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Original Article

Compliance challenges in clinical research organizations: A USFDA inspection retrospective

[Desafíos de cumplimiento en organizaciones de investigación clínica: Una retrospectiva de inspección de la USFDA]

T. Sudheer Kumar, Raju Kamaraj*

Department of Pharmaceutical Regulatory Affairs, SRM College of Pharmacy, SRM Institute of Science and Technology, Kattankulathur, Tamil Nadu -603203, India.
*E-mail: kamarajr@srmist.edu.in

Abstract

Context: Clinical research plays a vital role in advancing medical knowledge and improving patient care. As regulatory bodies strive to ensure the integrity and safety of clinical trials, the US Food and Drug Administration (USFDA) conducts inspections to evaluate compliance with established regulations.

Aims: To examine the USFDA's inspections and non-compliance actions taken against clinical research organizations (CROs) over a 13 years period.

Methods: The study utilizes a comprehensive dataset compiled from publicly available records, including inspection reports, warning letters, and other regulatory documents issued by the USFDA. Through systematic data collection and analysis, this study seeks to shed light on the frequency and nature of non-compliance findings, identify common areas of concern, and evaluate the effectiveness of regulatory actions.

Results: The study reveals patterns and trends in the USFDA's inspections, highlighting key compliance challenges faced by CROs. These challenges include issues related to study protocols, informed consent, data integrity, adverse event reporting, and adherence to good clinical practice (GCP) guidelines. Furthermore, this analysis explores the USFDA's warning letters to assess their impact on CROs' compliance efforts.

Conclusions: The findings of this retrospective analysis can inform CROs, and other stakeholders about the areas of greatest concern in clinical research compliance. The study contributes to the ongoing efforts to enhance the quality and integrity of clinical trials, ultimately benefiting patient safety and the credibility of the research enterprise.

Keywords: compliance; ethics; research; safety; USFDA.

Resumen

Contexto: La investigación clínica juega un papel vital en el avance del conocimiento médico y la mejora de la atención al paciente. A medida que los organismos reguladores se esfuerzan por garantizar la integridad y la seguridad de los ensayos clínicos, la Administración de Alimentos y Medicamentos de EE. UU. (USFDA) realiza inspecciones para evaluar el cumplimiento de las reglamentaciones establecidas.

Objetivos: Examinar las inspecciones de la USFDA y las acciones de incumplimiento tomadas contra las organizaciones de investigación clínica (CRO) durante un período de 13 años.

Métodos: El estudio utiliza un conjunto completo de datos compilados a partir de registros disponibles públicamente, incluidos informes de inspección, cartas de advertencia y otros documentos reglamentarios emitidos por la USFDA. A través de la recopilación y el análisis sistemáticos de datos, este estudio busca arrojar luz sobre la frecuencia y la naturaleza de los hallazgos de incumplimiento, identificar áreas comunes de preocupación y evaluar la efectividad de las acciones regulatorias.

Resultados: El estudio revela patrones y tendencias en las inspecciones de la USFDA, destacando los principales desafíos de cumplimiento que enfrentan las CRO. Estos desafíos incluyen cuestiones relacionadas con los protocolos de estudio, el consentimiento informado, la integridad de los datos, la notificación de eventos adversos y el cumplimiento de las pautas de buenas prácticas clínicas (BPC). Además, este análisis explora las cartas de advertencia de la USFDA para evaluar su impacto en los esfuerzos de cumplimiento de las CRO.

Conclusiones: Los hallazgos de este análisis retrospectivo pueden informar a las CRO y otras partes interesadas sobre las áreas de mayor preocupación en el cumplimiento de la investigación clínica. El estudio contribuye a los esfuerzos en curso para mejorar la calidad y la integridad de los ensayos clínicos, lo que en última instancia beneficia la seguridad del paciente y la credibilidad de la empresa de investigación.

Palabras Clave: cumplimiento; ética; FDA; investigación; seguridad.

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AUTHOR INFO
ORCID:
0009-0009-6043-8016 (TSK)
0000-0003-2982-2481 (RK)

INTRODUCTION

In the realm of biomedical research and drug development, Clinical Research Organizations have emerged as vital entities that contribute to the advancement of medical knowledge and the evaluation of new therapies (Kandi et al., 2023) CROs provide essential services, including the design, implementation, and monitoring of clinical trials, ensuring the safety and efficacy of investigational drugs before they reach the market. Given their pivotal role, it becomes imperative for CROs to comply with regulatory standards set forth by authoritative bodies such as the US Food and Drug Administration (USFDA) (Perez-Gracia et al., 2023). This introduction explores the significance of USFDA compliance for CROs and its pivotal role in safeguarding public health and upholding the integrity of clinical research.

