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

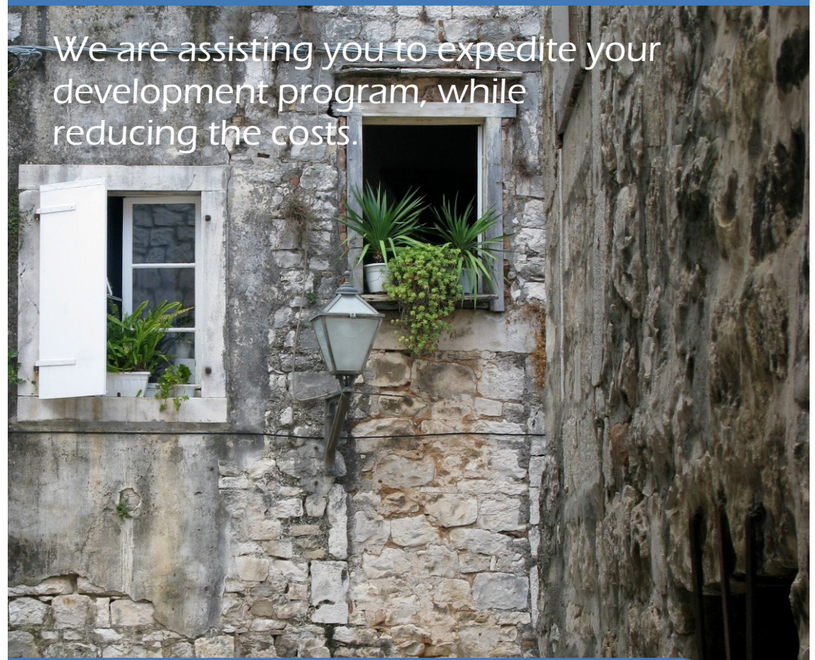
Our customers include pharmaceutical, biotech, device companies and contract research organizations.

Our recent clients 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, reimbursement and promotion strategies, data managementn, biostatistics, medical writing, GCP compliance and education and study salvage and rescue.

Your CRO in SE 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, and IRB/EC requirements. Our CRAs are predominantly MDs, having over 3 years of monitoring experience.

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

Clinres NOVA

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