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NIS, RWD and RWE: From Data to Evidence

In the previous issue, we discussed how NIS / RWD / RWE[1] address questions that cannot be resolved within the framework of classical clinical trials: how a drug is used in broad and diverse patient populations, how prescribing patterns change after launch, what safety and efficacy signals emerge with long-term use, and how patient pathways and decisions about treatment access are shaped. It is important to emphasize, however, that NIS do not replace clinical trials and should not be viewed as a simplified route to confirming efficacy. Their role is different — to show what happens with therapy in everyday practice, where the patient population, comorbidities, adherence, and the logic of clinical decision-making are far more complex than in registration trial protocols.

A logical continuation of this theme is the question of where real-world data come from — and why their quality is becoming a critical condition for trusting the conclusions drawn from them.

Sources of RWD: from registries to routine practice

Real-world data are heterogeneous in origin, and each source answers its own class of questions:

- **Patient registries and population-based databases** — provide long-term follow-up of defined cohorts (e.g., transplant recipients, patients with rare diseases), enable assessment of long-term outcomes, and allow for the construction of historical comparator groups;
- **Electronic medical records (EHR/EMR)**[2] — provide a detailed clinical picture, prescriptions, and laboratory and diagnostic results from routine practice;
- **Administrative and claims databases, reimbursement data** — reflect actual treatment utilization, adherence, costs, and access, but are limited in clinical granularity;
- **Patient registries and surveys, wearable device data** — add symptomatology, quality of life, and functional outcomes from the patient's perspective;
- **Cohort and observational studies (NIS)** — link the above sources into a prospective design with pre-defined endpoints.

It is the combination of sources, rather than any single database, that allows the full spectrum of a product's lifecycle questions to be addressed — from positioning and safety to access and management decisions. A separate analytical layer emerges during the period of patent expiry: RWD help to understand how products are used after the loss of exclusivity and what clinical questions arise in a mature therapeutic category.

It is important to distinguish between sources that genuinely form the evidence layer and those that provide only context. For example, the public pilot project for structured data presentation (EGISZ/M08, the Unified State Health Information System) currently does not provide a reproducible dataset suitable for automated analysis: the limitation is technical (data extraction tools are unavailable) rather than related to access rights. The Unified Register of Registered Medicinal Products of the EAEU (18,442 records[3]) is a valuable source of product context (products, registration dates and statuses, marketing authorization holders, ATC attributes), but it does not contain information on NIS and cannot substitute for the evidence layer. The same rule applies to any RWD: a source becomes evidence only after it has been verified for relevance and quality.

Data Quality as a Prerequisite for Evidence

Key thesis: RWD become RWE only after passing a quality assessment. Low-quality data are not a "weak argument" — they are a source of false conclusions. For this reason, work on data quality underpins any RWE project:

- **Completeness and accuracy** — the proportion of missing values and the correctness of coding for diagnoses, prescriptions, and outcomes;

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- **Traceability and auditability** — the ability to reconstruct the path from the source record to the endpoint;
- **Relevance to the clinical question** — alignment of the population, intervention, comparator, and outcomes with the research question;
- **Confounding control and work with historical comparator groups** — design and statistical methods that reduce the risk of systematic error;
- **Alignment with regulatory expectations** — the readiness of the data to withstand scrutiny within the regulatory process.

A separate risk is "false precision": when indirect metrics (the number of registry records, API activity, aggregated commercial data) are presented as evidence. Correct work with RWD begins with a clear separation of the verified evidence layer from contextual metrics. It is precisely data quality that turns observational studies from "supplementary material" into a full-fledged layer of the evidence ecosystem, on which regulators are increasingly relying when making decisions.

RWE in Regulatory Practice: The Prograf (Tacrolimus) Case

The most illustrative example of how RWE can serve as the basis for a regulatory decision is the expansion of indications for Prograf (tacrolimus) in **July 2021**.

The new indication — prevention of organ rejection in lung transplant patients — was approved on the basis of data from an observational study relying on the U.S. Scientific Registry of Transplant Recipients (SRTR).

