Regulatory Science Activity Report FY2025

PMDA
独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

CONTENTS

1. PMDA Regulatory Science Activity Report

The Pharmaceuticals and Medical Devices Agency (PMDA) is an incorporated administrative agency established by the Ministry of Health, Labour and Welfare, dedicated to promoting public health and safety through the evaluation and approval of pharmaceuticals and medical devices, safety measures, and relief services for adverse health effects (Figure 1).
(for additional details, visit the PMDA website: https://www.pmda.go.jp/english/index.html).

Figure 1. The Three Roles of PMDA—Safety Triangle

PMDA is required to incorporate the latest scientific knowledge and to make accurate predictions, assessments, and decisions based on clearer evidence. To improve the quality of these operations, the PMDA Regulatory Science Center (RS Center) promotes regulatory science (RS), which serves as the scientific foundation for these efforts.
This activity report introduces RS-related activities conducted by PMDA, including details of activities and annual achievements. In fiscal year 2025 (FY2025), the following major activities are highlighted:

- Collaborative activities with academia
- Science Board that facilitates scientific discussions with experts in various fields
- Cross-cutting projects addressing issues across multiple fields, and organization of symposiums and opinion exchange meetings
- Early Consideration providing reference information to promote the use of new technologies in drug development
- RS research workshops that discuss important themes from published papers with external experts from an RS perspective
- PMDA-involved research activities and dissemination of research outcomes
- Cross-cutting initiatives related to emerging topics, such as New Approach Methodologies (NAMs) and Artificial Intelligence (AI) utilization

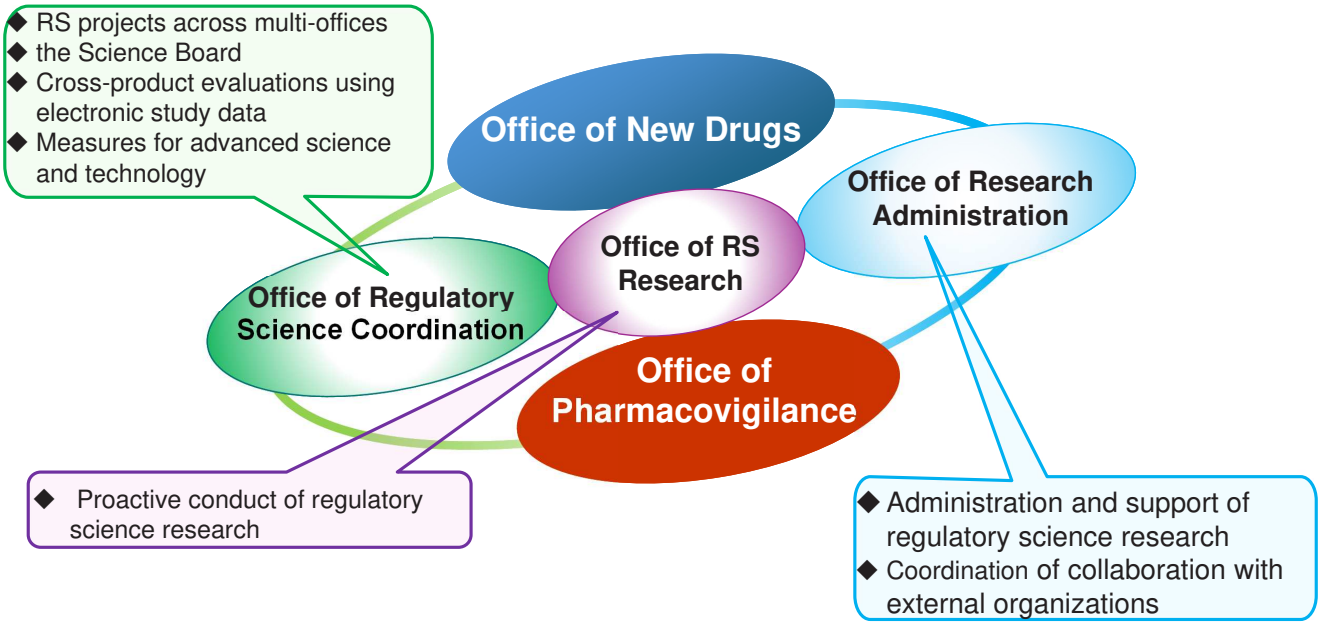
It is expected that publication of this report will widely disseminate PMDA's RS-related activities and serve as a valuable information source for academia, healthcare professionals, patients, and industry stakeholders.

2. Introduction

2.1 PMDA Regulatory Science Center

RS is defined as “the science to make precise prediction, evaluation and judgment based on evidence and adapt the achievements of technology to social and human needs in the most optimal way so that the achievements will help people and the society.”[1] National policy supports the promotion of RS in translating the outcomes of medical research and development into practical use within society. Based on this perspective, PMDA has been implementing various initiatives to promote RS[2].
To further promote RS, PMDA established the RS Center in April 2018. A framework was created to facilitate collaboration among RS-related specialized offices, the review departments, and the safety departments, with the aim of improving operational quality. In July 2023, to strengthen the in-house RS research framework, PMDA established the RS Research Department as a new division dedicated to RS research. Furthermore, in June 2024, PMDA established the RS Strategic Committee as an internal body to address RS-related issues across departments and to formulate policies for implementing RS-related activities more strategically.

Figure 2. Core Activities of the RS Center



1 Basic Program for Science and Technology (approved by the Cabinet on August 19, 2011)
https://www8.cao.go.jp/cstp/kihonkeikaku/4honbun.pdf
2 Law for Promotion of Health and Medical Care Strategy (Law No. 48 of 2014)
https://laws.e-gov.go.jp/law/426AC0000000048

2.2 PMDA Fifth Mid-term Plan and the FY2025 Annual Plan

Based on the mid-term targets issued by the Ministry of Health, Labour and Welfare[3] for the period FY2024–FY2028, PMDA formulated the Fifth Mid-term Plan[4] and established the FY2025 Annual Plan[5] . Activities of the RS Center focus on "strengthening human resources," "enhancing scientific evidence," and "strengthening public communication." The plan aims to further promote RS research and related activities, as well as to actively disseminate RS-related information.

Table 1. Pharmaceuticals and Medical Devices Agency Fifth Mid-term Plan

Improving operational quality through the promotion of RS	
Strengthening human resources	(1) Develop personnel with an understanding of clinical and related settings through exchanges with external institutions, including those with Comprehensive Partnership Agreements • Develop personnel with an understanding of clinical and related settings through exchanges with external institutions, including those with Comprehensive Partnership Agreements • Develop personnel with an understanding of clinical and related settings through exchanges with external institutions, including those with Comprehensive Partnership Agreements. Expand opportunities to learn about clinical practice through personnel exchange, opinion sharing, and external training with such institutions. (2) Develop professionals capable of leading scientific discussions through active engagement in RS-related activities. • Expand opportunities to improve logical thinking skills through RS-related training, participation in academic conferences and meetings both in Japan and abroad, and discussions with external experts
Enhancing scientific evidence	(1) Strengthen organizational research capacity by increasing research efforts • Promote development of the research environment, including securing resources necessary for research activities (2) Establish a system for consolidating issues in review and consultation and enabling cross-departmental discussion • Facilitate more systematic examination through organization of information at the RS Center, promotion of discussions in the Science Board, and strengthening of progress management for cross-departmental studies
Strengthening public communications	Publish findings from RS research and related activities in English-language journals and other academic platforms • Improve the environment for publishing research outputs and actively conduct exchanges of opinions with external stakeholders
Contributing to the further utilization of medical information*	(1) Further improve the accessibility of the Medical Information Database Network(MID-NET®) • Improve the usability of the Medical Information Database Network (MID-NET®) by understanding user needs through exchanges with pharmaceutical companies and other stakeholders. Examine approaches to expand data availability and improve system infrastructure. (2) Disseminate information on the standardization and quality control of medical information • Disseminate technological knowledge and expertise related to standardization and quality control obtained through MID-NET® development and operation

*The Office of Medical Informatics and Science, which collaborates in the operation of MID-NET®, was transferred from the RS Center to the Safety Department in April 2026.

3 Pharmaceuticals and Medical Devices Agency 5th Mid-term Target.
https://www.pmda.go.jp/files/000267755.pdf
4 Pharmaceuticals and Medical Devices Agency 5th Mid-term Plan.
https://www.pmda.go.jp/files/000267756.pdf
5 Pharmaceuticals and Medical Devices Agency Annual Plan FY2025.
https://www.pmda.go.jp/files/000277225.pdf

Table 2. Pharmaceuticals and Medical Devices Agency FY2025 Plan

Improving operational quality through the promotion of RS	
Strengthening human resources	(1) Develop personnel with an understanding of clinical and related settings through exchanges with external institutions, including those with Comprehensive Partnership Agreements • Proceed with consideration of specific initiatives in renewing of Comprehensive Partnership Agreemts • Steadily advance initiatives to secure and expand opportunities to learn about circumstances and practices in clinical settings through personnel exchange, opinion sharing, and external training with external institutions, including those with Comprehensive Partnership Agreements (2) Develop professionals capable of leading scientific discussions through active engagement in RS-related activities. • Secure opportunities to improve logical thinking skills, including RS-related training, lectures and discussions with experts at academic conferences in Japan and abroad, and consider ways to enable identification and organization of issues in daily work with a greater awareness of RS perspective • To promote research-related work, proceed with consideration of frameworks for supporting the conduct of research and appropriately evaluating research-related contributions.
Enhancing scientific evidence	(1) Strengthen organizational research capacity by increasing research efforts • Set a high effort rate for research-related work by the Office of RS Research staff and develop research environment, including securing research funds necessary for conducting research, managing their execution, and cooperation with other departments • Promote the development of research environments and organizational structures in preparation for applications for MEXT Grants-in-Aid for Scientific Research (KAKENHI), as a foundation for stable research activities as a designated research institution (2) Establish a system for consolidating issues in review and consultation and enabling cross-departmental discussion • Develop related regulations to establish a system to conduct studies more systematically through organizing information at the RS Center, promoting discussions in the Science Board, and enhancing progress management of cross-department studies
Strengthening public communications	Publish findings from RS research and related activities in English-language journals and other academic platforms • Actively publish the results of RS research-related work in English papers, reports, RS research workshops, and proceed with the improvement of the environment for further strengthening to disseminate information, and improve the environment for publishing research outputs and for disseminating information to external stakeholders.
Contributing to the further utilization of medical information*	(1) Further improve the accessibility of the Medical Information Database Network(MID-NET®) • Understand user needs of MID-NET® through exchanging opinions with pharmaceutical companies and explore ways to improve usability of MID-NET® • Examine data management methods and system infrastructure necessary to accommodate expansion of data size • Continue to review operational methods to ensure stable operation of MID-NET® (2) Disseminate information on the standardization and quality control of medical information • Actively share technological insights and knowledge related to standardization and quality control gained through the development and operation of MID-NET® at explanatory meetings, etc.

*The Office of Medical Informatics and Science, which collaborates in the operation of MID-NET®, was transferred from the RS Center to the Safety Department in April 2026.

