BIOIVT

ELEVATING SCIENCE

Accelerate your ADME research

ADME-TOX SERVICES

Expertise you can rely on

"I have the privilege of leading the team at our lab here in Kansas City. Our culture of collaboration supports pharmaceutical companies that rely on us for scientific expertise, and to provide deliverables on time and within budget."

Dr. Joanna Barbara Site Director

"I primarily help clients develop their IND-enabling strategies. We grew our company by consistently focusing on designing and implementing study programs that are truly aligned with our clients' objectives, whether that's lead optimization, adding value to new chemical entities that will be out licensed, or taking a compound all the way through regulatory approval."

Dr. Brian Ogilvie Vice President, Scientific Consulting

An Integrated Approach

BioIVT provides ADME / DMPK services including consulting on ADME strategies, design and implementation of *in vitro* and *in vivo* studies, bioanalysis, analysis of study data, and report development.

Whether you need our expertise for a single study or are looking for a partner for comprehensive preclinical programs, we will take a collaborative approach to your projects. We design research engagements based on our clients' objectives, consider existing data, and provide deliverables that meet the requirements of clients' internal and external stakeholders.

Tiered Service Offerings

BioIVT's fit for purpose study programs are designed to meet specific objectives. Tiered services enable us to efficiently provide high-quality deliverables while reducing turnaround time.

Tier 1

Basic Program

Designed for decision-making and informing future definitive studies.

Scientific support and expertise tailored to your research objectives.

Tier 2

IND-Enabling Program

Provides IND submission-ready data and comprehensive standard reports.

Tier 3

IND-Enabling Program with eCTD Report

All the study rigor of Tier 2, with eCTD readiness and the option of GLP compliance.

Study designs comply with current regulatory guidance

Consulting

Comprehensive ADME strategies

Our consulting team will review your existing preclinical and clinical data and provide recommendations to mitigate risk and accelerate the path to regulatory approval. Consulting services include: **Gap analyses, Due diligence** for in-licensing assets**, Technical writing,** and **Preparation** for advisory board meetings.

In Vitro ADME and DDI Programs

Our research team will design and implement ADME studies that achieve your preclinical R&D objectives. We have experience with diverse drug modalities including small molecules, ADCs, and oligonucleotides.

Drug Metabolism: Predict metabolic stability, biotransformation and metabolites

- Metabolic Stability
- Metabolite Identification
- CYP Reaction Phenotyping
- UGT Reaction Phenotyping

Drug Transporters: Predict the role of transporters in pharmacokinetics

- Transporter Inhibition Studies
- Transporter Substrate Studies
- Single-Transporter Studies
- Multi-Transporter Models
- Custom Transporter Panels

Enzyme Induction: Assess the potential of drug candidates to induce drug-metabolizing enzymes

- *In Vitro* CYP Induction
- *Ex Vivo* CYP & UGT Induction

Enzyme Inhibition: Assess the potential of drug candidates to inhibit drug-metabolizing enzymes

- CYP Inhibition
- UGT Inhibition

Hepatobiliary Disposition: Assess test article accumulation, clearance, and DDI potential in hepatocytes using B-CLEAR® Technology

- Disposition Evaluation and Prediction
- Disposition DDI

Hepatotoxicity: Evaluate and predict hepatotoxic effects of test articles

- Predictive Tox
- Cholestatic Tox (C-DILI™ Assay)

Supporting Assays: Assays to investigate drug PK profiles, including cell permeability, protein binding, lysosomal trapping, and RBC partitioning

Bioanalysis

Extensive capacity for bioanalytical services, implemented as part of other programs or as standalone projects

- *In Vivo* Metabolite Identification
- Small Molecule Analyses
- ADC / Oligonucleotide Analyses
- Toxicokinetic Analyses

In Vivo ADME and PK Studies

Full suite of capabilities implemented through well-established partnerships

- *In Vivo* Metabolite Identification
- Excretion Studies
- *In Vivo* Plasma Protein Binding
- Pharmacokinetics
- Radiolabeled Compound Synthesis
- Tissue Distribution

