

**DECISION**

February 12, 2016

**No. 29**

city of Moscow

**On Rules for Clinical and Clinical Laboratory Trials (Studies) of  
Medical Products**

In accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, paragraphs 4 and 5 of Article 4 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, paragraphs 105 and 106 of Annex No. 1 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014, and by Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 “On Implementation of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union”, the Council of the Eurasian Economic Commission **decided:**

1. To approve the attached Rules for clinical and clinical laboratory trials (studies) of medical products.

2. To establish that for medical products of classes of potential use risk of 3, 2b and implantable medical products clinical trials (studies) for the purpose of registration should be performed in the form of multicenter trials (studies) and meet one of the following conditions:

a) clinical trials (studies) were conducted in accordance with the legislation of member-states of the Eurasian Economic Union and in their territories before January 1, 2016 (by the date of the last visit of the last patient or subject of the trials (studies)) or continued to be performed as of January 1, 2016 (with the completed subject enrolment);

b) clinical trials (studies) were performed in the territories of the states which are not members of the Eurasian Economic Union, before January 1, 2016 (by the date of the last visit of the last patient or subject of the trials (studies)) or continued to be performed as of January 1, 2016 (with the completed subject enrolment) in accordance with recommendations of the International Medical Device Regulators Forum (IMDRF);

c) clinical trials (studies), initiated after January 1, 2016, were performed in accordance with the law of the Eurasian Economic Union, however one of the clinical trials (studies) was performed in one of the Member States of the Eurasian Economic Union.

3. This Decision shall enter into force after 10 calendar days have elapsed from the effective date of the Protocol, signed on December 2, 2015, on the accession of the Republic of Armenia to the Agreement on Common Principles and Rules for the circulation of medical products (medical devices and medical equipment) within the Eurasian Economic Union dated December 23, 2014, but not earlier than after 10 calendar days have elapsed from the date of the official publication of this Decision.

## Members of the Council of the Eurasian Economic Commission:

**For the Republic of  
Armenia**

Seal:  
*Eurasian Economic  
Commission.  
For documents*

**V. Gabrielyan**

**For the Republic of  
Belarus**

Seal:  
*Eurasian Economic  
Commission.  
For documents*

**V. Matyushevskiy**

**For the Republic of  
Kazakhstan**

Seal:  
*Eurasian Economic  
Commission.  
For documents*

**B. Sagintaev**

**For the Kyrgyz  
Republic**

Seal:  
*Eurasian Economic  
Commission.  
For documents*

**O. Pankratov**

**For the Russian  
Federation**

Seal:  
*Eurasian Economic  
Commission.  
For documents*

**I. Shuvalov**

APPROVED  
by Decision No. 29 of the Council of  
the Eurasian Economic Commission  
dated February 12, 2016

**RULES**  
**for clinical and clinical laboratory trials (studies)**  
**of medical products**

I. General provisions

1. These Rules are developed in accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014 and paragraph 4 and 5 of Article 4 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 in order to execute the specified Agreement and establish within the Eurasian Economic Union (hereinafter referred to as the Union) the rules for clinical and clinical laboratory trials (studies) of medical products.

2. For the purposes of these Rules the concepts are used having the following meanings:

“analyte” – a sample component with a measurable property;

“analytical performance of the medical product for in vitro diagnostics” – ability of the medical product for in vitro diagnostics to identify presence or determine content of the specific analyte in a biological sample;

“audit of clinical trials (studies)” – systematic and independent inspection of the documentation, arrangements related to trials (studies) and activities of the parties, participating in clinical trials (studies) of the medical product, which is performed to confirm implementation of activities of the evaluated trial (study), as well as to evaluate compliance of procedures of collection, analysis of data and records with the requirements of the clinical trial (study) programme, standard operating procedures and requirements of the legislation of Member States of the Union;

“investigator’s brochure” – a summary of the current clinical and non-clinical information on the test medical product related to the clinical trial (study);

“double blind method” - a procedure of clinical trials (studies) in which the subjects of the trials and researchers involved in the acquisition and processing of primary data are not aware of the actual application of the medical product to the subjects of the trials (studies);

“clinical trial (study) design” - a methodology to conduct clinical trial (study) involving a person as a subject of the study, with the help of which it is planned to obtain statistically reliable evidence of clinical safety and efficacy of the test (studied) medical product, including use of control groups of subjects of trials (studies), and (or) randomization of subject of trials (studies) to groups, and (or) use of single or double-blind method, as well as selection of basic and additional end points;

“additional end points” - an indicator (indicators) used to check an additional hypothesis of a clinical trial (study);

“legal representative” - a natural or juridical person who, in accordance with the legislation of a Member State of the Union, has a right to give informed consent for participation in a clinical trial (study) on behalf of a potential subject of the trial (study);

“applicant” - a juridical or natural person who initiates a clinical trial (study) and is responsible for its organization and (or) financing;

“individual registration card” - a document intended for inclusion in it of all information provided by the trial (study) programme about each subject of the trial (study);

“inspection of clinical trial (study)” – the action of the authorized authorities, which involves official verification of documentation, equipment, other materials related to the clinical trial

(study) of medical products located in the research center, premises of the applicant, as well as in other organizations having attitude to the trial (study), according to the procedure established by the legislation of Member States of the Union and international treaties and acts constituting the right of the Union;

“informed consent” - a written document in which the subject of the trial (study) or his legal representative confirms voluntary consent to participate in clinical trials (studies) based on the complete information on the clinical trial (study) provided to him;

“test (studied) medical product” – a medical product that is evaluated for safety and (or) efficacy in the course of a clinical trial (study) or clinical laboratory trials (studies) for medical products for in vitro diagnostics;

“investigator” – a natural person who is responsible for performance of a clinical trial (study) in a medical organization or other actual place of trial (study) in case of clinical and laboratory trials (studies) for medical products for in vitro diagnostics. If the trial is performed by a team of investigators, the head of this team is a principal investigator;

“clinical laboratory trials (studies) of a medical product for in vitro diagnostics” - systematic tests of analytical characteristics and, where applicable, clinical efficacy, conducted in order to establish and confirm compliance of the medical product for in vitro diagnostics with the purpose established by the manufacturer;

“clinical efficacy of a medical product for in vitro diagnostics” - ability of the medical product for in vitro diagnostics to show results that correlate with a specific clinical or physiological condition in a target population when it is administered by a user;

“clinical data” – data on safety and (or) efficacy obtained from clinical use of the medical product. Clinical data are also data on safety and (or) efficacy obtained from clinical use of medical products, equivalence of which to the medical product concerned can be proved;

“clinical trials (studies) of a medical product” – any trial (study) involving a person as a subject of the trial (study) conducted to examine safety and (or) efficacy of a test (studied) medical product and (or) method of diagnostics or treatment, associated with its use;

“clinical evidence of efficacy and safety of a medical product” - a report confirming clinical efficacy and safety of the medical product when it is used for the purpose, determined by the manufacturer, on the basis of clinical data;

“clinical evidence of efficacy and safety of a medical product for in vitro diagnostics” - a report containing data confirming scientific validity of the analyte, analytical performance and, where applicable, clinical efficacy of the medical product for in vitro diagnostics when it is used for the purpose determined by the manufacturer;

