Bioavailability and Bioequivalence services (PK/PD)

Studies audited by WHO & USFDA multiple times.

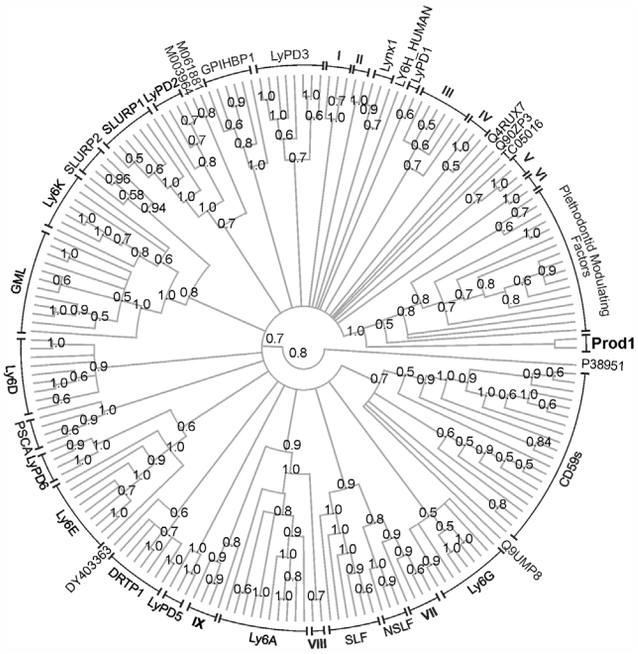
100+ marketing approvals in six continents

ECRON ACUNOVA is a CRO set up 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 serve global majors in the Pharma, Biotech and Nutrition industry from US, Canada, Europe & Asia.

ECRON ACUNOVA

Services

Our end-to-end service in Bioavailability and Bioequivalence services (PK/PD) comprises regulatory consulting, IP import and sample export, protocol design, ethics committee submissions, safety screening and bio analytical testing. We have proven expertise in clinical study management, method development and validation, data management with Oracle Clinical, PK analysis using Phoenix WinNonlin, statistical analysis using SAS and CDISC compliant reports in eCTD formats.



Wide Range Of Studies (Different Dosage Forms And Study Types)

- Tablet, Capsule, Suspension, ODT (Orally Disintegrating Tablets)
- Inhalation, Topical emulsion, Spray
- Sublingual, Dermal patch
- Apple sauce, ice cream fed
- Immediate and modified release formulations
- Light-sensitive compounds
- Multiple Dose steady state studies
- Single and Double blind studies & Reference scaling design
- Anti-diabetic with Glucose solution Capable to work with Light Sensitive IPs
- Dose escalation studies
- PK/PD end point studies in Healthy volunteers and Patient population
- Repeat 'first-in-man' studies
- Proof of concept and exploratory studies, Bridging and Drug interaction studies
- Nutritional studies
- Anti-hypertensive & Anti-epileptic
- Post-menopausal women study
- Mixed gender studies
- Drug-Drug Interaction studies
- Study with a cardio toxic molecule
- PK studies with intense sampling for every 5 minutes
- Injection study
- First-in-man studies in Singapore

Clinical Research Centres (CRCs)

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

1. Manipal Acunova KH Clinical Research Center (MAKHCRC) located in Cancer Hospital, Manipal with 32 beds.

Database of 10,500+ volunteers.

'First in country' to be accredited by Association for Accreditation of Human Research Protection Program (AAHRPP Inc.).

2. Manipal Acunova K M C Clinical Pharmacology Unit located in Medical College Hospital, Mangalore with 80 beds designed to conduct mixed gender studies (2 concurrent studies).
3. We have access to additional clinics in France, Jordan, China, Thailand and India to meet client needs of marketing.

Clinics are audited by DCGI and international regulators and are self-identified with US FDA as per GDUFA. Clinic design allows mixed gender studies as well as light sensitive molecules.

