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# Development of medical devices driven by academia-industry collaboration: An internal audit

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ABSTRACT

*Background:* Rapid and efficient processes are essential for medical device research and development. To address this need, we established an open innovation research and development platform involving clinicians, manufacturers, sales companies, and experts in intellectual property and regulatory, aiming to develop new medical devices for minimally invasive treatment. The purpose of this study is to retrospectively and internally evaluate the research and development activities and outcomes of this platform to identify factors contributing to successful development of medical devices.

*Methods:* A retrospective analysis of our team was conducted, focusing on successful device development, device classification, development duration, targeted medical areas, intellectual property rights, and manufacturer involvement. The study also evaluated external funding, academic publications, and international market expansion. Data were extracted from our team's project database and analyzed using descriptive statistical methods.

*Results:* The platform facilitated the development of 28 medical devices, achieving a successful device development rate of 50%. These devices primarily targeted endoscopy (48.2%) and laparoscopy (25%),with an average development of 36 months. The intellectual property acquisition rate was 50%, including patents (39.3%) and trademarks (44.6%). Collaboration with sales companies and manufacturers was high at 82.1% and 71.4%, respectively. External funding supported 44.6% of projects, and academic publications were associated with 32.1%. In addition, 12.5% of the projects achieved international market expansion. Key success factors included intellectual property acquisition ($P < .001$), external funding ($P = .003$), academic publications ($P = .003$), and involvement of sales companies in research and development ($P = .03$).

*Conclusion:* Our team has shown successful in research and development through collaborative efforts across academia, industry, and government. It highlights the importance of open innovation and interdisciplinary collaboration in addressing global health care challenges.



## Introduction

In 2008, our university inaugurated “project ENGINE,” an open innovation research and development (R&D) platform devised to transform the field of medical device R&D. This avant-garde model was strategically conceptualized as an open innovation platform, orchestrating a synergistic alliance among clinicians, manufacturers, and experts in intellectual property (IP) and regulatory affairs.[1] Through the creation of a cooperative ecosystem, our team aspires to expedite the trajectory of medical device development, with a particular emphasis on minimally invasive technologies poised to markedly enhance patient outcomes. This methodology not only catalyzes innovation but also integrates various expert insights, ensuring new medical devices achieve both clinical relevance and commercial viability.

The platform responded to an urgent demand for faster and more efficient development cycles within the medical device sector. Conventional R&D methodologies often fail to keep pace

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with the rapidly evolving needs of health care, characterized by protracted periods from concept to market-ready products.[2–5] By harnessing the collective strengths of academia, industry, and regulatory frameworks, our team creates a more fluid and responsive R&D paradigm, adept at addressing real-world health care challenges swiftly. This integrated strategy facilitates the combination of resources and expertise, an essential strategy for navigating the intricate terrain of medical device development and regulatory compliance.[6]

Fundamental to our team is its commitment to open innovation, promoting the unfettered exchange of knowledge and resources beyond the confines of organizational silos. Through concerted collaborative efforts, our open innovation R&D platform model endeavors to establish a sustainable platform that not only propels technological innovation but also fosters a more profound integration of clinical imperatives into the developmental matrix. The objectives of this study are to descriptively reassess the projects within our team to evaluate the factor that have contributed to their success and to foster collaboration among a diverse range of participants within the medical R&D community.

## Methods

### *Study design*

This investigation was conceived as a comprehensive retrospective examination of R&D initiatives from 2008 through October 2023 in project ENGINE. It scrutinized various outcomes such as project completion rates, device classifications, durations of development, targeted medical areas, and IP milestones, with the intent of delineating our team's influence on the medical device sector. The analysis encompassed both foundational experimental studies and advanced device development phases.

### *Data collection*

Data were meticulously extracted from our extensive archival project database, which contains prospectively registered records of all medical device projects initiated from the model's inception through October 2023. Variables extracted included the number of projects initiated, their current status (completed, in-progress, or terminated), classification of devices in accordance with medical device regulations, duration of R&D, targeted medical areas, and IP outcomes such as acquired patents and trademarks.

