ACTO
ASSOCIATION OF CLINICAL TRIALS ORGANIZATIONS

Timeframes' monitoring (2013 year)

The survey was carried out in February 2014.

The sample included submissions made from January 1, 2013 till December 31, 2013 as well as submissions made before January 1, 2013 if decisions on granting/refusing approvals were taken in 2013.

24 ACTO member companies took part in the survey (pharmaceutical companies and contract research organizations).

Table 1 (Timeframes for Issuing Approvals) provides information on average, minimum and maximum timeframes for issuing approvals to conduct clinical trials, permits to import medicines for clinical trials, permits to import/export biological materials, approvals to make amendments to the protocols and other approvals (to prolong clinical trials, to involve new sites, to enroll additional patients, etc.) It's worth noting that time spent to reply to Ethical Council's and FGBU requests wasn't taken into account.

The total time to begin a trial is the sum of average timeframes for issuing approvals to conduct clinical trials and average timeframes for issuing permits to import/export biological materials.

Actual timeframes are given in calendar days. Timeframes according to legislation are given in calendar as well as in business days.

Table 2 (Changes in average timeframes for issuing approvals to conduct clinical trials and permits to import/export) provides information on average timeframes for issuing approvals to conduct clinical trials and permits to import/export as well as total time to begin a trial in 2005-2013. It's worth noting that before 2011 year ACTO didn't differentiate timeframes for issuing permits to import/export biological materials and medicines.

Before September 2010 examinations carried out by FGU and Ethics Committee weren't part of the approval process. That's why average timeframes for issuing approvals to conduct clinical trials in 2004-2010 were calculated as the sum of average timeframes for carrying out examinations by Ethics Committee and FGU (the highest number was taken into account) and timeframes for issuing approvals by Roszdravnadzor.

Table 3 provides information on violations of timeframes.

Tables 4-8 provide detailed information on timeframes for issuing all sorts of approvals. Actual timeframes are given in calendar days. Timeframes according to legislation are given in business and calendar days. The column «Legislation» provides information on relevant sources of the numbers in the column «Timeframes according to legislation».

The column «Sampling» provides information on the number of submitted applications. The samples are different at different stages because companies apply various approaches to timeframes monitoring.

Table 1. Timeframes for Issuing Approvals

	Timeframes according to legislation (business/calendar days)	Average timeframes (calendar days)	Minimum timeframes (calendar days)	Maximum timeframes (calendar days)	Sampling
To conduct clinical trials*	41/57	87	32	223	177
To import medicines	8/12	14	6	43	355
To import/export biological materials	13/19	20	6	62	819
To make amendments to the protocol	34/48	45	3	132	350
Other approvals (to prolong clinical trials, to involve new sites, to enroll additional patients, etc.)	25/35	26	3	80	682
Total time to obtain approvals to conduct clinical trials and to import/export**	54/76	107	~	~	~

* It's the sum of average timeframes for issuing approvals to conduct clinical trials and average timeframes for issuing permits to import/export biological materials or to import drugs (the highest number was taken into account)

Table 2. Changes in average timeframes

	2005	2006	2007	2008	2009	Jan-Aug 2010	2011	2012	2013
Approvals to conduct clinical trials	66,3	77,8	98,9	77,6	77,0	85,2	130,0	116,0	87,0
Permits to import/export	14,9	17,8	23,7	33,1	30,5	26,9	34,0	20,0	20,0
Total	81,2	95,6	122,6	110,7	107,5	112,1	164,0	135,0	107,0

