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Review Article

Bridging the Digital Gap: A Comparative Analysis of Electronic Regulatory Submission Systems in India and Established Markets

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ABSTRACT

Regulatory agencies around the world now rely heavily on electronic submissions, which improve operational effectiveness and compliance. It is crucial to evaluate how developing economies, especially India, conform to standards such as the Common Technical Document (CTD) and its electronic Counterpart (eCTD), which have been adopted globally. To compare India's Electronic Regulatory Submission (ERS) systems with well-known worldwide systems like the FDA (USA), EMA (Europe), and PMDA (Japan) in a methodical manner, with an emphasis on the CDSCO's SUGAM site. Using secondary data sources such as books, peer-reviewed journals, regulatory publications, and official reports, this study uses a comparative framework. System architecture, submission procedures, eCTD standard compliance, and user accessibility will be the main topics of the analysis. The study intends to provide insights into areas for improvement and possible policy alignment by identifying India's ERS infrastructure's strengths and weaknesses in comparison to international standards. Stakeholders can improve submission procedures, foster international cooperation, and assist attempts to harmonize pharmaceutical regulation by having a better understanding of India's place in the global regulatory environment.

Keywords: Electronic Submission System, Legal Provisions, India, Drug Approval Process, Regulatory Framework.

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INTRODUCTION

The regulatory environment within the pharmaceutical and life sciences industries has experienced significant changes, largely influenced by the transition to entirely digital dossier submissions (Huma & Peng, 2023). Electronic Regulatory Submission (ERS) systems, focused on standardised formats like the electronic Common Technical Document (eCTD), have emerged as vital instruments for regulatory agencies globally. The systems optimise the submission process, automate technical and lifecycle validation, facilitate secure file exchange, and improve version control and auditability (Garg *et al.*, 2017).

In well-established markets like the United States, European Union, and Japan, ERS platforms demonstrate a high level of integration and maturity. Regulatory authorities have integrated automated checks, real-time tracking, and data interoperability throughout the stages of therapeutic and product life cycles. The implementation of modular updates instead of full-file resubmissions, along with the facilitation of electronic communication and feedback between regulators and industry, has led to streamlined workflows, expedited review timelines, and enhanced transparency (Algorri *et al.*, 2020).

Conversely, India's digital regulatory framework is in the process of development. The Central Drugs Standard Control Organisation (CDSCO) initiated India's first national e-governance portal, SUGAM, in 2015 (Pal *et al.*, 2023). This platform enables stakeholders to submit clinical trial applications, licenses, and post-market reports in a digital format. Although it represents a notable advancement from manual and paper-based practices, SUGAM presently functions with restricted automation, variable validation features, and fundamental lifecycle management tools (Dhole & Darade, 2024). These constraints reveal significant deficiencies when assessed against the functionalities of established global e-submission systems.

This review analyses the development of e-submission systems worldwide, assesses the present condition of India's ERS infrastructure, and highlights technological and procedural deficiencies. This comparative analysis seeks to elucidate the

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achievements and limitations of India's digital regulatory framework, with the goal of informing strategies that enhance system maturity and ensure full alignment with international standards.

METHODOLOGY

To fulfil the aims of the study, the current analysis relied entirely on the knowledge that existed in the literature. The analysis consisted of journal articles, books, articles, and published newspaper articles. The analysis utilised the following Boolean search strings: "electronic regulatory submission", "ERS", "legal provisions", "drug approval", "India", "FDA", "PMDA", "SUGAM", "CDSCO", "Japan" and "USA" were used to search. All papers were originally written in English; no translations were performed intentionally to assist this analysis. In addition, the current analysis excluded any research that was still in a pre-publishing stage. The analysis was restricted to papers that were previously published.

LITERATURE REVIEW

Evolution of Regulatory Submission Systems

Regulatory submissions in the pharmaceutical industry have undergone significant evolution in recent years. These changes necessitate that the regulatory expert consistently remain informed about new technologies required by regulatory agencies. The final two decades of the last millennium experienced a significant surge in the accessibility of information technology.

