RUSSIAN CLINICAL TRIALS MARKET: January – June, 2010

Comparative analysis

Introduction

For over fifteen years, Russia has conducted pivotal international clinical trials. In addition to the immediate benefit of a more expedient introduction of new pharmaceuticals to the market, such trials add a significant component of investment to the Russian economy. Furthermore, participation in clinical trials has a high social value for the Russian medical community – specifically, the ability to adapt the most progressive medical standards for pharmacology as well as establish direct contact with key opinion leaders of the international medical community. Clinical trials stimulate local pharmaceutical research and development, and Russian patients gain access to groundbreaking medical treatments and technologies. Free medical care utilizing high caliber technology is often the only way for many Russian patients to be included in state-of-the-art treatment programs. Those in this field understand that the participation level in international clinical trials reflects on the status of a country's medical care. Despite recent advancements, it is clear that Russia still lags behind other premier medical communities in terms of the quantity of clinical trials.

Market Structure

Based on the official report from Roszdravnadzor (Russian Federal Service on Surveillance in Healthcare and Social Development), there were 312 approvals to conduct clinical trials in the first 6 months of 2010 (table 1).

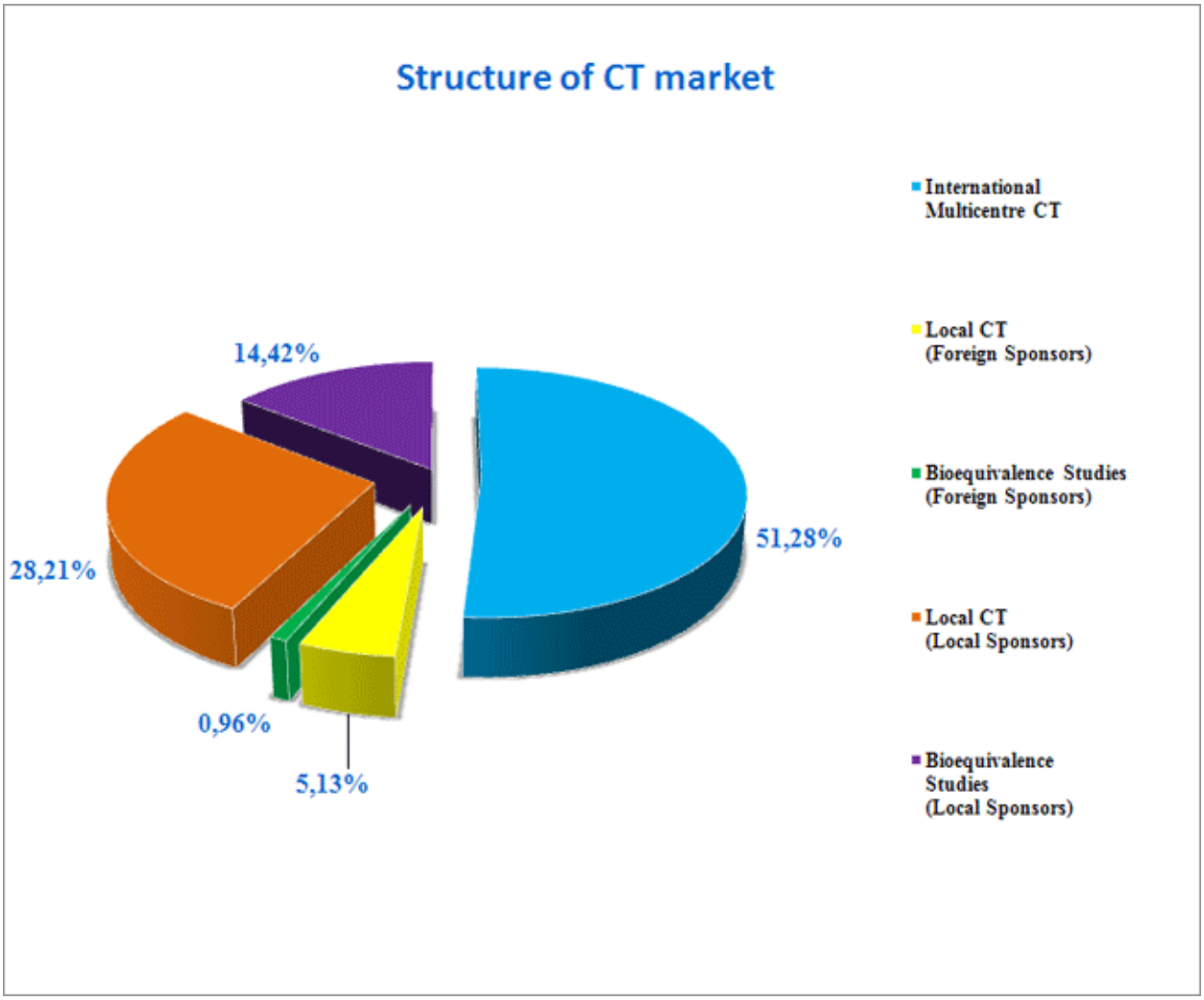
Table 1

Russian Clinical Trials Market for 2009					
International Multicenter Trials	Local trials (foreign sponsors)	PK/PD (foreign sponsors)	Local trials (local sponsors)	PK/PD (local sponsors)	Total number (Jan-Jun 2010)
160	16	3	88	45	312

