

White Paper

Beyond AI Hype: Improving Patient Outcomes Through Smarter Regulatory Affairs

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Executive summary

The adoption of Artificial Intelligence (AI) holds tremendous potential for regulatory affairs. While automation, accelerated submissions, and productivity gains remain important objectives, they represent only a fraction of AI's strategic value. The more important question for regulatory leaders is this: How can AI be deployed to strengthen strategic decision-making and improve patient access to safe, effective treatments and therapies?

This paper explores how AI can strengthen regulatory coherence, apply scientific context at scale, support global strategy, preserve institutional knowledge and enhance human expertise. Organizations will realize the greatest value from AI when they measure success on these factors. The paper concludes with a practical framework to help regulatory leaders identify AI investments that build lasting strategic capability rather than incremental operational efficiency.



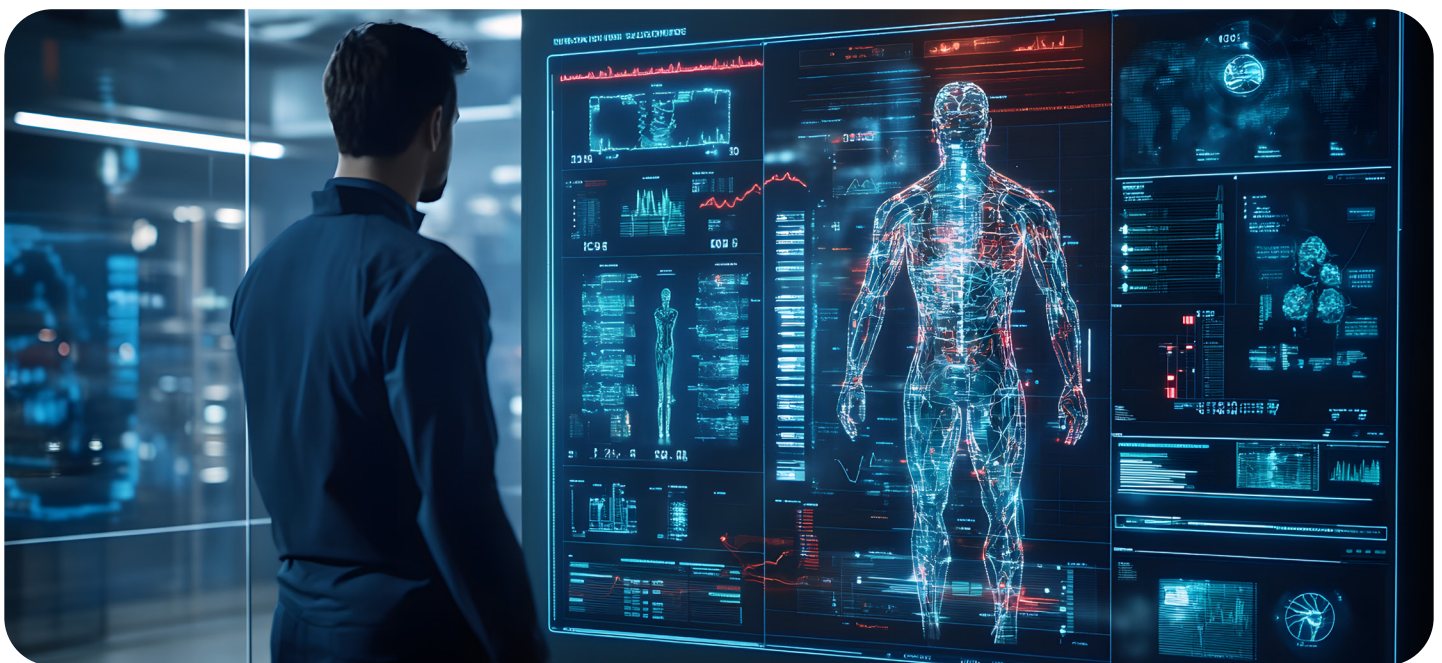
Introduction: Changing the conversation on AI's value in global regulatory affairs

While AI adoption across life sciences organizations is accelerating, so is the complexity of the global regulatory landscape.¹ Changes in global trends and regulations that cross industries have also picked up speed.²

Regulatory professionals are under pressure to deal with these combined challenges while handling multiple products and markets simultaneously. These complexities are compounded in countries such as Russia and China that require localized technical, toxicological and clinical activities for certain product types. Countries often impose market-specific testing, certification or evidence requirements before regulatory authorities will review an application. For example, Brazil requires certification from INMETRO, a national standards authority, for certain electromechanical products and high-risk devices before ANVISA's regulatory review can begin. These country-level requirements, shaped by diverging global regulations and layered over product-specific standards and requirements, drive increasingly complicated approval timelines.

