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Perceived Effects of Common Technical Document Adoption on Dossier Quality and Regulatory Review Processes in Nigeria: A Mixed-Methods Study

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Abstract

The Common Technical Document (CTD) has been widely adopted as a regulatory harmonisation tool intended to improve medicines dossier quality and regulatory review processes, yet evidence on its operational effects in low- and middle-income countries remains limited. This study examined the perceived impact of CTD adoption on dossier quality and regulatory review processes in Nigeria using a mixed-methods design. Quantitative data were collected through a structured questionnaire administered to 380 regulatory stakeholders, while qualitative insights were obtained from semi-structured interviews with 12 regulatory assessors and industry professionals. Quantitative data were analysed descriptively using SPSS and qualitative data were analysed thematically. Survey results indicated that 65.3% of respondents agreed or strongly agreed that CTD adoption improved overall dossier quality, while 68.9% reported that CTD modules were clearly structured and easier to navigate. In addition, 58.7% agreed or strongly agreed that regulatory queries became clearer and more consistent under the CTD framework. However, perceptions of review speed were mixed, with 46.9% reporting improvements and 30.0% reporting no improvement or slower feedback. A large majority (71.6%) indicated that ongoing CTD-related training is necessary to improve compliance and dossier quality. Qualitative findings supported these results, showing that although CTD improved dossier structure and communication clarity, substantive content deficiencies and repeated review cycles persisted due to capacity and training gaps. Overall, CTD adoption improved dossier structure and regulatory communication but produced uneven gains in substantive dossier quality and review efficiency.

Keywords: *Common Technical Document, Dossier Quality, Medicines Regulation, Nigeria, Regulatory Harmonisation.*

Introduction

Effective medicines regulation is a cornerstone of public health systems, ensuring that only products meeting acceptable standards of quality, safety, and efficacy are authorised for market use. Central to this regulatory function is the quality of the regulatory dossier, which constitutes the primary evidentiary basis for scientific assessment and decision-making across pre-clinical, clinical, and quality domains. Inadequate dossier structure, incomplete documentation, and inconsistent presentation of evidence have long been associated with regulatory inefficiencies, prolonged review timelines, and uncertainty in regulatory outcomes, particularly in low- and middle-income country (LMIC) settings [4, 7, 9, 10].

In response to these challenges, global regulatory harmonisation initiatives have

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increasingly prioritised the standardisation of dossier formats as a mechanism for strengthening regulatory systems and improving review predictability [1, 2]. The Common Technical Document (CTD), developed through the International Council for Harmonisation, represents the most widely adopted outcome of these efforts [1, 2]. By providing a unified structure for administrative, quality, non-clinical, and clinical information, the CTD is intended to improve submission discipline, reduce ambiguity in regulatory requirements, and facilitate more consistent scientific assessment across jurisdictions. Beyond its technical role, CTD adoption is widely regarded as a foundational step toward regulatory convergence, regulatory reliance, and the implementation of digital submission platforms [3, 20].

Despite its widespread adoption, empirical evidence on how CTD implementation translates into improvements in dossier quality and regulatory processes remains limited, particularly in LMIC contexts [7, 8]. Much of the existing literature has treated CTD compliance primarily as a formal regulatory requirement rather than examining its operational effects on dossier quality, review workflows, and assessor experience [7, 14]. As a result, an important distinction is often overlooked: adherence to a harmonised dossier structure does not necessarily imply improvements in the substantive quality of submitted evidence or in the efficiency and predictability of regulatory review processes [5, 6]. Clarifying this distinction is critical for evaluating the real-world impact of harmonisation reforms.

