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Addressing the Landscape Intelligence Challenge with AI and Human-In-The-Loop

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Artificial intelligence (AI) could generate $60-110 billion per year in economic value in the life sciences, according to analysis by the McKinsey Global Institute in 2024.[1] Getting the approach to AI right could be the single biggest factor separating success and failure in the coming years.

A major challenge drug developers face right now—and will face even more in the future—is dealing with the time-intensive manual work associated with generating landscape intelligence, which is a cornerstone of regulatory and commercialization strategy. AI-enabled solutions can certainly help here but they are not enough on their own. They have to leverage human expertise as well, in order to maximize the value they offer.

Dr.Evidence, a technology leader in the industry for over 20 years, uses the term 'augmented intelligence', which means using AI to complement rather than replace human intelligence. CEO Rose Higgins believes that we need to look beyond the buzz about generative AI (genAI) as the solution to every problem and make sure that the AI tools we use are fit-for-purpose and task-appropriate.

"We believe domain knowledge and expertise are critical parts of delivering intelligence," she says. "We believe very much in human-in-the-loop, with individuals at key parts along the process reviewing the outputs the AI and the tools are generating, ensuring that it's clinically accurate, then ensuring that the responses we're generating for our clients are as robust as possible."

Cutting A Path Through The Data

For Higgins, the key part of Dr.Evidence's remit is "helping our clients find their way through the vast array of potential source data to glean the key insights they need to get their products into the market and keep them there. As well as finding the data, it is necessary to monitor it, work with it, then create workflows to support obtaining insights from it."

"Fundamentally, our clients are trying to find faster paths to approval and our goal is to help them create the evidence they need to help accomplish that task," Higgins continues. "Often, however, they are also faced with what Dr.Evidence calls the 'in the moment ask' questions like 'How was a competitor able to do this?', 'How can we overcome this particular barrier?' or 'What has the regulator focused on?'"

Users, she adds, very quickly tune into the most appropriate answer at that point, whether they are trying to find an efficient path to approval, to maximize the opportunity for their particular therapy, or to be better facilitators of information within their own organizations.

"Regulatory affairs has increasingly become a strategic focus for organizations. They often influence the clinical strategy, development practices, and the go-to-market approach, particularly in early-stage companies," says Higgins. "For them, the ability to not only identify insights for their own purposes and to inform their own particular strategies, but also to share that with the colleagues they need to support in this process, is a really critical path."

Cross-Functional Collaboration

An emerging product company has used the Dr.Evidence platform to navigate precedent and identify clinical trial activity in terms of where research has been done and by whom, and the numbers of patients involved in the various phases. This has helped to improve cross-functional collaboration and inform this particular client's clinical development strategies.

"The data allows them not only to drive the regulatory strategy, but also to help the clinical development team understand how best to construct the trials to get the most effective outputs, looking as well at the clinical trial data to understand the primary and secondary endpoints," says Higgins.

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"They can then go directly to medical affairs, who are trying to develop the health economics and outcomes research (HEOR) needed for market access, to have the product priced appropriately and introduced to the market, and then to prepare for the conversation that the medical science liaison (MSL) needs to have with the various healthcare professionals to get the product prescribed."

Other clients, Higgins notes, have shared examples where they have been notified of an issue in their products. "They can very quickly find and discern the necessary evidence within our tools on which they have built their particular evidence set. Being able to refer to that and confirm within the data we provide to them on a daily basis what is new or different, they can rapidly prepare their response and, in turn, educate the regulator or reduce any risk of the product not being allowed to stay on the market."

Generic drug companies have used the tool to automate the brand label monitoring process across multiple geographies. This, Higgins says, "frees the teams who work on this process to carry out more strategic work in talking with regulators and preparing the necessary documentation while the automation does the blocking and tackling." The tool also contains information on impending patent expirations, enabling them to plan their strategies in advance.

The Client Experience

Barbara Briggs had a 45-year career spanning pharmaceutical research and development, focusing for the past 25 years on regulatory affairs. After receiving a PhD in Respiratory Medicine from Imperial College London, she worked for companies including Bayer, GSK, and Biogen, then becoming head of global labelling at UCB.

Briggs' specific expertise is in the management of company core datasheets (CCDS) and target core label profiles (TCLP). TCLPs are agreed upon cross functionally early in the development of an asset and should enable the delivery of a differentiated product; essentially the TCLP should shape the development program.

The data from the clinical trials will be then used to generate the CCDS, which is the basis for all the country and regional labels – it is the company's view of the data. As Briggs states, "The 'label' is everything; it is our contract with the regulatory agency, and it informs the physician and the patient of essential information on the product."

Developing a TCLP or line extensions for CCDS requires reviewing approved labels in different countries. Dr.Evidence's platform helps facilitate this strategic work.

