

RIKEN Cluster for Industry Partnership Advisory Council (CIPAC2016)  
REPORT

October, 2016

**Abstract**

CIP has three missions that are Baton Zone, problem-solving and interdisciplinary research, and intellectual property management and technology transfer. CIPAC2016 consists of three working groups as follows.

- RIKEN Innovation Center (RInC) and Collaborations Division
- Program for Drug Discovery and Medical Technology Platforms (DMP)
- Preventive Medicine and Diagnosis Innovation Program (PMI)

CIPAC assessed CIP activities and status from 2014 when the last AC was conducted. As a result, CIPAC summarized major opinions as follows.

RIKEN Innovation Center (RInC) and Collaborations Division

- 1) The system of the RInC and Collaborations Division has been well organized and the problems to be solved have become clearer in comparison with their status in 2014 when the last AC was conducted.
- 2) It is appropriate that the name of the organization, the “Research Cluster for Innovation”, was changed to the “Cluster for Industry Partnerships” giving a clear signal that RIKEN is open to forming partnerships with industry. Furthermore, following the RIKEN Initiative for Scientific Excellence, formulating a RIKEN innovation strategy, partly based on advice by the chief technical officers (CTOs) of major companies, was well timed.
- 3) Integrated Collaborative Research Program with Industry is commended as it has produced positive results that achieved the numerical targets of transition to the development stage by industry prior to product implementation.
- 4) It is appropriate that two new collaboration centers have been established under the RIKEN- Industry Collaboration Centers Program and collaborative research has been implemented that will lead to future business. Efforts to set up collaboration centers should be continued for RIKEN will be focusing research area, especially artificial intelligence (AI).
- 5) Sponsored Laboratories are commended as they have provided exceptional results such as placing new products on the market or starting new services.

- 6) A survey on seeds of research conducted at RIKEN, and an efforts to develop new routes for negotiations leading to closer relations with companies, are highly commended. It is desirable to target large joint projects such as those involving collaboration centers with big companies together with collaborative research with mid-sized companies in a wide range of areas, where possible, with RIKEN providing the seeds of research. Further activation of business development activities working together with the Collaborations Division should be promoted.
- 7) It is commended that income from RIKEN's collaborative research with industry has increased and income from patent licensing has exceeded patent expenses in 2015. The rate of patents which are reduced to practice, 27.2%, shows that outcomes from RIKEN's research activities are well utilized by industry. On the other hand, the number of consultations with researchers for new inventions has not increased by much. Further efforts to provide internal training programs and information to researchers will be necessary.
- 8) It is commendable that the number of RIKEN Ventures has steadily increased and two of them are listed companies. RIKEN's capacity for incubation is deemed insufficient. It needs to construct a system to foster entrepreneurs by developing its researchers' understanding of business and by holding business plan contests and the like.

#### Program for Drug Discovery and Medical Technology Platforms (DMP)

- 1) DMP is to be congratulated on making significant advances since the last AC meeting.
- 2) The emphasis on greater interaction with pharma companies is welcome, and will be important for future exits.
- 3) The output of DMP at least matches if not exceeds international standards for comparable drug discovery organizations.
- 4) DMP has a pioneering role in trailblazing cell-based therapies (for example, with respect to the evolving regulatory environment etc).
- 5) RIKEN Technology Transfer Office should anticipate the licensing arrangements when spinning out new ventures, to expedite subsequent agreements and avoid unnecessary delays.
- 6) The future structure and role of DMP needs to be clarified quickly by RIKEN senior management to facilitate recruitment of a replacement for Dr. Goto as Program Director.

### Preventive Medicine and Diagnosis Innovation Program (PMI)

- 1) The PMI mission continues to be important, both to RIKEN and to society as a whole.
- 2) Given the context of severe budget constraints, we support the way in which RIKEN and the PMI have devised a new survival strategy to secure funds for the PMI from external parties, while using RIKEN's research capabilities to achieve cross-sectional goals.
- 3) In a challenging environment, the PMI has been producing important outcomes by using an extensive range of approaches and by collaborating with industry to ensure the rapid and appropriate exit of technology to society.
- 4) RIKEN must increase its support and use of the PMI for the purposes of the RIKEN Initiative for Scientific Excellence. Activities such as the development of international cooperation centers with Hamad General Hospital in Qatar and the Kazan Federal University in Russia play an extremely important role in creating international hubs to support RIKEN.

