Clinical Trials in Kazakhstan

Y 2025 Research report

Overview of Kazakhstan

Kazakhstan is the second largest country among all the former Soviet Union republics with its population of 20.981 million people. The country has a large and ethnically diverse population and an adequate number of trained healthcare professionals.

- Ethnically diverse treatment-naïve patient population
- Population is concentrated in a few major cities with well-equipped medical facilities
- Patients motivated to seek higher-quality care
- Competitive 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.

This integration into a major economic bloc coincides with strong global industry growth. The worldwide clinical trials market, valued at USD 69.27 billion in 2026, is projected to expand to USD 120.75 billion by 2034, reflecting a compound annual growth rate (CAGR) of 7.20% (according to Fortune Business Insights).

Kazakhstan has harmonized its national regulatory framework with these EAEC standards, implementing significant reforms to optimize clinical trial oversight. Key achievements include reducing regulatory approval timelines from 180 to 30 working days, abolishing mandatory site accreditation to streamline site selection, and establishing clear rules for non-interventional studies. The country has adopted Good Clinical Practice (GCP) standards and its Central Ethics Committee has received international recognition (FERCAP/SIDCER), solidifying its alignment with international research ethics.

Advantages for global sponsors

Expedited Regulatory Review
Implementation of a fast-track procedure (up to 15 working days) for studies already approved by regulatory authorities in ICH member countries (e.g., EU, USA, Japan).

Global Protocol & Data Transparency
Mandatory registration of study protocols and results in international registries (e.g., clinicaltrials.gov), aligning with global best practices.

Enhanced Digital Infrastructure
Launch of a National Information System for Biomedical Research for electronic submission and mandatory national trial registration, improving transparency and process efficiency.

Framework for Innovative Therapies
Introduction of clear pathways for Advanced Therapy Medicinal Products (ATMPs) and harmonized rules for Medical Device trials according to ISO 14155, catering to cutting-edge research.

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 19 years' experience in delivering high quality clinical trials.

Data sources

This report utilizes data from two distinct public registries to provide a complementary overview of the clinical trial landscape in Kazakhstan for 2025. The figures from these sources are presented separately, as they reflect different regulatory and reporting scopes, leading to expected and logical discrepancies.

- The **National Center for Drugs and Medical Devices Expertise of the Republic of Kazakhstan** (www.ndda.kz) data reflects the formal regulatory activity and the priorities of the local pharmaceutical sector in Kazakhstan.
- The **ClinicalTrials.gov** data reflects the country's integration into certain global clinical development programs.

The discrepancies are not errors but a direct result of the different purposes and jurisdictions of these registries. Using both provides a more nuanced understanding than relying on either one alone.

Clinical trials in Kazakhstan in 2025, according to

National Center for Drugs and Medical Devices Expertise

The National Center is the official national regulatory authority, responsible for maintaining the mandatory registry of all clinical trials approved to be conducted within Kazakhstan. It offers the complete, official domestic view. This registry includes all trials that have received approval from Kazakhstani regulators, such as: locally sponsored trials, international trials approved for the Kazakhstani market, and bioequivalence (BE) studies, which are a key focus for the developing local pharmaceutical sector.

Trial Data

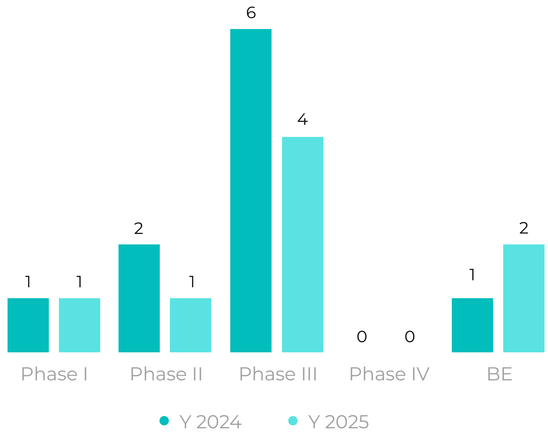
According to this source, eight clinical trials were initiated in Kazakhstan during the Year 2025. This represents a 20% decrease compared to the Y 2024, when the total number of studies was 10.