“Ethics Committee” – an independent expert authority that considers issues of enforcement of rights, safety and health of subjects of trials (studies);

“control medical product” - a product used in a clinical trial (study) for comparison with a test (studies) medical product;

“coordinating investigator” – an investigator appointed by the manufacturer (his authorized representative) and responsible for coordination of work during a multicenter clinical trial (study);

“medical products for in vitro diagnostics” - any instruments, apparatus, devices, equipment, materials, reagents, calibrators, control materials and other products used for medical purposes separately or in combination, as well as with accessories necessary for the use of the specified products (including special software) and intended by the manufacturer for use in in vitro studies of human biological material samples to obtain information on physiological or pathological state, congenital pathology, predisposition to certain clinical condition or disease, compatibility of tissues with a potential recipient, prediction of responses to therapeutic effects, selection of therapeutic agents and (or) treatment control;

“multicenter clinical (clinical laboratory) trial (study)” - a clinical (clinical laboratory) trial (study) that is conducted in two or more medical organizations under a single programme;

“clinical (clinical laboratory) trial (study) monitoring” - activities related to the monitoring of the clinical (clinical laboratory) trial (study) to verify that these studies are conducted and recorded, and a monitoring report is formed in accordance with a programme of clinical (clinical laboratory) trials (studies), documented procedures and these Rules;

“medical product designation” – a decision of the manufacturer regarding the intended use of a medical product based on its specific properties, ensuring achievement of medical use purposes and reflected in technical characteristics and instructions for use;

“scientific validity of the analyte” - connection of the analyte with a clinical or physiological state of a human body;

“single blind method” - a procedure of clinical trials (studies) in which subjects of trials (studies) are not aware of the actual application of the medical product to them;

“primary endpoint” - an indicator (indicators) used to verify the main hypothesis of a clinical trial (study);

“clinical (clinical laboratory) trial (study) report” - a written description of a clinical (clinical laboratory) trial (study) of a medical product involving a human as a subject, combining clinical (clinical laboratory) and statistical descriptions, data presentation and their analysis according to the established form;

“primary data” - any information in the form of original records or certified copies of original records of clinical facts, observations and other events during clinical trials (studies), necessary for monitoring and evaluation of the results of clinical trials (studies);

“amendment to a trial (study) programme” - a written description of changes or formal explanation of the text of the programme that affect or may affect reliability of the results obtained and outcome of the clinical trial (study);

“intended user” - a special group (groups) of persons specified in the supporting documentation for the medical product that can use the medical product in accordance with its purpose;

“clinical (clinical laboratory) trial (study) programme - a document that establishes a rationale, purposes, design of a clinical (clinical laboratory) trial (study) and the proposed analysis, methodology, monitoring, conduction and maintenance of records of the clinical (clinical laboratory) trial (study);

“subject of the trial (study)” – a natural person who participates in a clinical trial (study) within the group to which the test medical product is applied, or within a control group;

“technical file” - documented data confirming the compliance of the medical product with general requirements for safety and efficacy of medical products, requirements for their marking and operational documentation for them, approved by the Eurasian Economic Commission;

“authorized authority” – a government authority of a Member State of the Union authorized to carry out and (or) coordinate activities in the field of circulation of medical products in the territory of this Member State of the Union;

“vulnerable subjects of the trial (study)” -persons whose desire to participate in the clinical trial (study) may be affected by the expectation (reasonable or unreasonable) of some advantages associated with participation in the trial (study) or possible sanctions of superiors in case of refusal to participate in the trial (study). Vulnerable subjects of the trial (study) include students of higher and secondary medical, pharmaceutical and dental educational institutions, junior staff of medical institutions and laboratories, military personnel and prisoners, as well as patients suffering from incurable diseases, persons in care units, low-income and unemployed, persons without citizenship, patient in exigent condition, representatives of national minorities, homeless people, vagrants, refugees, stateless persons, minors and persons under guardianship or trusteeship, as well as persons incapable to give informed consent;

“medical product efficacy” – ability of the medical product to comply with the purpose determined by the manufacturer.

## II. Justification of safety and clinical efficacy of medical product, except for medical product for in vitro diagnostics

3. To prove safety and clinical efficacy of the medical product the manufacturer should:

a) determine requirements from general requirements of safety and efficacy of medical products, requirements for their marking and operational documentation for them, approved by the Eurasian Economic Commission, evidence of compliance with which should be based on clinical data;

b) determine clinical data related to the medical product and its purpose, which was obtained by the search in the scientific literature, from the experience of clinical use or from clinical trials (studies) of the medical product;

c) evaluate clinical data for possibility of their use to prove safety and efficacy of the medical product;

d) carry out clinical trials (studies) of those aspects of safety and efficacy of medical products, for which clinical data is insufficient;

e) perform analysis of both advantageous and disadvantageous clinical data, obtained by search in the scientific literature, from the experience of clinical use or as a result of clinical trials (studies), and make a reasonable opinion on safety and efficacy of the medical product in the form of a report. The analysis is performed taking into account potential risk of use, designation and specific properties of medical product use.

4. Justification of clinical efficacy and safety should be based on clinical data, obtained during clinical trials (studies) for:

a) implantable medical products and medical product of class 3 of potential risk of use, if it is not specially proved that clinical efficacy and safety of the claimed medical product can be proved in another way;

b) medical products, functional characteristics, principle of action, designation, indications for medical use or properties of medical use of which have not been examined previously;

c) modifications of medical products, previously approved for medical use, in case if the changes made are related to new functional characteristics, change of the software, principle of operation, designation or properties of medical use, which have been not examined previously;

d) medical products, containing new materials, which are in contact with human body, not examined previously in terms of biological action and known materials, which are in contact with those human organs and tissues, with respect to which there is no experience of their medical use or in case if such contact is more prolonged than the previously examined one.

5. Clinical data, obtained when performing clinical trials (studies) or when using medical product in states, which are not members of the Union, is recognized as a source of clinical data on the medical product when performing one of the following conditions:

a) clinical data is confirmed by publications in specialized journals or by reports of the World Health Organization on the programme of control of safety and efficacy of medical products ("The WHO prequalification project"), placed on web-site of the World Health Organization in the information and telecommunications network Internet;

b) results of clinical trials (studies) are provided in accordance with recommendations of the International Medical Device Regulators Forum (IMDRF). Evidence of compliance of the clinical trials (studies) performed with the international requirements should be verifiable.

Clinical data for the medical product of classes 3 and 2b of the potential risk of use and implantable medical products should be received as a result of clinical trials (studies). Clinical trials (studies) of medical products of classes 3 and 2b of the potential risk of use, initiated after January 1, 2016, are carried out based on multicenter trials (studies), including in one of the Member States of the Union (hereinafter referred to as the Member States).

6. Clinical data, received for another medical product can be taken into consideration only upon presentation of evidence of its equivalence to the medical product when simultaneously meeting the following conditions:

- a) the medical products considered have similar designation;
- b) technical and biological characteristics of the medical products concerned are the same to the extent as guarantees differences in their clinical efficacy and safety.

