

## MICROSAMPLING IN EARLY PHASE DRUG DEVELOPMENT

<u>Altasciences</u> is at the forefront of microsampling, leveraging innovative technology that allows for significantly reduced blood volumes to be taken from test subjects for analysis.

Our experts have developed **specialized workflows and methods to take full advantage of current microsampling technology at the preclinical, clinical, and bioanalytical levels,** supporting the efficient advancement of your drug development program. Our services are fully customizable, available as stand-alone, or as part of a complete development program.

Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, data management, formulation, manufacturing, and analytical services, all customizable to specific sponsor requirements.

# Benefits of microsampling throughout the early phase drug development continuum

#### PRECLINICAL

- Supports Altasciences' commitment to reduce and refine experimental animal use
- Allows rapid, straightforward and reduced-stress blood collection, resulting in accelerated animal recovery with less adverse effects
- Improves scientific quality of TK profiles via serial sampling from the same animal rather than composite sampling from several cohorts
- Permits direct correlation of study findings with exposure to drug and/or metabolites in individual animals by use of main study animals only, no satellite animals required
- Enriches data by collection of multiple endpoints (e.g., biomarkers to support interpretation of toxicological effects)

#### CLINICAL

- Simplifies sampling at home or in remote geographical locations
- Reduces blood volume significantly compared to standard blood sampling; low blood volume collection enables PK studies in children/neonates
- Provides opportunity for episodic sampling (e.g., migraine, epilepsy)
- Enriches PK trial data with samples taken for additional assessments (e.g., biomarkers, metabonomics, and co-medications)
- Ideal for population PK studies and trough sampling study designs
- Provides an alternative for patients with difficult venous access or trypanophobia
- Reduces participant burden associated with clinical trial visits; may improve recruitment efforts, reduce drop-out rate, and increase subject engagement\*

\*According to a survey of 16 clinical trial participants utilizing microsampling technology and comparing it to traditional venipuncture. Melanie Anderson, APA, 2018

#### BIOANALYTICAL

- Limits the complexities associated with cold chain shipping, storage, and sample processing of traditional wet matrices (e.g., plasma)
- Eliminates hematocrit-induced sampling volume bias when using Mitra® VAMS® technology
- Accelerates method development and sample throughput using novel workflows
- Improves compound stability in dried matrices for some drug classes

### See microsampling and our capabilities in action:



#### altasciences.com

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Altasciences' experts have developed innovative supporting processes for microsampling, including:

- Impact-assisted extraction to ensure maximum recovery from the Mitra® substrate
- Specialized sample storage and retrieval system to facilitate passing of ISR according to FDA guidelines
- State-of-the-art sensitivity and high-throughput bioanalytical capabilities utilizing the Nexera X2 and SCIEX 6500+ Triple Quad

#### **Integrated Research Services**

Our integrated preclinical to clinical service offering (including manufacturing and analytical services for small molecules) ensures that your program progresses in the most efficient and seamless manner possible. We ensure constant communication and proactive data sharing between preclinical and clinical teams, so that learnings from each phase are incorporated into the next. When you start your development program with us, you only need to **Tell Us Once™**, and we take care of the rest.

Our research services include:

- Strategic and regulatory guidance
- Protocol development
- Program management
- Biostatistics
- Data management
- Medical writing

We will support your drug development from start to finish, ensuring precision data at every step.

#### ALTASCIENCES IS HELPING YOU GET BETTER DRUGS TO THE PEOPLE WHO NEED THEM, FASTER.

#### Consult some of our publications:

Posters from the 11<sup>th</sup> EBF Conference

Large Molecule Application of Volumetric Absorptive Microsampling for Single-Rodent PK Profiling of Exenatide Determined by LC-MRM

Volumetric Absorptive Microsampling Combined with Impact-Assisted Extraction for Hematocrit Effect-Free Assays