Human AME Services

Overview

Tests to determine the absorption, metabolism and excretion (AME) of a compound are among the most vital for a new chemical entity. Worldwide Clinical Trials offers comprehensive clinical and bioanalytical human AME services. As indicated in the FDA MIST Guidance, 'the identification of differences in drug metabolism between animals used in nonclinical safety assessments and humans as early as possible in the drug development process' is encouraged.

AME testing identifies metabolic clearance pathways and defines long-lived, unique or disproportionate human metabolites. AME studies can also provide insight into pharmacologic activity, metabolism-mediated toxicity, and the potential for drug-drug interaction (DDI). AME studies allow researchers to identify liabilities in drug candidates early in the process and improves asset value of promising compounds by enhancing the understanding of drug metabolism and clinical pharmacology.

Facility Capabilities

Clients must perform the appropriate tissue distribution work that supports the testing of a radiolabeled drug in humans. If needed, WCT can offer assistance with dosimetry assessments or study design. Our Early Phase Services team performs analysis in a purpose-built AME laboratory with state-of-the-art analytical equipment dedicated to metabolism studies.

- Packard Oxidizer
- Beckmann Liquid Scintillation Counter
- Waters Acquity UPLC for high resolution separations
- Sciex API 5000 for NL and SRM profiling
- LEAP Fraction Collector and Top Count for high sensitivity radiochemical profiling and preparative isolation
- Thermo-Finnigan LXQ and Sciex QTRAP 6500 mass spectrometers for parent-product relationships (MSn fragmentation maps) and high resolution MS

Our clinical research facility in San Antonio, Texas, is licensed to handle carbon-14 (14C) and tritium (3H)-labeled compounds for traditional AME studies (50-150 microcurie range). In addition, our 85,000-square-foot facility has space set aside for conduct of nanotracer/microdose studies (< 1 microcurie). For nanotracer studies, WCT has performed AME studies with all three commercial accelerator mass spectrometry (AMS) laboratories. Specific procedural, sample processing and pharmacy storage areas have been identified and are appropriately monitored to support these studies. The comfortable, modern facility is designed for extended in-patient stays with a total of 300 beds. Our experienced Early Phase Services team has conducted numerous studies requiring interval urine and/or fecal collections over extended time periods. Samples collected and prepared for assay (whole blood, plasma, urine and fecal) can be conveniently and rapidly transported via ground courier to WCT's state-of-the-art AME laboratory in Austin, Texas. Urine and fecal radioactivity recovery results are returned quickly, allowing the release of subjects who have met study objectives.

KEY AME TESTS

- Blood-plasma partitioning
- Conventional and nanotracer dosing
- Mass balance
- Metabolite identification
- Metabolite profiling and quantification
- Pharmacokinetics

Analyst working in lab

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Specialized Research Personnel

In addition to our experienced research staff and physician investigators who are key to the successful execution on an AME clinical trial, we provide services of specialists in the areas of radiolabel research and procedures.

- **Health Physicist:** A health physicist consultant is available to review data from preclinical studies and assist in preparation of dosimetry and radiation exposure reports
- **Radiation Safety Officer (RSO):** The RSO is actively involved in staff training and creation and review of standard operating procedures pertaining to all activities involving radioactive materials. The RSO oversees contamination and sample collection testing, as well as reviewing dose calculation, preparation and administration procedures throughout the study
- **Radiologist/Sub-Investigator:** In addition to a primary physician investigator, a board-certified radiologist is on site during dose administration
- **Pharmacists:** A pharmacist experienced with handling radioactive materials and radiolabel dosing is highly involved in dose preparation and administration activities and documentation. They are also responsible for accepting radiolabel product, isolation storage, swipe tests in drug storage/preparation area and product accountability
- **Ethics Review Board:** We utilize the services of an independent Institutional Review Board (IRB) for approval of protocol, informed consent and other study-related documents. The IRB that reviews AME studies has a board membership experienced in AME study conduct, including a former RSO who serves as board chairperson
- **Pharmacokineticists and Medical Report Writers:** After a thorough quality control (QC) and quality assurance (QA) review, the AME study data are analyzed by our expert staff and presented in a format to meet your needs and conform to regulatory agency requirements

Research Subjects

Recruitment of suitable research volunteers to participate in any clinical trial is critical to success. This is especially important when multiple biological samples must be collected and length of confinement in the research facility may be extended. Subjects are carefully chosen for a flexible schedule and availability for a long-term stay. They are clearly instructed throughout the study on the importance of following protocol, including the importance of collecting all urine and fecal matter.

Meals are carefully planned to include adequate fiber content and fluid/water intake is encouraged throughout the study. Subjects are also encouraged to move/walk around and not become sedentary.

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Routine study testing

SUMMARY

The conduct of a human AME study is recognized as a necessary step in the drug development process. Worldwide Clinical Trials' Early Phase Services has been offering contract research services to the pharmaceutical, biotechnology and medical device industries for over 20 years. Our expertise and execution of AME trials is just one of several flagship services we offer to assist in your drug development plan.

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