Information regarding external funding was restricted to the presence or absence of funding, derived from financial records at the project level. Scholarly contributions were gauged through an analysis of publications in leading medical and engineering journals associated with our projects. Data pertaining to the international market expansion of the devices were compiled from sales and distribution reports, illustrating the geographical dissemination of the developed devices.

### *Data analysis*

Descriptive statistical methods were employed to analyze quantitative data, providing a summary of project outcomes including average development durations and the distribution of device classifications. Product completion rate was determined by the ratio of projects achieving full market implementation to the total projects initiated.

Noncompleted projects were categorized into "ongoing" and "discontinued" groups on the basis of project status at the time of analysis. Statistical comparisons between completed and noncompleted projects, as well as between ongoing and discontinued projects, were performed using the Wilcoxon rank sum test to assess differences in development timelines. These analyses were conducted to provide deeper insights into the temporal dynamics of project progression.

Resource-sharing across multiple projects was a key feature of the open innovation platform. Equipment such as endoscopes, laparoscopes, and reusable materials were shared among projects, whereas animal resources were used efficiently without compromising outcomes. Infrastructure development progressed alongside project advancements, leveraging facilities for large animal experiments.

All completed projects aimed to secure IP rights once a clear path to product completion was established. Patent protection was prioritized for market-ready products, ensuring that IP acquisition was completed wherever feasible before commercialization. The analysis of IP involved quantifying the incidence of patent and trademark filings and assessing the success rate of these filings in securing granted rights. The influence of external funding was examined by correlating its presence with product completion rates and the speed of development.

Correlation techniques were used to investigate the relationship between scholarly publications and project activities, assessing the extent to which R&D endeavors under our team enhanced academic output. The scope of international expansion was evaluated by cataloging the number of markets penetrated by the developed devices, sorted by geographic region and device type.

### *Ethical considerations*

Although the data used in this study were not anonymized, all analyses were conducted using aggregate data to maintain confidentiality and adhere to ethical standards. The study involved no direct human subjects, and all project data were managed in accordance with university research compliance regulations.

## Results

### *Project outcomes, collaborations, and device classifications in our open innovation platform*

Since its inception, a total of 35 companies have engaged in our team, with 21 companies currently continuing collaborative development. The open innovation platform has overseen the development of a total of 56 medical device projects since its inception, achieving a completion rate of 50.0% (Table I). Among these projects, 28 have been successfully completed, whereas the remainder are at various stages of development (Figure). The devices developed under our team span several classifications, with a notable focus on less-invasive technologies. According to the classifications of the Pharmaceuticals and Medical Devices Agency in Japan, Class 1 devices, which include the least-invasive tools with the simplest design, constituted 30.3% of the projects. Class 2 devices made up 19.6%, whereas more complex Class 4 devices accounted for 3.6% of the total. Collaborative efforts were extensive, with 71.4% of the projects involving partnerships with medical device manufacturers, 5.4% involving both medical and nonmedical device manufacturers, and 23.2% involving nonmedical device manufacturers. In addition, 82.1% of the projects included research and development in collaboration with sales companies.

### *Development timeline and medical application*

The development period for these devices varied significantly, ranging from as little as 1 month to as long as 114 months, with an average development timeline of 36 months (Table II). This variance

**Table I**
Project outcomes, collaborations, and device classifications*

| Category | Data ($n = 56$) |
|---|---|
| Product completion | |
| Completed projects | 28 (50.0%) |
| Product not finalized projects | 28 (50.0%) |
| Ongoing projects | 6 (10.7%) |
| Discontinued projects | 22 (39.3%) |
| Collaborating companies | |
| Medical device manufacturers | 40 (71.4%) |
| Medical/nonmedical device manufacturers | 3 (5.4%) |
| Nonmedical device manufacturers | 13 (23.2%) |
| R&D with sales companies | 46 (82.1%) |
| Medical device class | |
| Class 1 | 17 (30.3%) |
| Class 2 | 11 (19.6%) |
| Class 3 | 0 (0%) |
| Class 4 | 2 (3.6%) |
| Miscellaneous | 3 (5.4%) |
| Not applicable | 23 (41.1%) |

