ACTO
ASSOCIATION OF CLINICAL TRIALS ORGANIZATIONS

Timeframes' monitoring (2nd half of 2012 year)

The survey was carried out in February 2013.

The sample included submissions made from July 1, 2012 till December 31, 2012 as well as submissions made before July 1, 2012 if decisions on granting/refusing approvals were taken in 2nd half of 2012.

В опросе приняли участие 26 компаний - членов АОКИ (как фармацевтические компании, так и контрактные исследовательские организации).

26 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 provide changes in average timeframes for issuing approvals to conduct clinical trials and permits to import/export.

Tables 3-7 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	114	22	391	114
to import medicines	8/12	15	4	63	136
to import/export biological materials	13/19	19	5	58	300
to make amendments to the protocol	34/48	60	9	170	180
other approvals (to prolong clinical trials, to involve new sites, to enroll additional patients, etc.)	25/35	35	9	249	320
Total time to obtain approvals to conduct clinical trials and to import/export**	54/76	133	~	~	~

*Time spent to reply to Ethical Council's and FGBU requests wasn't taken into account

** 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. 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	in 4 times and more
to conduct clinical trials*	3,6%	96,4%	20,2%	33,3%	33,3%	6,1%	3,5%
to import medicines	39,7%	60,3%	37,5%	8,8%	11,0%	2,2%	0,8%
to import/export biologocal materials	61,7%	38,3%	29,3%	8,7%	0,0%	0,3%	0,0%
to make amendments to the protocol	43,3%	56,7%	27,8%	17,8%	10,0%	1,1%	0,0%
clinical trials, to involve new sites, to enroll	62,8%	37,2%	22,2%	9,7%	4,1%	0,6%	0,6%

*Time spent to reply to Ethical Council's and FGBU requests wasn't taken into account

Table 3. 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 165*						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	1	1	2	4	12	115
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	15	1	5	9	14	40	90
Receipt of the decision on carrying out/not carriyng out examinations (from the date of the decision)	6/8	1+2	24	5	14	21	30	71	94
Examinations (from the date of the decision)**	30/42	Paragraph 1 of the Article 20 of the Federal Law On Circulation of Medicines	73	15	54	63	91	181	51
Second application submission (from the date of the first application submission)	~	There is no such requirement in the legislation	95	36	64	75	102	264	96
Second application registration (from the date of the submission)	~	There is no such requirement in the legislation	4	1	1	2	4	24	37
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	12	1	5	11	18	46	36
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	17	3	9	14	21	40	114
Total time to begin a trial**	41/57	the sum of all stages	114	22	85	104	136	391	114

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

** Time spent to reply to Ethical Council's and FGU requests wasn't taken into account

Table 4. 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 154*						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)	3	1	1	2	4	20	101
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)	7	2	4	6	7	37	99
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)	8	2	5	7	9	55	137
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	15	4	10	14	17	63	136

Table 5. 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 319*						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)	2	1	1	2	3	13	222
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)	10	1	8	9	14	30	216
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	2	4	6	9	27	300
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	19	5	14	17	22	58	300

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

Table 6. 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 210*						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)	3	1	2	2	4	20	130
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	51	6	46	46	69	163	118
Receipt of the decision (from the date of the decision)*	3/5	Paragraph 10 of the MoH Order of August 31, 2010 N 775n	8	1	7	7	10	48	177
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	60	9	56	57	77	170	180

Table 7. 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 373*						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	4	1	2	2	4	21	229
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	24	1	14	21	29	145	216
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)	10	1	5	7	12	90	320
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	35	9	21	30	42	249	320

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