

BRD

Antiemetic **Sarcoptic**

mange Angiostrongylus vaso-

rum **TICKS** REPRODUCTION DIS-

ORDERS Cutaneous wounds Cardiology

DERMATOLOGY **Otodectic mange** Al-

lergic dermatitis **BDV** Gastrointestinal Nem-

atodes **CVBD** Heartworm Cheyletiella Thelaziosis

Lameness Tapeworms **Otitis** CanL therapy

AREAS OF EXPERIENCE Sugery

Louse infestation Metabolic diseases Respiratory bacte-

rial viral diseases GnRH Mastitis IBR ENTERITIS **Me-**

tritis FERTILITY Foot-root Ketosis **Capillaria** Meta-

bolic diseases **PRRS** Respiratory diseases Protozoa

Tapeworms Leishmaniasis vaccine Circo-

virus FVBD Lungworm Estrus synch **Demo-**

dectic mange **Hyperthyroidism** Hy-

podermosis Mycoplasma **Fleas** **En-**

teritis **Lyme disease** PNEU-

MONIA **FelV** Eimeria

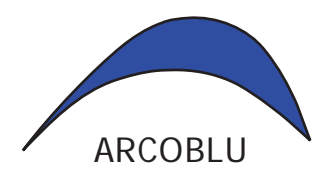
Sand flies



CLINICAL RESEARCH
AND DEVELOPMENT
IN VETERINARY MEDICINE



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ARCOBLU is an independent Contract Research Organization supporting Animal Health industries in research and development of medicinal products for veterinary use in Europe.



CLINICAL STUDIES - NEW VETERINARY PRODUCTS

The conduction of well-designed, controlled and animal welfare compliant, GCPV clinical studies is the basis for a fast and successful approval of the dossiers for National and EU marketing authorization of new veterinary products.

Statistical design and sample size
Study protocol and CRF development
Study approval from relevant authorities
Full study document production
Personnel training
Randomisation
Field monitoring and quality control
Study closure procedures
Adverse event management

Sponsor interim updates
Communication log
Quality system and process key point audits
Data control and validation
Data entry
Study report writing
Study master file
Administrative management

POST-AUTHORIZATION CLINICAL STUDIES



Clinical skills and specific internal procedures allow the collection of high quality and large scale controlled data to provide supplementary information on efficacy, safety and production performances of registered medicinal products for internal use or scientific publishing.



EPIDEMIOLOGY

The acknowledgment of frequency, distribution, and time dynamics of different diseases allows the adoption of short to long term strategies for the placement, use and marketing of veterinary products. Access to a wide group of qualified field veterinarian, farms, laboratories and the collaboration with qualified epidemiologists allows us to conduct large scale surveys on the main veterinary diseases in all the species.

QUALITY



Quality assurance system is an essential ingredient of the whole process that leads new medicinal products to the market and guarantees the production of reliable data in clinical research. All the key points of the management and running of our studies are compliant with guidelines and regulatory requirements and are implemented in our internal Quality System. Internal procedures (SOP's) designed and developed by Arcoblu QA unit, and a robust audit system guarantee that each commission is performed at the required standard.



NUTRITION AND PALATABILITY STUDIES

Palatability studies on companion animals in own domestic environment. Nutritional studies in large animals (beff and dairy cattle, pigs). Conducted in selected equipped farms, with different management, automation, computerisation and production systems, allows the quantitative evaluation of the impact of food and additives on production performances.

MICROBIOLOGICAL STUDIES



The knowledge of microbial susceptibility and resistance to new veterinary antimicrobial is a requirement to grant marketing authorisation. With a portfolio of field pathogen isolates responding to EMEA/CVMP/627/01 requirements and in collaboration with NCCLS complying laboratories we are able to conduct microbiological studies on efficacy, sensitivity, resistance and genetics of the main veterinary pathogens.



REGULATORY

The understanding of the regulatory environment and the application of the legal requirements for the marketing authorisation of new veterinary products is a challenging and time/resources consuming commitment. Our Regulatory Unit supports Animal Health companies in obtaining the approval for study conduction and to plan and deal marketing authorization process. Dossier setup and evaluation, submission to Regulatory Authorities, identification of qualified experts and expert report writing.

COMMUNICATION



ARCOBLU provides a list of services to support Animal Health companies in communication activities requiring specific technical and scientific skills, together with a deep knowledge of the in-field condition. Personnel training, bibliographical research, production of technical manuals, scientific publications, presentations, technical/scientific translations and technical brochures.



MULTIMEDIA

Images and new media platforms play a central role in education and promotion of industrial products in animal health. Arcoblu Multimedia Unit merges the technical and scientific background with the effectiveness of the new communication media to produce educational, corporate, advertising videos and multimedia products, which effectively deliver the correct information to the chosen target.