

AKT Health's 'Impakt Health' Remote Patient Monitoring Platform Receives Japan Class II Medical Device Certification

AKT Health's Impakt Health RPM SaMD unites telehealth, AI insights, & blockchain integrity to deliver secure, compliant hospital-to-home remote patient monitoring.

TOKYO, TOKYO, JAPAN, August 18, 2025 /EINPresswire.com/ -- AKT Health Co., Ltd., a leading strategic consulting and health-tech company, today announced that its [remote patient monitoring](#) application "[Impakt Health](#)" has been certified as a [Class II](#) (Designated Controlled) medical device in Japan under the Pharmaceuticals and Medical Devices Act (PMDA). The certification was issued by a Registered Certification Body (RCB) within the MHLW/PMDA framework (Certification No. 307AIBZX00024000; issue date: August 6, 2020). This certification establishes Impakt Health as a blockchain-integrated remote

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Impakt Health brings secure, auditable RPM to everyday care; AI-assisted insights, telehealth, and trusted data in one SaMD for timely, patient-centered decisions.”

Aditya Kumar Tallapragada

decentralized/hybrid clinical trials.

An Important Tool in the Move to Patient-Centered, Value-Based Care:

As healthcare systems adopt hospital-at-home models and outcome-based reimbursement,



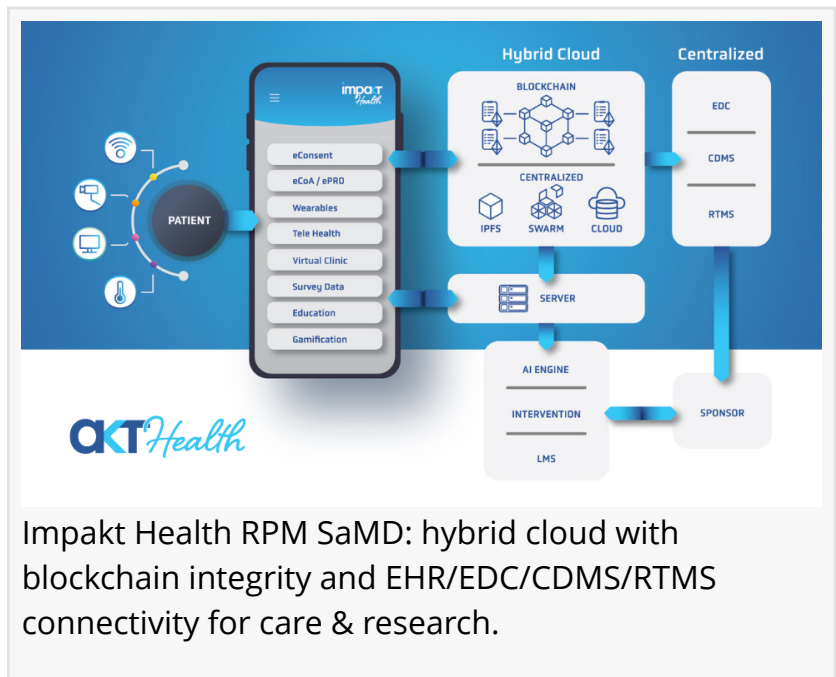
The image shows a smartphone displaying the 'impakt Health' app interface. The screen displays various health metrics: Heart Rate (78 bpm), Temperature (36°C), Blood Pressure (90/70 mmHg), and SpO2 (98%). Surrounding the phone are icons for features like Medication Adherence, Meaningful Physical Activity, Mood, Gamification, RPM, PROMS, Education, and Treatment Follow-up. To the right, a blue box contains the text: 'AKT Health Co. Ltd. announced that its Remote Patient Monitoring application "Impakt Health" has been certified as a Class II Medical Device in Japan under the Pharmaceuticals and Medical Devices Act (PMDA).'

Impakt Health RPM SaMD is Class II certified in Japan (PMDA), uniting telehealth, AI analytics, and blockchain integrity for secure, patient-centered care.

patient monitoring platform addressing core needs in data security, interoperability, and clinical decision support.

Impakt Health connects validated wearables, home sensors, and patient-reported outcomes to clinician workflows and research systems. Built on a hybrid architecture that combines blockchain for tamper-evident auditability with cloud performance, the platform enables secure, continuous data capture and near-real-time review across hospital-to-home care pathways and

early insight into patient status becomes essential. Impakt Health continuously ingests physiologic signals, such as heart rate, respiratory rate, SpO₂, temperature, and blood pressure, together with patient-reported inputs. AI-assisted analytics establish individualized baselines and surface clinically meaningful deviations so teams can intervene sooner, support smoother transitions from inpatient to home, and reduce avoidable escalations. For patients, a single mobile experience simplifies device use, education, and remote check-ins, improving engagement without adding burden.



“This certification under Japan’s PMD Act confirms Impakt Health’s conformity to applicable safety and quality requirements for Class II devices,” said Aditya Kumar Tallapragada, President, AKT Health. “By unifying RPM, telehealth, and research-grade data capture, we give clinicians timely visibility and provide sponsors with high-fidelity evidence, without adding burden to patients.”

Designed for Real-World Settings :

Impakt Health is engineered for day-to-day clinical operations. Role-based access and consent management help protect privacy while enabling multidisciplinary collaboration. Every data event is recorded with provenance, creating an auditable trail that supports quality management and compliance. The platform interoperates with EHRs and study environments through connectors to EDC/CDMS/RTMS and export options for statistical analysis, allowing sponsors and providers to use the same trusted data for both care and evidence generation.

Platform Overview:

Impakt Health connects the patient app, clinician console, and research tools in one platform. Patients complete guided onboarding, pair approved sensors, and submit secure check-ins; clinicians view longitudinal dashboards, set thresholds and alerts, and document actions. Supported signals include ECG, SpO₂, body temperature, and blood pressure from validated devices. Under the hood, a hybrid architecture combines high-performance cloud services with a blockchain anchor for integrity and traceability, balancing scale with compliance in regulated environments.

Impakt Health is available to healthcare providers, research institutions, and life sciences sponsors in Japan. AKT Health is accepting partners for prioritized pathways in cardiometabolic,

perioperative, and post-acute care. To request a demonstration or discuss deployment, contact info@akthealth.jp

About Impakt Health:

Impakt Health is AKT Health's remote patient monitoring and digital clinical operations platform. It connects wearables, home devices, and patient-reported outcomes with clinician dashboards and study systems, supporting continuous care, decentralized/hybrid clinical trials, and real-world evidence generation.

About AKT Health Co. Ltd.:

AKT Health is a data-driven life science consulting firm that empowers Medical and Commercial teams with AI-powered technology solutions, founded in 2019, operating across Japan, India, and the United States. We partner with pharmaceutical companies, biotechs, and healthcare organizations to transform complex healthcare data into actionable insights. Our integrated platform suite includes tools for KOL management, medical communications, commercial analytics, market access, and real-world evidence generation. By combining deep medical expertise with advanced analytics and digital innovation, we help clients optimize clinical development, enhance HCP engagement, accelerate market access, and demonstrate value to stakeholders. Our technology-enabled approach bridges the gap between scientific excellence and commercial success, enabling data-driven decisions across the entire product lifecycle.

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