*R&D*, research and development.
* Values are presented as number (%).

underscores the challenges and complexities involved in medical device development, particularly when tailoring innovations to specific clinical needs. The primary areas of application for these devices were in endoscopy and laparoscopy, representing 48.2% and 25.0% of the projects, respectively. These areas highlight the model's emphasis on enhancing minimally invasive procedures, which are critical in reducing patient recovery times and improving surgical outcomes for minimum invasive treatment.

Among the noncompleted projects, ongoing projects ($n = 22$) had a median development time of 12 months (range 1–70 months), whereas discontinued projects ($n = 6$) had a median development time of 20 months (range 19–67 months), with no statistically significant difference ($P = .166$). In contrast, completed projects ($n = 28$) had a median development time of 38 months (range 1–114 months), significantly longer than noncompleted projects ($n = 28$, median: 14 months, range: 1–70; $P = .0049$).

### *IP milestones*

In terms of IP, 39.3% of the projects successfully secured patents, demonstrating the model's robust capability to generate proprietary innovations that significantly contribute to the medical field (Table III). In addition, 44.6% of the projects registered trademarks, which are crucial for establishing brand identity and value in the competitive medical device market. On an international scale, 12.3% of the projects have successfully expanded into global markets, particularly in countries such as Singapore, South Korea, and Thailand.

### *Funding contributions and sources*

External funding played a pivotal role in our team, with 44.6% of the projects receiving financial support from sources outside the university. Various grants and subsidies were introduced in our team's projects. Specifically, funding was received from the following sources: the Ministry of Economy, Trade and Industry (17 grants, including subsidies from the Small and Medium Enterprise Agency), the Ministry of Health, Labour and Welfare (6 grants, including research funds and subsidies), the Ministry of Education, Culture, Sports, Science and Technology (4 grants, including grants-in-aid for scientific research), the Japan Agency for Medical Research and Development (4 grants), the Japan Society for the Promotion of Science (1 grant for academic exchange), private grants (22 grants), and crowdfunding (1 project) (Table IV).

