

RUSSIAN CLINICAL TRIAL MARKET: 2011 IN REVIEW

2011 has been a turbid year for the Russian clinical trial market. The Russian Federal Law on Circulation of Medicines which came into force on September 1st 2010 introduced special requirements to registration of new drugs on the Russian market, with the most relevant part being a requirement for a local registration study of the drug being registered.

When this law entered into effect, a significant amount of uncertainty ensued. Foreign pharmaceutical companies could not get a clear answer as to whether the whole registration trial had to be conducted in Russia; only part of it and if such, how large of a part?

It appeared that serious restructuring within the Ministry of Healthcare and Social Development had lead to a confusion and ineffectiveness within its ranks. No clear answers could be given by the government, which has caused a significant cooling on the part of Western Pharma, even its sector that was customarily interested in registering their NDEs in the growing Russian market.

Aforementioned situation had a negative impact on the number of clinical trial approvals in Russia in the beginning of 2011 but in overall number of approvals of international multicenter trials in 2011 was even higher than in 2010, what is a very positive trend in this year. Below please find a table that shows comparative analysis of clinical trial approvals in 2011 as compared to the same period in 2010 (data presented by Association of Clinical Trials Organizations [www.acto-russia.org]).

Table 1. Approvals for conduct clinical trials in Russia: 2011 vs 2010

	All clinical trials	International multicenter trials	Local clinical trials (Non-Russian pharma)	Local clinical trials (Russian pharma)	Other (bioequivalence, etc)
Q1-Q3* 2010	446	220	29	117	80
Q1-Q3 2011	332	247	13	49	23
2011 vs 2010	-26%	+12%	-55%	-58%	-71%

*for 3Q July and August only

Data from www.grls.rosminzdrav.ru, www.roszdravnadzor.ru and www.acto-russia.org

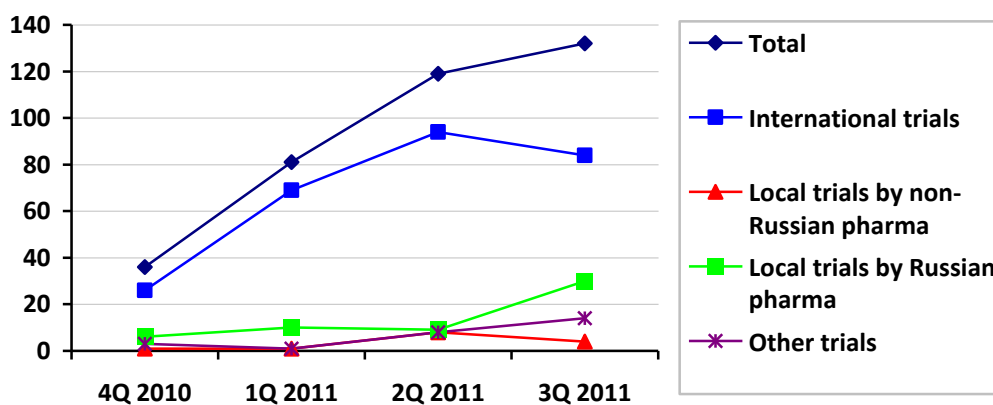
Another significant event of 2011 was a rather hasty request for accreditation of the Russian medical institutions for the right to conduct clinical trials (Resolution of Government of Russia No.683). Not only did this mandate come with a very short forewarning, a lot of experts felt that the timeline that was put forth – September 1st of 2011 – was unrealistic. It came as no surprise that only 190 medical institutions were able to receive accreditation by early August of

2011. Again, lack of full transparency of the regulatory bodies, their inability to explain what would happen with active clinical trial sites that were unable to obtain accreditation before the timeline became a source of alarm within the clinical trial community. Fortunately, the same month the Ministry of Healthcare and Social Development issued 10 executive orders that allowed 465 medical institutions to receive such accreditation. To date about 700 institutions (we call it a “critical mass”) have the right to conduct clinical trials and now we are assuming further increase in numbers of accredited sites.

One more negative issue that plagued Russian clinical research in 2011 was the change in ethics review process – another byproduct of the changes in the Russia’s regulatory system. It resulted in even more ambiguity when it came to tracking of submissions, delays in approvals and creation of a very cumbersome system of appeals.

With all the negative events listed above, we believe that there is a light at the end of the tunnel. Despite the fact that the general number of approvals has been on the decline during the studied period, the rate of decline has slowed significantly. The situation improved in the third quarter of 2011 with more clinical trial approvals issued to Russian companies.

Figure 1. Approvals for conduct clinical trials in Russia after implementation of a new legislation on drugs: from 4Q 2010 to 3Q 2011



Data from ACTO Newsletter #2, 3Q 2011, www.acto-russia.org

In the same quarter, 84 International multicenter clinical trials were approved, which exceeds the third quarter of 2010 by 24 trials.

Conclusions and interpretations

We at Cromos™ Pharma strongly believe that 2011 was one of the most challenging years in contemporary clinical trial landscape in Russia. A very raw and often illogical Russian Federal Law on Circulation of Medicines instituted in September of 2010 with resultant drastic and not

always well thought-through changes in regulatory processes has nearly paralyzed the clinical trial field for many months. Following recent positive trends we are very happy to report that this “Russian winter” is finally coming to an end. Our personal experience shows that the regulatory bodies are becoming more aware of what they should and should not do the timelines are becoming more and more manageable, and the overall climate more conducive to productive solutions.

We still see a number of issues that need to be addressed. For one, the definition of foreign registration trial for the purposes of NDA in Russia requires greater clarification. Secondly, the new ethics committee procedures should become more timely and transparent. Our great hope is in advocacy groups such as Association of Clinical Trials Organizations (ACTO, www.acto-russia.org). This organization has been a major crusader for the rights of clinical trial industry stakeholders and has been productive in achieving its aims.

To our foreign partners we continue to recommend Russia as a country with some of the best recruitment rates, very high quality of clinical data and very reasonable (especially lately) regulatory approval timelines.

Cromos™ Pharma is a full service CRO that prides itself on very high quality of work, full GCP compliance and some of the brightest minds in the CRO business. We help our clients to navigate through all stages of clinical trial process – starting from drafting of study protocol through regulatory support and monitoring and all the way to the final study report and statistical analysis. We provide services to both foreign and domestic pharmaceutical companies since 2005 and would be happy to hear from you, when the need for Russian CRO services arises.

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