PMDA Updates

2026
No. 2

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Highlights

Special Feature

Promotion of Regulatory Science

— To Further Enhance the Quality of PMDA Operations –

Regulatory Science (RS) is considered **science for appropriately delivering the achievements of science and technology***1. The Japanese government has announced a policy to promote RS for the commercialization of R&D achievements in the medical field*2.
To further promote RS, the PMDA RS Center has established a system to work in cooperation with the review division and the safety measures division and worked to enhance the quality of those operations. In the fifth Mid-term Plan from FY2024 to FY2028, we are focusing on "**Strengthening human resources,**" "**Enhancing scientific evidence,**" "**Strengthening public communications,**" and "**Contributing to the further utilization of medical information.**"

*1 Science and Technology Basic Plan (approved by the Cabinet on August 19, 2011); Click here for details (Japanese).
*2 Act on Promotion of Healthcare Policy (Act No. 48 of 2014); Click here for details.

1. Strengthening human resources

●Comprehensive Partnership Agreement and Joint Graduate School Agreement

In cooperation with universities, medical and research institutions engaged in clinical research, we promote human resource exchange (through seminars, lectures, site tours, etc.), conduct joint research, and co-host symposiums.

2. Enhancing scientific evidence

●The Science Board

To ensure more proper measures for advanced science and technology, we have established the Science Board consisting of external experts in various specialized fields to examine matters related to the scientific aspects of reviews and other operations concerning drugs, medical devices, and regenerative medicine products. We also exchange opinions with external experts on "Measures for advanced science and technology."

●RS projects Across Multi-Offices in PMDA

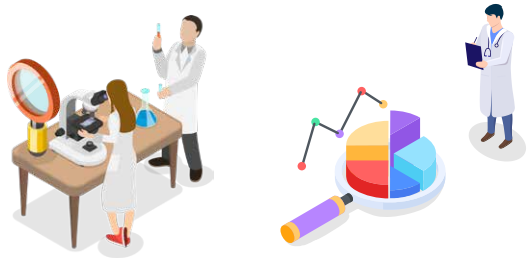
We examine cross-sectoral issues in approval reviews and safety measures, such as drug evaluation for pediatric diseases and rare diseases, at the Cross-Sectional Project Team and the Opinion Exchange Working Group. Toward the resolution of such issues, we share our views, formulate guidelines, disseminate the views, and exchange opinions (by holding symposiums, etc.).

●Early Consideration

Whereas scientific findings and information have not yet been sufficiently accumulated, we share the PMDA's views pertaining to the direction of development at each time point, as reference information to facilitate the commercialization of innovations and the development of innovative drugs.

●Research Based on Public Research Funding

We participate in research funded by public research funds (Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour and Welfare; and AMED) and conduct research projects with researchers in various fields.



3. Increasing messaging capabilities

● RS Research Workshop

The RS Research Workshop sessions are held regularly as a place for proactively sharing the achievements of RS research and to deepen understanding through discussions with external parties.

● PMDA Channel (YouTube)

We also share research introduction videos that explain scientific publications in an easy-to-understand manner.

● Scientific Publications

We have conducted RS research that examines issues in our operations and have published many research achievements. To widely share these achievements, we have established an institutional repository where anyone can access papers and other information.

● Regulatory Science Activity Reports

We publish our RS activity results that can be browsed as a document.

RS Activity Report
(Click here for Report 2024.)

4. Contributing to the further utilization of medical information

We exchange opinions with users in order to further increase the convenience of the MID-NET®. To maximize the utilization of MID-NET® data, we have started to construct a mechanism (a standard dataset analysis system) for automatically acquiring aggregate values, such as abnormal lab values, for each analysis group. For the further utilization of medical information, we also share information concerning the standardization and quality control of MID-NET®.

*MID-NET® refers to a distributed database system and its associated network comprising cooperating medical institutions at nine organizations in Japan (seven university hospitals and two medical institution groups, totaling 31 medical institutions). The database has accumulated data since 2009, including electronic medical records, claims data, and Diagnosis Procedure Combination (DPC) data.

The PMDA will continue to further improve and upgrade the quality of its operations based on RS. For more information on the activities of the RS Center, please see the RS Activity Reports.

RS Activity Report (English)

News 1

Upgrading Clinical Trials!

Promotion of drug development by improving the clinical trial environment in Japan

To rapidly deliver new drugs to patients, it is important to participate in global clinical trials from the early stages of development. The PMDA is promoting the clinical trial ecosystem project in cooperation with the Ministry of Health, Labour and Welfare, aiming to establish an environment that facilitates participation in more global clinical trials. In line with the implementation of ICH E6 (R3), the latest international standard, in Japan, we aim to realize a more flexible and high-quality clinical trial environment.

(See PMDA Updates 2025 Summer)

International agreement on ICH E6 (R3)

ICH E6*, the international standard for conducting clinical trials for pharmaceuticals (ICH GCP), has been revised to R3 in response to changing times. Among the components, the Principles and Annex 1 reached international agreement in January 2025 and Annex 2 in June 2026.

ICH E6 (R3) has been updated to provide flexibility to reflect the diversifying trial types and data collection means, while maintaining fundamentals of protecting the safety of trial participants and the reliability of trial results. All those who are engaged in clinical trials are expected to understand and employ the concepts outlined below.

- **Fitness for Purpose**
- **Quality by Design**
- **Risk-based and proportionate approach focusing on factors critical to the quality**

In Japan, the internationally agreed ICH E6 (R3) is planned to be incorporated into the regulatory framework (GCP Ordinance and related notifications including GCP guidance) within FY2026.

