

Israel Launches First Regulatory Sandbox for Artificial Intelligence in Healthcare

Three Israeli HealthTech Companies Selected to Advance Autonomous AI Systems for Pregnancy Care, Heart Failure Management, and Home Ultrasound

JERUSALEM, ISRAEL, July 13, 2026 /EINPresswire.com/ -- The Israel Innovation Authority and the Ministry of Health announced today the selection of the first three companies to participate in Israel's new Regulatory Sandbox Program for artificial intelligence in healthcare. Supported through the Israel Innovation Authority's Pilot Fund, the initiative is designed to enable the development, evaluation, and validation of highly autonomous AI-powered medical technologies within a supervised regulatory environment, while shaping the regulatory pathways that will support the next generation of healthcare in Israel and internationally.



Dror Bin, CEO of The Israel Innovation Authority
(Credits: Israel Innovation Authority)¹

The initiative is the first of its kind in Israel and is designed to support the development, evaluation, and maturation of breakthrough AI-powered medical technologies within a supervised regulatory environment through close collaboration between industry, the healthcare system, and the regulator.

A regulatory sandbox is a unique framework that enables the evaluation of innovative technologies that do not yet fit within the existing regulatory framework. Rather than waiting for legislation or regulatory procedures to be updated, participating companies operate in a controlled environment under the guidance of the Ministry of Health and the Israel Innovation Authority. The program is designed to identify regulatory barriers, evaluate the safety and

effectiveness of new technologies, and establish the regulatory pathways that will enable their adoption within Israel's healthcare system and in international markets.

Moshe Bar Siman-Tov, Director General of the Ministry of Health, said: "Artificial intelligence is no longer a theoretical concept; it is already transforming many sectors, including healthcare. The role of modern regulation is not only to establish safeguards but also to enable innovation to reach patients safely and responsibly. The regulatory sandbox will allow us to work alongside industry to determine the most appropriate regulatory framework for the next generation of medical technologies while maintaining the highest standards of quality and patient safety. It will also strengthen the position of Israel's healthcare system as a global leader."

Dr. Alon Stopel, Chairman of the Israel Innovation Authority, said: "Artificial intelligence is transforming healthcare at an unprecedented pace, and Israel is uniquely positioned to lead both the development of these technologies and the regulatory environment that will enable the adoption of these innovative solutions. The combination of an advanced healthcare system, a world-class healthtech industry, and forward-looking regulation represents a strategic advantage for Israel. The regulatory sandbox program will help Israeli companies develop the next generation of medical solutions, evaluate them under real-world conditions, and accelerate their path to international markets."

The Three Companies Selected for the First Cohort

Pulsenmore Ltd. will conduct a pilot at Rabin Medical Center (Beilinson Hospital) to develop an autonomous artificial intelligence system for analyzing at-home ultrasound examinations performed by pregnant women. The objective of the project is to establish a regulatory pathway that would enable the system to make autonomous clinical decisions without requiring physician interpretation of every routine ultrasound examination.

Cordio Medical Ltd. will conduct a pilot at the Heart Failure Clinic at Tel Aviv Sourasky Medical Center (Ichilov Hospital) to develop an AI-powered system that enables patients suffering from heart failure to manage their condition at home. The system combines voice analysis, medical questionnaires, smartphone data, smartwatch data, and electronic medical record information to identify early signs of clinical deterioration and recommend medication adjustments in accordance with a treatment protocol predefined by the treating physician. As part of the pilot, the regulatory framework for artificial intelligence systems capable of performing therapeutic interventions will also be evaluated.

Simahook Ltd. will conduct a pilot at Hadassah Ein Kerem Medical Center and Hadassah Mount Scopus Medical Center to evaluate an artificial intelligence system that enables healthcare professionals to perform fetal weight assessments using real-time intelligent guidance. The pilot will examine the regulatory changes required to expand the performance of ultrasound examinations beyond ultrasound specialists while maintaining high standards of quality, safety, and diagnostic accuracy.

Until now, most artificial intelligence solutions in healthcare have focused on clinical decision-support systems that assist physicians and healthcare professionals in making medical decisions. However, technological advances in recent years are enabling the emergence of a new generation of AI systems with significantly higher levels of autonomy. These systems are capable of independently performing certain clinical tasks, making decisions based on predefined medical protocols, and playing an active role in patient care.

This evolution has the potential to fundamentally transform healthcare delivery by automating clinical workflows, helping address workforce shortages, and expanding access to high-quality medical services.

At present, however, there is no comprehensive regulatory framework for technologies of this kind, either in Israel or in most countries around the world. They raise new questions regarding professional accountability, patient safety, risk management, the integration of generative AI into clinical workflows, and responsibility distribution between healthcare professionals and artificial intelligence systems. The sandbox is designed to enable the practical evaluation of these issues and generate the knowledge and experience needed to establish the regulatory framework for the next generation of healthcare.

As part of the program, the participating companies will conduct pilots in real-world clinical environments in collaboration with leading medical centers. In addition to the regulatory guidance provided through the sandbox, the companies will also receive support from the Israel Innovation Authority through the Pilot Fund, with the goal of accelerating the transition from development to commercialization while generating the clinical database and operational experience that will also support future engagement with international regulators.

The regulatory sandbox represents a new model of collaboration between industry, the healthcare system, and the regulator, positioning Israel among the first countries in the world to develop a dedicated regulatory framework for autonomous AI-powered medical systems. The insights generated through these pilots are expected to contribute both to the advancement of Israel's healthcare system and to strengthening the global competitiveness of Israel's healthtech industry.

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