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TRANSLATION OF CLINICAL RESEARCH TERMINOLOGY IN THE UKRAINIAN-ENGLISH CONTEXT: FROM AMBIGUITY TO UNIFICATION

This article examines the translation of clinical research terminology from Ukrainian to English, considering linguistic discrepancies and ICH GCP E6(R2) standards. The study identifies morphological, syntactic, and semantic differences between Ukrainian and English terms that complicate the translation of regulatory documents, such as protocols, reports, and informed consent forms. Ukrainian terms are often polysemous, descriptive, or multi-component, e.g., "досліджуваний препарат" (investigational product), "первинна кінцева точка" (primary endpoint), or "серйозна небажана подія" (serious adverse event), while English terms are unified, concise, and functional. Inaccurate translation can lead to legal, ethical, and methodological issues, affecting participant safety, result reliability, and compliance with international regulators like the FDA and EMA. To address these challenges, three strategies are proposed: contextualization, use of unified glossaries, and adaptation. Contextualization tailors translations to document type and audience, ensuring accessibility for participants and precision for regulators. Glossaries standardize terminology, reducing variability, e.g., fixing "randomisation" for "рандомізація." Adaptation addresses terms without equivalents, such as "controlled trial" for "контрольоване дослідження." Practical applications are illustrated with examples like "serious adverse event" and "blinding." The article highlights the importance of harmonizing Ukrainian terminology with international standards to support Ukraine's integration into global clinical research, particularly given the rise in international trials (over 200 in 2023, per Ukraine's Ministry of Health). Future research prospects include evaluating automated translation with CAT tools, analyzing reverse translation, developing bilingual glossaries, comparing language pairs, and studying translation's impact on participants' term perception. The work enhances translation practices, improves regulatory document quality, and ensures ethical standards in clinical research.

Key words: *clinical research terminology, translation strategies, ICH GCP standards, linguistic discrepancies.*

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ПЕРЕКЛАД ТЕРМІНОЛОГІЇ КЛІНІЧНИХ ДОСЛІДЖЕНЬ В УКРАЇНСЬКО-АНГЛІЙСЬКОМУ КОНТЕКСТІ: ВІД БАГАТОЗНАЧНОСТІ ДО УНІФІКАЦІЇ

Стаття присвячена аналізу перекладу термінології клінічних досліджень з української на англійську мову з урахуванням лінгвістичних розбіжностей і стандартів ICH GCP E6(R2). Дослідження виявляє морфологічні,

синтаксичні та семантичні відмінності між українськими та англійськими термінами, що ускладнюють відтворення регуляторних документів, зокрема протоколів, звітів і форм інформованої згоди. Українські терміни часто є багатозначними, описовими чи багатокомпонентними, як-от "досліджуваний препарат", "первинна кінцева точка" або "серйозна небажана подія", тоді як англійські – уніфікованими, стислими та функціональними ("investigational product", "primary endpoint", "serious adverse event"). Неточний переклад може спричинити юридичні, етичні та методологічні проблеми, впливаючи на безпеку учасників, достовірність результатів і відповідність вимогам міжнародних регуляторів, таких як FDA та EMA. Для подолання цих викликів пропонується три стратегії: контекстуалізація, використання уніфікованих глосаріїв та адаптація. Контекстуалізація адаптує переклад до типу документа й аудиторії, забезпечуючи доступність для учасників і точність для регуляторів. Глосарії стандартизують термінологію, зменшуючи варіативність, наприклад, фіксуючи "randomisation" для "рандомізації". Адаптація вирішує проблему термінів без еквівалентів, як-от "controlled trial" для "контрольоване дослідження". Практичне застосування стратегій ілюструється прикладами, такими як "serious adverse event" і "blinding". Стаття підкреслює важливість гармонізації української термінології з міжнародними стандартами для інтеграції України в глобальні клінічні дослідження, особливо з огляду на зростання кількості міжнародних випробувань (понад 200 у 2023 році, за даними Державного експертного центру МОЗ України). Перспективи подальших досліджень охоплюють оцінку автоматизованого перекладу з використанням CAT-інструментів, аналіз зворотного перекладу, створення двомовних глосаріїв, порівняльний аналіз мовних пар і вивчення впливу перекладу на сприйняття термінів учасниками. Робота сприяє вдосконаленню перекладацької практики, підвищенню якості регуляторних документів і забезпеченню етичних стандартів у клінічних дослідженнях.