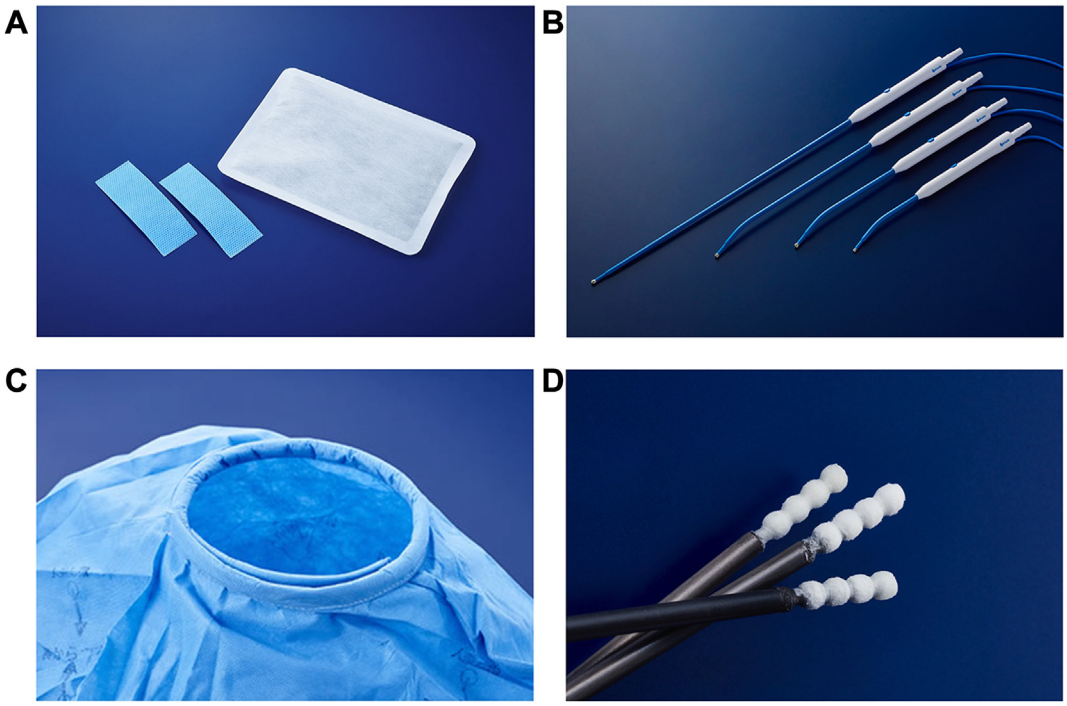


**Figure 1.** Medical devices developed under the open innovation consortium. These images showcase some of medical devices developed through our team: (A) Lapa-Hot: A scope warmer and cleaner for endoscopic surgery, noted for its affordability and long-lasting performance; (B) suction ball coagulator (SBC): a device allowing simultaneous suction and soft coagulation during surgery; (C) Self-Gown: a gown designed for single-person use, featuring a special ring spring around the neck that allows for easy, clean, and safe donning and doffing without assistance, (D) Dr.H uby micro: Durable medical ultra-thin cotton swabs (3 mm) that resist shedding even with prolonged use.

**Table II**
Development duration and targeted medical areas

| Category | Data ($n = 56$) |
|---|---|
| Research and development duration, mo* | 36 (1–114) |
| Production completed projects ($n = 28$)* | 38 (1–114) |
| Production not completed projects ($n = 28$)* | 14 (1–70) |
| Ongoing projects ($n = 6$)* | 12 (1–70) |
| Discontinued projects ($n = 22$)* | 20 (19–67) |
| Targeted areas | |
| Endoscopic | 27 (48.2%) |
| Laparoscopic | 14 (25.0%) |
| Open Surgery | 8 (14.3%) |
| Cross-disciplinary | 2 (3.6%) |
| Other | 5 (8.9%) |

* Values are presented as median (range) or number (%).

**Table III**
Intellectual property and design achievement*

| Category | Data ($n = 56$) |
|---|---|
| Patent status | |
| Patented | 22 (39.3%) |
| Not patented | 34 (60.7%) |
| Number of patents | |
| One | 19 (33.9%) |
| Two | 3 (5.4%) |
| Trademark status | |
| Trademarked | 25 (44.6%) |
| Not trademarked | 31 (55.4%) |
| Number of trademarks | |
| One | 25 (44.6%) |
| Design | |
| With design | 6 (10.7%) |
| Without design | 50 (89.3%) |
| Number of designs | |
| One | 3 (5.4%) |
| Two | 3 (5.4%) |
| Royalty status | |
| Royalties applicable | 13 (23.2%) |
| No royalties | 44 (76.8%) |
| International deployment | |
| With international deployment | 7 (12.5%) |
| Without international deployment | 49 (87.5%) |

* Values are presented as number (%).

**Table IV**
Breakdown of external funding sources*

| Category | Data ($n = 56$) |
|---|---|
| External funding | |
| R&D with external funding | 25 (44.6%) |
| R&D without external funding | 31 (55.4%) |
| Funding sources | |
| Ministry of Economy, Trade and Industry | 17 |
| Ministry of Health, Labour and Welfare | 6 |
| Ministry of Education, Culture, Sports, Science and Technology | 4 |
| Japan Agency for Medical Research and Development (AMED) | 4 |
| Japan Society for the Promotion of Science | 1 |
| Private grant | 22 |
| Crowdfunding | 1 |

*R&D*, research and development.
* Values are presented as number (%).

