Asia First and Collaborative Activities in Asia

FUJIWARA Yasuhiro, M.D., Ph.D.

Chief Executive, PMDA

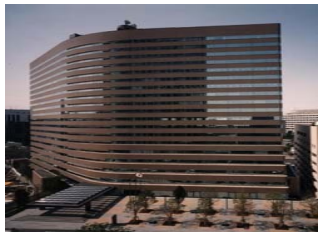
Today's Topic

- **PMDA and Asia**
- **PMDA's Actions against COVID-19**
- **Global cooperation against COVID-19**

4 Firsts

Patient First

Safety First



pmda

Asia First

Access First

Why Asia?

Ethnic Factor

-Similarity to Asia > US & Europe

- ✓ **Pharmacokinetics**
- ✓ **Pharmacodynamics**
- ✓ **Dose-response**
- ✓ **Efficacy and**
- ✓ **Safety**

Growing Population in Asia

Regional cooperation can promote R&D of medical products fit for needs in Asia

Cooperation with Asian Countries

APEC-LSIF-RHSC

(Asia-Pacific Economic Cooperation – Life Sciences Innovation Forum – Regulatory Harmonization Steering Committee)

Japan as co-Chair with the United States.

PWAs	Champion Economies
MRCT/GCP inspection	Japan, Thailand
Pharmacovigilance	Republic of Korea
Biotherapeutics	Republic of Korea
Advanced Therapies	Singapore
Good Registration Management	Chinese Taipei, Japan
Global Supply Chain Integrity	the United States
Medical Devices	Japan, the United States, Republic of Korea

Champion economies lead activities for Priority Work Areas (PWAs).

PMDA is endorsed as Center of Excellences (CoEs) for "MRCT/GCP inspection", "Pharmacovigilance", and "Medical Device" PWA to provide training seminars to promote regulatory convergence, capacity and cooperation.

Capacity Building Activities at PMDA

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

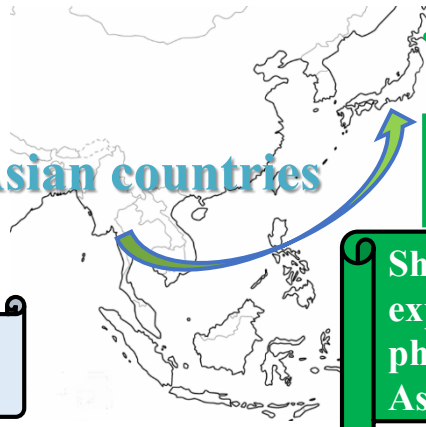
- Established in April, 2016.
- Endorsed as Centers of Excellence (CoE) of APEC-LSIF-RHSC
- Promote capacity building and human resource development through training seminars for Asian regulators

Action Policy of PMDA-ATC

Contribute to universal health coverage in Asia through developing a foundation for regulatory harmonization in the Asian region.

Visits sites and conducts lectures, case studies and practical trainings.

Provides trainings tailored to local needs for more people.



Invites Asian regulatory representatives and offers training seminars.

Shares Japanese knowledge and experiences in the regulation of pharmaceuticals and medical devices with Asian countries.

Trainings provided in FY2020

Contents	Date	Location
Medical Devices Review	August 26-27, 2020	Online (for Thai FDA)
Quality Control (Herbal Medicine)	September 9-11, 2020	Online
Pediatric Review	September 28-October 1, 2020	Online
Japanese Pharmacopoeia	October 20, 2020	Online (for Thai FDA)
Pharmaceuticals Review	November 6, 2020	Online (for Malaysia NPRA)
Medical Devices Review	November 16-20, 2020	Online
Pharmaceuticals Review	December 2, 2020	Online (for Vietnam DAV)
Pharmaceuticals Review	December 15-17, 2020	Online
Multi-Regional Clinical Trial (MRCT)	January 18-21, 2021	Online
Pharmacovigilance	February 1-4, 2021	Online
Regenerative Medicines Review	March 19, 2021	Online (for Malaysia NPRA)

Promoting Regulatory Harmonization in Asia

Basic Policy for Asian Human Well-Being Initiative

(determined by Headquarters for Healthcare Policy in July 2016, revised in July 2018)

- **In order to contribute to the elimination of drug lags between Japan and Asia, harmonization will be promoted so that the pharmaceutical approval and safety regulations in Asia will become more effective and reasonable, such as securing the interoperability of data used for drug approval in Asian countries.**

Circumstances surrounding Asia

Economic growth | **Population growth** | **Aging**

→

- **Increasing public interest in high-quality drugs/medical devices**
- **Expansion of drug/medical device market**

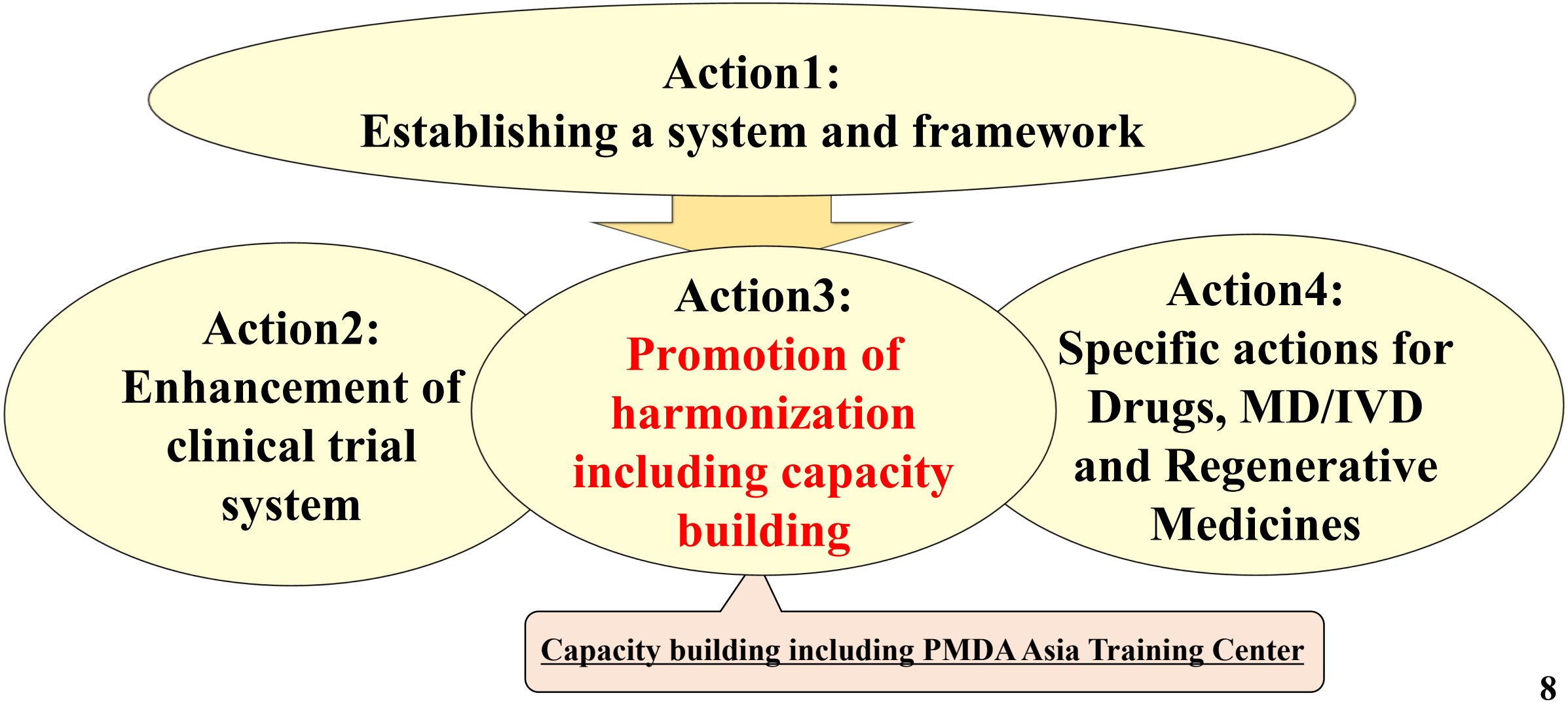
Issues of access to drugs/medical devices

