Development of Novel Phonocardiographic Digital Biomarkers and Establishment and Validation of Business Foundations in Key Markets (AMI Inc.)

City	Year of Establishment	Founder
Kumamoto	2015	Shimpei Ogawa

Partner VC	Latest round of Fundraising	Valuation
-	Series C	JPY 5,360 million

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◯ Business Plan

AMI Inc. is dedicated to transforming auscultation through the "Super StethoScope Project," developing a palm-sized medical device that simultaneously captures heart sounds and electrocardiograms, alongside AI models for cardiac disease estimation powered by advanced signal processing and deep learning.
In this project, we aim to create a world where quality medical care is available to everyone, everywhere.

◯ Research Outline

This R&D initiative aims to refine and newly develop AI algorithms for cardiovascular disease diagnostics and to develop a novel “Comprehensive Cardiac Assessment Index” that enhances the clinical value of "Super StethoScope." These efforts will drive adoption across diverse healthcare settings and accelerate product–market fit. In addition, AMI will expand its remote diagnostic support service, “Cloud Choushin®,” into a large-scale, diversified clinical data collection framework, establishing the new "AMI Cloud Platform." In parallel, AMI will pursue the development of "Super Stethoscope" models for international markets and conduct technology validation studies in Asia and North America.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2025～2026FY	JPY 374 million	North America, Asia

◯International collaborative technology demonstration
- Relationship development with potential local partner
- Supply chain

Asia: Conduct clinical evaluations and research in markets where non-invasive diagnostic devices, such as "Super Stethoscope," face fewer barriers to entry. These activities will verify the business model, build academic evidence, and aim to achieve regulatory approval and market readiness in each country.
North America: Develop and manufacture the next-generation "Super StethoScope" (v.2) in compliance with QSR (Quality System Regulation) requirements, and conduct small-scale clinical trials to demonstrate the technical feasibility of the cardiac load estimation AI, supporting FDA submission in the world's largest healthcare market.

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