Artificial Intelligence-enabled Solutions and Life Sciences Regulatory Strategy

How Purpose-built AI Is Transforming the Approach to Approval

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Introduction

For life sciences, the strategic integration of artificial intelligence offers an unprecedented opportunity to streamline processes and expedite time-to-market.

From a regulatory perspective, AI is positioned to potentially accelerate drug approval. This benefits both the companies developing new therapies and the patients whose lives can be transformed as a result. Currently, the average journey from discovery to market takes 12 years; even a marginal improvement can have a profound effect on patients' lives.

To be effective, however, AI must be applied precisely to purpose and guided by human expertise. In this playbook, we'll discuss how life sciences companies and the patients they serve can benefit from this transformative technology and how Dr.Evidence harnesses the power of AI to make this possible.

"For 20 years, Dr.Evidence has made generating market intelligence faster and more precise. We know firsthand how AI can help life sciences companies get their products to market and keep them there."

ROSE HIGGINS,
CEO, Dr.Evidence

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The big-picture promise of AI

Regulatory approval runs on data and lots of it. As life sciences companies craft regulatory strategies, they must interrogate countless documents, many of which are incredibly dense, to understand how similar or in-class drugs gained approval or failed in getting approval. For example, teams launching products in the US and EU need to query key documents in the Food and Drug Administration (FDA) and European Medicines Agency (EMA) regulatory review archives, including FDA summary basis of approval documents and EMA public assessment reports. Of course, those sources are disconnected from one another and relevant new documents are constantly being introduced.

AI-enabled solutions promise to streamline this process, helping companies gain efficiencies and make optimal use of limited resources. Research has shown that digitizing and automating regulatory processes could accelerate time-to-market by nearly 10%.

"Really being able to understand the competitor and regulatory compliance landscape is going to make you nimble and give you speed to market."

LYN HOPKINSON,
Regulatory Affairs and Quality Executive,
CoRA Consulting L.L.C.

Pain points AI addresses

Generating market intelligence has been an ongoing challenge for regulatory teams, whether they are launching a new product, expanding an indication or seeking to better understand the competitive landscape. The varied format, length and density of document sets, as well as differences among health authority approaches globally, make the process incredibly time- and labor-intensive.

When AI is leveraged as part of a domain-specific, fit-for-purpose solution, generating market intelligence can shift from a manual process taking days or even weeks to an automated process taking minutes. Tools that fit into existing workflows offer even more dramatic efficiency gains.

"Finding the appropriate data has never been easy, and without the right tools and accessible data, it's incredibly time-consuming."

LISA MACNEIR,
Executive Director of Global Labeling and Regulatory Operations, Stemline Therapeutics

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Key application and use cases

AI-enabled domain-specific solutions promise to generate dramatic efficiencies in regulatory approval by streamlining the generation of relevant market intelligence for competitive or similar in-class drugs – this is a key application. Before introducing new therapies or indications, life sciences companies need to conduct robust landscape analysis. Depending on the lifecycle phase of the product, market intelligence needs vary. For example, as Lyn Hopkinson from CoRA Consulting, LLC, indicates, early in development, users will be casting a wide net to understand the optimal product profile, seeking insights at the therapeutic area level for similar or in-class drugs to identify questions they will need to answer throughout the entire development program (e.g., appropriate dosage and administration and Phase 2 and Phase 3 endpoints). In later stages or if a product is approved, then questions will be more specific to competitive drugs, relating to post-marketing safety concerns, other indications or other dosing regimens to pursue.

AI-enabled tools can take on routine, time-consuming tasks, enabling users to focus on higher-level strategy. That's true whether the use case is supporting the development of regulatory strategy documents, informing original or supplemental submission strategies, preparing for health authority meetings, answering ad hoc questions from health authorities or colleagues, or engaging with clinical development colleagues on the development program.