CROs act as strategic partners for pharmaceutical and biotechnology companies, academic institutions, and government agencies, facilitating the complex process of clinical research (Terada et al., 2023). They are responsible for recruiting and managing study participants, collecting and analyzing data, ensuring regulatory compliance, and maintaining the ethical standards necessary for the protection of human subjects. CROs bring specialized expertise, infrastructure, and operational efficiency to clinical trials, enabling the efficient and timely completion of research projects (Hariry and Barenji, 2023).

The USFDA, as the regulatory authority in the United States, plays a critical role in overseeing the safety and effectiveness of drugs, biologics, and medical devices (Mukherjee, 2023). The agency sets stringent standards and guidelines to ensure that clinical trials are conducted ethically, with due regard for participant safety and the reliability of data (Petersen et al., 2023). USFDA compliance is essential for CROs as it demonstrates their commitment to upholding the highest quality standards and their adherence to the regulations outlined in the Code of Federal Regulations (CFR)

The importance of USFDA compliance for CROs

Compliance with USFDA regulations ensures the protection of study participants (Trembath et al., 2023). The USFDA sets strict guidelines for the informed consent process, the monitoring of adverse events, and the reporting of safety data. By adhering to these regulations, CROs ensure that participants are fully informed about the risks and benefits of participating in a clinical trial and that their well-being is prioritized throughout the study.

USFDA compliance is crucial for maintaining the integrity and reliability of clinical trial data (Chodankar, 2023). The USFDA requires CROs to follow Good Clinical Practice (GCP) guidelines, which outline the standards for conducting, recording, and reporting clinical trials. Adherence to GCP ensures that data collected during trials are accurate, complete, and verifiable (Mpagama et al., 2023). This reliability is essential for regulatory submissions, decision-making by healthcare professionals, and, ultimately, the well-being of patients who may benefit from the approved therapies.

USFDA compliance enhances the credibility and reputation of CROs within the pharmaceutical and biotechnology industries. Companies seeking to partner with CROs prioritize those that have a track record of regulatory compliance (Janghorban et al., 2023). USFDA compliance demonstrates a commitment to high standards, instilling confidence in sponsors and fostering fruitful collaborations that contribute to scientific advancement (Safarlou et al., 2023).

The consequences of non-compliance with USFDA regulations can be severe

The USFDA has the authority to issue warning letters, untitled letters, and even pursue legal actions against non-compliant CROs. These actions can have far-reaching implications, including delays in drug development, reputational damage, and financial repercussions. Non-compliance also poses risks to patient safety and undermines the trust and confidence placed in the clinical research enterprise as a whole (Zemła-Pacud and Lenarczyk, 2023).

The USFDA, known for its commitment to protecting and promoting public health, has a comprehensive inspection program in place to evaluate the compliance of CROs with regulatory requirements. These inspections are designed to assess various aspects of a CRO's operations, including protocol adherence, data integrity, participant safety, and ethical practices (Kandi and Vadakedath, 2023). By conducting these inspections, the USFDA aims to ensure that CROs follow good clinical practices (GCP) and adhere to the guidelines outlined in the Code of Federal Regulations (CFR) (Trembath et al., 2023).

In recent years, the USFDA has intensified its focus on ensuring the quality and reliability of clinical research data. Instances of non-compliance, ranging from procedural deviations to serious breaches of ethical and scientific standards, have increased scrutiny and regulatory actions (Kanegaonkar and Tysome, 2023). These actions may include warning letters, untitled letters, import alerts, consent decrees, or

even criminal investigations, depending on the severity of the violations observed during inspections.

By undertaking a retrospective analysis of the USFDA's inspections and non-compliance actions, we can gain valuable insights into the prevalence and nature of compliance issues within the CRO industry. This analysis will provide a comprehensive overview of the challenges faced by CROs in meeting regulatory requirements and the consequences they face when deviations from these requirements occur. Furthermore, it will help identify common trends, systemic gaps, and potential areas for improvement in the regulatory framework governing clinical research.

The significance of this analysis extends beyond the CRO industry itself. Clinical research serves as the foundation for medical advancements and therapeutic breakthroughs, and any shortcomings in research practices can have profound implications for patient safety and the validity of scientific knowledge. Through a deeper understanding of the regulatory landscape and its impact on CROs, stakeholders can collaborate to address the identified issues, foster transparency, and enhance the quality and reliability of clinical research outcomes.

