

RSNN ANNUAL WORKSHOP 2024 REPORT: ARTIFICIAL INTELLIGENCE IN REGULATORY INNOVATION

SUMMARY

The RSNN's annual 2024 workshop focused on the role of AI in healthcare, reflecting its growing importance in various fields. Speakers from academia, industry, patient advocacy, and regulatory agencies discussed AI's applications in medicine, such as drug discovery, regulatory processes, and patient care. Topics included generative AI, predictive models, and the challenges of integrating AI into clinical decision-making, particularly in building trust among doctors and patients. Ethical concerns, transparency, and data privacy were highlighted as critical for AI's future in healthcare. The event underscored the need for collaboration and clear regulations to ensure responsible AI use.

Luis Pinheiro (EMA) emphasized that AI is broader than just generative AI (genAI). Traditional AI focuses on analyzing structured data, recognizing patterns, and automating tasks, while genAI generates creative content and works with unstructured data. The EMA is exploring AI's potential in three key areas: improving internal analytics (e.g., using generative large language models for document search with tools like "ScientificExplorer"), extracting information from medical data for pharmacovigilance, and regulating AI in medicine development. The EMA is currently reviewing feedback on its AI reflection paper, but no AI will be used in this evaluation process.

Susan Sandler from Johnson & Johnson highlighted AI's long history, referencing Alan Turing's early thoughts on machine intelligence. From an industry perspective, the focus is on practical AI applications within the regulatory landscape. AI is actively being used in drug discovery, manufacturing logistics, supply chain management, and clinical trials. However, these applications must operate within appropriate regulatory frameworks. Sandler emphasized that the AI reflection paper is a good starting point for setting expectations, particularly regarding the transparency of AI models, including data and code, in the regulatory approval process.

Joanna Klotowska from Amsterdam UMC presented research on the attitudes of physicians and patients towards AI in healthcare, specifically in life-sustaining treatment decisions in ICU settings. While AI could improve predictions of ICU survival with quality of life, acceptance is hindered by several factors. Doctors often rely on intuition and family input, which AI cannot account for, and both doctors and patients lack knowledge about machine learning. Additionally, AI's "black-box" nature and difficulties in explaining predictions lead to distrust. Both groups prefer transparency in decision-making and AI model predictions. Enforceable regulations, standards, and education on AI use are necessary for broader acceptance and trust in AI-driven healthcare decisions.

Michael Renaudin from Swissmedic discussed the use of AI at the Swiss pharma regulator for tasks like automated data analysis, risk assessment, and compliance monitoring. A key theme was the need for trust in AI technologies, often seen as "black boxes." Understanding AI's capabilities and limitations is crucial, especially in healthcare, where errors can have serious consequences. Swissmedic promotes transparency by involving stakeholders and using agile methods to track and explain AI performance. An example of this is their "NightCrawler" tool, which uses AI to detect fake pharmacy websites, significantly improving screening efficiency.

Ellen Terwindt, founder of "Studio Migraine," discussed the challenges of managing migraines, which affect 2.5 million people in the Netherlands. Migraines have distinct phases, including a prelude (prodrome) and post-attack symptoms, making the disease complex. While AI tools like ChatGPT are already used to assist patients with tasks during migraines, specific AI applications, such as predicting migraine attacks, are being explored in studies. However, Terwindt emphasized that treatment and prevention are more critical for patients. She highlighted the importance of trust in AI, ensuring that information is reliable, patient-centered, and that patients maintain control over decisions, not algorithms.

The panel discussion, moderated by Mirjam Plantinga, focused on the responsible use of AI, touching on ethics and sustainability. Mirjam challenged the panel, suggesting that "ethics by design" and human interaction are overlooked in AI development for medicine. Luis and Susan emphasized the ethical checkpoints in their work, while Joanna highlighted the importance of ethics in decision-making for life-or-death predictions. Michael and Ellen stressed trust and engaging target groups in AI development. Regarding sustainability, the panel noted that AI tools must be used purposefully, and alternatives might be more suitable in some cases. Ellen suggested that the health benefits of AI would likely outweigh the environmental costs, while Luis argued that AI in healthcare is more justified than in less critical sectors.

CONCLUSION

The overarching theme of the afternoon was trust in AI, touching on various aspects such as trust in doctors, companies, regulators, algorithms, and data privacy. While AI is often viewed as a "black box", it was emphasized that this perception is only partly true. Many AI algorithms, like K-means and image recognition models, are understandable and transparent. New advancements, such as Grad-CAM and DeepDecipher, improve the ability to explain AI decision-making, which is crucial for building trust. However, data privacy remains a key concern, especially with sensitive health information. The European Health Data Space (EHDS) offers opportunities for AI research, but protecting patient data from misuse, particularly with emerging technologies like quantum computing, is essential. Ensuring a trustworthy AI future requires collaboration among all stakeholders. This workshop aimed to contribute to that effort.

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