7. Clinical evidence of efficacy and safety of the medical product, including clinical data, on which it is based, should be executed as a report, which is a part of the manufacturer's documentation.

8. Report of clinical evidence of efficacy and safety of the medical product should be maintained in actual condition taking into account data, received during after-sales monitoring and (or) if new confirmed information is provided from scientific literature related to its safety and efficacy.

### III. Ethics Committee

9. In order to protect life, health and rights of subjects of tests (studies) Ethics Committees operate in Member States during clinical trials (studies) of medical products.

10. In its work, the Ethics Committee follows principles of the Helsinki Declaration of the World Medical Association of 1964 "Ethical Principles for Medical Research Involving Human Subjects" and the legislation of the Member States.

11. Main operating principles of the Ethics Committee are:

- a) provision of rights, safety and health protection of natural persons, participating in clinical trials (studies) of medical products;
- b) observance of ethical and moral norms and public moral norms;
- c) observance of humanity principles;
- d) inner-directedness;
- e) observance of confidentiality of the information received;
- f) observance of professional ethics norms;
- g) prevention of conflict of interest.

12. The main functions of the Ethics Committee are:

- a) consideration of the programme of clinical trials (studies);
- b) rendering of an opinion on ethic validity or ethic invalidity of clinical trials (studies) of medical products within the submitted project of the programme of clinical trials (studies);
- c) evaluation of compliance of investigator's qualification to the proposed trials (studies).

13. The applicant should submit all documents, required for complete and strict examination of the planned study, to the committee. These documents should include:

- a) an application for consideration;
- b) a programme of the planned trial (study);
- c) individual registration cards, diaries and questionnaires, which will be filled in by the investigator;
- d) a description of data on safety of medical products, a trial (study) of which was planned, as well as its technical characteristics, data of the conducted toxicological studies with description of the existing clinical experience of the medical product use;
- e) an investigator's brochure;
- f) a current revision of the investigator's resume and (or) other materials confirming his qualification;
- g) materials (including advertising) used to attract potential subjects of trials (studies);
- h) a form of informed consent with the description of the process of its receipt and documenting, as well as other forms containing information for potential subjects of trials (studies);

- i) a description of all compensations for participation in the trial (study) for participants of the trials (study), including reimbursement of costs and medical care;
- j) information on conditions of payments and compensation to the subjects of the trial (study);
- k) a description of conditions of insurance of the study participants;
- l) a provision on consent to follow the ethical principles set forth in the relevant guidelines;
- m) previous decisions, adopted by other ethics committees.

14. The Ethics Committee should address the issue of conduction of the proposed clinical trial (study) within the relevant timeframes and give a written opinion in which the trial (study) should be identified with indication of the documents reviewed and the date of decision:

- a) on approval (issue of an opinion) to carry out a trial (study);
- b) on introduction of changes to the submitted documentation to obtain approval (issue of an opinion) to carry out a trial (study);
- c) rejection of approval (issue of an opinion) to conduct a trial (study);
- d) on cancellation (suspension) of the previous approval (issued opinion) to conduct a trial (study).

15. The Ethics Committee includes persons who collectively have necessary qualifications and experience in consideration and expert evaluation of the scientific, medical and ethical aspects of the planned trial (study).

16. The Ethics Committee should carry out activities in accordance with documented procedures.

Its activities should comply with these Rules and legislation of the Member States.

17. The Ethics Committee is responsible that he fully acts in interests of potential subjects of the trial (study), taking into account interests and needs of vulnerable subjects of trials (studies), as well as availability of legal representatives, if necessary.

#### IV. Permission to carry out clinical trials (studies)

18. To carry out clinical trials (studies) of medical products (except for medical products for in vitro diagnostics) a permission of the authorized authority of the Member State in the territory of which it is planned to carry out these trials (studies) should be obtained. To carry out clinical and laboratory trials (studies) a notice in free form should be sent to the authorized authority (expert organization) of the Member State.

19. To obtain a permission to carry out clinical trials (studies) of medical products a manufacturer or his authorized representative sends to the authorized authority, in the territory of which it is planned to carry out a clinical trial (study) of the medical product, an application to obtain a permit to carry out a clinical trial (study) according to the form in accordance with Annex No. 1 with a supporting documentation, containing the following data:

- a) an application of the manufacturer or his authorized representative that the medical product meets the requirements of safety and efficacy, other than properties and characteristics of safety and efficacy of the medical product, which should be examined during clinical trials (studies) and that with respect to them precautions were taken to protect health and safety of subjects of trials (studies);

- b) a copy of Ethics Committee's opinion issued in accordance with these Rules, certified by the manufacturer or his authorized representative;

- c) investigator's brochure, compiled in accordance with requirements according to Annex No. 2;

- d) example of an individual registration card of the subject of the trial (if any);

- e) technical file for the medical product, corresponding to the requirements according to Annex No. 3, except for properties and characteristics of safety and efficacy of the medical product, which should be determined during clinical trials (studies);



f) a programme of the clinical trial (study) with justification of the number of medical products, submitted for the clinical trial (study), timeframes of its performance in accordance with Annex No. 4;

g) a list of adverse events (incidents) in case of which it is necessary to notify the authorized authority (with indication of the period of notification);

h) a copy of a document about conditions of insurance and reimbursement (compensation) of the possible damage in case of adverse events (incidents) in accordance with the legislation of the Member State in the territory of which a clinical trial (study) is carried out.

20. If the originals of documents are drawn up in a foreign language, they shall be submitted with their translation into Russian certified by the manufacturer or its authorized representative.

21. The authorized authority (expert organization) verifies the completeness of the submitted materials and sends to the applicant a decision regarding the possibility of clinical trials (studies) within at most 30 working days.

In case of insufficient information submitted by the applicant and information for making a decision on the possibility to carry out clinical trials (studies), the authorized authority (expert organization) sends to the manufacturer or his authorized representative a request for the submission of necessary information (with indication of the nature of notices and way of their elimination) within 5 working days from the date of receipt of the application to obtain a permit for performance of clinical trials (studies) and supporting documentation.

The specified request is sent once and can be transferred to the manufacturer or his authorized representative personally against receipt, sent by the registered mail or transmitted in electronic form through the use of telecommunication channels or in the form of an electronic document with a digital signature.

The manufacturer or his authorized representative should submit a response to the request of the authorized authority (expert organization) within a period not exceeding 60 working days from the date of receipt of this request. In case if the applicant fails to respond to the request of the authorized authority (expert organization) after 60 working days, the decision is taken by the authorized authority (expert organization) based on documents at its disposal.

The time period from the date of sending the request by the authorized authority (expert organization) until the date of receipt of a response to the request or notification on non-provision of the response to the request is not taken into account in calculating the term for the authorized authority (expert organization) to take a decision regarding the possibility of performance of clinical trials (studies).

If a negative decision regarding the possibility of performance of clinical trials (studies) of the medical product is taken, the authorized authority notifies the manufacturer or his authorized representative in writing or sends a letter by registered mail with a delivery confirmation either in the form of an electronic document with a digital signature or in the electronic form through the use of telecommunications channels. An expert opinion substantiating reasons to refuse the permission to conduct clinical trials (studies) of the medical product is attached to the letter.

