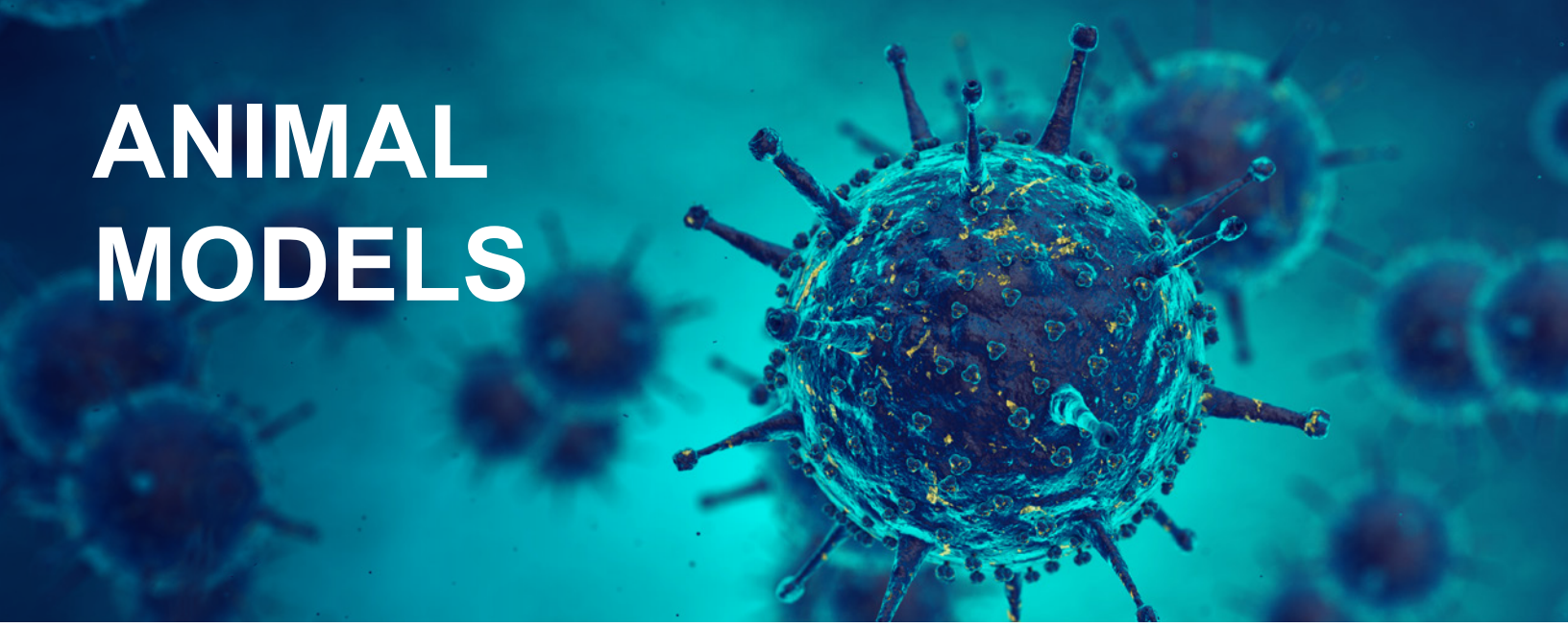
ANIMAL MODELS



INFECTIOUS DISEASE EFFICACY MODELS

The evaluation of the efficacy of a vaccine or therapeutic towards an infectious disease in animal models is a crucial milestone before moving forward with further development towards clinical use. Rigorous efficacy studies (Animal Rule Studies) are also essential when human clinical studies are not ethical or feasible. IITRI has extensive experience using rodent, non-rodent and non-human primate (NHP) animal models for bacterial or viral pathogens or toxins requiring BSL-2 or BSL-3+ facilities or vivarium, including biological agents and toxins designated as Select Agents.

ANIMAL MODEL DEVELOPMENT

We welcome the opportunity to work collaboratively with you on the development of new animal models using emerging pathogens or new animal species. Our PhD virology, microbiology, and immunology study directors provide the personalized attention and close communication that animal model development requires to ensure your program is positioned for success.

