Why Japan

for drug development

Attractive Market

Flexibility/ Predictability

Advantages

Further merit

Attractive Market

Flexibility/ Predictability

Japan: What is attracting?

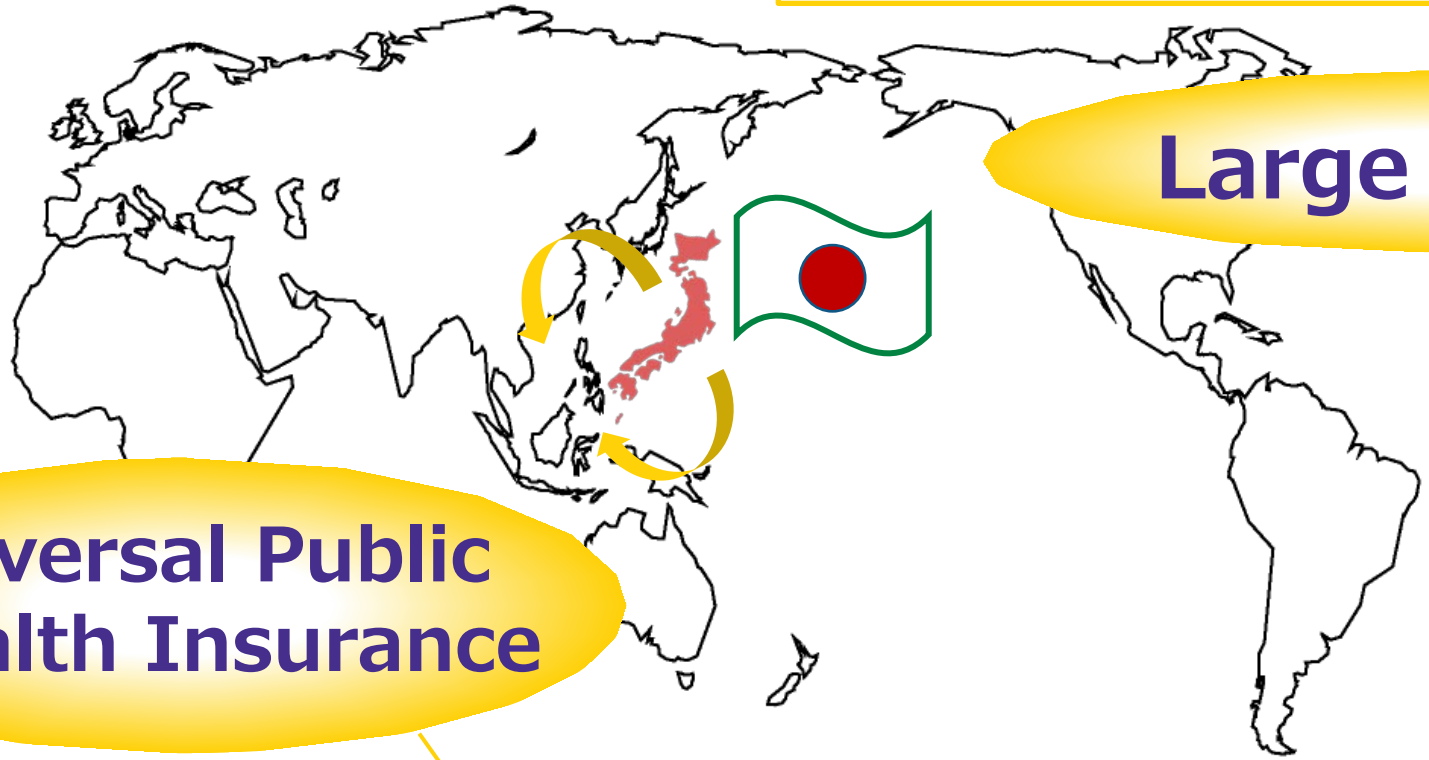
Advantages

Further merit

Attractive Market

- World 3rd largest pharma market.
  New drugs market : expanding.
- World 2nd largest medical device market.

Large Market



Universal Public Health Insurance

- Patients: accessible to new drugs.

Flexibility/Predictability

- High predictability
(Sales timing after NDA)
:Transparent review timeline

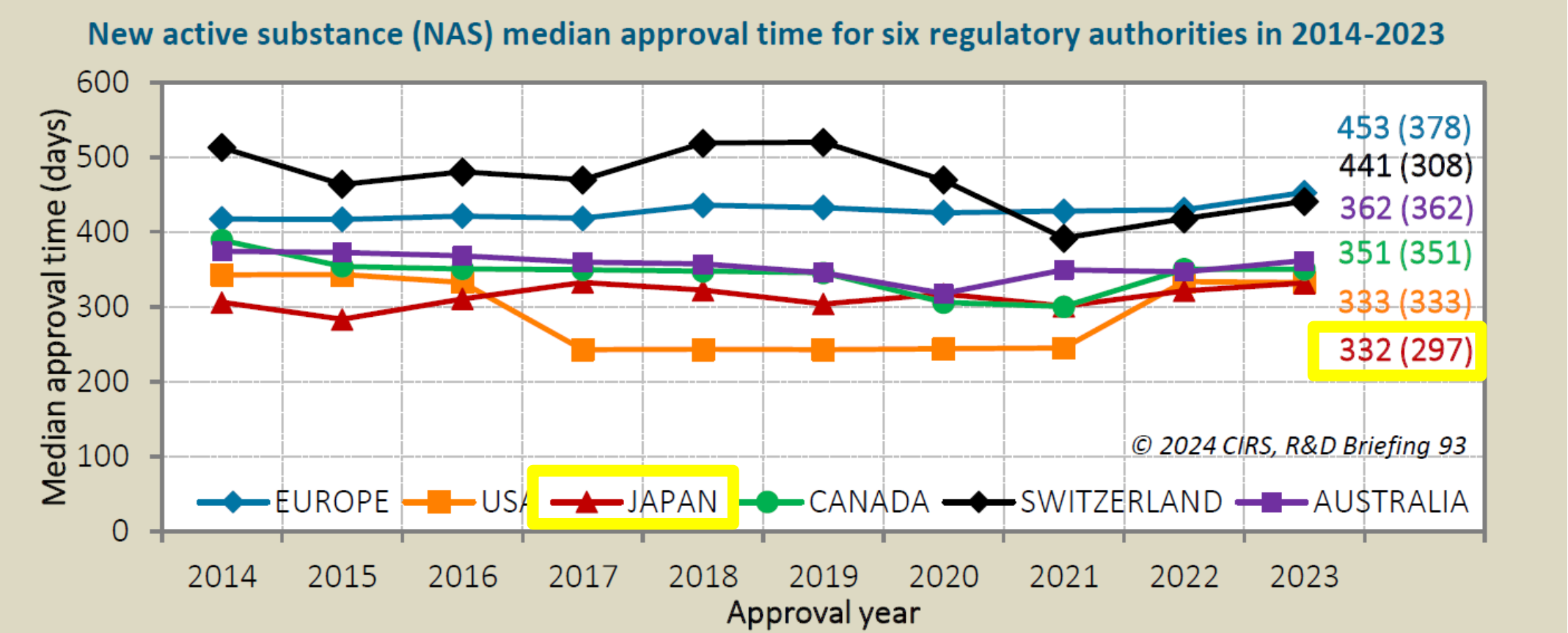
- The world-class faster NDA review
- Prompt NHI Drug Price
:within 60 days (without HTA)

