



The Golden Retriever Club of America, Inc.

Clinical Trials Offer Hope and Lead to Improved Therapies

As with any field of medicine, veterinary researchers and clinicians are constantly striving to bring improved therapies to their patients. This process often involves clinical trials of drugs, protocols, devices, or procedures; and no area of investigation is more active than oncology. This is certainly understandable since fifty percent of all dogs over the age of ten die from cancer, but clinical trials also address many other kinds of canine disease and disability.

Although extensive safety and efficacy (effectiveness) testing usually precedes the move from the laboratory to the clinic, it is only through actual use in dogs that the risk/benefit profile of novel therapies can be fully assessed. Clinical trials must follow specific guidelines to meet rigorous scientific and ethical standards¹, and it is expected that detailed results (regardless of the outcome) will be submitted for publication in a peer-reviewed journal for all to see. Most clinical trials are conducted at teaching hospitals associated with colleges of veterinary medicine, although sometimes independent veterinary practices may be involved. Some trials recruit dogs from within a single treatment center and others may involve dogs from a number of centers around the country, but all participating centers must follow the same guidelines to ensure uniformity.

Although the specifics will vary depending on many factors, there are several widely accepted study designs generally employed in clinical trials. These typically involve comparing results from two or more closely-matched² groups of dogs, where one group receives therapy that is considered to be high quality based on current evidence (standard-of-care therapy), and another group receives the therapy under investigation. Or sometimes all study dogs will receive the standard-of-care therapy, but one-half of the dogs also receive an additional therapy (such as a drug) while the other half receives a placebo. In some cases, all of the study dogs receive the novel therapy, and results are compared to outcomes of other therapies as reported in previously published scientific literature. In essentially all clinical trials, results of the new therapy must be compared to results from some kind of matched control group – even if that control group is comprised of totally untreated dogs – in order to determine how the risks and benefits compare to other available alternatives.

There are numerous reasons that owners may wish to consider enrolling their dog in a clinical trial. Sometimes the prognosis using standard-of-care therapy is poor, and owners are willing to try

¹ All schools of veterinary medicine have an Institutional Review Board (IRB) that must approve the proposed clinical trial, and whose oversight ensures that animal care and treatment meets ethical and humane standards.

² To be certain that a comparison of results is scientifically valid, factors that may influence results must be the same in each group. Depending on the exact details of the study, groups may be matched for such things as: exact diagnosis; stage or severity of disease; neuter status; size, age, or breed of dog; prior treatment; and many other factors specific to the study. Sometimes dogs are randomly assigned to one group or the other.

something new because it offers a measure of hope. Other times there may be very promising preliminary data on the novel therapy, and owners consider it a wonderful opportunity for their dog to receive cutting-edge therapy. In some instances, owners may not be able to afford to treat their dog without financial assistance, and clinical trials sometimes assume a portion of the cost of treatment.

Regardless of the trial design, there are certain common practices that owners can expect to encounter. As part of the enrollment process, owners will be asked to sign a consent form. The consent form details the tests and procedures that will be performed; defines whether the owner or the study will be responsible for certain costs; discusses anticipated benefits and risks to the dog³; and explains the owner's obligations. Owners should take the time to read the consent form carefully and ask questions if there is any part that concerns them or is not clear. It's important that enrolled owners fully intend to comply with all parts of the study, because noncompliance or lack of follow-through hampers the ability of the researchers to obtain meaningful information to benefit dogs in the future. Of course, the dog's best interests are always a priority, and there are times when unforeseen complications necessitate removing a dog from a study. This decision may be initiated by the owner or the veterinarian, but preferably it is a joint decision reached after mutual consultation.

Owners of dogs enrolled in clinical trials are usually very pleased with the care and attention their dogs receive. Although clinicians endeavor to provide the best care available to all of their clients, there is a special partnership formed when the dog is participating in research. Owners are usually encouraged to stay in close touch to resolve any questions or concerns during treatment, and are sometimes asked to – or voluntarily wish to – continue with follow-up visits beyond the treatment period.

Although there are sometimes wonderful and very exciting results for dogs treated with a novel therapy as part of a clinical trial, most often progress against disease comes in smaller steps. But regardless of their own dog's outcome, owners of dogs that have participated in a clinical trial usually get satisfaction in knowing that they gave their dog the best chance possible, and that their dog contributed toward an improved future for other dogs. Even in the saddest situations, most owners find that participating in a clinical trial provides a small measure of comfort by giving meaning to their personal tragedy.

Locating Suitable Clinical Trials

In most instances, the best source of information about clinical trials for which a specific dog may be eligible is the nearest college of veterinary medicine. Internet searches can sometimes locate other trials, but if these are being conducted far away from the dog's geographic location, it's unlikely that the dog would be able to meet the usual participation requirement of regular appointments.

Additional sources for locating clinical trials are listed below.

³ Although extensive preliminary testing may provide a good indication that the therapy will be beneficial and that side effects will be manageable, the very nature of a clinical trial is that the actual risks and benefits are not clearly and definitively known.

a. AKC Canine Health Foundation

www.akcchf.org/research/participate-in-research/clinical-trials.html

b. Veterinary Cancer Society (Links to clinical trials and a searchable database)

www.vetcancersociety.org/pet-owners/clinical-trials/

c. National Institute of Health/Center for Cancer Research/Comparative Oncology Program

(Links to clinical trials)

<https://ccr.cancer.gov/comparative-oncology-program/trials>

d. American Veterinary Medical Association (AVMA) (Searchable database)

<https://veterinaryclinicaltrials.org/>

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