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Global Standardized Guardrails for Cardiovascular Digital Therapeutics

The work highlights the significant advancements in digital therapeutics (DTx) for cardiovascular including a variety of tools such as mobile apps and AI chatbots. With an estimated thousands of medical mobile health apps for blood pressure, diabetes, clinical diagnosis and disease management, heart monitoring and other cardiovascular-related conditions, it's clear that this landscape currently lacks consistent global regulation, safety standards, and ethical oversight. The security vulnerabilities and lack of regulated and standardized approach to data governance and algorithmic bias further cause patients, regulators and clinicians to lack confidence in the integrity and use of these tools. To address these critical gaps, the IEEE SA has established a global standardized framework of guardrails assessing apps for clinical efficacy, technical soundness and ethical design and use of AI. The global standardized frameworks are not only necessary to protect the patient's security, privacy and safety, enable more innovation from tech developers, but also has the potential to harmonize regulatory standards worldwide and assist governments in developing their own guidelines for reviewing these digital health therapeutics.

Keywords: mobile health, apps, digital therapeutics, guardrails, patient, (maximum 6)

Biography

As the global practice leader, Maria is leading a global community of transdisciplinary volunteer experts to openly collaborate and develop solutions to enable trust in and validation of breakthrough technologies/applications that will enable sustainable equitable access to quality care and improve wellness for all.

Maria is an entrepreneur having founded various companies including DisruptiveRx™ Media, the first information company to explain viable use cases of emerging technologies (Blockchain/DLT, IoTs) in the bio/pharma value chain.

Maria currently holds an MBA from the Rutgers Graduate School of Business and a BA and BS from Rutgers College at Rutgers University (USA). She is an accomplished leader, public speaker, and writer having presented at various industry events and published blogs and articles in trade and peer-review publications.