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Audit experiences in investigational medicinal product management and errors in clinical trials

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Abstract

Background Clinical audits are essential to ensure that clinical research processes align with regulatory standards and best practices. Despite this, there has been no error assessment of the relationship between the errors in investigational medicinal product (IMP) management and clinical trial workers with audit experience.

Methods This study surveyed stakeholders with experience being audited to evaluate errors in IMP management and accountability during clinical trials through online survey system. The survey focused on errors in IMP export, dosing, storage, shipping, and labeling. Errors related to IMP management or accountability were evaluated with 22 specific criteria. Analysis included descriptive statistics and Pearson's correlation.

Results A total of 41 participants experiencing audits in clinical trial were enrolled in the current survey. The survey results revealed that the most frequent errors occurred in missing essential documents for shipment during IMP shipping and errors in label information, each accounting for 24 cases (58%). Additionally, a significant correlation was found between participants' age, work experience, and audit experience (coefficient = 0.77, p value < 0.05).

Conclusion A survey of individuals with auditing experience identified common errors in IMP management, particularly missing shipment documents and incorrect labeling. To address these issues, clinical trial systems should implement regular error monitoring, standardized procedures, and comprehensive staff training to ensure safer and more efficient trials.

Keywords Investigational medicinal product, Clinical trial, Audit, Survey, Clinical trial stakeholders

Introduction

For new drug approval, keeping the standards of safety and efficacy in clinical trials is essential for widespread use. To guarantee satisfying the standards of safety and efficacy, appropriate investigational medicinal product (IMP) management and accountability is a critical aspect in the clinical trial [1].

Reflecting the importance of IMP management, European Medicines Agency (EMA) and International Council for Harmonization (ICH) guidelines also particularly indicate the need of expertise to deal with IMPs for the trial integrity and subject safety [2, 3]. However, IMP management is still a complex process requiring careful attention to maintaining storage conditions, accurate labeling, or secure shipping and needs rigorous adherence to study protocols and responsibility [4]. With this complex process, IMP management encounters several challenges. Previous studies also indicated these

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challenges as potential errors in handling IMPs [4, 5] including incorrect dosing dates and improper storage conditions, miss-labeling associated with adverse events, patient safety incidents, and regulatory violations [6]. These issues ultimately impact the reliability of study results and the well-being of study participants.

To ensure the integrity of trials and improvement of safety, appropriate IMP error assessment and improved patient care along with clinical outcomes are needed. For satisfying these needs, audits on IMP management during clinical trials are routinely conducted with regulatory standards [7, 8]. Conducting internal or external audits regularly during clinical trials is mandatory to ensure protocol compliance and the success of trials, thereby providing assurance to stakeholders, including regulatory agencies [9, 10]. Given the importance of auditing in the clinical trial process, including IMP management, there is a need to evaluate error findings during audits. Focusing on leveraging stakeholders' experiences can contribute to preventing future errors closely associated with patient safety [11]. However, although previous studies have explored various aspects of IMP management, to the best of our knowledge, no study has investigated the relationship between errors in IMP management and stakeholders with audit experience. Previously, an interview study was conducted with representatives from pharmaceutical companies, courier services, and site study staff in Europe to explore the challenges of the regulatory complexity, IMP logistics, and operational burden of the direct-to-participant (DtP) model in IMP distribution [12]. In addition, Cruz and Brown conducted a survey study to assess pharmacists' perceptions of investigational drug services and the safety risks posed by IMPs to standardize error-prevention strategies in routine practice without considering audit experience [13]. Although pre-investigations were conducted on the analysis of IMP errors, safety risks such as risk assessment, the prevalence of medication error, and labeling error, these previous studies did not reflect outcomes of audits experienced by stakeholders [14–16].

Since, to enhance IMP accountability and management, more evidence related to IMP errors experienced during audits might be needed, the current study aims to investigate findings of errors and relationships in IMP handling based on the experiences of stakeholders.

Methods

Study design

To explore the common errors and challenges in IMP management, we conducted a survey targeting individuals with experience in auditing IMP management or accountability. The survey specifically addressed areas of IMP handling, including export, dosing, storage, shipping, and labeling. In order to conduct the survey, we tried to include key stakeholders of clinical trials who experienced audits [17]. Stakeholders were eligible to participate in the current survey if they self-reported that they (1) regularly reference ICH E6 GCP to implement their research, (2) conduct research for registrational purposes, (3) were willing to have the information they provided in the survey linked to their organization, and (4) were interested in sharing their experiences with implementing ICH E6 GCP on IMP management and audit. Among these eligible stakeholders, we purposefully selected and invited participants for the survey to ensure that the sample was diverse in employment and type of institution (e.g., university/academic center, pharmaceutical company, contract research organization (CRO)). The participants were categorized into two age groups: those under 35 years old (< 35 years) and those 35 years or older (≥ 35 years).