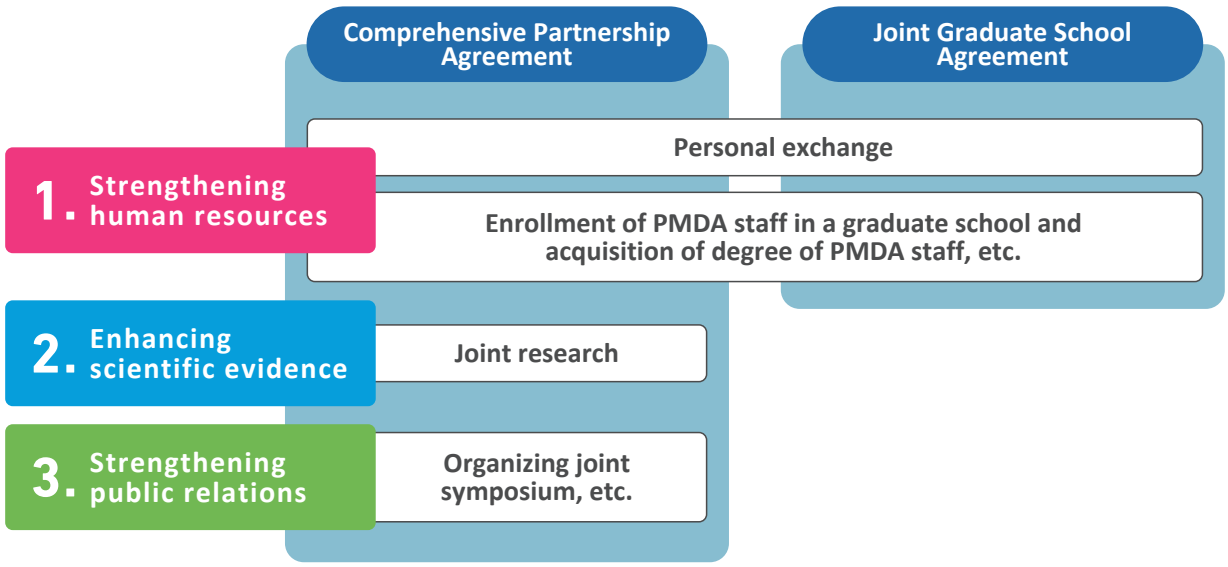
3. RS-related Activities in FY2025

3.1 Strengthening Human Resources

3.1.1 Activities under Comprehensive Partnership Agreement and Joint Graduate School Agreement for Development of RS Human Resources

PMDA has established a system to work in cooperation and collaboration with external organizations, such as universities, incorporated educational institutions, and research & development agencies in order to proactively solve the problems revealed in the course of operations and the issues for the practical application of state-of-the-art technologies. This system includes Comprehensive Partnership Agreements that strengthen human resources (e.g., personnel exchange, academic degree support), enhancing scientific evidence (e.g., joint research), and strengthening public relations (e.g., organizing joint symposium) as well as Joint Graduate School Agreements that primarily aim to strengthen human resources in RS (Figure 3).

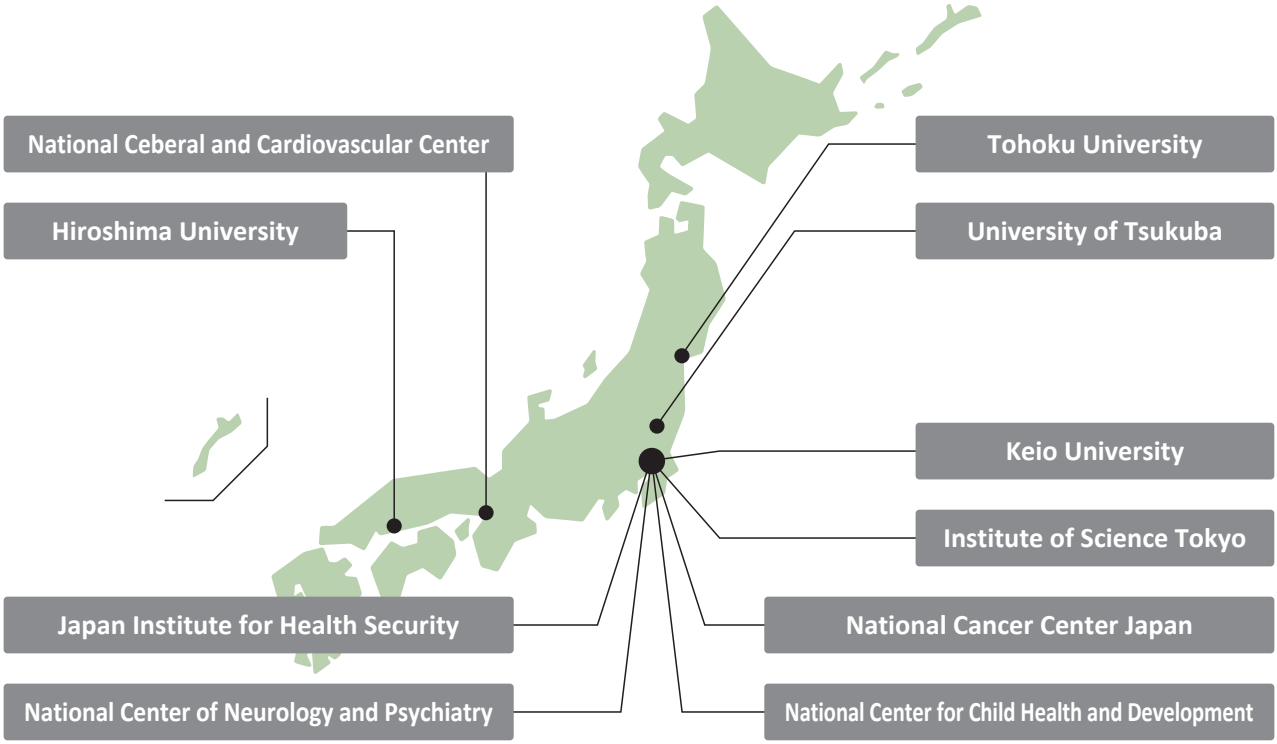
Figure 3. Activities under Comprehensive Partnership Agreement and Joint Graduate School Agreement



Activities conducted under these agreements are meaningful for both PMDA and its partner institutions, in terms of acquiring knowledge related to regulatory science (RS), enhancing understanding of clinical practice and research, and gaining access to the latest scientific technologies and insights. These activities also contribute to the development of personnel capable of leading discussions in the RS field. Furthermore, within PMDA, they contribute to improving the quality of reviews and other operations through the further promotion of RS

As of March 31, 2026, PMDA has concluded Comprehensive Partnership Agreements with 10 organizations (Figure4).

Figure 4. Comprehensive Partnership Agreement Organizations (as of March 31, 2026)



The major activities of each organization under the Comprehensive Partnership Agreement for FY 2025 are shown in Table 3 below.

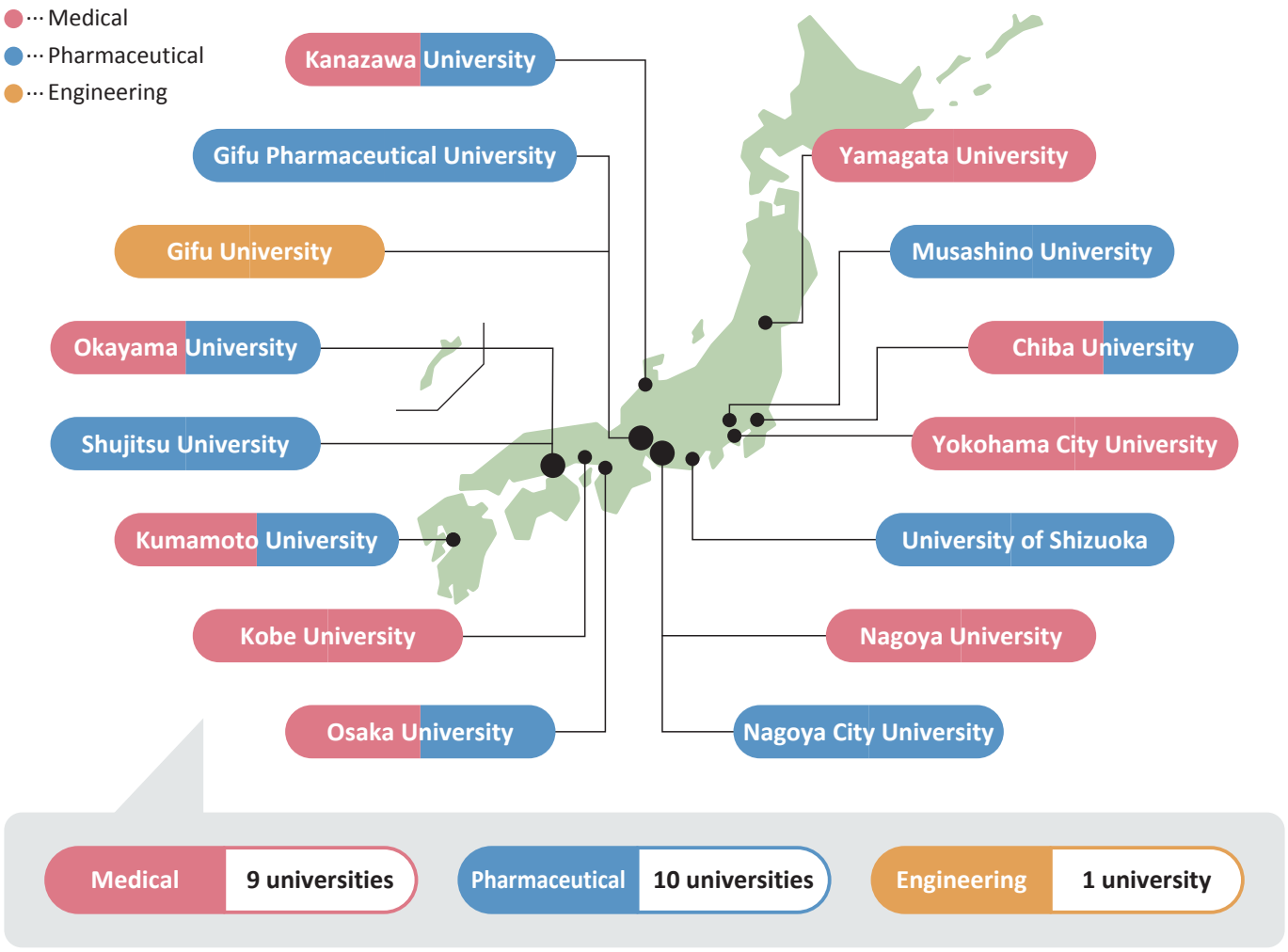
Table 3. Major Activities at the Comprehensive Partnership Agreement Organizations

Contract organizations (In order of the agreement concluded)	Major Activities in FY2025
National Cancer Center Japan Click here for website	• Long-term on-site training for PMDA staff (Pharmaceutical Department / Clinical Trial Management Department) • Training on research ethics for PMDA staff • Activities under the Japan Clinical Trials Methodology Innovation Initiative (JCI2), a joint platform for advancing innovative methodologies in biostatistics and clinical trials • Organizing joint symposiums on pediatric cancer
Hiroshima University Click here for website	• RS-related lectures by PMDA staff at the Graduate School of Biomedical and Health Sciences
Keio University Click here for website	• RS-related lectures by PMDA staff at the Faculty of Pharmacy and the Graduate School of Medicine • Specialized pharmacometrics training programs for PMDA staff • Medical site tours for PMDA staff
University of Tsukuba Click here for website	• RS-related lectures by PMDA staff at the Graduate School of Comprehensive Human Sciences • Medical site tours for PMDA staff
National Center of Neurology and Psychiatry Click here for website	• Committee tour training for PMDA staff (e.g., clinical trial review board) • Facility tours and opinion exchange on approved drugs • Joint research on a therapeutic app for depression
Tohoku University Click here for website	• Joint research on optimization of development and revision of guidelines for proper use of medical devices • Lectures delivered by PMDA staff at faculties of pharmaceutical sciences, graduate schools of pharmaceutical sciences, and graduate schools of biomedical engineering

Contract organizations (In order of the agreement concluded)	Major Activities in FY2025
Japan Institute for Health Security Click here for website	• Long-term on-site training for PMDA staff (Pharmaceutical Department) • Study tour training in clinical trial management for PMDA staff • Joint research on pharmaceutical safety measures
National Cerebral and Cardiovascular Center Click here for website	• Medical site tours for PMDA staff (e.g., clinical sites and nonclinical study labs)
National Center for Child Health and Development Click here for website	• Long-term on-site training for PMDA staff (Pharmaceutical Department) • Organizing joint symposiums on pediatric cancer
Institute of Science Tokyo (formerly Tokyo Medical and Dental University) Click here for website	• RS-related lectures by PMDA staff at the Industry–University Collaboration Council • Joint research in biostatistics • Activities under a joint platform related to biostatistics and clinical trial methodology

Institutions that have concluded Joint Graduate School Agreements as of March 31, 2026 are shown in Figure5.