Regulatory Intelligence

With Dr.Evidence's Regulatory Intelligence module, users can:

- Search and filter FDA and EMA documents based on an expansive list of key factors, such as drug class and drug name, to rapidly find the precise intelligence to inform strategy and answer questions
- Query Adverse Events in FDA labels and EMA European Public Assessment Reports (EPARs) and labels to identify Adverse Events associated with specific drugs and the context in which they are presented, mapped to MedDRA preferred terms
- Ask questions via a generative AI chat interface and get summarized answers based on filtered source documents

Label Intelligence

With Dr.Evidence's industry-standard Label Intelligence module, users can:

- Research prior precedent in drug labels using side-by-side comparison tables from health authorities in the US, Canada, EU, UK, France, Switzerland, Australia and Japan
- Monitor safety signals in drug labels with the Adverse Events comparator tool, reviewing how Adverse Events appear in labels, side-by-side
- Save and monitor label searches to stay up-to-date as landscape dynamics change

Literature Search

With Dr.Evidence's Literature Search module, users can:

- Easily and efficiently get to clinical trial information from clinicaltrials.gov, WHO International Clinical Trials Registry Platform (ICTRP), scientific literature and beyond
- Review trial details in peer-reviewed articles to understand how trials for similar and in-class drugs were designed and what their outcomes were
- Identify the investigators studying a particular endpoint globally and learn where they are located

"I see AI, for now at least, more as an accelerator in our mission than a pure enabler. There are not very many instances where there's something that AI could do that we couldn't already do in a theoretical world of endless resources and time. The challenge is that none of us lives in a world of endless resources, and we're constantly facing resource constraints that force us to prioritize."

ANDREW ROBERTSON,
Vice President, Global Regulatory Policy and Innovation, Takeda

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‘Augmented intelligence’: The intersection of AI and human expertise

Although this playbook has talked a lot about artificial intelligence, a more appropriate term (and the one Dr.Evidence uses) is augmented intelligence, which means using artificial intelligence to complement, not replace, human intelligence.

“We don’t treat AI as an autonomous, indiscriminate force,” said Rose Higgins, CEO, Dr.Evidence. “Instead, we wield AI as a precision tool, carefully selected and expertly applied based on our deep domain knowledge.”

What sets Dr.Evidence apart is its evolution from a services firm, dedicated to supporting evidence-based scientific research and guideline development, to a leading technology platform. Dr.Evidence empowers users to replace labor-intensive processes with efficient, effective workflows, enabling them to operate at peak capacity and make the maximum strategic impact.

AI operates both behind the scenes to enhance the efficiency and precision of Dr.Evidence products and within the user interface, enabling clients to directly access scientific content and receive rapid, accurate answers. With the AI models that power its platform, Dr.Evidence fine-tunes its models with the expertise of its human team, applying curated search strings for a specific use case, for example, to create a hybrid model. With client-facing generative AI, Dr.Evidence takes a collaborative approach, educating clients and guiding them with the tools to narrow their search to a specific set of documents. Then, it unleashes AI's power on that refined document set, creating a true partnership between humans and AI.

"We firmly believe that human expertise remains a vital component in the quest for the most relevant results," said Higgins. "Whether through generative AI or machine-learning models, AI is a collaborator, requiring expert human guidance and amplifying human knowledge with accurate scientific answers."

"The Regulatory Intelligence solution from Dr.Evidence represents a significant step forward in driving efficiencies for regulatory teams."

HAYLEY PARKER,
Vice President, Global Regulatory Affairs, PepGen, Inc.

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Conclusion

Like countless labor-saving innovations that have come before, AI-enabled solutions have the potential to free humans from repetitive, time-consuming, resource-intensive tasks so they can focus on higher-level strategic work that only humans can deliver. In life sciences, the Dr.Evidence platform empowers regulatory teams with fit-for-purpose technology to generate the market intelligence needed to help them get vital therapies into the hands of physicians and patients in the most efficient manner possible.

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Dr.Evidence is the preeminent evidence-based insights platform for life sciences, delivering value from development through commercialization. Through its platform, life sciences teams identify breakthrough insights grounded in the vast universe of published medical literature, drug labels, regulatory documents and beyond. It pushes the boundaries of healthcare technology and allows for new possibilities in science, enabling more informed decision-making and faster time-to-market for accelerated impact. By combining the power of AI with its twenty years of domain expertise, Dr.Evidence allows clients to focus on the strategic work that truly matters.

Learn more at **www.drevidence.com**

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