Data collection

Errors related to IMP management or accountability were evaluated with 22 specific criteria. The following questionnaire was distributed through an online survey system (https://www.surveymonkey.com/). The participants were allowed to select multiple answers to identify potential reasons for the export, dosing, storage, shipping, and labeling of IMPs. Through the survey, information was collected from the questions as below.

1) Demographic information includes sex, age, institute, work experience, clinical audit experience, institute-pertained workplaces such as clinical trial sites, CRO, and government agencies such as the MFDS (Ministry of Food and Drug Safety), pharmaceutical or biotech company. The years of work experience related to clinical trials and the experience of conducting clinical trial audits were also asked to survey participants.
2) IMP exporting includes errors of reporting (ex. documentation), errors in the amount of IMP, and errors in changes in the types of IMP (comparator vs. intervention) during the dispensing of IMPs.
3) IMP dosing includes errors in dosing dates, errors in dosing amounts, errors in dosing methods, and the intake of contraindications during the administration of IMPs.
4) IMP storage includes storage instruction confusion (e.g., temperature and humidity control confusion), malfunction of storage equipment (e.g., malfunction of temperature and humidity control devices), lack of appropriate storage facilities, and inadequate separation from other medications during storage.

5) IMP shipping includes delivery error (ex. institution/medication type mismatch), missing essential documents for shipment, inappropriate timing for receipt, and quantity error during IMP delivery.
6) IMP labeling includes errors in label information and label damage to IMP boxes.

Data analysis

The results were calculated as a percentage of the corresponding number of each question. The survey results were calculated by extracting the frequency of each question in the questionnaire via the open-source statistical program R (version 4.4.0). Pearson's correlation was performed for parametric variables, and a correlation matrix was generated to show the correlation coefficients between sets of variables with identified codes. This allowed us to identify pairs with high correlations, and the coefficients, *p* values of hypothesis tests, and 95% confidence intervals (CIs) were analyzed. This study was conducted after receiving a review of the research plan and obtaining approval from the Institutional Review Board (IRB) of Konyang University in Korea (IRB No. KYU 2022-10-024-001).

Results

Demographics of participants

A total of 41 participants working in clinical trial centers, CROs, regulatory agencies, and pharmaceutical companies were enrolled in the current survey, and their characteristics are described in Table 1. All participants who received the questionnaire were included in the evaluation. There were 21 (51.20%) for < 35 years and 20 (48.80%) for ≥ 35 years, and 12 (29.27%) male and 29 (70.73%) female participants. There were 7 (17.07%) with < 1 year, 9 (21.95%) with ≥ 1 year and < 3 years, 8 (19.51%) with ≥ 3 years and < 5 years, 5 (12.20%) with ≥ 5 years and < 10 years, and 12 (29.27%) with ≥ 10 years of work experience at clinical sites, CROs, regulatory agencies, and pharmaceutical companies. There were 19 participants (46.34%) with clinical audit experience.

Table 1 Characteristics of the clinical trial workers

Characteristics	Categories	Number of participants (%)
Age	< 35 years	21 (51.20)
	≥ 35 years	20 (48.80)
Sex	Male	12 (29.27)
	Female	29 (70.73)
Institutions	Clinical site	17 (39.02)
	CRO	5 (12.20)
	Regulatory agency	7 (12.20)
	Pharmaceutical company	12 (29.27)
Work experience	< 1 year	7 (17.07)
	≥ 1 year, < 3 years	9 (21.95)
	≥ 3 years, < 5 years	8 (19.51)
	≥ 5 years, < 10 years	5 (12.20)
	≥ 10 years	12 (29.27)
Clinical audit experience	Yes	19 (46.34)
	No	22 (53.66)

Types of errors in audits for IMP management or accountability

The results of the errors related to IMP accountability are shown in Table 2. There were 24 (58.54%) errors each related to missing documents and labeling. Delivery error (ex. the institution/medication type mismatch) was reported by the majority of respondents (56.1%), and inadequate separation from other medications during storage and label damage resulted in many errors of 46.34%. However, the number of errors associated with changes in the types of IMPs (comparator vs. intervention) was relatively low at 6 (14.63%).