Figure 5. Joint Graduate School Agreement Organizations (as of March 31, 2026)



In FY2025, to contribute to the development of human resources in the RS area, PMDA dispatched more than 160 staff members to give more than 250 RS-related lectures at more than 60 universities. Of these, RS-related lectures and related activities were given by 15 PMDA staff members under the Joint Graduate School Agreements and by 25 PMDA staff members under the Comprehensive Partnership Agreements. They served as visiting faculty members at the respective institutions.

3.2 Enhancing Scientific Evidence

3.2.1 The Science Board and Measures for Advanced Science and Technology

PMDA has established the Science Board composed of external experts with diverse areas of expertise to deliberate on the scientific aspects of reviews involving pharmaceuticals, medical devices, regenerative medical products, and related fields. The Science Board facilitates the appropriate evaluation and commercialization of advanced science and technology and aims to improve the quality of reviews and safety measures.
To address scientific challenges, PMDA implements timely measures in response to advanced science and technology through consultations and exchanges of opinions with external experts, depending on the context of each theme.
Additional information regarding the Science Board and initiatives related to advanced science and technology is available on the website below.

PMDA website The Science Board Measures for advanced science and technology

In 2025, the following report was published:

Theme

Regulatory Considerations for Developing Phage Therapy Medicinal Products for the Treatment of Antimicrobial Resistant Bacterial Infections

Background and Objectives

As the problem of antimicrobial resistant bacterial infections becomes increasingly serious, bacteriophages (phages) are expected to be a treatment option. Phages are viruses that selectively infect bacteria, replicate within them, and kill them.
In recent years, clinical trials have been conducted for phage therapy medicinal products that are developed to be used for multiple patients with pre-defined strains, compositions, etc., in addition to the personalized phage therapy, where a suitable phage is selected to treat a patient's pathogenic strain.
In this context, from October 2024 to July 2025, a series of Expert Discussions on Measures for Advanced Science and Technology was conducted. Through these discussions, exchanges of opinions were conducted with external experts regarding regulatory considerations for developing phage therapy medicinal products for the treatment of antimicrobial resistant bacterial infections.

Discussion Highlights

- Overview of the characteristics of phage therapy medicinal products and the regulatory frameworks and development trends in Europe and the United States
- Consideration of key issues in the development of phage therapy medicinal products for obtaining regulatory approval in Japan, including a quality control strategy, establishment of manufacturing methods, non-clinical evaluation, and clinical trial design, taking phage characteristics into account and referring also to the Cartagena Act

Results

The report summarizing these discussions, titled
“Regulatory Considerations for Developing Phage Therapy Medicinal Products for the Treatment of Antimicrobial Resistant Bacterial Infections,” was issued as an administrative notice from Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare (January 15, 2026)[6] .
In addition, the report was published as a review article in the scientific journal Frontiers in Pharmacology (December 2025)[7] .
This report is expected to support the appropriate development of phage therapy medicinal products by supplementing existing guidelines and previously issued notifications.

6 https://www.pmda.go.jp/files/000278699.pdf
7 Regulatory considerations for developing phage therapy medicinal products for the treatment of antimicrobial resistant bacterial infections. Front Pharmacol. 2025 Dec 18;16:1713471. doi: 10.3389/fphar.2025.1713471 https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2025.1713471/full

3.2.2 RS Projects Across Multi-Offices in PMDA

PMDA has launched “RS Projects Across Multi-Offices” (established in October 2024) to build a framework for systematically addressing cross-sectional issues in review and safety measures, and proceeding with considerations for publishing concepts and developing guidelines.

The “RS Projects Across Multiple-Offices” comprises two components: a Cross-Sectional Project Team (PT), which is responsible for drafting notifications and guidelines for each project, and an Opinion Exchange Working Group (WG), which facilitates discussions on cross-sectional issues related to review and safety measures.

The objectives of the activities conducted by PTs and WGs are summarized in Table 4.

PMDA website Japanese English

Table 4. Objectives of Activities Conducted by PTs and WGs in RS Projects Across Multi-Offices

Project Team(PT)	Objective of Activity
Project team for Consideration of Inquiries Concerning Pediatric Drugs Development Program*1	• To consider policies regarding inquiries concerning pediatric drug development programs in consultation service and approval review of a new drug development for adults.

Working Group (WG)	Objective of Activity
Multi-Regional Clinical Trials WG	• To standardize internal opinions and responses within the New Drug Department regarding the handling and necessity of Japanese data, including Multiregional Clinical Trials.
Pediatric Drugs WG	• To address various projects related to pediatric drug development through cross-sectional collaboration and by facilitating discussions with both domestic and international stakeholders.
Orphan Drugs WG	• To promote the development of orphan drugs in Japan, this WG disseminates relevant information domestically and internationally and engages in discussions with key stakeholders.
Companion Diagnostics WG	• To facilitate discussions on the rational use and development of companion diagnostics.
Patient Centricity WG	• To promote patient engagement initiatives, including cross-sectoral policy discussions on collaboration with patients.
AI Operations WG*2	• To engage in cross-departmental discussions on the appropriate use of AI in PMDA operations and associated challenges, and to exchange views with external stakeholders as necessary

*1 Following the issuance of the “Initiatives to Promote the Development of Pediatric Drugs” (PFSB/ELD Notification No. 1618 and the RS Center Notification No. 15, dated March 21, 2025) (https://www.pmda.go.jp/files/000274421.pdf), and in light of the achievement of the project team’s objectives, the activities were concluded (activity period: October 2024 to July 2025).

*2 A newly established Working Group that commenced activities in December 2025 (see also Section 4.1 (p.38-41) for AI-related activities)

3.2.2.1 Issuance of notifications and related documents

We are working to improve the quality of reviews and related processes, and to promote understanding of PMDA's perspectives in such processes, by organizing PMDA's views based on the outcomes of cross-sectional project teams and opinion exchange working groups, and by proposing the content of notifications, guidelines, and related documents.
Major notifications issued in FY2025 as a result of cross-sectional discussions are presented in Table 5.

Table 5. Major Notifications, etc. Issued through Cross-sectional discussions (FY2025)

WG/PT	Notifications, guidelines, etc.	Overview
Companion Diagnostics WG	Evaluation Report on Applicability to Drug-agnostic Companion Diagnostics (from the Pharmaceuticals and Medical Devices Agency, dated August 29, 2025) 000276953.pdf / English Version	For companion diagnostic products that detect EGFR gene mutations, the analytical performance results were evaluated. In addition, considerations were advanced regarding the cross-product use of companion diagnostics—i.e., use beyond the conventional framework of "a diagnostic tied to a single specific drug," enabling their application for determining the indications of multiple drugs—and the evaluation approach for such cross-product use was organized. A notification to disseminate the report was also issued.
	Application for Partial Changes Based on Evaluation of Applicability to Drug-agnostic Companion Diagnostics, etc. (EGFR gene mutations in patients with non-small cell lung cancer) (PSB/PED Notification No. 0905-1, PSB/MDED Notification No. 0905-1, PSB/PSD Notification No. 0905-1 , dated September 5, 2025) 000277665.pdf / English Version	
Pediatric Drugs WG	Partial Revision of "Planning of the Pediatric Drug Development Program during Development of Drugs for Adults" (PSB/PED Notification No. 0227-8, dated February 27, 2026) https://www.pmda.go.jp/files/000279515.pdf (Japanese)	In light of the amendment to the Pharmaceuticals and Medical Devices Act in May 2025, under which applicants for approval of new drugs intended for adults are required to make efforts to formulate pediatric drug development plans, the notification "Planning of the Pediatric Drug Development Program during Development of Drugs for Adults" (PSB/PED Notification No. 0112-3, dated January 12, 2024) and the related Questions and Answers (Q&A) were partially revised. As the main concepts of the revision, development of pediatric drugs, the basic principles for such development, and the procedures for confirmation by PMDA were newly added and organized.
	Revision of the Questions and Answers (Q&A) on "Planning of the Pediatric Drug Development Program during Development of Drugs for Adults" (Administrative Notice from the Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare dated February 27, 2026) https://www.pmda.go.jp/files/000279516.pdf (Japanese)	
	Questions and Answers (Q&A) on "Handling of Re-examination Period" (Administrative Notice from the Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare, dated February 27, 2026) https://www.pmda.go.jp/files/000279514.pdf (Japanese)	In connection with the handling of re-examination periods for prescription drugs, and following the partial revision of "Handling of Re-examination Period" (PSEHB/PED Notification No. 0831-16, dated August 31, 2020), a Questions and Answers (Q&A) document was newly compiled. As the main concepts, the need for development of corresponding pediatric drugs at the time of approval of drugs intended for adults, as well as the procedures and considerations related to incentives for such development (i.e., extension of the re-examination period associated with pediatric development), were organized.

3.2.2.2 Holdings of symposia, opinion exchange meetings, and related events

Under the RS Projects Across Multi-Offices, PMDA holds symposia, opinion exchange meetings, and related events to communicate the perspectives and initiatives discussed in the Opinion Exchange Working Group to external stakeholders, and to exchange views with such stakeholders on relevant issues and their possible solutions.
The symposia, opinion exchange meetings, and related events held in FY2025 are shown in Table6.

