ECRON ACUNOVA

STUDIES AUDITED BY
WHO & US FDA

Bioavailability And Bioequivalence
(PK/PD) Services

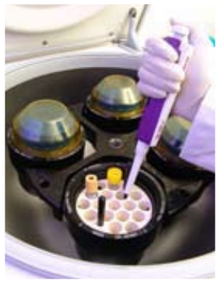
ECRON ACUNOVA is a CRO promoted by Manipal Group and AcuNova Life Sciences, bringing together the benefits of India and Europe. We are a full service expert CRO providing high quality data fast at competitive prices with a personalised service. We provide pharma, biotech, device and diagnostic companies with early development services using healthy volunteers and patients.

CLINICAL RESEARCH CENTRES (CRCs)

Bioavailability/Bioequivalence studies and intensive PK/PD studies are conducted in CRCs at the following speciality hospital campuses in India

1. *Shirdi Saibaba Cancer Hospital*, Manipal with 36 beds and a separate 6-bed phase I ward to conduct 'first-in-man' studies.
2. *Kasturba Medical College Hospital*, Mangalore with 48 beds designed to conduct mixed gender studies.
3. *Vydehi Institute of Medical Sciences Hospital*, Bangalore with 60 beds.

We can also organise phase I studies to be conducted by an ECRON ACUNOVA partner CRO in France.



CLINICAL PHARMACOLOGY UNIT (CPU)

Our Clinical Pharmacology Units are centrally air-conditioned facilities having a dedicated area for screening, counselling, phlebotomy, access-controlled pharmacy, recreation & dining room with state-of-the-art monitoring. The CPUs have intensive care unit (ICU) beds with defibrillators, ventilators, cardiac monitors, oxygen supply, a crash cart and all emergency medicines. The CPUs are housed as a separate unit inside the multi-speciality hospitals. Fully equipped ICU and physicians at the hospitals provide back-up to handle serious emergencies.

CLINICAL TESTING LABORATORY

The screening facility is well-equipped for physical and medical examinations to comply with study inclusion and exclusion criteria. Screening samples are tested at our ISO-certified Clinical Testing Laboratories accredited by the *College of American Pathologists*.

BIO ANALYTICAL LABORATORY

The bio analytical lab has state-of-the-art LCMS/MS, HPLC, and a library of validated methods. New methods can be developed and validated in 4 weeks.

BIOMETRICS

Our services include data management, bio statistics, PK analysis and medical writing of study reports. Reports can be generated in eCTD format.

STUDY TEAM

Our team is experienced and well-trained in ICH GCP and GLP guidelines. The team includes physicians, phlebotomists, scientists, statisticians and programmers well-conversant with regulatory guidelines.

VOLUNTEERS

We have a database of over 4,500 volunteers including female volunteers and special populations. We have access to patient populations with cancer, asthma, diabetes, and CNS disorders.

STUDIES OFFERED

- Dosage forms - tablets, capsules, suspension
- Immediate and modified release formulations
- Inhalation devices, topical emulsion, sprays
- Transdermal patches
- Light-sensitive compounds
- Food effect studies, apple sauce studies
- Multiple dose steady state studies
- Double-blind, multiple arm design
- Dose escalation studies
- Repeat 'first-in-man' studies
- Clinical end point studies
- Proof of concept and exploratory studies

REGULATORY SUBMISSION

- US FDA
- Health Canada
- EMEA
- MHRA
- WHO
- DCGI and others

By NABL
F. NO. A15169
F. NO. A15170
ISO 9001:2000
ISO 27001:2005
ISO 15189
MANIPAL ACUNOVA LTD

Studies conducted by us have been audited and approved by US FDA and WHO.

SERVICES

Regulatory including 505 (b) 2 consulting
IP import and sample export
Protocol design
Ethics committee submission
Volunteer and patient recruitment
Clinical study management
Method development and validation
Bio analytical testing
PK analysis using WinNonlin
Statistical analysis using SAS
Data management using Oracle Clinical
Report writing
Sample storage and archiving

WE ARE GUIDED BY

Vision
Become Global Benchmark of Excellence in CRO Services Enhancing Life

Mission
As an Expert CRO Deliver High Quality Data Faster, at Competitive Cost with Personalised Service

Values
Integrity, Quality, Caring, Speed

Quality Policy
We Strive to Meet and Exceed Quality Expectations on the Basis of International Best Practices

QUALITY BENCH MARK

First CRO with ISO 9001:2000 and ISO 27001certification for information security by *Underwriter's Laboratory*
Central lab for volunteer testing is ISO 15189-certified and accredited by the *College of American Pathologists (CAP)*
Independent ethics committee constituted as per ICMR and OHRP guidelines
Services audited by leading sponsors from Europe, Asia, and the Americas as well as independent auditors of high repute
Studies audited by US FDA and WHO and found GCP- and GLP-compliant.

KEY DIFFERENTIATORS

- Studies conducted with the highest standards of safety in compliance with international guidelines
- Early slotting of study with volunteer bank and method library
- Breadth of expertise in patient PK/PD studies, in bio similars and in early development studies
- Qualified by reputable sponsors from the UK, USA, Switzerland, Finland, Canada and India
- Personalised service to sponsor
- US FDA and WHO-audited

AWARDS

- Awarded as "India's No. 1 Emerging CRO" by *Proximare Inc.*
- Named as "The Partner of Choice for the conduct of BA/BE studies in India" by *Frost & Sullivan*

Choose ECRON ACUNOVA for an accurate, high quality study, carried out safely, as per committed schedule, ready for regulatory submission – on time, every time.

Clinical Research Centers on Manipal University Campus, *Manipal, India*

Asian Research Center, *Bangalore, India*

European Research Center, *Frankfurt, Germany*

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