meadowhawkbiolabs.com

DISCOVERY IN VIVO PHARMACOKINETICS

NON REGULATED RODENT PHARMACOKINETIC STUDIES INITIATED RAPIDLY. METICUOULOUSLY PERFORMED BY DEDICATED TEAMS TO PROVIDE EXCEPTIONAL IN VIVO DATA FOR BOTH SMALL AND LARGE MOLECULE THERAPEUTICS.

The teams at Meadowhawk Biolabs are highly skilled in performing non-regulated rodent in vivo Pharmacokinetic (PK) studies with short lead times. Utilizing purpose-built technologies and processes designed for speed and flexibility, standard study designs can routinely be initiated within days of initial contact. Our experienced, knowledgeable, teams can flexibly execute non-standard study designs that may use alternate routes of administration, pre-treatments and tissue collection. We are always happy to share our experiences and collaborate with clients on study designs.

When seamlessly combined with our Discovery Bioanalytical Assays, Meadowhawk aims to routinely deliver the fastest PK study "dose to data" in the industry.

Meadowhawk offers a fit-for-purpose tiered approach to our non-regulated in vivo PK studies, allowing the client to efficiently use resources and materials to obtain the required data across the continuum of the drug discovery process.

Exploratory Tier

Streamlined study designs and procedures to produce data in support of preliminary screening of compounds and exploratory investigations. Designed to provide the quickest study start and execution times, but flexible to meet your in vivo study needs.

Optimization/Pre-IND Tier

Tailored study designs and procedures for exploring attributes and variables of lead compounds with greater granularity to support design and conduct of IND-enabling studies. Including dose formulation analysis and gravimetric dose confirmation.

We believe communication and transparency are critical to successfully executing rapid turnaround studies. To that end, we assign each client a Study Director who is responsible for the management and conduct of all phases of all of their clients' studies and acts as the technical point of contact. The Study Director manages a dedicated technical team for the execution of these studies. We believe that this direct and consistent point of contact with the technical leader shortens the lines of communication, incentivizes team ownership, and facilitates building long-term trusting relationships. We hope that you will come to look at your Study Director as your colleague.

Meadowhawk utilizes industry leading animal vendors and our facilities feature custom-built vivarium equipped with sophisticated electronic data capture tools and caging systems.

We are committed to ensuring that Meadowhawk adheres to sound, ethical animal welfare programs and practices as well as all applicable Federal, state, and local regulations.

Count on Meadowhawk for rapid in vivo study initiation, exceptional care in performing your studies, and timely, transparent communication on all study aspects, delivered by client dedicated teams.

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In Vivo PK Study Tiering		
Attribute	**Exploratory**	**Optimization/Pre-IND**
Research Objective	To provide data which supports preliminary evaluations and/or binary decision making	To provide data derived from focused studies to support the design and conduct of IND-enabling studies
Outcomes	Result categorization, e.g., drug-like, not drug-like; inability to distinguish among small differences in attributes/variables	Continuous data enabling detection of smaller differences in attributes/variables with sufficient precision to support design and conduct of IND-enabling studies
Speed of Study Initiation	Within 2 days of study request for dosing in colony animals	Within 4 days of study request for dosing in colony animals (otherwise subject to vendor availability)
Experimental Complexity	++	++++
Cost	+	++
In Vivo PK Study Designs		
Animals per Group	≥ 2 in rats; ≥ 3 in mice	≥ 3 in rats and mice
Animal Strain	Colony male Sprague Dawley or Wistar rats; colony male CD-1 or C57bl/6 mice	Commercially available rat and mouse strains
Compound Administration	Discrete and cassette	Discrete with gravimetric dose confirmation
Blood Timepoint Collections per Animal	≤ 8 collections with no after hour (12h) or 24h	≤ 10 collections including after hour (12h) and 24h as appropriate; Sampling ≥ 21 days post dose in large molecule designs
Routes of Administration	Standard single dose IV/PO/SC/IP	Standard IV/PO/SC/IP and non-standard routes (infusion, oral aspiration, etc.), single and multiple dose administrations
Formulation	Simple, standardized and with limited vehicles; Discrete and/or cassette dosing	Fit-for-purpose formulations specific to the treatment and compatible with subsequent IND-enabling studies
Dose Formulation Analysis	No	Yes
Animal Pre-Treatments	No	As appropriate for intended study design and objectives
Additional Specimen Collections	Limited to major tissues, e.g., brain, lungs, kidneys, etc. with sample weights provided, no tissue sectioning or aliquots	All readily accessible tissues and biofluid specimens, e.g., major tissues, lymph nodes, intestinal segments, CSF, urine, feces, etc. and also, aliquots of samples supporting various readouts as requested, inclusive of clinical chemistry assessments
Post-Collection Specimen Processing	Limited, standardized	Fit-for-purpose as necessary for PK and PD readouts, inclusive of sample splits/aliquoting
Clinical Observations	As warranted at each blood collection timepoint	As warranted at each blood collection timepoint
Additional Study Treatments and Actions	No	As appropriate for intended study design and objectives
Reports	Standard Excel file format	Standard Excel file format with option to request full Word Report

For clients in the Boston or San Francisco area, a free same day courier service is available for shipment of time sensitive materials and biospecimen samples to and from Meadowhawk's facilities. Not only does this simplify logistics and reduce timelines, but it also allows for shipment of time sensitive materials.

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