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Innovation in Medical-Legal Regulatory Review: Improving Quality and Efficiency in Pharmaceutical Product Approvals

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ABSTRACT: Approval of pharmaceutical products hinges on evaluating clinical evidence, the benefit-risk profile in product labeling, the consistency of labeling information with claims, and the appropriate legal framing of product claims. In typical review processes where each factor is treated sequentially during the approval pathway, delays, iterative cycles, and inconsistencies become the norm, hampering patient access and driving up costs. This paper describes several practical methods for redesigning clinical review to reduce inefficiency and enhance quality by: involving medical expertise and legal perspective earlier in the process, leveraging structured decision tools, utilizing targeted digital tools such as text analysis in reviewing content against claims for consistency, and identifying and mitigating core risk points of inefficiency and error within review. The paper reviews innovative approaches already adopted by companies and regulatory agencies, proposes a conceptually organized, integrated, and modular approach that engages medical and legal expertise from the outset, and identifies specific measures of value (e.g., accelerated review cycles, improved label quality) that the framework should provide while upholding high standards for patient safety and legal robustness. The paper discusses concrete implementation steps, meaningful metrics, and persistent challenges to guide industry and regulatory reviewers.

KEYWORDS: medical-legal review, pharmaceutical approvals, labeling quality, regulatory efficiency, benefit-risk assessment

I. INTRODUCTION

The complexity of drug development has increased significantly over the last 10 years, as demonstrated by the growing presence of advanced therapy medicinal products (ATMPs), multi-indication programs, and increasing reliance on real-world evidence (RWE) or use of digital endpoints (DPE) in marketing applications with a health authority (Arlett et al., 2025; Hammad et al., 2024). While the amount of data in marketing applications has steadily increased over the years, so has the heterogeneity and interdependencies across study documentation (Arlett et al., 2025). For example, clinical study reports (CSRs) move from medical writing to labeling to legal/compliance and eventually to the regulatory build process. Traditionally, sequential models with downstream workflows do not meet current drug development complexities, increasing project lead times and version cycles while possibly impacting the quality of the final documents seen by regulators and, ultimately, the patient or health-care professional.

In the present paper, medical-legal-regulatory review is a comprehensive assessment of clinical evidence, relative risk-to-benefit ratio, accurate and complete product information, appropriate legal basis for claims, and readiness for marketing authorization. This review function bridges clinical, regulatory, and legal expertise. Medical-legal-regulatory review, which we apply prior to marketing authorization, is distinct from a medical-legal-regulatory review of post-approval advertising copy but based on the same legal requirements. A systematic approach to a benefit-risk appraisal outlined by the ICH M4E(R2) guideline or FDA's recent guidance of 2023 may pave the way toward clearer decisions, but better integration of medical judgment with labeling and legal aspects of drug claims remains less explored (FDA, 2023; ICH, 2017; Lackey et al., 2021).

In the current paradigm, medical, legal/compliance, labeling, and regulatory functions are commonly addressed sequentially, rather than in parallel: the clinical team finishes the study report; the medical writer begins the labeling draft; the legal and compliance professionals review the claims; and regulatory affairs pulls the final dossier. A subsequent step may raise a new question, causing revisits to an earlier document. Analysis of labeling workstreams

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reveals that sequential handoffs lead to foreseen delays, and problems are often uncovered very late, when the costs of remediation (in time and resources) are prohibitive. A cross-sectional review of FDA complete response letters for new drugs approved between 2020 and 2024 showed that labeling was the second-leading cause of complete response letters (44%) at that time, behind manufacturing. Similarly, an investigation of complete response letters in 2000-2012 concluded that labeling falls within the group of factors that can trigger first-cycle denial without any safety or efficacy problems (Sacks et al., 2014). It does not cause a delay while forcing a re-review, can confuse teams, and continued risks persist into post-approval through labeling amendments and promotion risks.

Regulators and sponsors face a dual challenge. They need to safeguard public health by allowing only products with acceptably positive benefit-risk profiles, acceptable labelling, and legally defensible claims to be on the market. However, they simultaneously face sustained pressures to shorten patient access timeframes meaningfully and to hold overall costs for advancing new medicines in check. While independent of regulatory timeframes and decision processes, conducting systematic evaluations of benefit-risk information early in the process can improve transparency and productivity in the review (Simonetti et al., 2024; Vokinger et al., 2025). The point at which the level of clinical evidence requirement intersects with legal and labelling requirements has been less systematically studied (Simonetti et al., 2024; Vokinger et al., 2025). The surge of interest in real-world evidence and patient perspective data in pre- and post-authorisation assessments, especially for means of advanced therapies, intensifies the demand for concerted medical-legal reviews (BioDrugs, 2025; Martin et al., 2025).