The emergence of personal computers, along with their swift decline in cost, has significantly accelerated this process. The rise in connectivity enabled by the emergence of the Internet has significantly influenced various aspects. Collectively, these resources have offered essential tools to facilitate the assembly of submission dossiers, enabling the integration of data from various authors and locations with remarkable efficiency. Before the advent of the information technology revolution, dossiers were compiled, typically in a single location by a specialised registration department. They utilised essential instruments such as typewriters, scissors, glue, and photocopiers. The introduction of advanced technologies has significantly streamlined the process (Ross, 2010).

The electronic Common Technical Document (eCTD) serves as an interface for the transfer of regulatory information from industry to the Agency, while also addressing the needs for the creation, review, lifecycle management, and archiving of electronic submissions. The content adheres to the Common Technical Document (CTD) format (Garg *et al.*, 2017). eCTD was developed by the International Conference on Harmonisation (ICH) Multidisciplinary Group 2 Expert Working Group (ICH M2 EWG). Effective January 1, 2008, the U.S. Food and Drug Administration declared the eCTD as the preferred format for electronic submissions (Zhu *et al.*, 2016). As of now, more than 80,000 eCTD sequences have been submitted to the FDA. The agency has yet to announce a target date; however, during the 2009 DIA Annual Meeting, the FDA indicated that it is considering draft legislation to mandate eCTD for all data and file submissions. Nancy Smekanavich, Vice President of Global Regulatory Affairs at Octagon Solutions, highlights that the eCTD presents numerous advantages and challenges (Ross, 2010). Benefits include established document standards, enhanced navigation through dossiers, and a reduction in processing time within the FDA document room. Nevertheless, several challenges faced include lifecycle management, which involves overseeing the complete lifecycle of a product from its inception, through design and manufacturing, to service and disposal; the proper utilisation of leaf titles, which are names used to identify each document within the submission; and the management of study tagging files, which serve as metadata to identify all files associated with a study. Despite numerous challenges, Smekanavich is confident that the advantages significantly surpass the difficulties.

The eCTD represents the inaugural electronic submission format that is universally applicable, encompassing both updates and original applications. The eCTD employs a standardised format that is effective for various marketing applications over time. This approach removes various obstacles to reuse, such as the necessity to format and present identical content in diverse manners for different regions (Riley & Nguyen, 2024). Additionally, it is capable of managing small, reusable content components. A small electronic data file, known as an XML backbone, is essential for accessing those benefits within the eCTD framework. The data file catalogues the submission's contents and offers comprehensive metadata regarding each physical file submitted (Ahammad *et al.*, 2019).

Present Status of e-Submissions in India

With the expansion of the pharmaceutical industry, the demand for innovative and effective medical treatments has increased. The clinical trials became fully operational in the 1990s. The change took place in 2012 when female activists submitted a petition regarding a vaccine intended for testing on teenage girls, addressing concerns about ethical misconduct during the trial at the Supreme Court (Imran *et al.*, 2013).

The Central Drugs Standard Control Organisation (CDSCO) serves as the primary regulatory authority in India, with the Drugs Controller General of India (DCGI) responsible for granting approval for clinical trials. In addition, another key organisation, the Indian Council of Medical Research (ICMR), is tasked with the regulation, coordination, and promotion of best practices in biomedical research (Sathian *et al.*, 2020).

The Government of India has introduced the New Drugs and Clinical Trial (NDCT) Rules to replace part XA and Schedule Y of the Drugs and Cosmetics Rules of 1945. The updated regulations

provide a framework for enhancing clinical research, outlining clear guidelines on critical areas such as clinical trials for orphan drugs and pre- and post-submission meetings, particularly in the context of a pandemic. The updated regulations introduce potential strategies to enhance clinical research while adhering to ethical and quality benchmarks. The approval system has been established in a timely manner to expedite the processing of applications submitted to CDSCO and to promote clinical research. Recent provisions have focused on expediting product approval in emergency situations, while pre- and post-submission meetings with authorities may enhance certainty and assurance (Jadhav & Ghooi, 2019).

