Clinres NOVA

Who we are

World of clinical research changes every minute. We move with it.

C-Nova is a contract research and consulting organization with legal seat in Zagreb, Croatia that provides clinical and regulatory expertise to the pharmaceutical and biotechnology industries.

Depending on your needs, we can manage all aspects of your clinical programs and regulatory submissions or offer different professional support and cooperation with your own staff. C-Nova has extensive experience in all phases of pharmaceutical product development, from phase I through IV. We are maintaining our own corporate Standard Operating Procedures (SOPs) which govern all critical operations, and are compliant with all regulations set by ICH, EMEA and FDA.

Our experience

Our customers include pharmaceutical, biotech, device companies and contract research. Our recent customers include Acraf S.p.A., Alkaloid a.d., Amway Corp., AstraZeneca, Boehringer Ingelheim, Bosnalijek d.d., CSC Pharmaceuticals Handels GmbH., Cyathus Exquirere Pharmaforschungs GmbH, Eli Lilly, Hemofarm a.d., Icon Clinical Research, Imunološki zavod d.d., Jadran Galenski Laboratorij, Jaka 80 a.d., Lek d.d., Lundbeck, Medical School - University of Zagreb, MindGuard Ltd., Pfizer, RoziStep d.o.o., Sanofi-Aventis Group, Scholl and Zak- Pharma Dienstleistung Ges.m.b.H.

C-Nova has expertise in a range of highly specialized clinical studies and regulatory services, including:

- Clinical study management
- Regulatory services
- Pharmacovigilance
- Reimbursement and promotion strategies
- Data management
- Biostatistics
- Medical writing
- GCP compliance and education
- Study salvage and rescue

Your CRO in Southeastern Europe

We are assisting you to expedite your development program, while reducing the costs.

Our professional staff and consultants have expertise acquired across a wide range of therapeutic areas and medical specialties. Whether you intend to outsource your entire project or want an objective third party to help set up your program, we customize our services to meet your needs.

We are specialized for South-Eastern Europe markets and are offering our services in Croatia, Slovenia, Romania, Bulgaria, Macedonia, Serbia and Montenegro.

Our network of experienced CRAs, trained by our clinical and regulatory professionals, have a broad range of therapeutic expertise, enabling them to ensure compliance with ICH, FDA and EMEA standards as well as IRB/EC requirements.

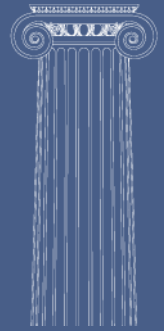
Our CRAs are predominantly MDs, having over 3 years of monitoring experience. In therapeutic areas of neurology, psychiatry, internal medicine and pediatrics, we are able to provide you with MDs having specialty in those areas.

We maintain an extensive database of study sites organized by therapeutic areas, enabling us to rapidly identify prospective sites for your trial.

Study Management

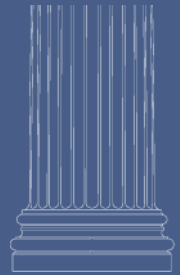
We have the expertise in bringing medical information, media and patients together to understand the advantages of your product.

Project management and administration
Monitoring plan and procedures development
Essential study regulatory documentation maintenance
Study monitoring and site management
Adverse event tracking and follow-up
Site recruitment and qualification
Site evaluation
Site initiation and training
Investigators meetings
Central lab and reading facility interface available
Patient recruitment
Study close-out activities
On-site support and Help-desk for EDC
Organizing and managing multi-site clinical trials through contractual relationships with site owners in selected therapeutic areas
Accelerated start-up studies in “special population groups”
Centralized enrolment and randomization



Regulatory Services

C-Nova has a special and unique insight into the workings, procedures, and requirements of the responsible regulatory bodies, that comes from years of experience working for and with those bodies.