The study aimed to demonstrate the efficacy and safety of tacrolimus-based immunosuppressive therapy for the prevention of transplant rejection in patients after primary lung transplantation. The analysis covered almost 20,000 patients (**19,741 adults** and **522 children**) who underwent transplantation of one or both lungs between 1999 and 2017. The cohort included patients receiving tacrolimus in combination with mycophenolate mofetil or azathioprine who survived to hospital discharge. Efficacy was assessed by one-year transplant survival from the time of discharge, and the results obtained were compared with the documented natural course of the disease in the absence of or with minimal immunosuppression. In adults, survival was **90.9%** for the mycophenolate mofetil regimen and **90.8%** for the azathioprine regimen; in children, **91.7%** and **84.7%**, respectively. Tacrolimus-based treatment demonstrated a clear advantage over the historical control, which the FDA considered sufficient to register the indication.

This case became a landmark precedent: the regulator recognized that high-quality observational data from a population-based registry can generate substantial evidence of efficacy and serve as the basis for expanding a drug's approved indications.

More cases of RWE use in FDA regulatory decisions — at the link [↗].

What This Means for the Russian Context

For Russia, the task today is not to prove the significance of the topic: the international agenda has already taken shape and is reinforced by regulatory requirements, market trends, industry activity, and a substantial body of observational data. **The task is different — to carefully systematize local data, clearly separate the verified evidence layer from indirect metrics, and consistently develop the infrastructure that will allow decisions to be made on the basis of real-world clinical practice without relying on false precision.** Data quality, transparency of sources, and reproducibility of analysis are the conditions without which local RWD cannot become an argument either for the regulator or for the system of decision-making on treatment access. We will continue to devote future issues of the Orange Paper to these questions.

[1]**NIS** — non-interventional studies; RWD (Real-World Data) — real-world data; RWE (Real-World Evidence) — evidence derived from real-world data.

[2]**EMR (Electronic Medical Record)** — an electronic medical record within a single healthcare facility; records do not extend beyond the organization. EHR (Electronic Health Record) — an integrated patient health record that follows the patient across healthcare facilities and covers the full spectrum of care.

[3]Based on data as of late August 2026: https://pharmnews.kz/article/... [↗]

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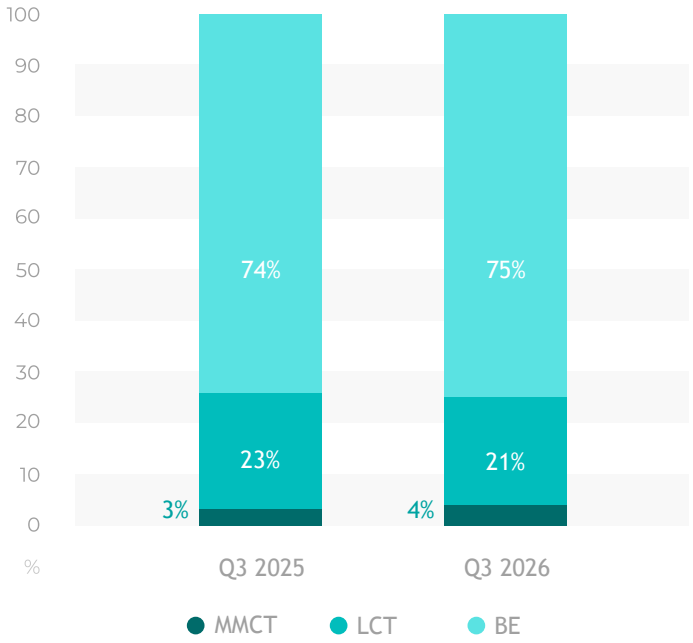
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Trial Data

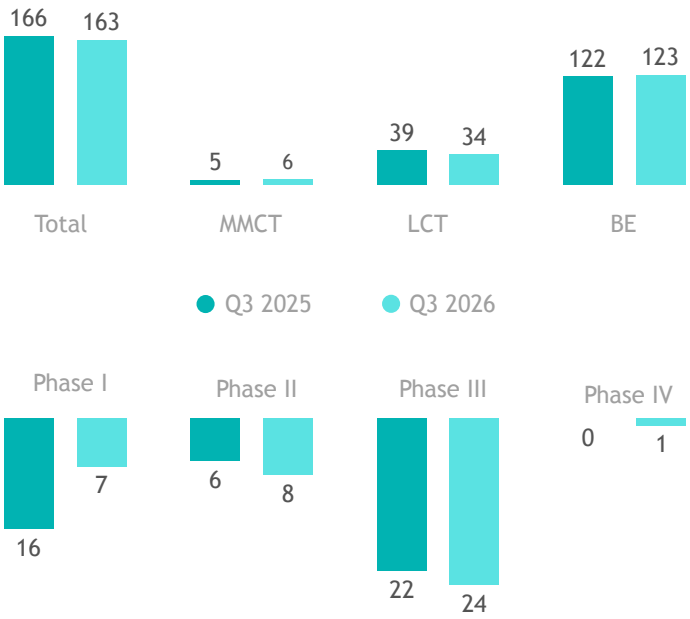
During Q3 2026 the Ministry of Health of the Russian Federation approved the start of 163 new clinical trials of all types, including local and bioequivalence studies. This represents a 2% year-on-year decrease in the total number of studies – 166 CTs were approved in Q3 2025.

