

### Location Data

Kazakhstan is the second largest country between all of the former Soviet Union republics with its population of 20,8 million people. The country has a large and very diverse population, with a sufficient number of trained workers in Healthcare industry.

- Ethnically diverse treatment-naïve patient population
- Most of the population is concentrated in a few major cities, where healthcare centers are usually well-equipped medical facilities
- Motivated patient population seeking quality care
- Moderate investigator fees
- Low number of studies per patient



Kazakhstan, along with Russia, Belarus, Armenia, and Kyrgyzstan, is a member of Eurasian Economic Union (EAEU). The EAEU agreement on unified principles and rules for circulation of drugs and medical devices came into force on February 12, 2016. This agreement facilitated clinical trial conduct in these countries and enhances transparency for partners.

A key opportunity for pharmaceutical companies and CROs is the option of unified electronic drug registration within the EAEU.

This allows clinical trials conducted in one member state to be used for marketing authorization applications in other participating countries through a simplified procedure.

For clients looking to initiate new studies and avoid potential challenges in the Russian Federation, Kazakhstan offers a cost-effective alternative location. SRG was the first CRO to establish itself in Kazakhstan and has 18 years' experience in delivering high quality clinical trials.

In previous editions of the Orange Paper, we used data from clinicaltrials.gov which includes data on interventional and observational trials, mostly sponsored by local medical universities and scientific societies.

Starting this year, we will also add data on clinical trials published by the National Center for Drugs and Medical Devices Expertise of the Republic of Kazakhstan, the national regulatory authority responsible for maintaining a registry of clinical trials for drugs and medical devices.



Clinical trials in Kazakhstan in 2024, according to

# National Center for Drugs and Medical Devices Expertise

### O Trial Data

According to the National Center for Drugs and Medical Devices Expertise of the Republic of Kazakhstan,
10 clinical trials were initiated in Kazakhstan during 2024.
One of these was a bioequivalence (BE) study.

BE studies is the relatively new field for Kazakhstan that is gaining momentum, driven by the country's ambitions to strengthen its pharmaceutical sector, enhance healthcare accessibility, and align with global regulatory standards. The most prevalent Phase of clinical trials conducted in Kazakhstani sites by total number of studies were Phase III studies with a 60% share (6 studies), followed by Phase II (2 studies) and Phase I (1 study).

The therapeutic areas of interventional clinical trials (excluding BE) initiated in Kazakhstan during 2024 include Cardiology and Gastroenterology (2 studies each), as well as Gynecology, Hematology, Oncology, Ophthalmology, and Rheumatology (1 study each).

### Sponsor Data

According to the National Center for Drugs and Medical Devices Expertise, clinical trials initiated in Kazakhstan during the Year 2024 were sponsored by pharmaceutical companies from Kazakhstan (3 studies) and four foreign countries: Russia (3 studies), United States (2 studies), Germany and Switzerland (1 study each).

#### **Domestic Trial Sponsors in Kazakhstan in the Year 2024**

	Combined market share	30%
2	Viva Pharm	1
1	Industrial Microbiology LLP	2
No	Site Name	No. Studies

#### International Trial Sponsors in Kazakhstan in the Year 2024

Nº	Site Name	No. Studies
1	Biocad	1
2	Boehringer	1
3	CTI Biopharma	1
4	F.Hoffmann-La Roche	1
5	Generium	1
6	Morphic Therapeutic	1
7	Polisan	1

**70%** 

Combined market share of these companies

#### **CRO Data**

#### CROs in Kazakhstan in the Year 2024 (all studies)

No	Company Name	No. Studies
7	PSI	2
2	Synergy Research Group	1
3	Combined share	30%



