Developing comprehensive and appropriate ADME strategies to accelerate drug R&D programs

The consulting team at BioIVT provides in-depth analyses of ADME properties and DDI risks for drug candidates. Our experts help researchers optimize their *in vitro* research programs and ensure data packages are ready for regulatory submissions. Our objective is to support our clients' R&D goals and minimize the risk of dangerous or unexpected clinical trial outcomes that can lead to late-stage failure.

Integrated Consulting Programs

Services	How We Partner With Clients	Deliverables
Gap analyses	Review preclinical plans and data with a focus on: • Determining whether existing *in vitro* DDI data meets current regulatory expectations • Identifying possible "missing studies" in the data package • Reviewing study design • Assisting with data interpretation	De-risk R&D programs by providing prioritized recommendations for additional studies and analyses.
Due diligence review for in-licensing assets	Provide an independent third-party review of critical in-licensing considerations, including: • Determining whether there are "red flags" with the asset • Assessing the preclinical *in vitro* data package • Proposing additional studies that should be done to accomplish our clients' objectives including regulatory submissions	Estimate *in vitro* R&D costs of in-licensed drug candidates by providing prioritized recommendations for additional studies and analyses.
Technical writing	Provide access to expert writers with extensive ADME and DDI experience who are familiar with current regulatory guidances.	Develop written materials, including: • Sections for INDs, IBs and NDAs • Responses to regulatory agencies' questions and comments • Peer-reviewed publications
Preparation for advisory board meetings	Coordinate and facilitate collaboration with drug development experts to support decision-making in advance of advisory board meetings.	Develop written materials incluing slide decks to present data, analyses, and summary reports.

Tap Into Our Expertise

Our ADME/DMPK experts have deep experience in many drug classes and numerous therapeutic areas and advise on critical considerations for preclinical strategies. Our consulting support includes the following projects:

- Review the DDI sections of IND and NDA submissions
- Evaluate preclinical data packages to ensure they are aligned with the FDA Guidance for Industry *(In Vitro Drug Interaction Studies—Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions, January 2020)*
- Determine whether gaps exist in critical information about drug candidates
- Outline how to proceed if similar studies conducted by multiple CROs have conflicting results
- Interpret data sent from different CROs
- Develop plans to address specific DDI-related regulatory questions
- Determine whether there are additional enzymes and transporters that should be evaluated as part of a regulatory submission, or identify other studies to consider, given the unique characteristics of the drug
- Evaluate what ADME and PK properties may be especially relevant, given the structure of the drug candidate

A Proven Partner

Our consulting services team, which is part of BioIVT's Scientific Affairs Department, provides in-depth analyses of ADME properties and DDI risks for new drug candidates. Our experts help researchers optimize *in vitro* research programs and ensure data packages are ready for regulatory submissions.

Our consultants have extensive experience at biopharmaceutical companies and CROs in all aspects of preclinical programs. They partner with clients on:

In vitro DDI study design and interpretation, for:

- Metabolism
- Transporter effects
- Enzyme inhibition and induction
- Plasma protein binding
- Basic and mechanistic static modeling for *in vitro* and *in vivo* extrapolation
- Developing responses to regulatory agency questions
- *In vitro* evaluation of small- and large-molecule drugs as immune modulators of drug transport and metabolism
- Nonclinical IND- and NDA-enabling toxicology studies

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