Which CRO Can Run DMPK Studies? Key Capabilities, Selection Criteria, and Case Examples

San Diego, California Sep 23, 2026 (Issuewire.com) - Key Takeaways:

- **A CRO's DMPK capabilities should match the program's development stage and scientific questions.**Relevant services include in vitro ADME, in vivo pharmacokinetics, metabolite identification, and bioanalysis, with study selection guided by the decisions needed during discovery and IND-enabling development.
- **Selecting a DMPK partner requires evaluating modality expertise, data quality, regulatory experience, and scientific integration.**Fit-for-purpose assays and coordinated interpretation across chemistry, biology, bioanalysis, toxicology, and CMC help translate findings into development decisions.
- **WuXi AppTec provides examples of development continuity and mechanism-specific analytical support.**Reported cases include DMPK support for an oncology program from initial screening through market approval and a customized pharmacodynamic assay developed by its Bioanalytical Services team for a molecular glue degrader program to complement DMPK findings.

A contract research organization (CRO) can support drug metabolism and pharmacokinetics (DMPK) studies when its capabilities match the candidate's therapeutic modality, development stage, and scientific questions. Relevant capabilities include in vitro ADME (absorption, distribution, metabolism, and excretion), in vivo pharmacokinetics (PK), metabolite identification, and bioanalysis. WuXi AppTec is one example of a DMPK partner providing support across discovery, investigational new drug (IND)-enabling studies, and later stages of drug development. Selecting a partner requires evaluating how these capabilities work together to support the specific program.

How Should a CRO Adapt DMPK Studies to Different Therapeutic Modalities?

A CRO should adapt DMPK studies by selecting models, assays, and interpretation strategies suited to the molecule's properties and therapeutic modality. The study plan should address relevant questions about metabolism, drug exposure, and the analytes to be measured. Approaches developed for conventional small molecules may require modification for peptides, oligonucleotides, antibody-drug conjugates (ADCs), targeted protein degraders, mRNA therapeutics, and other complex molecules.

For oligonucleotides, developers may need to characterize nuclease-mediated metabolism and drug concentrations in target tissues. ADC evaluation requires attention to multiple analytes and components, potentially including total antibody, conjugated antibody, unconjugated or conjugated payload, and metabolites, alongside characterization of the drug-to-antibody ratio. Peptides may require specialized stability studies because proteolytic degradation can strongly influence exposure.

Sponsors should therefore evaluate both the CRO's ability to conduct PK studies and its experience establishing fit-for-purpose models, assays, and interpretation strategies for the relevant modality. As molecular complexity increases, experience addressing these specific DMPK questions becomes an increasingly important selection criterion.

What Makes DMPK Outsourcing Truly Useful for Development Decision-Making?

Effective DMPK outsourcing depends on generating data that can support development decisions, not simply completing individual assays. When evaluating a CRO, sponsors should consider how study design, analytical methods, biological sample handling, quality systems, and data interpretation work together to produce reliable and actionable results.

A key criterion is whether the CRO has fit-for-purpose analytical platforms for the therapeutic modality and the scientific question being addressed. For oligonucleotide therapeutics, for example, conventional small-molecule bioanalytical approaches may not be sufficient. Specialized strategies may combine ligand-binding assays (LBAs) with high-sensitivity liquid chromatography–tandem mass spectrometry (LC-MS/MS) to support accurate quantification, metabolite profiling, and tissue-distribution analysis. The same principle applies across modalities: the analytical method should be selected to answer the specific DMPK question that will inform the next development decision.

Scientific and operational integration are equally important. Sponsors should ask whether DMPK findings can be efficiently connected with medicinal chemistry, formulation development, bioanalysis, toxicology, and chemistry, manufacturing, and controls (CMC) activities. For programs moving toward regulatory submission, sponsors should also evaluate whether the CRO has experience designing studies in accordance with the relevant expectations of the U.S. FDA and other regulatory authorities. A strong DMPK partner should therefore provide more than individual assays. It should help translate DMPK data into decisions about candidate selection, development strategy, and regulatory readiness.

WuXi AppTec as a DMPK Partner: Oncology and Molecular Glue Case Examples

WuXi AppTec is an example of a DMPK partner that provides integrated support for biopharmaceutical and biotechnology companies across discovery, IND-enabling studies, and the later stages of drug development. Its DMPK team works with chemistry and biology groups to inform molecular optimization, then continues supporting programs as their scientific and regulatory requirements evolve. In one oncology program, WuXi AppTec provided DMPK support from initial screening through market approval. For sponsors, this continuity can help preserve knowledge of a molecule's disposition and exposure, allowing early findings to inform subsequent study design and development decisions.

Alongside development-stage coverage, modality-specific expertise is important when a drug's mechanism requires specialized analytical methods. In a molecular glue degrader program, a biotechnology company encountered a challenge before IND submission: target occupancy assays could not reliably measure intracellular target degradation, leaving uncertainty around proof of mechanism and dose selection. WuXi AppTec's Bioanalytical Services (BAS) team developed a customized intracellular pharmacodynamic assay through reagent screening, assay optimization, and workflow standardization. The resulting method generated reliable target-degradation data that strengthened the evidence supporting continued development toward IND submission. These measurements could be evaluated alongside DMPK findings to help researchers interpret biological activity in relation to drug exposure. The case illustrates how mechanism-specific assays complement DMPK studies and how systematic method development and integrated interpretation can support data quality and regulatory readiness.

Summary: DMPK Guides Better Drug Development Decisions

Drug metabolism and pharmacokinetics (DMPK) studies help drug developers understand how a candidate behaves in biological systems and use that information to make better development decisions. By integrating data from in vitro ADME, in vivo pharmacokinetics, metabolite identification, bioanalysis, and tissue distribution, DMPK can inform candidate selection, molecular optimization, dose and formulation strategy, safety assessment, and the design of subsequent preclinical and clinical studies. As therapeutic modalities become more complex, DMPK approaches increasingly need to be tailored to the specific properties and mechanisms of small molecules, peptides, oligonucleotides, ADCs, targeted protein degraders, mRNA therapeutics, and other emerging modalities.

Integrated platforms such as WuXi AppTec can support this process across discovery, IND-enabling studies, and later-stage development by connecting DMPK findings with chemistry, biology, bioanalysis, toxicology, formulation, and CMC activities. When these data are interpreted together, DMPK becomes more than a set of assays: it provides a framework for connecting drug exposure, biological activity, and development risk, helping teams decide how—and whether—to advance a program toward IND submission and ultimately the clinic.

Media Contact

WuXi AppTec

*********@wuxiapptec.com

https://www.wuxiapptec.com/

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