Two of the eight trials initiated in 2025 were Bioequivalence (BE) studies, a field that is relatively new in Kazakhstan but 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 (4 studies), followed by Phase I and Phase II (1 study each).

The therapeutic areas of clinical trials initiated in Kazakhstan during the Year 2025 (excluding BE) include Allergology (3 studies), Gynecology, Oncology, and Pulmonology (1 study each).

Breakdown of Clinical Trials in Kazakhstan by Phase



Sponsor Data

According to the National Center, clinical trials initiated in Kazakhstan during the Year 2025 were sponsored by pharmaceutical companies from Kazakhstan (3 studies) and two foreign countries: Germany (4 studies) and United States (1 study).

That makes the share of clinical trials sponsored by international pharmaceutical companies equal to 63% in the year 2025 - a slight reduction from 70% in 2024.

International Trial Sponsors in Y2025

№	Site Name	No. Studies
1	ROXALL Medizin	2
2	AbbVie Inc	1
3	Berlin-Chemie	1
	Boehringer Ingelheim	1
	Combined market share	**63%**

Domestic Trial Sponsors in Y2025

№	Site Name	No. Studies
1	Industrial Microbiology LLP	1
2	Kazakh National Agrarian University	1
3	Viva Pharm	1
	Combined market share	**37%**

CRO Data

No data on CROs involved in the conduct of these clinical trials was provided by the National Center.

Clinical trials in Kazakhstan in 2025, according to

clinicaltrials.gov

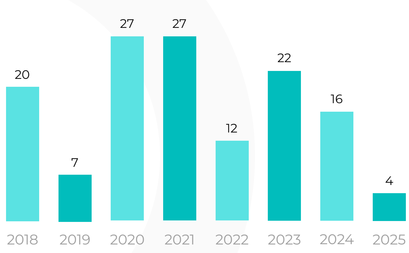
clinicaltrials.gov is an international database run by the U.S. National Institutes of Health. Registration is mandatory for certain U.S.-related trials but is also used voluntarily by sponsors worldwide as a global transparency tool. It offers a view of trials aligned with international R&D and reporting practices.

Trial Data

According to this source, during the Year 2025 4 clinical trials were initiated in Kazakhstan including local studies. That represents a 75% drop in comparison with the previous year when 16 studies were initiated. All clinical trials conducted in Kazakhstan in 2025 were interventional studies.

The therapeutic areas of clinical trials initiated in Kazakhstan during the Year 2025 (excluding BE) include Allergology, Infectious Diseases, and Pulmonology (1 study each).

Clinical Trials in Kazakhstan (Y 2018 - Y 2025)



Sponsor Data

According to data from clinicaltrials.gov, clinical trials initiated in Kazakhstan during the Year 2025 were sponsored by Kazakhstani (2 studies) and German sponsors (2 studies).

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 2025

№	Site Name	No. Studies	No. Subjects
1	Boehringer Ingelheim	1	1,755
2	Berlin-Chemie	1	26
	Combined market share of these companies	**50%**	**95%**

Kazakhstani Trial Sponsors in Kazakhstan in the Year 2025

№	Site Name	No. Studies	No. Subjects
1	Kazakh National Agrarian University	1	30
2	Scientific Center for Anti-infectious Drugs	1	62
	Combined market share of these companies	**50%**	**5%**

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 the Year 2025 reached a total of 1,873 subjects – a 34% decrease in comparison with the previous year when 2,847 subjects were planned to be enrolled. Within the total, the number of subjects planned for the listed BE study was 26.

Regulatory & Inpection Data

According to the U.S. FDA data, there were no FDA inspections conducted in Kazakhstani investigative sites during the Year 2025.

Breakdown of the Number of Subjects Enrolled by Phase

	Year 2024	Year 2025
Phase I	20	30
Phase II	529	62
Phase III	400	1,755
Phase IV	1,898	0

About Synergy Research Group

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

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

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.

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

We continuously work on improving our SOPs, study risk management, and IT infrastructure, replacing outdated R&D strategies with novel, more efficient approaches to clinical research.