- **Access to innovative drugs/medical devices is secured in Asian countries insufficiently.**
- **Access to drugs/medical devices is a complex issue comprised of research and development, regulation, securing of intellectual property, etc.**
- **Globalization and diversification of drugs/medical devices increase the importance of international regulatory cooperation.**

- **Necessary to specify the Asian Human Well-Being Initiative**
- **Work together to harmonize regulations/related matters with related ministries and agencies.**

- **Establish "Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization" at the HQ for Healthcare Policy of Japan on 20 June 2019.**

Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization



Today's Topic

- PMDA and Asia
- **PMDA's Actions against COVID-19**
- Global cooperation against COVID-19

PMDA's Actions against COVID-19

For COVID-19 Products

- Close interaction with sponsors
- Allowing quick start of clinical trial
- Publishing "Principles on Evaluation of COVID-19 Vaccines"
- Speedy approvals of COVID-19 products
- Cooperation with global regulators

For non-COVID-19 Products

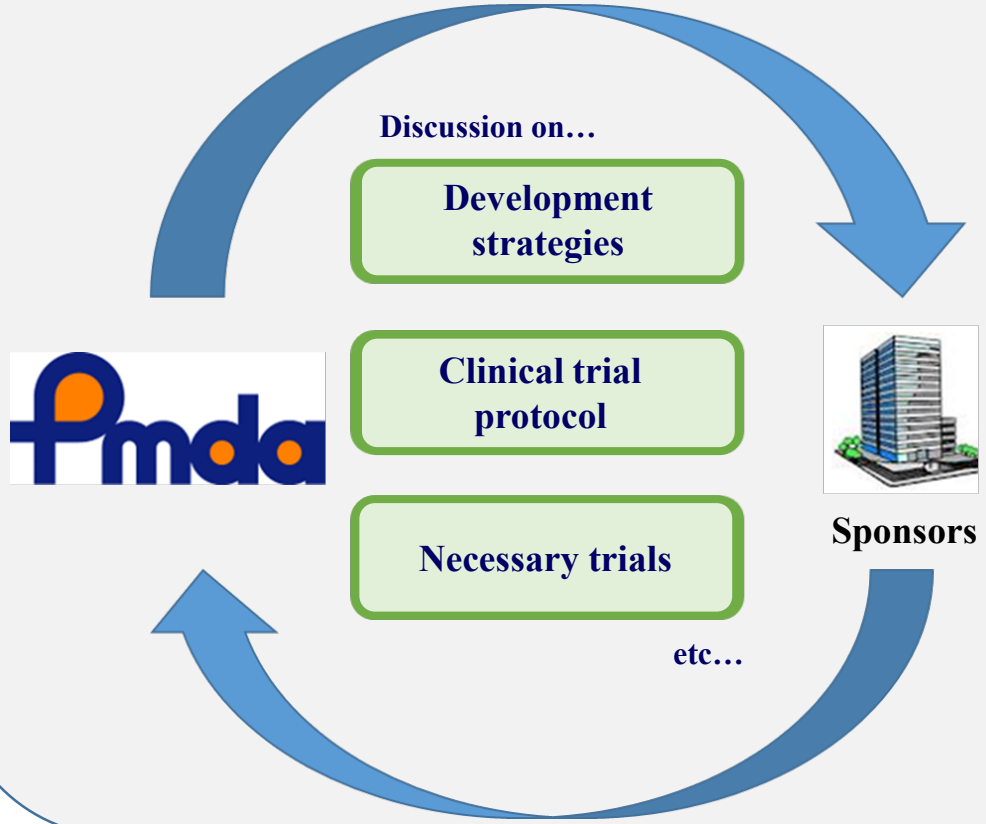
- Providing information on how to manage clinical trials
- Remote GCP inspections