Much of the industry's conversation around AI technologies is focused on productivity: document automation, submission acceleration and operational efficiency. These improvements represent only a fraction of AI's potential to strengthen global regulatory affairs teams and enhance the industry's ability to improve patient outcomes. By focusing on productivity gains, leaders may overlook how AI can support the strategic work within regulatory affairs. In this area, success on a global basis depends on far more than completing tasks faster, reducing costs and optimizing headcount. It requires:

- High-quality scientific narratives backed by expert interpretation and judgment
- Consistent regulatory positioning over time and multiple submissions
- Product-specific and clinical context
- Understanding the nuances of regional regulations
- Strong, trusted relationships with health authorities



These are not challenges that can be solved through automation alone; they require technology that strengthens, rather than replaces, global regulatory expertise. AI has significant value in improving decisions, strengthening regulatory strategy and helping organizations manage increasing global complexity in ways that optimize market access and ultimately improve patient outcomes.

Instead of asking “How can AI help us work faster?” global regulatory leaders should ask “How can AI help us strengthen the regulatory affairs function, make better strategic decisions and accelerate the provision of safe and effective product solutions?”

This shift in perspective lays the foundation for realizing the full value of AI. It is a change in mindset from leading with financial optimization alone to leading with patient outcomes first. A sustained focus on patient centricity then compounds that benefit with improved business operations and stronger commercial performance.



A shift in mindset in regulatory affairs



Operational AI focus



Automation



Faster submissions



Productivity



Cost reduction



Operational efficiency



Strategic AI focus



Better decisions



Higher-quality submissions



Regulatory quality



Accelerating patient access



Improved patient outcomes

Section 1: Regulatory affairs as a strategic discipline in the age of AI

Regulatory affairs is often viewed as a compliance-driven administrative function: preparing submission documents, managing approvals and meeting regulatory demands before product launch. These responsibilities, while essential, are only one part of a much broader strategic mandate.

At the global level, regulatory affairs sits at the intersection of science, innovation, business strategy and patient health. Its professionals present the evidence supporting scientific advances in therapies and technologies into a coherent submission that can be approved, leading to a product that can be launched and maintained in markets around the world. As life sciences organizations pursue larger global programs, a regulatory strategy that succeeds in one market may require significant adaptation for another. Leaders must constantly interpret changing guidance and product requirements across regions, anticipate regulatory concerns and align cross-functional teams around a clear regulatory strategy.

This strategic aspect has become more important as innovation accelerates. New therapies, solutions and devices challenge existing regulatory frameworks, changing expectations for evidence generation and regulatory engagement. At the same time, organizations are expected to bring these innovations to patients

more quickly while maintaining the highest standards of quality, safety and compliance.

Balancing these competing demands requires a strategic mindset and thoughtful decision-making. Over time, teams build credibility with health authorities when they provide consistent, well-supported submissions that demonstrate a thorough understanding of both the science and regulatory expectations.

Recognizing regulatory affairs as a strategic discipline also changes the role of artificial intelligence within it. If the function is viewed as mainly administrative, AI's value is limited to automating repetitive operational tasks, boosting productivity and improving operational efficiency. However, if regulatory affairs is understood as a discipline built on scientific interpretation, strategic planning, collaboration and informed judgment, a much more significant opportunity emerges.

The regulatory affairs ecosystem



Section 2: Regulatory affairs is both a science and an art

Every day, regulatory affairs professionals must balance scientific rigor with human judgment. Striking that balance is both a science and an art, grounded in hard, data-driven evidence yet dependent on human interpretation, collaboration and expertise. For this reason, AI is better positioned to assist regulatory affairs without replacing the contextualized, often undocumented knowledge of professionals that is born from their experience.

WHAT IS REGULATORY SCIENCE?

