Lovelace Biomedical has one of the longest-running gene therapy toxicology programs of any contract research organization, with more than a decade of experience conducting preclinical studies to evaluate safety, efficacy and biodistribution of gene therapy products.

Lovelace’s gene therapy toxicology program consults on experimental design and content of pivotal, pre-IND packages and provides final reports for submission to U.S. and European regulatory agencies. Preclinical studies in gene therapy are run in compliance with GLP standards in species ranging from rodents to nonhuman primates.

**What We Do**

- Develop novel study designs to concurrently measure safety and efficacy of gene therapies
- Monitor immune responses to vector or expressed protein
- Measure biodistribution of vector and transgene expression
- Evaluate traditional and non-traditional dosing routes

**Endpoints That Matter**

- Efficacy
- General toxicity
- Vector biodistribution (qPCR)
- Gene expression
- Immunogenicity

---

10+ years running complex IND-enabling programs to support gene therapy development

50+ Lovelace Biomedical scientific staff experienced with pre-IND gene therapy programs

300,000 Square feet lab space, including GLP-compliant operations

$204 million estimated sales of gene therapy products in the U.S. by 2020
Lovelace Biomedical is the leading CRO for performing Gene Therapy nonclinical development. We have been working with the FDA and scientists with leading pioneers in the industry to advance gene therapy products to the clinic for over 12 years. In 2007 our Gene Therapy toxicology Center was established by the NIH along with pioneers at the University of Pennsylvania. We have maintained this core for over 12 years, and have built on its foundation a successful resource for biotechnology and pharmaceutical companies aiming to advance their candidates from discovery to clinical stage by GLP enabling studies as rapidly as possible.

**End Points**
- PCR Development & Validation
- Biodistribution & Gene Expression
- Clinical Pathology/Histopathology

**Specialized Dose Delivery**
- Inhalation
- Intra-Articular
- Cerebral
- Epicardial
- Ocular
- Intravenous Infusion
- Spinal

**Disease Models**
- Animal Model Propagation
- Animal Model Development

**Animal Models**
- NHP
- Canine
- Swine
- Rabbit
- Ferret
- Guinea Pig
- Rat
- Mouse

**Regulatory Support**
- Pre IND
- Pre IND Package Development

**Notable Publications**

query@lovelacebiomedical.org | (202) 819-5108 | www.lovelacebiomedical.org