## CIPAC2016 Members

| RIKEN Innovation Center (RIInC) and Collaborations Division |   |
|---|---|
| (Chair)<br>Naoto Kobayashi                                  | Associate Director and Professor, Center for Research Strategy, Waseda University |
| Eiji Tanaka   | Adviser, Mitsubishi Chemical Holdings Corporation.                                |
| Mai Ban   | Licensing Manager, Technology Transfer & Entrepreneurship, Institut Pasteur       |
| Toshiya Watanabe  | Professor, Policy Alternatives Research Institute, The University of Tokyo        |

| Program for Drug Discovery and Medical Technology Platforms (DMP) |   |
|---|---|
| (Vice Chair)<br>Shuh Narumiya                                     | Director, Medical Innovation Center, Graduate School of Medicine Kyoto University |
| Yuzuru Matsuda  | President, Kato Memorial Bioscience Foundation                                    |
| Alun McCarthy   | VP, Novel Target Biology & Genomics, C4X Discovery Ltd.                           |

| Preventive Medicine and Diagnosis Innovation Program (PMI) |   |
|--|---|
| (Vice Chair)<br>Hans Wigzell                               | Professor, Karolinska Institutet            |
| Takaaki Kirino   | Professor Emeritus, The University of Tokyo |
| Yuji Yamamoto  | CEO, MinaCare Co., Ltd.                     |

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Terms of References

1. RIKEN Innovation Center (RIInC) (Advice on the Baton Zone)  
RIKEN Innovation Center manages the Baton Zone Program in which RIKEN scientists work together with corporate scientists to apply the results obtained from basic research to practical applications and technology transfer.  
CIPAC is asked to evaluate Baton Zone research projects and makes proposals regarding the following points.
  - 1) Evaluates whether research achievements fulfill international standards.
  - 2) Evaluates whether human resources fulfill international standards.
  - 3) Evaluates whether its achievements contribute to society.
  - 4) Clarifies which research areas are advantageous or disadvantageous for the Innovation Center.
  - 5) Proposes the proper direction for the next medium- to long-term (approx. 5-10 years) and specific measures which should be taken to make dramatic progress.
  - 6) Evaluates whether the efforts under the “RIKEN Initiative for Scientific Excellence” is proper and effective, and makes proposals for new measures which should be implemented by the Innovation Center.
  - 7) Evaluates whether efforts toward the maximization of research results are advantageous from the perspective of RIKEN’s research activities as a whole, and are taking place in a proper and effective manner, especially for efforts that involve collaborations between centers.
2. Business Development (Advice on business development)  
CIPAC is asked to evaluate whether business development and collaborative promotion activities, which lead to Baton Zone research, possess proper strategies and management systems, and makes related proposals.
3. Collaborations Division (Advice on promotion of collaborations)  
CIPAC is asked to evaluate whether technology transfer activities (securing intellectual properties, execution and management of contracts, licensing activities, approval of RIKEN ventures, and support for RIKEN ventures) are implemented under proper strategy and management, and makes related proposals.

The AC subcommittee has discussed the Baton Zone, business development, and the activities of the Collaborations Division, as well as the overall strategy and management based on the advisory points, and gives the following recommendation.

## 1. Introduction

In the recent global environment favoring open innovation, strengthened collaboration activities with industry are essential to increase the activities of RIKEN and make contributions to society as called for in the RIKEN Initiative for Scientific Excellence.

The system of the RIKEN Innovation Center and RIKEN Collaborations Division has been well organized and the problems to be solved have become clearer in comparison with their status in 2014 when the last AC was conducted.

Taking into account the steady results obtained in last two years, the AC commends the in-depth discussions on industry partnership activities during this period.

It is appropriate that the name of the organization, the “Research Cluster for Innovation”, was changed to the “Cluster for Industry Partnerships” giving a clear signal that RIKEN is open to forming partnerships with industry. Furthermore, following the RIKEN Initiative for Scientific Excellence, formulating a RIKEN innovation strategy, partly based on advice by the chief technical officers (CTOs) of major companies, was well timed.

It will be important for the Cluster for Industry Partnerships to implement the measures consistently based on RIKEN’s innovation strategy. These measures should be ranked according to their priority and firmly implemented.