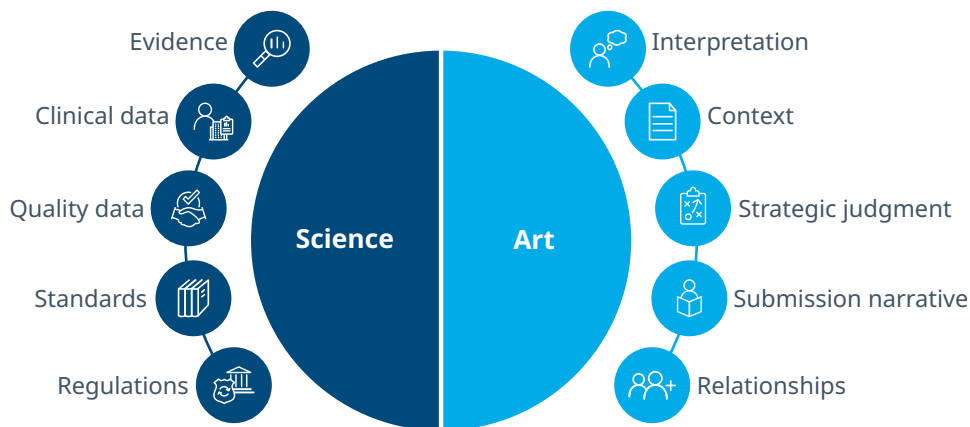
According to the FDA, “Regulatory science is the science of developing new tools, standards and approaches to assess the safety, effectiveness, quality and performance of FDA-regulated products.”³

Regulatory professionals are routinely evaluating clinical, scientific, technical and quality data. To meet these responsibilities, they must analyze, integrate and apply scientific and regulatory information in ways that support consistent, high-quality decisions. The role of regulatory affairs extends across the entire product lifecycle, encompassing interconnected responsibilities, including:

- Applying global and local regulatory requirements to specific product types
- Interpreting clinical and scientific evidence to demonstrate safety, effectiveness and performance
- Responding to evolving compliance expectations
- Driving remediation plans to maintain market access for approved products
- Updating submissions as new evidence becomes available
- Ensuring a consistent representation of a product’s safety and efficacy throughout a submission and within subsequent lifecycle management activities

These uniquely human capabilities continue to drive successful regulatory outcomes. Every regulatory decision requires human interpretation. This is where the art of regulatory affairs begins. The science alone is not enough. Its professionals must apply scientific evidence within specific contexts, balancing technical requirements with regulatory expectations and commercial objectives.

The Science + art continuum



AI strengthens both sides — but replaces neither.

Strategic judgment is central to this work. Experienced professionals know what regulators need and, over time, learn what helps build trust in a product and support a successful review. Skilled professionals can recognize potential concerns before they arise. They can make sophisticated decisions about how best to present evidence, sequence steps and navigate increasingly complex global regulatory pathways.

The ability to translate science into compelling regulatory narratives is just as important. A successful submission is not simply a collection of documents; it presents a clear, consistent and evidence-based story that demonstrates why a product meets regulatory expectations. Maintaining that narrative requires consistency not only within an individual submission but across the lifecycle as products evolve, indications expand and regulatory requirements change.

Relationships also matter. Regulatory work is built on the credibility, transparency and trust that regulatory professionals develop with regulators over time. Consistently providing well-supported, coherent submissions strengthens connections with regulators and health authorities. Productive dialogue, expert judgment and professional credibility are all critical elements that cannot be replaced by AI. In the end, strong relationships are one of the many factors that help make therapies available and support better outcomes.

The ability to apply context is equally critical. Experienced regulatory professionals draw upon knowledge gained across products, therapeutic areas and global markets to discern what the regulations alone cannot reveal: how scientific evidence, product context and regional expectations converge to shape successful regulatory outcomes. They see that the same regulation can be applied differently depending on product characteristics, clinical evidence, local market expectations or evolving agency guidance. This contextual understanding often distinguishes successful regulatory strategies from unsuccessful ones.

For these reasons, regulatory affairs remains an interpretive discipline rather than a transactional process. Improving patient outcomes depends on combining scientific expertise with the art of professional judgment, collaboration and experience to make decisions in situations where there is rarely a single correct answer. Here, the role of the regulatory expert becomes even more valuable, as human judgment remains essential for interpreting AI-generated insights and applying them appropriately for each product, market and regulatory challenge.