Close Interaction with Sponsors

Many different types of meetings with products developers such as…

From 1st October, 2020

Free Scientific Advice for COVID-19 Vaccines Development

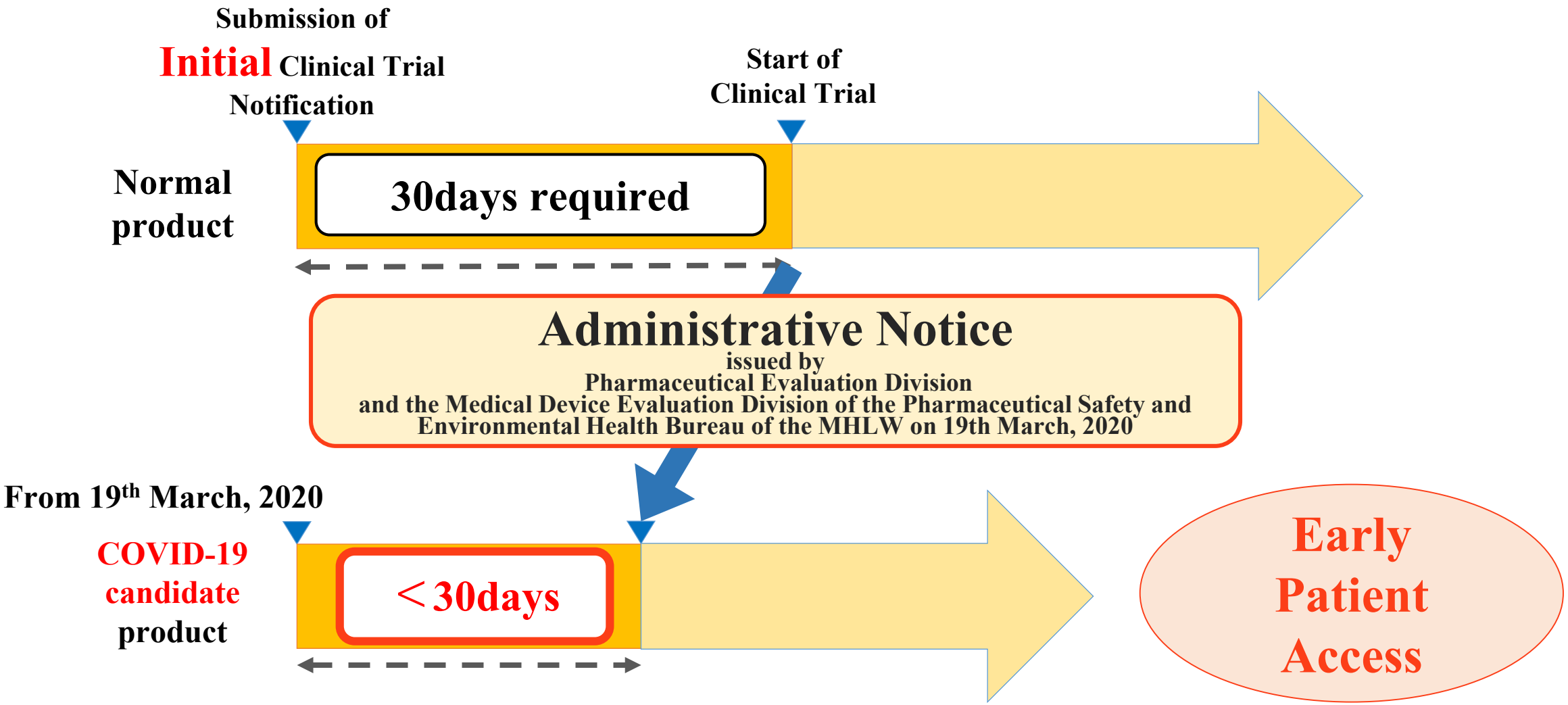


- **As many times as necessary**
- **No waiting time**
- **Free of charge**

Streamlined development for COVID-19 products

https://www.pmda.go.jp/review-services/f2f-pre/strategies/0010.html (Japanese only)

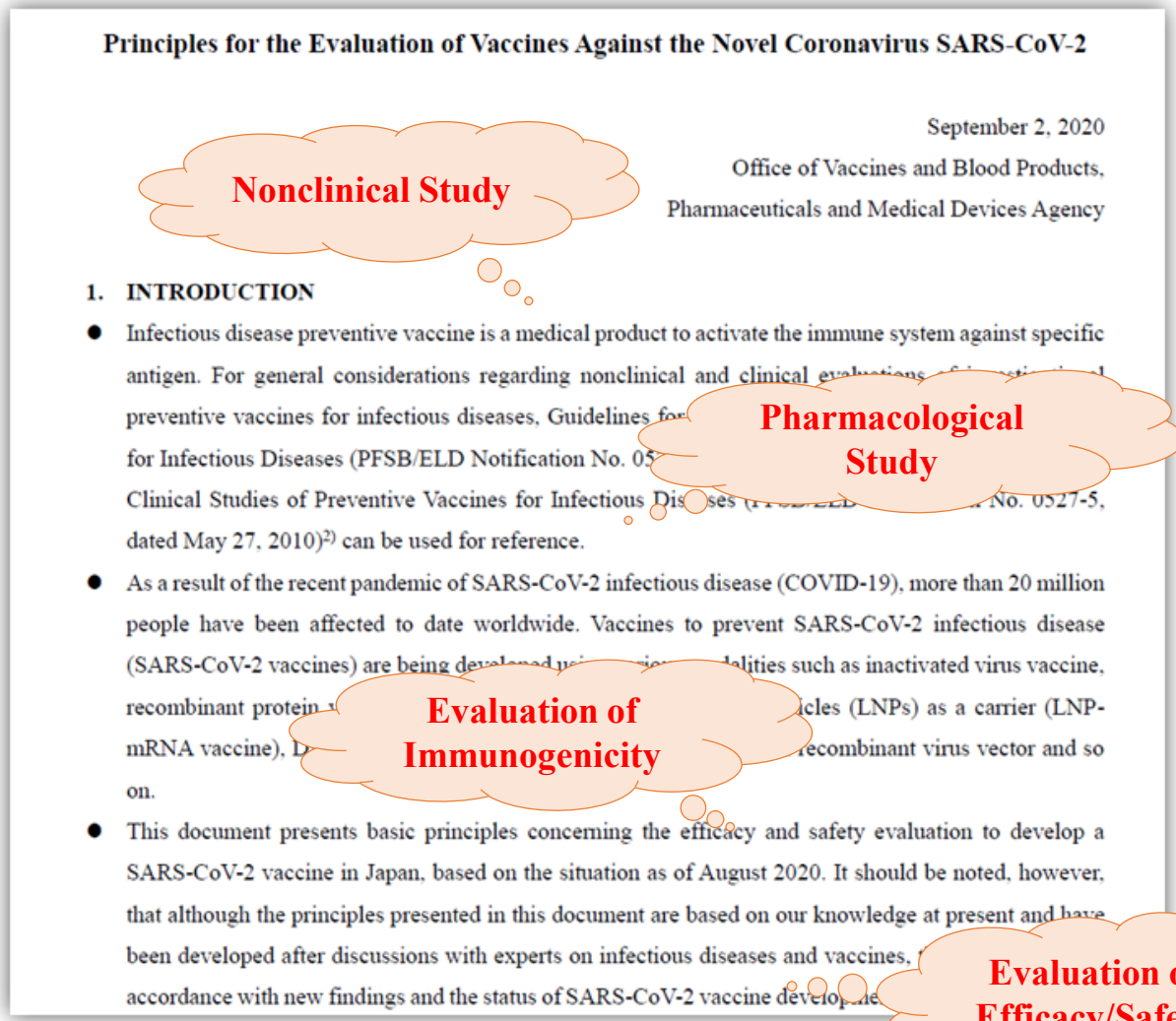
Allowing Quick Start of Clinical Trials



https://www.pmda.go.jp/english/int-activities/0001.pdf

Publishing Principles on Evaluation of COVID-19 Vaccines

Published on 2 September, 2020



Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2

September 2, 2020
Office of Vaccines and Blood Products,
Pharmaceuticals and Medical Devices Agency

