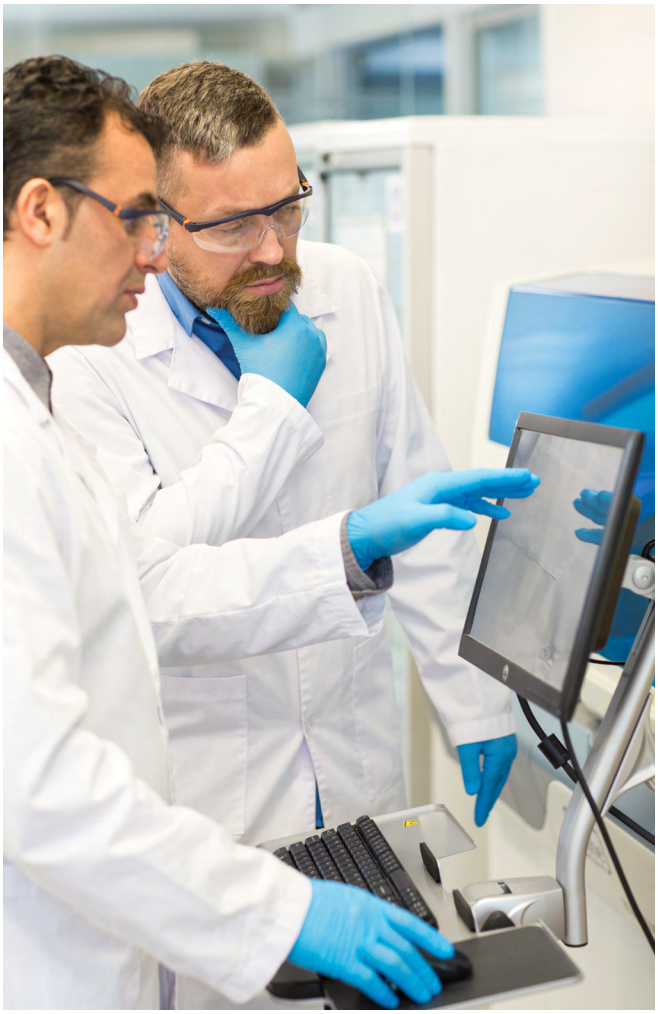
inotiv
analyze. answer. advance.

Drug Metabolism and Pharmacokinetics (DMPK) & Cell and Molecular Biology

Inotiv's DMPK & Cell and Molecular Biology services provide a broad range of expertise for all stages of R&D, from lead optimization in Discovery to IND and NDA. We offer a collaborative and investigative approach towards understanding ADME properties, exposure issues, and pharmacology/toxicology mechanisms, which could limit development of your therapeutic. Partner with our team of industry-trained scientists, and 40+ year track record of providing leading pharma and biotech companies with attentive and decisive consulting and laboratory services.



Gain the insight and expertise you need to progress to your next milestone with Inotiv's DMPK & Cell and Molecular Biology service offerings, which include:

In Vitro/Biotransformation

- Metabolic Stability (Subcellular Fraction and Hepatocytes)
- Plasma Protein Binding/Tissue (Non-Specific Binding)
- CYP Inhibition/Time Dependent Inhibition (i.e., IC_{50} Shift)
- CYP Time Dependent Inactivation Kinetics (K_I, kinact)
- CYP Phenotyping (Including Relative Activity Factor)
- CYP Induction (Human Hepatocytes, mRNA)
- UGT Phenotyping (Recombinant)
- *In Vitro-In Vivo* Correlations (IVIVC)/Human PK Projections/Allometry
- Metabolite Identification/Softspot Analysis (HRMS)

In Vivo Disposition

- Intravenous and Extravascular Dosing and Infusions
- Discrete and Cassette Dosing
- Standard IV/PO PK and Bioavailability Assessment
- Rapid Rat IV/PO PK and Tissue Distribution Models
- Biliary and Urinary Excretion Models (BDC and Metabolism Caging)
- Intestinal and Hepatic First Pass Models (PVC and Metabolism Caging)
- Rodents, Rabbits, Dogs, Swine, Non-Human Primates, and (Liver Humanized) Mice

Inotiv | 8520 Allison Pointe Boulevard | Suite 400
Indianapolis, IN 46250 | 800.845.4246
Discovery and Development: DDinfo@inotivco.com

Pharmacokinetics/Modeling

- Stand-Alone or Fully Integrated With *In Vivo* Capabilities
- Regulated (GLP/GCP) and Non-Regulated Analysis
- Validated Phoenix WinNonlin Software Package
- Integration of Pharmacokinetic Data (PK/PD Modeling)
- Repeat Dose Simulation/Modeling
- Interpretation and Submission Compliant Reporting
- CDISC/SEND Domain Preparation

Consulting Services

- Preclinical Development and Toxicology/Pathology
- Drug Lead Optimization
- Preclinical Safety Evaluation
- Investigational New Drug Application

Bioanalysis LC-MS/MS

- Featuring Sciex Triple Quad® 7500, etc.
- Traditional Small Molecule
- Pro-Drug With Active Metabolite
- Peptide and Protein Therapeutics
- Oligonucleotides
- Diverse Matrices (Hard and Soft Tissues)
- Dose Formulation Analysis (DFA)
- Matrix Stability

High-Resolution MS (HR-MS)

- Featuring Thermo™ Orbitrap Exploris™, etc.
- Metabolite Identification (*In Vitro* and *In Vivo* samples)
- Soft Spot Analysis
- Protein Analysis (Peptide Fingerprinting)

Biomarker Analysis

- Cytokine Panels (Multi-Species)
- ELISA/MSD/Luminex Platforms
- Antibodies
- Peptides
- Hormones

Gene Expression

- DNA/RNA/Protein Analysis
- CYP Induction (Human Hepatocytes, mRNA)
- Biodistribution (Vaccines Vectors, Oligonucleotides)

Cell-Based Assays

- Co-Culture Assays for Extended Culture Times
- Isolation of Species Specific Primary Cells
- Cell-Based Assays in 2D/3D Formats
- Drug Transporter Assays (per FDA Guidance)
- Biodistribution (Vaccines Vectors, Oligonucleotides)

Flow Cytometry

- Featuring Miltenyi MacsQuant® 16 and Thermo Fisher Attune NxT
- Immunophenotyping (Standard Panels/Custom)
- *In Vitro* Lymphocyte Simulation Assays
- Engineered and Modified Cell Line Generation / Validation
- Flexible and Customized Study Design

You deserve a broad scope of right-sized solutions that seamlessly align with your needs and goals.

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