These are the skills that organizations should strengthen when adopting AI. Professionals can make better decisions with AI providing more comprehensive evidence through:

- Rapidly analyzing large volumes of regulatory intelligence
- Revealing relevant precedents
- Identifying inconsistencies across submissions
- Synthesizing complex data

For example, through these capabilities, AI can help teams interpret the science and assemble critical information. This saves professionals time and energy, allowing them to focus on communication, both within their organizations to improve processes and with regulators to explain the science. Further, it supports the ultimate objective: the timely approval of safe and effective products so patients globally can have better healthcare outcomes.

Section 3: Where AI creates strategic value in regulatory affairs

Organizations investing in AI today are making architectural decisions they'll live with for years. Choosing AI solely for productivity may lock them into capabilities that don't strengthen regulatory affairs teams to their fullest potential.

Understanding the strategic role of regulatory affairs and the importance of human expertise helps organizations identify where AI can create the greatest value. Rather than replacing regulatory professionals or simply accelerating administrative tasks, AI has the potential to strengthen the capabilities that define successful regulatory affairs organizations.

One way to think about this distinction relates to the difference between speed and velocity. Speed alone measures how quickly an organization moves. Velocity adds direction. In regulatory affairs, moving faster has little value if submissions fail to address country-specific requirements, product-specific regulations or evolving health authority expectations. AI should be used to help organizations move with greater precision for stronger regulatory decisions, higher-quality submissions and better patient outcomes — not just greater speed.

We see five areas where AI can enhance regulatory quality, improve decision-making⁴ and help organizations navigate the increasing complexity of global regulatory affairs.

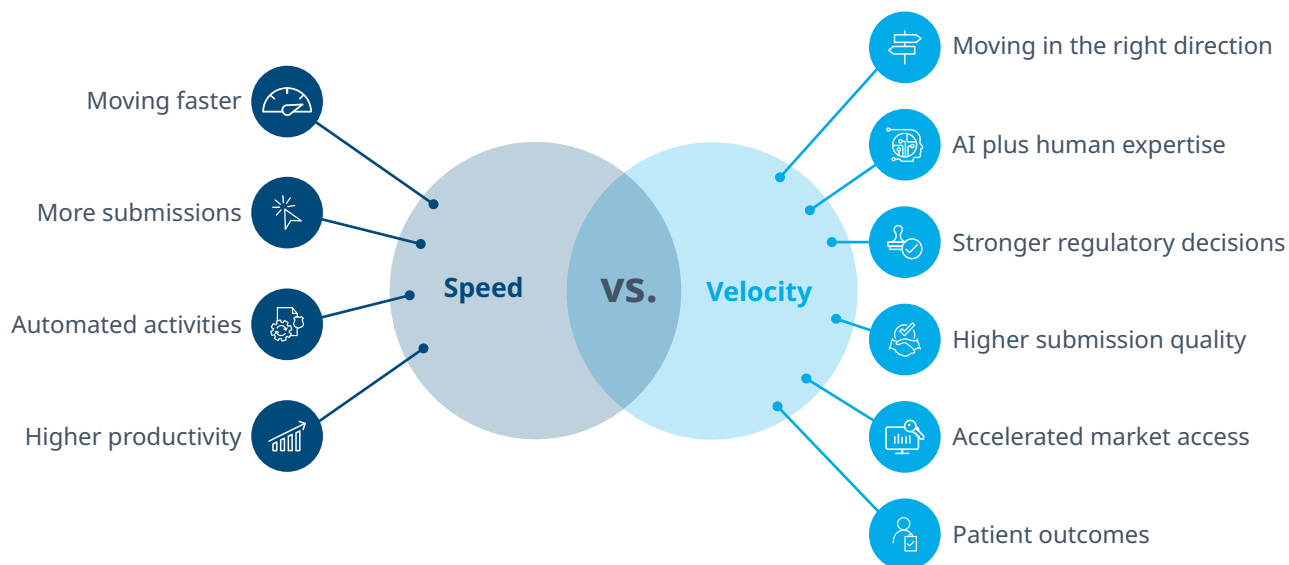
A. Improve regulatory coherence

As organizations manage increasingly complex global submissions and lifecycle management activities, coherence becomes essential. Scientific evidence, product positioning, benefit-risk reasoning and regulatory responses must remain aligned across submission components, markets and health-authority interactions. Harmonized frameworks such as the ICH Common Technical Document and M4E(R2) reflect the importance of presenting quality, safety, efficacy and benefit-risk information in a structured and integrated form that facilitates regulatory review.⁵

