

INFECTIOUS DISEASE SERVICES

Exceptional Experience • Seamless Collaboration • Flexible Communication

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.



THE IITRI ADVANTAGE

- Highly experienced team of scientists provided for each study
- Specializing in both infectious disease and GLP toxicology
- Hands-on study directors are easily accessible, keeping you personally connected to your study
- BSL 2/3 facilities and vivarium

Animal Models

Viral		
Avian Influenza (high path)	Ferret	IN
	Mouse	IN
Chikungunya	Mouse	SQ
Dengue	Mouse	SQ
	NHP	SQ
EEE (Eastern equine encephalitis)	Mouse	IN, IC
	Guinea Pig	IN, IC
Influenza (seasonal)	Ferret	IN
	Mouse	IN
RSV	Cotton rat	IN
SARS-CoV	Ferret	IN, IC
	Mouse	IN, IC
SARS-CoV-2	Syrian hamster	IN, aerosol
	hACE2 mouse	
	Ferret	
Vaccinia	Mouse	SQ
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 (PRV ABC59 strain)	Mouse	SQ
	NHP	SQ
Bacterial		
<i>Bacillus anthracis</i>	Rabbit	Aerosol
	Mouse	Aerosol
<i>Francisella tularensis</i>	Mouse	IN, IP, SC, aerosol
<i>Yersinia pestis</i>	Mouse	IN, IP, SC, aerosol
<i>Pseudomonas aeruginosa</i>	Mouse	Aerosol
<i>Burkholderia pseudomallei</i>	Mouse	IN, IP, SC, aerosol
<i>Staphylococcus aureus</i> (MRSA)	Mouse	IP
<i>E. coli</i> O157:H7	Mouse	IV
<i>Listeria monocytogenes</i>	Mouse	IV
Deep puncture thigh wound (MRSA)	Mouse	IM
Fungal		
<i>Candida albicans</i>	Mouse	IV
	Rat	IV
<i>Aspergillus</i>	Mouse	aerosol (intratracheal)
Toxins		
<i>Staphylococcal enterotoxin B</i> (SEB)	Mouse	Aerosol
Ricin	Mouse	IN, IP, IV, SQ, aerosol
	Rat	IN, IP, IV, SQ, aerosol

IITRI (IIT Research Institute)

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CORE SERVICES

IITRI (IIT Research Institute)

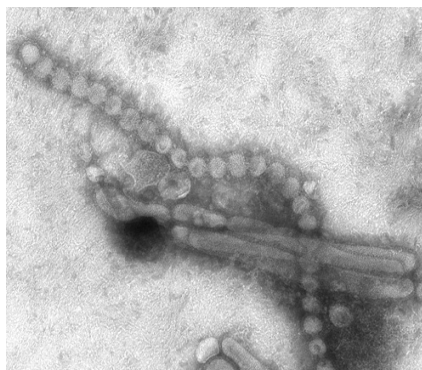
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DISCOVERY AND DEVELOPMENT

BSL-2/3+

Bacterial and viral strain library:

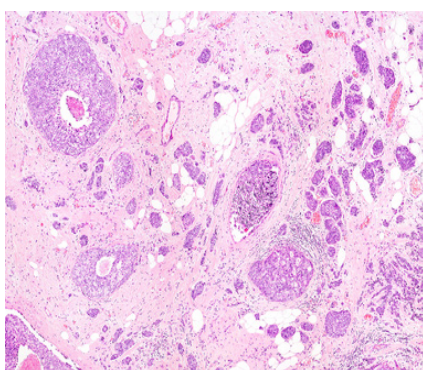
- Influenza, flavivirus (Zika, West Nile, dengue), VEE/ WEE/EEE, B. anthracis (anthrax), Y. pestis (plague) and Methicillin-resistant Staphylococcus aureus (MRSA) I

In vitro efficacy studies

- Viral, bacterial

In vivo efficacy studies

- Rodent, cotton rat, rabbit, ferret, minipig



GLP SAFETY & TOXICOLOGY

Biodistribution (non-GLP)

- ELISA
- qPCR, RT-qPCR

Repeat-dose GLP toxicology studies

- BSL-2
- All relevant routes of administration including inhalation
- Rodent, rabbit, minipig, canine, NHP • Histopathology, clinical chemistry
- Immunogenicity, immunotoxicology

Safety pharmacology



SUPPORTING ASSAYS (GLP AVAILABLE)

BSL 2/3+

Antibiotic potency

- MIC

Immunogenicity •

- ELISA • Plaque-reduction neutralization (PRN)
- Microneutralization (MN)
- Hemagglutination assay (HI)
- Yield-reduction assay

Modulation of cytokine expression

- Assessment of biomarkers
- Immunophenotyping (FACS)



MANUFACTURING SUPPORT

BSL 2/3+

Batch release testing (GMP)

Potency testing

- *In vitro* efficacy studies
- *In vivo* efficacy studie