МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
ХАРКІВСЬКИЙ НАЦІОНАЛЬНИЙ МЕДИЧНИЙ УНІВЕРСИТЕТ
КАФЕДРА ФАРМАКОЛОГІЇ ТА МЕДИЧНОЇ РЕЦЕПТУРИ

МАТЕРІАЛИ

ІІ науково-практичної інтернет-конференції з міжнародною участю на тему «Сучасні аспекти досягнень фундаментальних та прикладних медико-біологічних напрямків медичної та фармацевтичної освіти та науки»

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Затверджено вченою радою ХНМУ
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Сучасні аспекти досягнень фундаментальних та прикладних медико-біологічних напрямків медичної та фармацевтичної освіти та науки: матеріали ІІ науково-практичної інтернет-конференції з міжнародною участю (ХНМУ, Харків, 17 листопада 2023 р.)/Міністерство охорони здоров'я України, Харк. нац. мед. ун-т. – Харків : ХНМУ, 2023. – 366 с.

Матеріали, наведені у збірці, висвітлюють сучасні напрямки та шляхи підвищення якості медичної та фармацевтичної освіти, результати фундаментальних та прикладних наукових досліджень потенційних та нових лікарських засобів, інноваційні підходи підвищення якості фармакотерапії з позиції доказової медицини та управлінські, економічні та організаційні аспекти охорони здоров’я.

Збірка розрахована для широкого кола наукових та практичних працівників медицини та фармації.

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THE ETHICAL PRINCIPLES IN BIOPHARMCEUTICAL RESEARCH

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Abstract

An analytical review is devoted to the aspects of the biopharmaceutical ethics. The international guidelines and declarations which providing the development the effective and safety pharmaceutical healthcare products are described. The main ethical requirements on clinical drug testing are shown. The definition of bioethics concepts, principles, and rules within biomedical research with involving human subjects are considered. A promising approach aimed to widely incorporation appropriated knowledge in clinical trials is emphasized.

Keywords: drug development, autonomy, beneficence, non-maleficence, confidentiality, informed consent.

Абстракт.

Аналітичний огляд присвячено аспектам біофармацевтичної етики. Представлено опис міжнародних керівництв та декларацій, що забезпечують створення ефективних та безпечних фармацевтичних лікарських засобів. Наведено основні етичні вимоги при проведенні клінічного тестування ліків. Подано визначення концепції, принципів та вимог біоетики стосовно біомедичних дослідженнях за участю людей. Підкреслюється перспективний напрямок широкого впровадження відповідних знань у клінічні трайли.

Introduction. Scientific progress in medicine is characterized by appearance of the innovative generations of therapies. Medical interventions with the help of the pharmaceutical drugs are most often used in clinical practice. The emergence of the progressive technological development in medicine has been triggered to the new area in biomedical and life sciences and become the background of broader scope of ethics.

Purpose. The article is summarized the issues related to the implementation of bioethical standards in drug development with emphasis on biomedical research on human subjects.

Methods. Authors carried out the bibliometric analysis of the scientific publications in the available database Scopus, Web of Science, PubMed using appropriate keywords in English.

Results. Developing a potential and new drug is a long and complex process, directed to discovery an appropriate substances, compound synthesis, cloning of the receptors and enzymes, in vitro research, identification of potential medicine-candidate, experimental manufacturing, There are some research of different levels, providing results which relevant for the actual clinical practice: animal research, case report, cross-sectional studies, cohort studies, nonrandomized experimental studies on human, randomized controlled double blind studies, systematic reviews and meta-analyses, submission for market approval, post-approval research. This revolutionary trend has been named in recent years as the biopharmaceutical pipeline [1].

Since Hippocrates, the most widely accepted medical ethic has been to improve the well-being of patients and to avoid harm in doing so. This principle is being transformed into the development and assessment of potential and new drugs by clinical testing in human subjects. Ethical and scientific standards of carrying out biomedical research on human subjects have been developed and established in prominent ethical codes, international guidelines, and declarations.

The 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects superseded the 1993 Guidelines and were the third since 1982 in the series of biomedical-research ethical guidelines issued by Council for International Organizations of Medical Sciences (CIOMS). They were replaced the International ethical guidelines for health-related research involving humans published by CIOMS in 2016 "International Ethical Guidelines for Biomedical Research Involving Human Subjects" [4]. International Ethical Guidelines take the position that research involving human subjects in superficial aspects must universally incorporate applicable ethical standards into clinical testing of new drugs. [7].

The main purposes of clinical testing are the determination the safety and effectiveness of new drugs in people. For solving these tasks are done clinical trials, which are a set of procedures in medical research on groups of people are given drugs and that are conducted to allow obtained information about adverse drug reactions and efficacy data to be collected for health interventions.

Drug development is distinguished as multifaced process of the biopharmaceutical industry operates at the relationship with life sciences, pre-clinical and clinical researches, public health, and business, manufacturing which presents distinct operational and ethical challenges in order to create the safe and effective final product [8]. The ethics for individual patient was purchased more wide value as biopharmaceutical bioethics with the definition *"*the application of bioethics norms (concepts, principles, and rules) to the research, development, supply, commercialization, and clinical use of biopharmaceutical healthcare products" [9].

The biopharmaceutical bioethics derived from specific principles of biomedical ethics which are based by T. Beauchamp, J. Childress: bioethics concepts (values, moral ideals), principles (autonomy, beneficence, non-maleficence, and justice), and rules (informed consent, confidentiality, and privacy) [3].

Autonomy means self-determination and is the individual choice, freedom to act independently, the right of patient to participate in and decide on a course of action without undue influence. Beneficence: to do well, to promote well-being, the welfare of the patient. Non-maleficence: the principle and obligation of doing good and avoiding harm. These principal counsels a provider to relate to patient in a way that will always be in the best interest of the patient, rather than the provider. Justice: respect for moral laws and individual rights. Confidentiality/privacy is one of the core duties of medical practice. It requires health care providers to keep a patient's personal health information private.

An essential component of initiating a clinical trial is to recruit study subjects following procedures using a signed document called "informed consent "[5]. The notion of informed consent is grounded in the ethical principles of patient autonomy

and respect for a person's right to make decisions about their participation in a clinical trial. The patient should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding decision. The experiment should be designed and based only by scientifically qualified persons with superior skill [2].

Clinical trials should be conducted in accordance with the ethical principles that are followed the rules of Good Clinical Practice (GCP) and the applicable regulatory requirement(s). GCP is an international quality standard that is provided by International Conference on Harmonisation, an international body that defines rules, which governments can transpose into regulations for clinical trials involving human subjects [6]. Every research project shall be submitted for independent examination of its ethical acceptability to ethics committee. Values, moral ideals during medical intervention should be carry out on compliance with the dignity, rights, safety, and well-being of research participants according to international and national ethical guidelines

Conclusion. The biopharmaceutical industry takes an important place in healthcare system thanks to the drug development. Bioethical principles are mandatory in this process and make a significant contribution in creation the valid, efficiency, and safety biopharmaceutical product. Ethical standards of carrying out biomedical research on human subjects have been supplemented hence should be constantly updated within the medical specialists.

Conflict of interests

The authors declare that there is no conflict of interests regarding the publication of this article.

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