AI can support this work by helping regulatory professionals analyze large volumes of information and:

- Align scientific and regulatory narratives
- Retrieve relevant evidence and precedents
- Flag potential gaps or inconsistencies for expert review

Speed vs. velocity



When applied with appropriate governance and human oversight, these capabilities can contribute to clearer, more complete submissions and better-supported responses to health-authority questions. The European Medicines Agency (EMA) identifies better data insight and decision support as important regulatory applications of AI while also emphasizing that AI-generated content must be verified for accuracy and completeness.⁴

This does not guarantee fewer regulator questions, but stronger submission quality can reduce avoidable deficiencies, clarification cycles and rework. FDA guidance notes that the number and magnitude of application deficiencies generally correlate with the number of assessment cycles and encourages applicants to submit high-quality, complete applications.⁶

B. Apply clinical and scientific context at scale

AI helps regulatory professionals apply the right knowledge to the right product at the right time. One of its greatest strengths is its ability to analyze vast amounts of regulatory information while integrating clinical and scientific context at scale. For this reason, organizations miss a significant opportunity when they view AI primarily as a document-processing tool.

Regulatory decisions are shaped by many factors: therapeutic area, product characteristics, clinical endpoints and the evolving body of scientific evidence supporting a product. By incorporating this multidimensional context, AI can support stronger regulatory strategies throughout the product lifecycle. This ability to combine vast volumes of scientific knowledge with contextual analysis is one of the elements that transforms AI from an efficiency tool into a strategic driver in regulatory decision-making.

C. Support global regulatory strategy

With AI, teams can plan more proactively, using better information throughout the product lifecycle, resulting in stronger strategic planning. When it is invested appropriately, AI can help improve regulatory teams'

ability to assess changing requirements, anticipate challenges and refine approaches before decisions are made.

Teams benefit from AI's ability to:

- Synthesize large volumes of global regulatory intelligence
- Monitor evolving regulatory requirements across countries and regions
- Identify regional differences early in the development process
- Detect gaps between regulatory expectations and a product's positioning or supporting evidence
- Support planning for global submissions

These capabilities equip regulatory professionals to take a more holistic approach to strategy. By providing timely, context-rich intelligence, AI helps teams evaluate how product characteristics, scientific evidence and regional regulatory expectations intersect. Better strategies ease the development path, support more predictable market access and ultimately help bring needed therapies to patients sooner.

D. Leverage organizational knowledge

As with other business functions, regulatory organizations generate a wealth of valuable information over the course of a therapy's lifecycle. In the past, as this knowledge has accumulated, it has become harder to find useful information quickly and efficiently. A virtual mountain of previous submissions, past regulatory responses, agency feedback, internal precedents and lessons learned becomes dispersed across documents, drives, systems and people. Staff turnover is a major problem because valuable institutional knowledge is lost when employees retire or leave for other jobs.

With AI, these fragmented assets can be turned into a strategic resource, allowing teams to build on existing organizational learnings. AI can quickly find relevant past

examples, show records of earlier agency interactions and link current work to past institutional knowledge. Future teams do not have to relearn or recreate what previous teams already knew. This not only improves consistency across submissions and lifecycle management activities but also helps make valuable institutional knowledge usable.

Here, rather than replacing regulatory expertise, AI extends its reach and power by making organizational knowledge more accessible across teams and geographies. The result is a more informed, consistent and efficient approach to regulatory strategy — one that minimizes repeated effort while helping teams use shared knowledge in future decisions.