#### V. Requirements for medical organizations, carrying out clinical and clinical laboratory trials (studies) of medical products

22. Authorized authorities determine a list of organizations, which have a right to carry out trials (studies) of medical products with the purpose of their registration (hereinafter referred to as the list of organizations), which includes medical organizations for performance of clinical and clinical laboratory trials (studies) of medical products.

23. The list of organizations includes medical organizations for performance of clinical trials (studies) of medical products, corresponding to the following requirements:

a) availability of the license for carrying out of medical activities (with indication of the list of works (services) comprising the medical activities), corresponding to the purpose and scope of application of the medical product which are tested (studied);

b) availability of provisions (standard operating procedures), regulating clinical trials (studies) of medical products, which cover among other things:

qualification requirements and training of the personnel;

cooperation with the Ethics Committee;

receipt of the informed consent;

procedure of carrying out of clinical trials (studies);

registration and reporting of adverse events (incidents) to the authorized authority;

maintenance and keeping of clinical trial (study) documentation;

confidential information protection;

c) availability of conditions to carry out the claimed profile of clinical trials (studies) of medical products;

d) availability of conditions for intensive care and resuscitation;

e) availability of personnel with medical education and document which confirms training in rules of clinical trials (good clinical practice).

24. The list of organizations includes medical organizations for clinical laboratory trials (studies) of medical products for in vitro diagnostics corresponding to the following requirements:

a) availability of the license to carry out medical activities in the field of laboratory diagnostics (clinical laboratory diagnostics);

b) availability of provisions (standard operating procedures), regulating clinical laboratory trials (studies) of medical products for in vitro diagnostics covering among other things:

qualification requirements and training of the personnel;

procedure for equipment verification and calibration;

procedure for clinical laboratory trials (studies);

maintenance and keeping of clinical laboratory trials (studies);

confidential information protection.

25. Authorized authorities consider applications of medical organizations for inclusion in the list of organizations and a set of documents confirming compliance of the medical organization with the requirements set forth in paragraphs 23 and 24 of these Rules and makes a decision on compliance or non-compliance of the medical organization with the requirements of these Rules within 20 working days from the date of filing of the said documents.

If the decision on compliance of the medical organization with the requirements of these Regulations is taken, the authorized authority notifies the medical organization of the decision taken in writing within 3 working days from the date of such decision.

If the decision on non-compliance of the medical organization with the requirements of these Regulations is taken, the authorized authority notifies the medical organization of the decision taken in writing within 3 working days (with rationale) from the date of such decision.

26. The decision of the authorized authority is appealed against in accordance with the legislation of this state.

27. Authorized authorities provide storage, systematization, updating and modification of information on organizations that have a right to carry out trials (studies) of medical products in order to register them, as well as to protect this information from the unauthorized access.

The list of organizations is placed on the websites of the authorized authorities in the information and telecommunications network "Internet" and in the open part of the information system of the Union in the field of medical product circulation.

The authorized authority in the manner established by the legislation of this state controlled compliance of medical organizations having the right to carry out clinical or clinical laboratory trials (studies) of medical products with the requirements of these Rules.

28. The authorized authority of the Member State excludes the medical organization from the list of organizations in the following cases:

a) receipt of an application to exclude the medical organization from the list of organizations signed by the head of the medical organization;

b) based on the results of control of compliance of the medical organizations with the requirements of these Rules carried out by the authorized authority.

29. Within 3 working days from the date of introduction of changes to the information contained in the list of organizations the authorized authorities place the relevant information on their official websites in the information and telecommunications network Internet as well as its presentation to the Eurasian Economic Commission using integrated information system of the Union.

30. The information on organizations included in the list of organizations to interested persons is provided to the authorized authorities in accordance with the legislation of the Member States.

## VI. Requirements for clinical trials (studies) of medical products

31. Clinical trials (studies) of medical products should be carried out in accordance with principles of the Declaration of Helsinki of the World Medical Association of 1964 “Ethical principles for medical research involving human subjects”.

Clinical trials (studies) of medical products should be conducted on the basis of a clinical trial (study) programme so that the results of the trials (studies) can confirm or disprove the clinical safety and efficacy claimed by the manufacturer. The number of observations should be sufficient to ensure statistical reliability, reproducibility of results and scientific validity of the findings.

32. Clinical trials (studies) of medical products should be carried out under the conditions established by the manufacturer for the use of the medical product and should be provided for in the clinical trial (study) programme.

33. The investigator is responsible for carrying out of the clinical trials (study) of a medical product. The investigator should have access to all available technical and clinical data on the test medical product.

34. To provide necessary amount of information on the medical product to investigators, the manufacturer or the manufacturer’s authorized representative provides an investigator’s brochure in accordance with the requirements provided for in Annex No. 2 to these Rules.

35. The clinical trial (study) programme should include information in accordance with the requirements specified in Annex No. 4 to this Rules.

36. Description of the clinical trial (study) design should include:

a) a strategy to ensure clinical relevance and scientific validity of the results with justification of its selection;

b) main and additional end points with justification of their selection and measurement.

37. The clinical trial (study) programme is coordinated with medical organizations and coordinating investigator when carrying out multicenter trials (studies)) and approved by the manufacturer or his authorized representative.

38. In order to carry out a clinical trials (study) of the medical product, the manufacturer or his authorized representative submits the following documents to the medical organization (in case is the original documents are compiled in a foreign language, they are submitted with a translation into Russian, certified by the manufacturer or his authorized representative):

a) permission of the authorized authority to carry out a clinical trial (study) of the medical product;

b) application for carrying out of the clinical trial (study) of the medical product;

- c) an application confirming that the medical product meets all applicable safety and efficacy requirements, excluding those properties and characteristics that should be examined in the course of clinical trials (studies) of medical products;
- d) investigator's brochure;
- e) draft clinical trial (study) programme;
- f) a sample (samples) of the medical product together with accessories necessary for the intended use of the medical product (if accessories are available);
- g) information on the compliance of the medical product with general requirements for safety and efficacy of medical products, requirements for their marking and operational documentation for them;
- h) instruction for use (operational documentation) for the medical product with accessories necessary for the intended use of the medical product (if accessories are available);
- i) documents (materials) containing results of the manufacturer's own trials (studies), including analysis of data on the use of the medical product (if any);
- j) test results for the approval of the type of measuring instruments (for medical products included in the list of medical products relating to measuring instruments for which tests are carried out to confirm the type of measuring instruments);
- k) approval of the Ethics Committee to carry out a clinical trial (study) of the medical product;
- l) a copy of a document on conditions of insurance and reimbursement (compensation) of possible damage in case of adverse events (incidents), carried out in accordance with the legislation of the Member State in the territory of which the clinical trial (study) of the medical product is carried out;
- m) a form of the informed consent;
- n) a form of the individual registration card;
- o) a form of a report of adverse events (incidents);
- p) forms of a report of medical product defects
- q) forms of reports of a clinical trial (study) of the medical product including the interim report.

39. A clinical trial (study) of the medical product of class 3 or 2b of potential use as well as implantable medical product is carried out in a mandatory manner as multicenter trials (studies) including in one of the Member States.

