FRONTAGE
YOUR DRUG DEVELOPMENT PARTNER

Full Service Radiolabeled hAME Studies to **Support your Drug Development Programs**

A human absorption, metabolism and excretion (hAME) study is conducted to identify compound disposition in the body, and to characterize its metabolites.

When it comes to radiolabeled hAME studies, Frontage is your one-stop-shop. The combination of our in-house clinical and DMPK experts provides our clients full support, with a comprehensive approach from initial planning for their hAME study through final study report.

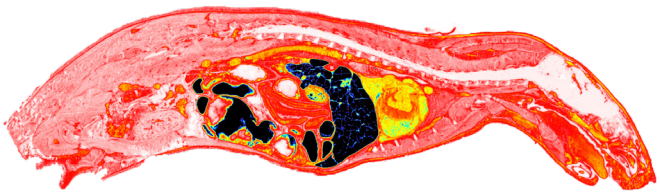
Frontage Collaborates With Clients To Design Studies That:

- Determine the pharmacokinetics, routes of elimination and clearance of a potential therapeutic agent.
- Identify metabolites in various biological matrices using high resolution mass spectrometry, other analytical techniques such as high field NMR, and by comparison with synthetic standards.
- Obtain the relative exposure of major metabolites and confirm adequate coverage in preclinical toxicology species.
- Maximize cumulative recovery of total radioactivity in excreta (mass balance).

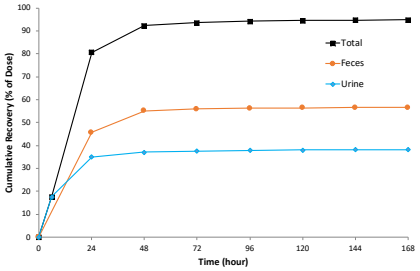
Frontage Clinical Services Approach:

- Purpose built clinical facility with a dedicated unit to conduct hAME studies.
- Expert hAME study protocol development/review, along with data management and biometrics support services.
- Rapid recruitment from a large database of healthy volunteer subjects, and study conduct by highly skilled and experienced research team.
- Dedicated, restricted access ward to accommodate up to 8 subjects in our 160-bed Phase 1 unit.
- On-site compounding pharmacy for dose preparation.
- Experienced nuclear pharmacist to prepare doses on site for oral or injection administration.
- Collection and processing of subject blood and excreta.
- Seamless integration with Frontage DMPK for sample analysis and real-time radioactivity counting that allows for timely subject release.

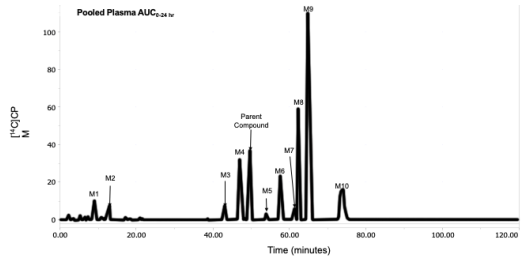
QWBA with MCID Analysis



Recovery of the Administered Radioactivity



Metabolite Profiling



Frontage Labs Highly Experienced DMPK Team Approach:

- Following QWBA, a radiation dosimetry report that is based on current regulatory recommendations is provided prior to hAME study conduct.
- A detailed analytical protocol is provided for the analysis of samples to support the hAME study.
- Daily reporting of mass balance data to demonstrate recovery and excretion pathways of administered radioactivity. Furthermore, daily mass balance data to ensure the timely release of subjects who meet the discharge criteria.
- DMPK-to-Clinical transition of information within Frontage fosters minimal delays in reporting data and enhances timeline efficiencies.
- Metabolite identification, characterization and profiling of samples by industry's leading experts equipped with the state-of-the-art instrumentation.

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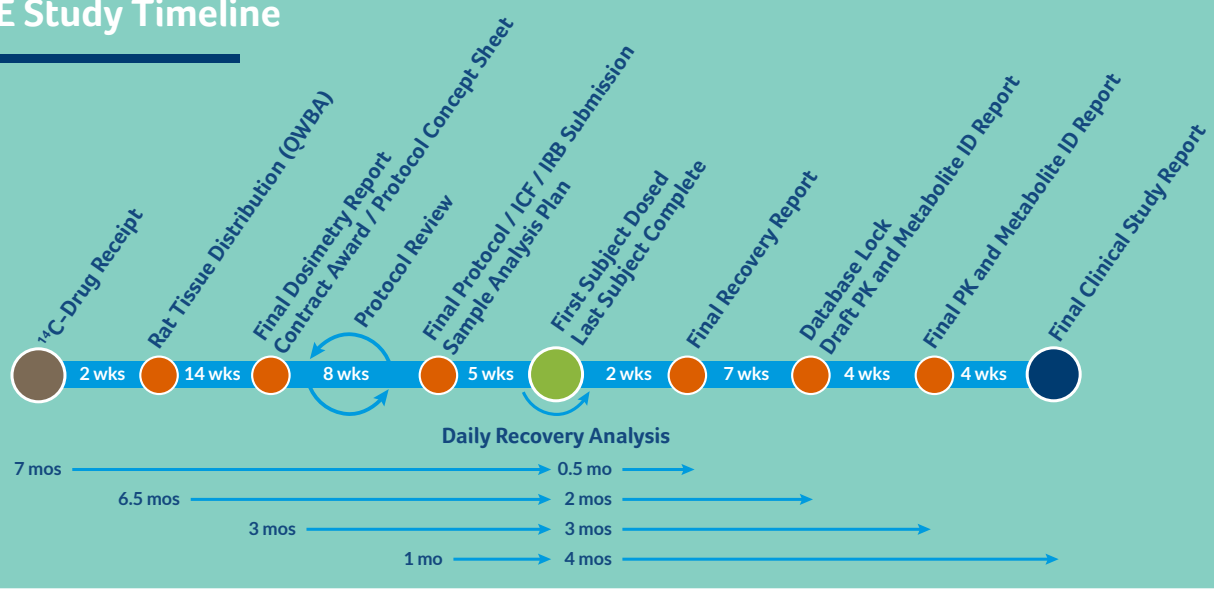
Frontage hAME Team

- Expert staff with an average of 25 years' experience in QWBA, dosimetry, hAME, and early phase clinical studies.
- QA staff to support all aspects of hAME studies.
- A science-driven team of scientists to provide scientific input and deliver high quality data in a timely manner.
- Proven history of flexibility, focus on communication, and successful execution of all pre-clinical and clinical studies.

hAME Study Timeline



Final Deliverables: ICHE3-formatted Clinical Study Report with pharmacokinetic, metabolite characterization and mass balance data, and CDISC-compliant datasets and e-submission documents.

The Frontage Difference: Experience the benefits and added value of Frontage's complete suite of clinical and analytical services for hAME studies - seamless conduct and precise analysis by the most client-focused experts in the industry.

Frontage Laboratories, Inc. is a contract research organization (CRO) that provides integrated, science-driven, product development services throughout the drug discovery and development process to enable pharmaceutical and biotechnology companies to achieve their development goals. Comprehensive services include drug metabolism and pharmacokinetics, analytical testing and formulation development, preclinical and clinical trial material manufacturing, bioanalysis, preclinical safety and toxicology assessment and early phase clinical studies. Frontage has enabled many biotechnology companies and leading pharmaceutical companies of varying sizes to advance a myriad of molecules through development and file regulatory submissions in the United States, China, and other countries.

FOR MORE INFORMATION, CONTACT US AT: *sales@frontagelab.com* **OR VISIT US AT:** *frontagelab.com*

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