The Eurasian Economic Union has approved new Rules of good clinical practice

FAO pharmaceutical companies, manufacturers of pharmaceuticals, and medical organisations.

Pepeliaev Group advises that the Council of the Eurasian Economic Commission has updated the Rules[1] of good clinical practice.

The Council of the Eurasian Economic Commission (EEC) has updated the Rules of Good Clinical Practice of the Eurasian Economic Union (EAEU). Resolution No. 63 of the Council of the EEC dated 1 August 2025, approves a new version of the EAEU's Rules of Good Clinical Practice (the "Rules"), which were previously adopted by Resolution No. 79 of the Council of the EEC dated 3 November 2016.

The purpose of the updates is to align the Rules with the updated version of the international Guidance on Good Clinical Practice ICH E6 (R2).

The amendments are aimed at harmonising the Rules with international standards. They entail the following: electronic systems for data processing being implemented; terminology being updated; the obligations of responsible participants in clinical studies being adjusted; and procedures being clarified for submitting safety data.

Updating the terminology

In accordance with the new version, the following are proposed:

- to add the terms "validation of computerised systems" and "certified copy" to the Rules;
- to exclude the definition of "monitor" from the Rules;
- to replace the term "researcher (medical institution)" with "researcher (medical organisation)". This replacement is stipulated throughout the entire text of the Rules to ensure that the terms used are stated in accordance with international standards and EAEU sectoral regulation.

The key new development us the new wording defining the term "clinical study". In the current version of the Rules, the definition contains conditions which, if met, a study of a medicinal product is considered a clinical study. These conditions cover specific features of prescription (outside routine clinical

---

[1] https://docs.eaeunion.org/documents/447/10180/

practice and at the same time as the patient is included in the trial), along with additional diagnostic and monitoring procedures for the medicine.

In the new version, the above conditions have been excluded:

A clinical study is any study involving humans as subjects that is aimed at identifying or confirming the clinical and pharmacological effects of medicines, identifying adverse reactions, and studying pharmacokinetics to assess safety and effectiveness.

Pepeliaev Group's comment

It is necessary to comply with the Rules when conducting any studies of medicines about which data is submitted to the authorised bodies of member states of the EAEU, as well as when other clinical studies are carried out that may impact the safety and well-being of a person (the person being tested). It can be concluded that the application of the new version of the Rules will also extend to cases involving post-registration studies of safety conducted in accordance with the provisions of the EAEU's Rules of good pharmacovigilance practices.

Extending the scope of participants' responsibilities of in clinical trials

The amendments to the Rules entail changes in the list of responsibilities of participants in clinical studies.

The obligations of researchers have been expanded. In comparison with the existing Rules, researchers will now have additional duties:

• to monitor the work of employees / other individuals entrusted with carrying out tasks in the study	• to properly maintain primary documents and records of the study, reflecting all significant data for each participant in the study
• to assure themselves that the individuals engaged for the purposes of the study are qualified to an appropriate level	• to inform the treating physician that the patient is participating in the study on condition that the patient has consented to such notification (note: previously, this provision had the nature of a recommendation)
• to implement measures ensuring that the individuals who are engaged properly perform their obligations as well as ensuring the integrity and security of the data obtained	

The new responsibilities of sponsors include the following obligations:

• to ensure a quality management system at all stages of a clinical study based on a risk-based approach	• to have standard operating procedures for using electronic systems that describe installing, setting up, and using the systems, validating and testing them, collecting and processing data,

	system support, security, change management, backup and recovery, emergency action plans, and decommissioning
• to identify processes and data that are critical for protecting participants in a study and that ensure the results are reliable	• to document the measures for managing quality and communicate them to interested participants
• to identify risks for critical processes and data of a clinical study at both the systemic level and the level of the specific study	• to oversee all duties and functions being performed on behalf of the sponsor
• to assess the risks that are identified by comparing them with existing control measures and determine whether the risks are acceptable	• to ensure the integrity of data when electronic systems are used
• to control an investigator's access to data from an individual participant's registration card	• to develop a systematic approach to monitoring clinical trials (on-site, centralised, or a combination of these)
• to base the approach to validating electronic systems for working with data from studies on an assessment of the system risks and its potential impact on the study	• in cases where non-compliance with applicable requirements is identified on the part of participants in studies, to carry out an analysis of the causes and take corrective or preventive actions

The obligation of sponsors has been removed to notify authorised bodies that clinical studies have begun.