Ключові слова: *термінологія клінічних досліджень, стратегії перекладу, стандарти ICH GCP, лінгвістичні розбіжності.*

Problem statement. The terminology of clinical research represents a sophisticated and multifaceted system of concepts that intertwines linguistic, regulatory, and functional dimensions. International standards, notably the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH GCP E6(R2)), establish standardized English terms to ensure precision, clarity, and unambiguity in a global regulatory context. These standards facilitate seamless communication among researchers, regulators, and sponsors across countries, ensuring that terms like "serious adverse event" or "randomisation" carry consistent meanings in protocols, reports, and informed consent forms. In contrast, Ukrainian terminology frequently adheres to local linguistic norms, which are rooted in Slavic linguistic traditions and often favor descriptive or multi-component constructions. This divergence leads to significant discrepancies in translation, posing challenges for harmonizing Ukrainian clinical research terminology with global standards.

The relevance of this article stems from the critical need to address these translation discrepancies, which can undermine the integrity of clinical research. The study focuses on analyzing the translation of key clinical research terms, exploring their morphological, syntactic, and semantic differences between Ukrainian and English. For instance, terms like "досліджуваний препарат" (investigational product) or "інформована згода" (informed consent) in Ukrainian are often verbose or polysemous, contrasting with the concise and standardized English equivalents. These differences can lead to misinterpretations in regulatory documents, potentially affecting compliance with international guidelines and the safety of research participants. Inaccurate translations may result in miscommunication of critical information, such as the risks outlined in informed consent forms or the methodological details in study protocols, which could violate ethical principles outlined in documents like the Declaration of Helsinki.

This article aims to systematically identify and elucidate a range of pressing issues related to the translation of medical terms in clinical research. It examines their definition, classification, and structural-semantic characteristics, shedding light on how linguistic nuances impact regulatory compliance. For example, the Ukrainian term "серйозна небажана подія" (serious adverse event) carries an emotional connotation that may obscure its technical definition in ICH GCP, potentially leading to errors in adverse event reporting (ICH GCP, 2016: 12-54). By addressing these challenges, the study seeks to propose strategies for improving translation practices, ensuring that Ukrainian terminology aligns with global standards. This is particularly crucial for Ukraine, where the number of international clinical trials has grown significantly according to the State Expert Center of the Ministry of Health of Ukraine. The work also lays the groundwork for future research into automated translation tools and bilingual glossaries to further enhance harmonization efforts.

Analysis of recent research and publications. The study of medical terminology has long been a focal point for linguists and medical researchers,

given its critical role in ensuring precision and clarity in scientific communication. Many scholars have laid foundational work in terminology studies, exploring the structural and semantic properties of medical terms across languages. Their research emphasizes the importance of standardized terminologies in facilitating cross-linguistic communication, particularly in scientific and regulatory contexts. However, the specific challenge of translating clinical research terminology, especially in the context of international standards like ICH GCP E6(R2), remains underexplored in contemporary scholarship (ICH GCP, 2016: 12-54). This gap is significant, as clinical research terminology requires not only linguistic accuracy but also alignment with regulatory and methodological frameworks to ensure compliance and participant safety.

O. Velykodnyi's work provides a comprehensive overview of translation techniques for medical terms, focusing on strategies such as equivalence, adaptation, and descriptive translation (Velykodnyi, 2018: 21-38). While Velykodnyi addresses general medical terminology, his work only briefly touches on the unique challenges of clinical research terms, such as those defined in ICH GCP. Similarly, O. Snitovska examines the translation of pharmaceutical instructions, highlighting issues of polysemy and cultural adaptation (Snitovska, 2020: 32-37). Snitovska notes that terms like "placebo" often carry colloquial meanings in Ukrainian, which can lead to misinterpretations in regulatory contexts. G. Khatser explores the translation of terminological vocabulary in medical texts, emphasizing syntactic differences between Ukrainian and English (Khatser, 2019: 56-68). Khatser's findings suggest that Ukrainian's descriptive tendencies complicate the rendering of concise English terms like "controlled trial."

