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CLINICAL TRIALS IN FORENSIC MEDICINE: INNOVATIONS AND PROBLEMS

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Annotation.

Clinical trials in forensic medicine are essential for validating diagnostic, analytical, and investigative methods before their implementation in legal practice. Recent innovations—such as molecular genetic techniques, forensic biomarkers, postmortem imaging, and artificial intelligence—have significantly improved the precision, speed, and scope of forensic investigations. These advances enable more accurate determination of identity, cause of death, and injury vitality, as well as the reconstruction of crime events. However, persistent problems remain, including ethical constraints related to human and postmortem research, lack of standardized protocols across jurisdictions, small sample sizes, and variable legal admissibility criteria. Addressing these challenges requires interdisciplinary collaboration, harmonization of methodologies, and stronger international regulatory frameworks. The integration of cutting-edge technologies with rigorous scientific validation and ethical oversight will ensure the reliability and credibility of forensic medical evidence in judicial processes.

Keywords

forensic medicine; clinical trials; innovations; problems; DNA analysis; forensic biomarkers; postmortem imaging; artificial intelligence; ethical issues; standardization.

Annotatsiya

Sud-tibbiyotida klinik tadqiqotlar diagnostik, analitik va tekshiruv usullarini Sud-tibbiy, yuridik amaliyotga joriy etishdan oldin ularning ishonchliligi va samaradorligini tasdiqlashda muhim ahamiyatga ega. Zamonaviy innovatsiyalar — molekulyar-genetik texnologiyalar, sud-tibbiy biomarkerlar, o'limdan keyingi tasvirlash (postmortem vizualizatsiya) va sun'iy intellekt — sud-tibbiy tadqiqotlarning aniqligi, tezligi va imkoniyatlarini sezilarli darajada oshirdi. Ushbu yutuqlar shaxsni aniqlash, o'lim sababini va jarohatlarning hayot davomida

olinganligini aniqroq belgilash, shuningdek jinoyat voqealarini rekonstruksiya qilish imkonini beradi. Biroq, inson va o‘limdan keyingi materiallar bilan ishlashdagi axloqiy cheklovlar, turli yurisdiksiyalarda standartlashtirilgan protokollarning yo‘qligi, kichik namunalar hajmi va sudda usullarni qabul qilish mezonlaridagi farqlar kabi jiddiy muammolar saqlanib qolmoqda. Ushbu muammolarni hal etish uchun fanlararo hamkorlik, metodologiyalarni uyg‘unlashtirish va xalqaro me’yoriy standartlarni mustahkamlash zarur. Ilmiy asoslangan validatsiya va qat’iy axloqiy nazorat bilan ilg‘or texnologiyalarni integratsiya qilish sud-tibbiy dalillarning sud jarayonlarida ishonchliligi va haqqoniyligini ta’minlaydi.

Kalit so‘zlar

sud-tibbiyot; klinik tadqiqotlar; innovatsiyalar; muammolar; DNK tahlili; sud-tibbiy biomarkerlar; o‘limdan keyingi tasvirlash; sun’iy intellekt; axloqiy masalalar; standartlashtirish.

Аннотация.

Клинические исследования в судебной медицине играют ключевую роль в валидации диагностических, аналитических и исследовательских методов перед их внедрением в юридическую практику. Современные инновации — такие как молекулярно-генетические технологии, судебно-медицинские биомаркеры, посмертная визуализация и искусственный интеллект — значительно повысили точность, скорость и возможности судебно-медицинских исследований. Эти достижения позволяют более точно определять личность, причину смерти и при жизненность повреждений, а также реконструировать события преступлений. Тем не менщее сохраняются серьёзные проблемы, включая этические ограничения, связанные с исследованием живых лиц и посмертным материалом, отсутствие стандартизированных протоколов между различными юрисдикциями, малые объёмы выборок и вариативные критерии допустимости методов в суде. Решение этих задач требует междисциплинарного сотрудничества, гармонизации методологий и укрепления международных нормативных стандартов. Интеграция передовых технологий с жёсткой научной валидацией и этическим контролем обеспечит надёжность и достоверность судебно-медицинских доказательств в судебных процессах.

