ECRON ACUNOVA

FORM MIRRORS FUNCTION

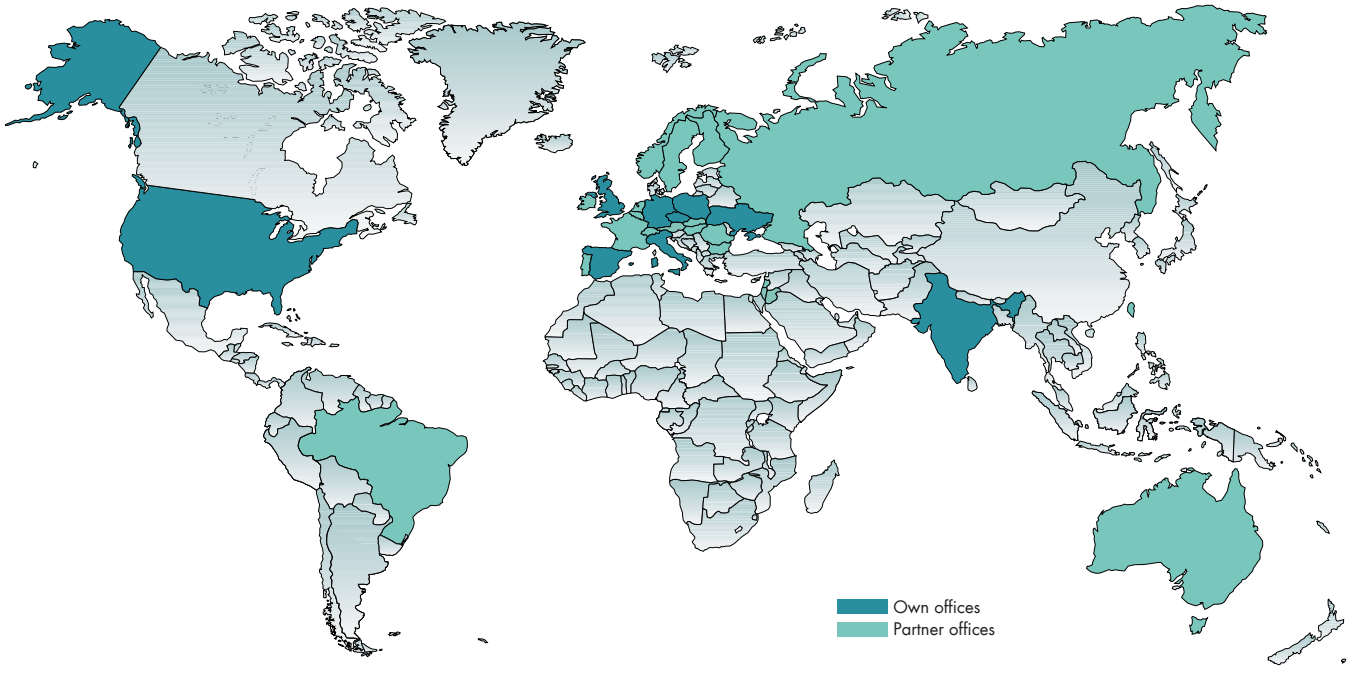
We Shape Our Services
According To Your Needs

FULL SERVICE CRO

With More Than Two Decades
Of Track Record

ECRON ACUNOVA

Passionate client focus, wide-ranging therapeutic expertise and a broad geographical spread have enabled us to grow continuously, building a basis of highly satisfied clients who have benefited from our full range of clinical development services for more than 20 years.



During the recent years we have conducted a number of clinical studies in:

Allergology	Gynaecology	Peripheral arterial diseases
Cardiovascular diseases	Metabolic disorders	Psychiatry
Clinical immunology/infectiology	Nephrology	Pulmonology
Dermatology	Neurology	Rheumatology
Diagnostic imaging	Nutrition	Urology
Endocrinology	Oncology	Surgery
ENT	(incl. Haemato-Oncology)	Women's health
Gastroenterology	Ophthalmology	

About ECRON ACUNOVA

ECRON ACUNOVA provides end-to-end services for phase I-IV clinical research, including clinical trial operations & management, clinical data management, PK/PD services and central laboratory. ECRON ACUNOVA has research facilities in Europe, India and the USA with headquarters in Frankfurt, Bangalore and Princeton.
As regional experts, we treat each region as a priority market.

ECRON ACUNOVA creates value

- Through its commitment to delivering high quality on time within budget and with personalised services through a proficient combination of capabilities and resources.
- Through its deep regional competence based on more than two decades of experience in clinical research with an established presence in various geographical areas.

Why choose ECRON ACUNOVA as your preferred provider?

Long company history
Expertise in conducting phase I-IV clinical trials for pharma, biotech and medical device sponsors.

Geographical presence and patient access
Our direct presence within new geographical locations such as India and East Europe provides access to large diverse patient pools that match the demographics of relevant indications and facilitate outstanding recruitment. Within India alone we have preferred access to 19 teaching hospitals at Manipal University - Asia's largest academic medical centre where more than 1,500 physicians treat 1,5 million patients each year. This privileged site access results in the additional service of SMO support in order to improve the research productivity of investigators. Excellent patient access and speedy recruitment usually lead to beneficial budget effects.

