REVIEW ARTICLE

CONTENTS

Criminalisation of fraud and misconduct in clinical trials on medicinal products

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ABSTRACT

Aim: To develop a scientifically grounded approach to defining the basis and limits of criminalizing fraud and misconduct in clinical trials of medicinal products, while also raising awareness and encouraging serious discussion of these issues.

Materials and Methods: The study relies on the Acquis Communautaire and the legislation of Ukraine, Germany, and Poland. It also uses judicial practices from the United States, France, and Ukraine, as well as legal statistics and draft legislation from Ukraine. Scientific research methods such as induction, deduction, comparison, analysis, case studies, and systems analysis were employed.

Conclusions: Criminal penalties for unlawful actions during clinical trials of medicinal products, guided by the ultima ratio principle, should be applied only to violations that threaten the lives or health of research subjects, infringe upon their rights, or involve falsification of clinical trial results regarding the efficacy and safety of the products, rather than to any violations alone.

KEY WORDS: clinical trials of medicinal products, criminal punishment, fraud, crimes against life and health, crimes against public health

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INTRODUCTION

Clinical trials of medicinal products are a necessary stage of their development. In accordance with paragraph 1 of part 2 of Article 2 Regulation (EU) No 536/2014 of the European parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [1] 'Clinical study' means any investigation in relation to humans intended:

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;

(b) to identify any adverse reactions to one or more medicinal products; or

(c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products;

with the objective of ascertaining the safety and/or efficacy of those medicinal products.

Since, according to paragraph 2 of Part 2 of Article 2 of this Regulation, clinical trials are a type of clinical study, they are conducted to ascertain the safety and/or efficacy of those medicinal products. Clearly, clinical trials always pose a risk to the research subject–an individual participating in a clinical trial, either as a recipient of an investigational medicinal product or as a control. This risk stems from the fact that the medicinal product being studied may be either unsafe or insufficiently effective, and its use may lead to a significant deterioration in the subject's health or even death.

The potential risk to the life and health of clinical trial subjects requires adherence to clinical trial regulations designed to minimize possible negative outcomes for the participants and to protect their rights and legitimate interests. Violating these regulations can lead to legal liability for those responsible. The most severe form of liability is criminal, which imposes strict restrictions on the rights and freedoms of individuals convicted of a criminal offense. However, debates continue over which specific violations of clinical trial rules should be subject to criminal punishment and what penalties should be applied to those found guilty. It is essential to balance legislation so that it, on one hand, safeguards the right to life and health of research participants, and on the other, does not create unreason-

able barriers to conducting research. Presently, laws in various countries approach this issue differently – some impose criminal penalties for any violations during clinical trials, while others punish only violations that result in death or serious harm to a participant. The ongoing scientific effort to find the best model for defining the grounds and limits of criminalization in this area keeps this topic highly relevant.

AIM

This article aims to develop a scientifically grounded approach to defining the basis and limits of criminalizing fraud and misconduct in clinical trials of medicinal products, while also raising awareness and encouraging serious discussion of these issues.

MATERIALS AND METHODS

The study was conducted in 2025 and based on the Acquis Communautaire, the legal acts of Ukraine, Germany, and Poland. It used legal practices, legal statistics, drafts of Ukrainian legal acts, and media publications from the USA, France, and Ukraine. In total, 8 laws, 2 drafts of laws, other documents, and 12 court decisions were analyzed.

Given the subject and purpose of the study, it was limited to examining the criminalization of violations during clinical trials on human subjects.

Research methods included induction, deduction, comparative, analytical, case study, and system analysis.

In the first stage of the study, induction and case study methods were used to analyze individual cases of criminal liability for violations of clinical trial procedures for medicinal products in the United States, France, and Ukraine. Following this, an analytical approach was employed to examine international documents, EU regulations (Aqui Communitare), Ukrainian legislation, and draft Ukrainian laws concerning liability for violations during clinical trials, as well as judicial statistics related to these criminal offenses. This facilitated deduction, comparative analysis, and systems analysis to highlight the advantages and disadvantages of different approaches to criminalizing violations of clinical trial procedures, and to develop scientifically grounded proposals for establishing the criteria and scope of such criminalization.

REVIEW AND DISCUSSION

Fraud and misconduct in clinical trials involving medicinal products pose a potential threat to the lives and health of both study subjects and patients who will be treated with these medicinal products. An analysis of cases involving criminal penalties for violating clinical trial procedures demonstrates that criminal law is applied in cases of: (a) harm to the life or health of subjects in a clinical trial of medicinal products during its conduct; (b) harm to the life or health of patients during the use of a medicinal product whose registration was preceded by distorted clinical trial data regarding its safety and/or efficacy.