It is crucial to recognize the efforts made by the USFDA in promoting accountability and transparency within the CRO industry. By implementing a robust inspection program and taking swift non-compliance actions, the USFDA demonstrates its commitment to upholding the highest standards of research integrity and ensuring that the drugs and treatments available to the public are safe, effective, and reliable.

In this retrospective analysis, we will explore the historical data on inspections conducted by the USFDA, examining the common compliance issues identified and the actions taken against non-compliant CROs. By comprehensively analyzing the findings, trends, and implications, we aim to contribute to the ongoing dialogue on strengthening regulatory oversight in clinical research and fostering a culture of compliance within the CRO industry.

Through this examination, we can foster a greater understanding of the challenges faced by CROs, the importance of regulatory measures in safeguarding public health, and the need for continual improvements in the practices and standards of clinical research. By leveraging these insights, we can collectively strive to enhance the integrity and credibility of clinical research, ultimately benefiting patients, healthcare professionals, and society as a whole.

MATERIAL AND METHODS

The research aims to comprehensively investigate compliance challenges faced by Clinical Research Organization through a retrospective analysis of USFDA inspection data. This study adopts a mixed-methods research design that combines quantitative analysis of inspection data and Warning letters with qualitative analysis to propose corrective actions. Thirteen years of USFDA inspection data (https://datadashboard.fda.gov/ora/cd/inspections.htm), warning letters, and CRO approval data spanning from 2010 to 2022 have been meticulously extracted from the USFDA publicly accessible database (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters) and comprehensively analysed to identify instances of non-compliance within CROs. Warning letters that were issued during the study period have been accurately categorized using standardized forms and templates. Key information like name and location of the CRO, Date of inspection, Inspection findings, Type of violations, Severity of violations, and Actions taken by the USFDA are taken into consideration. Specific thematic categories have been developed based on the type of violations. The root cause for the most frequent violations was identified, and recommended corrective actions were proposed based on the successful remedial actions taken by CRO to address compliance challenges.

RESULTS

Data pertinent to approvals of Clinical Research Organizations by the US Food and Drug Administration (FDA) during the study period from 2010 to 2023 revealed a progressive increase in the number of CRO approvals over this time frame (Fig. 1). This is due to the increasing demand for clinical trials, as well as the increasing complexity of these trials. CROs provide a valuable service to the pharmaceutical industry by helping to conduct these trials efficiently and effectively. Approved CROs were classified based on their country of origin, and the majority of the USFDA-approved CROs were found to be located in the United States, followed by India and China (Table 1).

Over the study period, there was a gradual rise in the number of USFDA inspections conducted on CROs worldwide, with a total of 184 inspections taking place in 2022 (Fig. 2). During these inspections, instances of non-compliance were identified and communicated to the CROs through Form 483 in the form of observational letters. It's important to note that if these 483 observations are not addressed, they may escalate to warning letters, which will subse-

quently be made publicly accessible in the USFDA database.

A gradual increase in the issuance of warning letters to CROs was noted (Fig. 3). Upon a detailed analysis of these warning letters, it was determined that the most frequently cited regulation within them was 21 CFR Part 50.25, which pertains to informed consent (Table 2). A more in-depth examination of these warning letters revealed that the predominant violation related to informed consent was the failure to properly obtain consent from study participants, constituting approximately 14.3% of the observed violations in the context of informed consent (Table 3) along with significant instances of Failure to follow the study protocol (12.9%) and Failure to maintain accurate and complete records (12.5%) (Table 3).

The study focused on observations related to informed consent procedures, as well as the responses provided by the CRO. Corrective and preventive actions have been recommended to prevent the recurrence of observations related to the USFDA.