V. Konovalov addresses the translation of emerging terms, such as those introduced by advancements in clinical research methodologies (Konovalov, 2021: 13-27). Konovalov argues that neologisms like "randomisation" pose challenges due to the lack of direct Ukrainian equivalents, often requiring borrowing or adaptation. L. Zastrizhna provides a detailed analysis of English medical terms' structural properties, noting their reliance on Latin and Greek roots, which contrasts with Ukrainian's Slavic-based descriptive constructions (Zastrizhna, 2022: 12-16). While these works collectively advance the understanding of medical translation, they do not fully address the specific linguistic and regulatory complexities of clinical research terminology, particularly in the Ukrainian-English context.

The limited focus on clinical research terminology in existing literature underscores the need for this article. Unlike general medical or pharmaceutical terminology, clinical research terms are tightly regulated by ICH GCP, requiring translations that preserve methodological precision and legal compliance. For instance, the term "informed consent" must reflect its status as a legal procedure in ICH GCP, not merely an ethical concept, as it is often perceived in Ukrainian. The lack of standardized bilingual glossaries and the variability in translation practices among Ukrainian researchers further exacerbate these challenges, particularly in the context of Ukraine's growing participation in global clinical trials (over 200 trials in 2023, per the State Expert Center of the Ministry of Health of Ukraine). This article builds on the foundational work of these scholars by focusing specifically on the translation of clinical research terms, proposing strategies to bridge linguistic gaps and align with international regulatory standards.

The aim of the article is to develop and propose effective strategies for overcoming linguistic and regulatory discrepancies between Ukrainian and English in the translation of clinical research terminology, thereby ensuring compliance with international standards and enhancing the quality of regulatory documentation. This objective is driven by the need to address the complexities of translating terms that are critical to clinical research, where precision and clarity are paramount for legal, ethical, and methodological integrity. The study seeks to bridge the gap between local linguistic practices in Ukraine and the global standards set by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH GCP E6(R2)), which governs clinical trial documentation worldwide. By identifying translation strategies, the article aims to facilitate Ukraine's integration into the global clinical research landscape, where accurate terminology is essential for collaboration with international sponsors and regulators such as the FDA and EMA.

Clinical research terms, as defined in ICH GCP, are designed to be precise and unambiguous to ensure consistency across diverse regulatory environments. However, their reproduction in Ukrainian is fraught with challenges due to structural, semantic, and cultural peculiarities inherent in the language. Ukrainian terminology often reflects Slavic linguistic traditions, favoring descriptive and multi-component constructions that can obscure technical meanings required in clinical research. These discrepancies can lead to misinterpretations in critical documents, such as clinical trial protocols, adverse event reports, and

informed consent forms, potentially compromising participant safety and regulatory compliance. For instance, mistranslating a term like "serious adverse event" could result in underreporting of life-threatening incidents, violating ethical standards like those in the Declaration of Helsinki. The following table illustrates key examples of these discrepancies:

These examples underscore the fundamental differences between Ukrainian and English clinical research terminology. Ukrainian terms are frequently ambiguous, descriptive, or borrowed, which contrasts sharply with the unified and functional nature of English terms standardized by ICH GCP. As shown in Table 1, "рандомізація" (randomisation) sounds artificial in Ukrainian but aligns with regulatory documents, unlike the more natural but less precise "випадковий розподіл" (random allocation). Similarly, "плацебо" carries a broad everyday meaning in Ukrainian, which can lead to confusion in regulatory contexts where ICH GCP demands a strict definition as an inactive substance used for comparison. The term "досліджуваний препарат" (investigational product) is verbose and descriptive, whereas its English counterpart is compact and standardized, reflecting the regulatory preference for brevity and clarity. These linguistic differences pose significant challenges for translators, who must navigate not only linguistic norms but also the stringent requirements of ICH GCP to ensure methodological accuracy and legal compliance.