So, in December 2023, a French court ruled that Drugmaker Servier must pay more than 430 million euros ($471 million) in connection with weight-loss pill Mediator, saying that the company was guilty of fraud and other charges because it knew the drug was potentially harmful when selling it. At least 500 people died of heart valve problems in one of France's worst health scandals because of exposure to the active ingredient in Mediator, which was widely prescribed as an appetite suppressant. The court found the company concealed the risk of harm and heart problems from patients and doctors and ruled the initial 1974 approval and its subsequent renewals until 2007 had been obtained illegally. [2] "It has been proven that in order to obtain marketing authorisation for Mediator° in 1974, Servier took the risk of developing and promoting a new amphetamine drug, concealing its appetite-suppressing effect and misleading people about its metabolisation to norfenfluramine, the cause of the drug's adverse effects on heart valves in particular. Over the decades that followed, Servier not only denied that the drug had serious adverse effects, but sought to expand its indications, even though it would have been withdrawn from the market had the pharmaceutical company not hidden what it knew from patients, health professionals and the regulatory authorities (2-4). The appeal court found that Servier's actions illustrated a peculiar concept of the harm-benefit balance: "financial benefit for the company, deadly harm to patients" (our translation) (2,4). It went further than the original court in its judgement, finding Servier guilty on all counts (2-5). Jean-Philippe Seta was given a 4-year suspended prison sentence (with 1 year of house arrest under electronic monitoring), and Servier was ordered to pay a fine of over €9 million. It also ordered the pharmaceutical company to pay €420 million in reimbursement to health insurance providers (2,3)." [3] Therefore, Drugmaker Servier's concealment of information gathered, including during clinical trials, about the side effects of Mediator°, and the failure to share this information during the drug's registration and re-registration processes, resulted in the deaths of at least 500 patients.

US judicial practice indicates that violations during clinical trials are regarded as serious crimes. Thus, on

May 11, 2021, a federal grand jury in Miami, Florida, returned an indictment charging Jessica Palacio with conspiring to falsify clinical trial data regarding an asthma medication. According to court documents Palacio worked as a study coordinator at a clinical trial firm in Miami called Unlimited Medical Research. Unlimited Medical Research was one of many companies hired to conduct a clinical trial designed to investigate the safety and efficacy of an asthma medication in children. The indictment alleges that Palacio participated in a scheme to falsify medical records to make it appear as though pediatric subjects made scheduled visits to Unlimited Medical Research, received physical exams from a clinical investigator, and took study drugs as required, when in fact these things had not occurred. The indictment also alleges that when Palacio was confronted by a Food and Drug Administration (FDA) regulatory investigator about her conduct, she made a false statement to that investigator.[4] В дальнейшем суд присяжных признал Palacio виновной лишь в for making a false statement to a government investigator related to a clinical trial that studied the effectiveness of asthma drugs in children. A federal judge sentenced Palacio to 36 months in prison and three years of supervised release [5].

Four co-conspirators previously pleaded guilty and were sentenced for their roles in the scheme at UMR. Yvelice Villaman Bencosme, M.D., 66, of Miami, was sentenced to 36 months' imprisonment, and Lisett Raventos, 48, also of Miami, was sentenced to 30 months' imprisonment. In addition, Maytee Lledo, 52, of Hialeah, Florida, was sentenced to 14 months' imprisonment, which the court later modified to time served, and Olga Torres, 50, of Miami, was sentenced to 3 years' probation [5].

On February 21, 2025 a federal jury convicted Naheed Mangi, 66, a former employee of Stanford University, of accessing a clinical research database for a multisite breast cancer study after her authorization was revoked and altering patient records in the database. As said Acting United States Attorney Patrick D. Robbins, "Naheed Mangi intentionally tampered with a breast cancer research database by entering false information and personal insults. Her senseless actions undermined a study into the safety and efficacy of a new treatment for breast cancer patients". She faces a maximum penalty of 10 years in prison as to each conviction for Intentional Damage to a Protected Computer and one year in prison as to the conviction for Accessing a Protected Computer Without Authorization.[6] However, as of now, there is no official information about whether Naheed Mangi has been sentenced or what type of punishment he has received.

A comparison of the cited decisions on criminal penalties for violations of clinical trial procedures shows that the US response to such violations is more severe. Penalties imposed for violations that merely posed a potential risk to patients are more severe than those imposed by the French court for violations that resulted in the deaths of at least 500 patients.

