

# Clinical Pharmacology

PAREXEL International



## George South Africa

### Introduction

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

The George Unit has more than 10 years experience conducting Phase I-III studies. The Unit is highly specialized with a dedicated Phase I facility with 55 beds. There is also an additional 15 beds within well appointed accommodation offering flexibility to accommodate long term efficacy studies and other complex study designs. Access to a dedicated psychiatric ward within a local private hospital provides the opportunity of conducting studies for patients with psychiatric disorders within a well controlled, specialized environment. The size of the facility is 28,384ft<sup>2</sup> (2,637m<sup>2</sup>).

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## 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** – The location provides unique access to large populations of diverse volunteer groups within the immediate community. The Unit's volunteer database holds a particularly large pool of young and elderly healthy volunteers alongside high numbers of patients with a wide variety of disease types.

**Highly Trained Experienced Staff** – Proactive training initiatives, including compulsory professional development (CPD) training programs, focus on developing clinical and supporting talents, ensuring that staff offer opinion leadership based on cutting edge knowledge combined with depth in industry experience.

**Expertise** – The Unit's primary focus is on Phase I and II studies utilizing extensive direct experience in the conduct of Phase I-III studies. The Unit has a close cooperation with medical experts within PAREXEL Clinical Pharmacology and therapeutic experts across local hospital networks/academic centers bringing together a highly experienced and dynamic team to facilitate successful solutions for even the most challenging study program.

**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.

## 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. The George Unit can accommodate studies with large numbers of subjects for rapid clinical completion.

**Respiratory Research Studies** – Facilities include a dedicated respiratory research laboratory, equipped with body plethysmography equipment which allows a range of respiratory capabilities. The George 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



- 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.

**Proof in Concept** – The George Unit has an excellent reputation for coordinating and managing multi-center Proof of Concept studies, gaining recognition from clients for frequently completing studies well ahead of schedule.

### **Experience with Complex Studies/Specialized Techniques**

The Unit has access to a dedicated psychiatric ward within a local private hospital. This, along with access to psychiatric patient populations, allows the Unit to provide highly specialized services for up to 20 patients with psychiatric disorders.

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 complex studies including First in Man studies.

### **In-house Pharmaceutical Services**

The Unit has the staff, expertise and storage facilities (including a temperature controlled pharmacy) to manage investigational supplies, dispensing and distribution in accordance with GMP and full compliance with directives.

### **Strategic Patient Recruitment**

The George Unit philosophy is to facilitate interdisciplinary cooperation. In practice, this involves strong relationships with numerous credible research centres and investigators across South Africa and overseas. George benefits from a superb healthcare infrastructure, offering many opportunities for collaborative research, fully supported by provincial and private hospitals. This results in high compliance of trial activities, high retention, high quality and reliable source data.

The Unit provides sponsorship to local community clinics for patient training initiatives to empower patients in adapting their lifestyles to prevent/manage disease.

PAREXEL Clinical Pharmacology in South Africa has built strong relationships with General Practitioners and specialists, who have also been provided with thorough GCP training.

## PAREXEL Clinical Pharmacology

### Strategic Locations

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