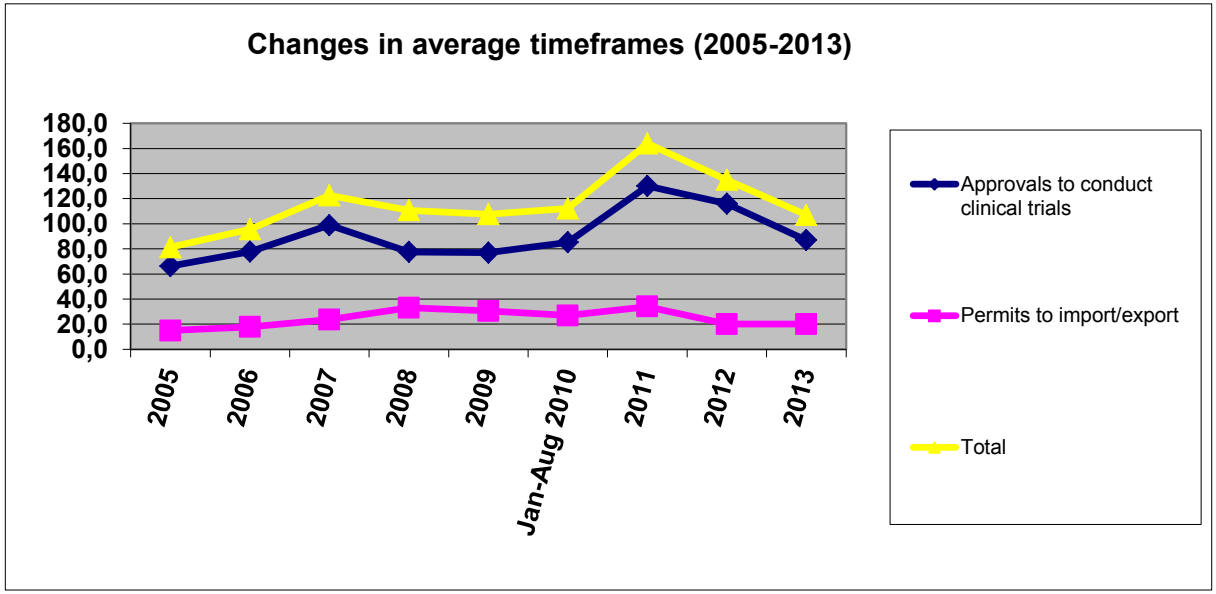

Table 3. Violations of timeframes

	Approvals issued on time	Approvals issued in violation of timeframes				
		Total	less than in 1,5 times	in 1,5-1,9 times	in 2-2,9 times	in 3-3,9 times
to conduct clinical trials*	4,0%	96,0%	51,4%	29,9%	12,4%	2,3%
to import medicines	43,7%	56,3%	30,4%	20,0%	5,1%	0,8%
to import/export biologocal materials	53,1%	46,9%	35,8%	10,0%	1,0%	0,1%
to make amendments to the protocol	60,3%	39,7%	30,9%	7,4%	1,4%	0,0%
clinical trials, to involve new sites, to enroll	86,2%	13,8%	11,9%	1,6%	0,3%	0,0%

Table 4. Timeframes for Issuing Approvals to Conduct Clinical Trials

Stages of review	Timeframes according to legislation (business/calendar days)	Legislation (references)	Practice (calendar days) *total number of applications is 267*						Sampling*
			average timeframes	minimum timeframes	1st quartile	median	3rd quartile	maximum timeframes	
Application registration (from the date of the submission)	1/1	Paragraph 16 of the Rules of proceedings in the federal executive bodies (Government Order of June 15, 2009 N 477)	1	0	0	0	1	26	179
Data completeness check and decision on issuance of an assignment to carry out expert examination (from the date of the registration)	5/7	Peragraph 3 of the Article 39 of the Federal Law On Circulation of Medicines	7	0	4	6	8	33	203
Examinations (from the date of the decision)	30/42	Paragraph 1 of the Article 20 of the Federal Law On Circulation of Medicines	48	22	44	48	53	66	41
Second application submission (from the date of the first application submission)	~	There is no such requirement in the legislation	67	30	54	62	71	153	142
Decision on issuance of an approval to conduct a clinical trial	5/7	Paragraph 2 of the Article 22 of the Federal Law On Circulation of Medicines	9	1	7	8	11	29	137
Receipt of the decision on issuance of an approval to conduct a clinical trial (from the date of the decision on issuance of an approval)	0/0	Paragraph 2 of the Article 22 of the Federal Law On Circulation of Medicines	11	2	7	10	14	38	167
Total time to receive a notification that a permit is refused (in case of refusal) from the date of the submission	41/57	the sum of all stages	57	5	51	57	63	101	59
Total time to receive a permit from the date of the submission	41/57	the sum of all stages	87	32	71	80	92	223	177
Total time to receive a permit from the date of the resubmission (if initial submission was refused)	41/57	the sum of all stages	81	14	64	79	90	171	54
Total time to receive a permit after resubmission from the date of the initial submission (if initial submission was refused)			197	126	162	188	223	289	30

*The samples are different as different companies apply different approaches to timeframes' monitoring