Across Africa, medicines regulatory authorities have adopted CTD-aligned requirements as part of broader regulatory strengthening initiatives aimed at improving governance, transparency, and international credibility [10-12]. These reforms are frequently implemented alongside capacity-building efforts, digitalisation initiatives, and regional harmonisation programmes. However, regulators in LMICs often operate under conditions of constrained human resources, uneven applicant preparedness, and hybrid paper–digital systems [7, 10, 11]. In such contexts, the benefits of dossier harmonisation may be mediated by assessor capacity, applicant familiarity with CTD standards, and the availability of clear guidance and training [8, 12, 14]. Without systematic evaluation, it remains unclear whether CTD adoption improves dossier quality in practice or merely shifts the burden of compliance without delivering commensurate process gains.

Nigeria provides a particularly instructive case for examining these dynamics. As one of Africa's largest pharmaceutical markets, Nigeria's national medicines regulatory authority has pursued an ambitious reform agenda aimed at aligning regulatory practice with international standards [10, 12]. The adoption of the CTD format for medicines registration formed a central component of this agenda, intended to improve the consistency and completeness of submissions and to strengthen the scientific basis of regulatory decision-making [2, 13]. At the same time, the regulatory system continues to manage high application volumes, diverse applicant capabilities, and evolving digital infrastructure, creating a complex environment for CTD implementation [7, 11].

Recent system-level evaluations of CTD adoption in Nigeria have reported limited immediate effects on aggregate regulatory performance indicators, such as approval volumes and safety signal rates, suggesting that dossier harmonisation alone does not automatically translate into measurable performance gains [7, 10]. These findings raise important questions about the underlying mechanisms through which CTD adoption operates. Specifically, it becomes necessary to examine whether CTD implementation has improved dossier structure, validation outcomes, and regulatory review processes in

ways that are not immediately captured by system-level performance metrics.

This study addresses this gap by examining the effects of CTD adoption on dossier quality and regulatory review processes in Nigeria. Focusing on dossier-level indicators and the experiences of regulatory assessors and stakeholders, the study moves beyond outcome measures to explore how CTD has reshaped regulatory practice. By analysing changes in dossier completeness, the nature of regulatory queries, and perceptions of review predictability and workload, the study provides insight into the operational consequences of dossier harmonisation reforms [7, 8, 17, 18].

By foregrounding regulatory processes rather than throughput outcomes, this paper complements existing system-level evaluations and contributes to a more nuanced understanding of regulatory reform in LMIC settings. The findings offer practical insights for regulators seeking to consolidate CTD implementation and inform broader discussions on how harmonisation reforms can be effectively translated from formal policy adoption into sustained regulatory practice [12, 19-22].

Materials and Methods

Study Design

This study adopted a mixed-methods explanatory design to examine the effects of Common Technical Document (CTD) adoption on dossier quality and regulatory review processes in Nigeria. The quantitative component utilised a structured questionnaire to capture stakeholder perceptions of changes in dossier quality and regulatory processes following CTD implementation. The qualitative component employed semi-structured interviews to explore in depth how CTD adoption influenced dossier preparation, regulatory review workflows, and assessor experience. Combining both methods enabled triangulation between perceived trends and experiential explanations.

Study Setting

The study was conducted within the national medicines regulatory system in Nigeria, which is responsible for the evaluation and authorisation of medicinal products. Mandatory adoption of the CTD format formed part of broader regulatory reforms aimed at improving the consistency and predictability of medicines registration processes. The study focused on experiences and perceptions relating to regulatory review processes before and after CTD implementation.

Quantitative Component: Questionnaire Survey

Quantitative data obtained from the structured questionnaire were analysed using the Statistical Package for the Social Sciences (SPSS), version 27. The analysis focused on summarising respondents' perceptions of changes in dossier quality and regulatory review processes following the adoption of the Common Technical Document (CTD).

Descriptive statistics, including frequencies, percentages, means, and standard deviations, were generated to describe response patterns across questionnaire items. Likert-scale responses were analysed to assess levels of agreement or disagreement with statements relating to dossier structure, content quality, review predictability, regulatory clarity, and institutional capacity. The analysis was exploratory in nature and aimed at identifying dominant trends and areas of consensus or divergence among respondents rather than establishing causal relationships.