An analysis of Ukrainian judicial practice shows that over the past 25 years, no convictions have been issued for violating clinical trial procedures. Between 2018 and 2025, pre-trial investigations and court hearings occurred in cases involving violations of drug registration procedures by officials of the State Enterprise "State Expert Center of the Ministry of Health of Ukraine." According to the prosecution, these violations involved registering generic drugs without completing pre-clinical studies and clinical trials. However, the prosecution was unable to prove the guilt of the officials from this state-owned enterprise, resulting in acquittals. For example, on November 20, 2020, the Holosiivskyi District Court of Kyiv found an expert from the Department for Registration of Medicines not guilty of the charge under Part 1 of Article 321-2 of the Criminal Code of Ukraine, which pertains to "Violation of the established procedure for pre-clinical studies, clinical trials, and state registration of medicines" [7]; similarly, on July 7, 2025, the same court found the acting director of the Department for Expertise of Registration Materials not guilty of the same charge [8]. Notably, the court decisions did not dispute that violations occurred during the medicine registration process, specifically related to pre-clinical studies and the failure to conduct clinical trials.

Therefore, the use of case studies has shown that fraud and misconduct in clinical trials involving medicinal products pose a serious threat to human life and health. However, detecting and investigating such violations is highly complicated and requires experts with extensive professional knowledge in this area. In many cases, even after confirming violations, it is difficult to establish the guilt of specific individuals in committing the crimes.

An analysis of the European Union's regulatory framework (Acquis communautaire) reveals that harm caused during clinical trials may result in civil and criminal liability. However, determining the precise nature of liability, its basis, and its limits is a matter for national legislation. Thus, according to Article 95 of the Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, "This Regulation is without prejudice to national and Union law on the civil and criminal liability of a sponsor or an investigator." [1]

An analysis of national legislation on fraud and misconduct in clinical trials involving medicinal products reveals two methods for establishing grounds for criminal liability. The first method asserts that only specific, clearly defined violations during clinical trials of medicinal products are punishable by law (Germany, Poland). The second method states that any violation of clinical trial procedures is formally punishable by criminal law (Ukraine).

Thus, in Germany, the Law on the Trade in Medicinal Products (Medical Products Act - AMG) establishes criminal liability for violations during clinical trials in Section 17 of this Law. Intentional violations of this Law, as listed in this section, including those committed during the clinical trials of medical products, are punishable by up to three years of imprisonment or a fine; in severe cases, imprisonment for one to three years may be imposed. If the offender acts negligently in the cases referred to in paragraph 1, the penalty shall be imprisonment for a maximum of one year or a fine. [9]

Criminal liability for violations during clinical trials on humans in Poland is governed by the Law on Clinical Trials on Medicinal Products for Human Use [10]. Section 11 of this Law, "Criminal Provisions," provides an exhaustive list of violations of clinical trial procedures, the commission of which shall be subject to a fine, restriction of liberty, or imprisonment for up to two years (Article 77). Harm to the life or health of clinical trial subjects or, later, patients, is not covered by the provisions of this Law and is punishable under the general provisions of the Polish Criminal Code regarding crimes against human life and health (Section XIX).

Unlike Germany and Poland, Ukraine provides criminal liability for any violation of the procedure for conducting clinical trials of medical products. Since Ukrainian criminal Law is fully codified, provisions on criminal liability for such violations are contained not in laws regulating pharmaceutical activity but in the Criminal Code of Ukraine (hereinafter, the CC of Ukraine) [12].

Unfortunately, the provisions of the Criminal Code of Ukraine regarding violations of the procedure for conducting clinical trials are contradictory. Article 141 of the Criminal Code of Ukraine, "Violation of the Rights of a Patient," establishes liability for clinical trials conducted without the written consent of the patient or their legal representative, or those performed on minors or legally incapable persons, where such actions lead to death or other serious consequences. This article handles only one type of violation: conducting a clinical trial without informed consent that results in death or other grave outcomes. In 2012, Article 321-2, "Violation of the Established Procedure for Pre-Clinical Studies, Clinical Trials, and State Registration of Medicines," was added to the Criminal Code of Ukraine. This article criminalizes intentional violations of the established procedures for pre-clinical studies and clinical trials of medicines, including falsification of their findings. It applies solely to clinical trials of medicines and does not encompass violations during clinical trials of other medical products. All violations during such clinical trials, including falsification of results, fall under this provision. If such violations result in the death of a research subject or other serious consequences, those found guilty under Part 3 of this article face deprivation of liberty for eight to ten years and may be deprived of the right to hold certain positions or engage in specific activities for two to three years.

