Overview of the main competencies of Clinical Trials Participants

Presentation for ACTO members

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Ernst & Young

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Purpose: to provide the results of the analysis of the effective Russian legislation for further discussion of the main obligations of the Medical Organization and the Investigator (**"Clinical Trials Participants"**) under Clinical Trial (**"CT"**) Agreements

The list of the applicable legal acts (in priority order):

- Federal Law of 12 April 2010 No. 61-FZ "On Circulation of Pharmaceuticals" ("**Law On Pharmaceuticals**")
- Order of the Ministry of Public Health and Social Development of the Russian Federation of 19 June 2003 No. 266 "On Approving of the Rules on Good Clinical Practice" ("**Rules**")
- "Good Clinical Practice. State Standard P 52379-2005" (approved by the Decree of the Federal Service on Technical Regulation of the Russian Federation of 27 September 2005 No. 232-st) ("**Standard**")

Limitations: The Information stated herein is for introduction of the effective Russian legislation only and shall not be used for preparation of final drafts of clinical trial agreements. The Overview does not include the analysis of the Sponsor's obligations during the conduct of Clinical Trials. Differentiation of competencies of Clinical Trials Participants is approximate. Clinical Trial Agreements may provide for another obligations of the parties depending on the specificity of the relations of the parties under a contract.

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List of possible obligations under Clinical Trial	Competence of the Medical Organization	Competence of the Investigator	Joint competence ("and/or")	Reference to legal act
General Provisions				
appointment of the Investigator and Co-Investigators ("**Research Staff Members**")	X			item 1 of Article 40 of Law On Pharmaceuticals; item 7.1 of Rules
enrollment of patients for participation in CT		X		item 2 of Article 40 of Law On Pharmaceuticals; items 7.5, 7.13 of Rules
familiarization of Research Staff Members with documents, information, functions and obligations under CT		X		item 7.12 of Rules; item 4.2.4 of Standard
prevention of CT documents from destruction			X	item 8.13 of Rules
keeping the list of persons carrying out CT activities		X		item 4.1.5 of Standard

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Usage of a Drug				
usage / application of a drug		X		item 8.5 of Rules; item 4.6.5 of Standard
accounting of a drug			X	item 8.1 of Rules; items 4.6.1, 4.6.3 of Standard
keeping records on receipt of a drug by patients		X		item 8.3 of Rules
compliance with randomization procedure during CT		X		item 8.7 of Rules; item 4.7 of Standard
performance of inventory, registration and consumption of a drug, return of a drug	X			item 8.2 of Rules

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Conduct of Clinical Trial				
informing the Ministry of Public Health and Social Development on initiation of CT conduct	X			item 3.1 of Article 40 of Law On Pharmaceuticals
informing patients and obtaining consents to participate in CT		X		item 4.5 of Rules; items 4.8.1, 4.8.5, 4.8.10 of Standard; Article 43 of Law On Pharmaceuticals
explanation of drug administration rules to patients and review for compliance with the rules		X		item 8.6 of Rules; item 4.6.6 of Standard
keeping documents under CT		X	X	items 8.8, 8.12, 8.13 of Rules; item 4.9.4 of Standard

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submission of reports / data to the sponsor on CT conduct		X		item 9.3 of Rules; items 4.9.1, 4.10.2 of Standard
registration of departures from CT Protocol		X		item 7.19 of Rules
prohibition on interference with monitoring / access to CT records			X	item 7.14 of Rules; items 4.1.4, 4.9.7 of Standard
prohibition on unilateral alterations in CT Protocol		X	X	item 7.18 of Rules; item 4.5.2 of Standard

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medical coverage during and after CT conduct			X	item 5.2 of Rules; item 4.3.2 of Standard
informing the sponsor on death / health hazard for patients during CT conduct		X		item 6 of Article 40 of Law On Pharmaceuticals
reporting to the sponsor on adverse events		X		item 9.4 of Rules; items 4.11.1, 4.11.2 of Standard

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informing patients on diseases requiring treatment			X	item 5.3 of Rules; item 4.3.2 of Standard
Suspension / early termination of Clinical Trial				
suspension of CT	X			item 6 of Article 40 of Law On Pharmaceuticals
notification to the Ministry of Public Health and Social Development on termination of CT conduct for the purposes of making the final decision	X			item 6 of Article 40 of Law On Pharmaceuticals
notification to patients / Medical Organization on suspension or early termination of CT			X	items 10.1, 10.3 of Rules; items 4.12.1, 4.12.2 of Standard

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List of possible obligations under Clinical Trial	Competence of the Medical Organization	Competence of the Investigator	Joint competence ("and/or")	Reference to legal act
Completion of Clinical Trial				
notification to the sponsor on completion of CT (if required)		X		item 4.13 of Standard
notification to the Medical Organization on completion of CT		X		item 10.7 of Rules
submission of conclusions to the sponsor for preparation of CT Report		X		item 11 of Article 40 of Law On Pharmaceuticals

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