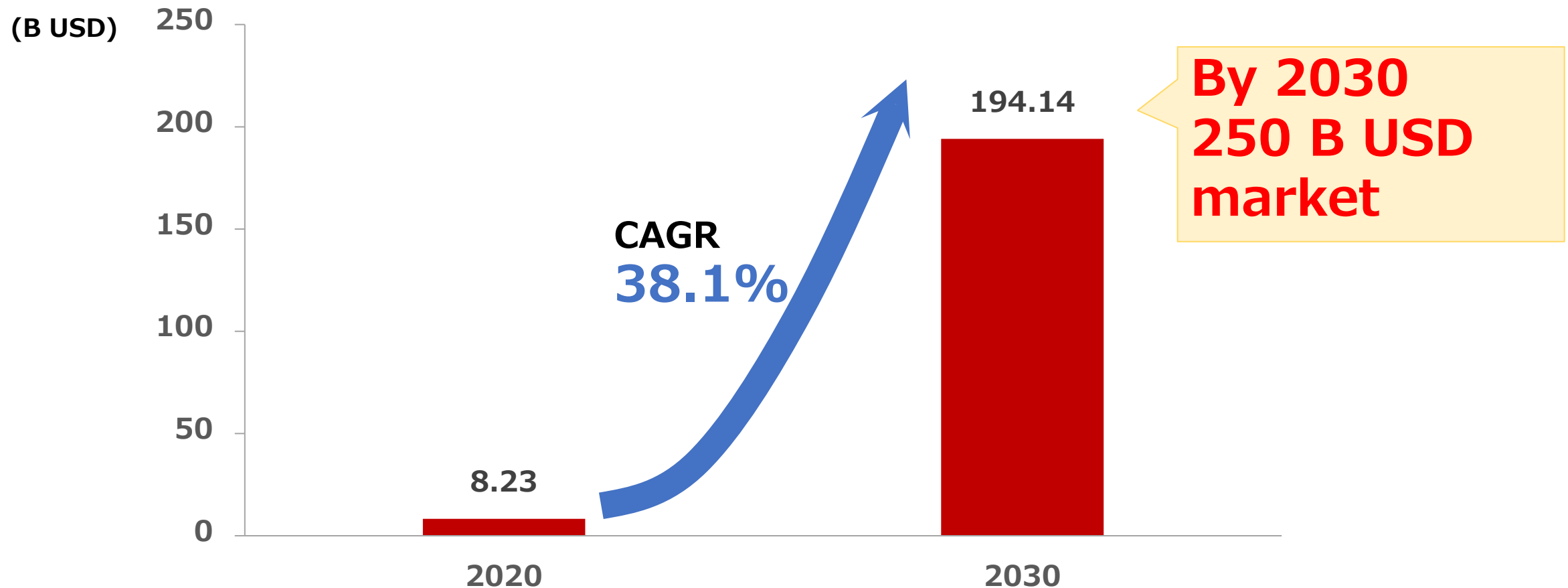




Considerations international development of digital health technologies

Tomohiro Tada
AI Medical Service Inc.

Market Size for “ Medical X AI ”



Social issues

Millions of lives are lost each year because cancer is not detected early^{*1}

Suspicion

Endoscopy
(screening)

Endoscopy examination
(definitive diagnosis and
treatment plan decision)

Treatment

Early detection^{*2}
Mostly cured



Symptoms



Screening

Barium

Fecal occult
blood

CT

Tumor markers

Liquid biopsy

Endoscopy

The only test that can definitively diagnose
gastrointestinal cancer

Challenges

1. Human eyes inevitably miss some lesions
2. Shortage of endoscopists in both quality and quantity



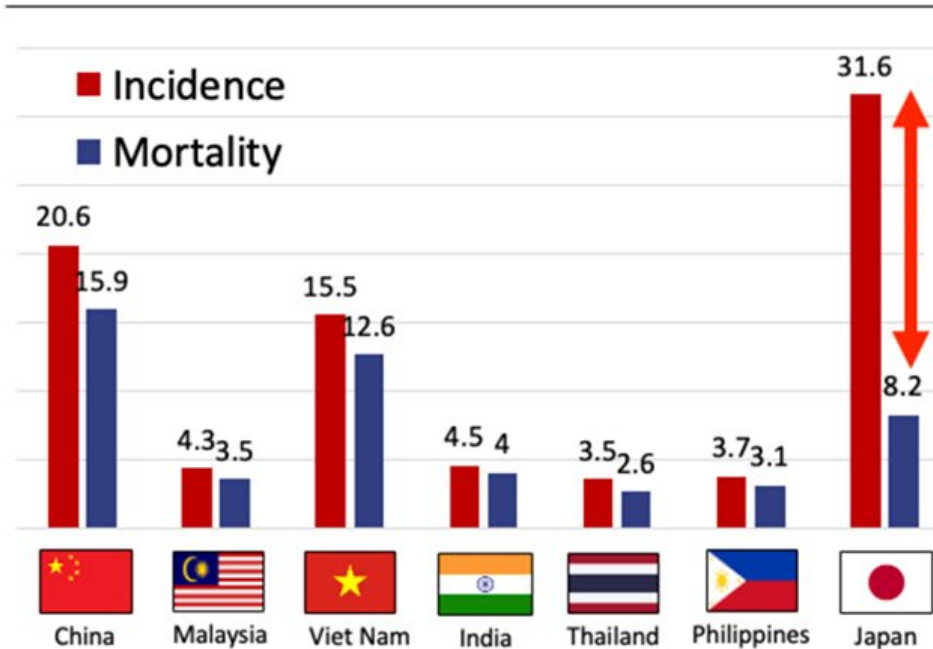
^{*1} National Cancer Center Cancer Information Service "Cancer Statistics" (Ministry of Health, Labour and Welfare Vital Statistics) 2019, WHO Cancer Today