Qualitative Component: Semi-Structured Interviews

Qualitative data obtained from semi-structured interviews were analysed using thematic analysis. Interview transcripts were reviewed repeatedly to achieve familiarisation with the data, after which initial codes were generated to capture recurring ideas and issues

related to CTD implementation, dossier quality, regulatory workflows, and assessor experience.

Codes were organised into broader themes reflecting patterns across participant responses. These themes were reviewed and refined to ensure coherence and relevance to the study objectives. Thematic analysis was used to provide contextual explanations for the quantitative findings and to explore mechanisms underlying perceived changes in regulatory processes following CTD adoption.

Data Analysis

Quantitative questionnaire data were analysed using descriptive statistics to summarise respondents' perceptions of dossier quality and regulatory process changes following CTD adoption. Frequencies, percentages, and central tendency measures were used to identify dominant patterns and areas of agreement or concern among respondents.

Qualitative interview data were analysed thematically. Transcripts were reviewed iteratively to identify recurring themes related to dossier quality, regulatory workflows, assessor experience, and systemic constraints. Themes were refined to ensure coherence and alignment with the study objectives.

Integration of quantitative and qualitative findings occurred at the interpretation stage. Survey findings were used to identify dominant perceived trends, while interview data provided contextual explanations for these perceptions.

Results

Respondent Characteristics

A total of 380 completed questionnaire responses were analysed. As shown in Table 1, respondents represented a wide range of roles involved in medicines registration, with regulatory affairs officers constituting the largest group. Participants were drawn mainly from importing companies and local manufacturers, reflecting the structure of the Nigerian pharmaceutical market. More than half of respondents reported ten or more years of regulatory experience, indicating substantial familiarity with medicines dossier preparation and regulatory review processes.

Table 1. Respondent Characteristics n = 380

Variable	Category	Frequency	Percentage (%)
Role within organisation	Regulatory Affairs Officer	242	63.7
	Consultant	52	13.7
	Technical Dossier Preparer	21	5.5
	Quality Assurance Officer	14	3.7
	Others	51	13.4
Type of organisation	Importer	153	40.3
	Local Manufacturer	143	37.6
	Multinational Affiliate	40	10.5
	Regulatory / Authority	15	3.9
	Others	29	7.6
Years of regulatory experience	≥10 years	210	55.3
	6–10 years	83	21.8
	2–5 years	66	17.4
	<2 years	19	5.0

Percentages may not total 100 due to rounding.

Perceived Changes in Dossier Structure and Quality

Respondents' perceptions of changes in dossier structure and quality following CTD adoption are presented in Table 2. A clear majority of respondents agreed or strongly agreed that CTD adoption improved dossier quality. Similarly, most respondents reported that CTD modules were clearly structured and easier to navigate, suggesting improved standardisation and organisation of submitted dossiers. Despite these generally positive perceptions, a notable proportion of respondents expressed neutral or negative views, indicating that improvements in dossier quality were not uniformly experienced. These patterns suggest that while CTD adoption enhanced the structural presentation of dossiers, perceived gains in substantive quality were uneven across respondents.

Table 2. Perceived Changes in Dossier Structure and Quality Following CTD Adoption n = 380

Variable	Category	Frequency	Percentage (%)
CTD adoption has improved dossier quality	Strongly Agree	130	34.2
	Agree	118	31.1
	Neutral	69	18.2
	Disagree	19	5.0
	Strongly Disagree	35	9.2
CTD modules are clearly structured and easy to navigate	Strongly Agree	141	37.1
	Agree	121	31.8
	Neutral	63	16.6
	Disagree	31	8.2
	Strongly Disagree	24	6.3

Percentages may not total 100 due to rounding.