Equipped with an advanced ICU to handle emergencies, clinics are centrally air-conditioned, access-controlled with dedicated areas for screening, counseling, housing, phlebotomy, pharmacy and recreation & dining rooms. The ICU beds are equipped with defibrillators, ventilators, cardiac monitors, oxygen supply, crash cart and required emergency medicine. Fully equipped ICU and physicians at the hospitals provide back-up to handle serious emergencies.

Our clinics are designed to meet highest standards of volunteer safety and comply with DCGI specifications.

Institutional Ethics Committee

All studies are approved prior to conduct by Manipal University Ethics Committee which is registered with office of Human Research Protection, US Dept. of Health & Human Services and DCGI. It has the distinction of being 'first in country' to be accredited by Association for Accreditation of Human Research Protection Program (AAHRPP Inc.).

Study Team And Volunteer Access

Team has many years of experience in conducting studies and consists of MDs in clinic and Pharmacy PhDs in lab.

We have a database of over 10,500 volunteers including female post-menopausal women and geriatric volunteers. Located in super-specialty hospitals, we have access to oncology, psychiatry, dermatology, diabetics and renal impaired patients.

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 and NABL located in Manipal.

PD endpoint studies (like Enoxaparin, Levothyroxine and Liothyronine BE studies etc.) can be taken up at Central Lab, Bangalore which is also ISO-certified Clinical Testing Laboratories accredited by the College of American Pathologists & NABL with platforms like Flow Cytometry, Automated blood coagulation analyzer etc.

Bio Analytical Laboratory

We have state of the art GLP and 21 CFR part 11 compliant Bioanalytical labs located in Manipal and Bangalore.

New methods can be developed and validated in 4 weeks.

Bioanalytical Lab, Manipal is equipped with 06 LC-MS/MS (03 Thermo Discovery Max + 02 Thermo Ultra + 01 Waters Xevo TQ-S) including UPLC.

Bioanalytical Lab, Bangalore is equipped with ICP-MS (Agilent 7700x) and LC-MS/MS (Thermo Ultra) in Class 10000 clean air lab facility for preparation, handling and analysis of low level trace elements in biological matrices.
Our Analytical experts are reputed for quick turnaround and have developed hundreds of methods (include many challenging methods) in different matrices (like blood, plasma, urine, skin and bone).

PK, Stat & eReports

Our services include data management, bio statistics, PK analysis and medical writing of study reports.

Our PK expert's opinion is often sought by formulators to make improvements.

Reports can be generated in eCTD format.

Regulatory Submissions Compliance And Quality Assurance

We have an independent QA department ensuring study compliance to current guidelines with SOP's, training and audits.

Periodic certification to ISO 9001, ISO 27001, ISO 15189, 21 CFR part 11 provides further assurance.

Based on GCP and GLP compliant BABE studies conducted at EA, marketing authorization has been given by US FDA, Health Canada, EMA, MHRA, TGA, MCC, Thai FDA, DCGI and WHO.

New methods can be developed in 4 weeks.

Our PK expert's opinion is often sought by formulators to make improvements.

Key Differentiators

Quality study, on time, at competitive cost, with personalized service, has earned us long customer loyalty.

We help bring your products to market *faster*.

ECRON ACUNOVA

GLOBAL RESEARCH CENTRE
Manipal Acunova Limited
Mobius Towers, SJR i-Park,
EPIP, Whitefield, Bangalore 560066
T: +91 80 66915700

NEW JERSEY / AMERICA
AcuNova LifeSciences Inc.
502 Carnegie Centre, Suite 100,
Princeton, NJ 08540 USA
T: +1 973 396 2742

FRANKFURT / EUROPE
Ecron AcuNova
Hahnstrasse 70,
60528 Frankfurt, Germany
T: +49 69 6680300

SINGAPORE/ASIA
Ecron AcuNova
420, North Bridge Road
03-38, North Bridge Centre
Singapore 188727
T: +65 6338 9355

www.ecronacunova.com