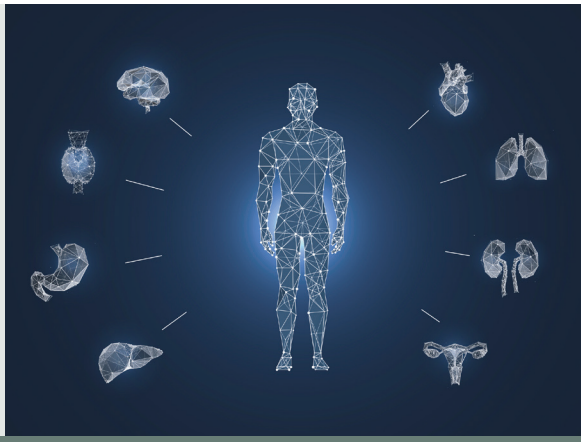
Celerion is the largest global provider of early stage clinical solutions with three facilities and more than 600 beds across North America and Europe. With 50 years' experience, Celerion's Lincoln, Nebraska facility offers a complete array of global clinical research services including on-site bioanalysis laboratory and comprehensive clinical pharmacology sciences (modeling and simulation, study design and protocol development, clinical data sciences, biostatistics, PK/PD statistics, and medical writing and reporting).



ADME Studies and Radiolabeled Capabilities

Lincoln, Nebraska is Celerion's primary facility for conducting radiolabeled compound and ADME studies. In addition, we offer metabolite profiling in Zürich, Switzerland. Celerion has invested in state-of-the-art equipment and laboratory space to perform on-site scintillation counting allowing for radioactivity recovery results to be delivered in real time. This service ensures high total recovery of radioactive dose while providing for efficient clinical study conduct.

Exceptional Value

- Clinical and scintillation counting services are located within the same facility, enabling faster access to quality data and savings in time and cost.
  - Real-time scintillation counting
  - Extended sampling
  - No sample shipping delays
- Dedicated, onsite ADME suite for pharmacy compounding, including mock and clinical radioactive drug preparations. Radioactivity concentration of preparations verified in real time by onsite LSC.
- Extensive experience with extemporaneous compound preparation and administration of radiolabeled drugs across many therapeutic classes and routes of administration.
  - IV, oral, and SQ dosing administrations options
  - Dosing preparations completed in dedicated radiolabeled nuclear pharmacy certified to USP <800> and USP <825> standards.
  - In-house nuclear pharmacist with over 20 years experience in clinical research
- Advanced radiation consulting services enables clients to leverage our experience in managing complete programs by taking animal data and extrapolating for human exposure.
  - Dosimetry calculations and preparation of dosimetry report
  - Protocol review/comments and general consultation on ADME design
  - Verification of dosing solution radioactivity prior to administration to participants

EXPERIENCE & EXPERTISE

Celerion has the experience and expertise that instills confidence.

Our extensive experience includes more than 100 radiolabelled clinical studies, dosing over 800 participants. We deliver real-time radioactivity recovery results with on-site scintillation counting equipment, enabling savings in time and cost. Clients may receive daily updates on the progress of the study, providing early indicators for excretion route data and aiding in release criteria.

Celerion has achieved an above average recovery rate of 94 percent for radioactive doses.

Celerion's experience ensures clients' studies run efficiently and effectively from initial planning through to the final report.

ADME Study Flow

- Planning
  - Final protocol, dosimetry and IRB submission
  - Receipt of investigational product
  - Pharmacy manual includes extemporaneous compounding with the development of a Master Formulation Record to document all compounding steps
- Drug preparation
  - On-site preparation for dosing of the study
    - Ability to prepare a variety of formulations including oral solutions/suspensions, intravenous solutions, and filling capsules and sub-q dosing.
  - Total Radioactivy Analysis Plan (TRAP) to include detailed instructions on sample handling
  - Completed by In-house nuclear pharmacist with over 20 years experience in clinical
- Conduct and sample collection
  - Excretion (recovery) of radioactive content measured through urine and feces
    - Monitor expired air where significant expiration losses are expected
    - Collect and analyze emesis for radioactivity content
    - Measure plasma, whole blood, and RBC for radioactivity content
  - Daily real-time mass balance results
  - Send required aliquots for metabolite profiling
- Generate total radioactivity report

Clinical Sample Timeline: 8-Week Window