Development of a non-invasive colorectal cancer screening system based on deep learning
（**Boston Medical Sciences, Inc.**）

Boston Medical Sciences

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

Partner VC	Latest round of Fundraising	Valuation
Beyond Next Ventures Inc.	Seed-round	JPY 1,000 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 project, we aim to develop a medical device software program, named AIM4CRC, that applies a deep learning approach to perform virtual colon cleansing and automatic polyp detection in colon CT images. The initiative seeks to solve the challenges associated with implementing a "completely laxative-free virtual colonoscopy," which has been clinically difficult to achieve. In the STS phase, we will complete the prototype version of the product and achieve the following Proof of Concept (PoC) objectives, leading to clinical trials and regulatory approval applications starting from the fiscal year 2025, with the goal of early domestic and international clinical implementation.
1. Evaluate the detection accuracy of colon polyps at domestic medical institutions (generalization performance verification) and demonstrate clinical effectiveness.
2. Demonstrate at U.S. medical institutions that the reading support provided by this product improves physicians' detection accuracy.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	STS 2023〜2024FY	JPY 190 million	Japan, the United States, Europe, China, and across all countries and regions around the world

◯International collaborative technology demonstration
・Contract with local partners
To demonstrate the clinical effectiveness of AIM4CRC in the United States and provide foundational data for FDA approval, a preclinical observer study (interpretation test) will be conducted. The hypothesis for validation posits that the interpretation of colon CT scans aided by AIM4CRC will enhance the detection capabilities of radiologists for colorectal cancer and polyps.

The study will utilize a validation dataset that does not involve laxatives and will conduct two sessions: "Session A: Non-AI-assisted reading" and "Session B: AI-assisted reading", to statistically compare their detection performance. All patient information and disease prevalence data will be anonymized, and a defined washout period will be implemented between the sessions.

As of March,2024