Table 6. Symposia, Opinion Exchange Meetings, and Related Events Held through Cross-Sectional Discussions in FY2025

WG	Symposia, Opinion Exchange Meetings, and Related Events	Date (Year/Month)
Multi-Regional Clinical Trials WG	Symposium on "Basic principles for conducting phase 1 studies in Japanese prior to initiating multi-regional clinical trials including Japan for drugs in which early clinical development is preceding outside Japan“ (co-hosted by PMDA and domestic and international pharmaceutical industry associations) [HP] https://www.pmda.go.jp/review-services/symposia/0184.html (Japanese)	August 2025
Pediatric Drugs WG	PMDA Pediatric Drug Development Symposium “Toward Enhanced Pediatric Pharmacotherapy: Advancing Together with Domestic and International Stakeholders” (hosted by PMDA) [HP] https://www.pmda.go.jp/review-services/symposia/0185.html (Japanese)	August 2025
	Symposium on Pediatric Oncology Drug Development (co-hosted by academia, industry, and government, including PMDA) [HP] https://www.pmda.go.jp/review-services/symposia/0195.html (Japanese)	January 2026
Patient Centricity WG	Opinion exchange meeting with the Inflammatory Bowel Disease (IBD) network (hosted by PMDA) [PMDA presentation materials (available on the website)] https://www.pmda.go.jp/files/000277476.pdf https://www.pmda.go.jp/files/000277477.pdf	September 2025
	Opinion exchange meeting with PPI Japan (hosted by PMDA)*	December 2025
	The 1st Dialogue Meeting jointly hosted by the National Cancer Center Hospital East (Fairy’s) and PMDA	March 2026

*Patient and Public Involvement (PPI) is an approach in which the experiences and perspectives of patients, their families, and the public are incorporated into healthcare, research, and policy development, with the aim of achieving better healthcare in collaboration with experts.

For the items listed in Table 6 above, one example from each related Working Group is provided below.

(1) Multi-Regional Clinical Trials WG

In the area of international multi-regional clinical trials, a symposium was held on the “Basic principles for conducting phase 1 studies in Japanese prior to initiating multi-regional clinical trials including Japan for drugs in which early clinical development is preceding outside Japan” (Notification No. PSB/PED Notification No. 1225-2, dated December 25, 2023 [Notification on Phase I studies in Japanese subjects]). The symposium aimed to foster a common understanding of this notification among stakeholders from industry, government, and academia, and to promote its appropriate use in future face-to-face consultations and clinical development strategies. A public symposium was held in August 2025, and the panel discussion mainly addressed points that are difficult to interpret in the notification, expectations regarding its issuance, and future perspectives. It was also confirmed that active utilization of international multi-regional clinical trials is desirable to address drug loss and lag.

This symposium was also featured in PMDA Updates.

PMDA Updates 2026 No.1 (p. 4–5)

(2) Pediatric Drug Development

In the area of pediatric drug development, a symposium organized by PMDA entitled “Advancing Pediatric Pharmacotherapy: Working Together with Domestic and International Stakeholders” was held in August 2025.

The symposium introduced recent PMDA initiatives and perspectives aimed at promoting the development of pediatric drugs and sought input from stakeholders across industry, academia, government, and patient representatives, and discussed measures to further advance pediatric drug development (including the issuance of notifications and guidelines). Through lectures and panel discussions involving stakeholders from industry, academia, government, and patient groups (including overseas regulatory authorities), it was shared that Japan’s proactive participation in international clinical trials from early stages of development is important. Furthermore, a commitment was expressed to promote pediatric drug development through collaboration among stakeholders beyond national/regional and organizational boundaries. The discussions at this symposium and PMDA’s related initiatives were also featured in PMDA Updates.

PMDA Updates 2026 No.1 (pp. 2–3)

(3) Patient Engagement

In the area of patient engagement, an opinion exchange meeting with the Inflammatory Bowel Disease (IBD) Network was held in September 2025.

The purpose of the meeting was to provide an opportunity for PMDA staff to gain a concrete understanding of issues faced by patients in their daily lives, and for patients to learn about PMDA, through interactive and specific dialogue.

In the discussion following presentations from both PMDA and the patient side, PMDA staff gained insight into the specific challenges faced by patients in relation to their disease and treatment. It also served as an opportunity for PMDA staff to recognize patients’ expectations for drug development and the presence of patients behind regulatory work.

For patients, the meeting provided an opportunity to better understand the drug development and approval processes in which PMDA is involved.

Overall Summary

Through the above symposia and opinion exchange meetings, PMDA’s perspectives were effectively communicated, and a shared understanding of future challenges was established with external stakeholders. These activities also provided valuable opportunities for continued discussion and collaboration going forward.

PMDA will continue to plan symposia and opinion exchange meetings within each Working Group and actively promote outreach activities.

3.2.3 Analysis using Electronic Study Data

PMDA promotes the cross-product secondary use of Electronic Study Data—study data submitted in electronic format as part of marketing authorization applications—accumulated through its review activities, and is engaged in generating and disseminating knowledge that contributes to facilitating drug development.

In FY2025, in addition to advancing analyses, efforts focused on the external dissemination of results and the development of an information dissemination infrastructure.

Specifically, PMDA established an implementation framework to enable full-scale cross-product analyses, including those using Electronic Study Data. Efforts were made to strengthen human resources, promote and support research using Electronic Study Data, examine analytical methodologies, and develop internal systems related to studies utilizing such data.

Through these initiatives, progress was made in establishing a foundation for continuously conducting analyses using Electronic Study Data and organizing the results into forms suitable for external dissemination.

As part of the dissemination of outcomes, presentations on analyses using Electronic Study Data were delivered at the following meetings:

- PMDA Pediatric Drug Development Symposium (August 27, 2025; oral presentation)
- The 46th Annual Scientific Meeting of the Japanese Society of Clinical Pharmacology and Therapeutics (December 6, 2025; poster presentation)
- Symposium on Anticancer Drug Development for Children (January 31, 2026; oral presentation)

In addition, PMDA created a dedicated webpage on its website for analyses utilizing Electronic Study Data and began disseminating information on these initiatives:
PMDA Regulatory Science – Electronic Study Data

Going forward, in order to enhance and strengthen scientific evidence, PMDA will continuously accumulate case examples of cross-product analyses using Electronic Study Data. It will also strengthen its information dissemination capability to support drug development by systematically sharing information through the dedicated webpage, academic publications, and conferences and symposia. In parallel, based on the accumulated analytical cases, the Regulatory Science Center and review offices will collaborate to set analytical themes and advance methodological sophistication, while further enhancing the infrastructure to enable stable and continuous utilization of Electronic Study Data.

3.2.4 Early Consideration, Guidance, and Guidelines

PMDA promotes approaches based on the latest scientific knowledge through the dissemination of Early Consideration and the development of guidelines.

Early Consideration

What is Early Consideration?

Early Consideration refers to the perspective of PMDA on the potential direction of product development, provided as reference information to support the practical application of innovation and the advancement of innovative drug development, even in situations where scientific knowledge and supporting data remain insufficiently established.

Early Consideration presents PMDA's perspectives at the time of publication regarding the practical application of innovative technologies and considerations related to the development and evaluation of pharmaceuticals. These perspectives may change in the future in response to new knowledge, scientific advances, and discussions with industry and academia.

Achievement

In FY2025, PMDA issued 20 Early Considerations, as listed in Table7, and published them on its website. PMDA intends to continue releasing the corresponding report beyond FY2026.

PMDA website Japanese English

Table7. Early Considerations (FY2025)

Titles	Overview
Early Consideration on Handling of Japanese Data for Confirmation of Comparability of Biosimilars to the Original Biopharmaceuticals, issued by Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency, September 19, 2025 https://www.pmda.go.jp/files/000277274.pdf	To further clarify the current regulatory concept for the contents shown in the “Questions and Answers (Q&A) on Guideline for Ensuring the Quality, Safety, and Efficacy of Biosimilars,” we have made the concept clear on Japanese data in the confirmation of compatibility of biosimilars to their original pharmaceuticals.
Concept of New Approach Methodologies (NAMs) use in quasi-drug applications, issued by Office of OTC / Quasi-drugs, Pharmaceuticals and Medical Devices Agency, September 25, 2025 https://www.pmda.go.jp/files/000277385.pdf	In recent years, interest in New Approach Methodologies (NAMs) has been increasing internationally from the perspective of animal welfare. Based on this trend, the current regulatory perspective on the use of NAMs in applications for quasi-drugs has been organized.
Mock-up of Application Form for Confirmation of Change Management Protocol, etc. Related to Change of Strains for Influenza Vaccine or COVID-19 Vaccine, issued by Office of Vaccines and Blood Products, Pharmaceuticals and Medical Devices Agency, October 3, 2025 https://www.pmda.go.jp/files/000280545.pdf	For influenza and COVID-19 vaccines, the production strains and antigen strains to be used in manufacturing are recommended and selected annually around spring by the World Health Organization (WHO) or the Ministry of Health, Labour and Welfare (MHLW) , and it is necessary to complete the regulatory procedures for strain changes within a short period by around the autumn. To reduce the burden of such procedures, the handling and operational approach has been organized so that the Post-Approval Change Management Protocol (PACMP) system can be utilized for strain changes.

Thoughts on the Use of Weight of Evidence Approach in Nonclinical Safety Evaluation, issued by Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency, October 24, 2025 https://www.pmda.go.jp/files/000278903.pdf	Based on the promotion of the 3Rs(reduce, refine, replace) in animal experiments and recent advances in New Approach Methodologies (NAMs), the current perspective on the use of the Weight of Evidence approach in nonclinical safety evaluation of pharmaceuticals and regenerative medical products has been organized.
Use of the Weight of Evidence approach as an alternative to nonhuman primate developmental and reproductive toxicity testing for biopharmaceuticals, issued by Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency, October 24, 2025 https://www.pmda.go.jp/files/000278904.pdf	As an example of the document “Thoughts on the Use of Weight of Evidence Approach in Nonclinical Safety Evaluation” dated 24 October 2025, we have summarized the current concept regarding using the Weight of Evidence approach as an alternative to developmental and reproductive toxicity testing in nonhuman primates for biopharmaceuticals
Quality of Fecal Microbiota Transplantation (FMT) Products at the Initial Development Stage, issued by Office of Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency, October 31, 2025 https://www.pmda.go.jp/files/000278117.pdf	In developing fecal microbiota transplantation (FMT) products, assessing the eligibility of fecal donors is critical for ensuring product safety. This document aims to present the current regulatory perspective on quality considerations for FMT products during their initial development.
Points to Consider for Clinical Development of Drugs Intended for Treatment of Psoriatic Arthritis, issued by Office of New Drug IV, Pharmaceuticals and Medical Devices Agency, November 13, 2025 https://www.pmda.go.jp/files/000277950.pdf	Based on the domestic clinical practice guidelines for Psoriatic arthritis (PsA) and the recent development landscape of PsA therapeutics in Japan, we have compiled key considerations for the clinical development of PsA drugs.
Considerations for Non-clinical Studies of Combination Prescription Drugs with Similar Formulations, issued by Office of New Drug II, Pharmaceuticals and Medical Devices Agency, November 18, 2025 https://www.pmda.go.jp/files/000278253.pdf	This document outlines considerations regarding new pharmacologic and toxicology studies prior to marketing authorization application submission for combination prescription drugs with similar formulations.
Points to Consider for the Efficacy Evaluation of Drug for IgA Nephropathy, issued by Office of New Drug I, Pharmaceuticals and Medical Devices Agency, December 24, 2025 https://www.pmda.go.jp/files/000278438.pdf	IgA nephropathy is a designated intractable disease that can progress to end-stage renal disease, but no standard treatment has yet been established. Given that the development of new therapeutic drugs for IgA nephropathy continues worldwide, this document summarizes key considerations for evaluating their efficacy.
Principles on Development of Combination Ophthalmic Solutions for Glaucoma, issued by Office of New Drug III, Pharmaceuticals and Medical Devices Agency, January 15, 2026 https://www.pmda.go.jp/files/000279888.pdf	The purpose of this document is to present points to consider, etc. when planning confirmatory studies to be conducted during the development of combination ophthalmic solutions for glaucoma containing only approved active ingredients for the treatment of glaucoma and ocular hypertension in Japan.
Points to Consider for Replacement of Conventional Tests for Viruses with Next Generation Sequencing (NGS) Assays, issued by Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency, January 22, 2026 https://www.pmda.go.jp/files/000278698.pdf	This document provides the current regulatory considerations for developers and marketing authorization holders who are considering using an NGS assay in place of a conventional test for viruses.
Consideration in the development of drugs for hypertrophic cardiomyopathy, issued by Office of New Drug II, Pharmaceuticals and Medical Devices Agency, January 27, 2026 https://www.pmda.go.jp/files/000278942.pdf	Drug therapy for hypertrophic cardiomyopathy (HCM) has historically focused on symptomatic treatment. However, given the recent progress in developing agents that directly target the underlying disease mechanisms, this document summarizes key considerations for planning clinical trials aimed at developing new therapeutics for HCM.