This article closes this void by first characterizing the main sources of delay and quality risk to the medical and legal review of new medicines. After synthesizing a range of process, methodological, and digital innovations that have been documented or have the potential to deliver impact in the near term, it then proposes a parsimonious, integrated early and simultaneous model of medical-legal collaboration enabled by accessible metrics and a short research agenda. Although this paper focuses on drug applications evaluated via FDA-, EMA-, and ICH-guided procedures for drug and small-molecule products, combination devices and the purely domestic review of these fall within the scope solely when they are briefly mentioned for illustration. The final labeling package benefits from the quality delivered by an integrated, early and ongoing rather than disparate and sequential last-step medical and legal examination of applications. These benefits extend to both agencies and sponsors, who will now find it as efficient as the approved label.

II. CONCEPTUAL FRAMING

The standards for quality in medical-legal regulatory review are five dimensions (FDA, 2023). Scientific reliability, where efficacy and safety depend on full investigatory non-clinical and clinical trial analysis; Legal defensibility, where textual claims adhere to the relevant legislation and regulations for truthful and non-misleading communications; Labeling accuracy, assuring the final language is congruent with the approved indications, doses, warnings and populations; Consistency, where measures yield a uniform interpretative output across related indications, related drugs and subsequent review cycles, and Auditability, where the path between data and determined label-language is completely traceable and reconstructable for quality assurance or investigation of post-approval modifications. These five standards bridge from the technical investigation to the legal clearance, summarising whether the approved product label will both safeguard patients and allow accurate clinical decisions (Arlett et al., 2025).

The four pragmatic axes by which efficiency can be quantified are the time it takes (the length of the clinical development reports and the labels to get approval ready for a medical-legal committee or MLCC, or as is stated by the FDA time between clinical study approval and the regulatory dossier/label approval), the quantity of human effort (person-hours), the rework frequency (the percentage of the time that you need to go back and restart labeling efforts from a review/work perspective), and the predictability of the medical legal process. The benefits in one domain must translate into advantages across those five quality domains, or the initiative will lack the desired impact (FDA, 2023). Risk-benefit models built on a common language accommodate all competing requirements, drawing from the ICH quality program (Q8-Q12) (ICH, 2009, 2019; O'Donnell et al., 2026).

The core supports for progress, therefore, integrate principles of regulatory science, knowledge, and risk-based requirements associated with ICHQ8-Q12, existing structured framework approaches to benefit-risk, and a limited set of principles of high reliability and Lean applied to knowledge-based work (Arlett et al., 2025). Within this framing innovation has been operationalized as any intended change to a process, supportive system, governance mechanism or data format, which demonstrably improves quality or efficiency or both, without decreasing patient safety. Innovation

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deliberately does not encompass changes only aimed to achieve a step up in rate without corresponding a step up in or scientific or legal rigor, and it also excludes changes adding only an additional load in terms of bureaucracy (Dilek etal., 2026; FDA, 2023).

III. CURRENT LANDSCAPE AND PAIN POINTS

The current clinical-validation framework of medical-legal regulatory review is largely sequential. Clinical study reports are set, initial draft labeling follows, legal and compliance review of claims occurs, and the process finally culminates in regulatory assembly of the life-cycle dossier. Such a linear formation system contains structurally weak links, by virtue of a tiered hierarchical sequential holding pattern that lacks feedback loops and parallel short-term resolution options. In the absence of an integrated review approach, possible discrepancies often emerge only toward the end of this procurement chain, requiring time-consuming reworking just before submission deadlines and thus compromising tight downstream timeframes. Strategic contacts and parallel review modes would still have been available resources to apply, for example, through early internal discussion and informal parallel fielding of safety signals, nuanced efficacy messages, and impending novel regulations. Sponsored projects are thus prone to cascading consequences and time-delay accrual, which, given reduced time allowances, rush all downstream activities. Consequently, documentation readability, completeness, accuracy, consistency, and so on are jeopardized, submitted to authorities, and further delayed (Dilek et al., 2026).