Associations between errors for IMP management or accountability

Associations between errors in IMP management and accountability were identified in IMP export, dosing, storage, shipping, and labeling during clinical trials via Pearson's correlation methods (Fig. 1 and Supplementary File Table 1). The matrix measured the linear relationship between pairs of column and row variables. The values range from −1 to 1, where 1 indicates a perfect positive linear relationship and blue color represents positive correlations where an increase in one variable is associated with an increase in the other and the intensity of the color indicates the strength of the correlation. We found a significant relationship between age and work experience and audit experience (coefficient = 0.77, p value < 0.05). Reporting error, such as documentation of IMP exports, was correlated with errors in the number of IMPs (coefficient = 0.31, p value < 0.05). Moreover, errors in dosing amounts showed a positive correlation with the intake of contraindicated substances during IMP dosing (coefficient = 0.51, p value < 0.05) and labeling damage error (coefficient = 0.50, p value < 0.05). Inappropriate timing for receipt during shipping was positively correlated with the malfunction of storage equipment (coefficient = 0.45, p value < 0.05). Additionally, shipping document errors were correlated with label damage (coefficient = 0.39, p value < 0.05). Meanwhile, there was no strong correlation with other error types in terms of age, institute, errors in

Table 2 Errors related to IMP accountability

Characteristics	Number of positive responses (%)
IMP export	
Errors of reporting (ex. documentation)	14 (34.15)
Errors of amount of IMP	10 (24.39)
Errors of changes of types of IMP (comparator vs. intervention)	6 (14.63)
IMP dosing	
Errors of dosing dates	13 (31.71)
Errors of dosing amounts	10 (24.40)
Errors of dosing methods	10 (24.40)
Intake of contraindications	12 (29.27)
IMP storage	
Storage instructions confusion (e.g., temperature, humidity control confusion)	13 (31.71)
Malfunction of storage equipment (e.g., malfunction of temperature and humidity control devices)	18 (43.90)
Lack of appropriate storage facilities	11 (26.83)
Inadequate separation from other medications during storage	19 (46.34)
IMP shipping	
Delivery error (ex. institution/medication type mismatch)	23 (56.10)
Missing essential documents for shipment	24 (58.54)
Inappropriate timing for receipt	15 (36.59)
Quantity error	6 (36.59)
IMP labeling	
Label information	24 (58.54)
Label damage	19 (46.34)

IMP investigational medicinal products

dosing methods, storage instruction confusion, or delivery error (p value > 0.05).

Discussion

The current study surveyed the findings of audits in IMP management or accountability during clinical trials from stakeholders. Errors relevant to IMP management and accountability were identified in IMP export, dosing, storage, shipping, and labeling during clinical trials.

Consistent with the findings of the current study, documentation of IMP management and accountability has been frequently reported as a common finding of clinical trial inspections [18]. In terms of data integrity, to reconfirm data, source documentation should be properly provided during audits or inspections. Similarly, "*Failure to maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation*" was cited in 6 out of 10 warning letters issued by the US Food and Drug Administration (US FDA) to clinical investigators in 2010 [18]. To ensure IMP adherence and patient safety, inappropriate documentation during clinical trials especially relevant to IMP export to participants might contribute to increase of risks. Since the FDA and EMA mostly focus on GCP inspection deficiencies [19], the EMA reported a lack of source documentation included in the top 10 critical findings in GCP inspection findings [20]. With respect to the potential importance of adherence information collected from accurate documentation influencing continuation of the trial [21], especially highly attended to by persons with audit experience in the current outcomes, improvements in complete source documentation such as IMP export are needed.

Even though errors in IMP dosing dates were responded to as the most common findings for IMP doses, other components such as dosing amounts, methods, and even confusion of contraindications for IMP administration were almost equally reported. Furthermore, based on the current results, errors in IMP administration were significantly associated with errors in IMP label information and damage. During the prescription and administration of IMPs, errors mostly occur, and some of them lead to serious adverse events and fatal outcomes [14]. Even in a cancer clinical trial, one of the most common types of errors was indicated as prescription errors (42.31%) [22]. Furthermore, another oncology