Research Facility in Kansas City, KS

Built For Your Research Needs

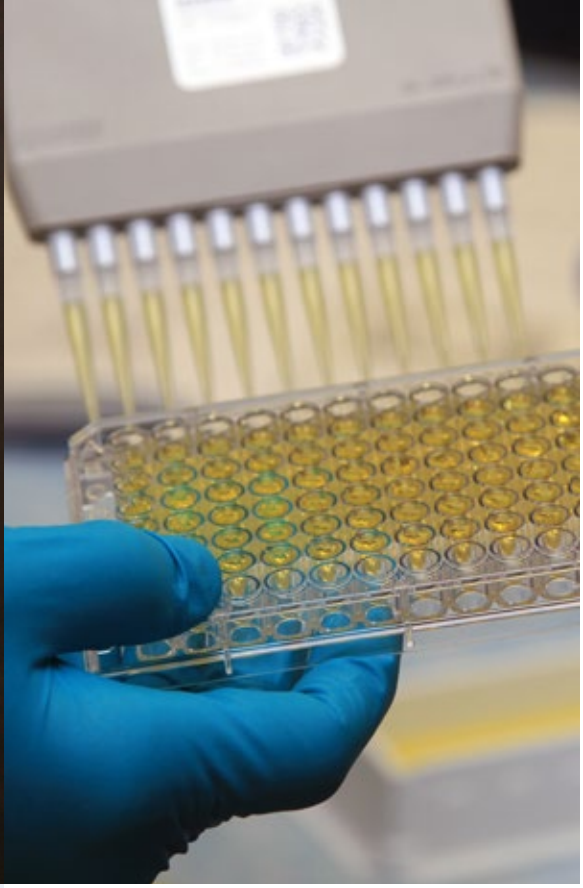
Infrastructure and Capabilities

With more than 44,000 square feet of laboratory space dedicated to ADME studies at our research facilities in Kansas City, KS and Santa Clara, CA, we have the capacity to operationalize our clients' programs and consistently provide the data and reports they need to inform their drug R&D decision-making.

In 2022, BioIVT acquired XenoTech, along with its 25-year reputation for innovation, exceptional quality, and excellence. BioIVT has continued to invest in its laboratory infrastructure leading to improved turnaround times.

ADME Product Market Leader

BioIVT is the only leading provider of ADME research services that is also the global leader in ADME products. As your research partner for metabolism and DDI studies and other services, we have access to an unparalleled selection of human and animal hepatocytes, subcellular fractions, and BACTOSOMES® and other recombinant enzymes. Additionally, we can incorporate proprietary technologies, including long-term HEPATOPAC® cultures, B-CLEAR studies, and the C-DILI™ Assay into our programs.



Innovative Proprietary Technology

Our experts recommend study programs based on our clients' needs using conventional and novel methodologies. Our scientific teams have developed the following technologies to investigate compounds and improve IVIVE:

HEPATOPAC® and HEPATOMUNE® Technologies: Stable, long-term hepatocyte cultures to investigate low turnover compounds and disease models.

LIVERPOOL® Hepatocytes: The original pooled hepatocyte technology, formulated for specific activity levels.

CryostaX® Hepatocytes: Pooled and individual-donor lots using CryostaX 'single-freeze' pellet technology.

Human TRANSPORTER CERTIFIED® Hepatocytes: Hepatocyte lots that have been shown to have *in vivo* relevant transporter function in sandwich-cultured models.

SPHEROID CERTIFIED™ Hepatocytes: Hepatocyte lots that demonstrate high functionality in 3D cultures.

Human BACTOSOMES® Enzymes: Metabolizing enzymes, ideal for reaction phenotyping and enzyme inhibition studies.

B-CLEAR® Technology: Methodology to quantitate biliary vs. basolateral efflux.

C-DILI™ Assay: Whole-cell system to evaluate potential for cholestatic hepatotoxicity.

OPTI-EXPRESSION™ Technology: Efficient, transient transfection system to create single transporter assays and multi-transporter models.

A Proven Partner

ADME-Tox Product & Research Services

BioIVT understands that you have a lot riding on your research. Our mission is to enable smarter science and accelerate medical breakthroughs that enhance and extend lives by delivering personalized biospecimen solutions to the life science and diagnostic industries.

As the leading provider of human and animal hepatocytes, subcellular fractions, and ADME research services, BioIVT offers unmatched hepatic expertise and a comprehensive portfolio of ADME-Tox solutions.

Learn More at BioIVT.com

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