White Paper

Futureproofing Post-Approval Compliance by Integrating LQPPV and Lifecycle Management with Applied AI

Align local pharmacovigilance and regulatory change under one governance model.

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Introduction

All approved drugs follow the same product lifecycle: discovery and development; clinical trials; evaluation and authorization; and finally, post-approval and safety monitoring. Though a drug's approval is a major achievement, it is only the beginning of an ongoing journey with no set finish line. Post-approval and safety functions require significant ongoing work that ebbs and flows as labels evolve, and safety signals emerge.

The post-approval environment is where global governance, legal obligations, volume variations, and market-specific expectations converge, making the operating model that sponsors adopt critical to maintaining speed and compliance. As this environment becomes more complex and globally interconnected, regulatory expectations are evolving alongside it.

Regulators now expect high-quality, traceable, data-driven submissions with fewer inconsistencies across markets. This is reflected in the EMA's adoption of the International Organization for Standardization — Identification of Medicinal Products (ISO IDMP) via the substance, product, organization, and referential data (SPOR) program, and the move toward electronic common technical document (eCTD 4.0), both of which underpin structured data, interoperability, and end-to-end traceability. In parallel, continuous signal management, as set out in GVP Module IX, has become the accepted regulatory standard for pharmacovigilance (PV).

The global-scale compliance challenges sponsors face

Manufacturing, distributing, and monitoring an approved therapeutic at a global scale is inherently complex. The burden is further complicated by managing compliance and consistency across a variety of jurisdictions. Local requirements and regulatory interpretations are not always consistent with global regulation, and though all regulatory agencies share similar goals, translating global principles into local realities, i.e., different timelines, templates, and regulatory engagement models, is a challenge. These distinctions can create friction and delays across markets.

Country-specific hurdles include translation nuances, health authority communication preferences, and expectations for local qualified persons for PV (LQPPVs). These micro-requirements compound to slow down even relatively simple updates. Furthermore, many sponsors lack dedicated in-country expertise and have difficulty managing workload peaks related to post-approval activities.

The volume of post-approval work keeps increasing and includes variations, renewals, labeling updates, manufacturing changes, and risk management actions, which are meant to run in parallel. While these activities are manageable individually, their collective volume at scale is high risk due to fragmented data and decision-making across PV, regulatory affairs, and local teams. If a single labeling change or safety update is pushed through 20+ regulatory systems, minor process differences create major coordination workloads.

Sponsor teams must coordinate across PV; regulatory affairs; chemistry, manufacturing and controls (CMC); quality assurance (QA); and local affiliate teams to maintain alignment on evidence and rationale. It often takes more time to synchronize updates than to produce them. To ensure speed and global compliance, operating models must respect local obligations, leverage structured data and shared governance, and deftly manage high volumes.

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A synergistic operating model

The post-approval stage requires work from both safety and regulatory teams. For example, a safety signal can affect labeling, and the labeling change will trigger a variation that requires coordinated submissions. When safety and regulatory functions are disconnected, time is lost and messages drift. A synergistic operating model brings PV and regulatory functions under one umbrella: a single governance structure with shared decision cycles, templates, and evidence. Instead of handoffs between teams, there is one coordinated workflow where both functions have access to the same information simultaneously. As a result, sponsors avoid duplicate work and miscommunication.

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This structure delivers several additional operational benefits:

- Affiliates receive an aligned package for local submissions.
- Fragmentation from isolated functions is eliminated.
- Inspection readiness improves.
- Parallel truths are replaced with a shared evidence base that improves quality and reduces affiliate questions.
- Timelines are shortened.

Perhaps most importantly, the synergistic operating model builds inspection confidence via shared decision logs, consistent wording frameworks, and clear accountability. When regulators audit sponsors, they will hear the same story across PV, regulatory, and affiliates. This integration removes friction, accelerates consensus, and hardwires consistency into every global update. While some sponsors may fear that a synergistic model requires organizational overhaul and major technology investments, this model is supported by two flexible, plug-and-play approaches: **adaptive resourcing** and **applied AI**.

Adaptive resourcing

Unfortunately, post-approval work does not follow a smooth, predictable curve. Pressure builds quickly during renewal waves, label cascades, safety-driven updates, inspection-readiness activities, and geographic expansion. Though cyclical demand spikes can be planned for, they are often too intense and uneven for a fixed team to absorb without timeline or quality risks. Adaptive resourcing aims to accommodate these realities, allowing companies to rapidly scale up with experienced professionals that understand PV, regulatory affairs, and a sponsor's operations, and scale down once a surge has passed without carrying a permanent headcount for peak work.