Despite the widespread criminalization of violations during clinical trials of medicines in Ukraine, judicial statistics show the ineffectiveness of this approach. Over the past five years (2020-2024), law enforcement agencies have recorded 16 criminal procedures under Article 321-2 - "Violation of the established procedure for preclinical studies, clinical trials, and the state registration of medicines." Of these proceedings, only one was sent to court with a charge [13], but an acquittal was issued in that case [8]. A negative aspect of such broad criminalization in the field of clinical trials is the potential for unfounded pressure from law enforcement agencies on the conduct of these trials. The European Business Association also pointed out the excessive criminalization of violations in clinical trials of medicines in Ukraine [14]. This situation, along with contradictions in Ukraine's criminal-legal regulation of clinical trials, prompted the development and submission of draft laws to Parliament that aim to amend the Criminal Code of Ukraine to improve criminal liability for violating the established procedures for preclinical studies, clinical trials, and market authorization of medicinal products (registration numbers 11181 and 11181-1) [15; 16]. These drafts aim to address the inconsistencies in criminal-legal regulation and to establish specific violations of clinical trial procedures that are criminally punishable.

An analysis of the scientific literature shows that researchers who have examined the criminalization of fraud and misconduct in clinical trials involving medicinal products confirm that such acts are widespread and pose potential dangers to human life and health. For example, Ashwaria Gupta states that «Research fraud is a reality which nobody can shy away from. Furthermore, clinical research is very vulnerable to fraud due to no effective mechanism in place for detecting, investigating and prosecuting fraud in most of the countries.» [17] Joseph M. Gabriel and Bennett Holman suggest that one possible origin point for the widespread fraudulent practices in clinical trials that

now characterize the pharmaceutical industry is the monopoly status of the ethical framework in which medical science took place, which was later replaced by clinical utility as the primary arbiter of pharmaceutical legitimacy [18].

The widespread presence of fraud and misconduct in clinical trials involving medicinal products, along with the high risk of harm to human life and health (both research subjects and patients) when using such products, calls for criminalization. However, excessive criminalization in this area does not lead to positive outcomes but instead obstructs the normal conduct of clinical trials for medical products [19]. The basis for criminalizing fraud and misconduct in clinical trials involving medicinal products is harm that has been or could be caused to: 1) the life and health of the research subject; 2) public health and the life and health of individual patients during future use of marketed medicinal products.

Violations that endanger the life and health of research subjects should include: (a) enrolling a person in a clinical trial without that person or, in cases provided by law, another person providing informed consent; (c) failure to take legally required measures to ensure the safety of a research subject during temporary or permanent termination of a clinical trial.

The spectrum of violations that endanger public health and pose a potential threat to the life and health of a patient should be limited to the following illegal actions: (a) conducting a clinical trial without permission obtained in the prescribed manner; (c) fraud, i.e., falsifying data obtained during a clinical trial or the results of a clinical trial.

Reasonable criminalization of fraud and misconduct in clinical trials involving medicinal products is a necessary tool for ensuring that those guilty of such violations face criminal penalties. Proper criminal regulation, in turn, aims to help prevent new crimes in this area. However, as Ukrainian judicial practice demonstrates in the application of criminal law provisions addressing violations during clinical trials, the lack of necessary mechanisms for identifying offenders hampers their criminal prosecution.

Researchers rightly raise the issue of the need to utilize modern technologies to develop monitoring systems that detect fraud in clinical trials of medical products. For example, William J. Cragg, Caroline Hurley, Victoria Yorke-Edwards, and Sally P. Stenning presented a scoping review of dynamic methods for ongoing assessment of site-level risk in risk-based monitoring of clinical trials [20]. The study "Detection of Fraud in a Clinical Trial Using Unsupervised Statistical Monitoring" concludes that "an unsupervised approach to central monitoring, using mixed-effects statistical models, is effective at detecting centers with fraud or other data anomalies in clinical trials." [21].

CONCLUSIONS

The study revealed that fraud and misconduct in clinical trials of medicinal products are widespread and can harm human life and health. Such harm includes damage to the research subject's life or health, as well as risks to public health and the safety of future patients who will use the medical product.

In European criminal law, there are two types of regulation concerning the criminal aspects of clinical trials of medicinal products: 1) defining specific violations related to clinical trials in criminal law; 2) establishing criminal penalties for any violations of clinical trials. The first approach is more justified because it prevents undue pressure from law enforcement agencies and avoids overcriminalization.

Criminal regulation of clinical trials should be limited to attacks on the life or health of the research participants, as well as on public health and the safety of potential patients. Violations against the research subject's life or health include: (a) enrolling a person in a clinical trial without their informed consent or, where legally required, without consent from another authorized person; (b) failing to implement legally mandated safety measures during the temporary or complete halt of a clinical trial. Violations affecting public health and future patients include: (a) conducting a clinical trial without the proper authorization; (b) fraud, such as falsifying data or results obtained during a trial.

The effectiveness of criminal law in regulating clinical trials depends both on its quality and on using modern monitoring methods that help detect fraud and misconduct in clinical trials involving medicinal products.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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