In particular, regarding innovation, it is important that RIKEN provides exceptional research results which lead to new business opportunities in the future for the industrial sector. Therefore, in order to have RIKEN’s achievements accepted by society in the form of products and services, it is desirable that present systems and concepts are adjusted to activate industry partnership activities.

As many of the researchers work under a fixed-term employment system, the organization of RIKEN has a high level of mobility. It is necessary to consider how industrial collaboration impacts the researcher’s performance, and consider measures which have positive effects on researchers, such as examining the number of papers or patents before and after the implementation of joint projects with industries.

RIKEN should have more researchers who will proactively contribute to partnerships with industry. For this, it is recommended that their job performance evaluations for those wishing to pursue an indefinite-term employment career include their achievements in industry partnership activities.

## 2. Baton Zone

Integrated Collaborative Research Program with Industry is commended as it has produced positive results that achieved the numerical targets of transition to the development stage by industry prior to product implementation. However, it has little strategic value in many cases where the companies utilize known technologies based on achievements from the past. RIKEN should clarify its industry partnership policy and make proposals to industry with an understanding of society's needs linked to the research topics that are qualified to receive the Industrial Cooperation Promotion Fund.

It is appropriate that two new collaboration centers have been established under the RIKEN-Industry Collaboration Centers Program and collaborative research has been implemented that will lead to future business. Efforts to set up collaboration centers should be continued. Furthermore, for specified areas of research and development on which RIKEN will be focusing—such as artificial intelligence (AI)—it is necessary to develop large-scale, long-term collaboration centers to create technologies leading to new partnerships with the private sector.

Although Sponsored Laboratories are commended as they have provided exceptional results—such as placing new products on the market or starting new services—achievements at their laboratories are seemed to be too dependent on the character of the research leaders. Here RIKEN will need to develop its own strategy in the future.

## 3. Business development

A survey on seeds of research conducted at RIKEN, and an efforts to develop new routes for negotiations leading to closer relations with companies, are highly commended.

Industry partnership strategies may vary depending on the partner company's business size. It is desirable to target large joint projects such as those involving collaboration centers with big companies, and smaller collaborative research with medium-sized companies, both in a wide range of areas, where possible, with RIKEN providing the seeds of research. Further expansion of business development activities working together with the Collaborations Division should be promoted.

It is also recommended to increase business development activity in the areas in which RIKEN is planning to get involved such as artificial intelligence and use of data for problem solving. For this, human resources specializing in target areas must be secured.

#### 4. Securing intellectual properties, contracts and licensing

It is commended that income from RIKEN's collaborative research with industry has increased and income from patent licensing has exceeded patent expenses in 2015. The rate of patents which are reduced to practice, 27.2%, shows that outcomes from RIKEN's research activities are well utilized by industry.

On the other hand, the number of consultations with researchers for new inventions has not increased by much. Further efforts to provide internal training programs and information to researchers will be necessary. RIKEN should identify researchers who are proactively interested in inventions and focus its efforts to cultivate those researchers.

To act more effectively, it is desirable to establish an operation ideal for RIKEN by understanding and analyzing more closely the number of inventors, the potential of intellectual properties of the research results by researchers who are less interested in invention disclosure, and the number of patent applications and associated expenses.

Since industry has not always been able to predict the areas of basic research that will expand, industry expects that RIKEN will secure intellectual property rights on its own decision. For RIKEN, securing of intellectual property rights is as important as publishing the research results in scientific journals and meetings.

However, intellectual property is not limited to patents. In the AI and Information and Communication Technology (ICT) fields, it is necessary to understand the development of the common guidelines established by the government for various intellectual property categories such as big data utilization.

Although small companies and venture companies sometimes agree to pay consideration to RIKEN to use the patents co-owned with RIKEN, large companies do not pay such consideration in most cases. It is possible to be flexible with terms and conditions of the contracts depending on the technology areas or business characteristics.

It is important to proceed carefully when entering into licensing contracts with foreign companies. If one institute is not chosen as a partner of the foreign company, then that institute may not be chosen as a partner by a Japanese company as well because the Japanese companies today are highly qualified as the foreign companies. License deals with foreign companies and acquisitions of venture companies by foreign companies may be criticized by the general public to some extent, but an overly cautious approach should not be taken.

Universities outsource their Technology Licensing Organization (TLO) functions as it is difficult to secure human resources specialized in licensing activities due to a

personnel rotation policy of administrative positions. As RIKEN employs specialized human resources internally, it probably will not need to employ an external TLO, although its specialists may not always be enough in their number.