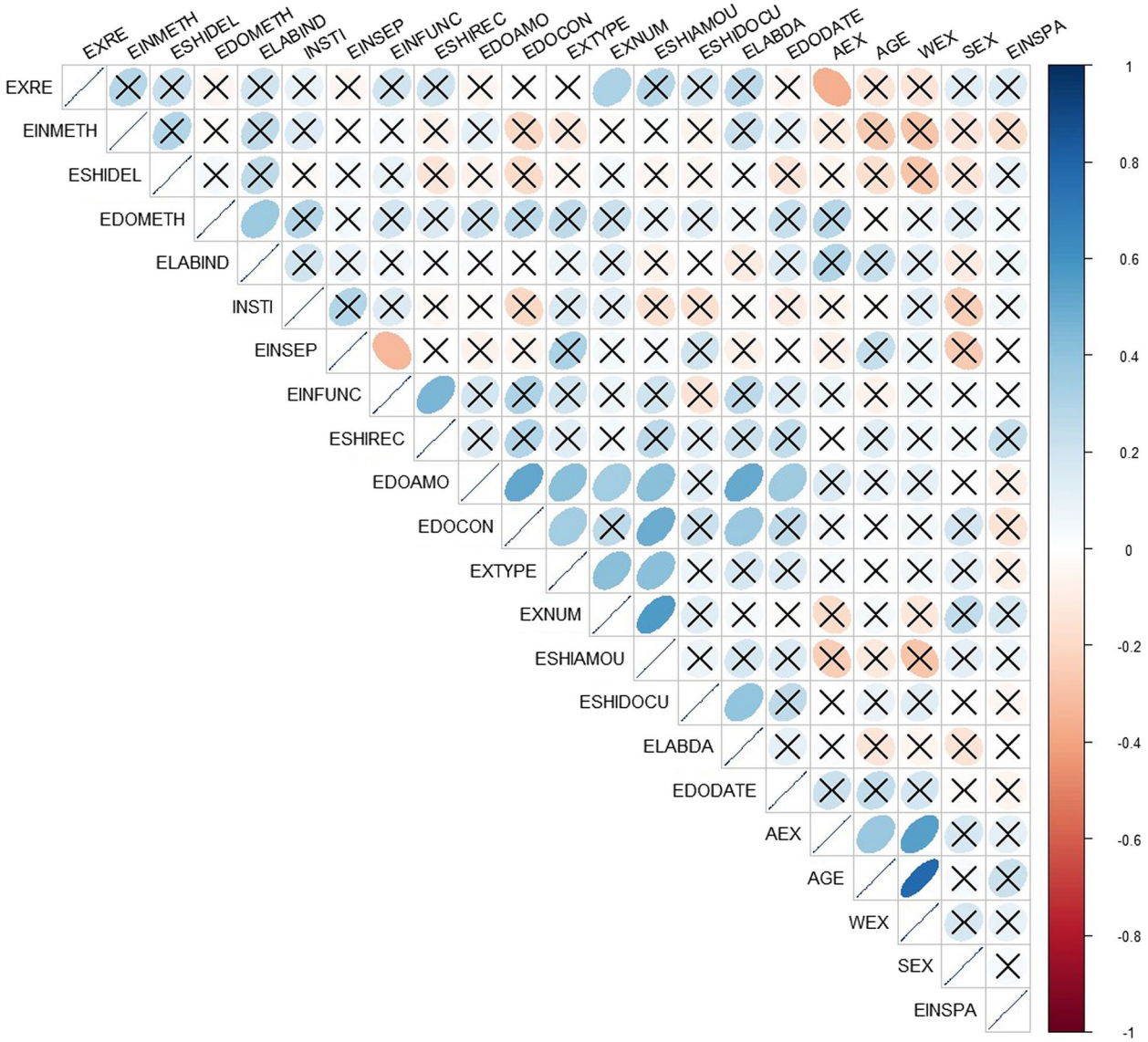

Fig. 1 Correlation matrix of IMP accountability and errors. This figure presents a color-coded correlation matrix illustrating pairwise correlations between various factors related to investigational medicinal products accountability and errors. The correlations were calculated using Pearson's correlation method and black "X" mark within a cell indicates insignificant correlation ($p > 0.05$). The color scale on the right presents the strength and direction of correlations (blue signifies a positive correlation, while red signifies a negative correlation, with darker shades indicating stronger relationships). The matrix includes the following variables: Errors of reporting (ex. documentation), EXRE; Storage instructions confusion (e.g., temperature, humidity control confusion), EINMETH; Delivery error (ex. institution/medication type mismatch), ESHIDEL; Errors of dosing methods, EDOMETH; Label information, ELABIND; Institute, INSTI; Inadequate separation from other medications during storage, EINSEP; Malfunction of storage equipment (e.g., malfunction of temperature and humidity control devices), EINFUNC; Inappropriate timing for receipt during shipment, ESHIREC; Errors of dosing amount, EDOAMO; Intake of contraindications, EDOCON; Errors of changes of types of IMP (comparator vs. intervention), EXTYPE; Errors of amount of IMP, EXNUM; Quantity error during shipping, ESHIAMOU; Missing essential documents for shipment, ESHIDOCU; Label damage, ELABDA; Errors of dosing dates, EDODATE; Audit experience, AEX; Age, AGE; Work experience, WEX; Sex, SEX; Lack of appropriate storage facilities, EINSPA