- Fine Support
:Scientific consultations from early stage

- Full International Harmonization
: Regulation based on ICH standard

Median approval time for New Active Substance

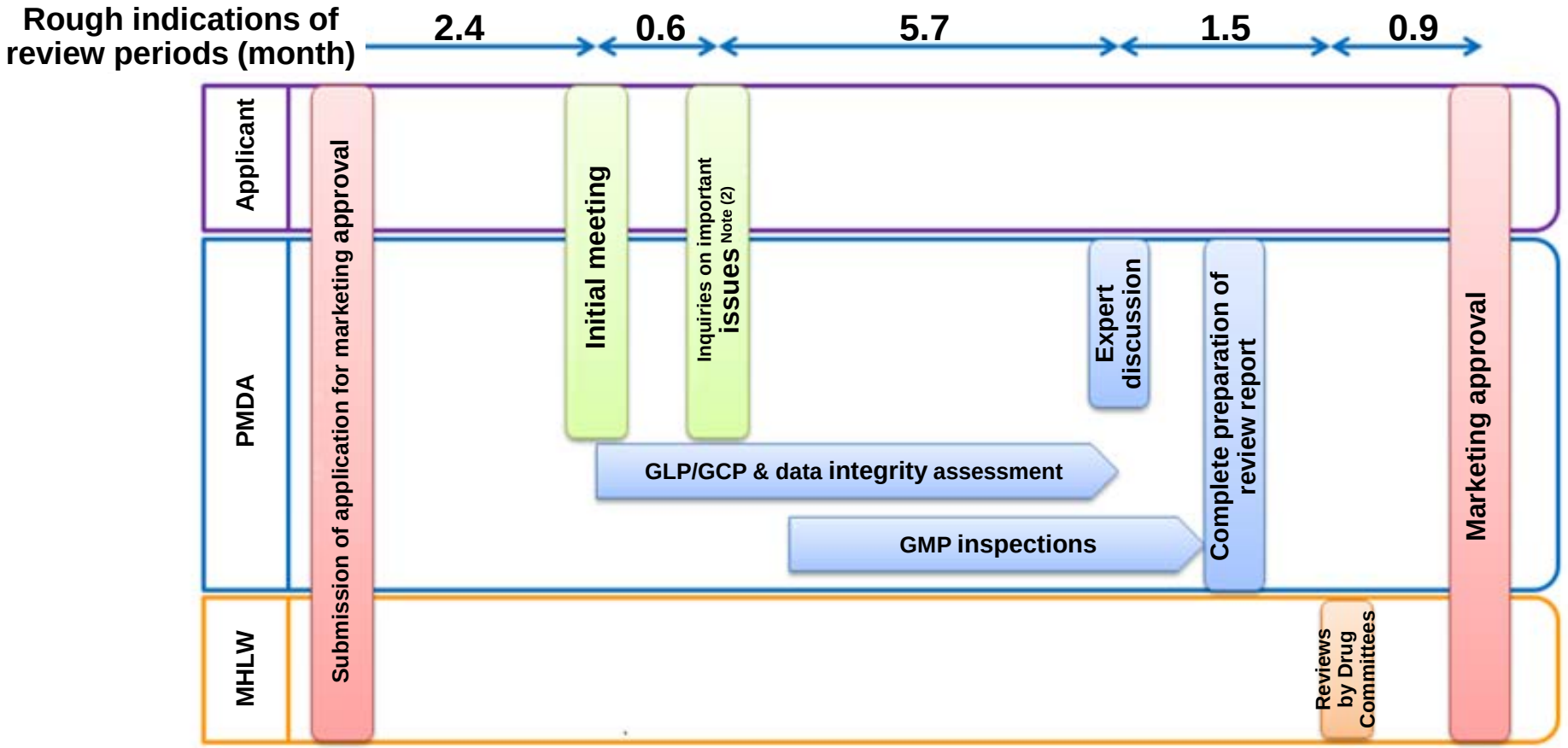
PMDA is one of the fastest review organizations In the world !



Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU commission time. N1 = median approval time for products approved in 2023; (N2) = median time from submission to the end of scientific assessment for products approved in 2023.

Timeline of the standard process of new drug approval review (ordinary review products)

To aid in achieving the target value of 12 months for the total review period from application to approval for ordinary review products, the following timeline gives a rough indication of the review periods Note (1) for each review stage based on our experience in regulatory reviews regarding applications for new drugs. This timeline applies to the standard review processes when there are no particular concerns in the course of review.



Note (1): The rough indications of the review period (median) are calculated based on past experience of approval reviews for new drugs in FY2013. The number of each event during the period from application to approval, which were used for the calculation, is 35 initial meetings, 31 inquiries on important issues, 85 expert discussions, 83 reviews by Drug Committees, and 96 Marketing approvals.

Note (2): “Inquiries on important issues” means the first inquiry made by the PMDA after the initial meeting.

Flexibility/Predictability

- High predictability
(Sales timing after NDA)
:Transparent review timeline

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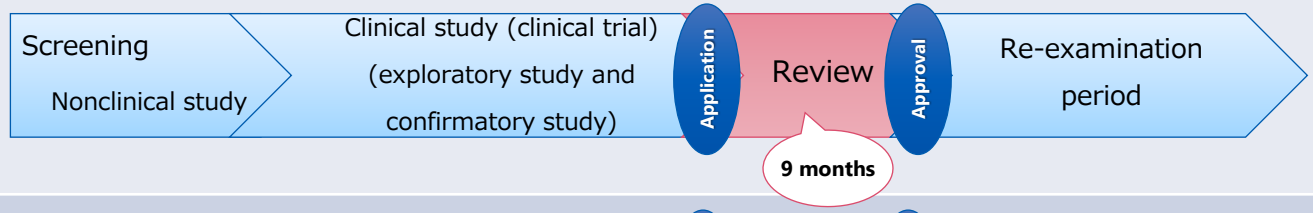
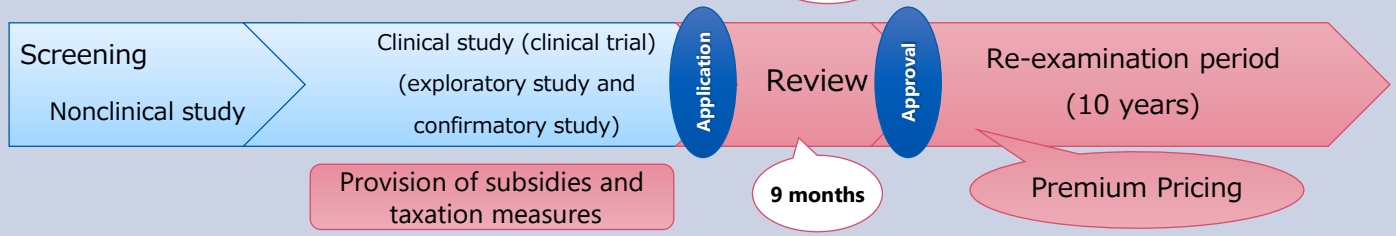
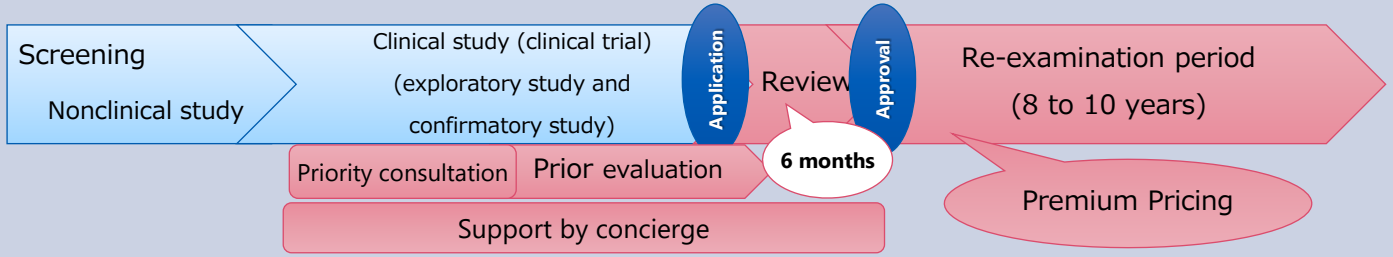
Accelerated Review Systems on Pharmaceuticals in Japan

