ECRON ACUNOVA

STUDIES AUDITED BY
WHO & US FDA

Clinical Data Management
Biostatistics
Medical & Scientific Writing
Medical Affairs

Our Departments

We at ECRON ACUNOVA provide comprehensive clinical data management, statistical programming, bio-statistical and medical writing services for early clinical development and late phase clinical development programmes. This includes managing data for pharmacovigilance, PK/PD services as well as radiology and cardiology services.

Integrated in a full-service Contract Research Organisation, we are supported by allied competencies in clinical research, medicine, pharmacology, central lab, quality assurance and regulatory affairs. Our service centres are located in Frankfurt, Germany, and in Bangalore, India's bio-cluster and silicon capital. Our goal is to support your clinical development program by delivering consistent, accurate, reliable and meaningful results in full compliance with the regulatory guidelines.

PROCESSES AND QUALITY

In our processes we emphasize close communication with the sponsor at all stages of a project. This ensures we meet our sponsors' needs and concerns. The processes are designed to minimise operative time, in particular at the final stage of a trial.

From project initiation to completion, our Standard Operating Procedures (SOPs) and guidance documents assure global consistency and medical accuracy. The entire team is trained in GCP, GCDMP, CSV and regulatory guidelines. A state-of-the-art technology platform, scalable to each client's requirements, is deployed in structured network architecture, hosting world class applications and qualified as per CSV life cycle and SOPs compliant to 21 CFR Part 11 and GxP standards. We use Oracle Clinical or work remotely on our sponsors' platforms. Our trial data process maintains security and confidentiality, is ISO 27001:2005 compliant and protects data and patient privacy. Our studies and processes have been audited by US FDA and WHO regulators and found compliant.

EXPERIENCE

Our expertise covers a broad range of therapeutic areas, data management technologies, statistical methodologies and various types of regulatory documents. Our team is drawn from leading pharmaceutical companies across the world and brings extensive global experience to every assignment.

We understand the entire drug discovery and development process, and therefore choose the right blend of resources for medical affairs, data management, programming, biostatistics, medical writing and project management.

Our Service Offerings

CONSULTING AND PROJECT MANAGEMENT

- Clinical development plan and study design
- Project monitoring and management
- Drug safety management
- Pharmacoepidemiology
- Product scientific advice for regulatory meetings

LABORATORY DATA MANAGEMENT

- Sample analytics for lab data
- Device interface with LIMS and automated result transfer
- Electronic data transfer in HL7, ASCII, CSV formats
- Lab and clinical data integration on any standard LIMS and CDMS

CODING AND DICTIONARY MANAGEMENT

- MedDRA and WHO-DD coding
- Dictionary updates and maintenance
- Standard coding software (Thesaurus management system TMS)

CLINICAL DATA MANAGEMENT

- Database design and study set-up
- CRF design, data entry and validation
- Electronic data capture
- Query generation and discrepancy management
- Non-CRF data handling
- Use of CDISC standards

BIOSTATISTICS

- Statistical planning and sample size calculation
- Statistical analysis plan
- Statistical programming and analysis
- SAS datasets according to sponsor's specification
- Integration of databases
- Electronic data transfer
- Statistical reports and summaries
- Meta-analysis

REPORTS AND QUALITY CONTROL

- Standardised and customised reports
- Data quality assurance and audits

PHARMACOVIGILANCE

- Periodic safety update reports
- Safety reports
- CIOMS on web
- Literature review and medical narratives
- Signal detection and trend analysis
- Medical monitoring

MEDICAL WRITING AND REGULATORY SUBMISSION

- Protocol preparation
- Integrated report writing (ICH E3) and electronic submissions
- Data review for specialised therapy areas by clinicians
- Sponsor-specific formats for reporting
- Safety summaries and narrative writing
- Scientific publications and presentations

Key Advantages Of Partnering With Us

- More than 20 years of study experience in new drugs, devices, diagnostics, biologicals, vaccines, biosimilars, neutraceuticals and generics
- CRO services with university backing
- Access to globally scarce talent in branches of medicine
- Experience in working on sponsors' IT platforms
- Leverage India competitiveness for global delivery of pharma R&D services

Our Commitment

Our clearly defined process guidelines emphasize the importance of information flow and communication. We help maximise client investment through the most effective use of human resources and skills, technology and processes.

