



**Your Partner  
for Clinical Research  
in Eastern and Central Europe**

- ✓ **Full Service CRO**
- ✓ **Clinical Services (Phase II - IV)**
- ✓ **International Project Management**
- ✓ **Contract and Finance Management**
- ✓ **Regulatory Services**
- ✓ **Data Management and Biostatistics**
- ✓ **Non-interventional Studies**

**DokumedS has provided services to more than 30 clients worldwide  
More than 80% of repeated business**

DokumedS - established in 1995, providing a comprehensive range of services for drug development to the pharmaceutical industry.

**Head office:**

LATVIA: Riga

**Offices:**

ESTONIA: Tallinn

LITHUANIA: Vilnius

POLAND: Warsaw

RUSSIA: Moscow

UKRAINE: Kiev

**Warehouse:**

RUSSIA: Moscow



As member of AcrossAlliance DokumedS is ISO 9001 : 2000 certified in International Project Management

DokumedS has established excellent and long-lasting relations with national Competent Authorities, national opinion leaders and investigators

The extensive national “know-how” and experience in International Project Management ensures DokumedS to handle easily the country specific procedures and comply with the national and international requirements to assure successful conduct of clinical trials

**Staff**

Physicians, pharmacists, biologists, statisticians, economists, philologists, lawyers and IT specialists. Master all Baltic languages, as well as English, Polish, Russian and Ukrainian

DokumedS personnel have particular expertise in managing and monitoring all aspects of Phase II – IV clinical trials, including regulatory submissions and medical / regulatory consultancy  
Trained in GCP, international and country specific regulations, as well as DokumedS / Sponsor SOPs

# Scope of Services:

## **Clinical Services (Phase II - IV)**

Feasibility Studies / International Project Management / Study Site Management  
Clinical Monitoring / Medical Monitoring / Medical Review  
Pharmacovigilance / Protocol Development / Study Drug and Study Material Logistics  
Contract and Finance Management

## **Regulatory Services**

Regulatory Submissions of Clinical Trials / Regulatory Consultancy  
Marketing Authorization Applications

## **Non-interventional Studies**

## **Data Management and Biostatistics**

Protocol Review and CRF Development / Database Design and Setup / Planning of Study Data Management Activities / Data Entry / Discrepancy Management / Interim Analysis and Status Reporting / Medical Coding / Database Lock / Final Analysis and Reporting

## **Quality Management**

## **Other Services**

GCP trainings for Investigators / Medical and Clinical Research Translations (Estonian, Latvian, Lithuanian, Polish, Russian, Ukrainian)

## **Advantages working with Dokumeds**

High flexibility

Local expertise, management and engagement

Effective qualification and close monitoring of investigational sites

Long term collaboration with national key opinion leaders

Web - based CT documentation management and tracking system

ISO 9001: 2000 certified in International Project Management

Collaboration with regional vendors experienced in clinical trials

Effective trial contract and finance management based on professional knowledge of country specific legislation

# Therapeutic Areas of Expertise

## Cardiovascular Diseases

- Congestive Heart Failure
- Arterial Hypertension
- Coronary Heart Disease
- Thrombosis Treatment and Prevention
- Atrial Fibrillation

## Pediatrics

- Appendicitis
- GERD
- Rheumatology

## Ophthalmology

- Glaucoma

## Hematology

- Hemophilia
- Leukemia

## Oncology

- Renal Cell Carcioma
- Breast Cancer

## Pain

- Cholelithiasis
- Urolithiasis/UTI
- Postoperative pain
- Posttherpetic neuralgia

## Transplantology

## Traumatology

## Urology

- Overactive Bladder

## Gynecology

- Hormonal Replacement Therapy

## Musculoskeletal Diseases

- Rheumatoid arthritis
- Osteoporosis

## Pulmonology

- Asthma
- Hospital-acquired Pneumonia

## Vaccines

## Infections

- Skin infections
- Tuberculosis

## Endocrinology

- Diabetes Mellitus
- Diabetic Foot

## Psychiatry

- Schizophrenia
- Depression

## Neurology

- Stroke

## Contact details

### CRO Dokumeds headquarters

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### Director Business Development

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