System name and designation requirements	Outline
Standard review	
Priority review (1) The disease is serious. (2) The efficacy or safety is much better than that of existing treatments.	
Orphan drug * In addition to priority review, (1) less than 50,000 patients or designated intractable diseases (2) the development possibility	
Conditional approval system for drug * In addition to priority review, (1) it is difficult to conduct the confirmatory study (2) certain efficacy and safety were confirmed in other studies	
Innovative drug, "Sakigake" (1) Innovativeness (2) For serious diseases (3) Prominent efficacy (4) Being applied in Japan for the first time in the world	

“SAKIGAKE” - Accelerated review system on innovative drugs

<Objective>

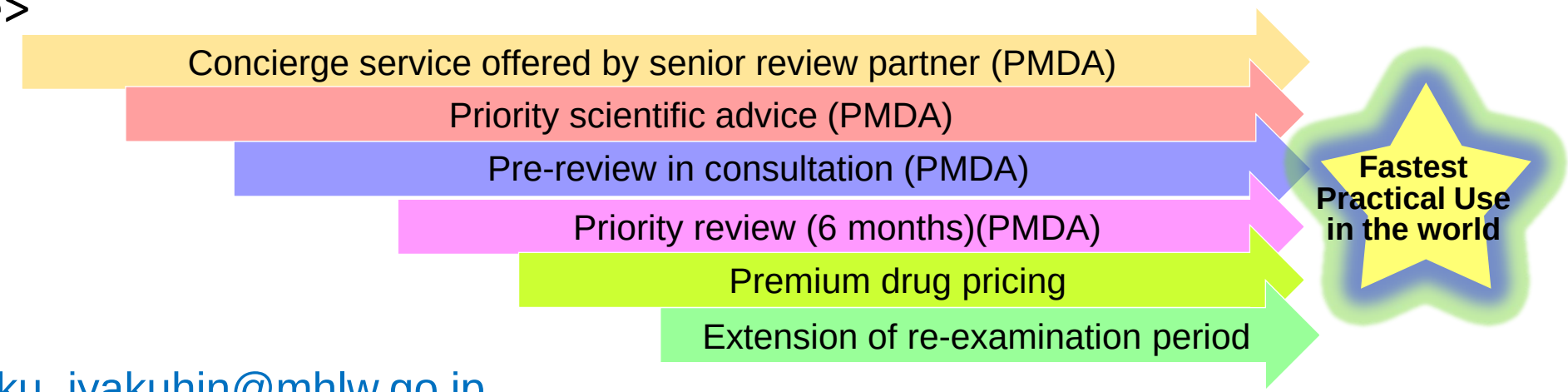
To put innovative products into medical practice in Japan

<Criteria for designation>

1. Innovativeness - new mode of action (in principle)
2. Severity of the target disease - life-threatening or no curative therapies
3. Prominent efficacy - no existing therapies or probable significant improvement in efficacy or safety compared to existing therapies
4. Plan/System - to submit the NDA in Japan first or at the same timing* as the first NDA submission to other national regulatory authority

*within 3 months

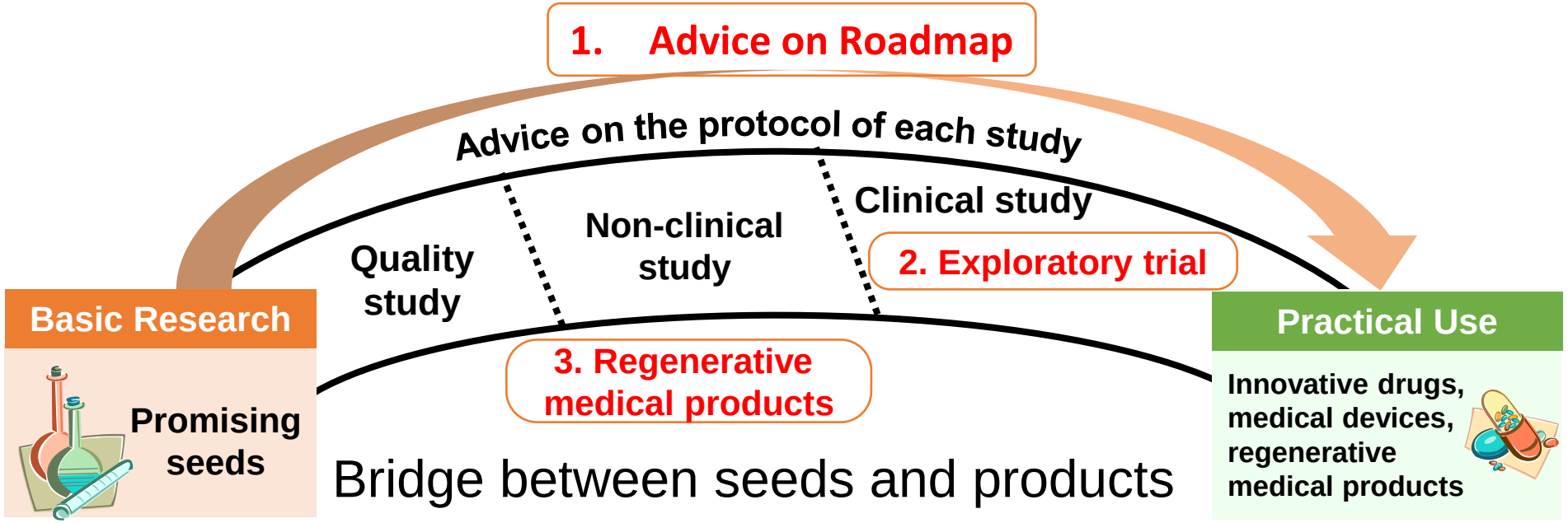
<Incentive>



senku_iyakuhin@mhlw.go.jp

Regulatory Science Consultation on R&D Strategy

1. Facilitate the development of medical products by developing a more reliable roadmap.
2. Accelerate the clinical trials led by academia.
3. For regenerative medical products, ensure the quality of the products and confirm the nonclinical safety before the clinical trial notification.



* In collaboration with the Japan Agency for Medical Research and Development (AMED), PMDA is proactively supporting the establishment of an exit strategy via Regulatory Science (RS) Consultation on R&D Strategy.

Outline of the RS Consultation

Category	Objective	Consultant	Style	Typical period from application to consultation	Duration	Fee	Minutes
General Consultation	Introduction of general information on: -Consultation system -Pharmaceutical and Medical Device regulatory system -Related guidelines	Technical Experts	F2F / Online	2 to 3 weeks	20min	Free	Not shared
Pre-consultation meeting	Clarification of discussion points, consultation dossiers	Technical Experts and Reviewers	F2F / Online	3 to 4 weeks	30min	Free	Not shared
Consultation	Scientific discussion	Technical Experts and Reviewers	F2F / Online	2 to 3 months	Max. 2hr	Charged	Shared

Please contact:

rs-contact@pmda.go.jp

PMDA offers 90% reduction to venture companies.