The structure of clinical trials in Russia remained essentially unchanged in Q3 2026. BE studies continued to dominate with a 75% market share (73% in Q3 2025), while MMCTs and LCTs held steady at 4% (vs. 3%) and 21% (vs. 23%), respectively.

Percentage Breakdown of Clinical Trials by Type



Breakdown of Clinical Trials by Type and Phase



The most prevalent Phase of clinical trials conducted in Russian sites by total number of studies was Phase III. The total number of Phase III trials increased by 9% vs. Q3 2025, accounting for 24 studies.

The largest number of clinical trials initiated in Russia during Q3 2026 were related to the following therapeutic areas: General Practice (10 studies), Oncology (9), Infectious diseases (6), Obstetrics & Gynecology and Ophthalmology (5 studies each), Cardiology, Dermatology, Endocrinology, ENT, Neurology and Urology (2 studies each).

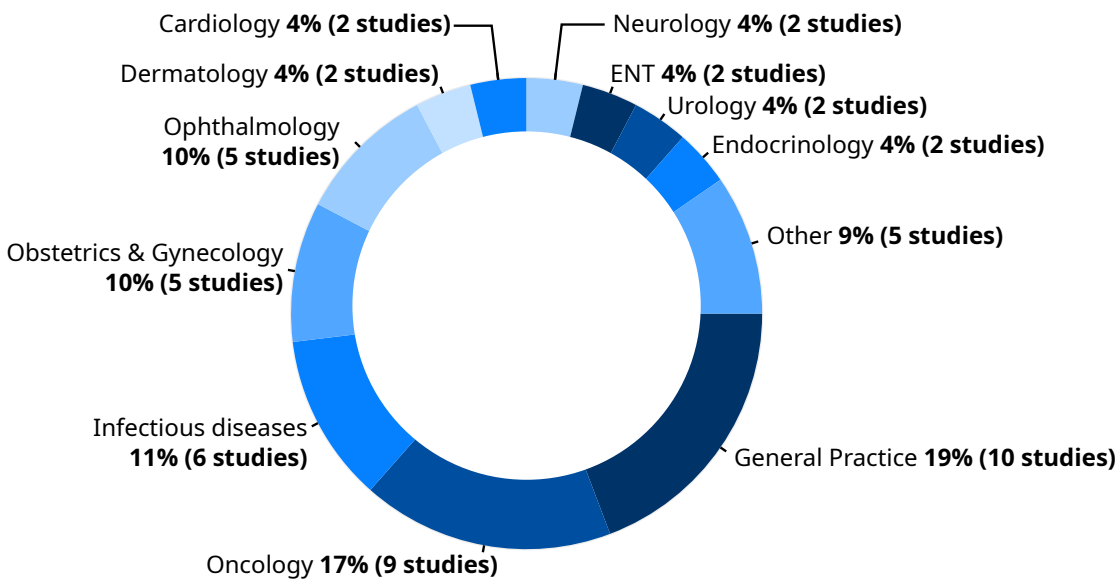
More than one therapeutic area may be assigned to a trial. BE studies were not included in any therapeutic area group.

