Celerion offers fully integrated early phase services and the industry's most extensive facilities across Europe and North America, including three clinics with over 650 beds. This enables biopharmaceutical companies to design, execute and complete early phase studies quickly and with high-quality data.

Our state-of-the-art, Medicines and Healthcare products Regulatory Agency (MHRA) accredited clinic in Belfast, United Kingdom, offers a complete array of early clinical research services. The clinical research facility has 78 beds across four clinical wards that are customizable to support both large numbers of healthy participants and small groups of patients for early clinical research studies.

Early Phase Clinic - Belfast, UK

Experience and Expertise

Our extensive experience from recruitment through to the final study report ensures efficient design and execution of even the most complex early clinical studies.

- Expertise in First-in-Human (FIH) studies with both new chemical entities (NCEs) and biologics
- Full service offering of protocol development, analysis, interpretation and reporting of clinical data through on-site Data Management and Biometrics team
- Access to a large network of internal and external medical practitioners and specialists
- Completed over 600 studies in more than 30 years of operation
- GMP pharmacy with qualified professionals on staff to handle all drug labelling requirements and clean room

Best-in-Class Recruitment Strategies Enable On-time Studies

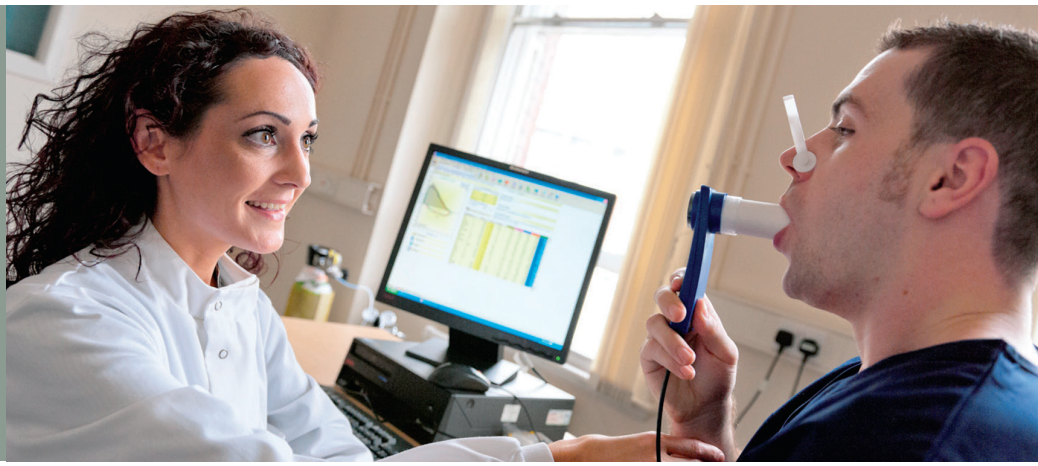
Celerion's exceptional ability to recruit healthy and patient populations enable clients' studies to start full and on time.

- Database of more than 30,000 active participants, call centre, physician networks, dedicated recruitment website and use of such technology as SMS and social media
- Successfully delivers full enrollment for multi-centre studies
- Extensive experience recruiting in COPD, cystic fibrosis, asthma, erectile dysfunction, ophthalmology, hypertension and obesity among others
- Active enrollment of healthy participants and patients in adaptive and innovatively designed studies to accelerate drug development from FIH to Proof-of-Concept (POC)
- Accelerated timeline for regulatory/ethics approval from submission to first patient in

STUDY EXPERTISE

- Bioavailability and bioequivalence
- Biosimilars
- Cardiovascular safety monitoring, including Thorough QT/QTc
- Dose-ranging: Single Ascending Dose (SAD) /
- Multi-Ascending Dose (MAD)
- Drug/alcohol interaction
- Drug/drug interaction
- Drug/food interaction
- Endotoxin
- Eye/ENT/dermal irritation
- First-in-Human
- GI: pH/mucosal toxicity/ endoscopy
- Long-term confinement
- Male erectile dysfunction and sexual health
- Obesity
- PK/PD
- Platelet aggregation
- Safety and tolerability
- Smoking cessation
- Special populations
- Steady state
- Vaccines

Clients benefit from faster access to data through Celerion's membership in UK's Translational Research Partnership in respiratory disease enabling faster access to target patient populations, specialists and techniques in phase I & II studies.



Centre of Excellence for Respiratory Medicine

Celerion is the global leader in respiratory studies and a recognized Center of Excellence for respiratory medicine including mild to moderate and severe asthmatics, COPD and cystic fibrosis.

- Membership within the UK's Translational Research Partnership in Respiratory enables Celerion to work with key decision makers and thought leaders in the UK to develop and conduct phase I and II studies with targeted patient populations
- Clients benefit from faster access to data to expedite decision making and speed up the path to clinical POC
- Dedicated on-site bronchoscopy suite allows bronchoalveolar lavage (BAL) to be performed within the Celerion clinic

Innovative Technologies Providing Real-time Actionable Insights to Manage Studies

ClinQuick®, used in all Celerion clinics, is a proprietary early phase clinical study management system with electronic data acquisition as its core function. ClinQuick assures consistency of clinical operations and data collection across sites, enabling faster go/no-go decisions based on accurate data. Patient safety is increased through preprogrammed alerts that ensure all events occur according to protocol.

Celexus®, directly populated with data from ClinQuick, is designed specifically to give clients visibility and transparency to their early clinical research data in real time, as it is collected in the clinics and laboratories. The viewable data includes screening, recruiting, adverse events, clinical laboratory, pharmacodynamics, pharmacokinetic and bioanalytical data. Celexus' Key Performance Indicator Dashboard provides visual displays of study progression including recruitment, deviations, study milestones, dosing and retention. This enables faster assessment of trends and identification of potential safety signals such as vital signs, dosing, adverse events, ECGs and inclusion/exclusion criteria.

Celerion's Highly Automated ECG Core Lab, located within the Belfast facility, enables faster access to high-quality data at a lower cost. This innovative capability uses cutting edge, automated technology and integrated processes to ensure data integrity from data collection to data analysis. Celerion's senior staff and board-certified cardiologists have extensive experience working closely with regulatory authorities as well as all aspects of study design, data analysis, and expert report writing. The benefits of this co-located ECG Core lab and clinical facility enables significant cost and time savings for the conduct of TQT studies and ECG assessment in SAD and MAD programs, by minimizing cardiologist review, integrating functions and decreasing overhead.

ACCREDITATIONS AND REGULATORY COMPLIANCE

- MHRA accreditation
- College of American Pathologists (CAP), Clinical Laboratory participates in CAP external QA scheme
- Authorized to import IMPs directly to the GMP-licensed facility from outside Europe
- Catering five-star hygiene accreditation
- Excellent history of regulatory audits through regular audits by FDA
- GCP, GMP and ICH compliant