According to the NDCT, the subsequent steps must be undertaken for clinical trials in India:

Pre-submission Meetings

According to the NDCT Rules, 2019, individuals seeking to conduct pre-submission meetings concerning the manufacturing and importation of new drugs or to initiate clinical trials may submit an application to request a pre-submission meeting with the CDSCO authority (Sahai & Parveen, 2020).

Authorisation for the Execution of Clinical Trials in India (Rule 122DA)

In accordance with the regulation, the application (Form CT-04) must be submitted via online mode. Permission may be granted through Form CT-06 if all conditions are met satisfactorily.

The required documents outlined in the second schedule must be included with the application, along with the fees specified in the sixth schedule of the NDCT Rules, 2019. The application will be submitted online through the SUGAM portal, which offers detailed step-by-step instructions. The submitted application will undergo review by the SEC, followed by the Technical Committee (TC) and the apex committee (Bhave & Menon, 2017).

According to the New Drugs and Clinical Trials Rules, 2019, it is mandatory for the investigator, sponsor or CT-NOC holder, and ethics committee to report any and all serious adverse events (SAEs) to the Central Licensing Authority (CLA) within a predetermined amount of time. Using the SUGAM portal, the Clinical Trials Service Organisation (CDSCO) initiated the process of electronically submitting applications for clinical trials. A hassle-free submission method is achieved through the use of electronic submissions. A further benefit is that it makes it simple to monitor apps. A program that allows for the filing of SAE reports online has been released, which is the most recent breakthrough in the field of electronic governance. Following the publication of a notice on February 25, 2021, the Central Drugs Standard Control Organisation (CDSCO) requested that all stakeholders engaged in clinical trials submit SAE reports online using the SUGAM portal (www.cdscoonline.gov.in) beginning on March 14, 2021. Beginning on March 14, 2021, CDSCO will no longer receive SAE reports in the form of physical or offline files for processing. By submitting SAE reports online, it is anticipated that both the amount of time and the cost of transactions would be reduced. To facilitate seamless transfer to the online platform, CDSCO has produced a user manual as well as a video instruction, all of which are now accessible on the website designated for CDSCO. If the sponsor wishes to report SAE on the SUGAM portal, they will be required to perform a series of procedures to complete the database and ensure that the data is linked correctly.[1]

The Drug Controller General of India (DCGI) will provide approval for the conduct of clinical trials following the acquisition of approval from all three stages. Additionally, registration on the Indian Council of Medical Research (ICMR) website is mandatory. The approval for clinical trials is valid for a duration of two years. The CDSCO will grant approval for further extension upon request by the investigator. CDSCO is also responsible for the marketing authorisation of the application. All applications submitted to CDSCO have been forwarded to the subject expert committee for their opinion and recommendation.

Current Status of Electronic Regulatory Submission Systems in Established Markets

Within twenty-four months of the publication of a final guidance document in which the Food and Drug Administration (FDA or Agency) has specified the electronic format for submitting submissions to the Agency, such content is required to be submitted electronically and, in the format, specified by the FDA. This is in accordance with section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Congress provided the Food and Drug Administration (FDA) specific authorisation to implement the statutory electronic submission requirements in guidance by requiring that the FDA "shall" produce such guidance. This authorisation was granted under section 745A(a) of the Food and Drug Administration Act. Accordingly, as indicated by the terms must or necessary, this document is not subject to the typical limits that are included in the Guidelines for Good Guidance Practice (GGP) rules that are imposed by the FDA. One of these restrictions is the requirement that guidelines do not establish legally enforceable duties.