Considerations on Utilization of the Platform-based Approach in Non-Clinical Safety Evaluation of mRNA-LNP Vaccines for Prevention of Infections, issued by Office of Vaccines and Blood Products, Pharmaceuticals and Medical Devices Agency, February 6, 2026 https://www.pmda.go.jp/files/000280547.pdf	The purpose of this document is to outline the concept for the utilization of a platform-based approach in non-clinical safety evaluation of mRNA-LNP vaccines for prevention of infections.
Considerations for clinical development of intravenous formulations containing the same active ingredient as oral products for patients who are temporarily unable to receive oral administration in epilepsy treatment, issued by Office of New Drug III, Pharmaceuticals and Medical Devices Agency, March 3, 2026 https://www.pmda.go.jp/files/000279991.pdf	The purpose of this document is to present basic considerations for clinical development of intravenous formulations containing the same active ingredient as oral formulations for patients who are temporarily unable to receive oral administration in epilepsy treatment.
Points to Consider in the Clinical Development of Radiopharmaceuticals for Positron Emission Tomography Targeting Prostate-Specific Membrane Antigen (PSMA-PET) , issued by Office of New Drug II, Pharmaceuticals and Medical Devices Agency, March 9, 2026 https://www.pmda.go.jp/files/000279587.pdf	The purpose of this document is to outline considerations for clinical development to facilitate the introduction into Japanese clinical practice of radiopharmaceuticals for PSMA-PET that are approved in Europe and/or the United States, with recommended use in the initial staging and detection of biochemically recurrent prostate cancer.
Considerations for Pre-specifying the Change Categories for Manufacturing Process Parameters Identified as Established Conditions for Drug Products (Chemical Products), issued by Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency, March 12, 2026 https://www.pmda.go.jp/files/000279889.pdf	This document summarizes the basic approach to pre-specifying change categories for process parameters to be described in the application (i.e., partial change approval application or minor change notification), on the premise that Established Conditions for the manufacturing process have been identified in accordance with the concepts described in the ICH Q12 Guideline.
Points to Consider in the Clinical Development of In Vivo Diagnostics, issued by Office of New Drug II, Pharmaceuticals and Medical Devices Agency, March 12, 2026 https://www.pmda.go.jp/files/000280748.pdf	The purpose of this document is to outline fundamental considerations for the clinical development of in vivo diagnostics, including diagnostic radiopharmaceuticals.
“Supplementary Explanation on Points to Consider When Preparing Biological Diversity Risk Assessment Reports for Applications for Approval of Type 1 Use Regulations (February 2026 Version) ” and “Example Descriptions of Biological Diversity Risk Assessment Reports for Adeno-Associated Virus (AAV) (February 2026 Version),” issued by Cellular and Tissue-based Products, Pharmaceuticals and Medical Devices Agency on March 16, 2026 https://www.pmda.go.jp/files/000279549.pdf (Japanese)	This document provides supplementary explanations on points to consider in the assessment of biological diversity risk required for applications for approval of Type 1 Use Regulations for products containing living modified organisms, particularly addressing considerations when using genetically modified viruses. In addition, it presents a revised example of how to prepare a biological diversity risk assessment report for products using adeno-associated virus (AAV).
Points to Consider for Small Clinical Trials, issued by Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency on March 19, 2026 https://www.pmda.go.jp/files/000280490.pdf	This document outlines key considerations for planning small clinical trials, as well as the explanations required for clinical trial consultations and marketing approval applications.
Points to Consider for the Evaluation of the Effects of Food on the Pharmacokinetics of Oral Drug Products, issued by Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency, March 30, 2026 https://www.pmda.go.jp/files/000279989.pdf (Japanese)	This document aims to present the points to consider for evaluating the effects of food on pharmacokinetics using food-effect clinical studies conducted with formulations other than the final formulation.

Guidance and Guidelines

Table 8 lists the guidance and guidelines (excluding Early Consideration, RS Projects Across Multi-Offices-related matters, and ICH Step 5 guideline notifications) issued or co-issued by PMDA in FY2025.

Table8. Guidance and Guidelines (FY2025)

Titles	Overview
Partial Revision of "Handling of Changes to Approved Product Information Pertaining to the Quality of Drugs", PSB/PED Notification No. 0409-1 and PSB/CND Notification No. 0409-1, issued by Director of Pharmaceutical Evaluation Division and Director of Compliance and Narcotics Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare on April 9, 2025 https://www.pmda.go.jp/files/000280115.pdf (Japanese)	This notification clarifies that prior procedural consultation with the PMDA is no longer uniformly required for rationalized descriptions in the specification column in approval application forms.
Rationalization of Descriptions in the specification column for Biopharmaceuticals, Administrative Notice, issued by Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare on April 9, 2025 https://www.pmda.go.jp/files/000280116.pdf (Japanese)	This administrative notice presents examples of rationalized descriptions in the specification column in approval application forms for biopharmaceuticals.
Review Points of Biological Safety Evaluation for Market Approval of Medical Devices, issued by Pharmaceuticals and Medical Devices Agency on June 4, 2025 https://www.pmda.go.jp/files/000276197.pdf	This document outlines review points for biological safety evaluation in medical device market approval applications in Japan, together with information on ISO 10993-1 and JIS T 0993-1.
Handling of Application for Confirmation of Change Protocol Related to Change of Strains for Influenza Vaccine or COVID-19 Vaccine, PSB/PED Notification No. 1003-1, issued by Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare on October 3, 2025 https://www.pmda.go.jp/files/000278427.pdf	This document organizes the handling of changes in approved items using a change protocol, when production strains or antigen strains used in the manufacture of influenza vaccine or COVID-19 vaccine need to be changed.
Questions and Answers (Q&A) about Handling of Application for Confirmation of Change Protocol Related to Change of Strains for Influenza Vaccine or COVID-19 Vaccine, Administrative Notice, issued by Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare on October 3, 2025 https://www.pmda.go.jp/files/000278426.pdf	Questions and Answers (Q&A) about Handling of Application for Confirmation of Change Protocol Related to Change of Strains for Influenza Vaccine or COVID-19 Vaccine.
Application of ICH Guidelines to Generic Drugs and Related Products, PSB/PED Notification No. 1117-1, issued by Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare on November 17, 2025 https://www.pmda.go.jp/files/000280149.pdf (Japanese)	This notification summarizes the policy on applying certain ICH guidelines to generic drugs in order to promote international regulatory harmonization, to enhance the transparency of review standards for generic drugs, and to enable scientifically sound and flexible quality control tailored to product characteristics.
Questions and Answers (Q&A) on the "Application of ICH Guidelines to Generic Drugs and Related Products", Administrative Notice, issued by Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau, Ministry of Health, Labour and Welfare on November 17, 2025 https://www.pmda.go.jp/files/000280150.pdf (Japanese)	This document provides a Questions and Answers (Q&A) on the application of ICH guidelines to generic drugs and related products.

3.2.5 Research Based on Public Research Funding

PMDA also participates in public research activities.
PMDA staff contribute to the promotion of research as Regulatory Science (RS) experts within public research groups and collaborate with external researchers to address various issues.

3.2.5.1 Research Based on Health Labour Sciences Research Grants and AMED Funding

In FY2025, PMDA staff were involved as principal investigators or co-investigators in a total of 21 public research groups. The research topics are outlined in Table 9 below. For detailed information such as research results reports, please refer to the relevant webpages listed below.

- Health Labour Sciences Research Grant database:
  https://mhlw-grants.niph.go.jp/
- Japan Agency for Medical Research and Development (AMED) project results:
  https://www.amed.go.jp/seika/

Table 9. Public Research Projects Involving PMDA Executives and Employees (FY2025)

Health Labour Sciences Research Grant

Research Area/Category	Research Title
Regulatory Science Research Project on Pharmaceuticals and Medical Devices	Research on improving the environment for the promotion of multinational clinical trials in the Asian region
	Research on optimization and development of guidelines for proper use of medical devices
	Research on environmental development for establishing and selecting general names for medical devices and in vitro diagnostics
	Study on the Utilization of PGF2α Products for Labor Induction and the Evaluation of the Efficacy and Safety of Their Dosage and Administration
	A Study on Quality Management and Standardization of Healthcare Information Databases with Consideration of International Harmonization for Appropriate Drug Safety Evaluation
	A Study on Approaches to Collecting and Providing Information on the Safety of Drugs in Pregnant and Lactating Women
	Project to promote human resource development for future acquisition of international standards in Japan (medical devices sector)
Comprehensive Research on the Promotion of Cancer Control	Study to establish a psychosocial support system and a safe long-term specimen storage system in cancer and reproductive medicine for pediatric, adolescent, and young adult patients with cancer, aimed at improving survivorship
Health and Labour Sciences Special Research	A Survey Study for Considering Marketing Authorization Applications for Generic Drugs That Are Chemically Synthesized Products Corresponding to Recombinant Biopharmaceutical Originator Products
	A Comprehensive Study on Risk Assessment and Validity Evaluation in Emerging Technology Areas Related to Regenerative Medicine
	A Study on Ensuring Cybersecurity for Medical Devices Without Established Cybersecurity Measures
	A Survey Study Toward the Development of Guidelines for the Development and Related Activities of Prototype Vaccines for Novel Influenza
	Standardization of Toxicological Terminology and Development of a Database to Contribute to Faster and More Accurate Toxicity Evaluation

ICT Infrastructure Development and Artificial Intelligence Implementation Research Program for Clinical Research and Related Studies	A Study to Promote the Preparation of Documents Related to Marketing Authorization Applications and Reviews Using Generative AI

AMED Project

Research Area/Category	Research Title
Pharmaceutical Regulatory Coordination and Evaluation Research Program	A Study on Type 1 Use Regulations under the Cartagena Act for the Initiation of Clinical Trials of Adeno-Associated Virus Vectors (AAVs)
	Research contributing to development of domestic infrastructure for evaluation methods, etc. to ensure the quality and safety of drugs and promotion of international harmonization
	Research on life cycle management in pharmaceutical manufacturing and management and evaluation methods using advanced techniques
	A Study on Quality and Clinical Evaluation in Response to Changes in the Regulatory Framework for Biosimilar Approval
Development of Basic Technology for Drug Discovery for Next-Generation Treatments and Diagnostics	Research on development of internationally-competitive, next-generation antibody drug manufacturing technology / technical research on physical properties, quality evaluation, and management methods toward practical application of next-generation antibody drugs / technical research on quality evaluation and management methods toward practical application of next-generation antibody drugs
Practical Research Project for Regenerative Medicine	International Standardization of a Novel NGS-Based Viral Safety Evaluation Method for Gene Therapy Products and Cell-Processed Products
Drug Discovery Infrastructure Promotion Research Project	Development of viral safety evaluation methods for exosome-based products

3.2.5.2 Research Based on Grants-in-id for Scientific Research

To enhance the quality of regulatory review, safety measures, and relief services for adverse health effects, PMDA has promoted the conduct of RS research within the organization and has worked to utilize research outcomes in its operations.