The documented inefficiencies directly result from this sequential approach. For example, in late-cycle labeling negotiations, review time is unnecessarily driven out by multiple rounds of sponsor Agency exchanges of revised text. Claim disputes frequently occur when legal teams find unsupported language after the medical writer has already finalized sections of prescribing information. Duplication of effort occurs when sponsor medical-legal teams and Agency reviewers independently conduct the same benefit-risk analyses. In complex filings with multiple indications or novel therapies, resource bottlenecks are even more acute, and lingering ambiguities often lead to downstream promotional strategies or post-approval changes to labeling (Arlett et al., 2025; Simonetti et al., 2024).

These problems are often exacerbated for global dossiers by inter-jurisdictional variation in process. The FDA employs continuous review with an information-request process and late-cycle meetings, which enable iterative labelling conversations. In contrast, the EMA uses scheduled Day 120 and Day 180 clock-stops coupled with comprehensive question lists. This often results in disparate labelling advice regarding the indication(s) that will ultimately feature on the product label, warnings, and eligible patients (Vokinger et al., 2025). Similar process root cause(s) can be identified in each environment: separate medical and legal deliberation in the final stage of the approval process and a lack of timely access and application of systematic benefit-risk assessment and feedback mechanisms to address discrepancies much earlier in product development (FDA, 2023; Lackey et al., 2021).

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IV. EMERGING INNOVATIONS

The transition in processes and organizations of medical legal review to models of concurrent review of medical evidence, claims, and legal compliance by cross-disciplinary teams allows for concomitant rather than serial review. The integration of systematic benefit–risk assessment and labeling strategy from target product profile stage ensures that development decisions match with final product information and surprises late in the process (CIOMS Working Group XII, 2025). The development of additional pre-submission advice that targets medical-legal issues further speeds the process to conclusion.

Methodological improvements encompass standardizing benefit-risk decision tables so that key risks and benefits are explicit, adopting modular or ‘living’ labelling approaches so that information components within labelling are

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understood to evolve, and systematically incorporating real-world data and patient preference information into labelling justification (Simonetti et al., 2024) to ensure consistent decisions.

Digital and AI capabilities enable the shifts. NLP models process free-text labels, classifying and validating them against structured segments, yielding more than 95 percent accuracy on test data, while retrieval-augmented hierarchical systems, like ClinicalRAG, validate all claims against source tables, achieving more than 96 percent internal validation accuracy (GreyGrey et al., 2023; Zhou et al., 2025). Knowledge graph-backed and ontology-based libraries provide version-controlled "approved language resources; secure collaborative platforms deliver fully audited activities. Existing review data feed prediction algorithms yield estimated cycle time and resourcing forecasts. Dedicated medical-legal positions with quality-metric dashboards connect process indicators to outcomes and serve as the backbone of the capability. Improvements in consistency and timeliness are palpable, while risks associated with algorithmic interpretability, bias, ownership and "hollowing" capabilities necessitated careful human involvement and context-based usage validation (Arlett et al., 2025).

