

## Capabilities Listing

### Contract Research

#### Organization

117 Campus Drive  
University Square  
Princeton, NJ 08540 USA  
Ph +1 609 818 1800  
Fax +1 609 818 0026

### Clinical Study Management & Monitoring

North American and International Clinical Trials  
Project Management  
Site Selection  
Proprietary Web-Based Study Tracking  
Contract Implementation  
Budget Negotiation  
Phase I-IV Study Monitoring  
Essential Documents Management

### Clinical Data Management

Screen and Database Design  
Double Key Data Entry  
Data Query Resolution  
Data Management Plan  
Validation / Edit Checks  
Case Report Form Design

### Clinical Information Systems

Database Set-up & Validation (SAS, Oracle Clinical)  
Dataset Merging, Legacy Data Integration

### Pharmacokinetics

PK, PD Analysis  
Report Preparation

### Biostatistics

Statistical Analysis Plan Preparation  
Statistical Analyses  
Statistical Report Preparation  
Power and Sample Size Calculation

### Medical Writing

Study Protocol Preparation  
Investigator Brochure Preparation  
Clinical Study Report Preparation

### Regulatory Affairs & Compliance

ANDA / NDA Submission  
Initial, Periodic, Annual IND Submissions  
Electronic CTD Submissions  
FDA Meeting Organization, Execution, Liaison  
Gap Analysis / Audits  
Regulatory / Clinical Development Plan Strategy

### Pharmacovigilance

SAE Tracking  
SAE Submission  
SAE/AE Coding (WHODrug, MedDRA)  
SAE Narratives

### Quality Assurance

Study Document Audits  
Study Site Audits  
Facilities and SOP Audits  
SOP Review and Preparation

### Phase I-II Clinical Research Center

241 Main Street  
Hackensack, NJ 17601 USA  
Ph +1 201 678 0288  
Fax +1 201 678 0349

### Clinical Research

#### Center Overview

72 Bed Facility  
12th Year of Excellence  
Experienced Medical / Research Staff  
Ethnically Diverse Population  
Special Populations  
Convenient to Major Medical Centers  
FDA Inspected  
-20, -70 °C Freezers (alarmed, recorded)  
Cold Centrifuges  
Registered Dietician  
ECG Telemetry  
24 Hour Security  
Controlled Access  
Digital ECG  
Holter Monitoring  
Pharmacy (alarmed, double-locked)

#### Clinical Research Center Services

Informed Consent (ICF) Preparation  
Source Document Preparation  
Case Report Form Preparation  
IRB (Ethics Committee) Submissions  
Paper or Electronic CRF Completion

A D V A N C E D



### Studies Conducted

Special Populations  
First in Human Trials (FIHT)  
Proof of Concept  
BA - Bioavailability  
BE - Bioequivalence (Absolute and Relative)  
PK/PD  
Definitive / Thorough QTc Evaluations  
Dose Formulation  
Dose Safety/Escalation  
Fed-Fasted  
Drug-Drug  
Drug-Alcohol

### Pharmacy

Drug Receipt and Storage  
Drug Compounding  
Drug Administration  
Drug Supply Reconciliation & Disposition  
Drug Retention Sample Storage

### Other Services through Collaborations

PK Drug Method Development & Assay  
Tests and Biomarker Assay  
Central Clinical Laboratory Services

### Training

SOP training  
GCP training



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