As part of strengthening organizational research capabilities, PMDA established the Office of Regulatory Science Research within the RS Center in 2023. Furthermore, in 2024, PMDA applied for designation as a research institution under the Grants-in-Aid for Scientific Research (KAKENHI) program of the Ministry of Education, Culture, Sports, Science and Technology (MEXT), and the Office of Regulatory Science Research was designated accordingly, enabling PMDA to conduct research funded by KAKENHI. In FY2025, the designation was maintained, and PMDA applied for KAKENHI funding, resulting in the adoption of two research projects. Going forward, PMDA will continue to promote research activities based on KAKENHI while further strengthening its organizational structure to ensure stable research implementation.

3.3 Strengthening Public Communication

3.3.1 PMDA RS Research Workshop

PMDA holds PMDA RS Research Workshops to proactively disseminate the findings and related information of Regulatory Science (RS) research conducted by PMDA through presentations by its staff, and to deepen understanding through discussions with external experts.

In FY2025, the 10th and 11th workshops were held, attracting 860 and 587 registered participants, respectively, from industry, healthcare professionals, academia, and students. The 10th workshop focused on the utilization of real-world data (RWD) and real-world evidence (RWE), while the 11th workshop addressed the potential of modeling and simulation (M&S) in drug development. Active discussions were held in both sessions.

Through these workshops, PMDA promoted a deeper understanding of the content and significance of RS research, and shared the latest trends in related fields as well as the importance of collaboration among stakeholders toward problem-solving. PMDA disseminates information through various approaches to promote scientific discussions and improve understanding of RS research conducted by PMDA.

10th RS Research Workshop:
Exploring the Use of RWD/RWE from a Regulatory Science Perspective
25 November 2025

Session 1: Presentations on PMDA Research
1.Early Safety Signal Monitoring Using MID-NET®
2.Association Between Bisphosphonate Use and the Risk of Hypocalcemia in Patients with Renal Impairment
3.Recent Review Cases Involving the Use of RWD/RWE as External Controls and Related Considerations

Session 2: PMDA Presentations on Notifications and ICH Guidelines
1.Overview of the “Points to Consider for External Control Studies” (Early Consideration)
2.General Principles for the Use of RWD/RWE in Pharmacoepidemiological Studies under ICH M14

Session 3: Presentations by External Experts
1.Development of Clinical Research Databases with the Quality and Reliability Required to Support Marketing Authorization Applications
2.Current Status and Future Prospects for the Use of RWD/RWE in Clinical Development from an Industry Perspective
3.Revisiting the Use of Post-Marketing RWD
4.Current Status and Future Perspectives on for the Use of RWD/RWE from the Perspective of Data Holders

Session 4: Panel Discussion

11th RS Research Workshop:
Exploring the Potential of Modeling and Simulation in Clinical Development from a Regulatory Science Perspective
28 November 2026

Session 1: Presentations on PMDA Research
1. Perspectives on the Use of Modeling and Simulation in Drug Development under ICH M15
2. Model-Informed Drug Development (MIDD) in Japan: A Regulatory Perspective
3. Potential of a Time-Realignment Disease Progression Model in Drug Development
4. An Integrated Approach Beyond MABEL

Session 2: Presentations by External Experts
1. Individualized Optimization of Pediatric Pharmacotherapy Using Modeling and Simulation
2. Current Status and Challenges of Physiologically Based Biopharmaceutics Modeling Research in Drug Development
3. Use of Quantitative Systems Pharmacology Models in Drug Development: Survey Findings and Case Studies

Session 3: Panel Discussion

The English titles of individual presentations are unofficial translations prepared by PMDA for the purpose of this report.

3.3.2 Dissemination on Social Media

PMDA disseminates information through Facebook, X, and YouTube on topics such as pharmaceutical and medical device approval reviews, safety measures, relief services for adverse health effects, as well as various events, publicly available materials, and updates on Early Consideration.

This section presents a selection of videos published on YouTube in FY2025 (Table 10), focusing on introductory videos of research papers authored by PMDA staff. The content of these papers has been summarized in a clear and accessible manner so that it can be easily understood by the general public.

For more information, please refer to PMDA's official social media channels.

PMDA official Facebook X YouTube

Table10. List of RS-related YouTube Videos (Click the image to view)

Videos Introducing Research

Videos Introducing Research These videos introduce research papers and provide an overview of studies conducted by PMDA staff.

	**Regulatory Evolution to Expedite Drug Development in Japan: A PMDA Initiatives** Introduces PMDA initiatives to promote understanding of Japan's regulatory framework among overseas startups, support for drug development including in Japan, and efforts to address issues such as drug loss. (Audio and slides are in English with Japanese subtitles) https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.70022 (Clinical Pharmacology & Therapeutics)
	**Trend Analysis of Non-clinical Safety Studies (GLP Studies) for Pharmaceuticals** Presents the results of an analysis of trends in GLP-compliant non-clinical safety studies submitted to PMDA with marketing authorization applications over the past six years. https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2025.1591433/full (Frontiers in Pharmacology)
	**Can Real-World Data (RWD) Be Used for Evaluating Drug Efficacy? — Use Cases and Considerations in Review** Introduces research examining the use of RWD in marketing authorization reviews in Japan https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.3540 (Clinical Pharmacology & Therapeutics)

3.3.3 PMDA Institutional Repository

PMDA actively publishes the results of regulatory science (RS) research and other outcomes in peer-reviewed academic journals.

In line with the “Basic Policy on Immediate Open Access to Scholarly Publications” (Integrated Innovation Strategy Promotion Council, February 16, 2024), PMDA has also established its own open access policy.

In accordance with this policy, PMDA has developed and prepared an environment that enables anyone to easily access, search, and view publications and research outputs by PMDA staff through the PMDA institutional repository.

The repository accumulates RS research outputs and related publications, and these resources are available free of charge. We encourage their active use.

- PMDA Open Access Policy
  https://pmda.repo.nii.ac.jp/search?page=1&size=100&sort=pyear&search_type=2&q=1760677156120
- PMDA Institutional Repository (publicly available from April 2026)
  https://pmda.repo.nii.ac.jp/?page=1&size=100&sort=pyear

3.3.4 Overview of Major Publications in FY2025

In the following pages, selected major English-language academic papers published in FY2025 are introduced.
Each paper is accompanied by a summary and commentary provided by PMDA authors.
Please note that these commentaries reflect the personal views of the authors and do not necessarily represent the official views of PMDA.
The commentaries include explanations newly prepared for this report and may contain excerpts from the original publications

Perspective of the Pharmaceuticals and Medical Devices Agency on Drug Development for Childhood Myopia

Relevant articles PubMed

Perspective of the Pharmaceuticals and Medical Devices Agency on Drug Development for Childhood Myopia
Arima M, Atsumi M, Takeuchi K, Aoki T, Inagaki E, Kobayashi Y, Kageyama T, Izumi K, Yoshimura A and Asakura W
Clin. Pharmacol. Ther.2026; 119(1): 26-9. Epub 20251003 doi: 10.1002/cpt.70086

New Drug Review Division III, Kumiko Takeuchi

Background

Myopia typically begins in childhood. An earlier onset is associated with a faster progression of the condition, as well as an increased risk of pathological myopia and severe visual impairment later in life. Therefore, it has become an important global public health issue. The prevalence of myopia is particularly high in East Asia, where it is considered to progress rapidly. This creates a need for the development of treatments that can slow myopia progression.
In this context, the low-concentration atropine ophthalmic solution (Ryjusea Mini Ophthalmic Solution 0.025%), hereafter referred to as “the product”, was approved in Japan as the first drug indicated for pediatric progressive myopia. This article outlines the review process for the product. Based on the findings obtained through the review, it presents the PMDA’s perspective and key considerations for the future development of drugs aimed at slowing myopia progression.

Summary

The randomized, double-masked, placebo-controlled, parallel-group comparative study was conducted on Japanese patients aged 5–15 years with mild to moderate progressive myopia.
The primary endpoint was the change from baseline in cycloplegic objective spherical equivalent refractive error (SERE), and the secondary endpoints included the change from baseline in axial length (AL). The primary evaluation time point occurred 24 months after treatment initiation. An additional 12 months were allotted to evaluate post-treatment rebound and the long-term efficacy and safety.
The superiority of the product over the placebo was demonstrated for the primary endpoint at month 24, and this treatment effect was maintained through month 36. Although an increased rate of myopia progression was observed after treatment was discontinued, there was no abrupt worsening beyond that experienced by the placebo group for at least 12 months.
In terms of safety, no serious safety concerns were identified. The main adverse events were associated with mydriasis and included photophobia. These events were considered manageable with the appropriate precautions. Based on this review, the product has been approved for the indication of slowing the progression of myopia.

Key considerations for future development include:

- As myopia progression rates differ among racial groups, clinical trials including Japanese subjects are required for approval in Japan.
- Principally, a randomized, placebo-controlled trial is required. However, post-approval ethical concerns may necessitate use of RYJUSEA as a comparator in superiority or non-inferiority trials.
- The confirmatory trials should enroll patients with progressive myopia. Eligibility criteria, such as SERE and age, should be based on the investigational drug's anticipated clinical positioning and expected post-approval use.
- The primary endpoint should be SERE and the secondary endpoint should be AL. Due to the need for long-term treatment and consideration of seasonal variation, clinical trials should generally be conducted for at least three years. This includes two years to evaluate efficacy and one year to assess rebound. Because myopia is irreversible, it is advisable to establish a rescue treatment protocol in case of rebound progression after treatment discontinuation.
- However, the appropriateness of each clinical trial's design should be assessed on a case-by-case basis according to the characteristics of the investigational drug.

Impact on RS

This paper presents the regulatory perspective on evaluating drugs for myopia progression and offers considerations for their development. It is expected to contribute to the advancement of future drug development in this field.

Current Status and Issues with CAR-T Cell Products in Japan: A Regulatory Perspective

Relevant articles PubMed

Current status and issues with CAR-T cell products in Japan: a regulatory perspective
Nakamura M, Noda S, Nishikawa A and Matsumoto J
Int. J. Hematol. 2026. Epub 20260309 doi: 10.1007/s12185-026-04189-z

Office of Cellular and Tissue-based Products Review, Miki Nakamura

Background

Since tisagenlecleucel was approved in the United States in August 2017 as the world's first chimeric antigen receptor (CAR)-T cell therapy, five CAR-T cell products have been approved in Japan since March 2019 for the treatment of hematologic malignancies, including lymphoma and multiple myeloma.
Although CAR-T cell therapy is highly effective, it is associated with several challenges, including high cost, manufacturing issues, and safety concerns. In particular, autologous CAR-T cell products are manufactured from patient-derived T cells, resulting in substantial inter-patient variability in product quality, and may occasionally lead to out-of-specification (OOS) products.
This report describes key issues and considerations in the regulatory review of CAR-T cell products by the Pharmaceuticals and Medical Devices Agency (PMDA), with a focus on OOS products and adverse events.

