



SAFETY ASSESSMENT

Clinical Pathology in Target Animal Safety

Expertise

- Six board-certified veterinary clinical pathologists
- More than 75 years of cumulative experience
- Expertise in veterinary drug development includes:
 - Standard laboratory species
 - Domestic species
 - Food-producing species
 - Avian species

The clinical pathology report optimizes the results of animal studies, from early discovery to clinical trials, enabling more informed, effective decision-making. Charles River veterinary clinical pathologists help animal health researchers elucidate study data by addressing critical questions about the effect of a test article or experiment on clinical pathology data.

Optimizing Study Results

The in-depth assessment of clinical pathology data in the context of safety assessment studies addresses if there is a real or toxicologically relevant change in the data, if the change is related to the investigational product or test article, and if the change is clinically significant for the target animal species. A clinical pathology report adds context and value to study outcomes by integrating clinical pathology with *in vivo*, histopathological and other data (e.g., biomarkers) and linking to pathophysiological processes and organ functions.

This assessment takes into consideration the animal species, method and route of administration, study design, and pre-analytical and analytical factors, including their unique biological significance for the species. When applicable, changes are linked to the pharmacological activity of the investigational product.

Veterinary clinical pathologists can help decide which clinical pathology parameters/variables should be assessed, depending on the intended population and nature of the investigational product. They can also determine if additional tests or biomarkers may be necessary to further characterize toxicity and/or pharmacological activity, as well as establish safety of the targeted population.

Veterinary clinical pathologists are among the most qualified scientists to help develop assays, bridging clinical medicine, laboratory medicine and basic sciences. Their comprehensive expertise equips them to interpret, integrate and translate results from preclinical studies to the clinical arena. As a veterinarian and a toxicologic pathologist, the contribution of the clinical pathologist engaged in veterinary drugs is pivotal to ensure the safety of animals and humans alike.

EVERY STEP OF THE WAY