Prerequisites for fee reduction in RS Consultation

In principle, all of the following prerequisites have to be fulfilled.

(Venture companies)

- An SME (i.e., the number of employees is 300 or less or the company's capital is JPY 300MM or less)
- Another corporate body does not hold shares or capital contributions equivalent to 1/2 or more of the total number of shares or the total amount of contributions.
- Two or more corporate bodies do not hold shares or capital contributions equivalent to 2/3 or more of the total number of shares or the total amount of contributions.
- Net profit is not recorded or is recorded without business revenue in the previous fiscal year.

Orphan drug – Designation System

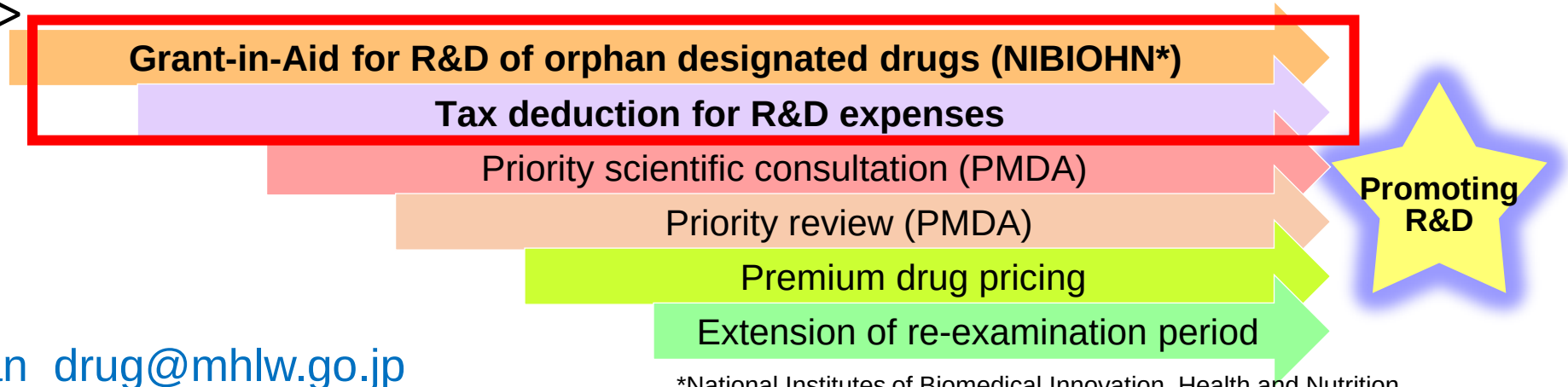
<Objective>

To promote the R&D of the products for rare diseases to provide the patients with safe and effective medicines/medical devices as early as possible

<Criteria for designation>

1. Number of patients (any of the following has to be met)
   - Less than 50,000 in Japan
   - The target disease is one of the designated intractable diseases
2. Medical needs
   - Serious diseases with high medical needs
3. Feasibility of development
   - Having organizations and plans for development in Japan

<Incentive>



orphan_drug@mhlw.go.jp

*National Institutes of Biomedical Innovation, Health and Nutrition

Subsidy・Tax credits for Orphan drugs

Subsidy period	Maximum of 3 years from the time of orphan designation in which the company files an application for marketing authorization
Expenses eligible for coverage	Honoraria, travels, equipment, consumables, printing and binding, communication and transportation, rents and leases, meetings, labor services, and subcontracting fee.
Subsidy ceiling	Maximum up to 50% of the R&D cost
Tax-deductible expenses	20% ×[R&D cost – subsidy amount]

Supported by National Institutes of Biomedical Innovation, Health and Nutrition(NIBIOHN)

https://www.nibiohn.go.jp/en/activities/orphan-support.html

Orphan drug – Designation System

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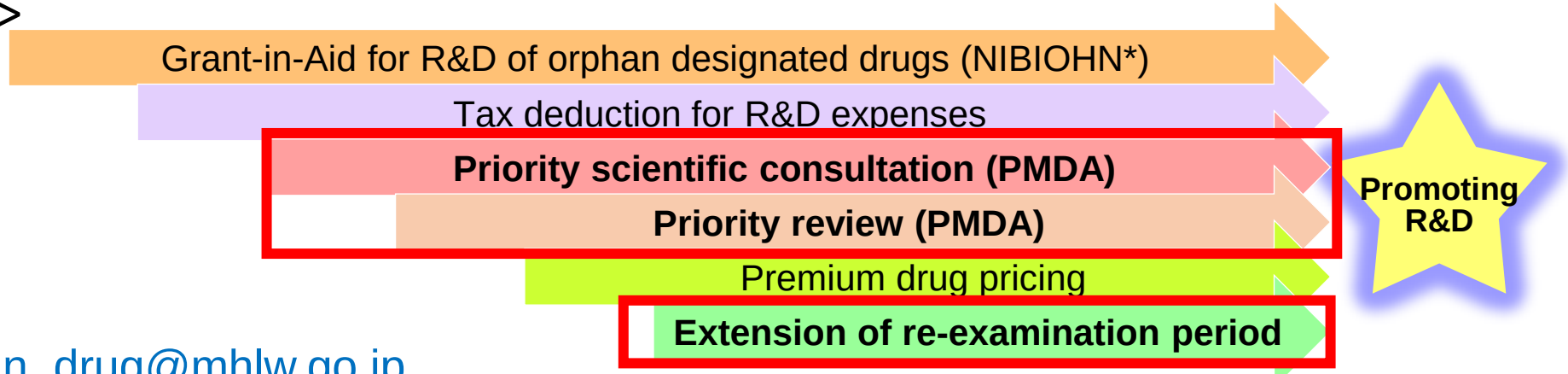

*National Institutes of Biomedical Innovation, Health and Nutrition

orphan_drug@mhlw.go.jp

Overview of orphan designations in Japan, EU and US

	Japan	EU	US
Establishment of orphan legislation	1993	2000	1983
Designation criteria	1.Number of patients • Less than 50,000 in Japan, or • The target disease is one of the designated intractable disease	1.The prevalence of the condition in the EU must not be more than 5 in 10,000	1.Affect less than 200,000 persons in the US or meet cost recovery provisions of the act
	2.Medical needs • For serious diseases with high medical needs 3.Feasibility of development	2. Life-threatening or chronically debilitating disease 3. Medical needs	

*1: https://www.ema.europa.eu/documents/annual-report/annual-report-use-special-contribution-orphan-medicinal-products-2019_en.pdf
*2: https://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm

“SAKIGAKE” - Accelerated review system on innovative drugs

<Objective>

To put innovative products into medical practice in Japan

<Criteria for designation>

1. Innovativeness - new mode of action (in principle)
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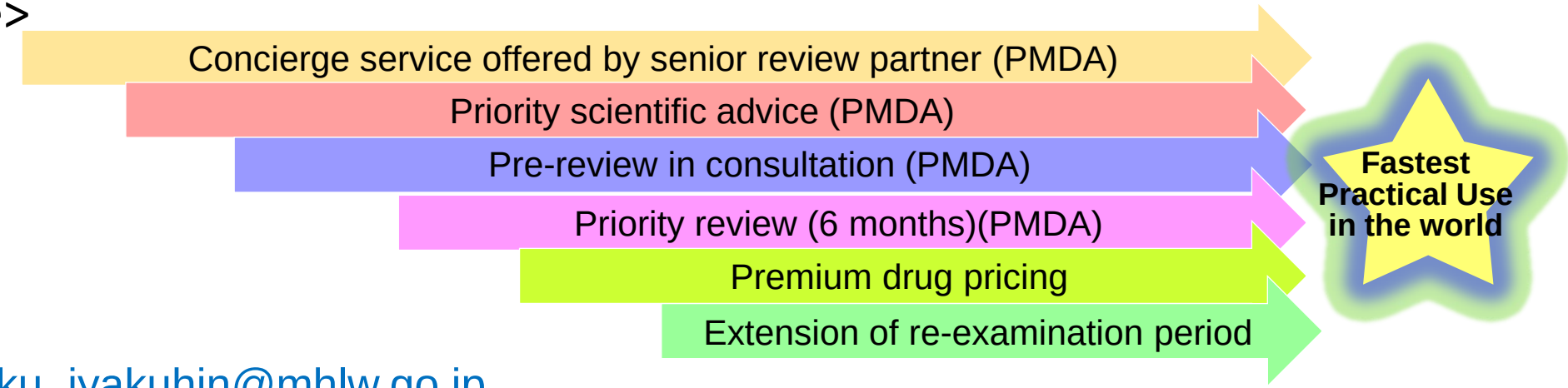
*within 3 months

<Incentive>



senku_iyakuhin@mhlw.go.jp

Rolling Review (Prior Evaluation Consultations for Drugs)

※$1=¥140

Purpose

- To enable substantial advance of reviews
- To perform prior evaluation based on quality, non-clinical and clinical data, from the pre-submission development stage
- To enable identification and resolution of issues at each pre-submission development stage, and as a result, reduction in review time

Subject products

- New drugs
- Drugs with new indications,
  Drugs with a new dosage, etc.
- Regenerative medical products

[Major user fees for consultations]
Quality ＄34,411,
non-clinical（each of Pharmacology, Toxicity or ADME）＄ 23,259,
Clinical Phase 1: ＄ 39,324, Phase 2: ＄ 50,751,
Phase 3: ＄ 78,832
A system that companies can choose and consult about what they want to evaluate first

Required documents

- Future development plan, issues until application, draft package insert
- Draft CTD Module 2, study reports

and so on

Cost of Product Lifecycle (pre-application～approval～post-marketing) for New Drugs

※$1=¥140

PMDA
- User fee for consultation
- User fee for review
- Contribution to safety measures

(1)Average new drugs **$936,890**

(2)Average new drugs **$946,570**

（Price maintenance premium items）

FDA
- User fee for human drug application
- Program fee

Drugs which require clinical data **$4,887,800**

(After the adjustment of purchasing power parity)

FDA costs 5.2 times as much as PMDA

Actual Conditions of Drug Lag/Drug Loss

- As of March 2023, there are **86 drugs (60.1% of unapproved drugs)** which are approved in the US and EU but **not yet started development in Japan**. It is noted that **drug lag/loss that means applications for approval are not performed in the first place (i.e. companies do not develop the drug) arises.**
- The analysis of trends for 86 drugs of which development are not yet started found that **the percentages of startup company-originated, orphan or pediatric drugs are relatively large**.

Status of drug lag/loss in Japan, EU and the US

(Number of drugs)

	Approved	Total of unapproved	Included number of unapproved: Under development	Included number of unapproved: **Not yet developed**
US	136	7	3	4
EU	86	57	26	31
Japan	0	**143**	57	**86** (drugs)

Break down →

Breakdown of drugs not yet started development in Japan

Startup-originated	Orphan	Pediatric
56% (48 drugs)	**47**% (40 drugs)	**37**% (32 drugs)

※Of 86 drug loss items, items that are not startup-originated, orphan or pediatric drugs are 14 (16%).

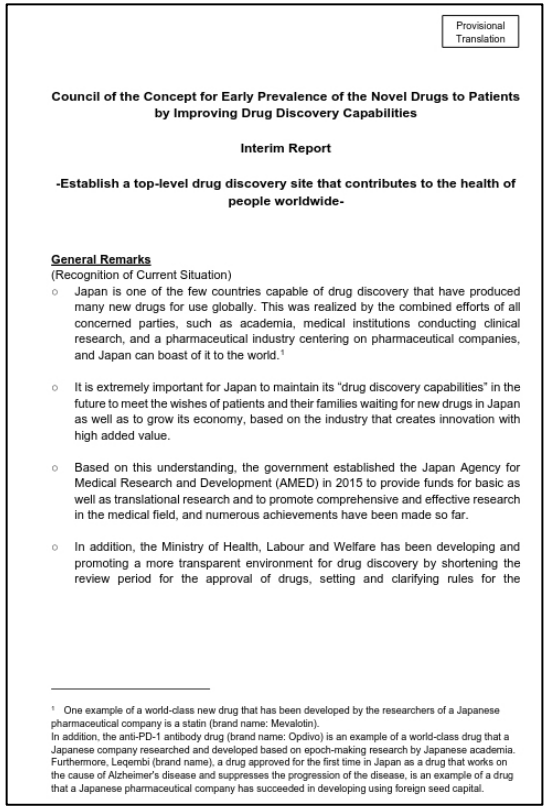
※Source: Based on public information from PMDA, FDA and EMA and "Asu-no-Shinyaku" (TECHNOMICS, INC.), prepared by Office of Pharmaceutical Industry Research(OPIR) and summarized by MHLW
※１：Of NMEs approved in EU and US between 2016 and 2020, items that were not approved in Japan as of the end of 2022 are counted as unapproved.
※２：Items that had not development information as of March 2023 are counted as not yet started development in Japan.
※３：Development companies that had approval in EU and US within 30 years of the establishment and their sales in previous year of approval are less than USD 500 million are counted as start-up.
※４：Drugs that were designated as orphan drug by the time of approval in EU and US are counted as orphan.
※５：Drugs that obtained pediatric indication in EU and US as of the end of 2022 are counted as pediatric.

Quote from Reference 4 of "the 1st investigational committee for pharmaceutical regulation for enhancement of drug discovery and securing of stable supply" conducted by Pharmaceutical Safety and Environmental Health Bureau (current Pharmaceutical Safety Bureau), Ministry of Health, Labour and Welfare

For your further understanding (other governments)

Interim Report

Council of the Concept for Early Prevalence of the Novel Drugs to Patients
by Improving Drug Discovery Capabilities



Provisional Translation

Council of the Concept for Early Prevalence of the Novel Drugs to Patients by Improving Drug Discovery Capabilities

Interim Report

-Establish a top-level drug discovery site that contributes to the health of people worldwide-

General Remarks
(Recognition of Current Situation)

- Japan is one of the few countries capable of drug discovery that have produced many new drugs for use globally. This was realized by the combined efforts of all concerned parties, such as academia, medical institutions conducting clinical research, and a pharmaceutical industry centering on pharmaceutical companies, and Japan can boast of it to the world.[1]
- It is extremely important for Japan to maintain its "drug discovery capabilities" in the future to meet the wishes of patients and their families waiting for new drugs in Japan as well as to grow its economy, based on the industry that creates innovation with high added value.
- Based on this understanding, the government established the Japan Agency for Medical Research and Development (AMED) in 2015 to provide funds for basic as well as translational research and to promote comprehensive and effective research in the medical field, and numerous achievements have been made so far.
- In addition, the Ministry of Health, Labour and Welfare has been developing and promoting a more transparent environment for drug discovery by shortening the review period for the approval of drugs, setting and clarifying rules for the

[1] One example of a world-class new drug that has been developed by the researchers of a Japanese pharmaceutical company is a statin (brand name: Mevalotin).
In addition, the anti-PD-1 antibody drug (brand name: Opdivo) is an example of a world-class drug that a Japanese company researched and developed based on epoch-making research by Japanese academia. Furthermore, Leqembi (brand name), a drug approved for the first time in Japan as a drug that works on the cause of Alzheimer's disease and suppresses the progression of the disease, is an example of a drug that a Japanese pharmaceutical company has succeeded in developing using foreign seed capital.

https://www.cas.go.jp/jp/seisaku/souyakuryoku/pdf/interim_report.pdf

Ministry of Health, Labour and Welfare website

unapproved drugs and off-label drugs with high medical needs Request solicitation

You can get various supports from Japanese government if you have the willingness to develop drugs in Japan.