For collaborations with multiple companies and partnerships with foreign companies, legal skills in contract management will become increasingly important. Specialized human resources, such as lawyers who can design a framework of industry partnerships and participate in negotiations at the early stage, should be secured.

## 5. RIKEN Ventures

It is commendable that the number of RIKEN Ventures has steadily increased and two of them are listed companies. But receiving large licensing fee from venture companies seems unrealistic. It is also possible to utilize venture companies for RIKEN's branding vis-a-vis the general public.

RIKEN should clarify its future direction once again and strongly encourage researchers to think more about practical applications and develop the skills for setting up collaborative projects between academia and industry.

RIKEN's capacity for incubation is deemed insufficient. It needs to construct a system to foster entrepreneurs by developing its researchers' understanding of business and by holding business plan contests and the like. From the viewpoint of regional cooperation, efforts must be made to expand activities by inviting external companies other than RIKEN ventures, and actively engaging in cooperative research with them utilizing existing incubation centers.

In addition, it is recommended to set up a forum for developing ventures by allowing key players, such as venture capitalists, angel investors, business-minded students, corporate capital specialists, and others to meet. Regular pedagogic seminars for establishing ventures (similar to entrepreneurship courses at universities) should be convened, in which topics include effective business practices and financial planning. As it takes a long time to succeed in a venture business, persistent effort will be necessary. The current system should be reviewed, and changed to a system that supports the expansion of venture businesses.

Moreover, it is necessary for RIKEN to work on related ministries to let RIKEN be granted the same rights as universities, which have been already given stock acquisition rights.

## 6. New measures based on the Innovation Strategy

RIKEN is expected to clarify its topics of research and seek opportunities with

industry on even more important projects through the Innovation Design and Pioneering Projects for collaboration of its Innovation Strategy.

Although the project to develop a pipeline for whole human cell analysis is an appropriate Pioneering Project for RIKEN, it is not the case for the technologies to support the independence of elderly citizens is already being developed by others. However, when taking on projects that others have already started, the focus must be on the specific activities that only RIKEN is able to perform.

Innovation is not achieved in a single and uniform way but created by the complex interaction of research seeds, processes, contributions by the environment and personnel, and other aspects. For RIKEN, innovation involves taking advantage of its best features, and we expect that RIKEN will establish a method to create innovation effectively and efficiently through in-depth assessment of the opportunities for academia-industry collaboration.

## 7. Conclusion

With the steady accumulation of achievements based on RIKEN's long-term plan, policies and measures of the Innovation Center and the Collaborations Division need to be clarified for the future. In particular, further developments are expected for RIKEN as it is upgraded to a Designated National Research and Development Institute in the autumn of 2016. Also, looking ahead at what is expected of RIKEN at the end of the fourth five-year term in 2022, developing medium- to long-term collaboration policies with industry based on the current RIKEN Innovation Strategy is highly recommended. RIKEN will be expected to present its policies openly and take a role of leadership and innovation for science and technology in Japan.

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Positives/strengths:

- DMP is to be congratulated on making significant advances since the last AC meeting
- The tankyrase project is an excellent example, showing world-standard application of different technologies (including X-ray crystallography, computational chemistry and medicinal chemistry)
- The iPSC & NKT technologies are further examples of unique expertise that has been nurtured within DMP
- The emphasis on greater interaction with pharma companies is welcome, and will be important for future exits
- The output of DMP at least matches if not exceeds international standards for comparable drug discovery organizations
- Portfolio management and matrix management is working very well
- The molecular dynamics research is addressing important questions and at least matches activities elsewhere
- The recruitment of 1) Uemura-san to Clinical Development Support Office, and 2) experienced medicinal chemists, has significantly improved the capability and capacity of DMP
- DMP has a pioneering role in trailblazing cell-based therapies (for example, with respect to the evolving regulatory environment etc). This was flagged as an important role at last AC, and it is good to see that the progress and momentum has been maintained (including adaptation to new legislation).

Weaknesses:

- Incentives for RIKEN researchers not employed by DMP to devote time and resource to DMP activities are still unresolved.
- For example, when option or licensing income is generated by DMP activities, a proportion needs to be returned to DMP.
- Regular interactions with RIKEN centers are encouraged. The recent Collaboration Centers Program is an example of the benefits of such

interactions.