40. The report on the clinical trial (study) (with the application of summary tables (graphs) of the results of the trials (studies) with relevant statistical processing and comments to them) should contain critical evaluation of all data obtained during the trials (studies), including negative data. Such report should be drafted in accordance with Annex No. 5, signed by the investigators and approved by the head of the medical organization.

When carrying out multicenter clinical trials (studies), a general report is prepared, which should be signed by investigators and managers of medical organizations and approved by the coordinating investigator.

41. The applicant has a right to supervise carrying out of a clinical trial (study) of the medical product at all stages by appointing persons of appropriate qualifications and performance of monitoring procedures or independent conformity assessment in order to obtain reliable data.

## VII. Justification of clinical efficacy and safety of medical products for in vitro diagnostics

42. Evidence of compliance of medical products for in vitro diagnostics with general requirements for safety and efficacy of medical products, requirements for their marking and operational documentation for them includes a justification of clinical efficacy and safety of medical products for in vitro diagnostics.

Justification of clinical efficacy and safety is based on determination or confirmation of scientific validity of the analyte, analytical performance and, if applicable, clinical efficacy of the medical product for in vitro diagnostics during its use for the purpose established by the manufacturer.

43. Determination or confirmation of scientific validity of the analyte is not necessary in case if the connection of the analyte with clinical or physiological state of a human body is well known and based on the available information.

44. For a new analyte and new designation of the medical product for in vitro diagnostics the scientific validity of the analyte can be established by one or some of the following ways:

a) on the basis of clinical experience of use of medical products for in vitro diagnostics, determining the same analyte and with the same designation;

b) based on data of the scientific literature;

c) in the course of clinical laboratory trials (studies) of the medical product for in vitro diagnostics.

45. Analytical performance should be established or confirmed by results of clinical laboratory trials (studies) of the medical product for in vitro diagnostics for the claimed medical product for in vitro diagnostics.

In case of inapplicability of values of the analytical and clinical efficacy to the medical product for in vitro diagnostics clinical laboratory trials (studies) of the medical product for in vitro diagnostics are not carried out.

46. Determination or confirmation of clinical efficacy in the course of clinical laboratory trials (studies) of the medical product for in vitro diagnostics is not necessary for medical products for in vitro diagnostics for which clinical efficacy is determined in whole by analytical performance and this fact is well known and based on the available information.

47. Clinical efficacy of the medical product for in vitro diagnostics can be established by one or some of the following ways:

a) in the course of clinical laboratory trials (studies) of the medical product for in vitro diagnostics;

b) based on data of the scientific literature;

c) based on clinical experience of use of the medical product for in vitro diagnostics in the Member States.

#### VIII. Requirements for clinical laboratory trials (studies) of medical products for in vitro diagnostics

48. Clinical trials (studies) of medical products for in vitro diagnostics are carried out as clinical laboratory trials (studies) of medical products for in vitro diagnostics.

Clinical laboratory trials (studies) of medical products for in vitro diagnostics should be carried out based on the programme of clinical laboratory trials (studies) in such a way, that results of trials (studies) can confirm or contest the claimed characteristics of analytical performance and, where applicable, clinical efficacy, the number of the laboratory test performed should be sufficient to ensure statistical confidence of results of trials (studies).

49. The programme of clinical laboratory trials (studies) should be drawn up in accordance with the requirements according to Annex No. 6.

50. Trials (studies) of medical products for in vitro diagnostics intended for the use by persons without medical education in the field of clinical laboratory diagnostics should be carried out under conditions simulating conditions of intended use of these medical products.

51. Clinical laboratory trials (studies) of medical products for in vitro diagnostics designed for the use in combination with each other in the form of analytical systems can be carried out within one trial (study) (together with accessories necessary for the intended use of medical products).

52. Specimens used in clinical laboratory trials (studies) of medical products for in vitro diagnostics can be collected from different sources, including residual samples, retained samples or intentionally selected samples.

Residual samples are considered residues of samples, collected in the course of diagnostic and treatment process.

Retained samples or specimens are characterized samples or specimens, which were selected previously and obtained from repositories (including banks of tissues, standard panels, archival test strains and other collections).

Intentionally selected samples are samples, which were taken from patients especially for the use in the specific trial (study). In this case, the patient should submit an informed consent signed by him.

53. The results of testing of samples during clinical laboratory trials (studies) of the medical product for in vitro diagnostics should not be used for other purposes than evaluation of its analytical and (or) clinical efficacy if ethical considerations fully shared by all investigators participating in the trial (study), do not imply the opposite (including the need to inform subjects of the trials (studies) of the testing results). In this case, the investigator assumes full responsibility for the consequences of other use of the data obtained.

54. Clinical laboratory trials (studies) of medical products for in vitro diagnostics of new or especially dangerous infectious diseases or rare diseases, including natural focal infectious diseases, can be carried out under laboratory conditions using retained samples and (or) samples, obtained in the genetic engineering way. In these cases, the manufacturer, in agreement with the authorized authority of the Member State, carries out post-registration clinical monitoring of safety and efficacy of medical products in accordance with the rules for monitoring of safety, quality and efficacy of medical products approved by the Eurasian Economic Commission in order to obtain statistically reliable characteristics of their analytical and (or) clinical efficacy.

55. To carry out a clinical and laboratory trial (study) of the medical product for in vitro diagnostics, the manufacturer or his authorized representative submits the following documents to the medical organization (if the originals of the documents are in a foreign language, they are submitted with a translation into Russian, certified by the manufacturer or his authorized representative):

a) application for carrying out of a clinical laboratory trial (study) of the medical product for in vitro diagnostics;

b) application confirming that this medical product for in vitro diagnostics meets all applicable safety and efficacy requirements, excluding those properties and characteristics that should be examined during clinical and laboratory trials (studies) of the medical product for in vitro diagnostics;

c) draft clinical and laboratory trial (study) programme;

d) samples (sample) of the medical product for in vitro diagnostics together with accessories necessary for the intended use of the medical product (if accessories are available);

e) information on the compliance of the medical product with general requirements for safety and efficacy of medical products, requirements for their marking and operational documentation for them;

f) instructions for use (operational documentation) for the medical product for in vitro diagnostics with accessories necessary for the intended use of the medical product (with accessories);

g) documents (materials) containing the results of the manufacturer's own trials (studies), including analysis of data on the use of the medical products for in vitro diagnostics (if any);

h) test results for the approval of the type of measuring instruments (for medical products for in vitro diagnostics included in the list of medical products relating to measuring instruments for which tests are carried out in order to approve a type of measuring instruments).

56. The programme of clinical and laboratory trials (studies) of the medical product for in vitro diagnostics is coordinated with medical organizations and approved by the manufacturer or his authorized representative.

57. When carrying out clinical and laboratory trials (studies) of the medical product for in vitro diagnostics the following is performed:

- a) procedures in accordance with the programme of clinical and laboratory trials (studies);
- b) keeping of unambiguously identifiable records of the evaluation of functional characteristics, containing all results of measurements;
- c) evaluation and analysis of obtained data in order to confirm their compliance in accordance with the claimed characteristics;
- d) modification of operational documentation for the medical product for in vitro diagnostics based on the results of trials (studies) (if necessary).

