celerion
Translating Science to Medicine

TRANSLATING SCIENCE TO MEDICINE

Celerion, a full-service, early clinical CRO, is the leader in accelerating development for Phase I-IIb. Our unique combination of medical expertise, clinical operations experience and scientific excellence, enables you to make timely decisions with expert advice and high-quality data. Our leadership in clinical pharmacology through Proof-of-Concept is focused on helping you translate your science to medicine.

CELERION HAS THE EXPERIENCE AND AGILITY TO

WHY CELERION

- Your study on time and on budget with high-quality data
- Industry leaders in early drug development
- Full-service global CRO
- Personalized service model
- Agility and flexibility to accommodate changes
- Efficiencies gained with technology and automation
- Unique rapid recruitment processes and technology

EARLY PHASE SERVICES

Speed, Flexibility, Agility, Quality; all are required in today's rapidly changing clinical and regulatory environments. Whether it is difficult to recruit trials in rare or orphan indications, multi-arm trials with sophisticated investigational products, complex logistics, or trials with heavy recruitment competition, Celerion will deliver robust and reliable results. We have helped hundreds of sponsors transition through Proof-of-Concept and beyond. We offer valuable insights from protocol development through study conduct and analysis by applying Celerion's experience of nearly 1000 studies in over 30 countries. Our integrated full-service offering provides immediate access to data for faster go/no-go decisions.

CLINICAL PHARMACOLOGY

With over 40 years of experience and more than 600 beds in the USA and the UK, Celerion is the industry leader in clinical pharmacology studies. With purpose-built clinic and laboratory facilities and highly automated technology, Celerion conducts and analyzes First-in-Human through clinical Proof-of-Concept. We provide full study services designed to optimize outcomes, reduce risk and shorten development timelines.

Specialized services include:

- Cardiovascular Safety
- Patient Dose-Response Studies
- Support for Product Labeling and Regulatory Submissions
- Respiratory Center of Excellence
- Fast to Patient Strategies
- Adaptive/Fusion Study Design
- ADME/Mass Balance
- USP <797> Compliant Clean Room

MEET ALL OF YOUR DRUG DEVELOPMENT NEEDS

BIOANALYTICAL SERVICES

Celerion laboratories focus on science, compliance and speed to provide you with fast access to high-quality data. Our state-of-the-art automated facilities in Zürich, Switzerland and Lincoln, Nebraska USA, are among the most recognized laboratories in the industry. They boast over 40 years of experience working with large and small molecules, from discovery through late stage drug development. Through consistent enhancements of the facilities, Celerion provides rapid turnaround through completely automated sample analysis processes.

DATA MANAGEMENT & BIOMETRICS

Celerion bridges the gap between medical practice and laboratory science by assessing the safety of drug products to maximize drug effects and minimize side effects. Celerion has one of the most experienced Data Management and Biometrics teams in the industry, with over 120 staff operating across five global locations. Our services include:

- Modeling and Simulation
- Study Design and Protocol Development
- Clinical Data Sciences
- Biostatistics
- Pharmacokinetics/Pharmacodynamics (PK/PD)
- Medical Writing and Reporting

INNOVATIVE TECHNOLOGIES SPEED RESULTS WITH REAL-TIME ACTIONABLE INSIGHTS

Celerion's ClinQuick® proprietary early phase clinical study management system is used in all Celerion clinics for electronic data acquisition. It assures consistency of clinical operations and data collection, enabling faster go/no-go decisions.

Celexus® secure client portal, directly populated with data from ClinQuick, gives you visibility and transparency to your early clinical research data in real time, as it is collected in the clinics and laboratories. Celexus' Key Performance Indicator Dashboard provides visual displays of study progression for faster assessment of trends and identification of potential safety signals.

CELERION'S THERAPEUTIC EXPERTISE

- Cardiovascular Disease
- Dermatology
- Hepatic Insufficiency
- Immunotherapy
- Infectious Disease
- Metabolic Disease
- Oncology
- Personalized Medicine
- Renal Insufficiency
- Respiratory Disease
- Vaccines and others

UNIQUE INSIGHTS FOR SUCCESSFUL DRUG DEVELOPMENT

GLOBAL CLINICAL DEVELOPMENT: RAPID ADVANCEMENT INTO PHASE 2

Celerion's clinical services range from First-in-Human to Proof-of-Concept as well as larger Phase II studies. Our unique combination of core competencies enables us to explore drug effects in healthy volunteers and then follow in patient studies. Celerion's Global Clinical Development team executes studies in patients at our in-house or partnering clinics. The team has extensive experience and expertise in managing multi-sitecomplex studies and helps you to transition through Proof-of-Concept and beyond with a particular focus on the following disease areas: vaccines, oncology, infectious disease (viral or bacterial), renal impairment, hepatic impairment, and respiratory disease (asthma, COPD, cystic fibrosis).

Our services include:

- Multi-site Phase II clinical research in patients
- Global network of qualified sites
- Clinical project management, site ID, monitoring and start-up
- Data capture through EDC
- Trial Master File (eTMF)

COMMITMENT TO SERVICE EXCELLENCE

Celerion is derived from the Latin *celeritas* meaning swiftness and speed. This word reflects one of our founding principles: to deliver services that enable you to get products to market faster by helping you find "the one."

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