In order to ensure compliance with the GGP regulations and to ensure that regulated entities and the general public are aware that guidance documents are not legally binding, the Food and Drug Administration (FDA) typically includes standard language that explains that guidance documents should be regarded as recommendations only, unless specific regulatory or statutory requirements are cited. Because this standard terminology does not provide an accurate picture of all of the consequences that this guideline will have, the Food and Drug Administration

[1] https://cliniexperts-research.com/clinical-trial-expert-articles/online-submission-sae-sugam/

has decided not to include it in this guidance. If this document defines the format for electronic submissions or provides "criteria for waivers of and exemptions from" the requirements of section 745A(a) of the FD&C Act, then it will have the effect of a binding document (Food and Drug Administration, 2018).

The European Medicines Agency (EMA) has established a well-developed electronic submission environment based on the eCTD standard. The EMA initiated its eSubmission Gateway in 2012, subsequently introducing a web-client in early 2013, to facilitate secure and efficient dossier transmission (EMA, 2012). As of March 1, 2014, eCTD submissions through these platforms have been required for all centralised procedures, thereby discontinuing the acceptance of physical media such as CDs and DVDs. This transition has greatly improved efficiency, transparency, and traceability (EMA, 2014a; EMA, 2014b). The system facilitates immediate receipt uploads, offers real-time technical validation, and integrates with the EMA's review infrastructure, ensuring smooth interactions between sponsors and regulators.

EMA is actively refining its eSubmission system. Effective March 2025, only eCTDs that comply with Module 1 version 3.1 and validation criteria v8.1 will be accepted, indicating a continued evolution of standards (EMA, 2024). The portal has been enhanced to incorporate a Product Lifecycle Management (PLM) feature, which facilitates electronic application forms (eAFs) for variations, PSURs, and paediatric filings, thereby enabling comprehensive tracking of lifecycle submission workflows (EMA, 2025). Additional improvements, including enhanced multi-factor authentication and API connectivity, are in the pipeline, underscoring the EMA's dedication to a strong, cohesive digital submission environment.

Simultaneously, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has embraced a more gradual, focused strategy for digitisation. The PMDA has transitioned from a historical reliance on paper to mandating electronic submission of Adverse Drug Reaction (ADR) and device defect reports during clinical trials through its e-Application Data System, effective April 1, 2023 (PMDA, 2023). This emphasis on safety-related reporting signifies a strategic transition in the digitalisation of regulations.

As of October 1, 2023, PMDA has removed the necessity for pre-specified data description forms (Forms A/B) when submitting clinical trial datasets. Sponsors must now submit trial data in formats compliant with CDISC, validated through PMDA's standardised Pinnacle 21 engine (version 6.0 as of March 2025), to ensure data integrity and consistency (PMDA, 2025).

In addition to safety reporting, PMDA has implemented digital pathways for emergency approvals. The updated Emergency Regulatory Approval System facilitates conditional authorisation grounded in real-world evidence, permitting sponsor-initiated submissions during public health emergencies, even in the presence of incomplete efficacy data (PMDA, 2024). This reflects a versatile, data-informed strategy for crisis management and is integral to Japan's wider alignment with global regulatory standards.

In conclusion, the EMA operates a sophisticated, centralised electronic submission platform characterised by strong lifecycle integration, rigorous compliance standards, and ongoing enhancements. Japan's PMDA has established essential digital systems for safety reporting, clinical data validation, emergency use pathways, and data harmonisation, positioning itself as an emerging leader in eSubmission. These agencies illustrate how various strategic approaches, mandated system-wide adoption (EMA) and targeted strategic digitisation (PMDA), can effectively influence the development of modern, resilient digital regulatory environments.