Changes in the requirements for the documents from clinical studies

The structure has been revised of the protocol of a clinical study. It is permitted for information concerning only a single study centre to be documented separately within the protocol or agreement, while part of the data may be contained in other documents with a reference to them within the protocol (e.g., in the researcher's brochure).

The researcher's brochure must use the wording of the updated terminology. Additionally, it is now mandatory to indicate the number, version, and the date of the previous revision of the brochure on its title page.

Furthermore, in view of the removal the obligation of sponsors to notify authorised bodies that clinical trials have begun, it has been proposed that a communication to this effect be excluded from the list of the required study documents.

The new version of the Rules also specifies that sponsors and researchers should maintain records of where documentation from the study is stored. The storage system must ensure that the documents are identifiable, versions of them are traceable and retrievable, and the documents are accessible.

Updating the procedure for submitting information about safety

The procedure for reporting information

The submission of information regarding serious unexpected adverse reactions applies to all similar reactions discovered at research centres, as well as reactions in clinical studies involving active substances used in such studies, regardless of their form, dosage, regimen, or indication.

In the new version of the Rules, it is established that, in cases where aggregated data cannot be provided or there is another need to do so, rapid reports are permitted.

Provision is made for sponsors to ensure that information about serious unexpected adverse reactions is submitted to the expert council (independent ethical committee) of relevant research centres through being passed to the centre's investigator. The terminology used in these communications must adhere to the Medical Dictionary for Regulatory Activities (MedDRA).

Reporting deadlines

The new Rules establish that the sponsor has an obligation to promptly report information about all serious unexpected adverse reactions relating to the medicine under investigation. The deadlines for submitting such information remain unchanged: 7 days for adverse reactions leading to death or a threat to life, and 15 days for other serious unexpected adverse reactions.

A final deadline for submitting reports on serious unexpected adverse reactions has been established. This is from the date of permission to conduct a clinical trial until the date of the last visit by the last participant in the study.

Content of information to be considered

Serious adverse events will include cases that are significant from a medical perspective but do not pose a threat to the patient's life and do not require hospitalisation. In such situations, based on a medical and scientific evaluation, a decision may be taken to notify urgently (by express reporting).

The new version of the Rules proposes the exclusion of the established requirements for submitting safety information regarding placebos unless a causal relationship is established between them being administered and serious unexpected adverse reactions occurring.

Regulatory sources

The new Rules do not allow for the opportunity to apply additional requirements for submitting information about identified serious unexpected adverse reactions in accordance with the national legislation of EAEU member states. Thus, the Rules provide for a single reporting mechanism to be created.

Introduction of an electronic format for periodic safety reports

In connection with the announced implementation of electronic systems for data processing under the Rules, the electronic submission of periodic safety reports has been established. A requirement has been established to ensure that text search functionality is implemented in documents.

The report may be drawn up in Russian, or in English with an obligatory Russian translation of the summary and conclusions. A translation of the other sections of the report must be completed within 30 calendar days if a request to this effect is received from the authorised body.

Periodic safety reports will not be mandatory for clinical studies lasting for less than one year.

What to think about and what to do

The EAEU's new Rules of Good Clinical Practice will come into effect on 9 March 2026 (180 days after being officially published). For participants in clinical studies it is recommended:

- to evaluate business processes relating to conducting clinical studies and to update internal documents (standard operating procedures, instructions, guidance, and other documents relating to their implementation);
- to adjust the forms pf documentation for conducting clinical studies;
- to update the rights and obligations of participants in clinical studies in agreements for conducting such studies, and so on.

Help from your adviser

The lawyers of Pepeliaev Group stand ready to advise on issues connected how to apply legislation in the field conducting clinical studies. This includes drafting agreements for conducting clinical studies and updating internal documents, as well as other matters**.**

Contact details

Konstantin Sharlovskiy
Partner

Tel: +7 (495) 767 00 07
K.Sharlovskiy@pgplaw.ru

Taisiia Kubrina
Senior Associate