

Oksana Karavaeva, MD, Director of Clinical Operations, IPHARMA LLC | Natalia Vostokova, PhD, Chief Operating Officer, IPHARMA LLC

Common Challenges in Clinical Trials:



Patients/Healthy volunteers

- Lack of knowledge about clinical trials
- Difficult to find information about ongoing clinical trials
- Difficult to contact a clinical site



Investigators

- Challenging patient recruitment with specific inclusion/exclusion criteria and limited enrollment timeline
- Lack of healthy volunteers and control over their clinical trial activity

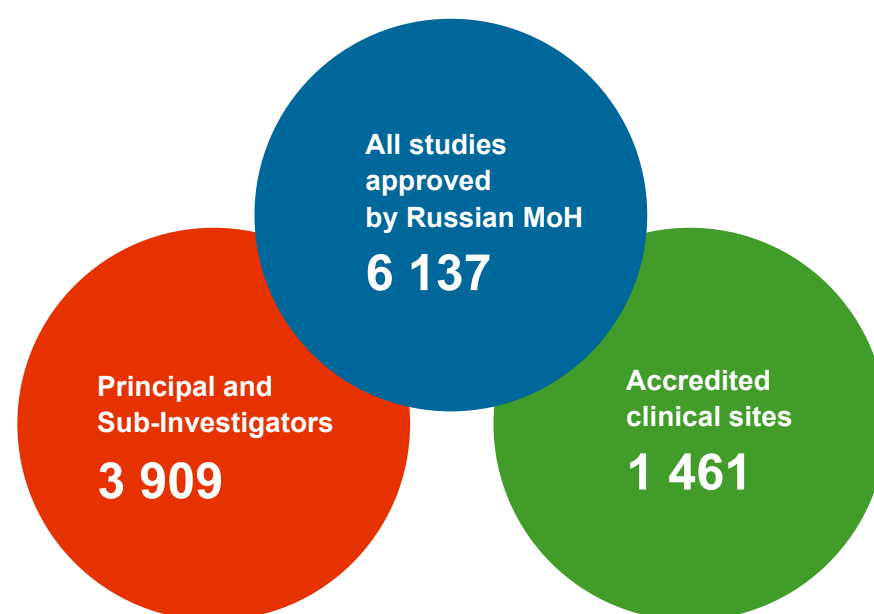


Sponsor/CRO

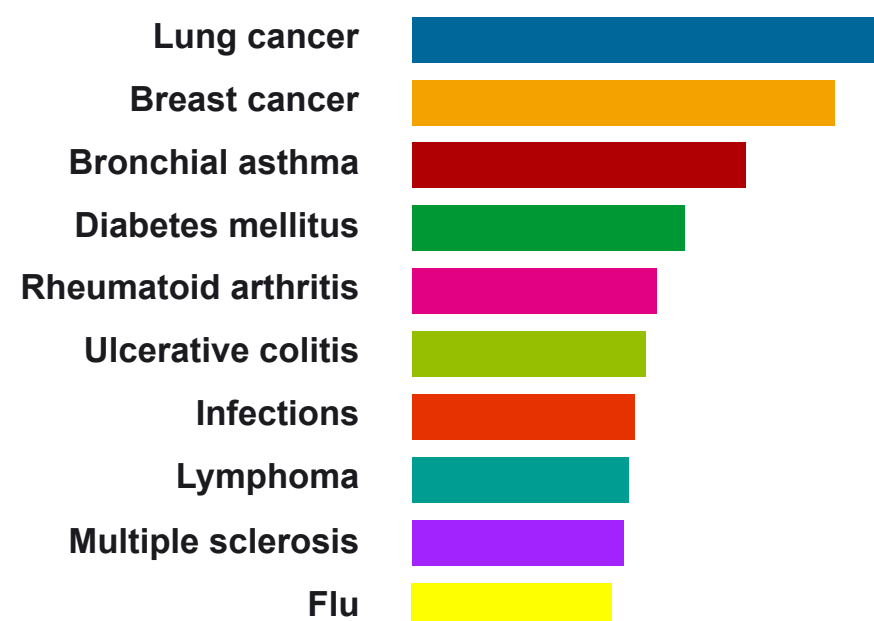
- Difficult to find new sites and investigators
- Lack of real-time analytics of the clinical trial market
- Lack of information exchange

The platform was launched in July 2018. The database for clinical trials, investigators and clinical sites was developed based on official MoH registers.

The database is up-to-date and synchronized with MoH clinical trial registers daily.



Top 10 indications for clinical trials in Russia:



ClinLine.ru – the new integrated infomedia platform for all parties involved in clinical trials, which could facilitate clinical trial search, site selection, patient recruitment, and improve transparency of clinical trial process in Russia.

ClinLine objectives:

- ✓ encourage more patients in drug development
- ✓ allow better access to clinical trials
- ✓ streamline communication between patients and investigators
- ✓ improve site selection, feasibility and pre-screening
- ✓ minimize enrollment timelines
- ✓ provide more transparency and understanding of drug research



The ClinLine functionality includes:

- ✓ cross-searching of clinical trials, sites and investigators
- ✓ registration and creating profiles of patients/healthy volunteers, investigators and sponsors/CRO
- ✓ authorization of investigators with access to patient registry
- ✓ application/invitation to a clinical trial
- ✓ chat between patients/healthy volunteers and investigators
- ✓ chat between investigators and sponsors/CRO
- ✓ rating of patients/healthy volunteers and investigators
- ✓ access to investigators profiles for sponsors/CRO
- ✓ real-time analytics of the clinical trial market for sponsors/CRO

The monthly web-site activity is approximately 13,000 page views with 5,000 individual visitors including over 20% visitors aged 45 year and older (6.0±0.3 minutes per visit).

We conducted several focus groups to evaluate the usability of ClinLine.ru. Based on the results and feed-back from users, we continue to develop the functionality of the platform.

Focus group - Investigators	Yes	No
Willing to receive information about potential patients/healthy volunteers by e-mail	64%	36%
Willing to perform search for potential patients/healthy volunteers in the register	64%	36%
Willing to provide Sponsors/CRO with access to their profile (CV, license, etc.)	86%	14%

Focus group - Patients

Mean age	54
Registration assessment (0 to 5)	4.2
Profile completion assessment (0 to 5)	4.1
Did you find a clinical trial of interest?	
Yes	32%
No	12%
Didn't search	56%

Focus group - Sponsors

General impression of the platform	4.5
Current functionality	3.9
Will you be using the platform in your work?	
Yes	61%
Maybe	33%
No	6%