LEGAL, CLINICAL, AND ETHICAL ISSUES IN BIOEQUIVALENCE RESEARCH

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Real-life clinical practice requires to confirm bioequivalence of medicinal products in everyday settings resulting in adequately assessed effectiveness and tolerability of drugs in diverse patient groups. When the studies are lacking, it cannot be warranted that therapeutic effects or safety profiles of the reproduced drug will be identical to those of original brand medicines, which may decrease the trust of doctors and patients in generics and, as a consequence, limit treatment affordability. Assessment of bioequivalence (or pharmacokinetic equivalence) of medicinal products (drugs) is currently considered one of the main types of biomedical quality control of reproduced (generic) medicines. The Russian pharmaceutical market is heavily dominated by generic drugs, which significantly outnumber original products. Thus, bioequivalence studies are of a huge economic and clinical value.

Keywords: bioequivalence studies, ethical aspects, legal issues

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ПРАВОВЫЕ, КЛИНИЧЕСКИЕ И ЭТИЧЕСКИЕ ВОПРОСЫ ИССЛЕДОВАНИЙ БИОЭКВИВАЛЕНТНОСТИ

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Реальная клиническая практика требует подтверждения биоэквивалентности препаратов в условиях, максимально приближенных к повседневному использованию, что позволяет адекватно оценить эффективность и переносимость лекарств в разнообразных группах пациентов. Без таких исследований нельзя гарантировать, что воспроизведенный препарат будет иметь равные терапевтические эффекты и безопасность, что может привести к снижению доверия врачей и пациентов к дженерикам и, как следствие, ограничению доступности лечения. Оценка биоэквивалентности (или фармакокинетической эквивалентности) лекарственных средств (ЛС) в настоящее время считается одним из основных видов медико-биологического контроля качества воспроизведенных (генерических) лекарственных препаратов. Среди препаратов, которые ежегодно регистрируются в России, отмечается значительно большее количество дженериков, чем оригинальных препаратов. В связи с этим исследования биоэквивалентности имеют большое экономическое и клиническое значение.

Ключевые слова: исследования биоэквивалентности, этические аспекты, правовые вопросы

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Now, when Russian generic pharmaceutical markets are expanding and regulatory requirements are getting stricter, bioequivalence (BE) studies become crucial at the stage where original and generic drugs are compared based on their pharmacokinetics ad safety profile. This is how risks for patients are minimized, therapy is optimized and an uninterrupted access to highly effective drugs to treat cardiovascular, oncological and other chronic diseases is provided. It increases the economic affordability for the healthcare system [1].

It is essential to develop national Russian programs targeted at the technological sovereignty in pharmaceutics where BE studies serve as the foundation for development of own medicinal products that correspond to the international standards. Meanwhile, modern international requirements and methods are integrated making data obtained for regulatory bodies and clinical practice reliable and pressing [2, 3].

In Russia, BE studies have seen significant growth during the last years. The record was reached in 2023 with 473–576 approvals contributing to 75.7–76.1% of all clinical trials (CT). In 2024, a decline was observed when the Ministry of Health issued 446–429 approvals for BE trials contributing to 67–71.5% of the total number of CT (628–600). This drop by 17–25% from 2023 is driven by the saturation of the market with generic medicines and tighter regulatory scrutiny (Table) [4–6].

The data show that BE studies for generic drugs currently dominate Russian clinical trials in spite of the massive

Table. Comparison of BE studies by year (according to the data of the Ministry of Health of Russia and Association of Clinical Research Organizations, 2021–2024) [4]

Year	Total CT	BE trials	BE rate (%)
2021	~908	218–369	41
2022	~740	367	~50
2023	761	473–576	75.7–76.1
2024	600–629	429–446	67–71.5

reduction in the market following the departure of foreign companies.

BE and pharmacokinetics studies have been conducted at the Department of Clinical Pharmacology of Yaroslavl State Medical University of the Ministry of Health of the Russian Federation based on Clinical Hospital No. 2 in accordance with article 21 of the Constitution of the Russian Federation and Federal Law No. 1-FZ On Circulation of Medicines as of 12 April 2010 (revision as of 23.07.2025) since 2011. The works are conducted in line with the national standard of the Russian Federation GOST R 52379–2005 Good Clinical Practice. It sets the international ethical and scientific standard for designing, conducting, monitoring, documenting and presenting the results of CT involving humans [7, 8].