#### Suggestions/recommendations:

- Efforts to improve the Molecular Dynamics algorithms are to be encouraged
- Progression rates for projects through the stages of drug discovery should be assessed, and compared with industry norms. This may flag stages in the process that would benefit from review to improve overall efficiency.
- Enlargement of the compound library for HTS is encouraged, using a variety of different sources to maximize the diversity of the library
- Natural product screening (of iPSC-derived phenotypes) will contribute to broadening the diversity of the screening library. This will need to be coupled to computation chemistry methodology to identify simpler (e.g. non-chiral) scaffolds where necessary.

#### Maximizing RIKEN achievements

- RIKEN Technology Transfer Office should anticipate the licensing arrangements when spinning out new ventures, to expedite subsequent agreements and avoid unnecessary delays.
- The future structure and role of DMP needs to be clarified quickly by RIKEN senior management to facilitate recruitment of a replacement for Goto-san as Program Director.

#### DMP Post 2020

- Option A (where the matrix structure is retained) is preferred: it minimizes the barriers between drug discovery and RIKEN technologies, and maximizes the opportunities to access future novel technology developments that might enhance drug discovery programs. However, the issues concerning incentives and reward for DMP and for investigators need to be addressed to make this option a success
- Options B, C and D raise additional barriers to accessing cutting edge technologies by drug discovery projects, and also run contrary to RIKEN's objectives.
- Option E fails to achieve RIKEN's objectives to maximize the impact of novel technologies and to deliver social benefit.

Recommendations from the CIPAC to President Hiroshi Matsumoto

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|-------|---|--|
| TOR 1 | <ul style="list-style-type: none"> <li>- Integration of world-class technologies (e.g. tankyrase)</li> <li>- Unique iPSC expertise in DMP</li> </ul>  | <ul style="list-style-type: none"> <li>- Poor incentives for DMP or RIKEN researchers involved in drug discovery activities</li> </ul> |
|       | <ul style="list-style-type: none"> <li>- Option A is preferred: it minimizes barriers between drug discovery and RIKEN technologies, and maximizes the opportunities to access novel technologies.</li> <li>- Options B, C and D raise additional barriers to reduce this access.</li> <li>- Option E fails to achieve RIKEN's goal to maximize impact of novel technologies</li> </ul>   |  |
| TOR 3 | <ul style="list-style-type: none"> <li>- A model framework for drug discovery for academia (e.g. iPSC, cell therapies)</li> <li>- Accessed and integrated RIKEN technologies for drug discovery</li> <li>- Attracted experienced staff to boost capabilities and capacity</li> </ul>  |  |
|       | <ul style="list-style-type: none"> <li>- Efforts to improve the molecular dynamics algorithms are to be encouraged</li> <li>- Benchmark progression rates with industry norms</li> <li>- Enlargement of the compound library for HTS is encouraged</li> <li>- Natural product screening (of iPSC phenotypes) will broaden the diversity of the screening library, coupled to computation chemistry</li> <li>- Regular interactions with RIKEN centers encouraged</li> </ul> |  |
| TOR 4 | <ul style="list-style-type: none"> <li>- Trail-blazing cell therapies (e.g. regulatory issues) for others to follow</li> <li>- Potential to increase the efficiency and competitiveness of Japanese industry</li> <li>- Integrating the culture of academia and industry</li> </ul>   |  |

## CIPAC2016

### Preventive Medicine and Diagnosis Innovation Program (PMI) Working Group REPORT

#### PMI-AC subcommittee Tasks

The PMI-AC subcommittee evaluated the PMI, taking into account the Terms of Reference (TOR) defined by the Executive Directors of RIKEN, in conjunction with the mission and specific characteristics of the PMI. The body of this document presents TOR items and the results of the evaluation. Elements of the TOR that are not relevant to the PMI evaluation have been excluded. For reference purposes, TOR items that have been evaluated and addressed in the report are listed at the end.

#### General Considerations for the Advisory Council in Assessing Various Tasks and TOR

- The PMI mission continues to be important, both to RIKEN and to society as a whole [TOR1]

The PMI was established in 2013 with a staff of 11, headed by Yoshihide Hayashizaki as Program Director. In a 2014 report, this subcommittee offered advice on the foundation and direction of the PMI. The PMI has continued to show steady progress, in line with RIKEN's vision of creating social and commercial value through innovative projects rooted in research.