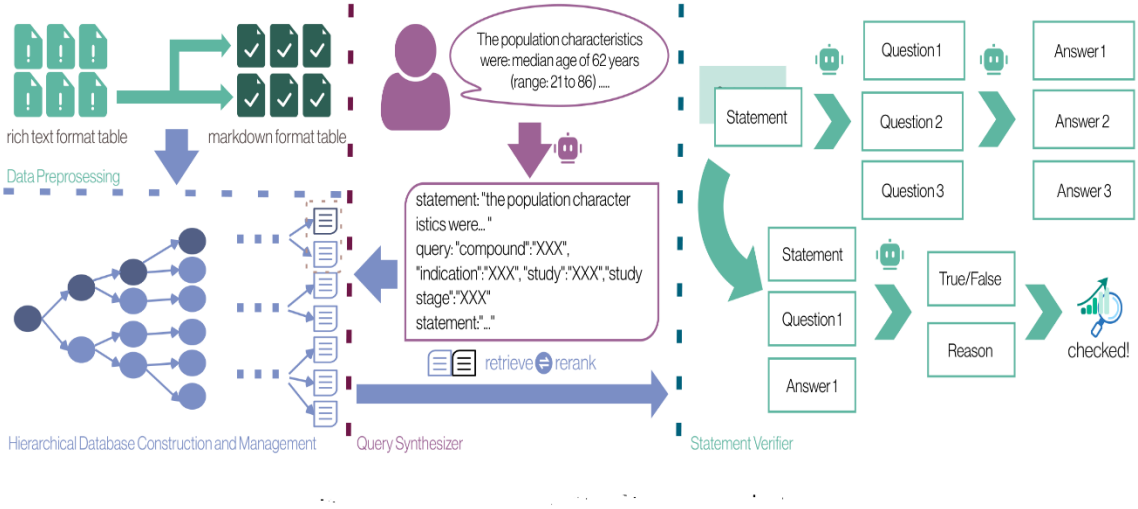

Figure 1. Architecture of the ClinicalRAG hierarchical retrieval-augmented generation pipeline for automated pharmaceutical label claim validation against source tables. Adapted from Zhou et al. (2025)

VI. PROPOSED INTEGRATED FRAMEWORK

An earlier, and perhaps simpler, set of principles can be synthesized from the work of various authorities: joint legal and medical assessment from the beginning; a formalised decisional process; visibility of reasons why things happen; ongoing feedback; human as well as ML skills; and flexible scope. Such an approach should ensure that improvements in both quality and speed of decision-making are symbiotic rather than antagonistic (Arlett et al., 2025; FDA, 2023).

Architecture has four layers. The 1st layer (strategic) addresses the portfolio-level labelling vision and benefit–risk priorities. The 2nd layer (tactical) translates those priorities into labelling review plans at each product level, with parallel workstreams and a narrowing of milestone gates. The 3rd layer (operational) provides the high-leverage tools, templates, AI-assisted consistency checks and collaborative workspaces. The 4th layer (learning) provides metrics, post hoc reviews and shared knowledge. An associated process map (Figure 1) depicts the flow across layers, using concurrency points where medical-legal input may occur in parallel. Operational elements of note include parallel workstreams (clinical, labelling, and legal assessment); designated milestone gates with defined criteria for medical-legal sign-off; escalation procedures for unresolved issues; and integrated quality overlays (triggering independent reviews when thresholds are surpassed) (Simonetti et al., 2024).

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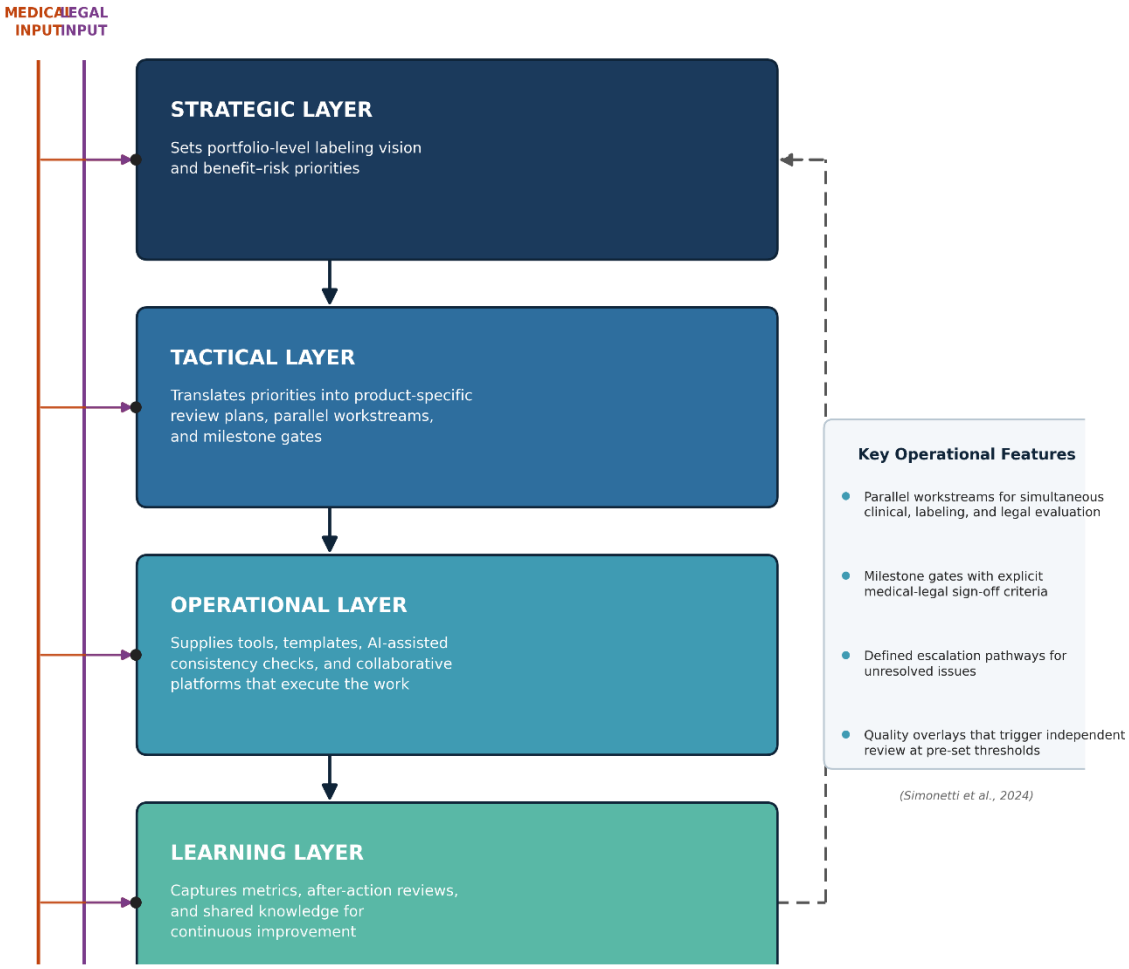