Briggs' reasons for valuing the platform began with the amount of work and time it can save for the labelling team. "When I used to do label comparisons, it would take an inordinate amount of time to find the labels, cut and copy pieces of text, and put them into a comparison table in a Word document. I felt it was such a waste of time because you could literally spend days on it," she says.

"What I also found was that I was more focused on the formatting than reviewing the labelling content and focusing on strategy. I don't think that's a good use of time. For me, the platform was the enabler to pull the content and the comparison table together quickly, then allow me to focus on what I should be focusing on, which was 'How do we as a company try to produce a differentiated label?'."

Another key deliverable here was a comprehensive knowledge of competitors' labels. Broadly speaking, Briggs says, pharma companies want to find a niche that will offer a different choice to the prescriber or the patient, or value for the payor. Using the platform enables Briggs to assess what is already approved and what is coming through the pipeline in order to think about how their label could be used to differentiate their specific assets.

Breaking Down Silos

Companies can choose different levels of access to platforms like Dr.Evidence's, but in Briggs' view they will get more value from it in terms of managing their information flow internally if different specialists and functions, including pharmacovigilance (PV) and clinical, have access and can look at different assets and facets of it.

"If only regulatory has access, others will inevitably have to come to them for the information. You end up just being an assistant and I don't think you will get as much from it. I think it really does help to have that cross-functional experience," she says.

Her words are echoed in a case study on Dr.Evidence's flagship module, Label Intelligence, which brought together about 20 team members in four countries at a top ten pharmaceutical company, from departments including regulatory affairs, regulatory labeling, and PV. The overall aim was to gain competitive intelligence from drug labels in a specific therapeutic area, finding all the marketed products indicated for a specific disease.

All involved agreed that Label Intelligence provided benefits over other approaches. This included reducing the time to compare label updates on a competitive drug's lifecycle from two hours to less than 30 minutes and, in one case, finding one approved indication on a label that two days of manual searching failed to find.[2]

Briggs expects AI to have a big impact in labeling, managing data flow across regions and functions, taking over routine tasks, as Label Intelligence does, and enabling people to work more strategically. However, she cautions that any AI tool should primarily be an enabler. It should not replace the cross-functional strategy that goes into creating the best possible dataset. This comes from many different functions, be they medical, clinical, or market access.

Outlook

"I see AI as a trusted assistant. Don't stop thinking, don't stop assessing, and use your own intelligence," says Briggs. This is particularly vital in the pharmaceutical industry, where AI is going to do more as time goes on. "Let's be very conscious that AI will have real-world impact on patients and let us make sure we're doing it the right way."

As for Dr.Evidence, Higgins says that the company will continue to refresh its information, look for new source content relevant and necessary for its regulatory affairs audience, and evolve its AI. She stresses above all that not all AI is right for every application; it is important to use the right piece of the kit.

"For us and, I think, for many others, the key issue is the evolution of the technology to suit the needs of the industry," she says. "We shouldn't get too far ahead in terms of the technology leading versus really understanding the business problem that the technology needs to solve. Tech is cool, but it has to be appropriate. Finding that right balance is really key."

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The Dr.Evidence Platform

The Dr.Evidence AI-enabled landscape intelligence platform offers over 100 million documents, including drug labels, regulatory approval packages, clinical trials, published literature and beyond. It is used by functions including R&D, regulatory affairs, medical affairs, real-world evidence, market access, PV/safety, and commercial.

The platform currently comprises three modules, which form an integrated ecosystem, with over 25 large language, machine learning, and natural language processing models in use today.

The flagship module, Label Intelligence, brings together approved labels from nine global health authorities; Regulatory Intelligence includes FDA and EMA approval packages, FDA and EMA guidance documents and Orange and Purple Book data, with genAI chat; and Literature Search offers genAI-powered summarization. A fourth module, Trials Intelligence, which offers a snapshot of the global trial landscape, is currently in beta.

The company has also developed a proprietary, genAI-derived large language model (LLM), which will enhance capabilities and provide added protection to clients by preventing IP leakage.

The platform brings the many different sources together into a single tool to reduce the noise, automate processes, and reduce the total cost of ownership to users.

"We are trying to make sure that that regulatory desktop is optimized, and that we're able to incorporate all the relevant content necessary to orchestrate and navigate the regulatory processes, then support that within the context of the product lifecycle," Higgins says. From client information, she adds, "this can give a ten times return on investment from efficiency gains alone."

References

1. McKinsey & Co., Generative AI in the pharmaceutical industry: Moving from hype to reality, 9 January 2024: https://www.mckinsey.com/industries/life-sciences/our-insights/generative-ai-in-the-pharmaceutical-industry-moving-from-hype-to-reality

2. Label Intelligence case study: case studies.indd

dr.evidence®

Dr.Evidence is the AI-enabled landscape intelligence platform for Life Sciences. We empower teams across clinical, regulatory, labeling, safety, market access, and medical affairs to rapidly and accurately answer critical questions to get their products to market and keep them there.

For more information, visit: www.drevidence.com

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