

Celerion is the largest global early clinical research provider, with three facilities and over 615 beds across North America and Europe.

With more than 40 years' experience and access to 236 beds (24 in-hospital), Celerion's Lincoln facility offers a complete array of early clinical research services including on-site bioanalysis laboratory, comprehensive PK/PD, statistics and data management.



Global Clinical Research – Lincoln, NE

First-in-Human Studies

Celerion has extensive First-in-Human (FIH) experience, having completed over 600 studies globally and over 300 in the Lincoln facility. This experience ensures proven processes and best practices are in place to provide timely and accurate data to clients. In turn, Celerion provides greater flexibility in dosing requirements, number of participants and rapid dose escalation decisions during the study.

- Over 75 FIH studies conducted for biopharmaceuticals
- Risk-based review of all FIH studies by an experienced team ensures the preclinical safety data supports the proposed study design and dose
- Access to real-time data through ClinQuick® and on-site bioanalysis provides precise and safe dose escalation in as little as seven days, allowing clients to make adjustments safely, quickly and accurately
- Celerion conducts clinical studies at Bryan Health hospital
 - Round-the-clock emergency care using the same staff, SOPs and IRB
 - Access to state-of-the-art hospital techniques and equipment, including X-rays, MRIs, PET scans, CTs, EMGs, EGDs and CNS/cognitive testing

On-site Bioanalysis Laboratory

Faster go/no-go decisions due to Celerion's on-site bioanalysis laboratory in Lincoln, allowing for 48-hour data turnaround.

- Ex vivo cell stimulation studies possible on fresh blood samples
- Access to biomarker development, LC-MS/MS bioanalysis, ligand binding services, cell-based assays, immunogenicity, flow cytometry and biosimilars development all in one location

EXPERIENCE & EXPERTISE

The Lincoln clinic is one of the most established Phase I clinics in the industry, with extensive experience in clinical operations from recruitment through to the final report. This ensures that no matter how complex the study, Celerion will help clients get their drugs to market faster.

Over the past five years, the clinic has averaged more than 60 studies per year.

The addition of the USP <797> Clean Room enables efficient execution of microtracer and microdosing studies and allows Celerion to perform complex compounding at all risk levels including low, medium and high.



CULTURE OF QUALITY

Celerion's quality and compliance systems, processes and personnel have instilled a culture of quality inherent in every program. This culture of quality focuses on developing efficient processes with real-time quality control and ensuring delivery of high-quality, accurate data.



The Lincoln facility is licensed to conduct radiolabeled compound and ADME studies. 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. Celerion has conducted over 50 radiolabeled clinical studies and dosed over 300 participants. An average recovery rate of 94% for radioactive doses has been achieved.

Technology for Data You Can Trust

ClinQuick®, used in all Celerion clinics, is a proprietary Phase I clinical study management system with electronic data acquisition as its core function. ClinQuick assures consistency of clinical operations and data collection across sites, giving access to accurate high-quality information. This information enables faster go/no-go decisions based on accurate data and reduces time to database lock. Preprogrammed alerts ensure all events occur according to protocol, thereby reducing potential error and increasing participant safety.

Accreditations and Regulatory Compliance

The Lincoln clinical research operations have been certified by the Association for the Accreditation Human Research Protection Programs (AAHRPP). Regularly inspected by the FDA, the clinic is also fully GCP/GLP compliant. The clinical lab is CLIA licensed and CAP certified and has earned the "Laboratory of Distinction" from CAP. The on-site pharmacy is DEA licensed.

STUDY POPULATIONS AND THERAPEUTIC AREAS

- Healthy normal
- Allergies
- Arthritis
- Asthma
- Dermatology
- Diabetes
- GERD
- Hypercholesterolemia
- Hypertension
- Obesity
- Post-menopausal
- Pre-menopausal women on birth control
- Sexual health
- Smokers

TYPES OF STUDIES

- Bioavailability and bioequivalence
- Cardiovascular safety monitoring, including Thorough QT/QTc
- Dose-ranging: SAD/MAD
- Drug/alcohol interaction
- Drug/drug interaction
- Drug/food interaction
- Ex vivo cell simulation
- Eye/ENT/dermal irritation
- First-in-Human
- GI: pH/mucosal toxicity/endoscopy
- Long-term confinement
- PK/PD
- Radiolabeled ADME
- Safety and tolerability
- Smoking cessation
- Smoking product comparisons
- Special populations
- Steady state

SPECIALIZED TECHNIQUES

- Cardiac/ECG/TQT
- Cognitive testing
- Ex vivo cell stimulation
- Extemporaneous compounding
- Flow cytometry
- Gastroscopy
- IV, sub-Q, transdermal
- Mass balance (ADME)
- Microdose
- Ophthalmic testing
- Platelet aggregation
- Pulmonary function testing
- Access to state-of-the-art hospital techniques and equipment with Bryan Health, including x-rays, MRIs, PET scans, CTs, EMGs, EGDs and CNS/cognitive testing

LINCOLN SPECIALISTS

- Anesthesiologist
- Cardiologist
- Dermatologist
- Neurologist
- Ophthalmologist
- Optometrist
- Pediatrician
- Pulmonologist
- Radiologist
- Ultrasound technician
- Urologist