58. Results of trials (studies) of the medical product for in vitro diagnostics are considered negative in cases if the results of clinical and laboratory trials (studies) of medical product for in vitro diagnostics show that the analytical and (or) clinical efficacy of the said medical product is lower than the claimed by the manufacturer.

59. The report on clinical and laboratory trials (studies) of the medical product for in vitro diagnostics should contain a critical evaluation of all data obtained during trials (studies), including negative data. Such report should be made in the form according to Annex No. 7, signed by the investigators and approved by the head of the medical organization.

In case of multicenter clinical and laboratory trials (studies) of the medical product for in vitro diagnostics a general report which should be signed by investigators and heads of medical organizations and approved by the coordinator investigator is drawn up.

---

Seal:

*Eurasian Economic Commission. For documents*

ANNEX No. 1  
to the Rules for clinical and clinical laboratory  
trials (studies) of medical products

(form)

**APPLICATION**  
**on permission for clinical trials**  
**(studies) of medical products**

\_\_\_\_\_ (full name of the medical product)

\_\_\_\_\_ (short name of the medical product (if any))

No. \_\_\_\_\_ dated \_\_\_\_\_ “ \_\_\_\_ ”, 20 \_\_\_\_\_

1. Name and address of the manufacturer \_\_\_\_\_
2. Address of the place of manufacture of the medical product (manufacturing site) \_\_\_\_\_
3. Name and address of the authorized representative of the manufacturer (in case of manufacture not in the territories of the Member States of the Eurasian Economic Union) \_\_\_\_\_
4. Surname, name, patronymic (if any), address, phone and fax numbers, e-mail (if any) of a contact person of this application \_\_\_\_\_
5. In case of reapplication on this medical product date and number of the previous application \_\_\_\_\_
6. Powers to carry out clinical trials (studies) \_\_\_\_\_
7. Period of clinical trials (studies) \_\_\_\_\_
8. Data on investigators, coordinating investigator (if any) \_\_\_\_\_  
(Full name, place of work, title, academic degree (if any))
9. Identification and description of the test medical product, including the list of versions, configurations and accessories to which test results are applied \_\_\_\_\_
10. Medical product designation \_\_\_\_\_
11. Class of potential risk of use \_\_\_\_\_
12. Code of the type in accordance with the nomenclature of medical products, used within the Eurasian Economic Union \_\_\_\_\_
13. Purposes and hypotheses of a clinical trial \_\_\_\_\_
14. Number of subjects of trials (studies) \_\_\_\_\_



15. Number of samples of the test medical product\_\_\_\_\_

16. Medical organization for carrying out of clinical trials (studies) with indication of the address, phone and fax numbers, as well as e-mail (if any)

Signature of Head of the manufacturing organization or authorized representative:

---

(surname, name, patronymic (if any), place of work, position)

Signature of the applicant:

---

(surname, name, patronymic (if any), place of work, position)

The list of the attached documents:

- 1) programme of clinical trials (studies);
- 2)...

**REQUIREMENTS**  
**to the contents of the investigator's brochure on the medical product**  
**(except for medical products for in vitro diagnostics)**

I. General description of the medical product

1. The investigator's brochure should contain the following information with description of the medical product:

- a) medical product name;
- b) general description and designation of the medical product;
- c) information, which allows to identify the medical product in particular model number, including version (modification) number (if any) or reference to the identifiable model number;
- d) type of the medical product in accordance with the nomenclature of medical products used within the Eurasian Economic Union;
- e) information on intended users;
- f) principles of action of the medical product;
- g) class of risk and applicable classification rules in accordance with rules for classification of medical products depending on potential risk of use, approved by the Eurasian Economic Commission;
- h) description of new properties and characteristics of the medical product;
- i) description of accessories, other medical products and products, which are not medical, but which should be used in combination with the test medical product;
- j) description and (or) list of possible versions (configurations) of the test medical product;
- k) general description of the main functional elements, including diagrams, photos and figures, demonstrating main parts (components) of the medical product and including descriptive notes, sufficient for understanding of diagrams, photos and figures;
- l) description of materials, which come into direct or indirect contact with human body.

II. Medical product use

2. The investigator's brochure should contain the following information on the use of the medical product:

- a) medical product designation;
- b) installation (commissioning) instruction;
- c) instruction of use, including conditions of transportation and storage.

III. Data on testing of medical products

3. The investigator's brochure should contain the following information on previously performed testing of medical products:

- a) results of preclinical tests and studies;
- b) available clinical data, including:
  - data of the scientific literature regarding construction, safety, efficacy and designation of similar or equivalent medical products;
  - data of the scientific literature regarding construction, safety, efficacy and designation of similar or equivalent medical products of the same manufacturer, including data on time of their circulation in the market, as well as data on all identified problems with safety and efficacy and corrective actions taken;

- c) results of risk analysis, data on adverse effects and contraindications;
- d) list of possible adverse events (incidents) and adverse effects of the medical product;
- e) list of standards, applied in whole or in part.

ANNEX No. 3  
to the Rules for clinical and clinical laboratory  
trials (studies) of medical products

**REQUIREMENTS**  
**to the contents of the technical file for the medical product**  
**(except for medical products for in vitro diagnostics)**

I. General description of the medical product

1. A technical file should contain the following information with the description of the medical product:

- a) medical product name;
- b) general description and designation of the medical product;
- c) information, which allows to identify the medical product in particular model number, including version number (if any) or reference to the identifiable model number;
- d) type of the medical product in accordance with the nomenclature of medical products used within the Eurasian Economic Union;
- e) intended users;
- f) principles of action of the medical product;
- g) class of potential risk of use and applicable classification rules in accordance with rules for classification of medical products depending on potential risk of use, approved by the Eurasian Economic Commission;
- h) explanation of properties and characteristics of the medical product;
- i) description of accessories, other medical products and products, which are not medical, but which should be used in combination with the examined medical product;
- j) description and (or) list of possible versions (configurations) of the examined medical product;
- k) general description of the main functional elements (diagrams, photos and figures, demonstrating main parts (components) of the medical product including descriptive notes to the diagrams, photos and figures);
- l) description of materials, which come into direct or indirect contact with human body.

II. Description of the medical product

2. The technical file should contain a list of main characteristics, dimensions and directions on operation of the medical product, its versions and accessories, which are in the technical documentation of the medical product and other materials, available to the end user, as well as a list of standards used by the manufacturer.

III. Reference to similar or previous medical product modifications

3. If the information on similar or previous modifications of the medical product is used to prove compliance with the general requirements for safety and efficacy of medical products, requirements for their marking and operational documentation for them, approved by the Eurasian Economic Commission (hereinafter referred to as the general requirements), the technical file should contain a brief description of:

- a) previous modifications of the examined medical product (if any);
- b) similar modifications of medical products being in circulation within the Eurasian Economic Union and in international markets.

#### IV. Supporting information

4. The technical file should contain:

- a) data on marking of the medical product and its package (marking designs);
- b) instruction of use (operational documentation) of the medical product.

#### V. Design and development of the medical product

5. The technical file should contain information which allows to obtain a general picture of the main stages of design of the examined medical product. This information can be provided in the form of process flow charts.

