

## Uniquely matched services for pharmaceutical, biotechnology and medical devices industries

**DOKUMEDS** is a business solutions and quality driven CRO providing a comprehensive range of services for clinical research and development. During almost 20 years of operations, DOKUMEDS services have been provided to more than 80 clients worldwide. More than 150 clinical trials had been performed under responsibility of DOKUMEDS covering wide range of therapeutic areas. Focus on customer needs and result-oriented approach to business operations are DOKUMEDS core values allowing reaching the ratio of repeated business over 80%.



**4Pharma** is a CRO providing state-of-art biostatistics and data management services. 4Pharma has provided data management and/or statistics services to more than 80 clients worldwide for more than 200 clinical phase I-IV trials and accumulated vast expertise in multiple therapeutic areas. 4Pharma's highly experienced people have played a key role in several successful regulatory submissions (FDA, EMA and PMDA). 4Pharma's clients are from small biotech companies to global pharmaceutical companies, with almost 90% repeated business ratio.

## Comprehensive service package for phase I-IV and post-marketing observational studies

**Clinical services:** feasibility studies; international project management; study site management; medical monitoring and medical review; subject recruitment; study contract and payment management.

### Medical and scientific consultation

**Regulatory services:** clinical trials applications; regulatory submissions; marketing authorization applications; authorization maintenance and support; post-approval license maintenance.

**Pharmacovigilance services:** responsible person for EudraVigilance; on-going monitoring and evaluation of safety profile; periodic reports; training.

**Non-interventional studies:** full scope services from protocol to final report.

**Study design, CRF and source data form design**

**Warehouse & logistics services in Russia:** customs clearance; IMP and study supplies storage and, distribution.

**Medical writing and translations:** protocol, informed consent and other study documents; study report.

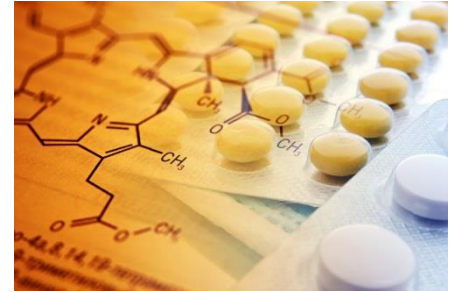
**Data management and medical coding:** both paper-based and electronic data capture processes; CDISC data standards; risk-based data monitoring; data migration.

**Biostatistics:** planning; sample size; statistical analysis; data visualization, reporting and documentation; bioinformatics and training.

**Data warehousing:** CDISC data standards, data integration, meta-data, signals & trends

**Information technology:** risk calculators, IWRS, study portals.

## Highly complementary services – the mutual benefit for service providers and customer's



Combined services of 4Pharma and DOKUMEDS are highly complementary and seamlessly benefit our clients and their products

Secured, easy-to-use communication and information sharing between clinical study team and client is available through the extranet solution

OECD GLP, ICH GCP and 21 CFR Part 11 compliant processes and systems

Vast experience in clinical research services, wide regulatory experience

# 4PHARMA

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**DOKUMEDS**  
CLINICAL RESEARCH ORGANIZATION

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