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Therapeutic areas of Clinical trials in Russia in Q3 2026



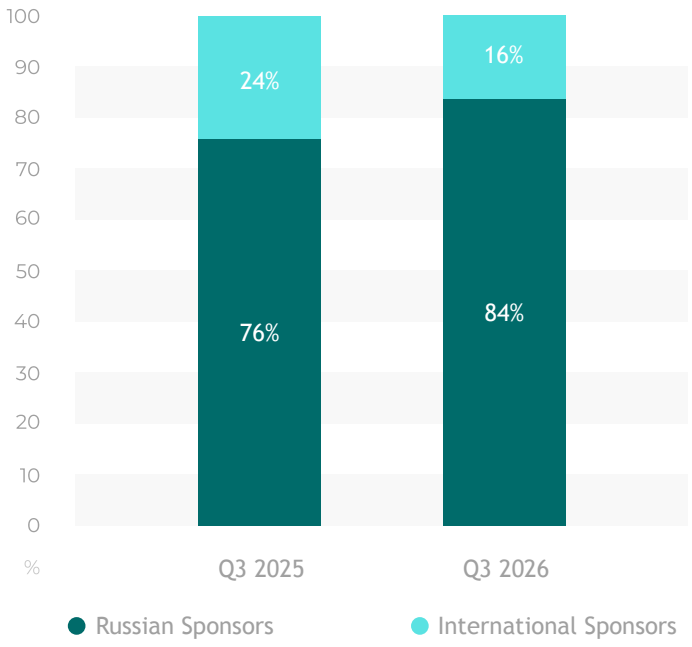
Sponsor Data

Clinical trials initiated in Russia during Q3 2026 were sponsored by pharmaceutical companies from Russia and 15 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian clinical trials market decreased from 24% in Q3 2025 to 16% of all studies in Q3 2026.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q3 2026 was Phase III (5 studies).

The most prevalent sponsor countries of origin in Q3 2026 were Russia (137 studies) and India (6 studies). Other prominent countries represented were Belarus (4 studies), Israel, Poland, Sweden (2 studies each), Australia, Bulgaria, China, Germany, Romania, Slovenia, South Korea, Spain, Switzerland, and Turkey (1 study each).

Percentage Breakdown of Clinical Trials in Russia in Q3 2026 by Sponsor's Country of Origin



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Top-10 Russian Trial Sponsors in Russia in Q3 2026

№	Company Name	Studies	Subjects
1	R-Pharm	5	3 028
2	Valenta Pharm	2	570
3	Gamaleya Research Institute of Epidemiology and Microbiology	2	304
4	Polysan	2	258
5	Generium	1	350
6	Saratov State Medical University n.a. V.I. Razumovsky	1	328
7	Moscow Endocrine Plant	1	250
8	Promomed	1	200
9	Scientific Center for Biomedical Technologies of FMBA	1	200
10	Otcpharm	1	180
	Combined market share*	**48%**	**51%**

*Combined market share based on total studies conducted by both sponsors and CROs.

Top-10 International Trial Sponsors in Russia in Q3 2026

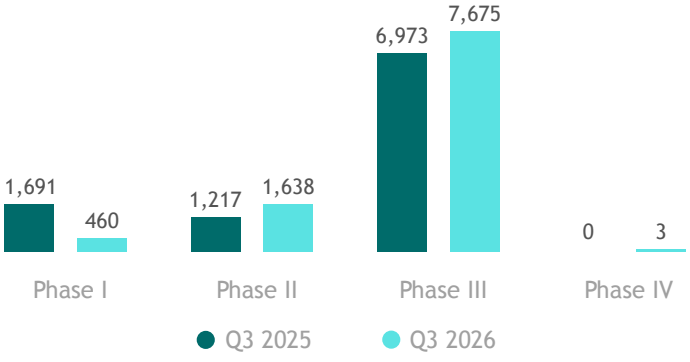
№	Company Name	Studies	Subjects
1	AstraZeneca	2	238
2	Dr. Reddy's	1	1280
3	Sopharma	1	350
4	Rompharm	1	220
5	Sentiss Pharma	1	218
6	Aristo Pharma	1	152
7	Eilean	1	40
8	Novartis	1	3
9	-	-	-
10	-	-	-
	Combined market share*	**23%**	**26%**

*Combined market share shown as a percentage of both international and Russian sponsors.
Observational Clinical trials and Clinical trials without FDA-defined phases (from I to IV) were not counted in this ranking.

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in Phase I–IV clinical trials initiated in Russia during Q3 2026 reached a total of 9,776 subjects – almost the same number compared to the previous year (9,881 subjects enrolled in Q3 2025). The most prevalent phase by number of participating subjects was Phase III, accounting for 79% of all enrolled subjects. The number of subjects enrolled (or planned to be enrolled) in BE studies accounted for 7,563 subjects – a 17% increase compared to Q3 2025.