Summary

All CAR-T cell products approved in Japan have been designated as orphan regenerative medical products and, as a result of priority review, have been granted standard approval rather than conditional and time-limited approval.

In addition to the “indications” described in the package insert, the optimal clinical use guidelines specify the patient populations considered appropriate for administration from the perspectives of efficacy and safety.
Because CAR-T cell products are therapies using autologous cells, regulatory review requires perspectives distinct from those applied to conventional pharmaceuticals. In Japan, reviews have been conducted with reference to relevant guidance, including the “Guidelines on Cancer Immunotherapy Development” (March 8, 2019). Related guidelines have also been established by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA).
For the five CAR-T cell products approved to date, no major differences have been observed between Japan and Western regions in the evaluation of non-clinical and clinical data, and no issues affecting approval decisions have been identified.
However, experience with CAR-T cell products remains limited in terms of the number of treated patients and duration of follow-up, and the possibility of unknown adverse events cannot be excluded. In addition, given the extremely high cost of therapy, considerations of health economics are essential.
Furthermore, as a challenge specific to regenerative medical products, out-of-specification (OOS) products exist. In Japan, OOS products are currently administered as investigational products in clinical trials. The efficacy and safety of OOS products have not been established; therefore, it is important not only to reduce the occurrence of OOS through improvements in manufacturing processes, but also to continuously collect information on quality, efficacy, and safety

Impact on RS

The development of CAR-T cell products is expected to continue to advance actively.
Providing information on key review points at the PMDA and on out-of-specification (OOS) products is expected to contribute not only to the development of CAR-T cell products but also to their appropriate use in clinical practice.

Clinical evaluation of medicines for patients with mild cognitive impairment and mild dementia due to Alzheimer's disease in Japan

Relevant articles PubMed

Clinical evaluation of medicines for patients with mild cognitive impairment and mild dementia due to Alzheimer's disease in Japan
Yanagihara R
Alzheimers Dement (N Y). 2025; 11(2): e70100. Epub 20250513 doi: 10.1007/s12185-026-04189-z

New Drug Review Division II, Reiko Yanagihara

Background

Lecanemab and donanemab were approved in Japan in 2023 and 2024, respectively, for the treatments of mild cognitive impairment and mild dementia due to Alzheimer’s disease (hereinafter, early AD). Regulatory decisions regarding these two products differed among authorities in Japan, the United States, Europe, and the United Kingdom. In particular, lecanemab was initially not recommended for approval in Europe, and was subsequently approved for a restricted patient population after re-evaluation. However, reimbursement has not yet been granted in many countries.
This paper describes the PMDA’s perspective on the clinical evaluation of therapies for early AD in Japan, including the role of Minimal Clinically Important Difference (MCID) in benefit-risk assessment.

Summary

At present, the Clinical Dementia Rating–Sum of Boxes (CDR-SB), which assesses both cognitive and functional decline, is one of the most recommended primary endpoints in confirmatory trials. Time to progression analysis should be also conducted to support clinical significance. Biomarker evaluations, particularly amyloid-beta (Aβ) reduction, should be included as secondary endpoints to confirm the mechanism of action.

Though biomarker assessments showed significant Aβ reduction for both anti-amyloid therapies, no direct correlation with clinical outcomes was observed, limiting their use as surrogate endpoints. Therefore, the minimal clinically important difference (MCID) for clinical symptom progression suppression cannot be inferred based on Aβ reduction.

Safety evaluation focused on amyloid-related imaging abnormalities (ARIA), a key risk associated with anti-Aβ antibody treatments. Under the condition where ARIA risk is managed through MRI monitoring and predefined risk mitigation measures, PMDA considers that the benefit-risk (B/R) balance of these anti-amyloid therapies is favorable.

While regulatory approval does not require meeting predefined MCID thresholds, it is based on a comprehensive benefit-risk assessment. For regulatory approval, future drugs will be required to demonstrate a B/R balance equivalent to or more favorable than that of the approved anti-Aβ antibody drugs.

Impact on RS / Future Expectations

To ensure a favorable B/R balance for anti-Aβ antibodies in patients with early AD, robust risk management of ARIA is essential. This requires appropriate patient selection, MRI monitoring, and careful clinical observation, supported by the establishment of a clinical infrastructure. In Japan, the Ministry of Health, Labour and Welfare developed the Optimal Use Guidelines, which specify requirements for physicians and healthcare institutions. These measures have contributed to the implementation of necessary clinical infrastructure for anti-Aβ antibodies under the national health insurance system while helping to maintain a favorable B/R balance.

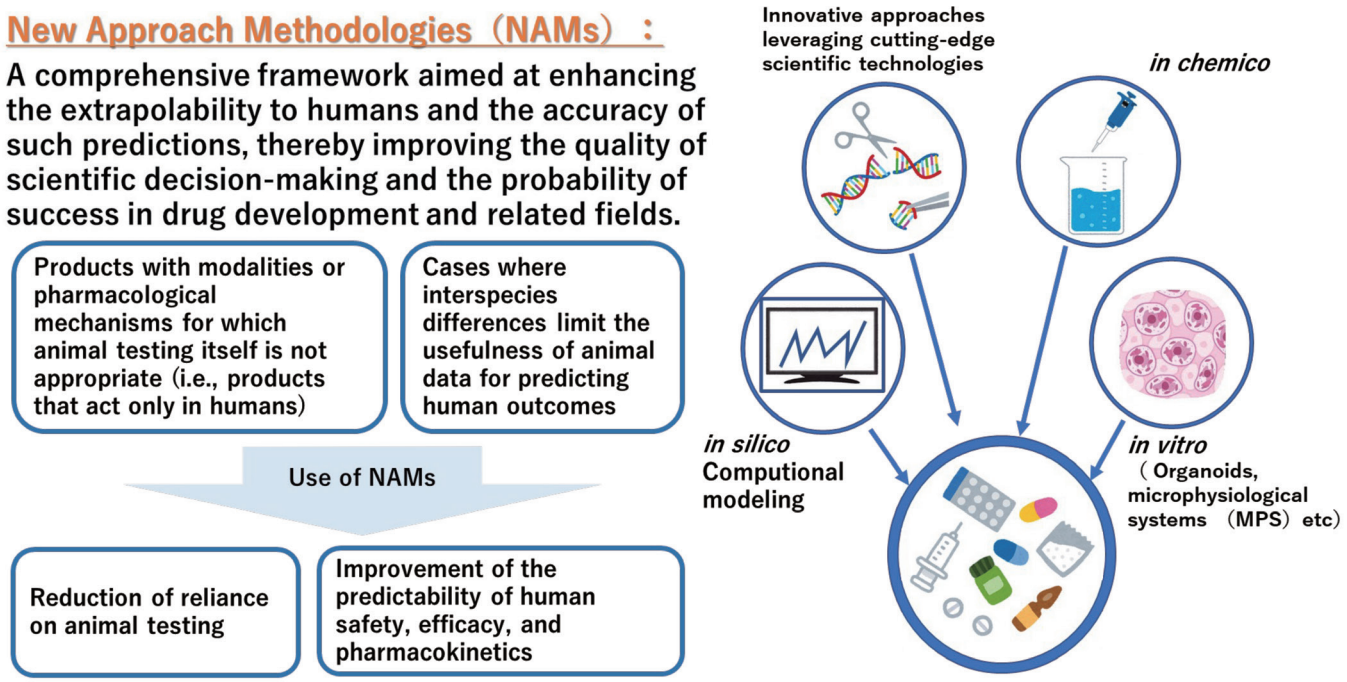
Beyond describing the PMDA's perspective on the clinical evaluation of medicines for early AD, this article highlights the role of the Optimal Use Guidelines in ensuring the necessary clinical infrastructure is in place to support the safe and appropriate use of anti-Aβ antibodies. Sharing this experience is valuable because it may serve as a model for the clinical implementation of innovative medicines that require specialized healthcare systems and risk-management frameworks both in Japan and internationally.

4. Latest Topics

PMDA conducts reviews and initiatives taking into account the latest scientific topics and findings.
This section introduces PMDA's efforts related to New Approach Methodologies (NAMs) and the use of AI in regulatory review and safety measures.

4.1 New Approach Methodologies : NAMs

In the development of pharmaceuticals, quasi-drugs, and medical devices, alternative methods to animal testing have been explored based on the ethical principles of the 3Rs (Refinement, Reduction, and Replacement).
In recent years, a comprehensive concept called "NAMs" has been advocated. This approach goes beyond simply replacing animal testing and aims to improve the quality of scientific decision-making and increase the probability of success in medical product development by enhancing extrapolation to humans and predictivity.
The use of NAMs is expected to reduce reliance on animal testing, and improve predictability of safety, efficacy, and pharmacokinetics in humans.



As part of efforts on NAMs, PMDA has collaborated with the National Institute of Health Sciences / Jaapanese Center for the Validation of Alternative Methods (JaCVAM), industry, academia, and overseas regulatory authorities.

In FY 2025, PMDA has issued three Early Consideration documents on NAMs, which are publicly available on its website (For overviews of each Early Consideration, please refer to “3.2.5. Early Consideration, Guidance, Guideline”).

- Concept of New Approach Methodologies (NAMs) use in quasi-drug applications (September 25, 2025 Office of OTC / Quasi-drugs, Pharmaceuticals and Medical Devices Agency)
  https://www.pmda.go.jp/files/000277385.pdf
- Thoughts on the Use of Weight of Evidence Approach in Nonclinical Safety Evaluation (October 24, 2025 Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency)
  https://www.pmda.go.jp/files/000278903.pdf
- Use of the Weight of Evidence approach as an alternative to nonhuman primate developmental and reproductive toxicity testing for biopharmaceuticals (October 24, 2025 Center for Product Evaluation, Pharmaceuticals and Medical Devices Agency)
  https://www.pmda.go.jp/files/000278904.pdf

PMDA symposium entitled “Toward Prompt Access to Pharmaceuticals and Quasi-Pharmaceutical Products Needed by the Public – Thinking About the Future of NAMs” was held on October 31, 2025, to share current challenges and discuss solutions for further promotion of NAMs. At this symposium, presentations were delivered by representatives from PMDA, the National Institute of Health Sciences, the Japan Pharmaceutical Manufacturers Association, and the Japan Cosmetic Industry Association.
In pharmaceutical development, nonclinical studies using animals are still currently conducted. However, the use of NAMs is expected to promote more efficient drug development. In the development of quasi-drugs, there are challenges in advancing the development of new active ingredients, as the import and sale of cosmetics and their ingredients that have undergone animal-based nonclinical testing are prohibited in Europe, and many companies in Japan have also discontinued such testing. PMDA has long accepted applications for quasi-drugs using alternative methods to animal testing and is now further promoting the use of NAMs.
Based on this background, this symposium served to share current initiatives and future perspectives on NAMs across industry, academia, and regulatory sectors both in Japan and internationally. In addition, the following points were recognized as common challenges in promoting the use of NAMs.

- establishment of evaluation methods for NAMs validity
- development of certification systems for NAMs
- implementation of concrete measures to promote their utilization

During the panel discussion held after the presentations, participants referred to the need for developing guidance and guidelines on the use of NAMs, and shared the view that international harmonization of their application is necessary.

PMDA will continue to promote regulatory science related to NAMs through stakeholder engagement with industry and overseas regulatory authorities, the publication of its perspectives on the development and use of NAMs, and the consideration of consultations on their application.