The standard has come into force since 1 April 2006 based on the Law of the Federal Agency on Technical Regulation and Metrology as of 27 September 2005 No. 232-ст and remains unchanged in 2026. The research activity is also based on the ethical principles of Declaration of Helsinki of the World Medical Association and takes into account additional regulatory requirements and methodical recommendations of the Ministry of Health of Russia that show modern requirements to BE clinical trials. It makes the results reliable and reproducible both in the national, and global pharmaceutical industry [9].

In Russia, the regulatory documents that establish the rules of BE studies have been in effect since 2025.

1. Order No. 157n of the Ministry of Health of the Russian Federation dated 31 March 2025, which amends the rules for the examination of medicines, including bioequivalent drugs (it establishes requirements for the composition and documentation, the procedure for conducting examinations and issuing bioequivalence conclusions) [10].
2. Methodological guidelines of the Ministry of Health of the Russian Federation for conducting qualitative and quantitative studies of bioequivalence of medicinal products for human use dated 08/10/2004 (valid in 2026), (it regulates methods for assessing pharmacokinetic parameters, selecting a group of volunteers, monitoring the condition of participants and statistical analysis of the results) [11].
3. Decision of the Council of the Eurasian Economic Commission (EEC) dated November 3, 2016 No. 79 On Approval of the Rules of Good Clinical Practice of the Eurasian Economic Union (EEU), https://docs.cntd.ru/document/456026110 [12].
4. Eurasian Economic Commission (EEC) Decision No. 85 dated November 3, 2016 On Approval of the Rules for Conducting Bioequivalence Studies of Medicinal Products within the Eurasian Economic Union (updated in 2026), containing rules for the development of research design, requirements for methods of selection and formation of groups, data blinding and grounds for replacing *in vivo* studies with *in vitro* studies [13].
5. Also, in order to compare the effectiveness and safety of drugs, minimize the variability of factors and harmonize with international GCP standards, the standard of the Russian Federation GOST R 57679–2017 Medicines for Medical Use. Bioequivalence Studies of Medicinal Products (approved by Rosstandart Order No. 1165 dated 19.09.2017) is used [14].

These documents provide a comprehensive regulatory framework that covers all stages of BE research from planning to examination and confirmation of compliance of medicines with established standards.

In 2024–2025, the following key changes were made to the Russian legislation regulating the BE study [15].

1. On September 1, 2025, new Rules for the Examination of Medicines, including BE studies, entered into force. They update the requirements for documentation procedures, research and expert opinion. These changes are aimed at increasing transparency and standardization of examination processes, taking into account modern international practices.
2. In 2024, the Methodological Guidelines of the Ministry of Health of the Russian Federation were updated. They regulated the procedure for planning and performing BE studies, including strict criteria for selecting research subjects and conducting control pharmacokinetic measurements.
3. Regulation regarding the ethical review of bioequivalence research has been strengthened, review of protocols in specialized ethics committees became mandatory considering the latest requirements of the Helsinki Declaration and international GCP standards.
4. Adjustments have been made to combine *in vitro* studies with pharmacokinetic data in some cases to confirm bioequivalence, which accelerates research processes and reduces the burden on volunteers.
5. The rules of interaction with the EEC have been improved, providing for the harmonization of requirements and mutual recognition of research results between the EEU countries.

All these updates show that Russian legislation is brought into compliance with international standards, improves the quality and safety of BE research and strengthens control over it while the domestic pharmaceutical industry is developed.

When conducting bioequivalence and pharmacokinetic studies, certain difficulties arose both at the stage of the clinical part and in subsequent phases. The problems of bioequivalence research include difficulties in assessing

bioavailability for certain dosage forms (for example, for dermatological products where skin penetration assessment is required), potential discomfort for study participants (blood collection, hospital monitoring), as well as possible misperception of differences between original drugs and generic medicines. Using non-specific methods for evaluating effectiveness and safety of drugs, as well as difficulties in providing standardized research conditions can serve as an example [16].

In this paper, we focus on the clinical issues of bioequivalence research. The ethical difficulties reported in practice of our clinical center over the past decade are also important. The issue of a unified volunteer database is still pressing for managing numerous clinical research centers across Yaroslavl and neighboring regions. Our clinical practice maintains its own database designed to track the last participation dates of volunteers, which allows us to control the minimum intervals between their participation. The lack of the centralized registration system, however, makes it difficult for volunteers to comply with the intervals when they change centers. The lack of centralized control leads to the possible participation of the same volunteers in several centers without observing minimum intervals, which threatens their health. Commercialization of clinical trials turns healthy people into "professional volunteers" who ignore long-term bodily effects. A unified database of volunteers for the Yaroslavl Region and surrounding regions could solve the problem.