#### VI. Manufacturing processes

6. The technical file should contain information which allows to obtain a general picture of manufacturing processes. This information can be provided in the form of a process flow chart, which gives a general picture of manufacture, assembly, final testing of the medical product and final package of the medical products.

#### VII. Manufacturing sites

7. The technical file should identify the manufacturing sites, on which the manufacturing activities related to the concerned medical product are carried out. If there are certificates of quality management system or equally valuable documents for these sites, their copies should be attached to the technical file.

#### VIII. Data on compliance with general requirements

8. The technical file should include data on compliance with general requirements.

#### IX. Results of analysis and risk managements

9. The technical file should contain a list of risks, identified during risk analysis and description of ways of management of these risks in order to reduce them to the permissible level.

#### X. Verification and validation activities

10. The technical file should contain the following information and documents on verification and validation, which were used to prove the compliance of the medical product with general requirements (including applicability of general requirements):

- a) test results in testing laboratories (centers);
- b) results of laboratory and (or) factory tests, including results of tests under conditions simulating operational ones;
- c) results of laboratory tests on animals to confirm the correctness of the concept of the finished medical product;
- d) declarations of conformity to standards from the list of standards, as a result of the use of which, on a voluntary basis, the compliance of the medical product with general requirements is guaranteed in whole or in part;
- e) declaration of conformity to standards that are not included in the list specified in subparagraph "d" of this paragraph, with justification of their application;

f) An overview of published literature sources regarding the examined medical product or similar medical products.

11. The technical file should contain:

- a) information on biological compatibility;
- b) information on drug products contained in the examined medical product;
- c) information on the biological safety of medical products, including cells, tissues or their derivatives, taken from humans or animals;
- d) information on sterilization methods;
- e) information on verification and validation of software when designing the medical product;
- f) a report on the justification of the clinical efficacy and safety of the medical product.

12. Statement of results of the conducted clinical trials (studies), except for the conclusions, should include protocols of trials (studies) in full.

13. The technical file should contain a list of all materials that are in direct or indirect contact with the patient's body if, in order to characterize physical, chemical, toxicological and biological characteristics of the material, it is necessary to carry out biological compatibility tests in accordance with the results of the risk analysis. The technical file should include detailed information on the tests carried out, standards applied, test protocols, analysis of the data obtained and summary of test results.

14. If the medical product includes drug products, the technical file should contain detailed information on the drug products, their manufacturer (manufacturers), the reason for inclusion in the medical product, safety of use and the mechanism of action in the product when using as intended, a document confirming registration of the drug product in the country of manufacture of the drug product.

15. The technical file should contain a list of all materials of animal or human origin used in the medical product. The technical file should contain detailed information on these materials related to the selection of sources (donors), sampling, processing, storage, research and handling of tissues, cells and substances of animal or human origin.

The technical file should also include results of process validation, confirming the existence of production procedures that minimize biological risks, in particular with respect to viruses and other pathogens.

It should also include a description of the record keeping system that allows traceability from the sources of materials to the finished medical product.

16. If the medical product is delivered in a sterile state, the technical file should contain information on the validation of the sterilization process (including test for biological burden, presence of pyrogenic substances, and residual amount of sterilizing agent) and validation of the packaging process. The information on validation should include the method used, achieved level of sterility, standards applied, sterilization protocol developed in accordance with these standards, and summary of the results obtained.

17. The technical file should contain information on the process of design and development of the software and validation of the software used in the finished medical product. This information includes a summary of results of verification, validation and results of tests performed by the producer organization, as well as information on all available hardware configurations and operating systems identified in the supporting documentation.

18. The technical file should contain information on performed animal studies to confirm compliance with general requirements (if any). The technical file should describe objectives of these studies, methodology, results, analysis and conclusions.

**REQUIREMENTS**  
**to the contents of the programme of clinical trial (study)**  
**of the medical product**

I. General description of the medical product

1. The programme of the clinical trial (study) should contain the following information with description of the medical product:

- a) medical product name;
- b) manufacturer and authorized representative of the medical product with indication of the address, phone number, e-mail and contact person;
- c) general description and designation of the medical product;
- d) information, which allows to identify the medical product in particular model number, including version (modification) number (if any) or reference to the identifiable model number;
- e) type of the medical product in accordance with the nomenclature of medical products used within the Eurasian Economic Union;
- f) group of patients and medical indications for which the medical product is designed;
- g) designation of the medical product;
- h) class of risk and applicable classification rules in accordance with rules for classification of medical products depending on potential risk of use, approved by the Eurasian Economic Commission;
- i) explanation of new properties and characteristics of the medical product;
- j) description of the way in which traceability is achieved during and after the clinical trial (study) of the medical product (by assignment of a batch number, lot number, factory serial numbers or otherwise);
- k) data on materials, which are in contact with human body;
- l) data on control medical products.

II. Data on clinical trials (studies)  
of the medical product

2. The programme of the clinical trial (study) of the medical product should contain the following information on the procedure of the clinical trial (study):

- a) name and identification data on the clinical trial (study);
- b) address and name of the medical organization carrying out clinical trials (studies);
- c) data on investigators, coordinating investigator (if any) and testing organization;
- d) description of special surgical and other medical procedures regarding the use of the medical product;
- e) requirements for the experience and training of the medical specialists;
- f) description of clinical trial (study) design;
- g) description of risks and benefit of use of the medical product when carrying out clinical trials (studies);
- h) description of conditions of carrying out of clinical trials (studies) determined by the manufacturer;
- i) description of accessories, other medical products and products which are not medical, but which are provided for the use in combination with the medical product;
- j) purpose and hypotheses of the clinical trial (study);
- k) selection of subjects of clinical trials (studies) including their number;

- l) number of the used test medical products (with justification);
- m) description of procedures of clinical trials (studies);
- n) plan of monitoring during clinical trials (studies) with indication of frequency of visits, number of monitors and their contacts;
- o) statistical methods of data analysis;
- p) process of receipt of the informed consent of subject of clinical trials (studies);
- q) description of ethical aspects of clinical trials (studies) including interests of vulnerable subjects of clinical trials (studies).



