Clinical trials in the Eurasian Economic Union

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doi: 10.56012/odis4682

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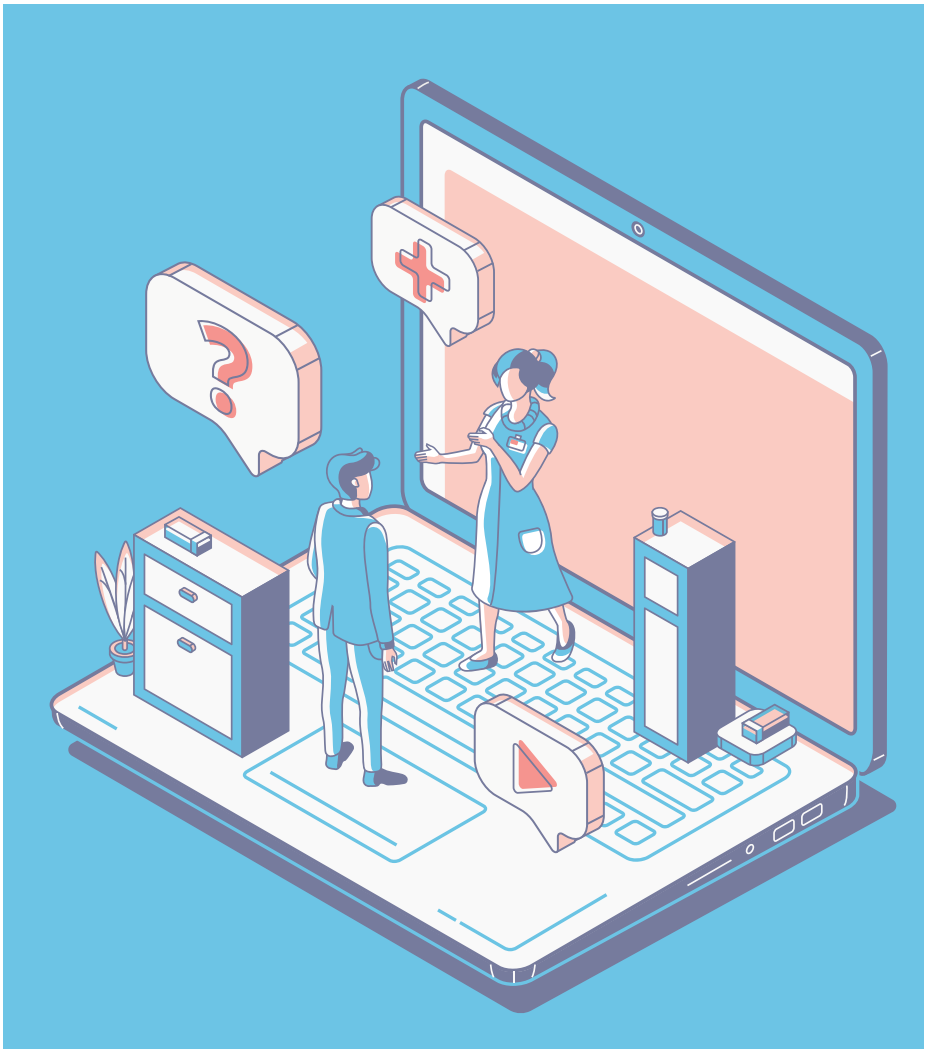
Abstract
In January 2021, the single market of medicines of the Eurasian Economic Union (EAEU) was launched. This article describes the current status of the transition to unified rules for the registration of medicinal products and the main regulatory documents for conducting clinical trials in the EAEU region.



The Eurasian Economic Union (EAEU) is an international organisation for regional economic integration, which includes the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Kyrgyz Republic, and the Russian Federation. With a total population of 183.6 million,[1] the EAEU provides free movement of goods, services, capital, and labour, and pursues coordinated, harmonised, and unified policy in the sectors determined by its treaty and international agreements within the Union.[2]

In December 2014, the EAEU countries signed the Agreement on Common Principles and Rules of Circulation of Medicinal Products Within the EAEU, which aimed to provide access to the unified market for medicines, regulating the safety, efficacy, and quality by current scientific standards.

