OCT is a full-service CRO providing comprehensive product development services for pharmaceutical, biotechnology and medical device companies. OCT clinical operations department is a critical component in all clinical studies. OCT highly skilled staff is well-versed in implementing, monitoring and managing clinical trials. From study start-up to close-out, experienced CRAs oversee study clinical processes to ensure proper planning, conduct, patient safety, and data quality, while maintaining good communication between study sites and sponsor.

**Clinical Trial Monitoring**

OCT provides the best team of clinical research associates in the industry. Our CRAs are MDs and have an average of 5 years experience with significant strengths in oncology, endocrinology, cardiology in addition to many other therapeutic areas.

Plus, CRAs are located regionally throughout Russia, CIS and CEE to facilitate travel cost containment measures. Their main responsibilities in clinical trials are to:

- Protect the rights, safety and well-being of clinical trial subjects
- Oversee the progress of the clinical trial
- Support speedy recruitment
- Ensure protocol compliance
- Apply SOPs, GCP and applicable regulatory requirements
- Ensure accurateness and reliability of clinical data
- Help increase acceptance of clinical data by the regulatory authorities

OCT provides the following services:

- Close out visits
- Training of investigators and site teams (e.g. GCP, safety reporting, IMP handling)
- Ethics committee and regulatory authority submissions
- Investigator Site File compilation and review
- Translation of study-specific documents including quality check
- GCP monitoring
- Site management, including telephone monitoring and proactive issue handling
- Study logistics support
- Support for site audits and inspections
- Preparation of investigator meetings
- Project management, including risk management
- Intensive training sessions during investigator meetings (e.g. GCP, safety reporting, IMP handling)
- Providing status of individual investigational site performance
- Providing working instructions
- Newsletters on trial progress or trial-specific topics (e.g. protocol compliance and how to archive it, GCP or most common misunderstandings of the CRF)

OCT CRAs are office-based. OCT performs clinical trials monitoring in Russia, Ukraine, Belarus, Latvia, Lithuania, Estonia and Bulgaria.