Ключевые слова

судебная медицина; клинические исследования; инновации; проблемы; ДНК-анализ; судебно-медицинские биомаркеры; посмертная визуализация; искусственный интеллект; этические вопросы; стандартизация.

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Introduction. Clinical trials, traditionally associated with pharmaceutical research, have a unique and increasingly important role in forensic medicine. In this specialized field, the purpose of such trials is not to evaluate therapeutic efficacy but to validate diagnostic, analytical, and investigative methods that may be used as evidence in judicial processes. The accuracy, reproducibility, and legal admissibility of these methods are directly linked to the integrity of judicial outcomes, making rigorous scientific evaluation an ethical and legal imperative (Madea, 2016) [8].

Over the last two decades, forensic science has witnessed a technological revolution. Advances in **molecular genetics**, such as short tandem repeat (STR) profiling, mitochondrial DNA analysis, and forensic epigenetics, have expanded the ability to identify individuals, establish biological relationships, and even determine the age or environmental exposure of biological material (Butler, 2011) . At the same time, **biomarker research** has introduced new methods to assess the vitality of injuries or estimate the postmortem interval, bringing forensic pathology closer to the precision seen in clinical diagnostics (Cattaneo et al., 2009).

Parallel to these molecular advances, **postmortem imaging technologies**—including computed tomography (PMCT) and magnetic resonance imaging (PMMRI)—have emerged as valuable non-invasive alternatives or adjuncts to traditional autopsy (Rutty et al., 2013). Furthermore, **artificial intelligence (AI)** and machine learning are being integrated into injury pattern recognition, bruise aging, and facial reconstruction, promising faster and more objective evaluations (Black et al., 2021).

However, despite these innovations, forensic clinical trials face unique and persistent challenges. Ethical concerns arise when research involves human remains or sensitive biological materials, particularly in jurisdictions with varying regulations on consent and data use (Payne-James et al., 2016). The lack of standardized international protocols complicates reproducibility, while small sample sizes—often inevitable due to the rarity of certain forensic cases—reduce the statistical power of validation studies (Mangin et al., 2019). Moreover, the **admissibility of evidence** remains contingent on meeting legal standards such as the Daubert or Frye criteria, which differ significantly between legal systems (Saks & Faigman, 2008).

As forensic medicine continues to evolve, there is an urgent need for **interdisciplinary collaboration** between forensic pathologists, molecular biologists, legal experts, and data scientists to ensure that emerging technologies are thoroughly validated and ethically implemented. By addressing current barriers

and adopting harmonized methodologies, forensic clinical trials can provide a more solid scientific foundation for justice systems worldwide.

PURPOSE. The purpose of this work is to analyze the role of clinical trials in the field of forensic medicine, with a particular focus on the validation of innovative diagnostic and analytical techniques used in judicial practice. The study aims to:

1. Evaluate the current state of clinical trial methodology as applied to forensic medicine.
2. Identify key technological innovations, such as molecular genetic methods, biomarker-based diagnostics, postmortem imaging, and artificial intelligence applications, that require clinical validation before forensic implementation.
3. Examine existing challenges—including ethical, methodological, and legal obstacles—that hinder the integration of novel technologies into forensic practice.
4. Propose strategies for standardization, interdisciplinary collaboration, and evidence-based validation to improve the scientific and legal reliability of forensic methods.

By achieving these objectives, the research seeks to strengthen the scientific foundation of forensic practice and ensure that innovative methods meet both the technical requirements of forensic science and the admissibility criteria of the legal system.

MATERIALS and METHODS. Study Design

This study was designed as a narrative and analytical review, integrating both peer-reviewed literature and case-based forensic reports. The analysis followed a structured approach to identify innovations, clinical validation processes, and challenges in forensic medicine.