Sophisticated study endpoints
We have experience in conducting studies with imaging and biomarker end points. Our well-equipped central laboratory has molecular diagnostic capabilities to provide pharmaco-genomic insight.

Regulatory credibility and quality standards
High credibility established with European, US and Indian regulators, namely FDA, EMEA, BfArM, DCGI and PEI, amongst others. In addition to the above authorities a number of sponsors have audited our studies with no major observations, and the investigational products concerned have received marketing approval. Our service delivery is characterised by the highest international quality standards. Our operations are ISO-compliant; our research sites are ICH GCP-compliant; our data management is 21CFR Part 11-compliant and central labs are CAP and ISO-certified.

Staff
265 full-time professionals, of which 47 are MDs and PhDs, provide personalised and flexible services. Our cultural diversity and capabilities enhance the benefits to clients.

Each of the above items on its own would probably be sufficient to justify a decision in favour of ECRON ACUNOVA. However, the entire spectrum represents even more than the sum of its parts.

Vision, Mission, Values and Quality Policy

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 Personalized Service

Values
Integrity, Quality, Caring, Speed

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

Quality and expertise

Quality
Quality is built into service by having an optimal infrastructure, deploying industry standard systems and processes and employing people with domain knowledge and a quality mindset.

ECRON ACUNOVA's operations are conducted at the highest standard. Our own phase I and BA/BE facilities with 144 beds, including a fully-equipped 6-bed intensive care unit, are located in specialised hospitals with excellent additional emergency management facilities. All our volunteer and patient facilities are environmentally friendly and comply with international specifications. Ambient conditions are maintained through monitoring devices and alert tools. Biometric controlled access guarantees data privacy and confidentiality.

The industry standard technology platforms, systems, hardware and software in use are validated through IQ, OQ and PQ. Processes are managed on the basis of standard operating procedures (SOPs). Common SOPs are used across geographic locations. Compatibility between our central laboratory unit in Bangalore and our partner laboratory based in Germany has been established.

Our own clinical operation teams and those of our partners are very experienced in their domain and are subject to periodic ICH GCP examination and certification procedures.

Quality validation is based on independent audits performed by certifying bodies of the highest credibility. Whenever requested by our clients, we subject our work to inspection by independent auditors. This policy has guaranteed that no significant regulatory observations have been identified to date.

Expertise

Regulatory expertise

a) Obtaining approval to conduct studies in countries within individual regions, import clinical trial supplies and export samples.
b) Providing up-to-date knowledge for submission.
c) Defending submission. Our experts are invited to serve on industry and regulatory advisory panels, bringing credibility to the submission.

Therapeutic expertise

Therapeutic experts in oncology, cardiology and neurology work full-time to provide insights into epidemiological disease data, standards of diagnosis and care and area-specific specialities. Their relationship with site physicians is often invaluable. Pharmacologists in our team support us with their knowledge and capabilities in bioequivalence, pharmacokinetics and pharmacodynamics, and drug delivery systems.

Biostatistical expertise

Our biostatisticians, who have extensive experience in NCEs, NBEs and generics, work to provide guidance on optimal trial design, definition of appropriate efficacy and safety endpoints, study hypothesis, statistical model and appropriate sample size. Our data management is concentrated at Frankfurt and Bangalore.

Educational expertise

We collaborate with University Capacity Building Programmes which are used to train CRAs, CDM personnel, PK/PD experts and regulatory specialists. This talent pipeline helps us expand our capacity. We offer continuing educational opportunities, including enrolment onto PhD programmes, which helps retain our talent. We have already retained entire project teams on several multi-year projects.

Risk identification & proactive management are key values we bring to each study.

Services overview

Regulatory

Our regulatory consultant group is experienced in the development of positioning strategies, integrated planning, management and submission of study related documents to regulatory authorities and ethics committees.

Regulatory experts of ECRON ACUNOVA foster effective and diplomatic liaisons with regulatory bodies in a wide variety of indications; they are at your service to represent and support you in meetings with regulatory authorities.

PK/PD studies

Equipped with an advanced infrastructure, we conduct PK/PD studies with healthy volunteers in three clinical units with 150 beds located in specialised hospitals. Volunteer screening tests are carried out in our CAP-certified laboratory. A library of validated methods is available. A sophisticated analytical laboratory analyses the samples in a wide range of matrices on a bank of HPLC, LCMS/MS. Pivotal studies have been conducted for submission to Health Canada, EU, DCGI, MHRA, US FDA and WHO. Studies have been audited by regulators including US FDA and WHO.

First-in-man studies

A 6-bed intensive care unit is available to conduct first-in-man, dose escalation and drug interaction studies.

Proof-of-concept and early phase studies

Our in-house therapeutic specialists conduct PK/PD studies in special populations and patients. Experience in biomarker and imaging-triggered studies enables us to perform state-of-the-art proof of concept studies.

