

# Clinical Pharmacology

PAREXEL International



## Baltimore

United States

### Introduction

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

The Baltimore Unit is highly specialized and hospital-based with 90 beds. The Baltimore Unit benefits from quick, convenient access to all hospital services including emergency response and treatment facilities, clinical laboratory services (with rapid results reporting), comprehensive subspecialty consultation, radiology services (including MRI and PET imaging), registered dietitians and dietary services. The size of the facility is 33,116 ft<sup>2</sup> (3,077m<sup>2</sup>).

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**PAREXEL**<sup>®</sup>

*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.

**Recruitment Excellence** – The Unit can provide rapid recruitment solutions for several healthy volunteer populations and access to patient populations through a network of seven local area hospitals.

**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.

**Highly Trained Experienced Staff** – Many of the Unit’s clinical team have extensive experience with a critical care background. The Physicians typically have advanced cardiac life support certification. Most of the Project Management staff and Clinical Research Coordinators, have Certified Clinical Research Coordinator Certifications, or are actively pursuing certification.

**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.

**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.

The Baltimore Unit can provide flexibility in working with sponsor-selected ECG core labs as well as the preferred providers of ECG core lab services, Medifacts International and eResearch Technology. A validated electronic transfer process, reducing study timelines and cost can be provided.

In addition to thorough QTc studies, this integrated approach contributes to the development of the right clinical protocol, study design and data analysis plan and facilitates the execution of definitive Phase I trials and First in Man studies that fully comply with new ICH/FDA/EU cardiac safety requirements.

**Central Nervous System (CNS) Studies** – The Baltimore Unit has a unique collaboration with a local, university based Positron Emission Tomography (PET) Neuroimaging center with an on-site cyclotron facility and expert Radiochemists to facilitate synthesis of Radioligands and the development of Novel Radioligands. This collaboration provides access to the full service clinical trial expertise of the Unit, as well as the PET Neuroimaging and Radiochemistry expertise found at a world-renowned academic PET center.

The collaborative PET neuroreceptor imaging model has the following potential applications in CNS drug development:



- Rational drug dose optimization (Receptor occupancy)
- Characterization of the biodistribution of drug bound to radiolabels (11C and 18F)
- Confirmation of therapeutic Proof of Concept for drug candidates
- Investigation of pathophysiologic mechanisms of action

**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 Baltimore site has significant pulmonary expertise which includes:

- Access to special patient populations: The database includes a high number of asthmatic and allergic rhinitis patients
- Computerized Spirometry
- Bronchial Provocation testing
- Impulse Oscillometry
- Exhaled Nitric Oxide measurement experience
- Exhaled Breath Condensate capture experience
- All inhaled delivery systems



### Experience with Complex Studies/ Specialized Techniques

The Unit has extensive experience of conducting First in Man studies including working with Recombinant vaccines, DNA therapeutic vaccines and monoclonal antibodies.

Unique study specific assays have been developed in collaboration with a local research laboratory for cost-effective and reliable examination of CD4 and CD8 lymphocyte responses.

The Unit is experienced in performing flow-cytometry studies of white cell activation markers.

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

Studies involving esophageal and gastric pH monitoring can be conducted by the Baltimore Unit.

The Baltimore Unit's state-of-the-art facilities alongside the experience of the team facilitates a number of possibilities for early phase development including:

- Japanese/Asian bridging studies (Available from Fall 2008)
- Neurological studies including cognitive function testing, EEG and nerve conduction studies
- Specialized PK/PD and biomarker studies
- Laser Doppler Perfusion Imaging

### Strategic Healthy Volunteer and Patient Recruitment

The Baltimore Unit benefits from a large pool of available local volunteers. The healthy volunteer populations include Postmenopausal women, elderly volunteers and CYP2D6 genotyped volunteers.

Patient populations are also readily available and include the following patient populations:

- Asthma / Allergic Rhinitis
- Coronary Artery Disease / Hypertensive
- Diabetics Type I And II / Obese / Hyperlipidemics
- Gastrointestinal - Gastro Esophageal Reflux Disease, Irritable Bowel Disease
- Hepatitis C
- Oncology

## PAREXEL Clinical Pharmacology

### Strategic Locations

#### North America

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