Figure 2. Four-layer integrated framework (strategic, tactical, operational, learning) showing top-down process flow, continuous feedback, and concurrent medical-legal input at every stage rather than a late-stage checkpoint.

The model can be rapidly adapted to other regulatory pathways. For a conventional review, the model enables each phase to be completed in parallel, from the target product profile phase through the approval stage. For an accelerated or priority review, the model reduces time by bringing forward the medical-legal interpretation process for the emerging evidence and applying predictive analytics to identify and allocate resources for high-yield tasks. For an adaptive or conditional review, the model enables iterative re-anchoring of labelling updates through flexible, modular components and real-time digital documentation. Risk mitigation measures include independent quality assessment of clinically significant labelling updates, formal viability testing of the legal defensibility of evolved labelling updates, and required human scrutiny of AI-generated labelling updates for the specific product before approval (CIOMS Working Group XII, 2025; Zhou et al., 2025).

VII. IMPLEMENTATION, METRICS, AND BARRIERS

Monitoring the integrated framework requires transparent measures to assess both efficiency and quality, including leading indicators to assess process health in real time and lagging indicators to assess longer-term outcomes. The table below summarizes the portfolio of core measures. Efficiency will be captured by (1) the number of days between the date of final clinical study report submission and the submission-ready labeling package; (2) the number of major revisions to the submission. Inter-document consistency scores will assess quality, the proportion of post-approval

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labeling amendments attributable to upstream medical-legal issues, and the number of promotional challenges to advice lines and addresses based on labeling claims (Dilek et al., 2026; Simonetti et al., 2024).

Table 1 Core Metrics for Medical-Legal Regulatory Review

Dimension	Metric	Type	Purpose
Efficiency	Time from final CSR to labeling package	Leading	Tracks cycle-time reduction
Efficiency	Number of major revision cycles	Leading	Identifies rework intensity
Quality	Cross-document consistency score	Leading	Detects internal inconsistencies early
Quality	Post-approval labeling amendments (upstream)	Lagging	Measures residual quality risk
Quality	Promotional-challenge rate	Lagging	Reflects legal defensibility of claims

Organisational enablers influence whether and how these metrics are realised. A culture accepting of concurrent (vs sequential) work processes, targeted education in formal benefit–risk methodologies and AI-enabled tools, innovative collaborative information technology platforms, and harmonised data standards are all key components. The critical change-management issues, therefore, are leadership alignment, multidisciplinary role clarity, and phased implementation with ongoing feedback (Arlett et al., 2025).

Principal obstacles still exist. Antiquated document management systems, ongoing lack of expertise in the medical-legal sciences, organisational reluctance toward risk, data islands separating clinical and legal functions, and different national rules governing claims and advertising all hinder adoption. Ethical and fairness issues also need to be considered: more rapid approvals of higher quality could be good for patients and prescribers, but bias in algorithms or uneven process design could harm some groups of users or smaller sponsors. Bias monitoring and transparent AI governance are hence needed (FDA, 2023; CIOMS Working Group XII, 2025).