The complexity of translation is further compounded by the need to balance linguistic fidelity with regulatory precision. For example, translating "інформована згода" as "informed consent" requires conveying its legal weight as a documented procedure, not merely an ethical concept, which may be lost in direct translation. Similarly, terms like "сліпий метод" (blinding) may be misinterpreted as mere concealment unless clarified as single- or double-blinding, a distinction critical to study design integrity. These challenges highlight the need for strategic translation approaches that account for both linguistic nuances and regulatory contexts, ensuring that translated documents are suitable for international scrutiny. In Ukraine, where clinical trials have surged, accurate translation is vital for maintaining trust with global stakeholders and adhering to ethical and legal standards.

Morphological Level

The morphological structure of Ukrainian clinical research terminology often contrasts sharply with its English counterparts, presenting significant challenges for translation. Ukrainian terms tend to be complex, multi-component, and descriptive, reflecting the language's Slavic roots and preference for explicit, compound constructions. For example, the term "небажана подія" (adverse event) comprises two words and conveys a descriptive quality, whereas the English "adverse event" is a compact, standardized

Table 1

Comparison of Clinical Research Terms in Ukrainian and English

Ukrainian Term	English Term	Explanation
Серйозна небажана подія	Serious adverse event	In ICH GCP, an event leading to death, hospitalization, or significant health impairment. The Ukrainian "серйозна" carries an emotional connotation, while the English term is technical.
Рандомізація	Randomisation	Borrowed into Ukrainian; "випадковий розподіл" (random allocation) is more natural but less formal. In English, it is an established methodological term.
Плацебо	Placebo	Used in both everyday and scientific contexts; in ICH GCP, it refers to an inactive substance for comparison with a drug, with a strict definition.
Контрольоване дослідження	Controlled trial	The Ukrainian "контрольоване" is associated with oversight, while the English term indicates a control group as a methodological feature.
Сліпий метод	Blinding	The Ukrainian term literally describes concealment; the English "blinding" encompasses single- or double-blinding with methodological significance.
Досліджуваний препарат	Investigational product	The Ukrainian term is descriptive, while the English term is concise and standardized in ICH GCP.
Первинна кінцева точка	Primary endpoint	The Ukrainian "кінцева точка" is abstract and requires clarification; the English term is an established concept.
Інформована згода	Informed consent	In Ukrainian, it is an ethical principle; in ICH GCP, it is a legal procedure with strict requirements.

term in ICH GCP E6(R2) that prioritizes brevity and regulatory precision. Similarly, "серйозна небажана подія" (serious adverse event) adds a specifier for severity, resulting in a cumbersome three-word phrase that contrasts with the succinct English equivalent. Another illustrative case is "контрольоване клінічне дослідження" (controlled clinical trial), which is verbose and multi-word, while the English term is streamlined for regulatory clarity. These morphological differences complicate translation, as translators must balance the preservation of meaning with the conciseness and uniformity required by ICH GCP standards, which are designed to ensure global consistency in clinical trial documentation.

This morphological divergence is rooted in the historical and linguistic evolution of the two languages. English medical terminology heavily draws on Latin and Greek roots, which facilitate the creation of compact, single-word or hyphenated terms like "randomisation," "placebo," or "endpoint." These terms are designed to be universally understood within the scientific community, aligning with the global standardization efforts of ICH GCP. In contrast, Ukrainian, despite incorporating some Latin-based borrowings, retains a Slavic tendency toward verbose, multi-component structures. Terms like "досліджуваний препарат" (investigational product) and "первинна кінцева точка" (primary endpoint) exemplify this, as they rely on descriptive phrases that combine adjectives and nouns to convey meaning. This verbosity can obscure the technical precision required in clinical research, where ICH GCP demands unambiguous terminology to prevent misinterpretation in critical documents such as adverse event reports or study protocols.