^{*2} Gastric cancer has a 5-year survival rate of over 97% when detected at an early stage (National Cancer Centers Council All Cancer Survival Rate Survey (November 2020))

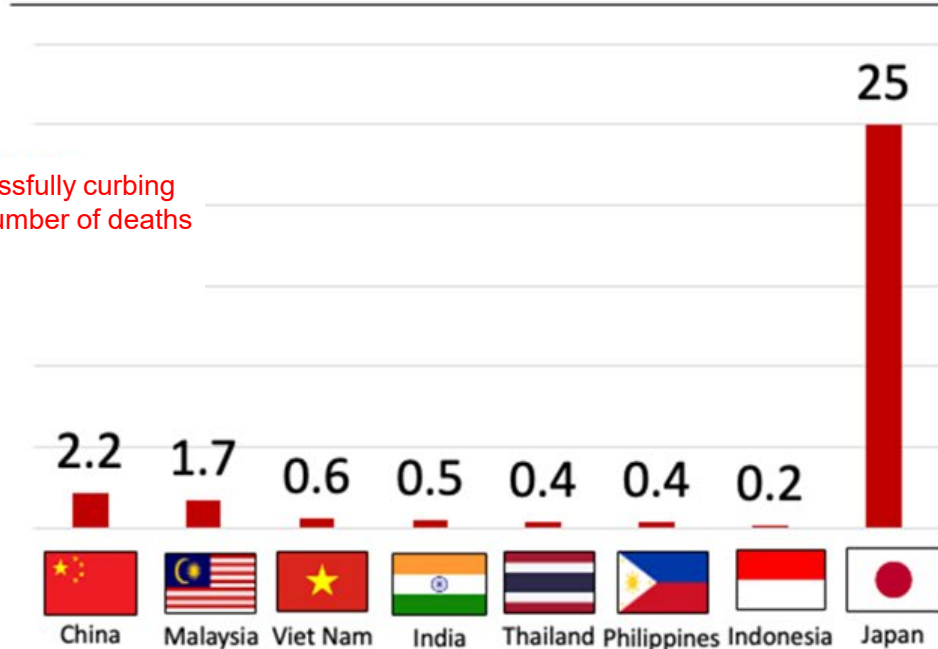
Endoscopy AI to the World

Promoting Japan's endoscopic technology and endoscopic AI to the world directly contributes to saving patients worldwide.

Incidence and mortality rates of gastric cancer per 100,000 people



Number of endoscopists per 100,000 people



Expectations for AI Medical Devices

AI medical devices are expected to contribute to improving medical safety, equalizing healthcare access, and reducing medical costs, with the AI market in healthcare projected to reach nearly 30 trillion yen.

Healthcare Challenges in Japan

1

Shortage of Healthcare Workers
1.87 million workers will be needed by 2030

2

Uneven Distribution of Physicians
Disparities of approximately twofold between prefectures

3

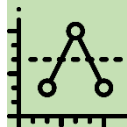
National Medical Expenses
46 trillion yen

Expectations for AI Medical Devices



Improving Medical Safety

- Improved sensitivity and specificity
- Enhanced survival rates through early detection of diseases such as cancer



Standardization of Medical Care

- Enabling even non-specialist physicians to make diagnoses comparable to those of specialists
- Eliminating disparities between national and regional areas

