Advancing vaccine candidates from research through IND submission requires careful confirmatory studies from \textit{in vitro} screening and \textit{in vivo} efficacy through GLP toxicology and safety studies.

IITRI offer a complete collection of preclinical services for vaccines against a wide range of bacterial and viral pathogens including select agents, influenza, Zika, and other emerging infectious diseases. IITRI provides IND-enabling vaccine programs, with over 30 years’ experience conducting GLP-compliant toxicology studies. We support vaccine basic research through FDA approval programs for sponsors from government, biotech, academic, and pharma institutions.

**IN VIVO ANIMAL CHALLENGE**
- Rodent, non-rodent, NHP
- Viral, bacterial, toxins
- Animal model development
- Biosafety Level (BSL)-2/3

**GLP VACCINE TOXICOLOGY**
- Rodent, non-rodent, NHP
- All dosing routes including inhalation
- Immunogenicity analysis

**SUPPORTING IN VITRO ASSAYS**
- ELISA
- PRNT
- Microneutralization
- HA (influenza)

**IMMUNOPHENOTYPING**
- Cytokine analysis
- Flow cytometry
- ELISpot

**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
CORE SERVICES

DISCOVERY & 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)

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 studies