[AN HCG OPINION PIECE]

AI'S IMPACT ON REGULATORY AFFAIRS

From data management to decision-making

Artificial intelligence (AI) is significantly transforming pharmaceutical regulatory affairs. Rather than replacing regulatory professionals, AI enhances their capabilities and allows them more time for strategic activities. This blog post explores how AI is revolutionizing the regulatory submission process, the challenges posed by the rapidly evolving AI regulatory landscape, and what regulatory affairs professionals need to do to stay at the forefront of the industry.

AI is reducing human error, ensuring consistency, and accelerating the submission and approval of regulatory applications in several key areas

Automated dossier creation and document management

By employing natural language processing, AI can extract relevant data from large volumes of clinical trial documents and identify gaps or inconsistencies that could delay regulatory approvals. It will automatically generate summaries and compile sections of regulatory dossiers, such as nonclinical and clinical overviews, based on standard formats like the electronic Common Technical Document.

Regulatory intelligence and compliance monitoring

AI-powered tools can track changes in regulatory guidelines across different regions (eg, FDA, EMA) to ensure submissions are compliant with current requirements. For instance, when the FDA releases new guidance on the use of real-world evidence, an AI system can alert the sponsor that their upcoming submission for a rare disease drug needs to include additional analyses of postmarketing surveillance data to meet the new requirements.

Risk analysis and benefit-risk modeling

In regulatory submissions, especially when presenting safety and efficacy data, AI can support benefit-risk analyses. For example, when a sponsor

>

is preparing to submit data on an oncology drug in a similar class/indication as a previous company, AI tools can identify potential safety signals by analyzing patterns across relevant clinical trials. This can allow for the proactive development of a risk management plan to strengthening the submission.

AI-driven responses to regulatory queries

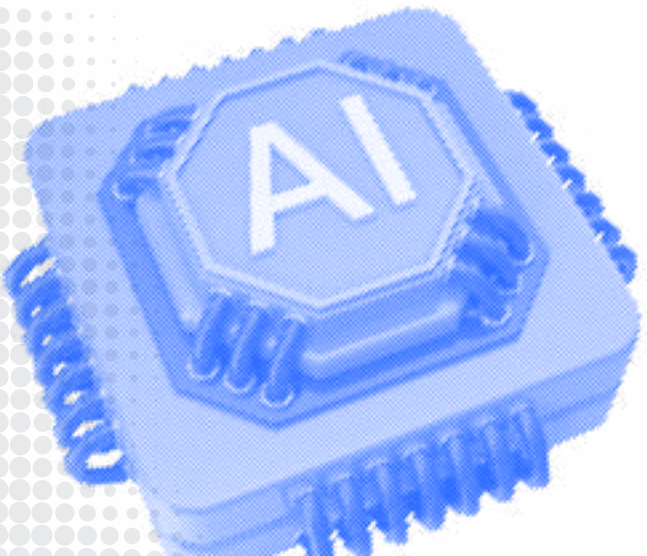
AI systems can quickly search through vast and complex clinical and preclinical datasets to find relevant answers to regulatory queries. They can provide quick summaries of previous responses to similar queries from the same agency and assist in drafting clear, consistent responses that align with regulatory standards. This can improve the speed and accuracy of replies to information requests.

Regulatory pathway optimization

AI is being used to model various submission strategies to determine the most efficient regulatory pathway. For example, a sponsor can use an AI platform to analyze historical approvals for drugs in the same indication or drug class. The system can then predict whether pursuing an accelerated approval by focusing on a novel biomarker endpoint might offer the highest likelihood of success, shaving months off the development timeline.

Clinical trial data presentation

AI can enhance how clinical trial data are presented to regulatory bodies. Machine learning can determine the most effective ways to display complex datasets to meet regulatory expectations, identify trends and patterns that might not be immediately obvious, and ensure compliance with agency requirements.



With more than 300 AI-related laws and regulations either in place or in development globally, regulatory affairs professionals cannot afford to ignore AI and must stay informed about AI-specific regulations such as the FDA's framework for AI/Machine Learning and the EU's AI Act. To stay competitive, regulatory affairs professionals need to advocate for internal AI governance frameworks within their organizations, proactively engage with regulatory bodies regarding AI innovations, and continually upskill and adapt to harness the potential of AI. ■

Aaron Csicseri, PharmD
Senior Scientific Director

Dr. Csicseri joined the ProEd team in November 2017 as a scientific director, responsible for scientific leadership, content development, strategic input, and effective moderation of team meetings. Aaron has extensive experience guiding Sponsor teams through the AdCom preparation process. He received his PharmD at the University of Buffalo, where he studied the clinical curriculum. Aaron has 10+ years of experience as a medical director/clinical strategist in the accredited medical education field (CME), as well as in the non-accredited PromoEd sphere. Over the past 7 years, he has been supporting sponsors in their preparations for FDA and EMA regulatory meetings in a wide variety of therapeutic areas. Aaron is based in Grand Island, NY, just outside Buffalo.

Sources

IQVIA. 2024. AI-augmented regulatory workflows. https://secure.constellation.iqvia.com/RADDSRegTech

Deloitte. 2024. AI risk and approaches to global regulatory compliance. https://www.deloitte.com/content/dam/assets-zone2/uk/en/docs/industries/technology-media-telecommunications/2024/deloitte-ai-risk-and-approaches-to-global-regulatory-compliance-pov.pdf

hcg-int.com