Powering regulatory strategy with artificial intelligence

How to streamline strategic processes and accelerate approval

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POWERING REGULATORY STRATEGY WITH ARTIFICIAL INTELLIGENCE: *HOW TO STREAMLINE STRATEGIC PROCESSES AND ACCELERATE APPROVAL*

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ABSTRACT

Regulatory strategy plays a crucial role in the speed and success of drug development and commercialization. Establishing the most effective regulatory strategy for drug approval is complex and time-consuming, often leading to delays and increased costs. Accessing the content of regulatory authority review documents is a critical step in understanding the landscape and making the right strategic decisions, ensuring speed to market for new treatments.

Regulatory intelligence tools powered by AI and applied to relevant content offer a path to expediting approval and reducing costs. Life sciences teams can inform the optimal strategy by rapidly scanning the breadth of regulatory authority reviews and communications to identify and interpret precedents. Searching based on regulatory authority, disease state, drug class, brand name, generic name and more enables teams to rapidly assess what's been approved, what's not been approved and identify insights leading to the most expedient path to approval.

This landscape analysis, as well as therapeutic area or product specific analysis, can play a key role in bringing solutions to market faster – successful precedents can be followed, and previous pitfalls avoided while formulating strategies.

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INTRODUCTION

The Covid-19 pandemic highlighted the importance of the healthcare market being able to bring new and improved treatments to patients faster. Working at an unprecedented pace, the urgency of the global situation brought stakeholders together to develop a series of vaccinations that have restored our way of life and saved many lives. From regulators and pharmacovigilance teams to clinical developers and academic researchers and many others in between, the healthcare ecosystem demonstrated how effectively it can operate in a very short space of time.

Central to bringing new drugs and therapies to market is an informed regulatory strategy, developed and led by global regulatory teams. As innovations are developed in laboratories, and throughout the drug development lifecycle, regulatory is at the center of project teams helping to ensure treatments get approval as expeditiously as possible.

Typically, establishing the most effective regulatory strategy for drug approval is complex and time-consuming, not least because it often requires scouring thousands of pages of Food and Drug Administration (FDA) and European Medicines Agency (EMA) review documents to uncover trends and precedents related to similar products. On average, the journey from discovery to market takes 12 years, with products and therapies in newer sectors taking up to 30 years. Further, just 1 in 5,000 compounds are approved – so the stakes are high to get it right.

This paper will explore this challenge in detail, explaining the difficulties faced by regulatory affairs leaders and how regulatory intelligence solutions powered by artificial intelligence offer a path to enhancing efficiency and accelerating approvals. Further, it will introduce Dr.Evidence's new Regulatory Intelligence Module, designed to instigate a simple and quick way of querying critical documents to understand past approvals and related communications from health authorities.
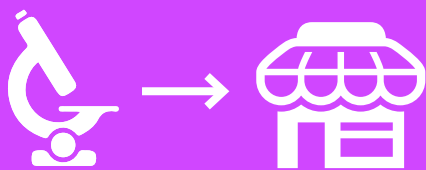
On average, the journey from discovery to market takes

12 years

PART 1: THE CHALLENGE

Why is establishing an effective regulatory strategy for drug approval complex and time-consuming, and what can be done to streamline the processes involved?

This is a question that is constantly occupying stakeholders working up and down the entire medical and pharma value chain.

For pharmaceutical and biotechnology companies, accelerating the approval process means bringing life-saving innovations to patients faster, and also saving valuable resources to bring the next innovation to market.

A key part of the regulatory journey undertaken by a new drug or treatment development involves examining the regulatory review archives of the FDA and EMA. Here, teams need to query key documents such as FDA Summary Basis of Approval (SBAs) and EMA Public Assessment Reports (EPARs). This enables strategies to be informed by precedents and real events from the past, thus increasing the likelihood of success.

However, regulatory authority reviews of life sciences company applications are extraordinarily dense and unstructured, making it burdensome to find and interpret precedents for competitive and similar in class products.

This information is critical to regulatory and project teams. If the process of extracting and analyzing relevant FDA and EMA documents continues to be unwieldy and time consuming, this will continue to place strain on regulatory and project teams and delay the finalization of innovative regulatory strategies to advance product approvals. This is not only costly for pharmaceutical companies but can also delay potentially life changing products from reaching the patients who need them.

PART 2: THE ROLE OF AI

Although just one aspect of a broad picture, speeding up interactions with regulatory authorities and interrogating their document archives is crucial to optimizing the approvals journey.

Currently, life sciences teams are burdened with having to scour libraries of information manually, a situation which not only takes significant amounts of time, but always carries the risk of human error, meaning critical information may be missed.

This raises another important question: what if thousands of documents and archives can be scanned automatically and intelligently at speed?

Plentiful research, analysis and forecasts have already highlighted the transformative impact artificial intelligence and automation solutions can have in medical treatment development circles.

