

Clinical Pharmacology

PAREXEL International



Berlin Germany

Introduction

Expertise, experience and attention to detail are critical in early phase research. PAREXEL's Berlin Clinical Pharmacology Research Unit is dedicated to helping clients achieve a faster go/no-go decision of their drug candidates.

The Berlin Unit has more than 30 years experience in clinical research. The Unit offers significant scientific depth with extensive experience in conducting Phase I/IIa studies. The Unit is highly specialized and hospital-based with 160 beds. The size of the facility is 59,202ft² (5,500m²).

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*Expertise
that makes the Difference™*

Key features of service include:

Full Service Capabilities – On-site consulting, regulatory support, clinical data management, biostatistics, pharmacokinetic data analysis, medical writing, monitoring and quality management services allow for complete solutions for clinical pharmacology study requirements – from protocol design to final study report.

Patient Recruitment Excellence - An excellent network of relationships with key opinion leaders within the Berlin hospitals, alongside external scientific experts allows the Berlin unit to provide clients with access to a vast pool of patient populations in addition to healthy volunteers.

Electronic Data Capture – Fully validated (CFR 21 Part 11 compliant) electronic source data capture and clinical trial management system (ClinBase™) with web access to data for clients and monitors.

Expertise – Alongside significant in-house expertise, a close cooperation with medical experts within PAREXEL Clinical Pharmacology and therapeutic experts across local hospital networks/academic centers brings together a highly experienced and dynamic team to facilitate successful solutions for even the most challenging study program.

Hospital Based Location – The Berlin unit has direct and convenient access to emergency and intensive care wards, offering the safest possible environment for study participants.

Specialized Services

In addition to providing comprehensive service solutions for many kinds of clinical trial type, the Unit offers specialized depth in expertise:

Thorough QTc Studies – The Unit boasts a very close coordination between PK/PD Phase I specialists, internal cardiology specialists and the Cardiologists at the centralized ECG core laboratory.

- Bedside Monitoring
- Blood Pressure Monitoring
- Ambulatory 24 hour ECG monitoring, Telemetry
- Impedance Cardiography
- Pulse Oxymetry

Central Nervous System (CNS) Studies – Specialized equipment and dedicated facilities within the Berlin Unit along with expertise and experience enable the Unit to provide a range of CNS services. Capabilities include:

- Access to special populations: Including parkinson's disease and insomnia
- Dedicated 8 bed sleep laboratory for providing Sleep Polysomnography services.
- Performance of Clinical EEG including Event Related Potentials (ERP) and quantitative EEG
- Experimental Pain Models
- Saccadic Eye Movement, Pupillometry, Nystagmography
- Availability of a variety of psychometric tests and scales

Dermatology Services – The team in Berlin has specialized dermatology expertise, and experience in providing dermatology research and methodology solutions to clients. Capabilities include:

- Access to special patient populations: psoriasis and atopic dermatitis patients
- Psoriasis Activity Scoring Index (PASI)
- Skin Biopsy techniques
- Laser Doppler Fluximetry
- Standardised scoring assessment technique for Atopic Dermatitis (SCORAD)
- Skin Prick Test, Finn Chamber(tm) patch testing
- Transdermal ultrasound (20 MHz)

Infectious Diseases – The available services for Infectious Disease include:

- Access to special populations: Hepatitis C Virus (various genotypes) and Human Immunodeficiency

Virus (naïve, non-responder, co-infected)

- Vaccine study performance

Respiratory Research Studies – Facilities include a dedicated respiratory research laboratory, equipped with 2 Jaeger Masterscreen® body plethysmography units which allow a range of respiratory capabilities. The Berlin site has significant pulmonary expertise which includes:

- Access to special patient populations: The database includes a high number of asthmatic and chronic obstructive pulmonary disease (COPD) patients
- Computerized Spirometry
- Ergospirometry (treadmill and bicycle)
- Bronchial Provocation testing
- Impulse Oscillometry
- Exhaled Nitric Oxide measurement experience
- Exhaled Breath Condensate capture experience
- Ozone challenge
- Provocation Challenge (Allergen, AMP and others are available)
- Respiratory Heat Exchange System (Oxycon Delta)
- Sputum Induction
- All inhaled delivery systems



Strategic Healthy Volunteer and Patient Recruitment

The Berlin Unit benefits from a large pool of available local volunteers. Innovative recruitment marketing campaigns ensure that subjects are readily available on the database. There is an on-site dedicated call-center for volunteers and patients. The healthy volunteer populations include postmenopausal women, elderly volunteers and CYP2D6 genotyped volunteers.

Patient populations are also readily available. A strong recruitment network with Berlin University Hospitals and other scientific experts provides access to many patient populations, highlighted in the specialized capabilities above.

Subjects can be pre-identified (e.g. HbA1c for diabetes) to expedite recruitment and reduce study specific screening failure rates.

Regulatory Environment

The Unit is in close contact with the regulatory authorities, Competent Authority (CA) and Berlin Ethics Committee (EC). Relevant documents for submission to the Ethics Committee, and Competent Authority (e.g. IMPD) can be compiled by PAREXEL for your convenience. Parallel submissions to the authorities can be completed at any time. Berlin benefits from 6 Ethics Committee Commissions with a review meeting held each week.

PAREXEL Clinical Pharmacology

Strategic Locations

North America

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