Source: acto-russia.gov

Multicenter international trials account for the largest share of all clinical trials conducted in Russia (graph 1).

Graph 1



	International Multicenter trials
	Local trials (foreign sponsors)
	PK/PD (foreign sponsors)
	Local trials (local sponsors)
	PK/PD (local sponsors)

Source: acto-russia.org

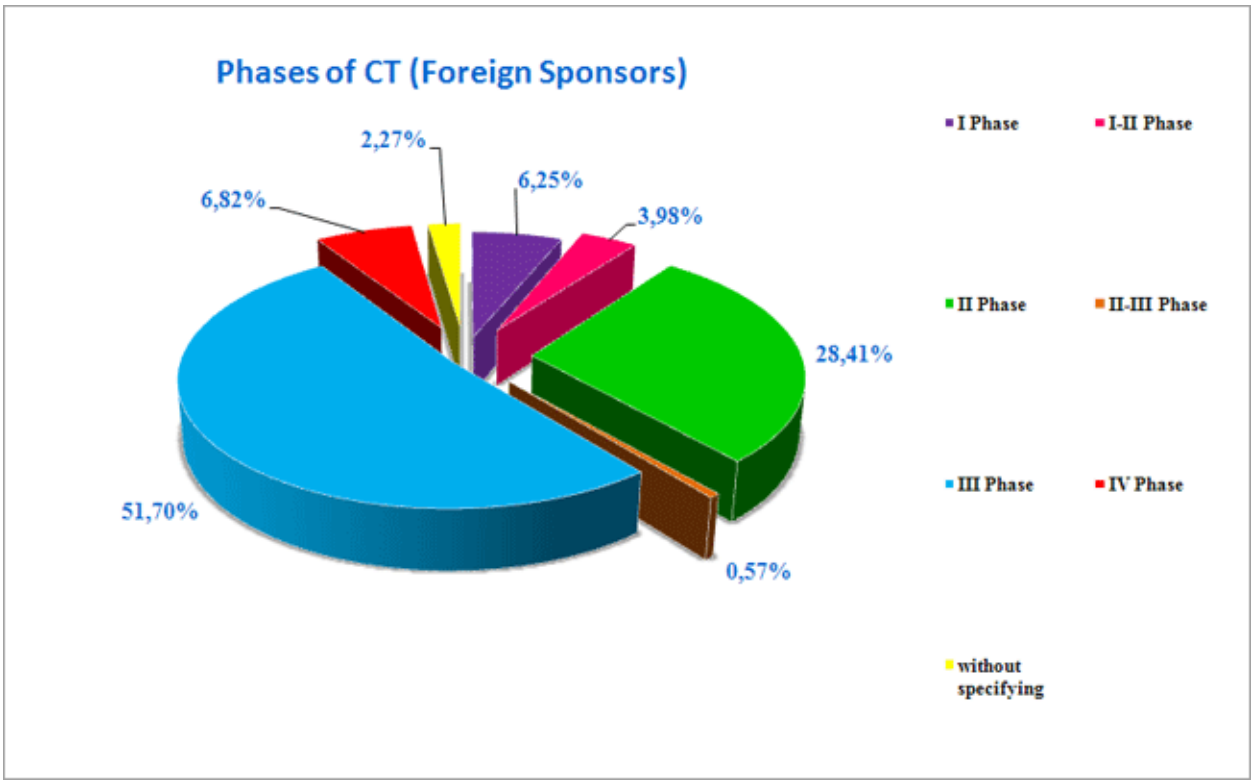
For international trials, phase III programs still dominate (table 2, graph 2).

Table 2

Clinial trial phases (foreign sponsors)							
Phase I	Phase I-II	Phase II	Phase II-III	Phase III	Phase IV	Without specifying	PK/PD (foreign sponsors)
11	7	50	1	91	12	4	3

Source: acto.ru

Graph 2



Source: acto-russia.org

Comparative analysis of clinical trial approvals between January and June of 2009 and the same period in 2010 exhibit some interesting trends (Table 3, Graph 3). The total number of clinical trials continues to grow. Note the increase in local clinical trials conducted by local sponsors. While local sponsors continue to concentrate on PK/PD studies, Russia has experienced more than a 2-fold increase in the number of later-stage trials.

