along with FDA CVM and is tasked with identifying best practices and optimal requirements for creation and submission of electronic data in both clinical and laboratory studies. This working group is about to release a white paper which will provide suggestions to FDA CVM regarding their policy on the issue.

Ben Moses, Clinical Operations Manager, regularly participates in the Society of Quality Assurance, the American Academy of Veterinary Pharmacology and Therapeutics, and the Generic Animal Drug Alliance (GADA). Ben is also the Chair of the Bioequivalence Subgroup at GADA, which provides excellent leadership opportunities and allows Dechra to help shape the evolving regulatory expectations related to the development of generic drugs.