Advantages and Disadvantages of ERS Systems: A Global and Indian Perspective

The Electronic Regulatory Submission (ERS) systems provide a multitude of appealing advantages on a worldwide scale. They do this by automating dossier assembly, version control, validation, submission tracking, and inter-agency communication, which ultimately results in improved accuracy and a reduction in mistakes (Macdonald *et al.*, 2021). This results in a considerable reduction in regulatory delays. As a result of the use of standardised formats such as eCTD, modular updates are made possible. This enables regulators to examine just relevant areas of dossiers rather than the complete dossier, which in turn reduces the amount of time and money required for review. In addition, ERS systems eliminate the need for physical documentation, which results in increased transparency, auditability, and long-term cost savings through their elimination.

On the other hand, these benefits are accompanied by significant difficulties. It may be difficult for smaller businesses to make significant initial expenditures in software, hardware infrastructure, and staff training due to the high expense involved. Despite this, there is still the possibility that submissions will be rejected or delayed due to technical reasons such as discrepancies in the metadata, incompatibilities in the format, and portal downtimes. Additionally, the ever-changing regulatory requirements and differences that are peculiar to each market necessitate ongoing adaptation, which makes global regulatory plans more difficult to implement.

Traceability and compliance have been enhanced in the Indian setting as a result of the use of ERS systems, which have created audit trails and digital processes that are visible. The implementation of digital technology was expedited by a number of regulatory organisations during the COVID-19 pandemic. This included the use of electronic submissions for clinical trials and post-market reporting. In spite of this, India is plagued by a number of infrastructure deficiencies, including sporadic internet

access, unstable systems, frequent technological breakdowns, and reluctance to change as a result of long-standing habits that rely on paper and uneven levels of digital literacy. In many cases, smaller clinical research organisations and Contract Research Organisations (CROs) may not have sufficient information technology infrastructure or specialised training, which results in increased implementation costs and delays the acceptance of the technology by a wider audience.

In general, the use of electronic records systems in India is progressing; nevertheless, the full potential of this technology can only be realised via systemic improvements. These improvements include a solid digital infrastructure, thorough training programs, and cultural shifts towards the acceptance of digital processes throughout the pharmaceutical ecosystem.

Research Gap

This electronic regulatory submission mechanism in India, which is demonstrated by the SUGAM site maintained by the CDSCO, represents a significant step forward in terms of digital governance. However, in comparison to more developed global systems, there are still a number of basic inadequacies. Firstly, the SUGAM platform struggles with limitations in terms of both its use and its adaptability. As a result of the inability to upload numerous documents under a single heading and the tight 10 MB file size limit, users are forced to resort to unpleasant workarounds such as merging files or sending placeholder PDFs. Furthermore, cosmetic submissions are restricted to a maximum of fifty goods per application, which necessitates the use of laborious batch processing for portfolios that are more extensive. The smooth processing of massive, diverse submissions in systems such as the Electronic Submissions Gateway of the FDA and the eSubmission platform of the European Medicines Agency (EMA) stands in stark contrast to the operational bottlenecks that impede effective operations.

In addition to these restrictions that are aimed at the end user, India's digital systems do not possess the structural resilience of lifecycle monitoring and global harmonisation that is present in established markets. India's adoption is still in its infancy and is still fragmented, in contrast to the frameworks of the United States and the European Union, which completely incorporate ICH CTD standards, make use of Unique Device Identifiers (UDI), and facilitate data transmission through RPS standards. In particular, the medical device industry does not have equivalent elements such as registries in the type of EUDAMED or integrated post-market surveillance procedures. Inconsistent registry compliance and electronic SAE processes are still in the planning stages, and SUGAM's capabilities for clinical trial registration and Serious Adverse Event (SAE) reporting are still in the process of developing further features.

The gaps in infrastructure and training that exist in India further restrict the country's use of digital technology. It is difficult to achieve interoperability and real-time regulatory assessment due to the fragmented landscape of Electronic Health Records (EHRs), different standards for data interchange, and uneven digital literacy among trial sites. Smaller factories and regional centres frequently face extra challenges, such as duplicate login processes, obsolete help literature, and frequent system problems. These challenges expose deficiencies in trustworthy information technology infrastructure and frontline user assistance.