Nonclinical Study

1. INTRODUCTION

- Infectious disease preventive vaccine is a medical product to activate the immune system against specific antigen. For general considerations regarding nonclinical and clinical evaluations of [illegible] preventive vaccines for infectious diseases, Guidelines for [illegible] for Infectious Diseases (PFSB/ELD Notification No. 05[illegible] Clinical Studies of Preventive Vaccines for Infectious Dis[illegible]ses ([illegible] No. 0527-5, dated May 27, 2010)[2] can be used for reference.
- As a result of the recent pandemic of SARS-CoV-2 infectious disease (COVID-19), more than 20 million people have been affected to date worldwide. Vaccines to prevent SARS-CoV-2 infectious disease (SARS-CoV-2 vaccines) are being developed using various modalities such as inactivated virus vaccine, recombinant protein [illegible] particles (LNPs) as a carrier (LNP-mRNA vaccine), DNA, recombinant virus vector and so on.
- This document presents basic principles concerning the efficacy and safety evaluation to develop a SARS-CoV-2 vaccine in Japan, based on the situation as of August 2020. It should be noted, however, that although the principles presented in this document are based on our knowledge at present and have been developed after discussions with experts on infectious diseases and vaccines, [illegible] accordance with new findings and the status of SARS-CoV-2 vaccine development.

Pharmacological Study

Evaluation of Immunogenicity

Evaluation of Efficacy/Safety

etc….

Strong tools to help vaccine developers advance their development faster

※ **Guidance on the COVID-19 Vaccines (PMDA)**
https://www.pmda.go.jp/files/000237021.pdf

Special Approval for Emergency

- **Under article 14-3 of the PMD Act**, a certain medical product may be approved when:

1. an emergency situation requires an unapproved medical product to be used to prevent damage to the public health caused by the spread of diseases
2. such emergency situation cannot be managed appropriately by any means other than the use of the unapproved product, and
3. such product is legally available in a country with a regulatory system for medical products that is equivalent to Japan

https://www.pmda.go.jp/english/int-activities/0004.pdf

Special Approval for Emergency
- Remdesivir -

Approval Date	Name of product (Applicant)	Indications
7th May 2020	**Remdesivir** **-Gilead Sciences K.K.-**	**Treatment for disease caused by SARS-CoV-2 infection (COVID-19)**

May 1, 2020 **The Emergency Use Authorization of Remdesivir by the U.S.FDA**

↳ May 4, 2020 **Regulatory Submission by Gilead Sciences to PMDA**

↳ May 7, 2020 **Discussed by Pharmaceutical Affairs and Food Sanitation Council of the MHLW**

Special Approval for Emergency of Remdesivir

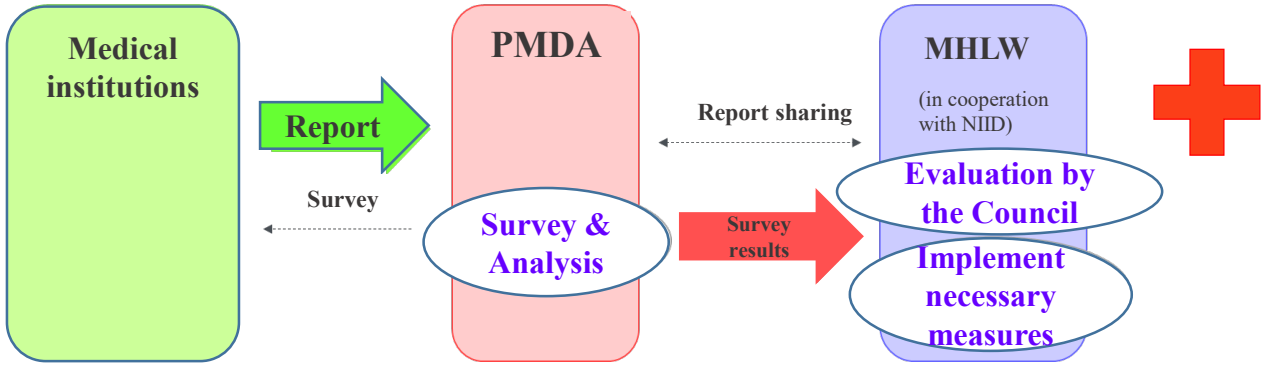
https://www.pmda.go.jp/english/int-activities/0004.pdf

Special Approval for Emergency
- COVID-19 Vaccine -

Approval Date	Name of product (Applicant)	Indications
14th Feb 2021	Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2) —Pfizer Japan Inc.—	Prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

＜Collection and Evaluation of Safety Information for COVID-19 ＞

AEFI (Adverse Events Following Immunization) reporting system



Post-marketing surveillance (by MAH)

Post-vaccination health status survey (by MHLW)

Early-phase health survey (by MHLW)

♦ **Special survey specific for COVID-19 vaccines** ♦

- ✓ **100% follow-up survey in very early-phase of vaccination campaign.**
- ✓ **Symptoms and illnesses for a certain period (about 1 month) after vaccination are collected in approx. 10,000 – 20,000 HCWs.**

Transparency
-Vaccine Safety-

MHLW Press Release:
Report of suspected death after receiving the COVID-19 vaccine

報道関係者各位

新型コロナワクチンの接種後の死亡事例の報告について（１例目）

新型コロナワクチンの接種後の副反応疑い報告において、死亡事例が報告されたため、情報提供します。

No.	事例	ワクチン名	接種日時	発生日時	年代･性別	基礎疾患等	報告者の評価
1	死亡	コミナティ筋注	令和3年2月26日	令和3年3月1日	60代･女性	なし	本剤との因果関係は評価不能

ワクチン接種後には、体内に異物を投与するため、様々な反応が生じます。この副反応疑い報告は、国がワクチンの安全性の評価を行うために、ワクチン接種によるものではない偶発的な症状も含めて、広く収集しているものです。
本プレスリリースは、副反応疑い報告制度の透明性の向上及び周知等のため、当面、接種後にアナフィラキシー又は死亡の報告を受けた際に公表するものです。
今後、厚生労働省では、専門家によるワクチン接種との因果関係の評価や審議会での検討を速やかに行い、ワクチン接種の安全性を評価する予定です。

https://www.mhlw.go.jp/stf/newpage_17104.html

Information contains:

- **Status**
- **Vaccine Name**
- **Date of vaccination**
- **Date of occurrence**
- **Age**
- **Sex**
- **Health issues**
- **Evaluation**