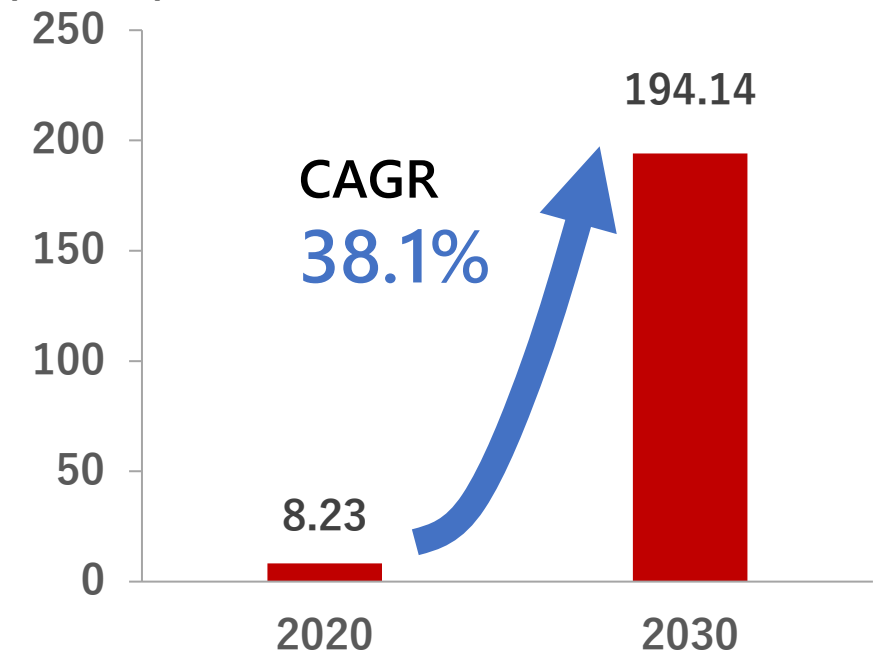


Reducing Medical Costs

- Reducing treatment costs is expected through the early detection of diseases such as cancer.

Market for AI Applications in the Medical Field

(B USD)



Regulatory Gaps in SaMD Between Japan and the U.S.

	United States (FDA)	Japan (PMDA)	Challenges
Review Process and Predictability	<ul style="list-style-type: none"> • Clear regulatory pathways: 510(k), De Novo, PMA • AI/ML SaMD Action Plan includes guidance for continuously learning algorithms 	<ul style="list-style-type: none"> • Case-by-case review process • “Review within 6 months” goal introduced in 2023 	<ul style="list-style-type: none"> • Unpredictable review timelines hinder development planning • Review periods may be prolonged
Guidelines and Development Support	<ul style="list-style-type: none"> • Active early consultation system (Pre-Sub) • Enhanced support through “DASH for SaMD” 	<ul style="list-style-type: none"> • Limited Q&A and interpretive guidance • Difficult to understand requirements from early stages • Request for stronger support for developers 	<ul style="list-style-type: none"> • It is difficult to grasp requirements from the initial stages • We would like to request further strengthening of developer support
Insurance Reimbursement and Commercialization	<ul style="list-style-type: none"> • Established CPT codes and reimbursement frameworks • High compatibility with value-based payment models 	<ul style="list-style-type: none"> • Few examples of insurance coverage • Often takes years via advanced medical care or evaluation treatment • Long time to profitability • High barriers for startup commercialization 	<ul style="list-style-type: none"> • High barriers to entry for startups • Takes time to monetize



Requests to HBD (Harmonization By Doing)

International Alignment & Regulatory Harmonization

- IMDRF's SaMD classification and risk-based approach are progressing
- Interpretations vary by country
- Global submissions often require separate data packages, increasing cost

Cost-Effectiveness & Reimbursement Evaluation

- No global standard for evaluating SaMD value (e.g., diagnostic accuracy, efficiency, cost reduction)
- Immature economic evaluation frameworks delay pricing and reimbursement

Personal Message from Dr. Tomohiro Tada

“The core challenge of SaMD lies in balancing the rapid evolution of software with the safety standards required for medical devices. While both Japan and the U.S. are advancing their systems, areas such as continuously learning AI, real-world data, cybersecurity, and cost-effectiveness evaluation remain exploratory. I strongly advocate for early legal development in these domains.”

Company



Founded: 2017

CEO: Tomohiro TADA, M.D., Ph.D

Location: Tokyo, Silicon Valley, New York, Singapore

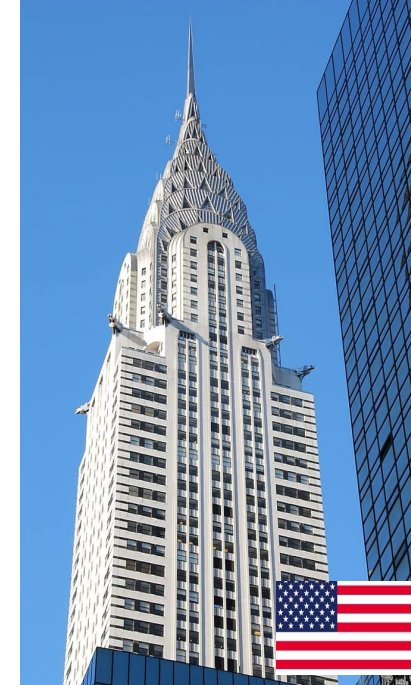
Employees: ~100

Certifications: ISO27001, ISO27701, ISO13485

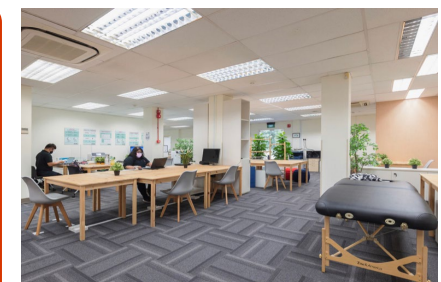
Tokyo Headquarters



New York Office



Singapore Office





Thank you/Questions

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