The restricted usage of new digital technologies is another aspect of the research gap that has to be addressed. Artificial intelligence and machine learning are now being tested by worldwide regulators for a variety of activities, including document triage, metadata extraction, and risk-based review prioritisation. However, India is still at the prototype or discussion stage for such developments. As a result of this delay, the potential efficiency and analytical rigour of regulatory procedures are restricted, and India's alignment with worldwide best practices is hindered.

CONCLUSION

The global landscape of electronic regulatory submission systems is marked by significant maturity, with agencies such as the EMA, US FDA, and Japan's PMDA showcasing advanced, integrated, and highly automated infrastructures. These systems enable compliance with eCTD standards, manage document lifecycles, provide real-time validation, and offer secure submission tracking capabilities that are largely lacking in India's ERS platforms. For example, EMA's required eCTD gateway and PLM tools facilitate centralised and traceable dossier management, whereas PMDA's structured clinical trial and ADR reporting in accordance with CDISC compliance standards demonstrate a significant degree of data standardisation and regulatory precision.

The CDSCO's SUGAM portal in India has implemented a digital framework for regulatory submissions, encompassing clinical trials, serious adverse events, amendments, and licensing procedures. Nonetheless, it continues to develop in various aspects. The primary limitations consist of constraints related to file size, the absence of batch upload capabilities, issues with portal stability, and insufficient validation feedback mechanisms. Additionally, although SUGAM has enhanced transparency and traceability through real-time application tracking and audit logs, it falls short in critical aspects such as lifecycle integration, technical validation, and seamless interoperability with trial data and ethics systems.

The comparative review emphasises that India encounters distinct infrastructural and socio-technical challenges, including inconsistent internet access, inadequate digital literacy, and resistance stemming from established paper-based practices. Smaller clinical and research entities, in particular, face challenges related to IT capacity and training deficiencies. In contrast, established regulators have made significant investments in

infrastructure, cybersecurity, and workforce development, promoting smooth adoption and uniform global alignment.

In light of these challenges, India's strategic digital investment indicates a favourable trajectory. The inclusion of CDSCO in IMDRF, the adoption of ADR e-submissions, and the gradual enrolment in global standardisation forums strategically position it for ongoing growth. India's expanding influence in global regulatory alignment, exemplified by its participation in ICH, could facilitate the swift adoption of modular ERS and enhance system preparedness.

ERS systems have developed into intricate, standardised, and interoperable platforms that guarantee reliability, efficiency, and security in regulatory submissions on a global scale. India's ERS framework, focused on the SUGAM portal, indicates notable advancement yet is still in the initial phases of development. Addressing this gap necessitates a multifaceted strategy: upgrading digital infrastructure; strengthening portal functionalities through effective validation, lifecycle integration, and data interoperability; committing to extensive training; and conforming to international technical standards such as eCTD, CDISC, and RPS. India has established significant foundations; however, future advancements will rely on strategic enhancements and ongoing stakeholder involvement to evolve its ERS systems into globally competitive regulatory platforms.

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ABBREVIATIONS

CTD: Common Technical Document; **eCTD:** Electronic Common Technical Document; **ERS:** Electronic Regulatory Submission; **FDA:** Food and Drug Administration; **EMA:** European Medicines Agency; **PMDA:** Pharmaceuticals and Medical Devices Agency; **CDSCO:** Central Drugs Standard Control Organisation; **SUGAM:** System for Unmanned Gateways Approval of Manufacturers; **ICH:** International Council for Harmonisation; **XML:** Extensible Markup Language; **DCGI:** Drugs Controller General of India; **ICMR:** Indian Council of Medical Research; **NDCT:** New Drugs and Clinical Trials; **SAEs:** Serious Adverse Events; **CLA:** Central Licensing Authority; **GGP:** Good Guidance Practice; **PLM:** Product Lifecycle Management; **CDISC:** Clinical Data Interchange Standards Consortium; **eAFs:** Electronic Application Forms.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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