Gene Therapy

Lovelace Biomedical is the leading CRO for performing Gene Therapy nonclinical development. We have been working with the FDA and leading scientists in the industry to advance gene therapy products to the clinic. In 2007, our Gene Therapy Pharmacology/Toxicology Center was established by the NIH and the University of Pennsylvania. We have maintained this core for over 16 years and have built on its foundation as a successful resource for biotechnology and pharmaceutical companies, aiming to advance their candidates from discovery to clinical stage.

Gene Therapy Expertise

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

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

End Points
- Biodistribution
- mRNA Concentration & Gene Expression
- Clinical Pathology/Histopathology

Regulatory Support
- Pre-IND-enabling package development

Disease Models
- Animal Model Development
- Colony Breeding

Noteable Publications


query@lovelacebiomedical.org | (505) 549-8353 | www.lovelacebiomedical.org
Lovelace Biomedical has one of the longest-running gene therapy 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 consults on experimental design and content of pivotal, pre-IND packages and performs preclinical studies in gene therapy that are run in compliance with GLP standards in species ranging from rodents to nonhuman primates generating final reports for submission to U.S. and European regulatory agencies.

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, mRNA concentration, and transgene expression
• Evaluate traditional and non-traditional dosing routes

ENDPOINTS THAT MATTER

• Efficacy
• General toxicity
• Vector Biodistribution
• mRNA concentration
• Gene expression
• Immunogenicity

400,000 square feet of laboratory space, including GLP-compliant operations

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

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

$42 billion estimated sales of gene therapy products in the U.S. by 2030