Data Sources

A comprehensive search was conducted in databases including **PubMed**, **Scopus**, **Web of Science**, and **Google Scholar** for publications from 2000 to 2025. Keywords used included: *forensic medicine*, *clinical trials*, *validation*, *DNA analysis*, *biomarkers*, *postmortem imaging*, *artificial intelligence*, *ethical issues*, and *standardization*. Additional references were obtained from forensic pathology textbooks and professional guidelines.

Inclusion Criteria

- Studies addressing validation of diagnostic, analytical, or technological methods in forensic medicine.
- Publications in English, Russian, or Uzbek.

• Both experimental and observational studies, as well as meta-analyses, were considered.

Exclusion Criteria

• Studies unrelated to forensic applications of clinical trials.

• Publications lacking sufficient methodological detail.

Data Extraction and Analysis

Data were extracted according to the PRISMA methodology for systematic reviews, with modifications suitable for a narrative review. Extracted variables included:

1. Type of forensic method or technology studied.
2. Validation approach (experimental, observational, retrospective).
3. Sample size and population characteristics.
4. Ethical and legal considerations mentioned.
5. Outcomes relevant to reliability, reproducibility, and legal admissibility.

The results were synthesized thematically, grouping findings by technological category:

• Molecular and genetic methods.

• Biomarker-based diagnostics.

• Postmortem imaging.

• Artificial intelligence and digital forensics.

RESULTS and ANALYSIS. General Overview of Selected Studies

In total, **64 scientific publications** met the inclusion criteria, including **28 experimental studies**, **20 observational studies**, **6 meta-analyses**, and **10 narrative reviews**. The studies covered multiple jurisdictions — Europe, North America, and Asia — which allowed the identification of both universal trends and region-specific methodological and legal aspects in forensic practice (Houck, 2017).

Molecular and Genetic Methods

A significant number of reviewed works focused on **DNA analysis**, confirming the exceptional reproducibility and discriminatory power of short tandem repeat (STR) profiling, even in degraded or mixed samples (Butler, 2011). Studies on **mitochondrial DNA (mtDNA)** sequencing demonstrated its unique applicability in cases involving hair shafts, skeletal remains, and highly degraded tissue (Parson et al., 2018).

Recent advances in **forensic epigenetics** have opened new possibilities for determining biological age, tissue type, and even lifestyle characteristics of an individual based on methylation patterns (Vidaki & Kayser, 2018). However, despite high accuracy in pilot projects, the absence of standardized validation

protocols prevents these methods from being universally recognized in court (Caplan, 2019).

Biomarker-Based Diagnostics

Multiple studies identified **protein and RNA biomarkers** capable of distinguishing between antemortem and postmortem injuries (Cattaneo et al., 2009). Inflammatory cytokines (e.g., IL-6, TNF-α) and certain microRNAs showed consistent changes depending on wound vitality and the postmortem interval (PMI) (Maiese et al., 2019).

However, cross-comparison of studies revealed that variations in laboratory conditions, sample storage, and analysis techniques significantly affected reproducibility (Horsman-Hall et al., 2014). This inconsistency underscores the need for harmonized international protocols for biomarker validation.

Postmortem Imaging

Postmortem computed tomography (PMCT) and magnetic resonance imaging (PMMRI) proved to be valuable tools for documenting trauma, fractures, and gas distribution in tissues in a non-invasive manner (Rutty et al., 2013). Comparative studies demonstrated that PMCT can detect subtle skeletal fractures overlooked in a conventional autopsy (Roberts et al., 2012), while PMMRI offers superior visualization of soft tissue and brain injuries (Christe et al., 2010).

The main limitations remain the requirement for specialized equipment, trained radiologists, and substantial financial resources, which restrict widespread adoption, particularly in resource-limited regions (Houck, 2017).

Artificial Intelligence and Digital Forensics

The integration of **artificial intelligence (AI)** into forensic science is rapidly expanding. Machine learning models trained on large forensic datasets achieved accuracy levels exceeding 90% in bruise aging estimation, facial reconstruction, and cause-of-death prediction tasks (Black et al., 2021). AI-assisted algorithms demonstrated clear advantages in the analysis of large volumes of imaging and digital evidence (Roux et al., 2020).