* ICH Good Clinical Practice (GCP) is the international standard that aims to ensure the safety of participants and the reliability of trial data in clinical trials. E6 is a code for the ICH guidelines, and R3 signifies the third revision.

(About ICH E6)

"Latest achievements of the clinical trial ecosystem project": Continued on the next page

Latest achievements of the clinical trial ecosystem project

In FY2024, we collected opinions from medical institutions and sponsors on "**difficulties in conducting clinical trials**" and identified the main issues. Issues are broadly grouped into **three** categories: **quality of clinical trials**, **operation of regulation** (GCP ordinance), and **standardization of format**. In FY2025, we examined solutions to these issues in collaboration with medical institutions and industry groups.

1 Quality of clinical trials

A mindset change will change the workplace

Many issues are considered to result from the pursuit of excessive quality, such as keeping detailed records on minor modifications, which are required "for the time being" or "just in case" regardless of the importance in clinical trials. Going forward, we must promote a mindset change in cooperation with medical institutions and sponsors, focusing on issues arising in Japan.

2 Operation of regulation

Single IRB for streamlining

At present, clinical trial reviews in Japan are often conducted by the institutional review board (IRB) of each medical institution, even for multicenter trials. The introduction of Single IRB for deliberating a clinical trial at a single IRB is to be added to GCP Ordinance. We are standardizing review matters and procedures to ensure efficient conduct by medical institutions.

3 Standardization of format

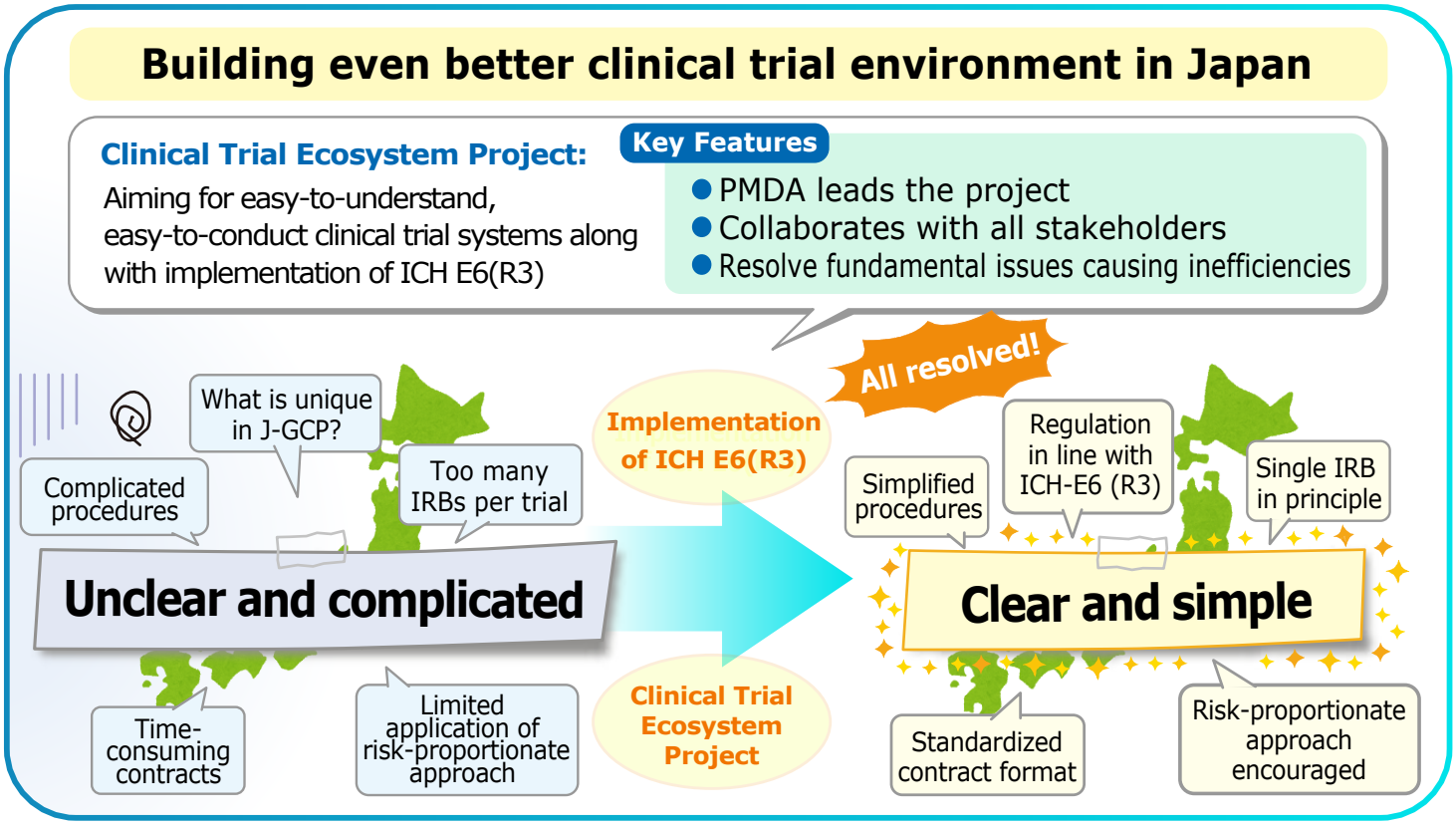
To reduce the burden of material preparation

We have prepared draft standardized formats for the main materials (10 types) to be prepared by medical institutions.