trial also revealed dosing errors in IMPs, such as the dosing amount (16.11%), total amount (12.46%), and period (8.51%) related to IMP administration [23]. Since IMPs often lack distinguishing features for conceal allocation and an adequate level of detail or information [24], compliance with protocol-specific dosing regimens or recommended processes of care frequently cannot be guaranteed [25]. In particular, as the current outcome shows, Nayak et al. reported that labeling and packaging issues are the cause of 33% of all medication errors,

can be linked to confusion or errors arising from how a medication is labeled and packaged [26]. According to Kane et al., although 68% of medication errors in clinical trials were intercepted before reaching the patient, 32% reached the patient, potentially leading to temporary harm [24]. An American survey also revealed many packaging issues associated with investigational drugs with a lack of differentiation, the absence of an expiration date, and the font size and color [13], which are major areas for improving iatrogenicity prevention [26, 27]. Practices for the safe processing and dispensing of IMPs have not been widely standardized [28], and, even, IMP label quality is significantly heterogeneous despite of rigorous national regulation [14, 29–31], which might contribute to increasing of the number of dosing errors associated with IMPs. Thus, to prevent IMP dosing and/or labeling errors and reduce the risk of harm, any system should be able to analyze errors, periodically identify opportunities for quality improvement, and further consider system changes [32].

Recent advancements in digital health technology, such as electronic labels (e-labels), offer promising solutions for reducing labeling errors by regular error monitoring providing real-time updates of information in clinical trials [33]. Japan supports e-labeling for prescription drug package inserts targeting healthcare professionals, while Singapore has launched a pilot project extending from prescription to non-prescription medicines under regulatory guidelines [34, 35]. In Europe, electronically provided medicinal product information (ePI) is being developed, with pilot projects defining its core principles and implementation strategies [36]. South Korea, since 2023, has been using QR codes for 109 injectable prescription drugs, replacing paper attachments [37]. Furthermore, improving personnel training on labeling requirements [5], establishing standardized protocol [38], the distribution of audit policy manuals [39], and improving systems including utilizing digital tools based on artificial intelligence for real-time error detection [40] could also contribute to enhancing IMP management and reducing errors.

Although this study has provided valuable scientific insights, several limitations need to be addressed. First, this study did not include a cost-effectiveness analysis as it was considered outside the scope of this research. Second, patient safety was not directly assessed as this study involved a simple survey without patient recruitment. Finally, the data was collected through a survey of stakeholders who have experience with IMP audits, which may not fully represent the entire population involved in IMP management. This could potentially introduce bias in terms of the types of errors reported and the perspectives provided. Moreover, to involve the participants, we did not consider the role of subjects in their employment, while we only considered their experience in IMP management and audit during clinical trials. Additionally, the study was conducted within a specific regulatory environment, and findings may not be fully generalizable to international contexts. However, considering that many clinical trials in Korea are multinational, we believe that international standards are indirectly reflected. Regarding these limitations, future research that includes a broader range of participants, including international researchers, and direct assessment of patient safety depending on the role would further strengthen our understanding of IMP management challenges.

Conclusion

To explore the common errors and challenges in IMP management, we conducted a survey targeting individuals with experience in auditing IMP management or accountability. As a result, most errors were identified in missing essential documents for shipment during IMP shipping and in label information during labeling IMPs. These errors can lead to risk outcomes when not handled properly in clinical trials. To mitigate these issues and improve IMP management, clinical trial systems must regularly monitor and analyze errors, identify areas for quality improvement, and implement corrective actions. By focusing on these areas, the risk of errors can be minimized, ultimately leading to safer and more efficient clinical trials.

Abbreviations

IMP	Investigational medicinal product
EMA	European Medicines Agency
ICH	International Council for Harmonization
DtP	Direct-to-participant
CRO	Contract research organization
MFDS	Ministry of Food and Drug Safety
CI	Confidence interval
IRB	Institutional Review Board
US FDA	US Food and Drug Administration
e-label	Electronic label

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08795-w.

Supplementary Material 1.

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Authors' contributions

Heeyoung Lee contributed to the design, methodology development, analysis, and reviewing and editing; Yunjeong Kim contributed to writing the first draft of the manuscript.

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Data availability
All the data generated or analyzed during this study are included in this published article and supplementary file.

Declarations

Ethics approval and consent to participate
The research plan and approval were obtained from the Institutional Review Board (IRB) of Konyang University in Korea (IRB No. KYU 2022–10-024–001).

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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