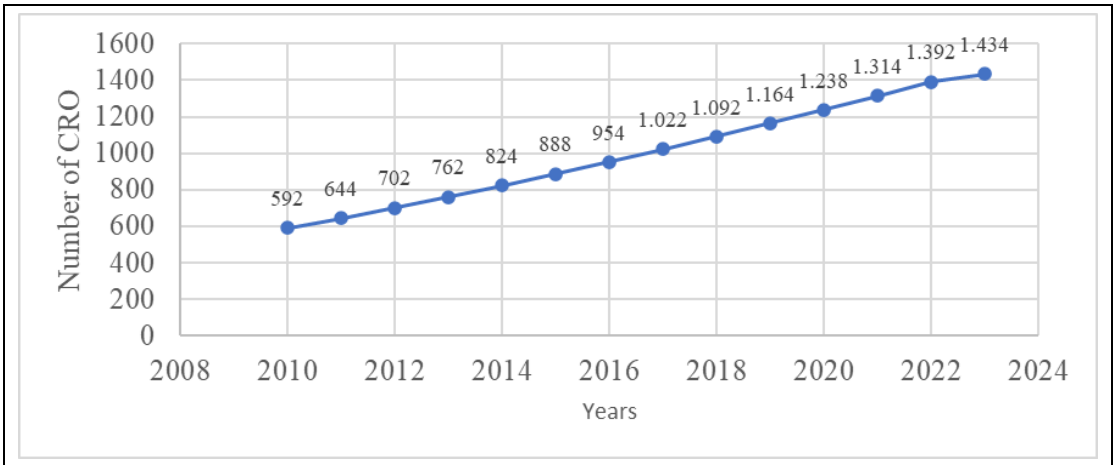

Figure 1. Number of USFDA approved CRO from 2010 to 2022.

Table 1. Number of USFDA approved Clinical Research Organizations (CRO) as of 2022.

US	India	China	Others
708	256	190	280

Total number of USFDA approved CRO: 1434.

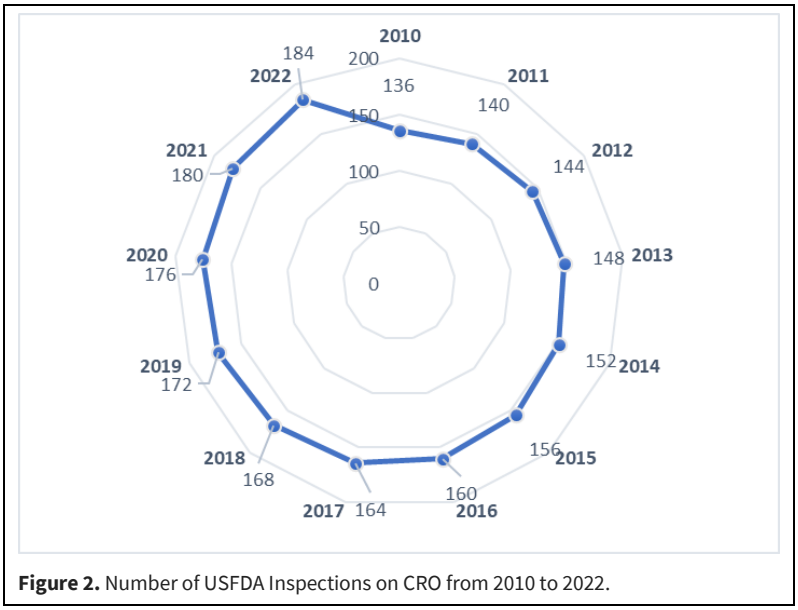

Figure 2. Number of USFDA Inspections on CRO from 2010 to 2022.

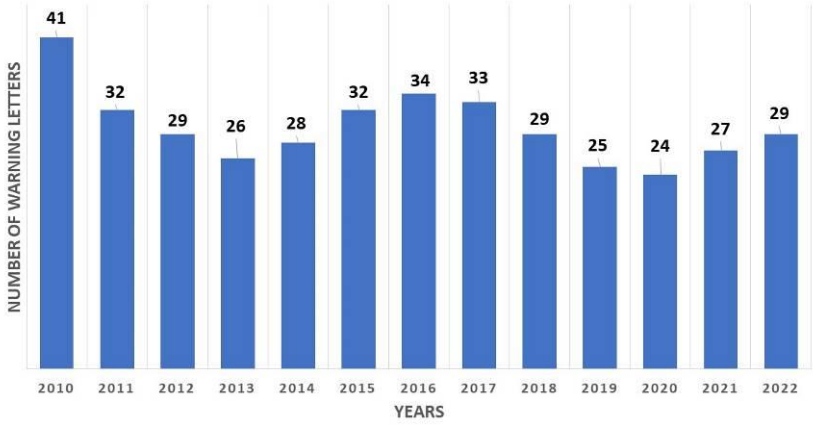

Figure 3. Number of USFDA warning letters issued to CRO from 2010 to 2022.

Table 2. Frequency of CFR violations cited in warning letters Issued from 2010 to 2022.

CFR Cited in warning letters	CFR theme	Frequency of CFR violations cited in warning letters (2010-2022)
21 CFR Part 50.25	Informed consent	56
21 CFR Part 58	Good clinical practice for clinical trials	56
21 CFR Part 11	Electronic records and signatures	30
21 CFR Part 312	Investigational new drug application	22
21 CFR Part 820	Quality system regulation	17

Table 3. Frequency of observations cited in warning letters issued from 2010 to 2022.