The main document that details the procedures for the transition to a single drug market is the Rules for Registration and Expertise of Medicinal Products for Medical Use, issued in December 2016. According to this document, starting January 1, 2021, the registration of medicines in EAEU countries must be carried out in accordance with the unified requirements of the Union. This provision also changed the scope of clinical trials for such drugs. Now, clinical trials must be planned and conducted according to EAEU procedures. For drugs that have already been registered in EAEU countries, a transitional period has been contemplated until December 31, 2025, within which companies must bring the registration dossiers of drugs in line with EAEU legislation. (It is important to note that the dossier structure is now fully compliant with the Common Technical Document standard).

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The single unified market for medicines has been actively developing in recent years. A specialised platform named "Common market of medicines",[3] available in six languages including English, contains complete and accurate information about the authorised drugs. It also contains results of pharmacological inspections and state supervision of the turnover of medicines, both conducted by authorised bodies of the member

states of the EAEU, as well as other information about the circulation of medicines.

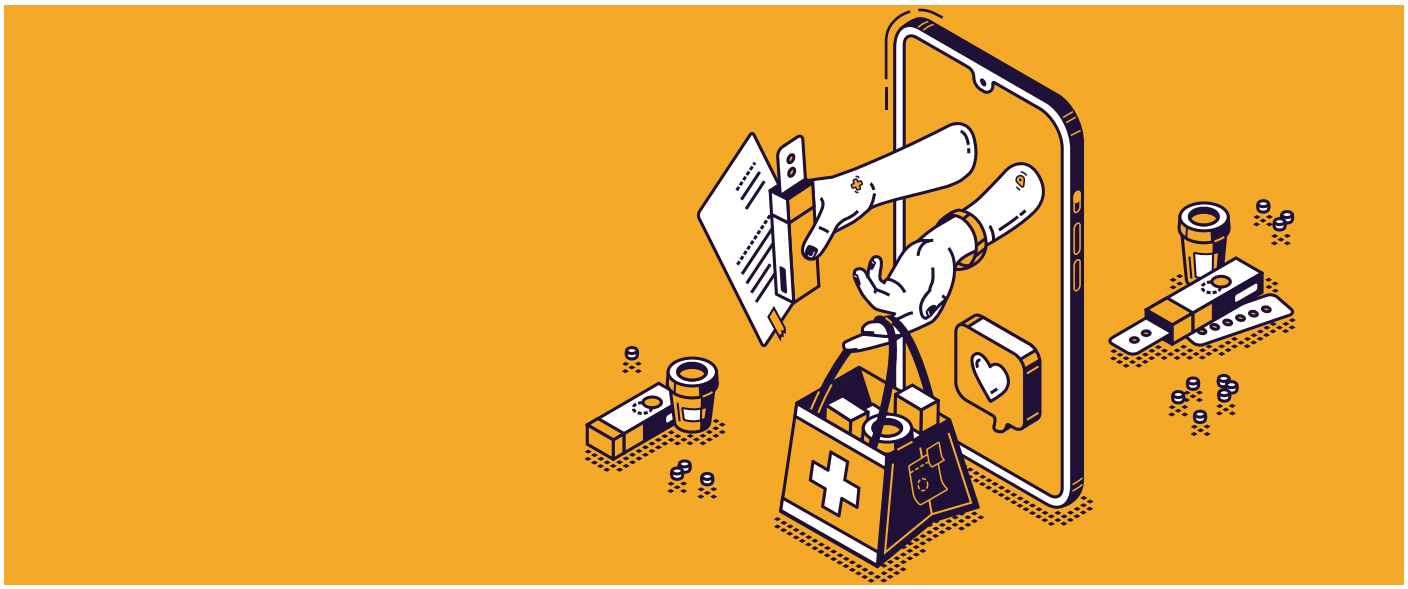
All regulatory documents are published in the EAEU legal portal.[4] The main documents governing the planning and conduct of clinical trials are summarised in Table 1. Importantly, documents related to clinical trials are thoroughly harmonised with the requirements of International Council on Harmonisation (ICH), FDA, and EMA, making it convenient for all parties, including those outside the EAEU.