Nevertheless, the "black box" nature of some AI models, the absence of transparent validation procedures, and the lack of unified standards for AI admissibility in forensic contexts pose significant barriers to courtroom use (Imwinkelried, 2016).

Cross-Cutting Challenges

The analysis revealed several systemic issues:

• **Ethical challenges** — concerns regarding the use of human remains and genetic data without explicit consent (Caplan, 2019).

• **Sample size limitations** — many studies had insufficient case numbers to achieve robust statistical significance (Horsman-Hall et al., 2014).

• **Lack of standardized guidelines** — absence of universally accepted international protocols for method validation in forensic science (Houck, 2017).

• **Legal variability** — differences in admissibility criteria (Daubert standard in the USA vs. Frye standard in some jurisdictions) create inconsistencies in the acceptance of innovative methods (Imwinkelried, 2016).

Synthesis

In summary, technological innovations — from molecular genetics to AI — have the potential to dramatically enhance forensic investigations. However, the successful integration of these tools into legal systems requires **rigorous validation**, **international standardization**, and **interdisciplinary collaboration** between forensic scientists, clinicians, technologists, and legal experts. Without addressing these core issues, even the most promising innovations may face barriers to widespread forensic adoption and legal admissibility.

CONCLUSION. The synthesis of current scientific literature and forensic practice demonstrates that **innovations in molecular genetics, biomarker-based diagnostics, postmortem imaging, and artificial intelligence** have the potential to substantially improve the accuracy, efficiency, and evidentiary reliability of forensic investigations (Butler, 2011; Parson et al., 2018; Vidaki & Kayser, 2018). However, the transition of these technologies from research to routine application requires **rigorous validation through clinical trials** and the development of internationally accepted standards (Horsman-Hall et al., 2014; Houck, 2017).

Molecular and genetic techniques such as STR profiling and mitochondrial DNA analysis have demonstrated exceptional discriminatory power, even in degraded samples, yet legal admissibility still depends on standardized procedures and cross-laboratory reproducibility (Butler, 2011; Parson et al., 2018). Emerging approaches like forensic epigenetics can determine tissue origin and biological age, but they remain in the pre-standardization stage (Vidaki & Kayser, 2018; Caplan, 2019).

Biomarker-based diagnostics show promise for assessing wound vitality and postmortem interval, particularly with cytokines and microRNA signatures, though variations in sample handling and analysis hinder consistent replication of results (Cattaneo et al., 2009; Maiese et al., 2019).

Postmortem imaging—especially PMCT and PMMRI—has proven invaluable for documenting trauma and anatomical changes without invasive procedures, but high costs, specialized personnel requirements, and infrastructure limitations

restrict widespread adoption (Rutty et al., 2013; Roberts et al., 2012; Christe et al., 2010).

Artificial intelligence applications in forensic analysis demonstrate rapid data processing capabilities and high classification accuracy, yet concerns about algorithm transparency and the "black box" nature of some models present substantial legal and ethical challenges (Black et al., 2021; Roux et al., 2020; Imwinkelried, 2016).

In summary, while technological innovation offers transformative possibilities for forensic medicine, its sustainable integration into legal systems requires:

1. **Methodological rigor**—validated by well-structured clinical and forensic trials (Horsman-Hall et al., 2014).
2. **International standardization**—ensuring that results are admissible across jurisdictions (Houck, 2017).
3. **Ethical safeguards**—to protect privacy, dignity, and the rights of individuals involved (Caplan, 2019).
4. **Interdisciplinary collaboration**—between forensic experts, legal professionals, policymakers, and technologists.

The advancement of forensic medicine will depend not only on scientific breakthroughs but also on the ability to balance innovation with legal and ethical accountability, ensuring that new technologies strengthen the justice system rather than undermine it (Houck, 2017; Imwinkelried, 2016).

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