Summary

Together creating the future of clinical trials

In cooperation with the Ministry of Health, Labour and Welfare, the PMDA will further strive to share the achievements to date in an easy-to-understand manner and to deepen understanding in each person engaged in clinical trials in cooperation with medical institutions and industry groups. We will continue to make efforts to achieve a **clinical trial environment for easy-to-understand and easy-to-conduct clinical trial system**.



News 2

Forefront of Next-Generation Medical Devices: Guidance for evaluation indices for Brain-Computer Interfaces (BCIs) have been published

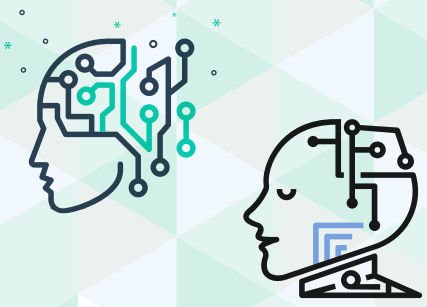
The National Institute of Health Sciences is conducting the Project for Establishing Evaluation Indices for Next-Generation Medical Devices, aiming to organize and publicize in advance the points of review for approval of innovative medical devices.
In this project, experts in the fields subject to the establishment of evaluation indices, the Ministry of Health, Labour and Welfare, the National Institute of Health Sciences, and the PMDA will have cumulative discussions on evaluation indices and finalize the document. Brain-Computer Interface (BCI) was selected into the scope of the project starting FY2024.

What is Brain-Computer Interface (BCI)?

BCI is a technology consisting of a series of systems that measure brain activity using medical devices implanted in the brain, decode the information into input signals, and move external devices. For example, BCI is expected to be applied to medical devices to complement or restore the functions of patients who are unable to move or communicate. With the rapid development of AI technology using deep learning, the performance of BCI is improving dramatically. These evaluation indices are also useful for development companies that develop innovative medical devices using BCI.

The evaluation indices describe the non-clinical evaluation of the measurement, decoding, control, and controlled units that comprise the BCI system, as well as usability evaluation and clinical evaluation to explain efficacy and safety. In the process of development and a review for approval of a medical device, BCI-specific issues that need to be examined include 1) the presence of limitation to the explanation of performance based on non-clinical studies using animals, and 2) the presence of limitation to performance for decoding patients' intentions and outputting them as physical functions. These points are also mentioned in the evaluation indices.

These evaluation indices were officially notified by the Ministry of Health, Labour and Welfare on March 30, 2026 (Click here Japanese). These evaluation indices will enable development companies and the PMDA to share the same guideposts. We expect to rapidly gain access to the latest medical devices for patients.



Topics

Introduction to Early Consideration

What is Early Consideration?

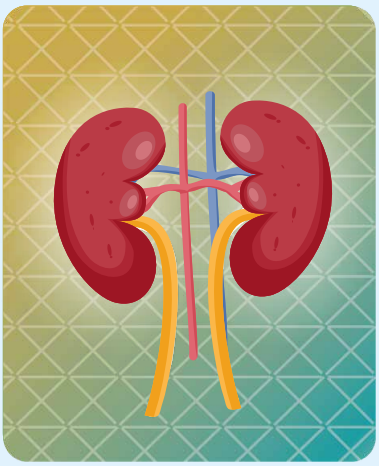
It refers to the PMDA's views **pertaining to the direction of development at each time point**, whereas information has not yet been sufficiently accumulated.
Please visit the PMDA website for more information on Early Consideration related to development areas.

Click here for details English／Japanese

Early Consideration ①

Points to Consider for the Efficacy Evaluation of Drug for IgA Nephropathy

Although IgA nephropathy is a designated intractable disease and is a serious disease that may lead to renal failure, there is no established treatment yet, and the development of new therapeutic drugs has been progressing globally. For evaluating efficacy in clinical trials for chronic kidney diseases, including IgA nephropathy, renal failure-related events such as the occurrence of end-stage renal disease requiring renal replacement therapy have been used as a primary endpoint. However, such evaluation requires a long period. For this reason, the possibility of using surrogate endpoint has been explored domestically and internationally. This Early Consideration shares our basic view on efficacy evaluation, especially the estimated glomerular filtration rate (eGFR) and urine protein/creatinine ratio (UPCR), aiming to promote the development of drugs for IgA nephropathy in Japan.



Click here for details English ／ Japanese

Early Consideration ②

Consideration in the development of drugs for hypertrophic cardiomyopathy

Hypertrophic cardiomyopathy (HCM) is a designated intractable disease characterized by the hypertrophy of the left or right ventricular myocardium and impairment of left ventricular diastolic function due to the hypertrophy. HCM is broadly classified into obstructive HCM (oHCM) and non-obstructive HCM (nHCM) according to the degree of left ventricular outflow tract obstruction. Whereas pharmacotherapy for HCM is primarily symptomatic treatment, the development of new therapeutic agents is vigorous these days, including drugs that directly act on the disease mechanism. Based on these circumstances, we have summarized considerations when planning clinical trials for the development of therapeutic drugs for HCM.

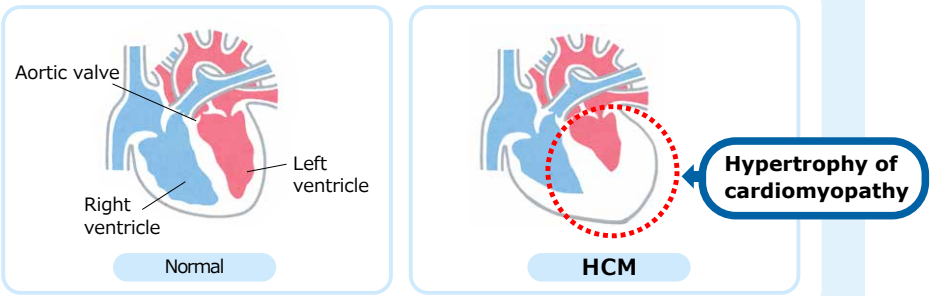
Point

Development strategy

It is appropriate to conduct confirmatory trials separately for oHCM and nHCM.