VIII. DISCUSSION AND RESEARCH AGENDA

Together, the innovations covered and the four-layer framework advanced in this paper set the stage for the double focus on quality and efficiency: concurrent process models, value-based benefit-risk analytic tools, modular labelling, and binarised, well-governed AI systems each lower the sequential chain of bottlenecks and increase the foundation of scientific credibility, legal defensibility and consistent best practices. Operating in a transparent architecture with well-defined milestones, escalation points, and ongoing learning points, cycle times can shrink without sacrificing patient protections and claim integrity (Arlett et al., 2025; Simonetti et al., 2024).

For sponsors, the framework maps out a streamlined path to leaner revision cycles and more predictable submissions. By bringing the medical, legal, and labelling perspectives to the target product profile stage, the pharmaceutical development team can proactively flag claims and consistency concerns (initially) and later work through their worst-case drivers sooner, reducing late-stage rework and optimising resource deployment throughout complex applications. For regulators, it can provide a simplified record of decision-making and early input on labelling issues utilising benefit–risk tables, easily auditable launching pads (e.g., digital safe havens), and explicit sign-off guidance that may reduce iteration and enable more uniform regulation. For patients, it can promise earlier availability of more accurately labelled medicines that more comprehensively capture the evidence- and risk-managed outcomes, with particular benefit in high-need conditions. However, little evidence currently exists to support this: most accounts of concurrent review models or AI-augmented consistency detection are pilot or internal experience, and few validated industry-wide metrics exist that link these process adaptations to long-term impacts (such as reduced post-approval labelling and promotional modifications). The framework itself remains a theoretical construct; prospective validation across multiple product types, industry sizes, and regulatory agencies beyond the primary FDA, EMA, and ICH domiciles elucidated here (Dilek et al., 2026; FDA, 2023; Simonetti et al., 2024) has not yet been reported.

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Hence, priority research questions should involve rigorous, head-to-head comparisons of concurrent versus sequential medical-legal review pathways to quantify the impact on cycle time, number of revisions, and label quality. Independent validation of AI-enabled claim proof supporting and cross-document consistency checking tools should focus on accuracy, transparency, bias and accountability issues in a real regulatory environment. Development of common, publicly available quality metrics –both process-oriented indicators and also outcome measures over the longer term –could provide meaningful comparators between different organisations and agencies. Multi-jurisdiction pilot analyses are necessary to test the framework's transferability in complex procedural contexts such as the US FDA and EMEA, as well as facilitate the identification of practical hurdles in global dossier unification. Long-term evaluation of the impact of these process innovations on post-marketing safety, labelling updates and promotional compliance will reveal if the initial process improvements are truly advantageous for patients and the healthcare system. In order to address these questions, multi-dimensional collaboration among all stakeholders, sponsors, regulators, academia, patient advocacy groups and dedicated investment in medical-legal science are essential (CIOMS Working Group XII, 2025; Zhou et al., 2025).

IX. CONCLUSIONS

Deliberate innovation at the medical-legal regulatory review interface can and should be achieved. Innovative medical-legal regulatory practices can be supported by the straightforward empirical data highlighted in this review, because a linear, stove-piped workstream inherently promotes delay, rework, and labelling inadequacy. At the same time, a structured benefit-risk approach, earlier cross-functional inclusion, and focused tools will measurably improve throughput without sacrificing science or legal defensibility. The streamlined integrated framework is the natural embodiment of these observations into a clean, operational architecture, offering four networked layers of innovation, six governing principles of design, and built-in checkpoints in a regulatory environment in which concurrent medical, legal and labelling efforts take place simultaneously, but where derivation is still tracked and monitored. The elegant parsimony and scalability ensure that a targeted integrated framework may apply to Standard, Accelerated, or Adaptive pathways across the lifespan of each additional and/or accelerated product innovation. Whether to facilitate North American or worldwide submissions, generic or innovator programs, or issues related to additional manufacturing sites, the insights in this review will provide an effective framework that enables targeted innovations to achieve timely access while preserving legitimacy. The medical-legal interface should be a platform for future innovative medical-legal regulatory science given the rapid expansion in advanced therapies, evidence-based applications, and use of AI in regulatory review. Unlocking this future necessitates disciplined continued governance, prudent validation of new metrics, and far-sighted partnership between sponsors, regulators, and academics in the pursuit of balance.

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