Transparency
-Health Sciences Council-

厚生科学審議会（予防接種・ワクチン分科会副反応検討部会）

回数	開催日	議題等	議事録／議事要旨	資料等	開催案内
第53回	2021年3月12日（令和3年3月12日）	（1）新型コロナワクチンの接種及び副反応疑い報告の状況等について （2）新型コロナワクチンの先行接種者健康調査について （3）その他	－	▸ 資料 NEW 3月12日 ▸ 遵守事項等資料 NEW 3月12日	▸ 開催案内 NEW 3月5日
第52回	2021年2月26日（令和3年2月26日）	（1）新型コロナワクチンの接種及び副反応疑い報告の状況等について （2）新型コロナワクチンの先行接種者健康調査について （3）その他	▸ 議事録 NEW 3月12日	▸ 資料 NEW 2月26日 ▸ 遵守事項等資料 NEW 2月26日	▸ 開催案内
第51回	2021年2月15日（令和3年2月15日）	（1）新型コロナワクチンの副反応への対応について （2）その他	▸ 議事録 NEW 3月1日	▸ 資料 ▸ 遵守事項等資料	▸ 開催案内

12th Mar. 2021

26th Feb. 2021

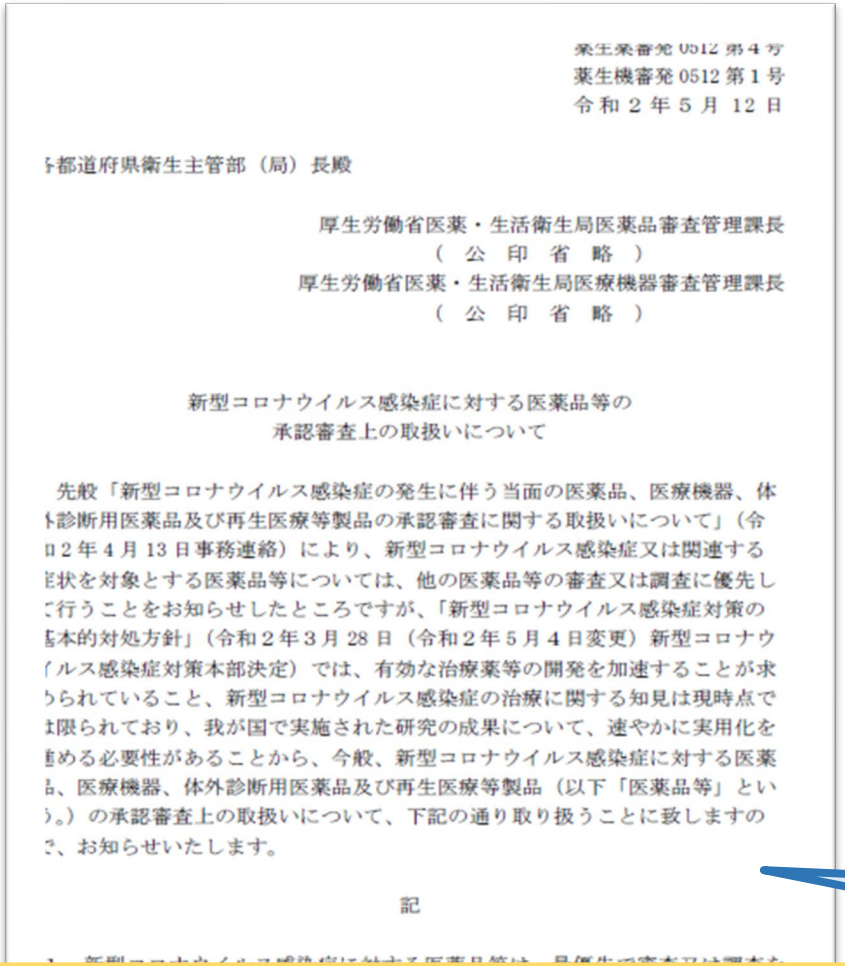
15th Feb. 2021

Side Effect Subcommittee of the Immunization and Vaccine Section Meeting in the Health Science Council has been held frequently to provide an overview of the status of instances of suspected adverse reactions to COVID-19 vaccines.

As of 15 March, 2021

Speedy Approvals of COVID-19 Products

Administrative Notice issued in 12 May, 2020※1



薬生薬審発 0512 第4号
薬生機審発 0512 第1号
令和２年５月 12 日

各都道府県衛生主管部（局）長殿

厚生労働省医薬・生活衛生局医薬品審査管理課長
（ 公 印 省 略 ）
厚生労働省医薬・生活衛生局医療機器審査管理課長
（ 公 印 省 略 ）

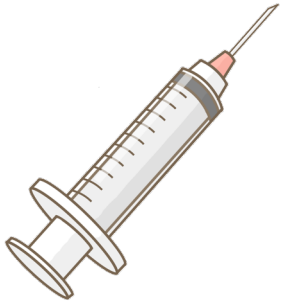
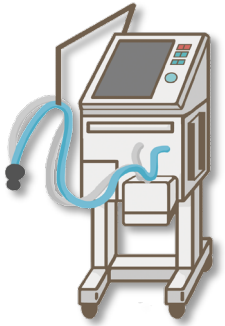
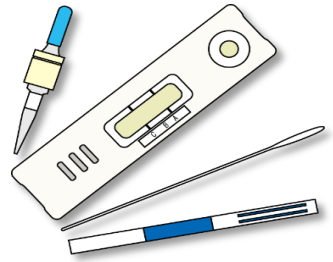
新型コロナウイルス感染症に対する医薬品等の
承認審査上の取扱いについて

先般「新型コロナウイルス感染症の発生に伴う当面の医薬品、医療機器、体外診断用医薬品及び再生医療等製品の承認審査に関する取扱いについて」（令和２年４月13日事務連絡）により、新型コロナウイルス感染症又は関連する症状を対象とする医薬品等については、他の医薬品等の審査又は調査に優先して行うことをお知らせしたところですが、「新型コロナウイルス感染症対策の基本的対処方針」（令和２年３月28日（令和２年５月４日変更）新型コロナウイルス感染症対策本部決定）では、有効な治療薬等の開発を加速することが求められていること、新型コロナウイルス感染症の治療に関する知見は現時点では限られており、我が国で実施された研究の成果について、速やかに実用化を進める必要性があることから、今般、新型コロナウイルス感染症に対する医薬品、医療機器、体外診断用医薬品及び再生医療等製品（以下「医薬品等」という。）の承認審査上の取扱いについて、下記の通り取り扱うことに致しますので、お知らせいたします。

記

Publishing Approval Information in English
URL: https://www.pmda.go.jp/english/about-pmda/0002.html