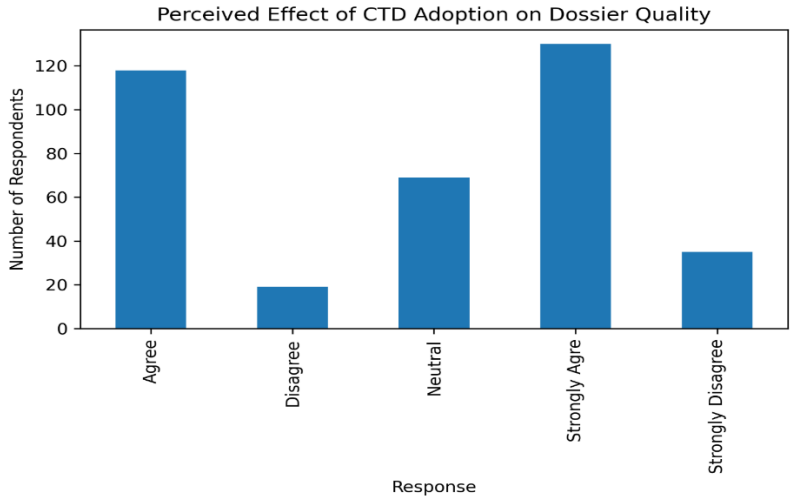

Figure 1. Distribution of Respondents' Perceptions Regarding the Effect of CTD Adoption on Dossier Quality

Perceived Effects of CTD Adoption on Regulatory Review Processes

Perceptions of changes in regulatory review processes following CTD adoption are summarised in Table 3. Most respondents agreed or strongly agreed that regulatory queries had become clearer and more consistent under the CTD framework. This suggests that CTD adoption was widely perceived to have improved the clarity and structure of regulatory feedback.

In contrast, perceptions regarding the speed of regulatory feedback were more mixed. While a substantial proportion of respondents reported improvements, a sizeable minority disagreed or strongly disagreed that CTD adoption had accelerated review timelines. This indicates that improvements in communication clarity were not necessarily accompanied by uniform improvements in review speed.

Table 3. Perceived Effects of CTD Adoption on Regulatory Review Processes n = 380

Variable	Category	Frequency	Percentage (%)
CTD adoption has improved the speed of regulatory feedback	Strongly Agree	58	15.3
	Agree	120	31.6
	Neutral	66	17.4
	Disagree	82	21.6
	Strongly Disagree	32	8.4
Regulatory queries are clearer and more consistent under CTD	Strongly Agree	55	14.5
	Agree	168	44.2
	Neutral	66	17.4
	Disagree	48	12.6
	Strongly Disagree	34	8.9

Institutional Capacity, Guidance, and Training Needs

Respondents' perceptions of institutional capacity and support mechanisms are presented in Table 4. Most respondents agreed or strongly agreed that regulatory guidance documents and checklists were comprehensive, indicating general satisfaction with available support materials for CTD implementation.

At the same time, strong agreement emerged regarding the need for ongoing CTD-related training. A large proportion of respondents indicated that additional training would be beneficial, underscoring the importance of sustained capacity-building to support consistent application of CTD requirements and to translate structural improvements into substantive dossier quality gains.

Table 4. Institutional Capacity, Guidance, and Training Needs Related to CTD Adoption n = 380

Variable	Category	Frequency	Percentage (%)
Regulatory guidance and checklists are comprehensive	Strongly Agree	54	14.2
	Agree	175	46.1
	Neutral	51	13.4
	Disagree	37	9.7
	Strongly Disagree	54	14.2
Ongoing CTD-related training is required	Strongly Agree	154	40.5
	Agree	118	31.1
	Neutral	48	12.6
	Disagree	12	3.2
	Strongly Disagree	39	10.3

Qualitative Results Table

Table 5. Summary of Qualitative Themes and Exemplar Quotes n = 12

Theme	Description	Illustrative Quote
Improved dossier structure	CTD enhanced organisation and navigation of dossiers	"CTD has made the dossiers easier to navigate…"
Persistent content deficiencies	Structural compliance did not ensure substantive quality	"The quality inside the modules is still a problem…"
Clearer regulatory queries	Feedback became more structured and module-specific	"The questions are clearer now…"
Capacity and training gaps	Effectiveness of CTD depended on skills and experience	"Without continuous training, CTD becomes a format exercise…"
Digital system constraints	E-submission systems enabled tracking but posed challenges	"Sometimes the system slows the process instead of helping."