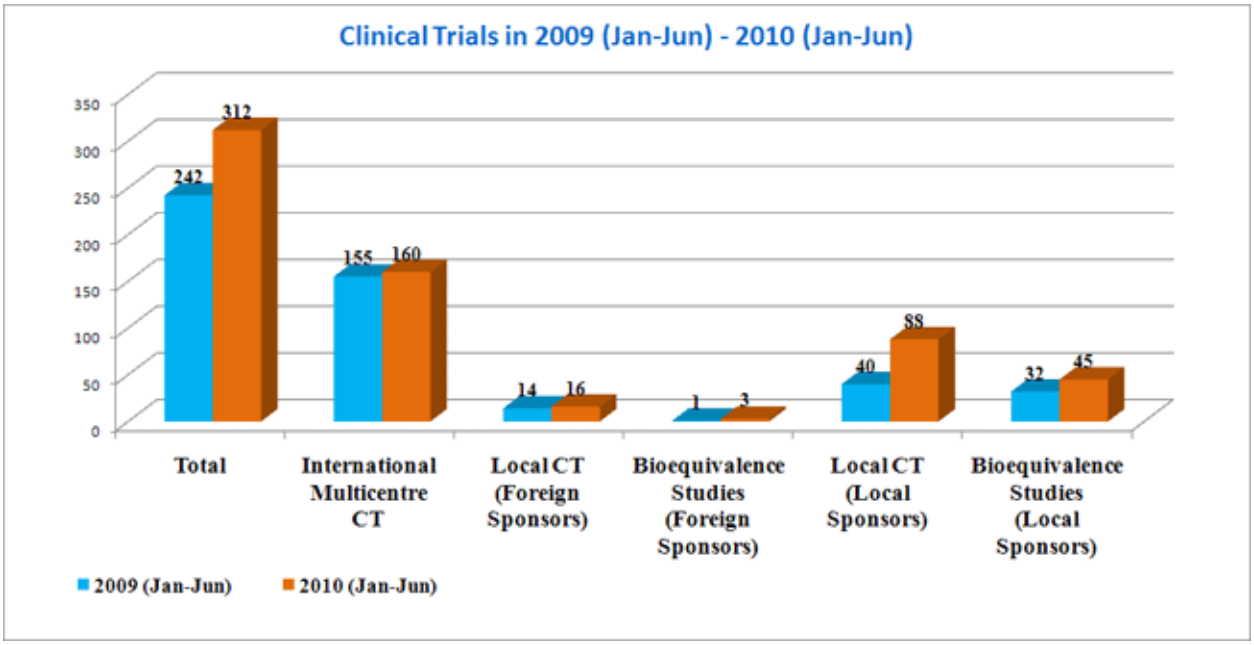
There has also been an increase in the number of international multicenter clinical trials, of which there is moderate growth of early phase trials.

Table 3

Clinical Trials in 2009 (January-June) - 2010 (January-June)						
	Total	International Multicentre CT	Local CT (Foreign Sponsors)	Bioequivalence Studies (Foreign Sponsors)	Local CT (Local Sponsors)	Bioequivalence Studies (Local Sponsors)
2009 (Jan-Jun)	242	155	14	1	40	32
2010 (Jan-Jun)	312	160	16	3	88	45

Source: acto-russia.org

Graph 3



Source: acto-russia.org

Conclusions and interpretation

The state of the Russian clinical trial market in 2010 showed no surprises; however, the increased activity of local Pharma is noteworthy. We believe that this increase in local Pharma reflects a new Russian State policy that calls for a dramatic increase in both generic and innovative locally produced medications.

A new "2020 initiative," devised by central and local government, aims to improve the competitiveness of the domestic pharmaceutical industry through harmonization of Russian standards of medicinal product development and utilizing international production requirements. Significant energy is being expended to emphasize the technical remodeling of the Russian pharmaceutical industry. By 2020, the overarching goals are to: (1) increase the domestic products' share to 50% of revenues for internal market consumption, (2) improve the variety of medications sold in Russia, including a 60% monetary increase of locally derived innovative products, and (3) increase the export of pharmaceutical products by 800% of today's levels.

As we have mentioned in our previous communications, the Russian government has recently passed new legislation that requires locally conducted trials (at least in part) for all new drug entities seeking approval in Russia. If the manufacturer does not fulfill this requirement, then phase II and III trials will need to be repeated from scratch in Russia. We anticipate that this new legislation will greatly increase Russia's participation in late stage clinical trials as early as in Q4 of 2010.