We, Ministry of Health, Labour and Welfare of Japan (MHLW), are looking for the companies to develop unapproved drugs in Japan!

Unapproved drugs are the ones which are approved in some European countries or US, etc. but not in Japan. In February 2010, we began accepting requests from patients including patient groups and academic societies etc. and since then has held the committee to evaluate the medical needs of such drugs.
We are looking for the companies which can develop these unapproved drugs that were evaluated as "High medical needs" in this committee but no companies in Japan which can develop them have been found. We would appreciate your cooperation so that these unapproved drugs can be developed in Japan as soon as possible and used in the medical field as well.

What kinds of support can we provide?

We will provide various supports such as subsidy, management supports, etc. when certain requirements are met for each support.

R & D
- Subsidy: Maximum up to 50% of R&D cost within budget
- Tax-deduction: 20% x [R&D cost – subsidy amount]
- R&D support: Support matching and communication between companies in joint development and coordination with regulatory authorities
- Priority consultations and Priority review

Application for approval
- Subsidy: Maximum 30 million JPY grant amount for each application
- Management support: Provide comprehensive support for each stage from R&D to practical use, and the other supports in the whole process for Startup companies

Drug price
- Incentives for drug prices

For more detailed information on the unapproved drugs we are recruiting to develop, please see this link.
Pharmaceutical Development Support Center (PDSC)
http://www.pdsc.or.jp/about/information/medicine/index.html

MHLW
For inquiries, please contact Ministry of Health, Labour and Welfare of Japan (MHLW).
Clinical Trial Promotion Office,
Research and Development Policy Division, Health Policy Bureau
Mail : Unapproved-Med@mhlw.go.jp

https://www.mhlw.go.jp/content/11120000/kousei_iyaku_shiryou_en_ol_230704.pdf

Measures against Drug Loss

Support for practical application of orphan drugs, pediatric drugs, etc.

- **Orphan drugs: address new systems including earlier designation**
- **Pediatric drugs: address new systems for facilitation of development**
- **Establishment of the Consultation Center for Pediatric and Orphan Drugs Development (dated July 1, 2024)**
- **SAKIGAKE designation system: aim at 6-months total review time**
- **Promotion of early introduction of clinical trial eco system**

Environmental improvement and information dissemination on foreign origin innovative drugs toward development and introduction in Japan

- At foreign academic societies, disseminate information on the regulatory system in Japan and PMDA's services and provide Regulatory Science general consultation, etc. to foreign start-up companies.
- Provide consultations and supports to foreign start-up companies through the PMDA Washington DC office (scheduled to be established by the end of 2024), as a point of contact.
- Exact advice during clinical trial consultations regarding the participation in global clinical trials.

Establishment of the Consultation Center for Pediatric and Orphan Drugs Development (CCPODD)

Since 1 July 2024

For promoting development and introduction of medicinal products for pediatric and rare diseases, ***the Consultation Center for Pediatric and Orphan Drugs Development (CCPODD)*** *is established to provide the necessary consultation.*

* By the Evaluation Committee on Unapproved and Off-label Drugs with High Medical Need. (Independent of the Center)

Development of consultation system

❖ Consultation on Confirmation of the Pediatric Drug Development Program

➢To confirm the pediatric development plan during the development of drugs for adults, which leads to an additional premium on the NHI Drug price list

❖ Consultation on Orphan Drugs eligibility for Priority Review

➢To evaluate whether products designated as orphan medicinal products are eligible for priority review

❖ Drug application data package consultation for unapproved or off-labeled drugs with high medical needs

➢Consultation on the study design and others of the main clinical trial.

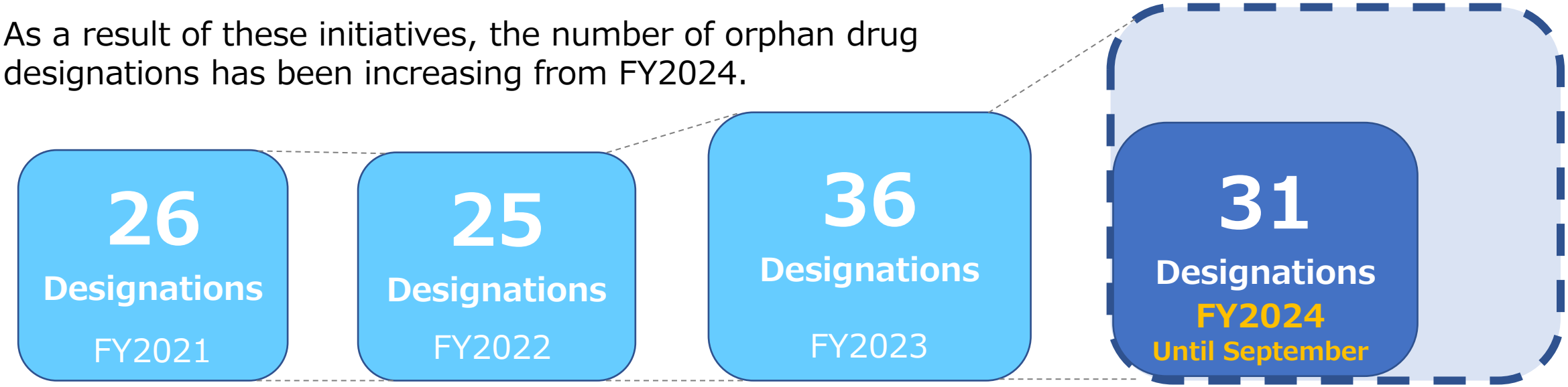
➢Consultation on compilation of application materials, sufficiency of materials based on the results such as the main clinical trial

Trend in the Number of Orphan Drugs Designated in Japan

Factors contributing to increase number of orphan drugs designated in Japan.

1. Criteria for orphan drug designation were revised. (January 2024)
   - ➢ Each designation criteria for number of subjects, medical needs and possibility of development were clarified.
2. The Consultation Center for Pediatric and Orphan Drugs Development (CCPODD) was established in PMDA. (July 2024)

As a result of these initiatives, the number of orphan drug designations has been increasing from FY2024.