ANNEX No. 5  
to the Rules for clinical and clinical laboratory  
trials (studies) of medical products

**FORM**  
**of the report on the clinical trial (study)**  
**of the medical product**

APPROVED

\_\_\_\_\_  
(Head of the medical organization, surname, name,  
patronymic, signature (coordinating investigator,  
surname, name, patronymic, signature – in case of  
multicenter studies))

**REPORT**  
on the clinical trial (study) of the medical product

\_\_\_\_\_  
(medical product name)

No. \_\_\_\_ dated \_\_\_\_ “ \_\_\_\_”, 20 \_\_\_\_

1. Drafted by

\_\_\_\_\_  
(name and address of the medical organization)

2. Powers to carry out a clinical trial (study) \_\_\_\_\_

3. Authorization to carry out clinical trials (studies) \_\_\_\_\_

4. Period of the clinical trial (study) \_\_\_\_\_

5. Name and address of the manufacturer \_\_\_\_\_

6. Address of a place of manufacture of the medical product (manufacturing site) \_\_\_\_\_

7. Name and address of the authorized representative of the manufacturer (for manufacturers from third countries) \_\_\_\_\_

8. Data on investigators

\_\_\_\_\_  
(surname, name, patronymic (if any), place of work, title, academic degree (if any))

9. Identification and description of the test medical product, including the list of versions, configurations and accessories to which results of clinical trials (studies) are applied \_\_\_\_\_

10. Medical product designation \_\_\_\_\_

11. Class depending on the potential risk of use \_\_\_\_\_

12. Code of the type in accordance with the nomenclature of medical products, used within the Eurasian Economic Union \_\_\_\_\_

13. Purposes and hypotheses of a clinical trial (study)\_\_\_\_\_

14. Scheme of the clinical trial (study) including description of end points\_\_\_\_\_

15. Number of subjects of the clinical trial (study) (in case of multicenter trials (studies) number of subject of clinical trials (studies) in each medical organization)\_\_\_\_\_

16. Number of samples of the test medical product  
\_\_\_\_\_

17. Medical organization in which clinical trials (studies) were carried out (for multicenter trials (studies))\_\_\_\_\_

18. Statistically processed data of the clinical trial (study)\_\_\_\_\_

19. Evaluation of results of clinical trials (studies)\_\_\_\_\_

20. Conclusions based on the results of clinical trials (studies)\_\_\_\_\_

Signatures of Heads of medical organizations  
(in case of multicenter trials (studies))

\_\_\_\_\_  
(surname, name, patronymic (if any), place of work, position)

\_\_\_\_\_  
(surname, name, patronymic (if any), place of work, position)

Signatures of investigators:

\_\_\_\_\_  
(surname, name, patronymic (if any), place of work, position)

\_\_\_\_\_  
(surname, name, patronymic (if any), place of work, position)

The list of the attached documents:

- 1) programme of the clinical trial (study);
- 2) initial data of the clinical trial (study).

**REQUIREMENTS**  
**to the contents of the programme of the clinical laboratory trial (study)**  
**of the medical product for in vitro diagnostics**

I. General description of the medical product for in vitro diagnostics

1. The programme of clinical and laboratory trials (studies) should contain the following information with description of the medical product for in vitro diagnostics:

- a) name of the medical product for in vitro diagnostics;
- b) manufacturer and authorized representative of the medical product for in vitro diagnostics with indication of the address, phone, e-mail and contact person;
- c) general description and designation of the medical product for in vitro diagnostics;
- d) information, which allows to identify the medical product for in vitro diagnostics in particular model number, including version (modification) number (if any) or reference to the identifiable model number;
- e) type of the medical product for in vitro diagnostics in accordance with the nomenclature of medical products used within the Eurasian Economic Union;
- f) characteristics of samples and specimens, used in clinical and laboratory trial (study);
- g) class of risk and applicable classification rules in accordance with rules for classification of medical products depending on potential risk of use, approved by the Eurasian Economic Commission;
- h) explanation of new properties and characteristics of the medical product for in vitro diagnostics.

II. Data on clinical and laboratory trials (studies)  
of the medical product for in vitro diagnostics

2. The programme of clinical and laboratory trials (studies) of the medical product for in vitro diagnostics should contain the following information on the procedure of the trial (study):

- a) purpose and tasks of the clinical and laboratory trial (study);
- b) name of the medical organization, taking part in the clinical and laboratory trial (study);
- c) places of carrying out of measurement (analysis) (if they are located not in the specified medical organizations);
- d) data analysis methods;
- e) statistical significance;
- f) size of the sample for evaluation of clinical efficacy values;
- g) target population;
- h) sample suitability criteria, sample volume and criteria of sample exclusion;
- i) details of pre-analytical stage;
- j) procedures of blank samples;
- k) recording of impact of interference factors caused by the conditions of sampling, or pathological (physiological) state of the sample donor or treatment;
- l) selection and justification of the comparison method;
- m) calibration procedures, including data on calibrator traceability;
- n) criteria for retesting and data deletion;
- o) appropriate measures to prevent the risk of infection of the user.

ANNEX No. 7  
to the Rules for clinical and clinical laboratory  
trials (studies) of medical products

**FORM**  
**of the report on the clinical and laboratory trial (study)**  
**of the medical product for in vitro diagnostics**

APPROVED

\_\_\_\_\_  
(Head of the medical organization, surname, name,  
patronymic, signature (coordinating investigator,  
surname, name, patronymic, signature – in case of  
multicenter studies))

**REPORT**  
on the clinical and laboratory trial (study) of  
the medical product for in vitro diagnostics

\_\_\_\_\_  
(name of the medical product for in vitro diagnostics)

No. \_\_\_\_\_ dated \_\_\_\_\_ “ \_\_\_ ”, 20 \_\_\_\_\_

1. Drafted by

\_\_\_\_\_  
(name and address of the medical organization)

2. Powers to carry out a clinical and laboratory trial (study) \_\_\_\_\_

3. Notice of the clinical and laboratory trial (study) \_\_\_\_\_

4. Period of the clinical and laboratory trial (study) \_\_\_\_\_

5. Name and address of the manufacturer \_\_\_\_\_

6. Address of a place of manufacture of the medical product for in vitro diagnostics  
(manufacturing site) \_\_\_\_\_

7. Name and address of the authorized representative of the manufacturer (for manufacturers  
from third countries) \_\_\_\_\_

8. Data on investigators

\_\_\_\_\_  
(surname, name, patronymic (if any), place of work, title, academic degree (if any))

9. Identification and description of the test medical product for in vitro diagnostics, including the  
list of versions, configurations and accessories to which results of clinical trials (studies) are  
applied \_\_\_\_\_

10. Designation of the medical product for in vitro diagnostics \_\_\_\_\_

11. Class depending on the potential risk of use \_\_\_\_\_

12. Code of the type in accordance with the nomenclature of medical products, used within the Eurasian Economic Union\_\_\_\_\_

13. Purposes of the clinical laboratory trial (study)\_\_\_\_\_

14. Selection and justification of comparison method\_\_\_\_\_

15. Size of the sample for evaluation of values of analytical and, where applicable, clinical efficacy\_\_\_\_\_

16. Number of samples of the test medical product for in vitro diagnostics  
\_\_\_\_\_

17. Medical organization in which clinical and laboratory trials (studies) were carried out, and (or) places of measurements\_\_\_\_\_

18. Statistically processed data of the clinical and laboratory trial (study)\_\_\_\_\_

19. Evaluation of results of clinical and laboratory trials (studies)\_\_\_\_\_

20. Conclusions based on the results of clinical and laboratory trial (study)\_\_\_\_\_

Signatures of Heads of medical organizations  
(in case of multicenter trials (studies))

\_\_\_\_\_  
(surname, name, patronymic (if any), place of work, position)

\_\_\_\_\_  
(surname, name, patronymic (if any), place of work, position)

Signatures of investigators:

\_\_\_\_\_  
(surname, name, patronymic (if any), place of work, position)

\_\_\_\_\_  
(surname, name, patronymic (if any), place of work, position)

The list of the attached documents:

- 1) programme of the clinical laboratory trial (study);
- 2) initial data of the clinical laboratory trial (study).