McKinsey, for example, calls for a rethink of the approach to regulatory submissions so that pharma companies can reduce timelines and increase their chances of successful product approvals. The consultancy outlines six areas to target to achieve consistent excellence in submissions, one of them being to take advantage of technology and automation. At the time of publishing in September 2021, just two of eleven pharmaceutical firms reported implementing automation solutions to accelerate approvals.

Meanwhile, further research suggests that digitizing and automating regulatory processes such as document scanning could accelerate drug development timelines by 10 months, cutting the time to market by nearly 10%.

By leveraging AI-enabled tools to quickly scan the landscape of regulatory authority reviews to identify and interpret precedents, regulatory affairs personnel will have the information at their disposal to support optimal approval strategies. Searching based on disease state, drug class, brand name, generic name and more allows teams to rapidly assess what has been approved and what has not been approved, while at the same time identifying insights leading to the most expedient path to approval.

"What's critical to our regulatory affairs clients at life sciences companies is that technology solutions are fit-for-purpose, and that AI is applied based on the content and insights they uniquely seek, which is something we offer based on twenty years of domain expertise."

**– Rose Higgins, MPM, BSN, RN
CEO, Dr.Evidence**

PART 3: THE DR.EVIDENCE REGULATORY INTELLIGENCE MODULE

AI technology alone is not enough to achieve expediency. Domain expertise is also required to inform the design of the AI and deliver value in two key ways. First, domain experts must train the AI to discern what is and is not relevant. Beyond that, the design of the AI is crucial to increasing the precision of the results being provided. This will enable the reviewer to reap the full benefit of intelligent automation.

Through its new Regulatory Intelligence Module, Dr.Evidence has launched an AI-enabled tool designed to do just this, all while removing the burden of scanning FDA and EMA review documents, which for a single product could mean weeding through thousands of pages.

Adopting generative AI throughout, the tool is designed to meet the demands of regulatory and project teams who need to efficiently develop innovative regulatory strategies and rapidly and accurately respond to regulatory authority queries.

The major benefit of the Regulatory Intelligence Module is to offer teams a radically simple and fast-tracked way to query regulatory authority review documents, allowing them to understand past applications and related correspondence from the regulatory authorities.

It does so through several key features, which include:

- **Search and filter:** Users can search and filter within documents based on a wide range of key factors. Results from searches can be exported and incorporated into critical workflows.

- **Generative AI-powered Q&A:** ChatGPT interface enables users to interrogate health authority content, delivering summarized answers based on filtered source documents.

- **Finding adverse events:** Quickly find adverse events mentioned within health authority content, mapped to Medical Dictionary for Regulatory Activities (MedDRA) terminology.

Thanks to these features, the Regulatory Intelligence Module eliminates the inefficiencies in accessing and interrogating regulatory documents from the FDA and EMA with a one-stop, centralized source of scientific insights. The module can easily support teams' workflows with an intuitive user interface and relevant filters to obtain the answers they need, at speed.

> "The Regulatory Intelligence Module developed by Dr.Evidence is poised to transform the way regulatory affairs professionals conduct regulatory precedent and competitor surveillance. For the first time, regulatory and project teams will be able to truly harness the mine of information in these SBAs and EPARs to inform and refine regulatory strategy."
>
> **– Lyn Hopkinson**
>   **Principal, CoRA**
>   **Consulting LLC**

CONCLUSION

The ability to bring innovations to market at speed is essential to advancing positive healthcare outcomes.

Central to this are efficient and smart regulatory strategies, which rely on scanning and analyzing archives of FDA and EMA documents to uncover precedents related to similar innovations which have gone through the approvals process.

AI-enabled tools such as the Regulatory Intelligence Module by Dr.Evidence automate and fast-track this crucial task. With the ability to filter and search, find adverse events, and interrogate through generative AI-powered chat, life sciences teams can drastically reduce the time and resources required to find the information they need.

To discover more: Visit www.drevidence.com

Why Dr.Evidence?

Dr.Evidence is the preeminent evidence-based insights platform for life sciences, delivering value from discovery through commercialization. With 20 years of domain expertise serving top tier pharma and biotech clients, Dr.Evidence understands when and where to apply advanced technology to generate breakthrough insights and create dramatic efficiencies. The platform serves as a central source of scientific truth, with expansive data sets and robust ontologies, and intuitive workflows so clients can break down silos and eliminate manual work. And the company's expert-led technology-enabled services support life sciences teams in accelerating their impact.

The Dr.Evidence platform is an enterprise-wide solution that enables life sciences teams to ask and answer critical business and research questions in the most rapid and accurate way possible. The breakthrough new Regulatory Intelligence module sits alongside the next generation Literature Search and industry gold standard Label Intelligence modules and is designed to support life sciences leaders in accelerating regulatory approval.