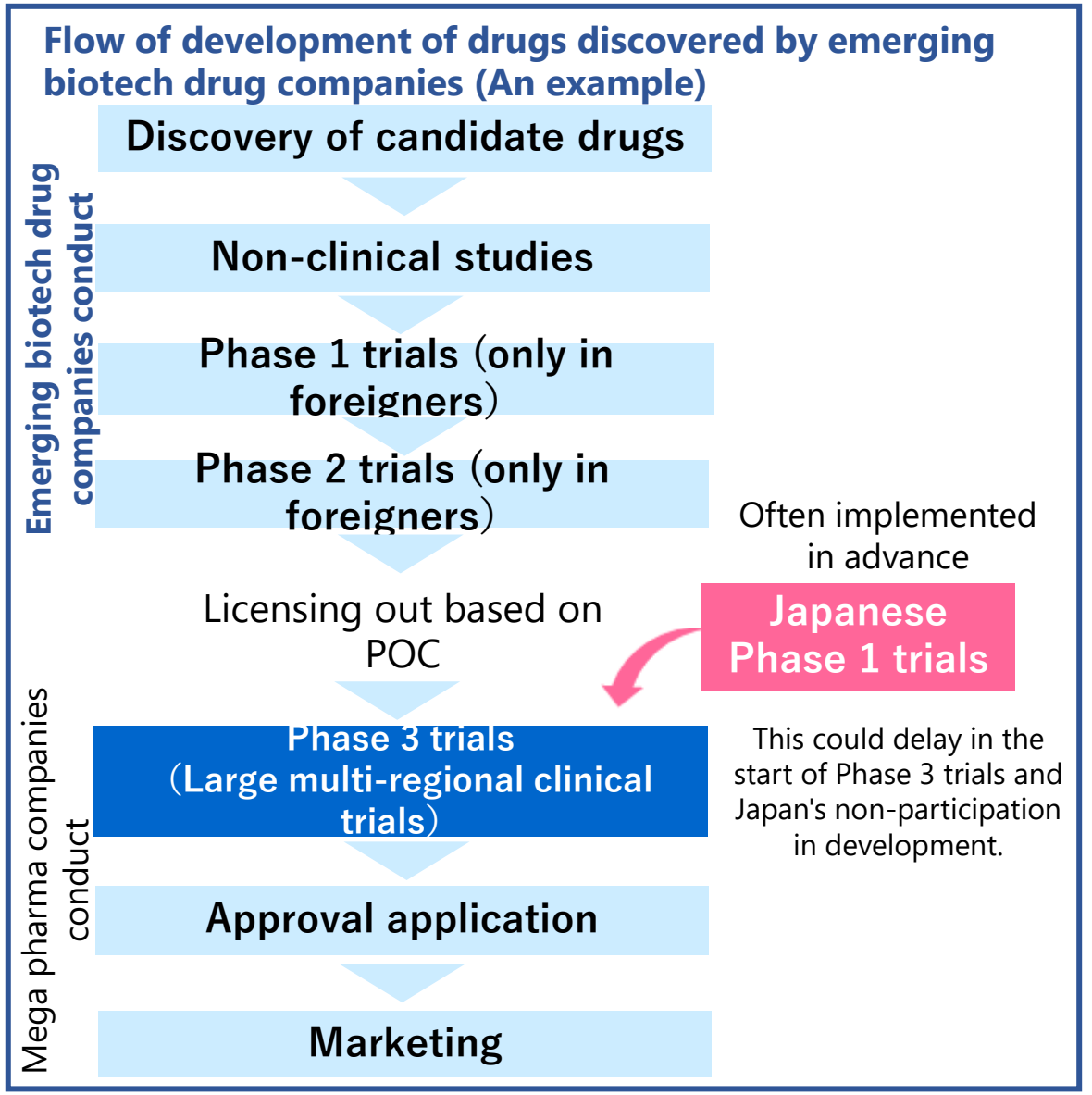
Necessity of Japanese Phase 1 Trial before Initiating Multi-Regional Clinical Trials for Drugs in which development is preceding outside Japan

[Backgrounds]

- When Japan participates in multi-regional clinical trials, if the explanation on safety in Japanese is insufficient, it is necessary to conduct Phase 1 trials in Japanese.
- Because it takes certain time and cost to conduct Phase 1 trials in Japanese, it is noted that development in Japan is abandoned in order to avoid delay in the start of Phase 3 trials.

[PMDA's principle]

- If there are ethnic differences between Japanese and foreigners, we recognize that the Japanese data are important in using drugs safely in Japan
- From the previous, we <u>have not uniformly required</u> Phase 1 trials in Japanese before participating in multi-regional clinical trials, and determines <u>synthetically by considering multiple perspectives</u>.
- It is desirable that Japan participates in multi-regional clinical trials from early stage in development and Japanese data are collected.



(only in Japanese) https://www.mhlw.go.jp/stf/shingi/other-iyaku_128701_00006.html

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•Q&A

PSB/PED Notification No. 1225-2, dated December 25, 2023, by Director, Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau of MHLW
Administrative notice, dated December 25, 2023, by Director, Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau of MHLW（Q&A）

参考 1

Appendix 2

English translation was also issued simultaneously

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

It is stated that in principle, **an additional phase 1 trial in Japanese is not needed, if the safety and tolerability in Japanese participants can be explained and the safety is clinically acceptable and manageable based on the available data.**

1. Introduction

The possibility for Japanese to participate in [illegible] significantly affect the success or failure of [illegible]

https://www.pmda.go.jp/files/000266773.pdf

https://www.pmda.go.jp/files/000266774.pdf

Basic Principles on Japanese Data when Confirmatory Trials are Conducted Only Overseas

PSB/PED Notification No. 1023-3, dated October, 23, 2024, by Director, Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau of MHLW

(1) If drugs meet all of the case 1 to 3, it is possible to submit an application for approval without clinical trial data in Japanese patients

1. Overseas clinical trials for primary evaluation have already been conducted properly

2. It is difficult to newly conduct additional trials due to very few patients, etc.

3. The benefits for Japanese patients are expected to outweigh the risks in general, based on the information available on efficacy and safety

(2) However, if characteristics of drugs and status of similar drugs suggest that there are clinically significant ethnic differences between foreigners and Japanese specifically, and it is determined that additional information concerning the appropriateness of safety and dosage is required, it may be concluded that clinical trials in Japanese including clinical pharmacology study must be conducted.

PMDA Washington D.C. Office

*The office was established in November 2024

PMDA Office
North-America
(4Q 2024)

USA
(Washington DC)

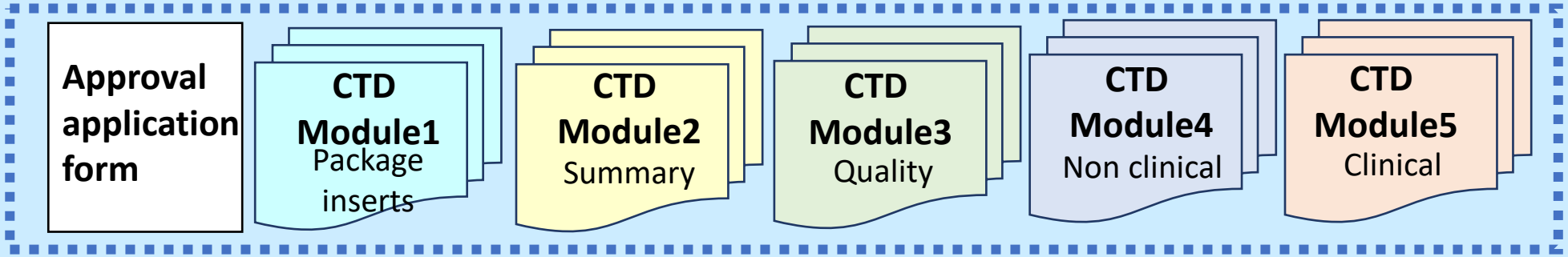
Support venture companies through
- **dissemination of relevant information**
- **General-consultation**

Further collaborations with US-Governmentorganizations (e.g., FDA)

Promoting global product development including Japan

Submitting documents to be attached in the application for approval of new ethical drugs

- Acceptable to submit the entire document, including the written application for approval and the draft package insert, in English at the time of submission of the application.