Endpoints in confirmatory trials

- It is recommended to use exercise tolerance (peak VO_2) as a primary endpoint.
- Use improvement in clinical symptoms as a secondary endpoint.



Click here for details English ／Japanese

Topics

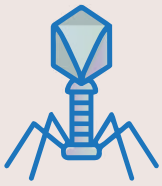
Early Consideration ③

Points to Consider for Replacement of Conventional Tests for Viruses with Next Generation Sequencing (NGS) Assays

In the ICH Q5A (R2) revised in 2025, "Guideline on viral safety evaluation of biotechnology products derived from cell lines of human or animal origin," additions were made concerning tests for viruses using Next-Generation Sequencing (NGS) technologies and potential use of an NGS assay in place of conventional test for viruses. However, use of the NGS assay in place of a conventional test for viruses itself needs to be further investigated according to the test to be replaced. Therefore, we published the Early Consideration on our current regulatory consideration concerning the use of NGS assay in place of a test for viruses, based on the PMDA's recent experience and scientific papers.

Click here for details English ／Japanese

Regulatory Considerations for developing phage therapy medicinal products for the treatment of antimicrobial resistant bacterial infections



At the PMDA, we exchange opinions with external experts on scientific issues in measures for advanced science and technology.* Based on the discussions held from October 2024 to July 2025, we published considerations on the development of phage therapy medicinal products for the treatment of antimicrobial resistant bacterial infections.

* Website page on measures for advanced science and technology.

As the problem of antimicrobial resistant bacterial infections becomes increasingly serious, bacteriophages (phages) are expected to be a treatment option. Bacteriophages 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.

Therefore, considerations have been prepared on the development of phage therapy medicinal products for acquiring regulatory approval in Japan, taking into consideration the pharmaceutical regulations and development trends in Europe and the U.S. It summarizes our current view on the quality control strategy, the establishment of manufacturing methods, non-clinical evaluation, and clinical trial planning, taking phage characteristics into account and referring also to the Cartagena Act.

Click here to view the published paper and the Administrative Notice English ／Japanese

Topics

Introduction to Guidelines

Evaluation indices for next-generation medical devices and regenerative medicine products

Technological development is rapidly progressing for next-generation medical devices and regenerative medicine products. Therefore, we have prepared and published in advance key evaluation points (i.e., evaluation items) that can be listed at present, in order to streamline the development of such products and to expedite their review for approval.
For example, we have published 20 guidelines*, including the "Evaluation of the Treatment of Ischemic Cardiomyopathy using Human (allogeneic) iPS Cells-derived Cardiomyocyte Sheets." Among these guidelines, we share recently issued guidelines below.

*As of May 10, 2026.

Please note the following points when using the guidelines!

- Depending on product characteristics, evaluation may be required on metrics other than the evaluation indices, or some of the evaluation indices may be dispensed with.
- When collecting necessary materials to file approval application for individual products, examine in advance the matters included in evaluation indices and use the PMDA's consultation service at the earliest possible stage.

Guideline (1)

Evaluation of human (allogeneic) iPS cell-derived corneal epithelial cell sheet

At the WG,* established by the Ministry of Health, Labour and Welfare, aimed at collecting the necessary materials to file an approval application and expediting approval review, evaluation indices were formulated for human (allogeneic) iPS cell-derived corneal epithelial cell sheets applied to the treatment of corneal epithelial disorders. The guidance summarize points to be noted in evaluating quality, efficacy, and safety in product development.

* WG: Working group on evaluation indices for next-generation medical devices and regenerative medicine products

Click here for details English ／ Japanese

Guideline (2)

Evaluation for shedding associated with gene therapy products using viruses/vectors

Based on the latest scientific knowledge, we have summarized, for gene therapy products using viruses/vectors as main ingredients, the points to be considered in the preparation of protocols for shedding studies in non-clinical and clinical studies, as well as principles applied to risk assessment for shedding based on results from the shedding studies, through the AMED Project of Research on Regulatory Science of Pharmaceuticals and Medical devices. This shows examples of analytical methods for shedding studies and presents consideration given according to characteristics of the product, to allow estimation and assessment of a risk of transmission to third parties and the potential impact on public health.

Click here for details English ／ Japanese

Series

Activities of Overseas Offices Part4 Asia Office

Hub of Asia that Connects through Dialogue — Greetings from the New Head of the PMDA Asia Office

Head of PMDA Asia Office
Dr.Shinichi Noda

Nice to meet you! My name is Shinichi Noda, and I assumed the position of Head of the PMDA Asia Office in April 2026.

First, I would like to express my sincere gratitude to my predecessor, Dr. Kitahara, for the wonderful foundation he built during his tenure. I will carefully carry on the bonds that he established together with Asian colleagues.

I have been engaged in reviews of cell/gene therapy products and safety measures for blood products and other pharmaceuticals for more than 10 years. For the past two years, I have worked for outreach activities in the international division to communicate Japan's regulatory affairs to foreign countries.

Asia is attracting attention not only as a growth market, but also as a strategic product development base. At the same time, in response to recent changes in the international situation, there is a growing awareness for securing a stable supply of medical products and strengthening industry in the region.