Adaptive resourcing provides sponsors with access to specialist capabilities that may be inefficient or difficult to hire on a full-time basis, including labeling strategists, literature and surveillance experts, regulatory information management (RIM) specialists, publishers, and local affiliate support. Capacity is planned around predictable regulatory and safety cycles, enabling pre-trained surge resources to be quickly deployed, while operating under the same governance, QA controls, systems, and documentation standards as the core team.

As priorities shift, this resourcing model adapts to accommodate different scenarios without triggering full recruitment, onboarding, and offboarding cycles. Adaptive resourcing provides coordinated, pre-trained support that seamlessly locks into a workflow that results in a coordinated and inspection-ready support that reinforces quality and compliance during high-demand periods.

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Applied AI

AI-supported PV and regulatory workflows are no longer the future — they have arrived. Though technology will not replace experts or perform unsupervised work, AI will execute repetitive work and structured tasks that consume much of an expert's time. AI is effective in supporting high-volume, low-judgment activities such as screening, literature triage, document summarization, data extraction, early signal detection, label impact assessment, and most activities in which consistency and speed are more important than scientific interpretation. With applied AI workflows, PV and regulatory experts will focus on providing inputs, guidance, and judgment for ongoing compliance.

For AI integration to succeed, guardrails are essential: primarily human-in-the-loop configurations that apply risk-based validation consistent with regulatory expectations. With AI applications, regulators are looking for validated systems, risk assessments, and tools trained on appropriate healthcare data sources with traceability. A human-in-the-loop provides a mandatory review of AI output for accuracy and accountability. The goal is to deploy AI in a way that accelerates workflows without creating regulatory discomfort or compliance and inspection risks.

At IQVIA, our team has developed technology-agnostic models that embed AI directly into existing safety or RIM systems. To ensure successful application, we begin by working with sponsors to apply AI to a single high-volume, high-value workflow. From there, we establish metrics for time and quality and run a control pilot to evaluate performance. Once validated, the AI application is scaled. Standard playbooks are used to train the tool and local teams. As a result, AI completes high-volume, repetitive work with speed, saving hours while supporting compliance.

Applied AI adapts based on real performance. As reviewers interact with the system, they can refine prompts, adjust guardrails, and recalibrate the model as needed. Over time, these adjustments improve accuracy and reduce the amount of time experts must spend correcting outputs. However, achieving this improvement requires appropriate governance.

An effective AI governance approach

To enact effective AI governance, the first step is establishing clear scope and accountability. AI should be applied only to clearly defined, low-risk tasks with a human-in-the-loop configuration built by design. In this model, AI conducts first-pass activities while experts review, interpret, and sign off on the results. At the same time, risk-based validation must be scaled to the level of impact, using lighter controls for assistive use cases.

Equally important, data integrity and change controls must support inspection readiness. Thus, inputs are controlled, outputs are traceable, and content is versioned to maintain a clear record of activity. As workflows evolve, performance is monitored, and formal change control is applied to align with regulatory standards. At IQVIA, we use a consistent governance model, training record, and role-based access and audit trails to record what AI did and what humans decided. While AI accelerates workflows, people retain responsibility for final decisions, ensuring the model remains inspection ready.

Support models with strategic partnerships

Sponsors need operating models that are modular-by-design, enabling support for different parts of a portfolio. Some sponsors may need LQPPV support and regulatory maintenance added to an existing operating model, while others may want to implement a fully integrated PV and regulatory affairs setup. IQVIA tailors solutions to fit a sponsor's model and pace, working directly within their existing system and requiring no tech migration or internal workflow disruption. Our goal is to establish true partnerships that meet customers where they are, adding markets, adjusting resources, and introducing automation and AI at their discretion.

To futureproof global compliance, sponsors must do the following:

1. **Unify the data spine** with one clean product dataset (IDMP-ready) and metadata-driven submissions (eCTD 4.0). This reduces rework by only updating once across markets.
2. **Treat change as a process** by expecting post-approval work to come in waves. Ensure consistent, defensible decisions by using standardized risk-based playbooks for post-approval changes, and plan work sharing as needed.
3. **Embed local and global work by design**. Maintain an LQPPV presence where required while using global governance templates and KPIs to support consistency and inspection readiness across markets.
4. **Adopt safe automation**. Apply AI and automation where they are proven to increase operational speed and align with compliance expectations.

With these steps, sponsors will benefit from faster compliance updates, fewer inspection surprises, and a model that scales as portfolios and regulations evolve. There are two strategies for applying this configuration to post-approval workflows.