- Consult with the PMDA, in advance of the submission

Scope	foreign companies without a Japanese corporation or office in Japan
Target products	new ethical drugs (limited to Drugs containing new active ingredients, drugs with new administration routes and new medical combination drugs

https://www.pmda.go.jp/files/000270639.pdf

For your further understanding（PMDA）

Reference materials on development in Japan for overseas ventures

Drugs

https://www.pmda.go.jp/files/000266927.pdf

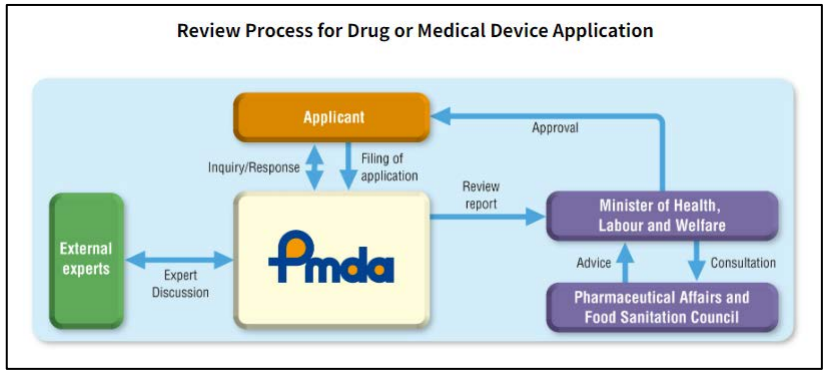
Medical Devices

https://www.pmda.go.jp/files/000264825.pdf

Regenerative Medical Products

https://www.pmda.go.jp/english/review-services/reviews/0003.html

Outline of PMDA services



https://www.pmda.go.jp/english/pnavi_e-04.html

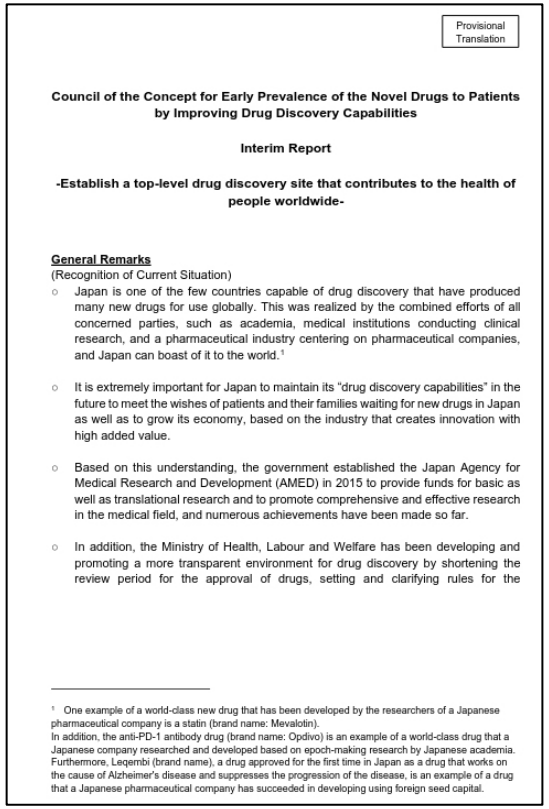
Regulation/Notification

https://www.pmda.go.jp/english/review-services/regulatory-info/0002.html

For your further understanding (other governments)

Interim Report

Council of the Concept for Early Prevalence of the Novel Drugs to Patients
by Improving Drug Discovery Capabilities



Provisional Translation

Council of the Concept for Early Prevalence of the Novel Drugs to Patients by Improving Drug Discovery Capabilities

Interim Report

-Establish a top-level drug discovery site that contributes to the health of people worldwide-

General Remarks
(Recognition of Current Situation)

- Japan is one of the few countries capable of drug discovery that have produced many new drugs for use globally. This was realized by the combined efforts of all concerned parties, such as academia, medical institutions conducting clinical research, and a pharmaceutical industry centering on pharmaceutical companies, and Japan can boast of it to the world.[1]
- It is extremely important for Japan to maintain its "drug discovery capabilities" in the future to meet the wishes of patients and their families waiting for new drugs in Japan as well as to grow its economy, based on the industry that creates innovation with high added value.
- Based on this understanding, the government established the Japan Agency for Medical Research and Development (AMED) in 2015 to provide funds for basic as well as translational research and to promote comprehensive and effective research in the medical field, and numerous achievements have been made so far.
- In addition, the Ministry of Health, Labour and Welfare has been developing and promoting a more transparent environment for drug discovery by shortening the review period for the approval of drugs, setting and clarifying rules for the

[1] One example of a world-class new drug that has been developed by the researchers of a Japanese pharmaceutical company is a statin (brand name: Mevalotin).
In addition, the anti-PD-1 antibody drug (brand name: Opdivo) is an example of a world-class drug that a Japanese company researched and developed based on epoch-making research by Japanese academia. Furthermore, Leqembi (brand name), a drug approved for the first time in Japan as a drug that works on the cause of Alzheimer's disease and suppresses the progression of the disease, is an example of a drug that a Japanese pharmaceutical company has succeeded in developing using foreign seed capital.

https://www.cas.go.jp/jp/seisaku/souyakuryoku/pdf/interim_report.pdf

Ministry of Health, Labour and Welfare website

unapproved drugs and off-label drugs with high medical needs Request solicitation

You can get various supports from Japanese government if you have the willingness to develop drugs in Japan.

We, Ministry of Health, Labour and Welfare of Japan (MHLW), are looking for the companies to develop unapproved drugs in Japan!

Unapproved drugs are the ones which are approved in some European countries or US, etc. but not in Japan. In February 2010, we began accepting requests from patients including patient groups and academic societies etc. and since then has held the committee to evaluate the medical needs of such drugs.
We are looking for the companies which can develop these unapproved drugs that were evaluated as "High medical needs" in this committee but no companies in Japan which can develop them have been found. We would appreciate your cooperation so that these unapproved drugs can be developed in Japan as soon as possible and used in the medical field as well.

What kinds of support can we provide?

We will provide various supports such as subsidy, management supports, etc. when certain requirements are met for each support.

R & D
- Subsidy — Maximum up to 50% of R&D cost within budget
- Tax-deduction — 20% x [R&D cost – subsidy amount]
- R&D support — Support matching and communication between companies in joint development and coordination with regulatory authorities
- Priority consultations and Priority review

Application for approval
- Subsidy — Maximum 30 million JPY grant amount for each application
- Management support — Provide comprehensive support for each stage from R&D to practical use, and the other supports in the whole process for Startup companies

Drug price
- Incentives for drug prices

For more detailed information on the unapproved drugs we are recruiting to develop, please see this link.
Pharmaceutical Development Support Center (PDSC)
http://www.pdsc.or.jp/about/information/medicine/index.html

MHLW
For inquiries, please contact Ministry of Health, Labour and Welfare of Japan (MHLW).
Clinical Trial Promotion Office,
Research and Development Policy Division, Health Policy Bureau
Mail : Unapproved-Med@mhlw.go.jp

https://www.mhlw.go.jp/content/11120000/kousei_iyaku_shiryou_en_ol_230704.pdf

Thank you for your attention

Please visit the PMDA website