

Clinical Pharmacology

PAREXEL International



Bloemfontein

South Africa

Introduction

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

The Bloemfontein Unit has more than 30 years experience in clinical research. The Unit offers significant scientific depth with extensive experience in conducting Phase I-III studies. The Unit is highly specialized and hospital-based with 80 beds alongside a GLP and ISO 17025 accredited Bioanalytical Laboratory. The size of the facility is 102,258ft² (9,500m²).

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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 – A strategic alliance with the academic group practice of the local medical school affords expanded patient access to diverse patient populations and 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.

Prime Location – Situated on a University campus with a Medical School allowing access to numerous credible experts across a broad range of therapeutic areas.

Global Regulatory Experience – Experienced in performing studies for submission to the US Food and Drug Administration (FDA), Canadian Authorities, European Medicines Agency (EMA) and the South African Medicines Control Council (MCC).

Highly Competitive – Very competitive pricing solutions, allowing clients to fully benefit from currency exchange rates, are on offer.

Global Strategy – Close collaboration with other PAREXEL Clinical Pharmacology Research Units in South Africa, Europe and the United States facilitates expedited recruitment rates in large multi-site studies.

Bioanalytical Services – Provides a dedicated GLP, ISO 17025 accredited Bioanalytical Laboratory

Specialized Services

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

Bioequivalence Expertise – Personnel are highly experienced in managing bioequivalence studies. Due to the high bed count (80 beds), the Bloemfontein Unit can accommodate studies with large numbers of subjects for rapid clinical completion.

Thorough QTc Studies – The Unit boasts a very close coordination between PK/PD Phase I specialists, internal cardiology specialists and the on-site Cardiologist.

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



Respiratory Research Studies – Facilities include a dedicated respiratory research laboratory, equipped with body plethysmography equipment which allows a range of respiratory capabilities. The Bloemfontein 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
- Exhaled Nitric Oxide measurement experience
- Provocation Challenge (Allergen, AMP and others are available)
- Bronchoscopy/BAL
- Blood gas analysis
- All inhaled delivery systems



The southern hemisphere location provides seasonal benefit for studies where seasons may have impact on the study performance such as respiratory studies.

Experience with Complex Studies/Specialized Techniques

The Unit boasts a 10 bedded Glucose Clamp Unit for performing manual clamp studies.

There is an Infrared Breath Isotope analyzer (IRIS system) for determining gastric emptying time available in-house.

The team are experienced in performing studies using DEXA technology for bone densitometry and body composition assessments

Electro Retinogram (mf-ERG), EOG ocular safety and visual function testing is an available service from the Unit.

With a high number of intensive monitoring beds, the team has extensive experience in managing studies with telemetry.

Personnel are highly trained with extensive clinical research experience. The team includes a dedicated resident Cardiologist alongside a number of experienced Research Physicians, Qualified Nurses and highly trained Medical Technicians.

In-house Bioanalytical Laboratory

The Bioanalytical Laboratory is fully GLP and ISO 17025 accredited and has been both FDA and WHO inspected. Standard specifications/equipment/techniques used include LC-MS/MS, GC-MS and HPLC. Immunochemistry/biomarker assays (RIA, ELISA) are also available. The laboratory has more than 350 validated assay methods which have been developed in-house.

Haematology, clinical chemistry and drugs of abuse analyses are routinely performed. Central laboratory services can also be provided.

Strategic Healthy Volunteer and Patient Recruitment

The Bloemfontein Unit benefits from a large pool of available local volunteers ensuring that subjects are readily available on the database. The healthy volunteer populations include postmenopausal women and elderly volunteers.

Unrivalled local access to patient populations including:

- Respiratory
- Metabolism
- Cardiovascular
- Immunology
- Haematology
- Ophthalmology
- Psychiatry
- Oncology

Regulatory Inspections

The Bloemfontein Unit has hosted a number of successful Regulatory Inspections. Previous Inspections include:

- United States Food and Drug Administration (FDA) – Clinical Division – 2007
- Medicines Control Council (MCC), South Africa – 2007 and 2003
- World Health Organisation (WHO) – Bioanalytical Laboratory – 2005
- United States Food and Drug Administration (FDA) – Bioanalytical Laboratory – 2004
- Medicines and Health Care Products Regulatory Agency (MHRA), UK – 2004 (voluntary inspection)
- Brazilian Health Authorities (ANVISA) – 2003
- South African National Accreditation System (SANAS) – Bioanalytical Laboratory – 2001
- Agence Française de Sécurité Sanitaire des Produits de Sante (AFSSAPS) – 2000 and 1997

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Strategic Locations

North America

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