The number of approved products（As of 20 February, 2021）

Drugs	Vaccines	Medical Devices	IVDs
			
1 product	**1 product**	**14 products**	**46 products**

Priority review for COVID-19 candidate products

※1 https://www.pmda.go.jp/files/000235010.pdf

“The pandemic presents an opportunity for establishing comprehensive no-fault compensation schemes for COVID-19 medical products”

Fujiwara Y et al. Lancet in press 2021

Statements by the Chief Executive Dr. FUJIWARA

9 statements issued:

As of 20 February, 2021

- Special Approval for Emergency on First COVID-19 Vaccine in Japan (16 February, 2021)
- PMDA Reveals Principles on Evaluation of COVID-19 Vaccines (12 October, 2020)
- PMDA to Offer Free Scientific Advice for COVID-19 Vaccines Development (6 October, 2020)
- For Your Access to Japanese Clinical Trial/Clinical Research Information (4 June, 2020)
- First Approval of Antigen Test for COVID-19 (13 May, 2020)
- Special Approval for Emergency on Remdesivir for COVID-19 (8 May, 2020)
- Four IVDs Approvals for COVID-19 and Response to the Increased Ventilator Demand (21 April, 2020)
- PMDA Takes Further Steps to Speed up Clinical Development of COVID-19 Products (10 April, 2020)
- PMDA pledge to tackle COVID-19 Pandemic (31 March, 2020)

PMDA's Actions against COVID-19

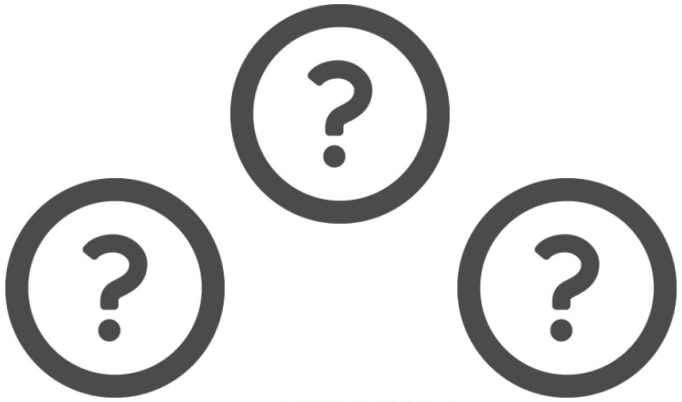
For COVID-19 Products

- Close interaction with sponsors
- Allowing quick start of clinical trial
- Publishing "Principles on Evaluation of COVID-19 Vaccines"
- Speedy approvals of COVID-19 products
- Cooperation with global regulators

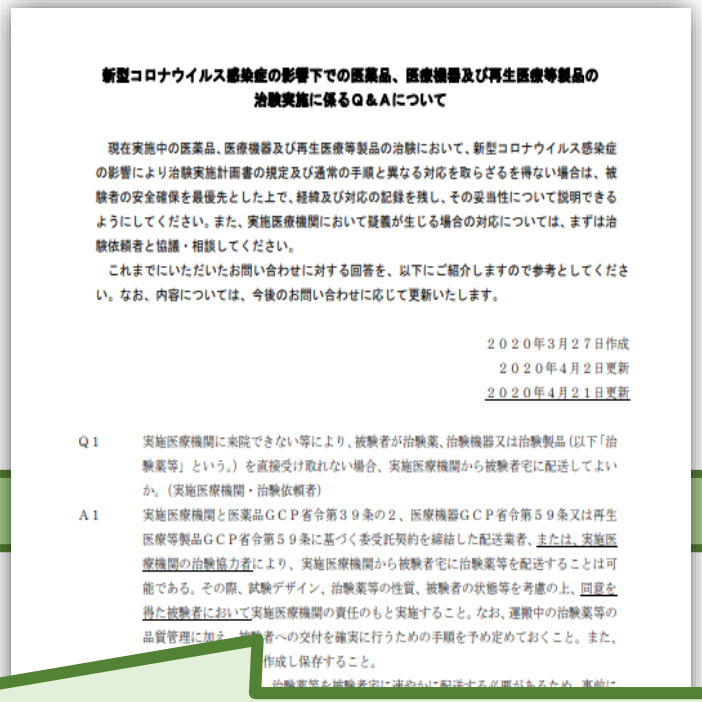
For non-COVID-19 Products

- **Providing information on how to manage clinical trials**
- **Remote GCP inspections**

Q&A on Management of Clinical Trials during COVID-19 Pandemic



Sponsors



新型コロナウイルス感染症の影響下での医薬品、医療機器及び再生医療等製品の治験実施に係るＱ＆Ａについて

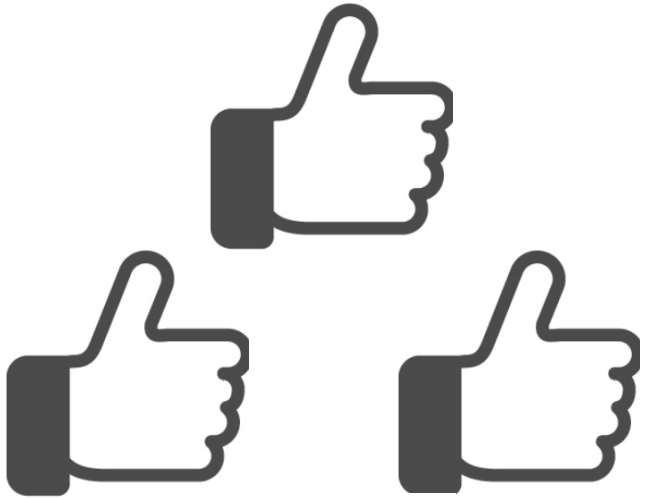
現在実施中の医薬品、医療機器及び再生医療等製品の治験において、新型コロナウイルス感染症の影響により治験実施計画書の規定及び通常の手順と異なる対応を取らざるを得ない場合は、被験者の安全確保を最優先とした上で、経緯及び対応の記録を残し、その妥当性について説明できるようにしてください。また、実施医療機関において疑義が生じる場合の対応については、まずは治験依頼者と協議・相談してください。

これまでにいただいたお問い合わせに対する回答を、以下にご紹介しますので参考としてください。なお、内容については、今後のお問い合わせに応じて更新いたします。

２０２０年３月２７日作成
２０２０年４月２日更新
２０２０年４月２１日更新

Ｑ１　実施医療機関に来院できない等により、被験者が治験薬、治験機器又は治験製品（以下「治験薬等」という。）を直接受け取れない場合、実施医療機関から被験者宅に配送してよいか。（実施医療機関・治験依頼者）

Ａ１　実施医療機関と医薬品ＧＣＰ省令第３９条の２、医療機器ＧＣＰ省令第５９条又は再生医療等製品ＧＣＰ省令第５９条に基づく委受託契約を締結した配送業者、または、実施医療機関の治験協力者により、実施医療機関から被験者宅に治験薬等を配送することは可能である。その際、試験デザイン、治験薬等の性質、被験者の状態等を考慮の上、同意を得た被験者において実施医療機関の責任のもと実施すること。なお、運搬中の治験薬等の品質管理に加え、被験者への交付を確実に行うための手順を予め定めておくこと。また、作成し保存すること。



Sponsors

Provides alternative measures that can be taken when the process predetermined in the study protocol is not deemed feasible due to the COVID-19 situation.