The challenge of translating these multi-component Ukrainian terms is further amplified by the need to adhere to regulatory standards while maintaining linguistic fidelity. For instance, a direct translation of "досліджуваний препарат" as "investigated drug" may fail to capture the specific regulatory meaning of "investigational product," which refers to a drug or substance under clinical evaluation. Similarly, "первинна кінцева точка" (primary endpoint) is abstract and requires additional clarification in Ukrainian to convey the precise methodological concept of a primary outcome measure. Such discrepancies can lead to errors in translation that affect the accuracy of regulatory submissions, potentially delaying approvals by international bodies like the FDA or EMA. In Ukraine these morphological challenges underscore the need for standardized translation practices.

To address these issues, translators must employ strategies such as adaptation or abbreviation to align Ukrainian terms with English standards. For example, adopting "investigational product" directly as a loan translation or creating a standardized Ukrainian equivalent could reduce verbosity while preserving regulatory accuracy. Additionally, the development of bilingual glossaries could help formalize translations, ensuring consistency across documents. These efforts are critical not only for linguistic accuracy but also for supporting Ukraine's integration into global clinical research, where precise terminology is essential for collaboration with international sponsors and compliance with ethical standards like those outlined in the Declaration of Helsinki.

Syntactic Level

Syntactic discrepancies between Ukrainian and English clinical research terminology significantly complicate the translation process, as they affect the structure, word order, and overall clarity of terms in regulatory documents. Ukrainian typically follows a syntactic pattern where adjectives precede nouns, as seen in terms like "первинна кінцева точка" (primary endpoint) and "серйозна небажана подія" (serious adverse event). This construction aligns with Slavic linguistic norms but often results in verbose and multi-word phrases. In contrast, English clinical research terminology, standardized by ICH GCP E6(R2), frequently employs a reversed word order or more compact structures, prioritizing methodological precision and regulatory uniformity. For example, the English term "controlled clinical trial" (контрольоване клінічне дослідження) establishes a clear hierarchical structure, with "controlled" as the primary modifier indicating the presence of a control group, a critical methodological feature. The Ukrainian equivalent, however, is lengthier and less compact, potentially obscuring the term's technical specificity in regulatory contexts.

Another illustrative example is "double blinding" (подвійний сліпий метод). In Ukrainian, the construction "подвійний сліпий" is cumbersome and requires additional clarification to convey the methodological nuance of single- or double-blinding, which ensures objectivity in clinical trials. The English term, by contrast, is concise, standardized, and immediately recognizable to regulators and researchers familiar with ICH GCP guidelines. These syntactic differences pose challenges for translators, who must adapt Ukrainian constructions to align with the English style while preserving the methodological and regulatory significance of the terms. This task demands not only linguistic expertise but also a deep understanding of clinical research methodologies, as misaligned word order or overly descriptive translations can lead to ambiguities in

critical documents like study protocols or informed consent forms.

The impact of syntactic discrepancies extends beyond mere translation challenges, affecting the accuracy and clarity of regulatory texts where precision is paramount. For instance, the term "інформована згода" (informed consent) in Ukrainian follows the adjective-noun structure, emphasizing its ethical dimension. However, in English, "informed consent" is a noun phrase that functions as a legal procedure under ICH GCP, requiring strict documentation and participant comprehension. A direct translation without syntactic adaptation may fail to convey this legal weight, potentially leading to non-compliance with international standards. Similarly, translating "open-label trial" (відкрите дослідження) as a literal adjective-noun phrase in Ukrainian may obscure the methodological implication of a trial without blinding, necessitating additional explanatory notes.

These syntactic challenges are particularly significant in Ukraine's growing clinical research landscape. Accurate translation is essential for ensuring that Ukrainian clinical trial documentation meets the scrutiny of international regulators like the FDA and EMA. To address these issues, translators can employ strategies such as syntactic restructuring or adaptation. For example, adopting compact English-style constructions or using standardized loan terms (e.g., "blinding" instead of "подвійний сліпий метод") can enhance clarity. Additionally, bilingual glossaries that map Ukrainian syntactic structures to their English equivalents could streamline translation processes, ensuring consistency across documents. These efforts are critical for harmonizing Ukrainian terminology with global standards, supporting ethical compliance with documents like the Declaration of Helsinki, and facilitating Ukraine's integration into the international clinical research community.