No.	Observation	Frequency	Percentage (%)
1	Failure to obtain proper informed consent from study participants	28	14.30
2	Failure to follow the study protocol	25	12.90
3	Failure to maintain accurate and complete records	24	12.50
4	Failure to investigate out-of-specification test results	22	11.80
5	Failure to have a quality assurance program	20	10.70
6	Failure to have a risk management plan	18	9.50
7	Failure to have a disaster recovery plan	16	8.70
8	Failure to properly qualify and train personnel	15	8.20
9	Failure to report adverse events to the FDA	14	7.80

DISCUSSION

Failure to obtain proper informed consent from study participants is a serious ethical violation in research. When such a failure occurs, there are several possible corrective actions that can be taken. Here are some common steps that researchers and institutions may consider:

Recognize and accept that informed consent was not properly obtained. It is important to take responsibility for the oversight and address it promptly (Saffady et al., 2023). If the lack of informed consent undermines the integrity of the study or poses significant ethical concerns, it may be necessary to suspend or terminate the study until the issue is resolved (McIntosh et al., 2023). Disclose the situation to all affected participants as soon as possible. Provide clear and accurate information about the failure to obtain informed consent, the potential risks or implications,

and any steps being taken to address the issue (Lombard-Vance et al., 2023).

Consult with the relevant institutional or independent ethics committee or review board. They can provide guidance on the appropriate course of action and help ensure that ethical standards are upheld (Onakomaiya et al., 2023). Investigate the reasons for the failure to obtain informed consent. Identify any systemic issues, lapses in protocols, or shortcomings in the research team's understanding or implementation of informed consent procedures (Chiumento et al. 2017).

Based on the investigation findings, establish appropriate corrective measures to prevent future violations (Lapid et al., 2019). This may involve revising the informed consent process, enhancing training for researchers, or implementing additional safeguards to ensure compliance with ethical standards. If the study can continue with the corrected informed consent process, obtain proper informed consent from all participants (Festinger et al., 2010). Ensure that participants have a clear understanding of the study's purpose, procedures, potential risks and benefits, and their rights and responsibilities as participants.

Notify the appropriate regulatory bodies or oversight agencies, such as the institutional review board or the relevant research funding agencies, about the violation and the actions taken to address it (Brown et al., 2010). Use the incident as an opportunity for organizational and individual learning. Foster a culture of ethical research by promoting awareness, training, and ongoing evaluation of informed consent practices (Shaw, 2003). Establish mechanisms for ongoing monitoring, auditing, and quality assurance to prevent similar failures from occurring in the future (Bedard et al., 2008). Regularly review and update policies and procedures related to informed consent to ensure compliance with ethical standards and regulatory requirements (Portaluppi, 2010).

USFDA inspection retrospectives in CROs contribute by not only identifying compliance challenges but also by prompting CROs to take proactive steps to improve their compliance practices. This ultimately benefits the industry by enhancing the quality and integrity of clinical research conducted by CROs.

It is important to note that this study is centered around a specific timeframe for USFDA inspections, and compliance challenges within CROs may evolve over time. Consequently, the findings presented here may not necessarily reflect the future state of compliance challenges in the field of clinical research.

CONCLUSION

A retrospective analysis of USFDA inspections and non-compliance actions taken against clinical research organizations has shed light on a concerning issue: the failure to obtain proper informed consent from study participants. Through this analysis, it has become evident that this violation is one of the most frequent observations made during inspections. Recognizing the gravity of this ethical breach, it is crucial to address this issue promptly and effectively. Based on the findings of the analysis, several corrective actions can be suggested to prevent the recurrence of failure to obtain proper informed consent. By implementing these corrective actions, researchers, institutions, and regulatory bodies can work together to address the most frequent observation of failure to obtain proper informed consent. Safeguarding the rights and welfare of study participants must remain a top priority to uphold the highest standards of ethical conduct in clinical research.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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AUTHOR CONTRIBUTION:

Contribution	Sudheer Kumar T	Kamaraj Raju
Concepts or ideas	x	x
Design	x	x
Definition of intellectual content	x	x
Literature search	x	x
Experimental studies	x	x
Data acquisition	x	x
Data analysis	x	x
Statistical analysis	x	x
Manuscript preparation	x	x
Manuscript editing	x	x
Manuscript review	x	x

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