Initially published on 27 March, 2020

https://www.pmda.go.jp/english/int-activities/0002.pdf

Remote GCP Inspections

- **Remote GCP inspections have started from May 2020. ※1**
  - **PMDA can conduct remote inspections to Sponsors.**
  - **Confirmation of management on clinical trial sites by sponsor can be done without GCP on-site inspection**
- **Notification documenting the method of remote GCP inspections was published on Nov. 16, 2020. ※2**

  - **Implementation policy**
  - **Procedure**
  - **Consideration for preparing evidence material**
  - **Consideration for web conference system**

薬機審長発第 1116002 号
令 和 2 年 11 月 16 日

（別記） 殿

独立行政法人医薬品医療機器総合機構
審 査 セ ン タ ー 長
（ 公 印 省 略 ）

医薬品及び再生医療等製品の適合性調査におけるリモート調査の実施方法について

独立行政法人医薬品医療機器総合機構（以下「機構」という。）が、厚生労働大臣の委託を受けて実施する調査のうち、医薬品及び再生医療等製品の承認申請資料の適合性書面調査及びＧＣＰ実地調査、医薬品の中間評価、再審査及び再評価申請資料の適合性書面調査及びＧＰＳＰ実地調査並びに再生医療等製品の条件及び期限付承認後の承認審査、再審査及び再評価申請資料の適合性書面調査及びＧＰＳＰ実地調査（以下「適合性調査」と総称する。）の実施手続きについては、「医薬品の承認申請資料に係る適合性書面調査及びＧＣＰ実地調

※1 https://www.pmda.go.jp/files/000235011.pdf ※2 https://www.pmda.go.jp/files/000237602.pdf

Today's Topic

- PMDA and Asia
- PMDA's Actions against COVID-19
- **Global cooperation against COVID-19**

Multilateral Cooperation
- Leading International Discussion -

Asia-Pacific Economic Cooperation

IMDRF

PIC/S

IPRP International Pharmaceutical Regulators Programme

ICH harmonisation for better health

ICMRA

OECD /GLP BETTER POLICIES FOR BETTER LIVES

I'm here.

Staff from Office of Int'l Programs

Discussion in ICMRA

Discussion on product development at ICMRA:

As of 20 February, 2021

Global regulatory workshop on COVID-19 vaccine development

ICMRA

International Coalition of Medicines Regulatory Authorities

A virtual meeting, held under the umbrella of the International Coalition of Medicines Reg... experts from medicines re... Organisation (WHO) and th...

18 March 2020

The SARS-CoV-2 pandemic that has infec... extraordinary challenge to global health. C... developing SARS-CoV-2 vaccine candidat... DNA, protein and viral vectored vaccines. ... development timelines for SARS-CoV-2 va... trials. Hence, the type and extent of preclin... development program for SARS-CoV-2 va...

Global regulatory workshop on COVID-19 therapeutic development

ICMRA

International Coalition of Medicines Regulatory Authorities

A virtual meeting, held under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA), convening experts from medicines regulatory authorities, the World Health Organization (WHO) and the European Commission