Respondents anonymised using coded identifiers.

Table 5 summarises the key themes identified from semi-structured interviews with regulatory assessors and industry stakeholders. Participants consistently reported that CTD adoption improved the structural organisation and navigability of medicines dossiers. However, interviewees also highlighted that substantive content deficiencies persisted despite improved dossier structure. Clearer and more structured regulatory queries were widely reported, although participants noted that multiple review cycles continued when dossiers contained technical weaknesses. In addition, respondents emphasised the role of institutional capacity and training in shaping CTD outcomes, with several indicating that inadequate training limited the effectiveness of CTD implementation. Perceptions of digital submission systems were mixed, with participants identifying both improvements in transparency and ongoing technical constraints.

Discussion

This study examined how adoption of the Common Technical Document (CTD) reshaped dossier quality and regulatory review processes in Nigeria using a mixed-methods design. By integrating perception-based survey evidence (Tables 2–4), qualitative interview findings (Table 5), and respondent context (Table 1), the discussion clarifies not only *what* changed following CTD adoption but also *how* and *why* those changes manifested unevenly. This approach responds to calls in the regulatory science literature for implementation-focused evaluations of harmonisation reforms in low- and middle-income countries (LMICs) [3, 4, 7].

Structural Gains without Uniform Substantive Quality Improvement

The findings indicate that CTD adoption was widely perceived to have improved dossier structure and navigability. Survey respondents largely agreed that dossiers became more standardised and easier to organise under the CTD framework (Table 2), a pattern reinforced visually in Figure 1. These results are consistent with the core objectives of CTD development, which emphasise standardisation, clarity, and predictability of dossier presentation across jurisdictions [1, 2].

Qualitative findings corroborate this perception, with interview participants consistently reporting improved clarity in dossier layout and information retrieval (Table 5). However, the results also reveal that structural improvements did not uniformly translate into improvements in substantive dossier quality. Interview participants highlighted persistent deficiencies relating to

data completeness, technical justification, and internal consistency, particularly within quality documentation. This distinction between structural compliance and substantive quality has been observed in other regulatory reform contexts, where harmonised formats improve organisation but do not automatically improve scientific content [5, 6, 8].

These findings underscore a critical limitation of dossier harmonisation reforms: while standardised formats reduce ambiguity and variability in presentation, they do not, in isolation, address gaps in applicant capacity, technical expertise, or data quality [6, 7].

Improved Clarity of Regulatory Communication with Limited Efficiency Gains

Perceptions of regulatory review processes following CTD adoption show a similar pattern of partial improvement. Respondents widely perceived regulatory queries to be clearer and more consistent (Table 3), suggesting that CTD facilitated more structured and transparent communication between regulators and applicants. This aligns with regulatory governance literature emphasising the role of standardised documentation in improving reviewer–applicant interactions and reducing interpretive ambiguity [4, 9].

However, perceptions of improved review speed were mixed (Table 3). While some respondents reported faster or more predictable feedback, others perceived little or no change. Qualitative findings provide explanatory insight into this pattern: clearer queries did not eliminate repeated review cycles when dossiers contained substantive weaknesses (Table 5). Similar findings have been reported in LMIC regulatory systems, where process clarity improves without corresponding reductions in review timelines due to underlying quality and capacity constraints [7, 10, 16].

These results suggest that CTD adoption improved the *quality of regulatory communication* more consistently than the *efficiency of regulatory review*, reinforcing the need to distinguish between procedural transparency and operational performance.

