CRBI
Catalyzing Innovation

CLINICAL RESEARCH AND BIOSCIENCES

Overview

CRBio is an independent Contractual Research Organization based in Hyderabad (INDIA).

The state-of-the-art facility spreads across 30,000 square-foot, providing services for Clinical research, Regulated bioanalysis, Bio-statistics, Quality control and Data management.

We offer end-to-end services in a broad range of clinical research activities such as BA/BE studies, Patient based PK end point studies & Phase studies .

Regulatory Approvals

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Regulatory Experience

Experience in conducting wide range of more than 400 studies across a spectrum of major regulatory markets.

- US Studies Conducted > 50
- EU Studies Conducted >100
- UK MHRA Studies Conducted > 20
- AUS Studies Conducted > 20
- Canada Studies Conducted > 15
- WHO Studies Conducted > 10

Clinical Infrastructure

- >8000 Volunteer database (~5% females)
- 5 Flexible and Independent clinics comprising a total of 114 beds
- Capacity to conduct 15 studies / month
- Two fully functional ICUs – (3+3) beds
- Access and environment controlled pharmacy
- 21 CFR Part 11 compliant Eurotherm for temperature monitoring (-30^{o}C) deep freezers
- Provision for cardiac ambulance in addition to the stand-by ambulance for all studies

Clinical Capabilities and Strengths

Expertise in executing different types of studies:

- ❑ Crossover
- ❑ Parallel
- ❑ Partial Replicate/Full Replicate
- ❑ Steady State
- ❑ Endpoint
- ❑ Safety and Tolerability
- ❑ Patient-based studies
- ❑ Hormonal Studies (Post menopausal)
- ❑ Phase trials

- The total number of Studies executed at CRBio are >400
- Experience in handling first-to-file molecules
- First CRO to prepare an unconventional study design for Highly Variable Drugs accepted by regulatory authorities
- Strategy to minimize the extrinsic/intrinsic factors that may impact study outcome (Eg; Extra housing, diet standardization etc.)

Experience with various dosage forms

- Immediate Release
- Modified Release
- Biphasic Release
- Effervescent Tablet
- Dispersible Tablets
- Mouth Dissolving Films
- Suspension
- Nutraceutical (Measurement of glycemic and insulinemic index as clinical endpoints)

Clinical Study Management

- Stringent Inclusion and Exclusion Criteria applied during volunteer selection based on category of the drug.
  E.g., BMI range, RBC count & haemoglobin etc.

- Audit-trail enabled biometric software to control cross-participation of volunteers

- IVIVC software to reduce the chances of failure

- Specialist doctors and medical experts are contracted during critical studies for management of adverse events (E.g., High dose combination drug studies).

Therapeutic Areas Handled

Antidepressant	Anticancer	Anti Platelet	Antidiabetic
Antimalarial	Antiepileptic	Anti-hyperlipidemic	Antidiuretic
Antispasmodic	NSAID	Antihypertensive	CNS Agent
Antifungal	GI drugs	Antibiotic	Skeletal Muscle Relaxant
Antiulcer	Antihistaminic	Antipsychotic	Asthama
Antiretroviral	Erectile dysfunction	Premature Ejaculation	Irritable bowel syndrome
Overactive bladder	Benign Prostate Hyperplasia	Hypnotic	Allergic rhinitis & Urticaria

Bioanalytical Capabilities and Strengths

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- >140 Validated methods
- Single analyte and simultaneous methods
- Method for combination drugs
- Chiral analysis and analysis involving derivatization
- Selective and sensitive methods with LLOQ upto 5 pg/ml
- Tricky molecules (5 metabolites)
- Total drug estimation (conjugated and unconjugated)
- As a commitment to quality, we proactively re-validate old methods as per current regulatory guidelines

Bioanalytical Capabilities and Strengths

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Infrastructure

- 7 LC-MS/MS (5 Thermo Ultra and Discovery Max + 2 Triple Quad API-4000)
- 7 Deep Freezers (-86^{o}C) connected to Eurotherm for online temperature monitoring.

Medical Writing, Biostatistics and IT

Medical Writing

- Protocol, ICF & CRF
- Integrated CSR (ICH E3), CTD and eCTD preparation

Biostatistics

Pharmacokinetic analysis is performed using Phoenix WinNonLin 6.3,

Statistical analysis by SAS 9.4 and IVIVC software

- In Vitro- In Vivo Correlation for drug development
- Sample size calculation
- Randomization

Information Technology

- 3 server for domain control and LCMS data backup, synchronizing every 30 minutes
- Data backup is stored onsite and offsite

Quality Management

- Independent QA team reporting to the Managing director
- QA will implement and maintain procedures in compliance with GCP/GLP & other local regulatory requirements
- QA is responsible to conduct Audits
  - Study based audits (In-process & Retrospective)
  - System & Facility audit
  - Vendor audits
- Oversee the In-house and external training of the employees
- Co-ordinate sponsor/ regulatory audits
- Archival management
- Each department has an internal QC for implementation of procedures

Project Management

- Dedicated team to give individual customer focus
- Project manager is assigned to every project to direct, control the flow of activity and adjust schedules to provide customized solutions to suit individual client requirements
- Streamlined procedure for client management, focused approach to ensure timelines are delivered as per commitment
- All project related updates are communicated with sponsor on timely basis

Marquee Customers

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Marquee Customers

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Apicore

Auden Mckenzie
Group

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BRISTOL LABORATORIES Ltd.

Xepa sp

WOCKHARDT

RPG
RPG LIFE SCIENCE LIMITED

torrent
Torrent Pharmaceuticals Limited

MICRO LABS
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THANK YOU

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