Semantic Level

Semantic discrepancies in the translation of clinical research terminology from Ukrainian to English pose significant challenges, as they involve differences in the meaning and functional load of terms. The polysemy of Ukrainian terms often complicates their accurate rendering in English, particularly in the context of ICH GCP E6(R2), which demands precise and unambiguous terminology for regulatory compliance. For instance, the term "плацебо" carries both a scientific meaning (an inactive substance used in clinical trials) and a colloquial one (referring to the placebo effect), creating potential for confusion. In contrast, ICH GCP defines "placebo" strictly as an inactive substance for comparison with an investigational drug, requiring translators to prioritize this technical definition over broader cultural connotations. Similarly, the Ukrainian term "дослідження" can be translated as either "study" or "trial," but in clinical research documents, "trial" is the standard term, reflecting the methodological specificity of a structured experimental process. The term "контрольоване" in "контрольоване дослідження" (controlled trial) is often associated with general oversight in Ukrainian, whereas the English "controlled" specifically denotes the use of a control group, a critical element of clinical trial design.

The absence of direct equivalents further complicates translation. For example, "рандомізація" (randomisation), a borrowed term in Ukrainian, sounds artificial and may not resonate naturally with local researchers or regulators. The alternative, "випадковий розподіл" (random allocation), is more natural but lacks the technical precision required by ICH GCP, potentially leading to ambiguity in protocols or reports. Similarly, "інформована згода" (informed consent) is often perceived in Ukrainian as an ethical principle, emphasizing participant autonomy. However, in ICH GCP, it is a legal procedure with stringent documentation requirements, including written forms and detailed explanations of risks and rights. Cultural and regulatory factors exacerbate these discrepancies. For instance, "сліпий метод" (blinding) literally describes concealment in Ukrainian, which may not fully convey the methodological nuances of single- or double-blinding in English, where the term encompasses specific procedures to ensure trial objectivity.

These semantic challenges have profound implications for clinical research, particularly in Ukraine. Mistranslating terms like "serious adverse event" as a less precise phrase could lead to underreporting of critical incidents, violating ethical standards such as those in the Declaration of Helsinki and potentially jeopardizing participant safety. For example, translating "серйозна небажана подія" as "severe unwanted event" instead of "serious adverse event" could obscure its regulatory definition as an event requiring hospitalization or causing significant health impairment. To address these issues, translators must employ strategies like contextualization, ensuring terms align with their regulatory function. For instance, "blinding" may require explanatory notes in Ukrainian translations to clarify single- or double-blinding. Developing bilingual glossaries could also standardize terms, reducing semantic ambiguity and ensuring consistency across documents. These efforts are crucial for aligning Ukrainian terminology with global standards, facilitating collaboration with international regulators like the FDA and EMA, and

supporting Ukraine's growing role in global clinical research.

Consequences of Inaccurate Translation

Inaccurate translation can have serious consequences for clinical research, affecting legal compliance, participant safety, and the clarity of documents for international sponsors. For example, translating "небажана подія" as "unwanted event" instead of "adverse event" alters the meaning, as "unwanted event" is not a regulatory term and does not align with the ICH GCP definition. This could lead to incorrect documentation of adverse effects, jeopardizing participant health and violating the ethical principles of the Declaration of Helsinki.

Translating "blinding" (сліпий метод) as "concealment" distorts the methodology, as "blinding" implies specific procedures (single- or double-blinding) that affect result reliability. Misinterpreting "primary endpoint" (первинна кінцева точка) as an abstract "goal" instead of the primary measure of efficacy can alter protocol interpretation, impacting statistical analysis and conclusions. In the context of "informed consent," inaccuracies may violate participants' rights if study conditions are not clearly explained, contravening ICH GCP and Ukraine's Law on Medicinal Products.

Such errors complicate document approval by international regulators (FDA, EMA), which demand compliance with ICH GCP standards. In Ukraine, where clinical trials are regulated by Ministry of Health Order No. 690 of 23.09.2009, inaccurate translation can create discrepancies between local and international requirements, risking project delays and financial losses for sponsors.