Many sponsors to whom we demonstrated the quality of our proof-of-concept capabilities also engaged us to manage their early phase II projects.

Rescue studies

ECRON ACUNOVA has taken over responsibility for a considerable number of projects which had been initiated by other CROs elsewhere but did not meet client expectations. We offer:

- Immediate set-up of rescue model
- Intensive measures adequately chosen to push your project
- Large investigator pool to speed up recruitment
- Competent contact with investigators
- Relocation of trial to countries with known high recruitment rates

Phase II to IV studies

We have extensive experience in conducting multi-national phase II, III and IV studies. We are currently engaged in conducting over 80 such trials.

Peri-approval studies

ECRON ACUNOVA shapes PAS studies to the needs of late stage research and performs national/multinational large scale studies with appropriate design.

Clinical trial supply management

To overcome the logistic and supply chain hurdles to get investigational products to study sites, we offer in-house services relating to import, customs clearance, storage, supply to site and randomisation. We oversee drug accountability and arrange the return or destruction of samples at the end of the study.

Clinical operations

Our CRAs attend in-house education courses and are kept up-to-date with the latest literature on current and upcoming developments in the industry. CRA supervisors perform site-by-site visits with CRAs. They discuss site-specific findings and provide guidelines on what and how to follow-up consistently.
ECRON ACUNOVA performs annual ICH GCP exams to ensure the highest working standards. Project teams are trained for each study in advance with regard to the study's medical background, study goals, prevention of pitfalls and study plan.

Project management

Outsourcing project management to ECRON ACUNOVA means your project will be managed by a highly dedicated interdisciplinary team steered by one project expert who is the key person for client contacts and issues throughout the project. We have an outstanding track record of continuity in our project management teams, which in turn significantly facilitates communication with the sponsor's study team.

Central laboratory testing service

We offer a CAP-certified central testing laboratory service to support clinical trials. Test design, report design, kit design, kit supply to study sites, site set-up, briefing at investigator meetings, project management, site feedback, laboratory data integration to trial data base and sample archiving are all part of our end-to-end service. ECRON ACUNOVA's central laboratory at Bangalore is fully compatible with a partner central laboratory based in Germany. We can provide harmonised services in Europe and Asia. Our laboratory has molecular diagnostic capabilities which include biomarker validation.

Clinical data management

ECRON ACUNOVA provides state-of-the-art data management for clinical studies with respect to both procedures and equipment. Our services range from traditional paper-based workflow to modern remote data capture and are fully compliant with 21 CFR part 11. Detailed SOPs describe contents and responsibilities as well as procedures and quality measures for all tasks. We use OPA 4.5 (Oracle Pharmaceutical Applications), encompassing Oracle Clinical 4.5, TMS 4.5 (Thesaurus Management System), and RDC (Remote Data Capture). Electronic CRF as well as paper CRF can be designed and derived directly within the system allowing conventional study conduct, purely electronic data management as well as hybrid solutions. The newest SAS version (Statistical Analysis System) is used for data export from Oracle Clinical to the statistical analysis and to the sponsor.

Biostatistics

ECRON ACUNOVA provides continuous biometric advice during the study covering: study planning, sample size calculation, randomisation procedures, analysis plan, interim analysis, blinded review committee, definition of analysis sets, statistical analysis using SAS™ and statistical reports.

Medical writing

Our medical writers are involved in the study through every stage to ensure a comprehensive understanding of the project. The final data will be presented in paper copy as well as password-protected electronic files.

Pharmacovigilance

Our team consists of dedicated, skilled, and experienced physicians, life science professionals, and other experienced clinical professionals in drug safety. Our services encompass safety management, regulatory reporting, post-marketing surveillance as well as technical support.

This snapshot of our expertise, which is backed by the valuation of our services by global regulators and sponsors, is indicative of our commitment to global quality. Accreditation majors and research houses like Frost & Sullivan and Proximare have recognised our contribution to the growth of the industry and have ranked us amongst the leading emerging CROs in India; we also received the Frost & Sullivan Award 2007 as BA/BE Partner of Choice.

We look forward to being a valuable partner to you in this knowledge-based industry.
Please feel free to contact us using the coordinates below.
We would be delighted to provide you with our expertise and services.

Asian Research Center, *Bangalore, India*

European Research Center, *Frankfurt, Germany*

Americas

ACUNOVA LIFE SCIENCES Inc
502 Carnegie Center, # 100
Princeton NJ, 08540

USA
T: +1 973 396 2742
F: +1 212 918 7903
E: bd.americas@ecronacunova.com

Asia

MANIPAL ACUNOVA Ltd
Mobius, SJR i – Park, Whitefield
Bangalore – 560066

India
T: +91 80 66915700
F: +91 80 66915719
E: bd.asia@ecronacunova.com

Europe

ECRON ACUNOVA GmbH
Hahnstrasse 70
60528 Frankfurt

Germany
T: +49 69 66 80 300
F: +49 69 66 80 30 29
E: bd.europe@ecronacunova.com

www.ecronacunova.com

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