Breakdown of Number of Subjects enrolled by Phase in



Studies indicated by sponsors as Phase I–II in the applications submitted to Ministry of Health, are shown in Phase II studies group, Phase II–III – in Phase III group, Phase III–IV – in Phase IV group.

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Research Site Data

Top-6* Russian research sites (all studies) in Q3 2026

№	Site name	City	No. studies
1	Eco-safety	Saint-Petersburg	17
2	Clinical Hospital #3	Yaroslavl	13
3	North-Western Scientific Center for Hygiene and Public Health	Saint-Petersburg	10
4	Tomsk National Research Medical Center of the Russian Academy of Sciences	Tomsk	10
5	AX Clinic	Yaroslavl	9
6	Ligand Research	Moscow	9
	Combined market share of these sites		**42%**

*Top-6 instead of Top-5 due to a tie at the 5th position (9 studies each).

CRO Data

Top-10 CROs in Russia in Q3 2026 (Phase I–IV studies)

№	Company Name	No. studies	No. subjects
1	Vita Aeterna	2	318
2	Accellena	1	715
3	Axon Clinical Trial Lab	1	367
4	Innovation LK	1	220
5	National Scientific Center for Research and Pharmacovigilanc	1	200
6	ELC	1	196
7	X7 Clinical Research	1	152
8	iPharma	1	40
9	LABMGMU	1	32
10	-	-	-
	Combine market share of these TOP-10 players	**25%**	**23%**

Observational Clinical trials and Clinical trials without FDA-defined phases (from I to IV) were not included in this ranking.

Top-5 CROs in Russia in Q3 2026 (BE studies)

№	Company Name	No. studies	No. subjects
1	Medical Development Agency	6	240
2	Eco-safety	6	253
3	ClinPharmDevelopment	5	215
4	X7 Clinical Research	3	144
5	Probiotech	2	210
	Combined market share of these TOP-5 players	**18%**	**14%**

Only BE (bioequivalence) studies were included in this ranking.

In applications submitted to the MoH of Russia, the Sponsor may be listed as the organization conducting the clinical trial, whereas the practical execution of the trial is carried out by a CRO.

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Regulatory Data

The Center for Drug Evaluation and Research (CDER) of the FDA approved 50 new drugs during Q3 2026; including 18 new molecular entities (NME). The remaining approvals concerned new active ingredients, new dosages, combinations, formulations, or manufacturers. Five of these 50 drugs (two of 18 NMEs) were tested in clinical trials involving Russian sites.

Appr. date	Drug (active ingredient)	Company
09.07.2026	Sarclisa Escena (isatuximab-irfc)	Sanofi-Aventis
31.07.2026	Zimrixby (rituximab-cdxx)	Dr Reddys labs
13.08.2026	Zenbexus (iberdomide hydrochloride)	Bristol Myers Squibb
04.09.2026	Etcamah (camizestrant)*	AstraZeneca
25.09.2026	Degevma (denosumab-adet)	Teva Pharmaceuticals, Inc

*Clarification to Q2 2026: Etcamah (camizestrant, AstraZeneca), approved 21.05.2026 by EMA, was tested in Russian CTs (SERENA-2). The previous issue is hereby corrected.

During Q3 2026, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) approved 24 new drugs including 13 new (non-orphan) drugs, 5 generics/ hybrids, 3 biosimilars and 3 orphan drugs. Three of the approved drugs were tested in clinical trials involving Russian sites.

Appr. date	Drug (active ingredient)	Company
23.07.2026	Lynavoy (linerixibat)	Glaxosmithkline Trading Services Limited
23.07.2026	Susvimo (ranibizumab)	Roche Registration GmbH
17.09.2026	Gevalka (ensartinib)	SFL Pharmaceuticals Deutschland GmbH

FDA Inspections

According to U.S. FDA data, no inspections were conducted at Russian investigative sites during Q3 2026.

Roszdravnadzor Inspections

According to Roszdravnadzor data, as of 16 October 2026, no regulatory inspections were conducted by the agency during Q3 2026.

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About The Orange Paper

The Orange Paper is a free publication produced by Synergy Research Group for the pharmaceutical industry since 2007. It consolidates data from numerous public sources into a single concise document to aid decision-makers planning clinical trials. The report is published quarterly, with an annual summary issued at the end of each year.

All data contained within this document is current as of 16 October 2026.

About Synergy Research Group

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

Year after year, our company ranks among the market leaders in the number of conducted clinical studies and enrolled patients.

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

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

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

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