Capacity and Training as Central Mediators of CTD Effectiveness

A central contribution of this study lies in identifying institutional capacity and training as key mediators of CTD outcomes. Strong agreement regarding the need for ongoing CTD-related training was evident in the questionnaire data (Table 4), and interview participants repeatedly emphasised that both applicant competence and assessor familiarity shaped the effectiveness of CTD implementation (Table 5).

This finding is consistent with broader regulatory strengthening literature, which emphasises that the effectiveness of harmonisation tools depends on sustained investments in human capital, guidance dissemination, and institutional learning [3, 11, 12]. Without these complementary measures, CTD risks functioning primarily as a formatting requirement rather than a mechanism for substantive quality improvement. In this respect, the Nigerian experience reflects a broader pattern observed across African regulatory authorities, where formal adoption of international standards precedes, rather than follows, full institutional readiness [10-12].

Digital Systems as Enablers with Persistent Constraints

The study also highlights the dual role of digital submission systems in shaping CTD outcomes. While respondents acknowledged improvements in transparency and traceability associated with electronic submissions (Table 4), interview findings point to ongoing technical and usability challenges that may offset efficiency gains (Table 5). These findings align with evidence that digitalisation can enhance regulatory oversight while simultaneously introducing new operational bottlenecks if systems are inadequately

resourced or poorly integrated [13, 14]. This suggests that digital transformation should be viewed as a complementary reform that amplifies, rather than substitutes for, capacity-building and process optimisation efforts.

Implications for Regulatory Harmonisation in LMIC Settings

Taken together, the integrated findings indicate that CTD adoption in Nigeria delivered clear structural and communicative benefits but produced uneven gains in substantive dossier quality and regulatory efficiency. These outcomes align with broader observations from regulatory reform initiatives in LMICs, where adoption of international standards does not automatically translate into improved regulatory performance [3, 6, 7].

By triangulating survey perceptions with qualitative explanations, this study demonstrates that harmonisation reforms operate through identifiable mediating mechanisms—particularly capacity, training, and system readiness—rather than through format standardisation alone. This insight complements system-level evaluations and reinforces the need for regulators to treat CTD adoption as a foundational step within a broader, capacity-driven regulatory strengthening strategy [11, 12, 15].

Conclusion

This study examined the effects of Common Technical Document (CTD) adoption on dossier quality and regulatory review processes in Nigeria using a mixed-methods approach. By integrating perception-based survey data with qualitative insights from regulatory assessors and industry stakeholders, the study provides a process-level understanding of how dossier harmonisation reforms operate in practice within a low- and middle-income country regulatory context.

The findings demonstrate that CTD adoption delivered clear and widely recognised improvements in dossier structure, standardisation, and the clarity of regulatory communication. Respondents consistently perceived dossiers to be easier to organise and navigate, and regulatory queries to be more structured and transparent following CTD implementation. These outcomes indicate that CTD effectively fulfilled its core harmonisation objective of improving the form and consistency of regulatory submissions [1, 2].

However, the study also shows that these structural and communicative gains did not translate uniformly into improvements in substantive dossier quality or regulatory review efficiency. Persistent content-related deficiencies, continued multiple review cycles, and mixed perceptions of review speed highlight the limits of format-based reforms when implemented without commensurate investments in technical capacity and institutional readiness. These findings reinforce evidence that harmonisation tools alone are insufficient to produce sustained quality and efficiency gains in regulatory systems [3, 6, 7].

A key contribution of this study lies in identifying capacity, training, and system readiness as central mediators of CTD effectiveness. Both quantitative and qualitative findings underscore the importance of continuous training for applicants and assessors, consistent application of guidance, and reliable digital infrastructure in translating CTD adoption into substantive regulatory improvements [11-14]. Without these complementary measures, CTD risks functioning primarily as a compliance framework rather than a catalyst for quality enhancement.