4.2 Use of AI in PMDA Operations

4.2.1 Formulation of Action Plan for AI Utilization

In recent years, PMDA has faced a range of challenges, including drug lag, ensuring a stable supply of pharmaceuticals, and the need to develop appropriate regulatory approaches in response to technological advances and global development of medical products.

Under these circumstances, PMDA is expected to maintain and improve the quality of its operations while making effective use of its limited resources.

At the same time, the use of artificial intelligence (AI), particularly generative AI, has become a major global trend, with organizations increasingly using AI to improve operational efficiency. Against this backdrop, PMDA formulated the Action Plan for the Utilization of AI in PMDA Operations on September 26, 2025. The Action Plan sets out a phased and systematic approach to the introduction and utilization of AI technologies.

The Action Plan positions AI not as a substitute for staff judgment, but as a tool for supporting PMDA's operations and enhancing their quality and efficiency. As an initial step, PMDA will focus on introducing AI technologies that are already in practical use for cross-functional tasks, including document retrieval, summarization, preparation of meeting minutes, and translation.

These initiatives are expected to reduce the burden associated with organizing information and performing routine tasks, thereby creating an environment in which staff can devote greater attention to specialized analysis and decision-making. Regulatory administration requires both timely action and careful deliberation. The use of AI can provide a foundation for achieving an appropriate balance between these requirements.

In recent years, PMDA has faced a rapidly changing environment characterized by challenges such as drug lag and drug loss, ensuring a stable supply of pharmaceuticals, and the increasing sophistication and globalization of technologies. Under these circumstances, PMDA is expected to maintain and improve the quality of its operations while making effective use of its limited resources.

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https://www.pmda.go.jp/english/about-pmda/0023.html

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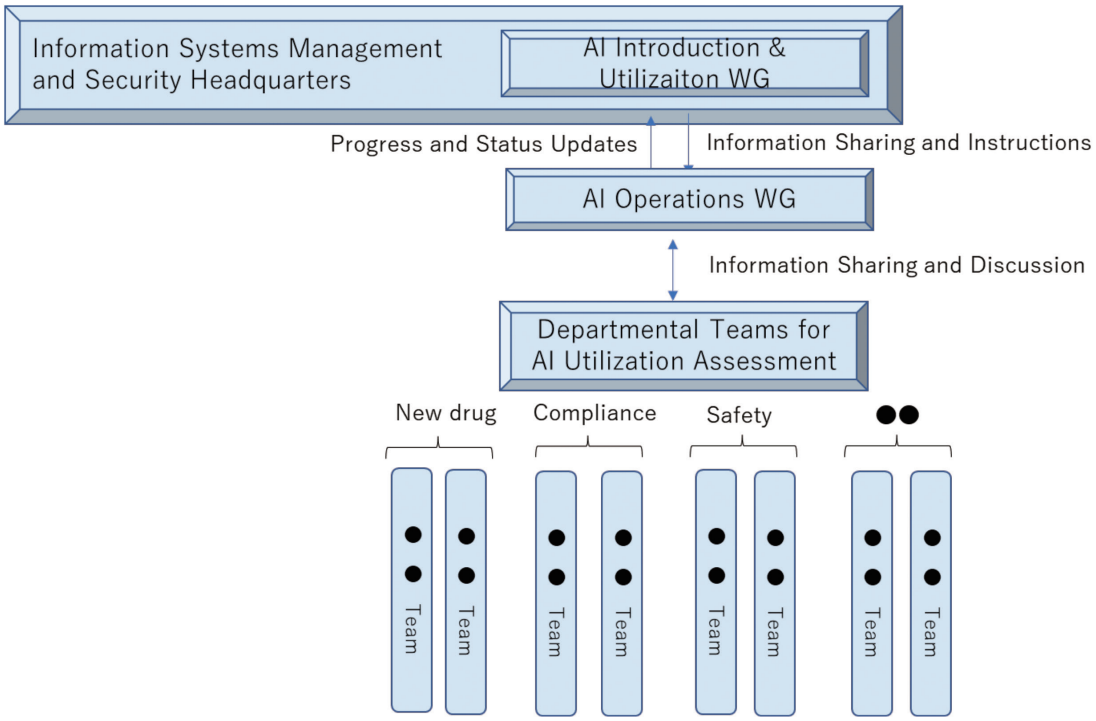
4.2.2 Establishment of AI Operations WG

To promote the action plan, PMDA established an “AI Operations WG(AI WG)” as a cross-functional regulatory science project.

The AI WG places emphasis not only on top-down discussions but also on considerations grounded in the realities of each department.
Prior to the introduction of Copilot, staff were invited to provide input on tasks they would like AI to handle, and a wide range of opinions was received from across PMDA, including review, safety, relief, international, and administrative divisions.
These inputs reflect challenges encountered and areas for improvement identified in daily operations. The AI WG has organized them by categories of AI functionalities and is advancing discussions based on feasibility and priority.



In discussions within the AI WG, it is emphasized that the introduction of AI should not be an end in itself.
Instead, the approach is to first review existing workflows and operational practices, organize them from a business process re-engineering (BPR) perspective, and then consider how AI can be effectively utilized.
In addition, efforts are being made to facilitate the smooth adoption of AI by improving staff AI literacy, including the development of a shared platform for usage guidance, the establishment of consultation services, and the sharing of prompt examples. Outcomes and challenges following implementation are expected to be shared across departments and used to drive continuous improvement.

4.2.3 Research on AI Utilization

PMDA is promoting the introduction and utilization of AI to improve the efficiency and quality of its operations and pharmaceutical development.

As one example, under a Health and Labour Sciences Research project in which PMDA participates, the following research is being conducted to improve the efficiency of preparing submission documents, including clinical study reports (CSRs), required for regulatory approval applications. Within this research, PMDA is examining the automated generation of review reports. Based on the results obtained, PMDA will further consider improvements in the efficiency and quality of both submission document preparation and regulatory review.

Research Project Title	Research on Promoting the Preparation of Documents Related to Regulatory Approval Applications and Reviews Using Generative AI
Background and Objectives	With the increasing number of investigator-initiated clinical trials and drug development led by academia and startups, the preparation of CSRs and regulatory submission documents has become a significant burden in terms of both time and human resources. At the same time, at PMDA, the quality of submitted documents is directly linked to the speed and accuracy of regulatory review, making improvements in the efficiency of both document preparation and review processes an important issue. Internationally, the use of generative AI is advancing, for example, at the U.S. Food and Drug Administration (FDA). In Japan, a pilot study conducted by the National Cancer Center has demonstrated the high utility of automated CSR generation. Against this background, this research aims to establish a technological foundation for the high-accuracy and efficient automated generation of CSRs and regulatory submission information summaries (including draft review reports) using generative AI. It also aims to provide recommendations for the social implementation of AI in the regulatory field and for future regulatory development and promotion of its use.
Major Objectives by Fiscal Year	FY2025 • Automated generation of CSRs for investigator-initiated clinical trials and further improvement of accuracy • Development of an initial model for automated generation of submission information summaries at PMDA FY2026 • Examination of generalized CSR automation using multiple investigator-initiated trials and data from other institutions • Assessment of applicability to company-sponsored clinical trials • Survey of international trends in the use of generative AI FY2027 • Establishment of a system for CSR automation without vendor support • Improvement of the quality of submission information summaries • Development of policy and regulatory recommendations regarding AI utilization in the regulatory field
Expected Outcomes	This research is expected to improve both the efficiency and quality of the entire process, from research and development to regulatory review through the use of generative AI for document preparation. Specifically, it is anticipated to significantly reduce the time, labor, and costs required for document preparation for investigator-initiated trials and startups that have limited human resources and expertise, thereby enabling greater focus on clinical trials and application preparation. Furthermore, the standardization and improvement in the quality of documents from development through review stages are expected to enhance consistency in documents submitted to PMDA, contributing to improved efficiency of review, increased reliability, and more timely decision-making. In addition, this research aims to establish a practical model for AI utilization that reflects the needs of diverse stakeholders. By organizing considerations such as security and implementation issues, it is also expected to contribute to future regulatory development and broader social implementation of AI. This research is expected to improve both efficiency and quality across the entire process from research and development.

PMDA's efforts in AI utilization are being advanced in a phased and steady manner. In pharmaceutical and medical device regulation, scientific validity and social trust are essential, and this premise remains unchanged in the use of AI. Rather than making the use of AI an end in itself, PMDA will continue to carefully and proactively consider how AI can be utilized to enhance the quality of operations and regulatory review, and ultimately contribute to public health and safety.

5. Message from External Expert

Hitoshi Nakagama

President

Japan Agency for Medical Research and Development (AMED)

In recent years, the environment surrounding healthcare and pharmaceutical research and development (R&D) has been changing rapidly, and the importance of regulatory science (RS), which provides an overarching perspective on the entire process from the identification of drug seeds to their practical application, has further increased. Addressing pharmaceutical and medical device regulations is essential for the practical application of pharmaceuticals, medical devices, and other medical products. However, for innovative products, including those based on new modalities, there are still limited approval precedents, and regulatory concepts are not yet sufficiently established. Clarification of regulatory requirements even at early developmental phases — such as the development of regulations that take into account the characteristics of each modality and the formulation of guidelines for predicting and evaluating quality, efficacy, and safety—is extremely important for indicating the direction of necessary research and accelerating practical application. It is indeed RS research that plays the essential role in establishing the scientific basis for such pharmaceutical regulations.

As a funding agency responsible for promoting R&D in the medical field and for the establishment of the relevant environment in Japan, AMED has worked closely with PMDA and other related organizations to generate scientific knowledge and promote its appropriate utilization in the society. The initiatives described in this report—including PMDA's human resource development, measures in response to advanced science and technology, the strengthening of information dissemination, efforts to address cross-disciplinary issues, safety evaluation using real-world data, and the utilization of NAMs and AI—are important foundations that support the quality of healthcare and capabilities of pharmaceutical R&D in Japan. AMED has also madeefforts on strengthening the scientific foundation underpinning these activities through the appropriate allocation of research funding and the development of a supportive research environment.

In emerging fields such as gene therapy, regenerative medicine, digital health, and data-driven healthcare, it is essential that R&D and regulation proceed in the same direction, and that scientific issues should be shared in the community from early stage of development. PMDA's Early Consideration initiatives and discussions at its Science Board are practical examples of such efforts. AMED will also continue to contribute to the generation of scientific evidence and the assurance of international harmonization through collaboration with the research community.

AMED intends to strive to strengthen the collaboration between R&D and RS, and will continue its efforts to contribute to the advancement of evidence-based healthcare and the improvement of public health and safety. I hope that this report will further deepen understanding of PMDA's RS activities and serve as an opportunity to consider together the future of healthcare and pharmaceutical R&D in Japan.

Editorial Note

We have finally published the third RS activity report. We hope this report is useful for the readers to understand the PMDA's efforts in regulatory science. We will continue working to enhance the content of future reports to meet your expectations..

If you have any comments, please contact us at

MAIL **rs-research-toiawase(at)pmda.go.jp**

("(at)" is used here to prevent spam mail; To contact us, please change "(at)" to "@").

Disclaimer

This English report was prepared based on a translation of the Japanese version. If there is any conflict or inconsistency between these two reports, the Japanese report shall prevail.

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Regulatory Science Activity Report

FY2025