The Role of Clinical Trials in Veterinary Oncology

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KEYWORDS

• Clinical trials • Veterinary • Comparative oncology • Pathobiology

KEY POINTS

- Clinical trials in veterinary oncology serve to advance knowledge of tumor pathobiology, guide drug development and licensing, increase clinicians' ability to practice evidence-based medicine, and provide access to novel therapies.
- Well-designed clinical trials have potential to benefit both veterinary and human oncology and are essential to enhancing the practice of evidence-based medicine.
- Companion animals' owners may seek guidance from their primary care veterinarian when contemplating participation in a veterinary clinical trial; understanding the various types of clinical trials and their associated goals, risks, and benefits is important to counsel clients regarding treatment and clinical trials options for their pets.
- The goals, benefits, and risks of the clinical trial, as well as the responsibilities of the client and veterinary team during the clinical trial, should be clearly delineated through use of informed client consent documents.

INTRODUCTION

Clinical trials are used in veterinary medicine to assess the efficacy and benefit of novel chemotherapy drugs or treatment protocols, surgical interventions, and diagnostic techniques. In addition, clinical trials may be used to identify molecular targets or other tumor biomarkers and determine whether an investigational drug modifies a specific therapeutic target. Research studies involving companion animals of a particular species are most commonly designed to gain information regarding tumors in that same species and cancer therapies specific to veterinary oncology. However, spontaneously occurring tumors in companion animals are also an excellent model for many

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human malignancies, and clinical trials may be performed in pet animals to gain more information regarding an agent ultimately designated for use in people.[1–3] Implementation of well-designed clinical trials is essential to advance the knowledge of cancer biology and cancer therapy, in both human and veterinary medicine.

Owners pursuing cancer treatment of their pet may be presented with the opportunity to participate in a clinical trial as one of their treatment options and they may seek the guidance of their trusted primary care veterinarian when making a decision regarding clinical trial participation. Based on previous exposure to clinical trials or proximity to a veterinary center that regularly conducts clinical trials, practitioners may have variable comfort levels in counseling clients in this regard. This article provides veterinary practitioners information regarding types of clinical trials and their associated goals, describes potential patient benefits and risks associated with clinical trial participation, outlines mechanisms of patient protection and safety during a trial, and offers resources regarding available clinical trials in their area and nationwide.

PHASES OF DRUG DEVELOPMENT

Clinical trials performed in companion animals most often evaluate drugs or drug delivery, or surgical or diagnostic techniques that are ultimately designed for use in that same species. However, many cancers diagnosed in companion animals are similar in biological behavior to cancers that occur in people; companion animals therefore can serve as an excellent large animal model for evaluation of therapeutic agents before or in parallel with early testing in people.[2] Clinical trials performed in companion animals with the goal of informing human medicine are considered by physicians to be preclinical studies rather than traditional clinical trials. The term clinical trial has a broader definition in veterinary medicine and is used to describe any clinical research study that enrolls client-owned companion animals, regardless of whether the information gained from the study will be used to inform veterinary or human oncology.[4] The study end points of phase I, II, and III clinical trials, which represent the steps in the traditional drug development program, are discussed later (**Table 1**). The lack of well-defined standard-of-care treatment of many of the cancers diagnosed in veterinary

Table 1
Phase I, II, and III clinical trials

Trial Type	Primary Goal	Secondary Goal	Potential Benefits	Potential Risks
Phase I	Determine MTD Define DLT	Elucidate dosing schedule Gain info regarding PK/PD	Access to novel therapies Often financial incentives	Adverse events not fully known Additional blood and tumor sampling
Phase II	Determine efficacy Inform decision regarding phase III study	Better define adverse event spectrum	Access to novel therapies Often financial incentives	Efficacy not known Adverse event profile not fully described
Phase III	Compare with standard-of-care therapy	Cost and quality of life comparisons	Access to novel therapy ± Financial incentive	Unknown improvement compared with standard of care

Abbreviations: DLT, dose-limiting toxicities; MTD, maximally tolerated dose; PD, pharmacodynamics; PK, pharmacokinetics.

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