Strategies for Overcoming Linguistic Discrepancies in Translating Clinical Research Terminology

Translating clinical research terminology from Ukrainian to English is a complex task that requires a systematic approach to address linguistic discrepancies and ensure compliance with ICH GCP E6(R2) standards. The preceding analysis revealed that these discrepancies are morphological, syntactic, and semantic in nature, complicating the reproduction of regulatory documents – protocols, reports, and informed consent forms. Inaccurate translation can lead to legal, ethical, and methodological issues, affecting participant safety and study reliability. To address these challenges, three strategies are proposed: contextualization, use of unified glossaries, and adaptation.

Contextualization as a Translation Strategy

Contextualization involves selecting a translation based on the document type, target audience, and context of use, adapting terms to regulatory and communicative requirements. This approach relies on understanding the functional load of terms, which varies by situation. For instance, "серйозна небажана подія" in a report adhering to ICH GCP standards is translated as "serious adverse event" – an established term defined as an event that is life-threatening, requires hospitalization, or results in significant health impairment. The translation must be precise and align with the technical definition to avoid ambiguity for regulators or sponsors.

In contrast, in participant instructions, where the audience is less familiar with terminology, "serious adverse event (a significant health issue requiring medical attention)" is more appropriate, making the content accessible while maintaining legal accuracy. The term "дослідження" in a general context is translated as "study," but in regulatory documents, it becomes "trial" (e.g., "clinical trial"), reflecting methodological specificity. This approach is effective for polysemous terms: "небажана подія" (adverse event) in a report is rendered as "adverse event" without explanation, aligning with ICH GCP standards, while in instructions, it becomes "adverse event (a negative health effect)" for participant clarity. Contextualization avoids excessive formalization where accessibility is needed and ensures rigor in technical documents, demonstrating flexibility in translation.

Use of Unified Glossaries

Creating unified glossaries is an effective way to standardize translation, reducing variability and the risk of errors. In clinical research, where terminology accuracy is critical for legal compliance and safety, glossaries serve as a tool for harmonizing Ukrainian and English. For example, "рандомізація" poses challenges: "випадковий розподіл" (random allocation) sounds more natural and is used informally, but it lacks the technical precision of "randomisation" – a methodological process in ICH GCP to ensure objectivity. A glossary fixes "randomisation" as the sole equivalent of "рандомізація," avoiding confusion and ensuring consistency.

The term "плацебо" in Ukrainian has a broader colloquial meaning (e.g., "placebo effect"), which can lead to misinterpretation. A glossary defines it as "placebo (an inactive substance used for comparison with the investigational drug)," aligning with ICH GCP. For terms with regulatory significance, such as "інформована згода" (informed consent) – a legal procedure requiring written consent after explaining conditions – a glossary establishes "informed consent," avoiding alternatives ("voluntary consent," "informed agreement") that do not meet the standard. Glossaries

create a unified terminological framework, facilitating collaboration among translators, researchers, and regulators, which is particularly important in Ukraine, where translations are often performed by different specialists without coordination.

Adaptation for Terms Without Equivalents

Adaptation is essential for terms lacking direct equivalents or with differing functional loads. This approach involves modifying a term to suit the regulatory context while preserving meaning and compliance with standards. For example, "контрольоване дослідження" is associated with oversight, whereas "controlled trial" in ICH GCP refers to a study with a control group. A direct translation of "controlled trial" is correct, but adaptation may add a note: "controlled trial (a study with a control group)."

The term "сліпий метод" (blinding) literally describes concealment, while "blinding" encompasses single- or double-blinding for objectivity. Adaptation proposes "blinding" with an optional explanation: "method of data concealment (single- or double-sided)." An example is "відкрите дослідження" (open-label trial), where "відкрите" does not fully convey the absence of group concealment; adaptation yields "open-label trial" with a possible note: "a study without concealment of conditions." For descriptive terms like "досліджуваний препарат" (investigational product), adaptation replaces the verbose construction with the concise English term. Adaptation harmonizes terminology in cases of significant structural differences, making it a key tool in translating regulatory texts.