### *Academic impact and global expansion*

All academic activities within the consortium involved the principal investigator at ENGINE consortium (K.N.) as the overarching coordinator. In addition, numerous specialists, including surgeons, endoscopists, internists, radiologists, emergency physicians, and gynecologists affiliated with the platform, actively participated in these activities. A significant indicator of the success is its academic impact, with 33.3% of the projects contributing to academic publications (Table V). These publications serve as a testament to the model's commitment to advancing medical science and disseminating new knowledge. Among the 32 academic publications generated within the consortium, 31 were authored primarily by physicians, including surgeons, endoscopists, internists, radiologists, emergency physicians, and gynecologists actively participating in the platform. One additional paper was authored by an industry collaborator, demonstrating the multidisciplinary nature of the consortium's activities.

### *Factors associated with completed projects*

The analysis of 56 medical device projects revealed significant differences between completed ($n = 28$) and noncompleted ($n = 28$) projects. Intellectual property was present in 82.1% of completed projects compared with 25.0% of nonfinalized projects ($P < .001$) (Table VI). External funding was secured for 64.3% of completed projects, whereas only 25.0% of nonfinalized projects received such funding ($P = .003$). Publications were associated with 53.6% of completed projects, significantly greater than the 10.7% in nonfinalized projects ($P = .003$). Collaboration with sales companies was observed in 92.9% of completed projects, compared with 71.4% of nonfinalized projects ($P = .03$).

## Discussion

Our open innovation platform has emerged as a bastion of transformative force in medical device R&D, elevating "manufacturing" to a revered "science" and an "academic discipline." This shift goes beyond technical proficiency, foresting comprehensive understanding of the entire lifecycle of medical devices, from conception to market deployment. By embedding scientific methodology into the manufacturing, each phase is rigorously supported by empirical research and evidence-based practices. Central to our team is a robust human capital development strategy, integrated into its core operations.[7] The model nurtures talent through traditional education and direct involvement in R&D projects, ensuring participants actively contribute to innovation. The educational framework cultivates “fusion professionals” with expertise in medical, engineering, and regulatory

**Table V**
Overview of collaboration, international deployment, and publication in medical device projects

| Category | Data ($n = 56$) |
|---|---|
| Collaborating companies | |
| Medical device manufacturers | 40 (71.4%) |
| Medical/nonmedical device manufacturers | 3 (5.4%) |
| Nonmedical device manufacturers | 13 (23.2%) |
| R&D with sales companies | 46 (82.1%) |
| Related publications | |
| With related publications | 18 (32.1%) |
| Without related publications | 38 (67.9%) |
| Number of publications | |
| 1 | 12 (21.4%) |
| 2 | 3 (5.4%) |
| >3 | 3 (5.4%) |
| International deployment | |
| With international deployment | 7 (12.5%) |
| Without international deployment | 49 (87.5%) |

Values are presented as number (%).
*R&D*, research and development.

**Table VI**
Impact of various factors on product finalization status*

| | Production compilation ($n = 28$) | Production not completed ($n = 28$) | *P* value |
|---|---|---|---|
| Intellectual property | | | |
| Presence | 23 (82.1%) | 7 (25.0%) | <.001 |
| Absence | 5 (17.9%) | 21 (75.0%) | |
| External funding | | | |
| Presence | 18 (64.3%) | 7 (25.0%) | .003 |
| Absence | 10 (35.7%) | 21 (75.0%) | |
| Publication | | | |
| Presence | 15 (53.6%) | 3 (10.7%) | .003 |
| Absence | 13 (46.4%) | 25 (89.8%) | |
| R&D | | | |
| With sales companies | 26 (92.9%) | 20 (71.4%) | .03 |
| Without sales companies | 2 (7.1%) | 8 (28.6%) | |

$P = .05$ was considered statistically significant.
*R&D*, research and development.
* Values are presented as number (%).

fields. This interdisciplinary approach, enhanced by industry and clinical collaborations, redefines industry roles and mentor the next generation, ensuring continuous enhancement and innovation.

