

GENE THERAPY CAPABILITIES

Biomere has developed deep expertise in handling and dosing viral and non-viral gene therapies in small and large animal models including adeno-associated viruses, lentiviruses and other modalities including oligonucleotides, RNA-based therapies (mRNA, siRNA) and gene editors including CRISPR and base editing. The team has experience in evaluating PK/PD characteristics of nonviral gene delivery systems such as LNPs (lipid nanoparticles) and has expertise in various dosing routes of administration.

VIRAL VECTORS

Biomere has experience evaluating PK/PD and ADME characteristics of different types of viral vectors including adeno-associated viruses (AAV9, AAV5 etc.) and lentiviruses. Client formulated viral vectors are dosed in rodent or large animal models using specified routes of administration.

NONVIRAL GENE DELIVERY

Our team has successfully completed several nonviral gene therapy programs primarily using Lipid Nanoparticles (LNPs) to deliver therapeutic payloads. LNPs are known to cause adverse effects, and our team is highly experienced in preparing and countering anticipated toxicity in tolerability studies. In addition to therapeutic payloads, Biomere has successfully evaluated biodistribution and early toxicity profiling of gene editing platforms including CRISPR and base editing.

RODENT MODELS

Intravenous is the most common route but additional routes such as subcutaneous, intraperitoneal and intramuscular are available. Specialty dosing methods are also available including ICV and neonate dosing. Specific rodent strains and models are sourced from reputable providers, and we have an established process of quarantine and health monitoring of new models and strains.

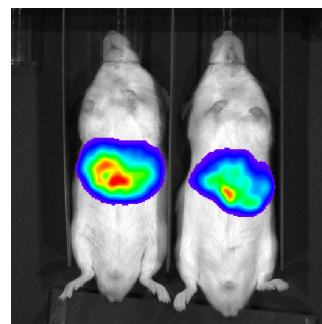
LARGE ANIMAL MODELS

NHPs and other large animals are amenable to a wide range of dosing methods including intravenous, oral gavage, nebulization, ocular routes including intravitreal and CNS tissue specific delivery such as ICV. Biomere's colonies include naïve and non-naïve animals of different origins to suit your program timelines and budgets.

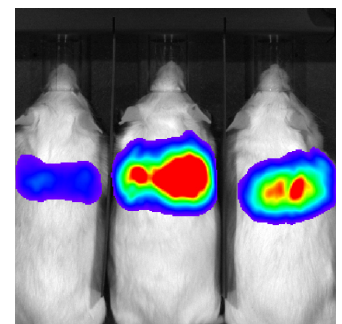
SAMPLE COLLECTION AND ANALYSIS:

Once the cohorts are dosed with the test article, in-life blood and tissue samples are collected for analysis along with terminal samples. Biomere offers a growing portfolio of endpoint assays including:

- Flow cytometry panels of cell surface markers to support population profiling.
- Sandwich ELISAs to assess specific analytes.
- Multiplex MSD assays to measure changes in cytokine expression.
- Bioluminescent and fluorescent imaging (IVIS) to monitor distribution and clearance of test articles.
 - Biomere has partnered with EMIT imaging to offer cryo-fluorescence tomography of whole rodent and large animal organs.
- Histopathology and Immunohistochemistry analysis in partnership with established providers.



IVIS imaging of intravenously injected test article accumulation in the liver



IVIS imaging of test article administered intratracheally to target lungs