As a foundation to support these efforts, it is considered important to develop a regulatory environment while maintaining international harmonization. In Asian countries, expectations are increasing for the strengthening of regulatory capabilities and practical cooperation among authorities.

My role is to strengthen regulatory cooperation with regulatory authorities in Asian countries and to lead efforts towards resolving regulatory issues. I would like to contribute to the development of a regulatory environment that facilitates efficient regulatory processes in Asia.

In a rapidly changing international environment, it is extremely important to have dialogue not only with regulatory authorities in Asian countries, but also with local companies and organizations. Our office will consolidate knowledge collected through such dialogue and promote meticulous responses tailored to the situation in each country as a hub for regulatory affairs in Asia.

By sincerely listening to the voice of stakeholders and having repeated dialogue rooted in Asia, I intend to further develop the solid foundation that my predecessor built. I sincerely look forward to taking the leap to a new stage together with all stakeholders and making new steps in the history of the Asia Office. Thank you in advance for your continued guidance and support.

Series

The PMDA's efforts towards the use of real-world data

In recent years, the use of real-world data (RWD) in medical products development and regulatory decision making has become increasingly important in Japan and overseas. In this series, we will introduce the PMDA's efforts for the use of RWD in three installments. In the first installment, we will introduce our efforts at the drug development stage.

1. Use of RWD at the Drug Development Stage

Present situation and global trends

In drug development, the efficacy and safety of an investigational treatment is usually evaluated in a randomized comparative clinical trial with appropriately selected controls. However, there are cases where it is difficult to conduct a comparative clinical trial owing to a limited sample size in a rare disease, etc.

In global trends, the use of RWD/RWE in efficacy evaluation is examined in many countries. Recently, there has been a movement to harmonize the definitions of RWD/RWE and the principles of evaluation. At the ICH Meeting in Madrid in May 2025, new related topics were adopted: "Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making with a Focus on Effectiveness of Medicines" and "Natural History Studies and Registry Data to Advance Rare Disease Drug Development." Examination has been started for the former topic as ICH-E23.

The PMDA's initiatives and future prospects

To promote the use of RWD at the drug development stage, the PMDA has issued a notification on its basic principles concerning the use of registry in approval applications, etc., and has introduced various initiatives, including consultation services related to the use of RWD.

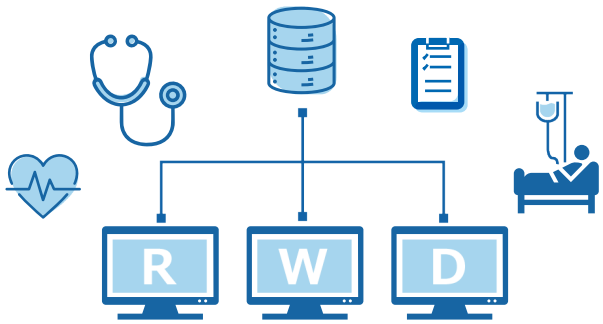
Recently, we have also issued Early Consideration for externally control clinical trials using various data sources, including registries, as external controls.

Examination is also in progress for efficacy and safety evaluation by conducting an open-label uncontrolled study on an investigational treatment and comparing the results with the registry and other RWD as external controls. There are actually drugs in Japan that were approved by using a registry data and other RWD as external controls for efficacy and safety evaluation in clinical trials.

(Click here for the published paper)

Recent examples of approval include the use of overseas disease registry data as external controls for Zokinvy 50 mg capsules, etc. (indication and efficacy: Hutchinson-Gilford Progeria Syndrome and Processing Deficient Progeroid Laminopathy).

Going forward, the further development of discussions on the use of RWD/RWE at the drug development stage is expected to contribute to the streamlining of drug development and expedited access to new drugs for patients.



Information

PMDA-ATC
PMDA Asia Training Center for pharmaceuticals and medical devices regulatory affairs

Introduction to Our Activities in Asia

APEC-RHSC Meeting

The APEC-RHSC* meeting was held in Guangzhou, China on February 1 and February 2, 2026 (Chair: Mark Abdoo (USFDA), Vice-Chair: Chief Secretary for International Affairs Yasuda (PMDA)).

APEC-RHSC is promoting regulatory harmonization of medical products by improving competence through training based on existing international guidelines. The PMDA leads discussions as a lead economy in multiple areas and provides training as the PMDA-ATC.

At this meeting, in addition to the conventional training activities, discussions for regulatory harmonization were held through regulatory dialogue, concerning future activities toward the implementation of the ICH E17 guidelines (for global clinical trials) and the risk-based approach for pharmaceutical quality. It was recognized that there were disparities in the acceptance and implementation of the guidelines among countries and regions, and measures are to be taken toward resolution. The PMDA will continue to participate in various activities led by RSHC and proactively promote regulatory harmonization.

* Regulatory Harmonization Steering Committee (RHSC): An organization established to promote regulatory harmonization for pharmaceuticals and medical devices in the APEC region

Information

Introduction to Our Activities in Asia

PMDA-ATC
PMDA Asia Training Center for pharmaceuticals and medical devices regulatory affairs

The 8th Asian Network Meeting

The Asian Network Meeting (ANM), co-organized by the Ministry of Health, Labour and Welfare (MHLW) and the PMDA, is the only high-level forum where representatives of regulatory authorities from Asian countries gather to discuss pharmaceutical regulations. It plays an important role in strengthening collaboration among Asian countries.

Held annually in Tokyo, the meeting provides an opportunity to share the latest developments in pharmaceutical regulations across the region and to exchange views on common challenges. Through these discussions, ANM aims to reduce regulatory disparities within the region and promote the harmonization and convergence of regulatory systems.

