VACCINE DEVELOPMENT

Discovery • Proof of Concept • Preclinical Toxicology • Clinical Support • Mfg Support

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

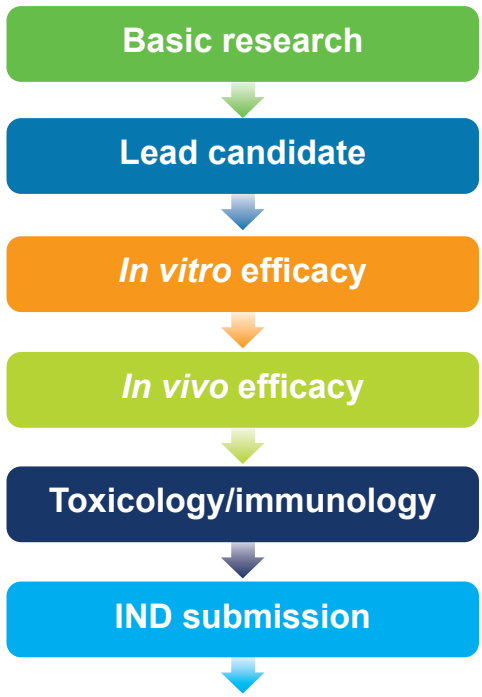
IITRI offer a complete collection of preclinical services for vaccines against a wide range of bacterial and viral pathogens including select agents, influenza, Zika, and other emerging infectious diseases. IITRI provides IND-enabling vaccine programs, with over 30 years' experience conducting GLP-compliant 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)

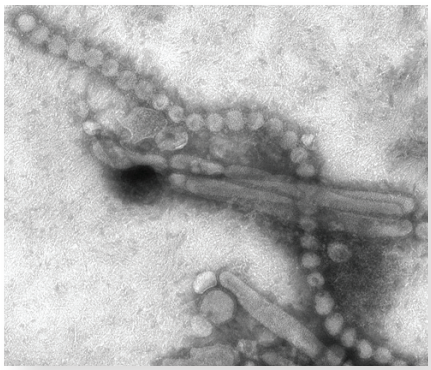
IMMUNOPHENOTYPING
- Cytokine analysis
- Flow cytometry
- ELISpot



IITRI

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



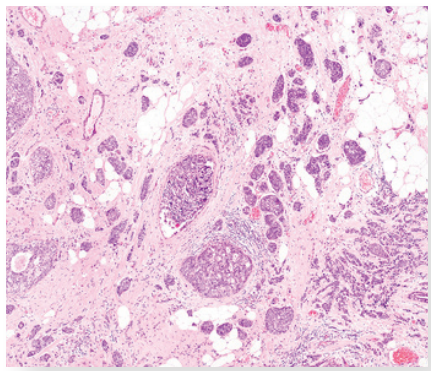
DISCOVERY & DEVELOPMENT

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

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