IPHARMAUNION

# Clinical trial local operator

Oncology and hematology
Russia & EAEU

## Local operator for clinical trials in oncology and hematology in Russia & EAEU

We execute local clinical trial operations on behalf of international sponsors, coordinating feasibility, site activation, patient recruitment, monitoring and documentation.

“We act as a local clinical trial operator, ensuring full execution and coordination of all key processes across Russia and EAEU on behalf of the sponsor.”

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# Oncology and Hematology: High Complexity



Fast evolution of therapies: immuno-oncology, targeted and cell-based treatments

Strict requirements for data quality and patient safety

Timely and reliable patient recruitment is critical

Execution takes place in a complex regulatory and operational environment

**Delayed execution and recruitment directly affect study timelines and outcomes.**

# Why Russia & EAEU Matter



Access to large patient populations in oncology and hematology

Network of federal and regional specialized centers

Recruitment potential including rare diseases

Structured regulatory pathway within the EAEU framework

**Access to this potential requires strong local operational execution.**

# Who We Are

Local operator for clinical trials

Oncology and hematology focus

Direct working relationships with clinical centers

Hands-on experience across federal and regional institutions

More than 6 years of practical experience in clinical and regulatory projects

**Our value is not advisory only — it is execution on the ground.**

# Scope of Responsibility



Regulatory submission to the Ministry of Health

Site selection and activation

Patient recruitment coordination

Study monitoring and management

Full documentation control

**We act as a single point of local responsibility on behalf of the sponsor.**

# How We Work



Feasibility assessment

Site selection and activation

Regulatory submission

Patient recruitment

Monitoring

Documentation

**Outcome: a controlled and executable clinical project.**

# From Clinical Trials to Registration



Regulatory strategy development

Preparation of the registration dossier

Interaction with regulatory authorities

Transition from clinical data to market authorization

**We help turn clinical data into a coherent registration pathway.**

# Specialized Logistics



Temperature-controlled logistics for sensitive products

+2…+8°C, –78.5°C and –196°C conditions

Continuous monitoring with data loggers

Critical for biologics and cell therapies

**Reliable cold-chain handling protects product integrity and study continuity.**

# Why Partners Choose Us



Established network of oncology and hematology centers

Deep understanding of local regulatory requirements

Hands-on execution model, not consulting only

Focus on data quality and patient safety

Transparent communication with the sponsor

**We help reduce operational risks and increase predictability of local execution.**

# Next Step

Start with a feasibility assessment of your study

Evaluate site availability, recruitment potential and regulatory pathway

Discuss whether Russia & EAEU are the right fit for your program

**Contact us to review your protocol and study objectives.**