Our team's scholarly contributions are notable, marked by significant project milestones. For instance, the developing an RFID-based system for visualizing the usage has advanced laparoscopic procedures and explored areas previously dominated by robotic surgeries.[8,9] Similarly, the creation of a dual-function disposable hot pack for laparoscopic surgery exemplifies innovation, addressing specific clinical needs and achieving commercial success in Japan.[10–12] By ingeniously amalgamating antifogging and cleaning capabilities, this innovation significantly elevates surgical efficiency and safety. Furthermore, the development of the "Self-Gown," a sterile disposable surgical gown that can be donned independently, showcases broad applicability in caregiving, health care, waste management, and radioactive decontamination. Featured in the 2016–2017 World Health Organization Compendium of Innovative Health Technologies for Low-Resource Settings,[13] the gown highlights the model's ingenuity. Other projects have generated foundational data, leading to numerous scholarly publications,[14–18] understanding the corroborative model's legacy of continuous innovation and scholarly excellence.

Funding is crucial in R&D, facilitating the transition from innovation to commercialization. IP ownership reflects a product's competitive advantage, emphasize the importance of securing IP rights. R&D grounded in scientific rigor often culminates in academic publications, validating research and enhancing innovation credibility within the scholarly community. IP and publications drive and reflect success within the R&D ecosystem.

Early involvement of sales companies is vital in medical device R&D, bridging the communication gap between the development team and business managers.[7] In our platform, sales companies were engaged at varying stages of project development, depending on the specific requirements of each project. Some projects included sales company participation from the outset, allowing for seamless integration of market perspectives and eliminating the need for pitching efforts later. Other projects involved matching sales companies midway through development or at the prototype stage, when commercialization prospects were being assessed. Notably, the selection of sales companies was not determined by the companies themselves but was proactively initiated by the principal investigator or development team based on strategic alignment and product readiness. Early collaboration among medical professionals, engineers, and business managers ensured seamless information exchange regarding regulations, quality management systems, and IP. This approach not only facilitated a smoother transition from R&D to commercialization but also contributed to greater success rates for commercialization in cases where sales companies were involved early.

This internal audit had several limitations. Its retrospective design, relying on archival data, may introduce elements of incompleteness or bias. Quantitative metrics, while valuable, do not capture the nuanced qualitative dimensions of collaboration and transformative impact of innovation. The inclusion of projects relied on the participation of sales companies, but records of projects where sales companies declined participation or were excluded are not available, limiting the comprehensiveness of the evaluation. The platform's emphasis on resource-sharing to maximize efficiency, such as sharing equipment and animal resources across multiple projects, made it difficult to evaluate cost-effectiveness for each development process. While this approach optimized resource use, it limits precise cost allocation analyses. In addition, the findings, primarily from Japanese projects, limit the broader applicability to diverse international contexts. Nevertheless, our team holds significant potential for catalyzing innovation and fostering collaboration in medical device development. Its holistic approach and advocacy for open innovation suggests that, with further refinement and global application, the model could transcend regional boundaries, amplifying its impact.

In conclusion, the success of the open innovation consortium in fostering innovation highlights the importance of publishing research outcomes, facilitating commercialization and securing project funding, and collaborating with sales companies. These elements are associated with product completion and are significant in medical device R&D, highlights the importance of open consortia.

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## Confict of Interest/Disclosure

All the authors (Yuki Ushimaru, Takamitsu Kato, Motoki Sasaki, Taishi Hata, Makoto Hosaka, Hidetoshi Eguchi, Yuichiro Doki and Kiyokazu Nakajima) declare that they have no relevant financial disclosures.

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## CRediT authorship contribution statement

**Yuki Ushimaru:** Writing – original draft, Formal analysis, Data curation. **Takamitsu Katoh:** Writing – review & editing. **Motoki**

**Sasaki:** Writing – review & editing. **Taishi Hata:** Writing – review & editing. **Makoto Hosaka:** Writing – review & editing. **Hidetoshi Eguchi:** Writing – review & editing. **Yuichiro Doki:** Writing – review & editing. **Kiyokazu Nakajima:** Writing – review & editing, Project administration, Methodology, Conceptualization.

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