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CLINICAL RESEARCH UNIT

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The Clinical Research (CRU) Unit has been facilitating Phase 2 and 3 clinical drug trials at the University of Pretoria for over 15 years, with Steve Biko Academic Hospital, within the following fields of treatment:

- Dermatology
- Diabetes
- Gastroenterology
- Gynaecology
- Haematology
- Hypercholesterolemia
- Nephrology
- Neurology
- Oncology
- Ophthalmology
- Orthopaedics
- Rheumatology
- Surgery
- Urology
- Vaccines

Given the extensive experience of its staff additional fields of treatment can be accommodated as well as the ad hoc facilitation of Phase 1 trials. CRU conducts these trials within a multidisciplinary experienced team.

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1 The site and facilities:

- Studies facilitated at the Prinshof Campus, Steve Biko Hospital and Kalafong Hospital
- Consulting rooms and a twelve-bed patient ward
- Electrocardiograms (ECGs) and intravenous drug administration
- High recruitment figures, up-to-date data entries and adherence to quality standards
- Fully equipped emergency trolley, defibrillator, suction unit, oxygen and infusion pumps
- Phlebotomy and specimen processing
- Secure, temperature-controlled pharmacy facility
- Storage facilities, including a freezer (-20˚ Celsius) and fridges (2–8˚Celsius)

2 Experienced and Knowledgeable staff:

- Onsite Doctor
- Experienced study coordinators, dispensing physicians and investigators
- All staff have GCP, IATA and BLS training

3 Services offered include:

- A dedicated Clinical Trial Manager to facilitate initial engagement with a Sponsor:
  - Review of a feasibility in collaboration with an identified Principal Investigator
  - Contract and budget negotiation with Sponsor
- Co-ordination of start-up activities:
  - Coordinates all start-up activities, including Ethics Committee approvals, contracts and pre-screening
  - Ensures readiness to screen patients within two weeks after receiving regulatory approval
- Patient recruitment:
  - Database available
  - Access to and recruitment from various primary care clinics
  - A tertiary hospital – Steve Biko Academic Hospital
  - Two district hospitals – Kalafong and Tshwane Hospitals
- Operational and financial support:
  - Capturing of data by in-house data capturers on Sponsor's online platform
  - Capturing and reviewing of data by in-house data capturers on the CRU's Clinical Trial System thereby ensuring effective management of all records in order to facilitate accurate invoicing on all studies
  - Provision of financial statements for each clinical trial administered
  - Administration of funds in accordance with the University of Pretoria's Financial Model
  - Management of debtors
  - Management of payments/remuneration to all

Meet the team

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