E. Enhance human expertise and judgment

AI technologies cannot replace human expertise, nor should they be used alone to make regulatory decisions. In the highly regulated GxP (Good Practice)⁷

environment that governs healthcare and life sciences, qualified human experts remain responsible for scientific interpretation and strategic judgment. Current global regulatory guidance emphasizes that AI should support regulatory decision-making within a framework of human oversight, multidisciplinary expertise and risk-based governance. Responsibility for regulatory decisions continues to rest with human experts. Consistent with this principle, AI should be implemented to augment expert decision-making, not replace it.⁸

For example, an AI system may successfully identify relevant regulations or historical precedents for a submission. However, professional expertise is still needed to determine whether those precedents truly apply to a novel therapy, an evolving clinical dataset or a specific regulatory authority. That is where expertise creates value and where AI delivers its greatest potential as a strategic support to regulatory professionals.



Section 4: Designing AI around patient outcomes, not productivity metrics

In the effort to shift the discussion about AI from operational efficiency to patient impact, it is important to understand where patient outcomes fit into the broader context.

Global regulatory affairs exists for one fundamental purpose: to ensure healthcare products are supported by sound science, approved by regulatory authorities, safely maintained in market, and ultimately accessible to the patients who need them. Whether introducing a new therapy, expanding into additional markets or managing post-market changes, the true deliverable of regulatory affairs is improved patient outcomes, not submission packages or paperwork.

With this in mind, the most valuable AI initiatives for regulatory affairs begin with a simple question: How will this improve patient outcomes?

This change in focus — from the technology to the patient — involves a two-step process. First, identify the problem and define the opportunity for improvement. Second, ask: Is AI the appropriate solution? If so, how can it create the greatest value?

Approaching AI's potential to help address regulatory challenges this way puts patient care where it should be, at the forefront of decisions about its application. It also

prevents regulatory affairs teams from automatically thinking AI holds the solution to every issue.

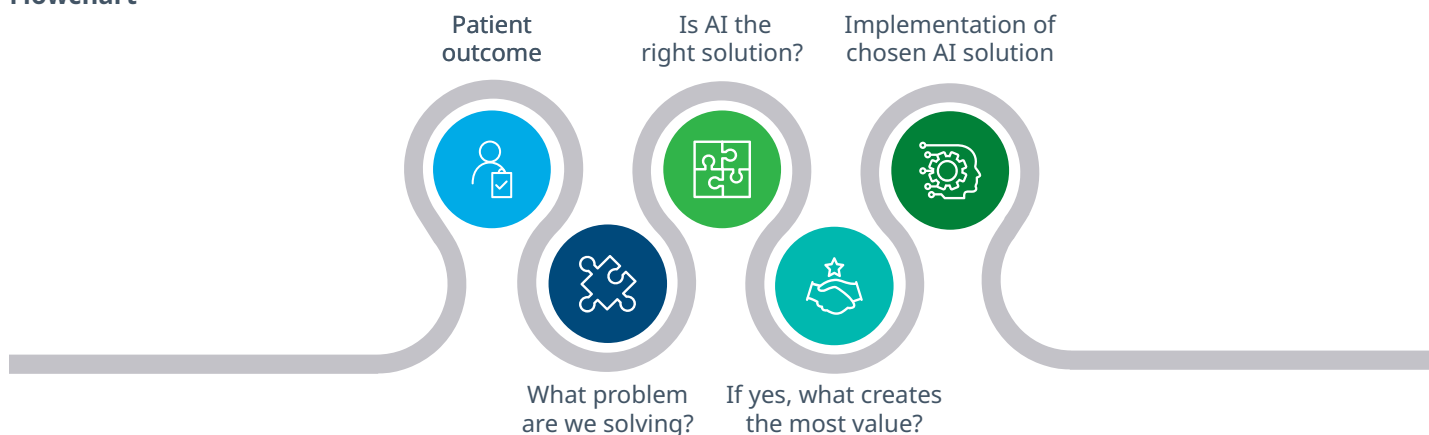
AI is an exceptionally powerful technology, but it is not the answer to every regulatory challenge. Some solutions need to go beyond automation, requiring decision support, knowledge management, predictive insights or enhanced collaboration. By starting with the desired patient outcome, organizations can see the true opportunity for improvement before selecting the best technology to address it.

