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Industry Sponsorship of Clinical Trials: Use of Gemcitabine Chemotherapy in Dogs with Spontaneously Occurring Lymphoma (5-Sep-2003)

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Clinical trials are conducted by industry sponsors as a part of the drug development pathway to demonstrate that the drug of interest is both safe and effective in the target species. Within the United States, the majority of oncology studies will be regulated by the FDA's Center for Veterinary Medicine. However, the industry sponsor will attempt to design a study that could receive regulatory approvals throughout the world. To that end, the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) has issued a guidance document on Good Clinical Practice outlining the requirements for the conduct of a clinical trial. The industry sponsor must adhere to this document as it relates to protocol development, study documentation, monitoring, audits, data analysis and report writing. This document is designed to ensure that the same ethical and scientific quality standard is adhered to for all clinical trials. After identifying the appropriate regulatory agencies and understanding those agencies' expectations, the industry sponsor will partner with one or more investigators to conduct an "adequate and well controlled" study. Investigators are selected from private, specialty and university practices based on knowledge of the subject matter, experience, case load, and facilities. The ability to comply with the industry sponsor's time and budget constraints may also impact investigator selection. Utilizing the VICH principles of Good Clinical Practice, 24 dogs presenting with a histologically confirmed diagnosis of lymphoma were entered into a prospective open-labeled, multi-institutional, phase II study designed to evaluate the efficacy of Gemcitabine as a single chemotherapeutic agent in the treatment of lymphoma. The planned dosing interval was 400 mg/m² administered intravenously over 30 minutes once a week for three weeks followed by a one week rest period for a maximum of four cycles. Dose reductions, delays and escalations were allowed as dictated by the protocol. Unanticipated safety issues coupled with a limited response to therapy resulted in early termination of the study.

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