Responding to the needs of the medical treatment field and business by using RIKEN's technology seeds to help hospitals implement the latest treatment technologies is an important aspect of RIKEN's contribution to society. PMI-AC recognizes PMI's activities and progress over the last 3 years and evaluates them highly. In response to the current challenges facing Japanese society (a decreasing birthrate and aging population), the PMI proposes the extension of healthy life expectancy as one potential solution.

- Given the context of severe budget constraints, we support the way in which RIKEN and the PMI have devised a new survival strategy to secure funds for the PMI from external parties, while using RIKEN's research capabilities to achieve cross-sectional goals. RIKEN aims to decrease its ratio of operating expense subsidies to annual income; in this, the PMI is an exceptionally positive model, demonstrating an innovative response to the pressing challenge of financial structural reform. [TOR1, TOR3(3), TOR4]

The operating subsidy budget environment in which the PMI currently operates is totally different from the situation envisaged at the time when the PMI was founded. The operating expenses subsidy budget is substantially lower than it was expected to be: despite the development of numerous cross-sectional projects through individual investigations, it has not been possible to allocate operating expense subsidies to any projects other than the development of a kit for the rapid diagnosis of influenza. For this reason, RIKEN's fiscal reform pilot program has focused on compensating for the decrease in grants that cover operating expenses throughout the organization as a whole. Because the PMI cannot rely on subsidies to cover its operating expenses, a policy turnaround ensured that the bulk of its financial support would come from competitive external funding and organizational consigned research funds. In the future, the PMI's operational methods will offer a useful model for RIKEN's application of science-based activities. The current situation, in which sponsors' wishes are reflected in project themes, should be viewed in a positive way, as evidence of a clearer orientation towards the needs of society. The PMI continues to discover valuable and disparate elements within RIKEN and to link them together while planning creative projects that fit RIKEN's mission. The PMI's approach to research-planning operations should serve as a model for RIKEN as a whole. RIKEN also should give an incentive fund to those who get outside money, since it's a social expectation for RIKEN potential.

- In a challenging environment, the PMI has been producing important outcomes by using an extensive range of approaches and by collaborating with industry to ensure the rapid and appropriate exit of technology to society.
  - A kit that enables fast and precise testing for the influenza virus is an exceptional example of the cross-disciplinary basic research performed by RIKEN researchers. Our collaboration with Japanese organizations aiming to commercialize a superior diagnostic system and transfer this technology to industry is worthy of special mention [TOR1, TOR4].
  - The biomarker research project achieves goals outlined in RIKEN's vision through interdisciplinary research, which may in the future lead to exciting developments in clinical medicine. We eagerly anticipate the practical implementation of recently discovered and clinically significant biomarkers. Testing and practical applications can be achieved only through continued research and business development; in a context of limited resources, appropriately and reduce activities as required. Project development

- capabilities (personnel) must be strengthened. [TOR1, TOR4]
- In one of its first milestones, the PMI established a project on “Development of a portable nucleic acid diagnostic device” (DEPOC) that leverages RIKEN engineering seeds. This project searched for seeds throughout most of RIKEN’s research areas. The project has used genome science expertise to develop a system capable of transmitting medication indexes and alerts (based on individual genome data) to doctors prescribing medication. [TOR4]
  - The needs of hospitals and organizations have been thoroughly considered. Projects such as “Building laboratory-developed tests (LDTs) for genetic diagnosis” have been planned to take advantage of RIKEN seeds. It is particularly impressive that this project has led to the development of standard reference materials for the diagnostic testing of bioresources held by RIKEN BioResource Center (BRC). DEPOC has the potential to provide members of the public with a very powerful tool to manage their own personal health. “A new electronic medical record (EMR) system highlighting genetic test reports” gives important therapeutic information to doctors.
  - The simulation center is a successful example of RIKEN’s ability to link the academic and industrial sectors. It provides a space for future RIKEN research activities, and it can be viewed as an open-innovation science and technology hub. It makes a valuable contribution to the lifelong education of doctors; such education is currently becoming a pressing problem in medical settings. [TOR3(3), TOR4]
  - The PMI has strengthened access to hospitals and clinical samples. In particular, linkages with multiple clinical institutions are extremely important for key biomarker research and the investigation of diagnostic equipment. [TOR 4]
  - The financial reduction in PMI’s operating expenses subsidy budget poses a threat to the program’s autonomous operation. In fact, it prevents PMI from recruiting senior personnel for business development and weakens its ability to plan product exit strategies, ultimately resulting in a loss of opportunities for RIKEN’s future returns and benefit. RIKEN needs to strengthen the PMI’s budget fundamentals and its discretion in employment.
- RIKEN must increase its support and use of the PMI for the purposes of the RIKEN Initiative for Scientific Excellence. Activities such as the development of international cooperation centers with Hamad General Hospital in Qatar and the Kazan Federal University in Russia play an extremely important role in creating