In circumstances where AI *can* be a solution, it contributes to positive patient impact by enabling regulatory professionals to:

- Create more complete country submissions
- Reduce regulator questions during the country review process
- Strengthen regulator confidence and relationships with health authorities
- Smooth registration approvals and improve launch timelines

The organizations that realize the greatest benefit from AI will be those that center AI initiatives on patient outcomes rather than productivity metrics. This approach helps regulatory professionals to identify the most important challenges and apply AI technology where it creates genuine strategic value. In doing so, organizations strengthen the role of regulatory affairs as a driver of innovation, market access and better health outcomes worldwide.

Flowchart



Section 5: A framework for prioritizing AI investments in regulatory affairs

A key question for organizations adopting AI in regulatory affairs is: Which investments will create meaningful strategic value? As regulatory leaders evaluate new AI capabilities, they need a framework that distinguishes transformational investments from incremental automation.

The following five questions provide a practical lens for evaluating AI, not by productivity gains alone but by its ability to strengthen regulatory quality, scientific rigor, global readiness, expert judgment and, ultimately, patient outcomes:

1. Will this investment improve regulatory submission quality?

A strategic AI investment should help regulatory teams produce submissions that are more complete, accurate and aligned with requirements. The relevant measure is not how quickly documentation is produced (i.e., speed) but whether the technology helps professionals improve the quality and credibility of the information submitted for regulatory review to achieve registration approval (i.e., velocity).

2. Will it strengthen scientific and regulatory coherence?

Regulatory submissions must present a clear, consistent account of the product, its supporting evidence and its benefit-risk rationale. AI should help professionals connect information across submission components, identify conflicting statements and maintain alignment between scientific evidence and regulatory positioning. Strategic value comes from helping the experts synthesize large volumes of information into a coherent regulatory narrative.

3. Does it account for global regulatory complexity and regional variation?

AI deployed in global regulatory affairs must be able to recognize and accommodate differences

among many different elements: countries, product classifications, evidence expectations, submission pathways and lifecycle requirements. AI should help teams monitor and understand these critical aspects down to the country level and do so early enough in the cycle to impact development and submission planning.

4. Does it enhance our team's professional judgment and support the use of precedent?

AI should make regulatory expertise more accessible and scalable. The most valuable AI capabilities can uncover relevant regulations, prior submissions, scientific advice, historical agency questions and organizational precedents for expert evaluation. This gives professionals stronger evidence for decision-making while preserving the role of human interpretation. Scientific conclusions, strategic choices and accountability must remain with qualified regulatory experts.

5. Does it improve patient outcomes by accelerating market access?

The degree to which AI can help safe and effective healthcare solutions reach patients more efficiently is the ultimate test. Better submission quality, earlier identification of regulatory risks and stronger global planning all matter when evaluating AI-powered solutions. Organizations should take a broader view and consider whether a potential AI investment improves the path from product development through to regulatory approval and patient access.

Regulatory leaders and teams that prioritize AI through this multifaceted lens are investing in long-term strategic capability. They will direct technology toward the work that matters most: strengthening regulatory decisions, helping experts manage global complexity and advancing innovative healthcare solutions for patients with greater quality, confidence and purpose.

FIVE QUESTIONS TO EVALUATE AI INVESTMENT:

1. Will this investment improve regulatory submission quality?
2. Will it strengthen scientific and regulatory coherence?
3. Does it account for global regulatory complexity and regional variation?
4. Does it enhance our team's professional judgment and support the use of precedent?
5. Does it improve patient outcomes by accelerating market access?

Beyond automation: The future of AI in regulatory affairs

The use of AI in healthcare must remain centered on the most important aspect — improving patient outcomes. The future of regulatory affairs will be defined by organizations that approach AI this way while balancing science and technology with human expertise.

Organizations that measure AI by its contribution to the strategic capabilities of regulatory affairs will be best positioned to realize its full potential. In deploying AI as a strategic driver, they will benefit from higher-quality regulatory decisions, greater predictability and timeliness in global submission approvals, better relationships with health authorities, improved market access to their solutions and, finally, improved patient outcomes.

About SmartSolve®: SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps life sciences organizations streamline and automate global quality management and regulatory compliance. [SmartSolve® eQMS](#) centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while [SmartSolve® RIM](#) manages regulatory submissions, product registrations and health authority interactions. Built on industry best practices, SmartSolve connects teams, data and workflows in a single platform to drive an optimized focus on patient safety, product quality and commercial performance.

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