How are Clinical Studies Conducted?

It all begins with an idea. A clinician, resident, intern, technician or student may have a patient with a specific condition that does not respond to traditional therapies. This could lead to a “what if” moment—“What if we try this combination of chemotherapy drugs?” or “What if there is a genetic link to this condition?” or “What if there is a better way?”

After the idea comes the plan or study proposal. The proposal includes the condition to be studied, species, expected outcome, potential consequences, etc. As outlined in our previous issue of Advancing Health with Clinical Studies, the proposal then goes through a rigorous animal welfare review process prior to submission to potential funding sources.

Once funded, the study begins with recruitment of patients. Clients learn of studies through many sources. UW Veterinary Care staff or local veterinarians may inform clients directly or clients may learn of the study through other means - online, friends, flyers, presentations, etc. Prior to entering a study, the client receives much information on the intent of the study, benefits and risks involved and any compensation. This is known as informed consent. After this agreement is signed, the pet is screened to determine if it meets all of the requirements to enroll in the study. The next steps vary greatly depending on what the study entails. The patient may undergo simple testing such as radiographs (x-rays) or blood tests, all performed on one day. However, the study may be much more involved, for example, when trying a new treatment for cancer that includes multiple hospital visits.

Whatever the study entails, the welfare of the patient always comes first. If a patient becomes stressed, uncomfortable or experiences unexpected side effects the study stops and provides a back-up plan for continued support of the patient.

Studies generally enroll a set number of patients to provide enough data to evaluate the study results. The number of patients and length of enrollment is determined within the study proposal. Upon completion, all of the information is analyzed to determine the most important findings of the study. Results are often published to share the investigator’s knowledge with others. The entire process may take several years to complete.

Looking for Dogs with Mast Cell Tumors

The General Surgery service is enrolling dogs with mast cell tumors in a clinical study. To qualify, the patient’s mast cell tumor must be at least 2cm. The study compares the histopathology grades of samples obtained via punch biopsy versus those from whole tumor specimens. Grading a mast cell tumor helps to establish the extent of additional treatment and a patient’s prognosis. This study hopes to determine if these tumors can be graded with a smaller, less invasive sample.

For more information, please visit our website: uwveterinarycare.wisc.edu/clinical studies
Clinical Studies

**Frequently Asked Questions**

1. **What is a Clinical Study?**
   Clinical studies involve researching new medications, treatments, tests or devices to determine if they improve patients’ health and well-being. Clinical studies may be called clinical trials or clinical research.

2. **How can my pet participate?**
   All studies have specific criteria regarding species of animal, condition to be treated, current medications, etc. Information on the requirements for each study are included on our website. Check back often for new studies to open. Clinical studies are always voluntary. No animals are entered into a study without the full understanding and permission of the pet owner.

3. **What are the benefits or risks?**
   Patients participating in a study may receive treatments not available to the general population. A pet may or may not benefit from this, however, all studies advance scientific knowledge. New drugs and protocols may have side effects and studies may require more frequent visits to the UW Veterinary Care for recheck exams and laboratory tests. All studies are reviewed and require approval by the School of Veterinary Medicine’s Animal Care and Use Committee to assure minimal risk to the patient.

4. **What does it cost?**
   The cost of participation varies with the individual study. Many studies are funded by grants that cover part or all of the treatment costs. All charges are discussed prior to a patient entering a study.

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**Genetic Conditions**

Genetic studies and genome sequencing help to determine if a medical condition is heritable. The 400 modern breeds of dogs descended from wolves over 15,000 years. However, most of those breeds developed within only 100 generations—very short in evolutionary terms. This led to a concentration of disease-causing genetic variations in specific breeds. Genome-wide association studies within a breed can help to identify a disease trait. Identifying animals with particular genetic conditions may lead to changes in breeding decisions, thus reducing the incidence of these diseases. Comparing the genome of affected animals to healthy animals is imperative for this work to continue.

There are several current clinical studies looking at genetics. They include dogs with laryngeal paralysis and unaffected Labrador and Golden Retrievers over 11½ years old; Labradors and Rottweilers with cranial cruciate disease and unaffected dogs of the same breeds over 8 years of age; healthy, neutered male Golden Retrievers over 8 years old to compare to similar patients with cancer, any dog with bladder cancer and horses with degenerative suspensory ligament disease. For more information, visit vetmed.wisc.edu/lab/corl/genetic-studies/ or the genetics lab on Facebook: SVM Genetics.