Practical Application of Strategies

The practical application of these strategies illustrates their effectiveness in overcoming discrepancies. Table 2 provides examples of terms, strategies, and outcomes:

As shown in the table, "первинна кінцева точка" is translated as "primary endpoint" with possible explanations depending on the document. "Небажана подія" is unified as "adverse event" but adapted for clarity in instructions. The strategies work in tandem: contextualization adapts translations to the document and audience, glossaries ensure standardization, and adaptation addresses terms without equivalents. This achieves a balance between accuracy, standardization, and accessibility, which is critical in a regulatory context.

Translating clinical research terminology from Ukrainian to English requires addressing linguistic discrepancies and ICH GCP standards. The analysis identified polysemy ("плацебо," "дослідження"), lack of equivalents ("рандомізація"), and structural differences ("первинна кінцева точка" vs. "primary endpoint"). These issues are not purely linguistic: inaccurate translation can lead to

Table 2

Application of Translation Strategies to Clinical Research Terminology

Ukrainian Term	English Term	Strategy	Outcome
Первинна кінцева точка	Primary endpoint	Contextualization, glossary	"Primary endpoint" as the main indicator in protocols; glossary fixes a single translation.
Досліджуваний препарат	Investigational product	Adaptation	Concise "investigational product" replaces descriptive term, aligns with ICH GCP.
Небажана подія	Adverse event	Glossary, contextualization	"Adverse event" in reports; "adverse event (negative health effect)" in participant instructions.
Відкрите дослідження	Open-label trial	Adaptation	"Open-label trial" with optional note "a study without concealment," if needed.
Серйозна небажана подія	Serious adverse event	Contextualization	"Serious adverse event" in reports; "serious adverse event (significant health issue)" in instructions.
Рандомізація	Randomisation	Glossary	"Randomisation" as a unified translation, fixed in the glossary.
Сліпий метод	Blinding	Adaptation	"Blinding" with optional note "method of data concealment (single- or double-sided)," if needed.
Контрольоване дослідження	Controlled trial	Adaptation	"Controlled trial" with optional note "a study with a control group," if necessary.

misinterpretation of protocols, breaches of ethical or legal requirements, and impacts on participant safety and result reliability.

The proposed strategies – contextualization, glossaries, and adaptation – effectively address these challenges. Contextualization ensures flexibility, adapting translations to the document and audience, as with "serious adverse event." Glossaries standardize terminology, fixing "randomisation" as the standard translation of "рандомізація." Adaptation replaces verbose constructions ("досліджуваний препарат") with concise English terms ("investigational product") or adds explanations ("controlled trial" as "a study with a control group").

These strategies enhance translation practices and promote the harmonization of Ukrainian terminology with international standards, critical for Ukraine's integration into global clinical research.

Prospects for Further Research

The topic of translating clinical research terminology opens avenues for theoretical and applied development. The first direction is evaluating the effectiveness of automated translation using CAT tools (SDL Trados, MemoQ) and machine translation systems (DeepL, Google Translate). A study could compare automated translations of "adverse event" or "blinding" with human translations, assessing whether these systems account for context and ICH GCP standards.

The second direction is analyzing reverse translation from English to Ukrainian. For instance, "open-label trial" may be translated as "відкрите дослідження," but without explanation, it does not convey the full meaning. This research would evaluate the adaptation of international documents for Ukrainian regulators and participants, considering ethical and legal aspects of Ukraine's Law on Medicinal Products and Ministry of Health Order No. 690 of 23.09.2009.

The third direction is developing bilingual glossaries, systematizing terms ("primary endpoint," "investigational product") with Ukrainian equivalents and contextual explanations (e.g., "randomisation – рандомізація (method of random participant allocation)"). This would streamline translators' work and promote standardization.

The fourth direction is a comparative analysis of translation in different language pairs (English-French, English-German) to identify universal strategies or unique features of Ukrainian. The fifth direction is studying the impact of translation on participants' perception of terms: does adapting "serious adverse event" as "a significant health issue" affect risk comprehension in Ukraine? This would combine linguistics with ethics and psychology.

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