Table 5. Timeframes for Issuing Permits to Import Medicines

Stages of review	Timeframes according to legislation (business/calendar days)	Legislation (references)	Practice (calendar days) *total number of applications is 286*						Sampling*
			average timeframes	minimum timeframes	1st quartile	median	3rd quartile	maximum timeframes	
Application registration (from the date of the submission)	1/1	Paragraph 16 of the Rules of proceedings in the federal executive bodies (Government Order of June 15, 2009 N 477)	1	0	0	1	2	5	150
Data completeness check and decision on whether to grant a permit or to notify that a permit is refused (from the date of the registration)	5/7	Paragraph 12 of the Rules of Import of Medicines for Medical Use into the Russian Federation (Government Order of September 29, 2010 № 771)	6	0	5	6	7	37	292
Receipt of the decision (from the date of the decision)*	2/4	Paragraph 22 of the Rules of proceedings in the federal executive bodies (Government Order of June 15, 2009 N 477)	7	1	4	6	9	32	265
Total time to receive a permit or a notification that a permit is refused (from the date of the submission)	8/12	the sum of all stages	14	6	10	13	18	43	355

Table 6. Timeframes for Issuing Permits to Import/Export Biological Materials

Stages of review	Timeframes according to legislation (business/calendar days)	Legislation (references)	Practice (calendar days) *total number of applications is 617*						Sapmling*
			Average timeframes	minimum timeframes	1st quartile	median	3rd quartile	maximum timeframes	
Application registration (from the date of the submission)	1/1	Paragraph 16 of the Rules of proceedings in the federal executive bodies (Government Order of June 15, 2009 N 477)	1	0	0	1	1	6	470
Data completeness check and decision on whether to grant a permit or to notify that a permit is refused (from the date of the registration)	10/14	Paragraph 5 of the Rules for Import and Export of Biological Materials into and outside of the Russian Federation (Government Order of September 3, 2010 №673)	13	0	9	13	14	55	711
Receipt of the decision (from the date of the decision)*	2/4	Paragraph 22 of the Rules of proceedings in the federal executive bodies (Government Order of June 15, 2009 N 477)	7	1	4	6	8	26	627
Total time to receive a permit or a notification that a permit is refused (from the date of the submission)	13/19	the sum of all stages	20	6	15	19	22	62	819

*The samples are different as different companies apply different approaches to timeframes' monitoring

Table 7. Timeframes for Issuing Approvals to Make Amendments to the Protocol

Stages of review	Timeframes according to legislation (business/calendar days)	Legislation (references)	Practice (calendar days) *total number of applications is 379*						Sampling*
			average timeframes	minimum timeframes	1st quartile	median	3rd quartile	maximum timeframes	
Application registration (from the date of the submission)	1/1	'''Paragraph 16 of the Rules of proceedings in the federal executive bodies (Government Order of June 15, 2009 N 477)	2	0	0	1	3	27	214
Decision on whether to grant an approval or to notify that an approval is refused (from the date of the registration)	30/42	Paragraph 5 of the Article 40 of the Federal Law On Circulation of Medicines, Paragraph 7 of the MoH Order of August 31, 2010 N 775n	38	1	27	41	49	111	352
Receipt of the decision (from the date of the decision)*	3/5	Paragraph 10 of the MoH Order of August 31, 2010 N 775n	7	0	4	6	8	35	335
Total time to receive an approval or a notification that an approval is refused (from the date of the submission)*	34/48	the sum of all stages	45	3	32	47	56	132	350

Table 8. Timeframes for Issuing Other Approvals (to Involve New Sites, To Enroll Additional Patients, to Prolong Clinical Trials etc.)

Stages of review	Timeframes according to legislation (business/calendar days)	Legislation (references)	Practice (calendar days) *total number of applications is 638*						Sampling*
			average timeframes	minimum timeframes	1st quartile	median	3rd quartile	maximum timeframes	
Application registration (from the date of the submission)	1/1	Paragraph 16 of the Rules of proceedings in the federal executive bodies (Government Order of June 15, 2009 N 477	2	0	0	1	3	22	409
Decision on whether to grant an approval or to notify that an approval is refused (from the date of the registration)	22/30	Article 12 of the Federal Law On Russian citizens' requests consideration of May 2, 2006 № 59	19	1	12	18	26	75	685
Receipt of the decision (from the date of the decision)*	2/4	Paragraph 22 of the Rules of proceedings in the federal executive bodies (Government Order of June 15, 2009 N 477)	7	0	4	6	8	66	646
Total time to receive an approval or a notification that an approval is refused (from the date of the submission)*	25/35	the sum of all stages	26	3	18	25	33	80	682

*The samples are different as different companies use different approaches to timeframes' monitoring