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Media Release

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For Immediate Release

Bias in Healthcare Artificial Intelligence Examined in Whitepaper

Unintended bias in AI and AI-driven healthcare applications is an evolving topic that developers, reviewers, and experts are still learning to address effectively and consistently. The Good Machine Learning Practices Working Team of the AFDO/RAPS Healthcare Products Collaborative believes the topic of bias could benefit from standard taxonomy, consistent approaches to identification, and addressing any identified sources of bias.

“Unintended bias in AI-enabled systems is a challenge in the development of ML algorithms” says Pat Baird, working team co-chair and Sr. Regulatory Specialist at Philips. “The whitepaper outlines a framework for bias opportunity detection, assessment, and mitigation of unintended bias that can be used by product developers.”

Leveraging established and proven methods currently used for risk analysis in healthcare systems specifically for unintended bias should enable more robust management, adds Baird.

The paper asserts that bias can occur at points in the data supply chain and product supply chain. While focused on product developers, the paper also discusses perspectives from regulatory reviewers or other stakeholders of these solutions

“Our hope is that this paper provides the foundation for new learnings and best practices in this rapidly evolving field to help deliver the promise and potential of AI, “ says Baird.

Baird says the whitepaper is intended for a broad audience in AI. It includes developers, implementers, researchers, quality assurance and regulatory affairs professionals, validation personnel, business managers, regulators, and end-users faced with the challenge of assessing the quality and performance of AI-based healthcare applications.

This is the third paper from the GMLP Working Team. The team is an industry-led volunteer team that has come together to lift the use, adoption, and implementation of AI through the teams’ collaborative and innovative efforts. Previous papers include: [“Building Explainability and Trust for AI in Healthcare”](#) and [“Good Practices for AI and Continuously Learning Systems](#)



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[in Healthcare](https://www.healthcareproducts.org/ai/working-teams/)". The team's mission is to inspire collaboration, lead innovation, and make a difference focuses on sharing work in AI to benefit the health of the patients. To learn more about the AI Working Teams and how to get involved, visit <https://www.healthcareproducts.org/ai/working-teams/>

You can download the whitepaper at <https://www.healthcareproducts.org/wp-content/uploads/2022/10/Final-Bias-in-Artificial-Intelligence-11.27.22.pdf>

About the AFDO/RAPS Healthcare Products Collaborative www.healthcareproducts.org

The AFDO/RAPS Healthcare Products Collaborative is a joint venture established in 2021 between the Association of Food and Drug Officials (AFDO) and the Regulatory Affairs Professionals Society (RAPS). Continuing and expanding upon Xavier Health's legacy, the Collaborative supports idea-sharing, innovation, and action across the global healthcare products community by fostering purpose-driven discussions between regulators, industry, academia, and thought leaders about the most pressing issues facing the industry.

The Collaborative's distinct events portfolio — which includes the MedCon Conference, AI Summit, Combination Products Summit, and PharmaLink Conference — highlights just one of the ways the partnership inspires collaboration. This unique blend of mission and values guides purpose-driven community building and innovative solutions to make a difference in patients' lives.