

Development of a non-invasive colorectal cancer screening system based on deep learning

(Boston Medical Sciences, Inc.)



City	Year of Establishment	Founder
Chuo-ku, Tokyo	2023	Masaki Okamoto

Partner VC	Latest round of Fundraising	Valuation
Beyond Next Ventures Inc.	Series A	JPY 4697 million

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○ Business Plan
Colorectal cancer ranks second worldwide in both incidence and mortality among cancer types (in Japan, it ranks first in incidence and second in mortality), making it a malignancy with a significant disease burden. Over the next 20 years, both the incidence and mortality rates of colorectal cancer are expected to deteriorate rapidly. Despite the fact that early detection and early therapeutic intervention can prevent cancer death and significantly improve life prognosis, the situation is worsening due to the reality that detailed examinations of the lower gastrointestinal tract are often avoided. The mental and physical invasiveness of the preparation involving the consumption of large amounts of laxatives starting the day before, the insertion of a scope through the anus, and the need for sedation and recovery are contributing factors to this avoidance. Our goal is to solve this "examination aversion issue" by implementing a completely laxative-free virtual colonoscopy, thereby promoting early detection and early therapeutic intervention to ultimately eradicate deaths from colorectal cancer.

○ Research Outline
In this research and development initiative, we aim to develop a software as a medical device (SaMD) for CT colonography (product name: AIM4CRC), which integrates deep learning-based virtual bowel cleansing and automated polyp detection. By implementing a “completely laxative-free virtual colonoscopy,” a clinical approach that has long been considered highly challenging, this project seeks to overcome fundamental barriers in colorectal cancer screening. During the PCA phase, building upon the prototype developed in the STS phase, our objective is to advance AIM4CRC to the stage where it resolves key challenges faced by target populations in major markets and fulfills the requirements necessary for sustained revenue generation or the initiation of commercial production. The development will focus on the following six priorities:

1. Refinement of UI/UX design
2. Establishment of efficacy and safety
3. Attainment of regulatory approval in Japan
4. Development and validation of the U.S. version of AIM4CRC
5. Acquisition of FDA clearance
6. Regulatory alignment and policy research to support global deployment

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2025～2026FY	JPY 792 million	Japan, the United States, Europe, China, and across all countries and regions around the world

○ International collaborative technology demonstration
Through collaborative research with the 3D Imaging Research Laboratory at Massachusetts General Hospital, Harvard Medical School, we will conduct a reader study in the United States to demonstrate the clinical significance of AIM4CRC. The results will serve as bridging data for FDA clearance by extrapolating from the clinical trial outcomes obtained in Japan. The central hypothesis to be validated is as follows: For laxative-free CT colonography images, concurrent reading assisted by AIM4CRC will achieve per-patient sensitivity that is significantly superior to the sensitivity reported in prior clinical trials and meta-analyses of standard CT colonography performed with laxative preparation.