C-Nova provides regulatory submission services and local regulatory compliance consulting for the pharmaceutical, biotechnology and medical device industries. More than 10 years of experience determines our understanding of regulatory challenges facing healthcare providers and industry today. Our regulatory affairs group is composed of individuals with extensive experience and has the knowledge and skills required to advise and manage all regulatory aspects of your development program. As regulatory requirements become more rigorous, we work closely with you and the local regulatory authorities to prepare successful regulatory strategies and submissions.

Our regulatory team is comprised of regulatory professionals with many years of experience either working for or with the regulatory authorities.

Our Croatian regulatory service is designed to provide up-to-date guidance on local regulatory requirements for pharmaceutical products and medical devices. The expertise covers human and veterinary medicines, medical devices, in vitro diagnostics, herbal products and foods, cosmetics and toiletries.

C-Nova handled regulatory submissions and offers submission services for:

- Marketing authorizations (applicant/MAH)
- Clinical trials authorizations
- Reimbursement authorization

We offer variety of ways in accelerating appearance of your product in Croatian market and customized regulatory solutions:

- We can work with you to prepare your regulatory submission
- We could provide you with tactical guidelines for you to develop your own submission
- We could temporary provide you with our consultants (ad hoc regulatory consultancy)

Statistics & Writing

Our team of statisticians, professional medical writers and IT personnel can plan and execute even the most complicated tasks in statistical analysis and assist in publishing of your results.

Biostatistics

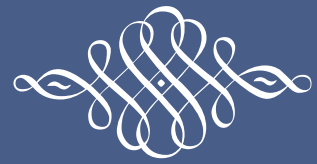
Sample size estimations
Randomization schedules
Statistical analysis plan development
Statistical programming
Statistical and study report writing
Statistical consulting
Meta-analyses

Medical Writing

Clinical study design and study protocol development for phase I-IV studies
Investigators Brochure development
Case Report Form design, printing and distribution
Clinical study report production, ICH E3 compliant
Interim reports
Pre-clinical and clinical summaries and overviews
Literature reviews
Manuscript and journal article development
SAE reporting
SmPC and PIL preparation
Graphics and visuals
Poster and presentation design

Data Management

We provide the complete range of data management services, with emphasis on Phase IV studies.



Data management plan development

Database development and validation

Electronic and conventional (paper) CRF development

Conventional (paper) CRF logging and tracking

Data acquisition in paper, electronic and optical character recognition scanning forms

Data entry and independent verification

Accuracy and logic data checks

Accelerated query management

SAE reconciliation

Medical coding of adverse events (MedDRA, WHO-ART, COSTART) and of concomitant medications (WHODRUG and BNF)

Incorporating third party databases (central lab, readings)

Data quality assurance

ECD system 21 CFR 11 compliant already available in partnering cooperation

PHARMACOVIGILANCE

We provide a comprehensive plan to help you manage your pre- and post-marketed product safety program.

Safety and continuous surveillance of adverse and serious adverse events has gradually become one of the most essential responsibilities for pharmaceutical companies. The regulatory requirements have become increasingly complex in recent years and specialist knowledge is needed to fulfill the stringent obligations. This is why our pharmacovigilance staff includes clinical professionals, pharmacists and MDs with various areas of expertise. This team of experts provides our clients with the full support and flexibility they need to meet their obligations for adverse event reporting.

Our services include:

- Risk Management Plans
- Pharmacovigilance Plans
- Routine safety surveillance
- Safety strategy, procedures and systems
- Review of new safety issues
- Preparation or review of periodic safety update reports (PSURs)
- Annual Reports, End of Study Reports
- Representation to regulatory authorities
- Review of risk-benefit
- Audit of company, department or site practices and procedures
- Training on pharmacovigilance

GCP Compliance and Education

We could assist you with our consultants experienced in inspections or investigators who successfully passed inspections, to prepare for FDA, EMEA or local inspections of your study sites.

Study staff training program
Monitor training services to clients
Training materials production
Site audits
Site set-up and training for Electronic Data Capture (EDC)
GCP tutorials
Clinical SOP development
Assistance with FDA and EMEA inspections
Readability testing/Bridging
Translation services
QRD reformatting

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