international hubs to support RIKEN. [TOR1, TOR3(3), TOR4].

The PMI is creating comprehensive links with a number of hospitals, including Juntendo University Hospital, to enable RIKEN (which does not itself operate any hospitals) to perform activities that will help advance medicine. As of March 2016, the PMI had conducted more than 565 interviews with hospital doctors to investigate medical treatment needs in detail. Furthermore, to investigate seeds in the majority of RIKEN's active research fields (146 in total), the PMI is leveraging the fact that its Program Director, Yoshihide Hayashizaki, has been with RIKEN for a long time. The PMI has conducted 246 business-needs surveys to explore the field of organizational medical project development. An impressive amount of work has gone into implementing these detailed investigations of RIKEN technology seeds, as well as the medical treatment needs of hospitals and the development needs of organizations. Most of these projects have the potential to create new and unique products that span a wide variety of research fields.

RIKEN faces a situation in which operating cost subsidies are gradually decreasing and even slight growth is difficult. However, the activities of the PMI, under the robust governance of the Board of Directors, are making an important contribution to the RIKEN Initiative for Scientific Excellence and are creating tangible public benefits by linking RIKEN's seeds and research capabilities with the needs of society. We need to diversify research funding and activate the PMI as a pilot program to decrease substantially the rate of dependence on operating expenses subsidies.

#### Recommendations and Conclusions

Despite a challenging operating environment, the PMI, under the robust leadership of Program Director Yoshihide Hayashizaki, continues to develop its clear and solution-focused mission; its talented staff members are hardworking and highly motivated. Given RIKEN's current internal and external environments, we support the PMI strategy of attracting and using external funding. The Advisory Council provides the following recommendations to further improve the PMI, so that it may continue to create important value for both RIKEN and society as a whole.

- RIKEN must provide stable financial resources for its activities to PMI headquarters personnel. [TOR1, TOR3(3), TOR4]
  - It is essential to establish a stable foundation, meeting personnel costs through

operating cost subsidies for headquarters staff members tasked with performing central PMI activities. If this cannot be achieved, then it will not be possible to cultivate external sources of funding or attempt a pilot model in which cross-cutting projects are run by collaborating with medical treatment institutions and other organizations. The 2015 results show that headquarters staffs were supported through operating cost subsidies; an increase in the PMI's income of 1.8 times the operating cost subsidies was achieved through competitive external funding and consignment of research funds to cover the research costs distributed within RIKEN. It is clear that this will become the operating model for RIKEN in the very near future. In the event that an external grant is successfully obtained, the operating subsidy budget should never be reduced as a result

- It is essential that the PMI continues to select and develop activities. The program also needs to strengthen its enterprise development capabilities. [TOR1]
  - Given the fact that PMI enterprises broadly target the area of medical treatment, in which large numbers of products—all with special characteristics— need to be developed, it is important to choose and focus on activities in an appropriate manner. The PMI's enterprise development capabilities also need to be strengthened. To achieve this, operating cost subsidies must be used to employ high-quality, talented personnel who are brimming with entrepreneurial spirit and possess specialist knowledge of competition and business models in the areas of medical treatment and health care.
  
- RIKEN should further organize a taskforce or team to promote the social implementation of its latest technologies. The PMI could be a model for this.
  - If RIKEN intends to obtain external financial resources (other than a government operating subsidy budget) so that it can act as an academic research institute with high autonomy, then collaboration with—and fund-raising from—industry should be seriously considered by top management. To realize this goal, systems should be established that enable investment in private companies.
  - The taskforce or team that will be used to commercialize RIKEN's seeds should involve entrepreneurial personnel with strong track records.

We hereby conclude the report from the PMI-AC.