A unified system without reorganization

In many organizations, PV and regulatory affairs are separate global functions. This structure is not wrong, and it does not need to change. However, as an example, a safety signal could be centrally confirmed to trigger a cascade: label wording updates, safety communications, and variations across markets with different timelines and rules. In a traditional model, this triggers parallel work streams: PV builds on the safety rationale, regulatory affairs addresses the justification for labeling and updates, and LQPPVs provide interpretation when health authorities ask questions. While each function performs its role effectively, the lack of a formal coordination mechanism can introduce delays and inconsistencies.

To address this without reorganization, sponsors and partners can create a coordination layer for each safety issue via a joint process validation and regulatory affairs (PVRA) decision forum established as needed. PV leads signal assessment and regulatory affairs uses the same evidence package for labeling strategy and submissions. The LQPPVs maintain oversight and continue to serve as primary health authority contacts, with the benefit of an aligned safety rationale, agreed-upon wording, a singular product dataset, and clear guidance on impacted markets and submission routes.

One operating model with integrated PV and regulatory functions

The integrated operating model is built around a single global change function. This approach is common for sponsors with growing portfolios. In this model, PV and regulatory affairs operate as a hybrid, post-approval function. They share leadership governance and a single resource pool. Unlike the previous model, the trigger is not the safety signal but a wave of post-approval activity, such as safety-driven label updates, manufacturing changes, and renewals across regions. To manage these surges efficiently, the model relies on a single global change workflow.

The safety signal goes to label decision-making and then variation route and local implementation. Within this structure, LQPPVs are embedded in the global model, where they remain locally accountable and available to health authorities while making upstream decisions alongside the EU QPPV. Standard playbooks define when to use work sharing. To support this process, applied AI helps manage high volumes of work with predictable, scalable outcomes, enabling faster global rollouts with fewer inconsistencies and stronger inspection readiness. Along the way, sponsors maintain control and credibility.

Conclusion

The post-approval environment must be flexible to evolving regulations and waves of high-volume global activity. With a system that is prepared to adapt, provide continuous oversight, support large volumes, and guarantee global consistency as regulations shift, sponsors will find themselves ahead of the curve no matter how quickly the landscape shifts.

About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of clinical research services, commercial insights and healthcare intelligence to the life sciences and healthcare industries. IQVIA's portfolio of solutions are powered by IQVIA Connected Intelligence™ to deliver actionable insights and accelerate innovations. With approximately 91,000 employees in over 100 countries, IQVIA is dedicated to accelerating the development and commercialization of innovative medical treatments to help improve patient outcomes and population health worldwide.

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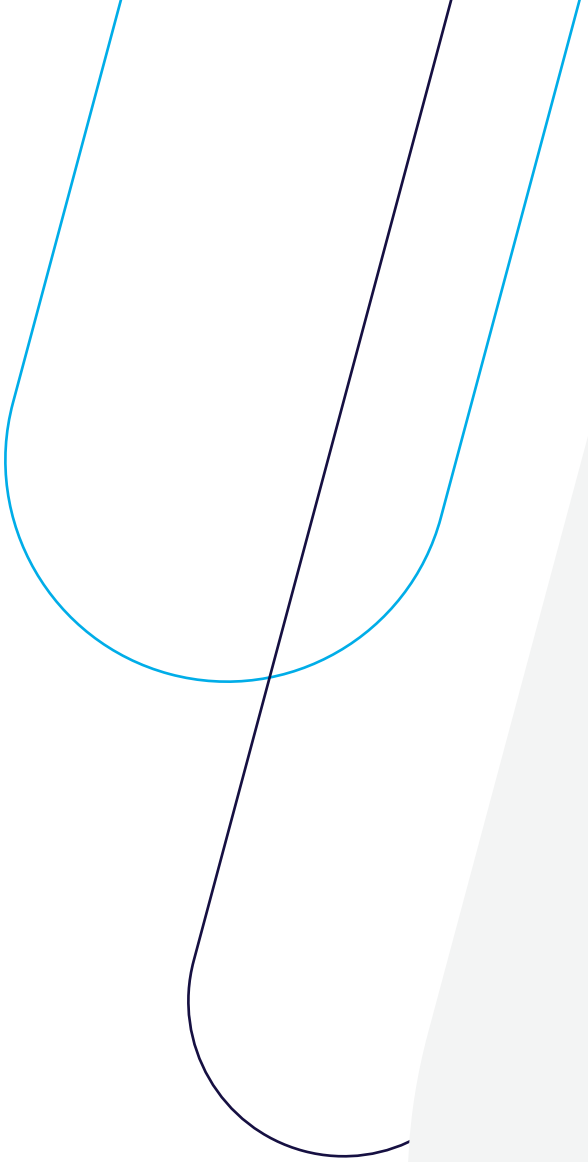

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