Violation of data confidentiality or invasion of privacy during monitoring is another problem that is the reason for a psychological and social trauma among subjects [17, 18].

Violation of data confidentiality in bioequivalence research involves the unauthorized disclosure of volunteers' personal and medical information to third parties. This raises serious ethical concerns, as such data often contains sensitive information that can affect a person's reputation or social status [19].

Invasion of privacy in research occurs when monitoring methods become extremely aggressive or exceed necessary boundaries of medical supervision, involving overly intimate surveillance of participants. For example, constant monitoring or collection of excessive data without transparent information violates the subject's rights to personal space and autonomy [20].

Psychological trauma from personal data misuse or fear of disclosure triggers significant anxiety, stress, and feelings of vulnerability. Social trauma stemming from health-related stigma involves the fear or experience of condemnation and discrimination if personal health information or participation in clinical trials is revealed.

Thus, protecting confidentiality and respecting the privacy of volunteers are key elements of ethical research used to avoid negative consequences for participants and maintain trust in the research process.

The experience of our clinical center shows that ethical challenges seen while working with volunteers are inevitably combined with a whole range of methodological difficulties that arise during research planning and conducting. Therefore, along with ethical aspects, it is important to analyze methodological problems that affect accuracy of bioequivalence assessment and reproducibility of results [21].

Many daily challenges that formerly dominated clinical research are currently practically not recorded or minimized. This is due to a significant improvement in the quality of preparation of pharmacokinetic and bioequivalence research protocols, which are now being developed with more accuracy and at a high professional level. In addition, monitoring in clinical research by research organizations and sponsors has become more thorough and systematic, which ensures strict adherence to established standards. Regularly conducted, specialized staff training on interacting with volunteers improves team competence. The staff of the research center face almost no difficulties in monitoring volunteers, and subjects are always hospitalized before dosing to minimize risks and ensure data accuracy [22].

However, despite the successes achieved, difficulties in post-discharge study protocol compliance still arise in clinical practice from time to time. Informed consent often fails to ensure strict participant adherence to established requirements such as restrictions on driving, smoking, and behavioral norms while on medications affecting reaction, attention, and cognitive functions. These disorders can significantly distort the pharmacokinetic data and undermine the reliability of the study results. To solve this problem effectively, it is advisable to increase the length of stay of volunteers at hospitals until the investigational drug is completely eliminated from the blood, which will ensure full compliance control and minimize external factors of influence. However, there remains a dilemma that prolonged hospitalization of volunteers, when participants regularly undergo numerous procedures, including multiple blood draws, can become a source of physical discomfort, stress, and psychological stress, as well as restrict freedom and make daily lives of volunteers inconvenient. In addition, the specific requirements for diet, physical activity, and lifestyle during hospitalization add additional restrictions, which can also affect the motivation and morale of participants. All these factors must be taken into account when planning and conducting research to minimize the negative impact on volunteers and obtain high-quality data [21, 23].

There are some other problems in the clinical part of BE research that can be noted. They include genetic and physiological factors (polymorphism of CYP3A4 enzymes, influence of gender, age, ethnicity), volunteers or patients as subjects of BE research (BE is usually proven in healthy people, but pharmacokinetics may vary in patients).

CONCLUSION

Bioequivalence studies are still critical for ensuring that Russian-manufactured generic drugs are safe and effective, supporting technological sovereignty of Russia in the pharmaceutical sector, minimizing risks for patients and increasing the availability of therapy for chronic diseases. Despite advancements in regulatory harmonization and methodology, significant hurdles to clinical practice still persist including genetic polymorphism, the choice of healthy volunteers or patients with altered pharmacokinetics, as well as ethical dilemmas.

Future development focuses on integration of pharmacogenetics to create personalized protocols, a combination of *in vivo/in vitro* methods, and digitalization of volunteer records, which will enhance drug reproducibility and safety. Taking into account ethical issues, we are still continuing our BE studies at the Department of Yaroslavl State Medical University of the Ministry of Health of the Russian Federation based on Clinical Hospital No. 2 and are trying to contribute to real clinical practice under realistic, everyday conditions.

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