The 8th ANM was held on April 22, with China, India, Japan (MHLW/PMDA), and Singapore serving as co-hosts. Regulatory authorities from Korea, Indonesia, Malaysia, the Philippines, Thailand, and Vietnam also participated.

In the morning session, each country presented its initiatives and progress in pharmaceutical regulations, sharing the latest regulatory updates and deepening mutual understanding among participants.

In the afternoon session, discussions were held on measures to ensure the safety of pharmaceuticals, with a focus on reliance*, and to mitigate impurity risks. Participants exchanged views on national initiatives and best practices. Discussions were also held on a draft document entitled "Shared Understanding on AI," which covers regulatory perspectives on the use of AI, and a shared understanding of AI was reached. Through active discussions, participants reaffirmed their commitment to strengthening collaboration and promoting continued cooperation and information sharing within the region.

* Reliance refers to the practice by which a regulatory authority takes into account and gives significant weight to the assessments performed by another regulatory authority when making its own regulatory decisions.

The meeting summary and the "Shared Understanding on AI" document, Click here for details.

PMDA-ASEAN Reliance Meeting

PMDA hosted the PMDA-ASEAN Reliance Meeting on April 20 in Tokyo, attended by representatives in ASEAN countries, the World Health Organization (WHO), and the ASEAN Secretariat. The meeting was co-chaired by Singapore's Health Sciences Authority (HSA) and PMDA.

During the morning high-level session, representatives from each authority exchanged views on the positioning of reliance, its use as a policy tool, and future directions for its utilization. There was a shared recognition that reliance contributes to the efficient use of resources and improves patient access to pharmaceuticals, and that its use should continue to be promoted. Participants also expressed views on expanding reliance in the future beyond marketing authorization to include GMP and GCP inspections as well as post-marketing safety measures.

In the afternoon working-level session, participants shared key considerations for reliance-based assessments, emphasizing the importance of scientific evaluation. Discussions were also held on the capabilities required for implementing reliance, with participants sharing best practices and recognizing common challenges.

Through the meeting, the following points were reaffirmed:

- The promotion of reliance requires regulatory development and strengthening of implementation, trust-building, smooth communication, and capacity building.
- Advancing global cooperation, including among WHO, ASEAN countries, and PMDA, with the aim of strengthening regulatory capabilities.

Activities of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

PMDA-ATC aims to support the development of regulatory frameworks for pharmaceuticals, medical devices, and related fields in overseas regulatory authorities. To this end, ATC organizes seminars on various regulatory topics for regulatory officials and provides e-learning courses for overseas regulatory authorities, as well as learning videos for the general public online.

As part of the ATC learning videos available to the public, the following content has been newly added and updated since April and can be viewed on the PMDA Channel (YouTube). In response to strong demand from Asian countries, content on herbal medicines has also been added. New videos will continue to be uploaded regularly.

- Regulation of Herbal Medicines in Japan
- MDSAP (Medical Device Single Audit Program)
- Orphan Drug Designation System in Japan (Updated)
- Regulation and Review Process of OTC Drugs in Japan (Updated)

In addition, the ATC e-learning courses for overseas regulatory authorities consist of four areas: pharmaceuticals, advanced medical products, herbal medicines, and medical devices. Each course consists of several video modules. The herbal medicine course underwent a major revision in the previous fiscal year and has been comprehensively updated. The course consists of two videos introducing the regulatory classification, as well as the quality and approval standards, for crude drugs and Kampo products in Japan.

For more details on PMDA-ATC online content, Click here for details.

The seminar schedule for April 2026 to March 2027 has been published on the PMDA-ATC webpage.

Through the initiatives of ATC, PMDA will continue to promote the enhancement and harmonization of regulatory standards, particularly in Asia, and further strengthen cooperative frameworks.

English Translations of Review Reports

The following links provide the latest information on the English versions of the review reports on the PMDA website:

Drugs Review Reports: Drugs

Brand Name	Non-Proprietary Name	Indication	Posting Date (Approval Date)
Spikevax Intramuscular Injection	Coronavirus (SARS-CoV-2) RNA Vaccine	The prevention of disease caused by SARS-CoV-2 infection (COVID-19).	February 16, 2026 (May 19, 2025)
Camzyos Capsules 1 mg, Camzyos Capsules 2.5 mg, Camzyos Capsules 5 mg	Mavacamten*	The treatment of symptomatic obstructive hypertrophic cardiomyopathy.	February 16, 2026 (March 27, 2025)
Airwin for Subcutaneous Injection 45 mg, Airwin for Subcutaneous Injection 60 mg	Sotatercept (Genetical Recombination)*	The treatment of pulmonary arterial hypertension.	February 16, 2026 (June 24, 2025)

*Japanese Accepted Name (modified INN)

Medical Devices Review Reports: Medical Devices

Brand Name	Term Name	Intended Use	Posting Date (Approval Date)
Peripheral Rotablator PRO	Atherectomy ablative angioplasty catheter	An atherectomy ablative angioplasty catheter is intended to be inserted percutaneously to ablate atherosclerotic plaques and/or solid calcified below-the-knee stenotic lesions in which a balloon catheter for percutaneous transluminal angioplasty cannot pass through or cannot be expanded, thereby assisting in endovascular treatment in patients with chronic limb-threatening ischemia (CLTI).	April 3, 2026 (July 3, 2025)
Visual-ICE Cryoablation System	General-purpose cryosurgical unit	A cryosurgical unit is composed of the device main body that generates low temperature, etc., a needle that is inserted to freeze and necrotize the target tissue, and a multipoint temperature sensor that detects the temperature of the tissue, etc.	April 3, 2026 (June 19, 2025)
TriClip System	Percutaneous repair system for tricuspid valve coaptation failure (To be newly created)	A percutaneous repair system for tricuspid valve coaptation failure consists of a delivery system with a clip to coapt the tricuspid valve with regurgitation and a steerable guide catheter to deliver the delivery system into the right atrium.	April 3, 2026 (July 17, 2025)

English Translations of Notifications and Administrative Notices

We introduce the latest information on the English versions the notifications and administrative notices published on the PMDA website.