Clinical trials should be conducted in accordance with the EAEU Good Clinical Practice (GCP), which is harmonised with the ICH E6 (R1) guideline. However, it is worth noting that the EAEU GCP guideline (named Rules of Good Clinical Practice of the Eurasian Economic Union) has a different document structure and includes several stand-alone regulatory parts: a GCP guideline, requirements for the structure and content of the clinical study report (harmonised with the ICH E3 guideline), a list of essential protocol amendments, the procedure for submitting safety information during the study, and requirements for the writing of the safety update report.

Within the EAEU agenda, there are also plans to create various information resources regarding data on the circulation of medicines. More specifically, the Unified Register of Medicines of

Table 1. The Eurasian Economic Union regulatory guidelines

The Eurasian Economic Union (EAEU); http://www.eaeunion.org/
EAEU legal portal; https://docs.eaeunion.org/
Eurasian Economic Commission Council Resolution No. 78 of November 03, 2016 **Rules of marketing authorization and assessment of medicinal products for human use** (updates available)
Eurasian Economic Commission Council Resolution No. 79 of November 03, 2016 **Rules of Good Clinical Practice of the Eurasian Economic Union**
Eurasian Economic Commission Council Resolution No. 85 of November 03, 2016 **Rules for conducting bioequivalence studies of medical products within the framework of the Eurasian Economic Union** (updates available)
Eurasian Economic Commission Council Resolution No. 87 of November 03, 2016 **Rules of pharmacovigilance practice (GVP) of the Eurasian Economic Union** (updates available)
Eurasian Economic Commission Council Resolution No. 89 of November 03, 2016 **Rules for research of biological medicinal products of the Eurasian Economic Union** (updates available)
Decision of the Board of the Eurasian Economic Commission No. 202 of November 26, 2019 **Guidelines for preclinical safety studies for the purpose of conducting clinical trials and drug registration**
Recommendation of the Board of the Eurasian Economic Commission No. 11 of July 17, 2018 **Guidelines on general considerations for clinical trials**
Recommendation of the Board of the Eurasian Economic Commission No. 8 of March 12, 2019 **Guidelines for the selection of the dose of drug**
Recommendation of the Board of the Eurasian Economic Commission No. 25 of September 2, 2019 **Guidelines for the preclinical and clinical development of drug combinations**
Recommendation of the Board of the Eurasian Economic Commission No. 42 of December 17, 2019 **Guidelines for the selection of non-investigational drugs for clinical trials**
Recommendation of the Board of the Eurasian Economic Commission No. 15 of September 15, 2020 **Guidelines for quality assessment and bioequivalence studies of certain groups of drugs**
Recommendation of the Board of the Eurasian Economic Commission No. 19 of November 03, 2020 **Guidelines on the principles of biostatistics in clinical trials of medicinal products**



the EAEU has been created, which contains information on all drugs that have been registered or re-registered in accordance with the rules of the Union. Unfortunately, there is no unified register of clinical trials yet. This information is still only available on the national platforms of each respective EAEU member state.

On the one hand, the transition to the requirements of the EAEU allowed all participants in the drug market of the EAEU countries to speak the same language and provided uniform approaches to clinical trials and registration of drugs that comply with international standards. On the other hand, the procedure appeared to be quite stressful for the industry. For instance, new processes have to be planned and implemented from scratch, and there are gaps in the EAEU regulations for clinical trials and drug registration. Additionally, the existing guidelines are constantly updated, making it challenging to follow all the latest updates and regulatory news, which is compounded by the lack of an established procedure for scientific advice to obtain timely clarifications from the regulator.

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At the same time, it is hard to ignore the importance of the very fact of the establishment of a single market for the circulation of drugs in the EAEU and all the effort the working groups of the EAEU put into the formation of regulatory requirements that meet international standards. For experts involved in the planning and conducting of clinical trials that involve medical writing, the introduction of universal requirements for the structure and content of documents and clinical trial design has greatly simplified their working routine and facilitated communication between experts from EAEU countries and pharma companies that plan to bring drugs to the EAEU market.

All stakeholders count on the resolution of existing issues, which will ultimately ensure the circulation of high-quality, safe, and effective drugs in the unified EAEU market.

Disclosures and conflicts of interest

The authors declare no conflict of interest.

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