Our global delivery model offers exceptional quality, project management and visibility that are essential for success on complex global projects. Other approaches allow adopting sponsor's processes and specifications. Based on our long-term experience, we provide integrated solution of various service components, accessing a global network of resources, technologies, facilities and processes to efficiently, consistently and rapidly address your unique needs.

We wish to partner you to provide a wide range of high quality clinical research-related services according to the ethical, scientific and regulatory standards of today.

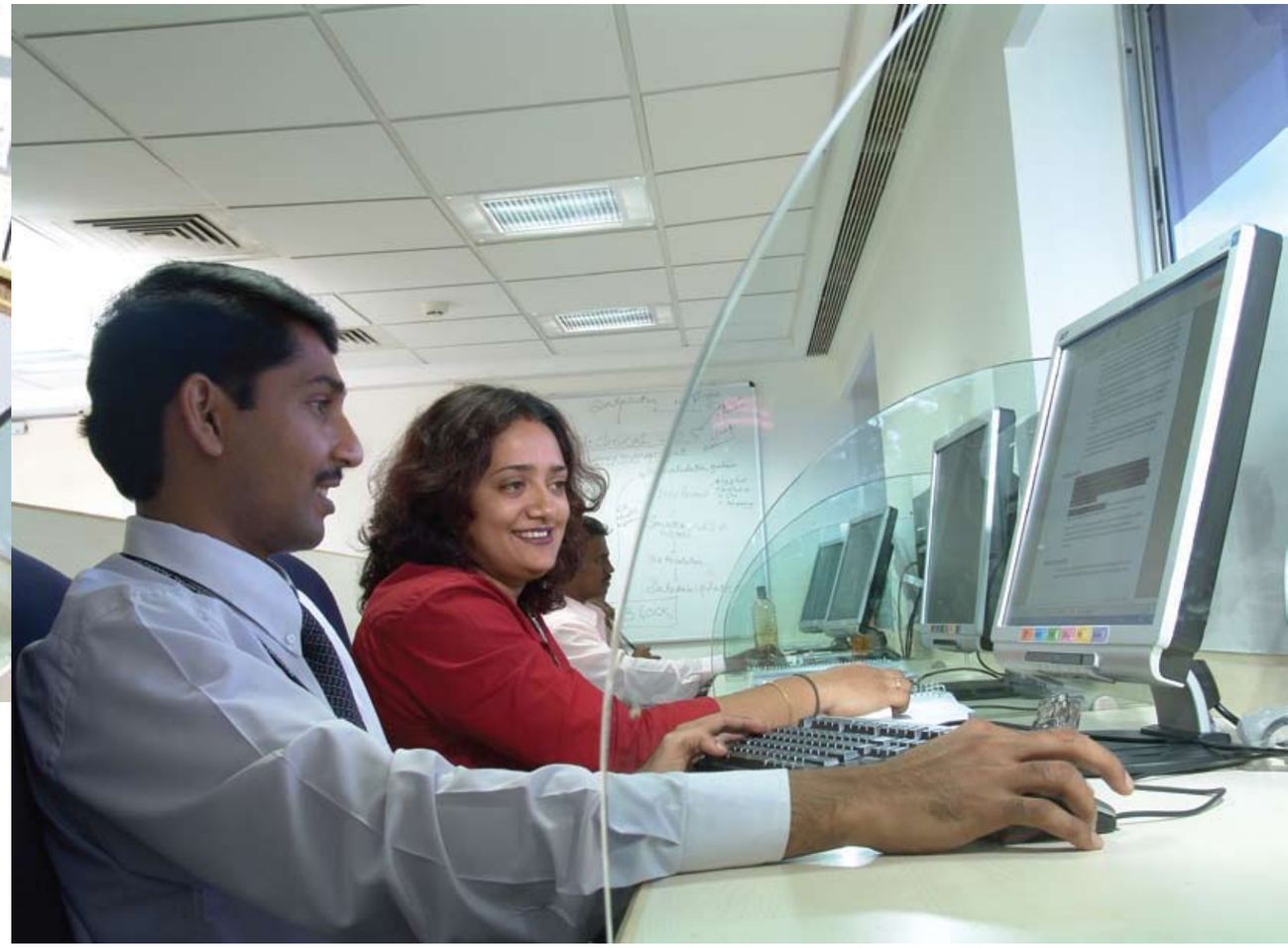
WE ARE GUIDED BY

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



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 service, carried out diligently, as per committed schedule, ready for regulatory submission - on time, every time.

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