EFFICACY STUDY DESIGN

Our study directors work with you to design pilot studies through rigorous efficacy studies for regulatory submissions. We have extensive experience conducting animal efficacy studies for viral, bacterial and toxin pathogens for government, biotech, academic, and pharma sponsors, and can guide you through the design and execution of your study through data interpretation. Areas of particular expertise include seasonal and high-path influenza mouse and ferret models; Zika mouse and NHP models; *B. anthracis*, *B. pseudomallei* and *Y. pestis* aerosol infection models; and fungal infections.

BIOAEROSOL INFECTION

Our proprietary system for generating aerosols from suspensions of biologic materials such as bacterial or viral cultures (“bioaerosols”) uses a 64-port, flow-past, nose-only inhalation exposure chamber and six Pari LC Plus jet nebulizers running concurrently. This system operates at lower pressures to minimize damage to biomolecules and deliver stable spray factors to a large number of animals in parallel, and can be used with mice, rats or rabbits. Aerosol exposure of NHPs is available using a head-only system.

SUPPORTING *IN VITRO* ASSAYS

We offer a full suite of *in vitro* assays for support of efficacy studies, or for screening of vaccine or therapeutic candidates for further development. Assays can be performed in BSL-2 or BSL-3, as non-GLP or GLP-compliant.

- ELISA
- Plaque reduction neutralization test (PRNT)
- Hemagglutination inhibition assay (HI)
- Flow cytometry immunophenotyping
- Bacterial minimal inhibitory concentration (MIC)
- ELISpot
- Cytokine analysis
- RT-qPCR

EFFICACY TO TOXICOLOGY/SAFETY STUDIES

As a GLP-compliant facility offering full IND programs, IITRI offers the continuity of animal efficacy studies through GLP-compliant toxicology and safety studies. Our PhD, DABT study directors provide guidance on study designs and over 15 years of experience conducting vaccine toxicology, immunogenicity, and safety studies for regulatory submissions.

IITRI

THE IITRI ADVANTAGE

- A highly experienced and integrated study team from a broad range of disciplines including virology, bacteriology, immunology, analytical chemistry, molecular biology and toxicology
- Personalized attention and flexible communication
- Over 10,000 square feet of Biosafety Level ABSL/BSL-2/3+ facilities
- Hands-on study directors work closely with you on every aspect of your study

ANIMAL MODELS

IITRI has animal models available for a wide range of pathogens, animal species, and routes of administration. For a full list of available animal models, visit our website at www.iitri.org

VIRAL		
Avian Influenza (high path)	Ferret	IN
	Mouse	IN
Dengue	Mouse NHP	SQ SQ
EEE (Eastern equine encephalitis)	Mouse	IN, IC IN, IC
	Guinea Pig	IN, IC IN, IC
Influenza (seasonal)	Ferret	IN
	Mouse	IN
RSV	Cotton rat	IN
SARS-CoV-1	Ferret	IN
	Mouse	IN
SARS-CoV-2	Ferret	IN
	Hamster	
VEE (Venezuelan equine encephalitis)	Mouse	IN, IC
	Guinea Pig	IN, IC
WEE (Western equine encephalitis)	Guinea Pig	IC
Yellow fever	Mouse	SQ
Zika (pregnancy model)	Mouse	SQ
Zika	Mouse	SQ
	NHP	SQ
BACTERIAL		
Bacillus anthracis	Rabbit	IN, IP, SQ, aerosol
	Mouse	IN, IP, SQ, aerosol
Francisella tularensis	Mouse	IN, IP, SC, aerosol
Yersinia pestis	Mouse	IN, IP, SC, aerosol
Pseudomonas aeruginosa	Mouse	Aerosol
Burkholderia pseudomallei	Mouse	IN, IP, SC, aerosol
Staphylococcus aureus (MRSA)	Mouse	IP
E. coli O157:H7	Mouse	IV
Listeria monocytogenes	Mouse	IV
Deep puncture thigh wound (MRSA)	Mouse	IM
FUNGAL		
Candida albicans	Mouse	IV
	Rat	IV
Aspergillus	Mouse	Aerosol (intratracheal)
	Rat	Aerosol (intratracheal)
TOXINS		
Staphylococcal enterotoxin B (SEB)	Mouse	IN, IV, IP, SQ, aerosol
Ricin	Mouse	IN, IP, IV, SQ, aerosol
	Rat	IN, IP, IV, SQ, aerosol

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