Document Type & No.	Title		Posting Date (Issue Date)
PSB/PED Notification No. 0905-1 PSB/MDED Notification No. 0905-1 PSB/PSD Notification No. 0905-1	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)	EN / JP	January 29, 2026 (September 5, 2025)
PSB/PED Notification No. 0327-1	Guidelines for Nonclinical Studies of Vaccines for Infectious Disease Prevention	EN / JP	March 9, 2026 (March 27, 2024)
Administrative Notice	Questions and Answers (Q&A) on Guidelines for Nonclinical Studies of Vaccines for Infectious Disease Prevention	EN / JP	
PSB/PED Notification No. 0327-4	Guidelines for Clinical Studies of Vaccines for Infectious Disease Prevention	EN / JP	March 9, 2026 (March 27, 2024)
Administrative Notice	Questions and Answers (Q&A) on Guidelines for Clinical Studies of Vaccines for Infectious Disease Prevention	EN / JP	
PSB/PED Notification No. 0327-7	Guidelines on the Development of Recombinant Virus Vaccines for Infectious Disease Prevention	EN / JP	March 9, 2026 (March 27, 2024)
Administrative Notice	Questions and Answers (Q&A) on Guidelines for the Development of Recombinant Virus Vaccines for Infectious Disease Prevention	EN / JP	
PSEHB/PED Notification No. 0630-5	Principles for Obtaining Indications based on Comparative Evaluation, etc. of the Quality Attributes of Intravenous Human Immunoglobulin Products	EN / JP	March 9, 2026 (June 30, 2023)
Administrative Notice	Questions and Answers (Q&A) on the "Guidelines for Clinical Evaluation of Drugs for the Treatment of Heart Failure" (Part2)	EN / JP	April 6, 2026 (May 23, 2022)
PFSB/ELD Notification No. 0329-18	Revision of the "Guidelines for Clinical Evaluation of Drugs for the Treatment of Heart Failure"	EN / JP	April 6, 2026 (Mar 29, 2011)
Administrative Notice	Questions and Answers (Q&A) on the "Guidelines for Clinical Evaluation of Drugs for the Treatment of Heart Failure"	EN / JP	