Overall, the study concludes that CTD adoption represents a necessary but not sufficient condition for strengthening medicines regulatory processes. While dossier harmonisation improves structural clarity and transparency, its long-term impact depends on sustained capacity development, operational support, and system integration. These conclusions provide important lessons for

regulatory authorities in Nigeria and other LMICs pursuing international harmonisation, and they inform the policy and practice implications discussed in the subsequent sections.

Policy Implications

The findings of this study have several implications for medicines regulatory policy and practice in Nigeria and similar low- and middle-income country settings. First, while CTD adoption has demonstrably improved dossier structure and the clarity of regulatory communication, policymakers should recognise that harmonised formats alone are insufficient to deliver sustained improvements in dossier quality and regulatory efficiency. Regulatory reforms should therefore be accompanied by deliberate and continuous capacity-building programmes for both applicants and regulatory assessors.

Second, regulatory authorities should prioritise targeted training focused on substantive dossier quality, particularly in technical and quality-related documentation. Training interventions should move beyond familiarisation with CTD structure to address common sources of content deficiencies identified during regulatory review. Such efforts would help translate structural compliance into meaningful improvements in scientific quality.

Third, the mixed perceptions regarding review speed and digital systems highlight the need for ongoing investment in regulatory infrastructure. Strengthening electronic submission platforms, improving system reliability, and integrating digital tools into end-to-end review workflows may enhance the efficiency gains associated with CTD adoption. Finally, regulators should incorporate routine process-level evaluations of harmonisation reforms to ensure that implementation outcomes align with intended policy objectives.

Strengths and Limitations of the Study

A key strength of this study lies in its mixed-methods design, which enabled triangulation between quantitative survey data and qualitative interview findings. This approach provided both breadth and depth, allowing the study to capture not only perceived changes following CTD adoption but also the mechanisms underlying those perceptions. The inclusion of respondents with substantial regulatory experience further strengthens the credibility of the findings.

However, several limitations should be acknowledged. The quantitative component relied on self-reported perceptions rather than objective regulatory performance metrics, which may be subject to response bias. Additionally, while the qualitative interviews provided rich explanatory insight, the sample size was limited and may not capture the full diversity of experiences across all stakeholder groups. Finally, the cross-sectional nature of the questionnaire limits the ability to assess changes over time. These limitations suggest that future research could benefit from longitudinal designs and the integration of dossier-level performance data.

Scope for Future Work

While this study provides important process-level insights into the effects of CTD adoption on dossier quality and regulatory review practices, several areas warrant further investigation. Future research could incorporate objective dossier-level metrics, such as validation outcomes, number of review cycles, and time-to-decision, to complement perception-based findings. Longitudinal studies tracking dossiers submitted before and after CTD adoption would also allow for more robust assessment of change over time.

In addition, comparative studies across multiple regulatory authorities within Africa or other low- and middle-income regions could provide broader evidence on how institutional capacity, digital maturity, and training

frameworks mediate the effectiveness of dossier harmonisation reforms. Further work could also explore the interaction between CTD adoption and regulatory reliance or regional harmonisation initiatives to better understand cumulative reform effects.

Ethical Approval

Ethical approval for this study was obtained from the College of Medicine, University of Ibadan Ethics Committee. The approved protocol reference number is UI/EC/25/01199. The study involved a questionnaire survey and semi-structured interviews with professional stakeholders. Participation was voluntary, informed consent was obtained from all participants, and all data were anonymised prior to analysis. No personal identifiers or confidential commercial information were collected, and the study was conducted in accordance with institutional ethical guidelines.

Competing Interests

The author declares that there are no competing interests associated with this study.

Author Contributions

The author conceived and designed the study, developed the data collection instruments, conducted the quantitative and qualitative analyses, interpreted the findings, and drafted the manuscript. The author also reviewed and approved the final version of the manuscript.

Data Availability

The quantitative and qualitative data supporting the findings of this study were generated for research purposes and analysed in anonymised form. Due to ethical considerations and the involvement of professional stakeholders, the data are not publicly available. However, aggregated data or additional methodological details may be made available from the author upon reasonable request.

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