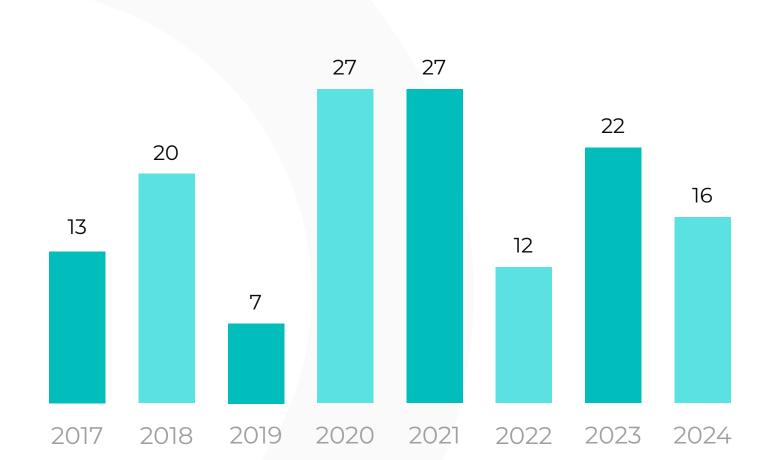
## clinicaltrials.gov

### O Trial Data

According to data from clinicaltrials.gov, during the Year 2024 there were 16 clinical trials initiated in Kazakhstan including local studies. That represents a 27% decrease rate in comparison with the previous year when 22 studies were initiated. Most clinical trials conducted in Kazakhstan in the Year 2024 were interventional studies with a 63% market share.

Among interventional studies, the dominant type of intervention was drug (4 studies), followed by drug supplement (2), procedure, biological and other (1 study each) intervention types.

#### Clinical Trials in Kazakhstan (Y 2017 - Y 2024)



### Sponsor Data

According to data from clinicaltrials.gov, most of clinical trials initiated in Kazakhstan during the Year 2024 were sponsored by Kazakhstani sponsors with an 88% market share. Russia and United States were the only international sponsors, each initiating one study.

Combined market share based on total studies conducted by both sponsors and CROs, and by both international and Kazakhstani sponsors.

#### International Trial Sponsors in Kazakhstan in the Year 2024

No	Site Name	No. Studies	No. Subjects
1	Morphic Therapeutic, Inc	1	210
2	St. Petersburg State Pavlov Medical University	1	83
	Combined market share of these companies	13%	10%

#### Kazakhstani Trial Sponsors in Kazakhstan in the Year 2024

No	Site Name	No. Studies	No. Subjects
1	Nazarbayev University	2	474
2	Asfendiyarov Kazakh National Medical University	1	600
3	Kazakhstan's Medical University "KSPH"	1	400
4	MIPO Clinic	1	200
5	Karaganda Medical University	1	193
6	Kazakhstan Scientific Society for Study of Intestine Diseases	1	169
7	The Society of Bariatric and Metabolic Surgeons of Kazakhstan	1	150
8	National Research Oncology and Transplantology Center, Kazakhstan	1	120
9	National Centre for Neurosurgery, Republic of Kazakhstan	1	102
10	National Research Center for Cardiac Surgery, Kazakhstan	1	50
	Combined market share of these companies	<b>69</b> %	10%

# Subject Data

According to data from clinicaltrials.gov, the overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Kazakhstan during 2024 reached a total of 2,847 subjects – a collapse in comparison with the previous year when 21,958 subjects were planned to be enrolled. Most subjects were enrolled in interventional studies (55%).

# O Regulatory & Inpection Data

According to the U.S. FDA data, there were no FDA inspections conducted in Kazakhstani investigative sites during the Year 2024

#### About Synergy Research Group

Synergy Research Group is a contract research organization successfully operating in Russia since 2002 and Kazakhstan since 2007.

and for final study data.

ers We continuously work on improving our SOPs, study

For all clinical studies conducted by our company we maintain world-class quality standards for both SOPs and for final study data.

Our company consistently ranks among the market leaders in terms of conducted clinical studies and enrolled patients.

risk management, and IT infrastructure, replacing outdated R&D strategies with novel, more efficient approaches to clinical research.

The high recruitment rates in emerging markets, combined with innovative technology, allow Synergy to offer faster, more cost-effective studies without compromising quality for our clients.

All of the data within this document are actual on date: February 27, 2025.