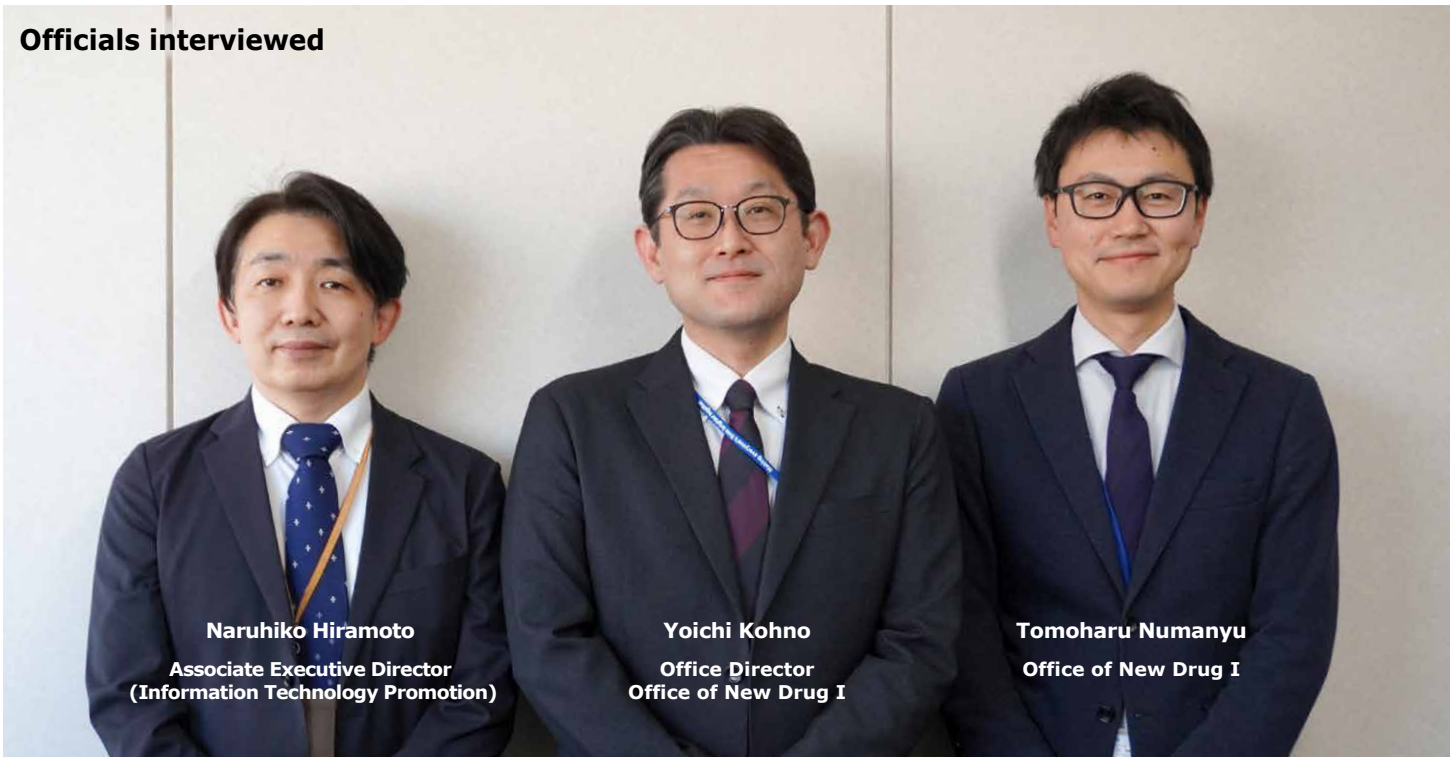
Special Information

Interview

PMDA A to Z: Step Inside

In this section, we at the PMDA provide a look inside the PMDA. The PMDA has promoted the review and Digital Transformation(DX) of various operating processes in order to improve the quality and efficiency of its operations. However, the environment surrounding the PMDA continues to change, and it needs to further strengthen its scientific abilities and enhance its entire operational capabilities in order to fulfill its expected roles in coming years. In the third installment, we share our activities on the use of artificial intelligence (AI) at the PMDA.

3. Promoting the use of AI in PMDA operations



— How will you promote the use of AI at the PMDA?

Hiramoto: Based on the Action Plan for the Use of AI in Operations at the PMDA formulated and published in 2025, we will promote the introduction and use of AI-related technologies in our operations in order to further streamline and upgrade the three major tasks of the PMDA (relief services for adverse health effects, reviews, and safety measures). We have appointed a Chief AI Technology Officer (CAIO) to promote initiatives under effective governance. In addition to natural expectations for reduced work hours by replacing relatively simple tasks with AI, an environment will be established where staff can concentrate on deeper thoughts.

— What is the Action Plan for the Use of AI in Operations at the PMDA?

Hiramoto: It stipulates three policies. The first is to streamline PMDA operations by introducing and using AI technologies that have already been commercialized. The second is to verify technologies and collect information toward the introduction of AI technologies specializing in PMDA operations. The third is to establish promotional systems and rules, and to implement measures for improving IT literacy in PMDA executives and staff.

— In what specific tasks will AI be used?

Numanyu: As an example, the introduction of the AI chatbot service will improve efficiency in routine work performed by staff, regardless of their job type. If AI specializing in PMDA operations can be developed, the technology may be applied to more advanced operations. It will be important to compare and examine the respective features of commercialized AI products and technologies and the specific operations of the PMDA.

— What are the actual initiatives for the implementation and use of AI?

Numanyu: We are considering a cross-functional initiative to share and exchange opinions on the actual examples of AI use at departments in the PMDA, not only the successful cases, but also the cases with issues identified. By sharing findings from individual departments, we will lead initiatives to the streamlining of entire operations at the PMDA.

— Do you plan to develop AI specializing in PMDA operations?

Kohno: For example, PMDA's review report for new drugs includes sections summarizing study designs and results, and I believe AI may have the potential to support the preparation of such summaries. A new MHLW research grant project* has recently been launched, and PMDA is participating in the project. Related discussions have already begun.

* MHLW Research Grant Project
Project Title: Research for Promoting the Preparation of Documents Related to Regulatory Approval Application and Review Using Generative AI
Principal Investigator: Dr. Kenichi Nakamura, National Cancer Center Hospital

— What are the risk measures concerning AI use?

Hiramoto: The basic rule concerning AI-based outputs is that staff carefully check them before use in accordance with the purpose of use. Therefore, it is necessary to improve system readiness and AI literacy of staff users across the organization toward implementation. Necessary measures will be taken, including seminars.

— We look forward to your activities in the coming years. Thank you very much.

Reference:
Action Plan for the Use of AI in Operations at the PMDA
Click here for details

Upcoming Events

Booth exhibition and individual consultation at the 32nd Annual Meeting of the Japan Society of Gene and Cell Therapy

July 23, 24, and 25, 2026
in Osaka

At the 32nd Annual Meeting of the Japan Society of Gene and Cell Therapy (Grand Cube Osaka, July 23 to 25), the PMDA will participate with a booth exhibition and individual consultations.
For those who are considering the development of regenerative medicine products in Japan and those planning consultation with the PMDA in the future, we will present details and procedures for consultation services provided by the PMDA. We will also provide an opinion exchange service at a general level concerning efficient consultations for products under development and points of discussion.
Details of individual consultations will be announced on the PMDA website in advance. We hope that participants will leverage this opportunity in concurrence with the Annual Meeting for future product development.

Audience for individual consultation

- ○ Those who are considering the development of regenerative medicine products in Japan
- ○ Those planning consultation with the PMDA in the future

About the Cover Image

Aomori Nebuta Festival

The Aomori Nebuta Festival is held from August 2 to 7 every year in central Aomori City and is one of the three major festivals in Tohoku, designated as an important intangible folk cultural property by the Japanese government.
There are various theories about its origin, but the festival is considered to have derived from the Nebuta floating event for driving away summer sleepiness and praying for good health.
A Nebuta is a giant lantern made by attaching paper to a three-dimensional frame and lighting it up from the inside. Various lanterns are produced every year depicting historical stories and other themes.
On August 7, the final day of the festival, the award-winning Nebuta floats cruise the sea and cap off the festival along with fireworks.

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