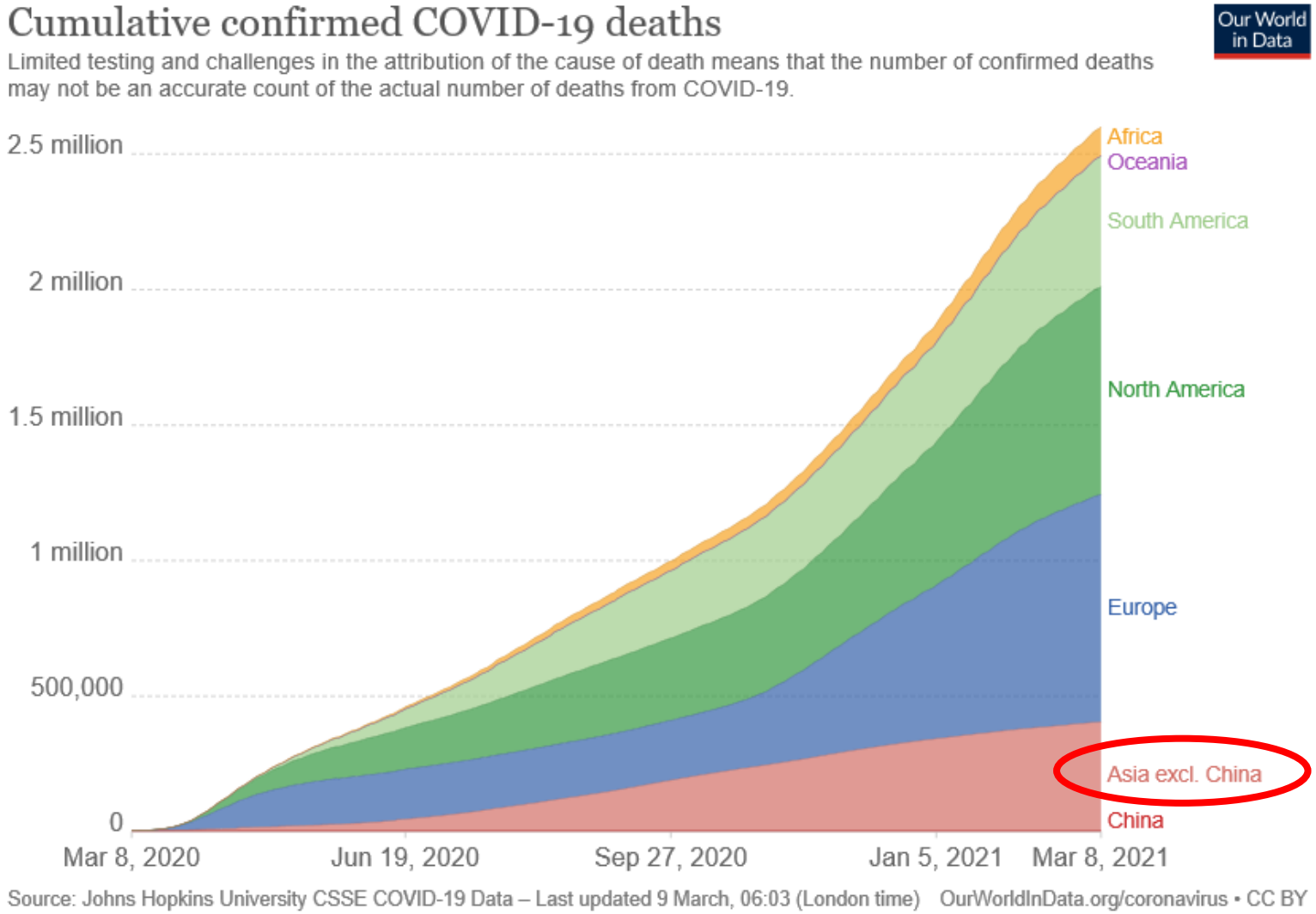
2 April 2020

The COVID-19 pandemic that has infected to date around 1,000,000 people worldwide presents an extraordinary challenge to global health. SARS-CoV-2 therapeutic candidates, including (repurposed) direct acting antivirals and immunomodulating agents are being considered and investigated.

The rapid spread of SARS-CoV-2 requires prompt development for therapeutic candidates to enter clinical trials; additionally, the need of developing pre-exposure prophylaxis (PrEP) and post-exposure

- Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #4 (13 October, 2020)
- Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #3 (22 July, 2020)
- Global regulatory workshop on COVID-19 therapeutic development #2 (20 July, 2020)
- Global regulatory workshop on COVID-19 vaccine development #2 (22 June, 2020)
- Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #2 (19 May, 2020)
- Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #1 (6 April, 2020)
- Global regulatory workshop on COVID-19 therapeutic development #1 (2 April, 2020)
- Global regulatory workshop on COVID-19 vaccine development #1 (18 March, 2020)

Low COVID-19 Mortality in Asia

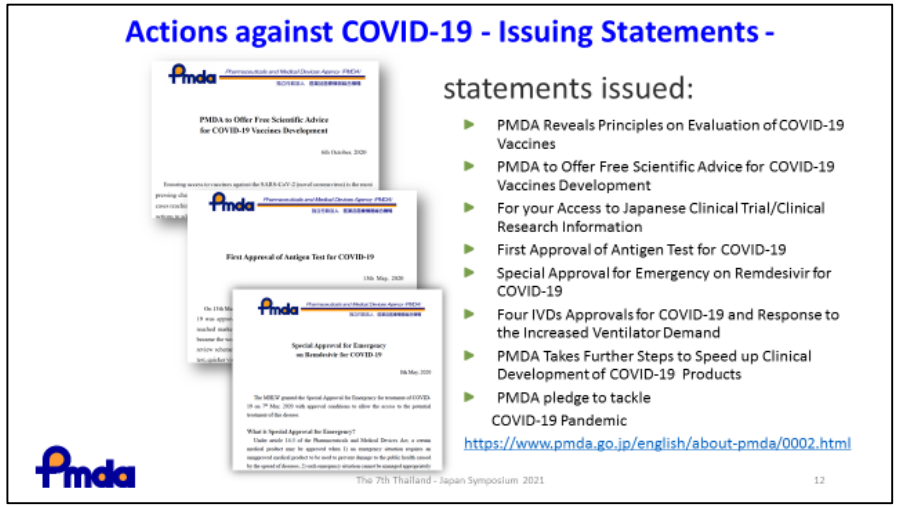


https://ourworldindata.org/grapher/cumulative-covid-deaths-region

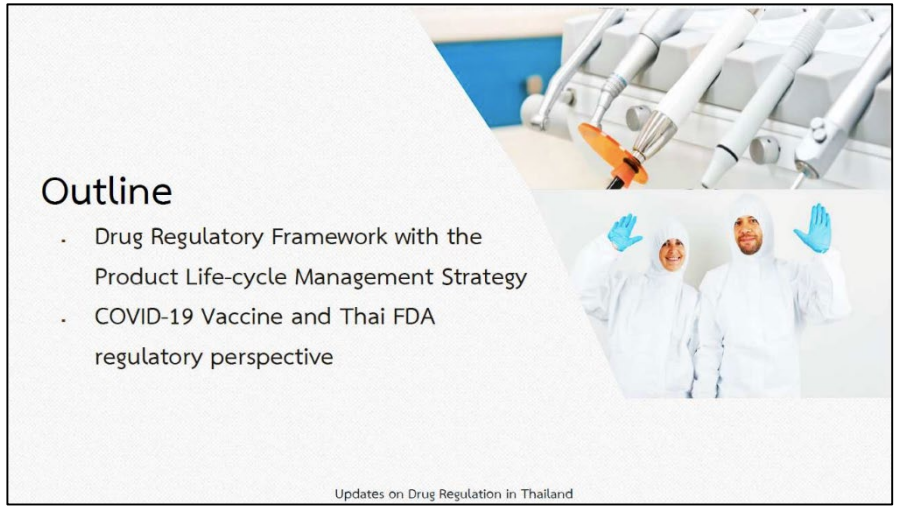
Discussion in Joint Conference

The 7th Thailand-Japan Symposium (January 13 and 14, 2021)

Slide from Japan side



Slide from Thai Side



Discussion in Bilateral Meeting

1. Thailand-Japan Bilateral Meeting

PMDA held Thailand-Japan Bilateral meeting together with Thai Food and Drug Administration (Thai FDA) via the internet on July 15.

Key participants from PMDA included Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. UZU Shinobu (Senior Executive Director), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), Dr. SATO Junko (Director of Office of International Programs). In addition, from Ministry of Health, Labour and Welfare (MHLW), Mr. YASUDA Naoyuki (Director of Office of International Regulatory Affairs) participated. Key participants from Thai FDA included Dr. Paisarn Dunkum (Secretary-General), Dr. Surachoke Tangwiwat (Deputy Secretary-General), Dr. Poonlarp Chantavichitwong (Deputy Secretary-General).

In the bilateral meeting, Dr. Dunkum and Dr. FUJIWARA made opening remarks and then measures against COVID-19 in Thailand and Japan were shared. After that, any other topics of Thailand –Japan cooperation concerned with pharmaceutical and medical device regulation were discussed by the participants. PMDA and Thai FDA decided to continue the effective cooperation, but it is actually difficult to hold face-to-face events due to COVID-19 outbreak.

PMDA Updates August, 2020
https://www.pmda.go.jp/files/000236329.pdf

5. Malaysia-Japan Bilateral Meeting

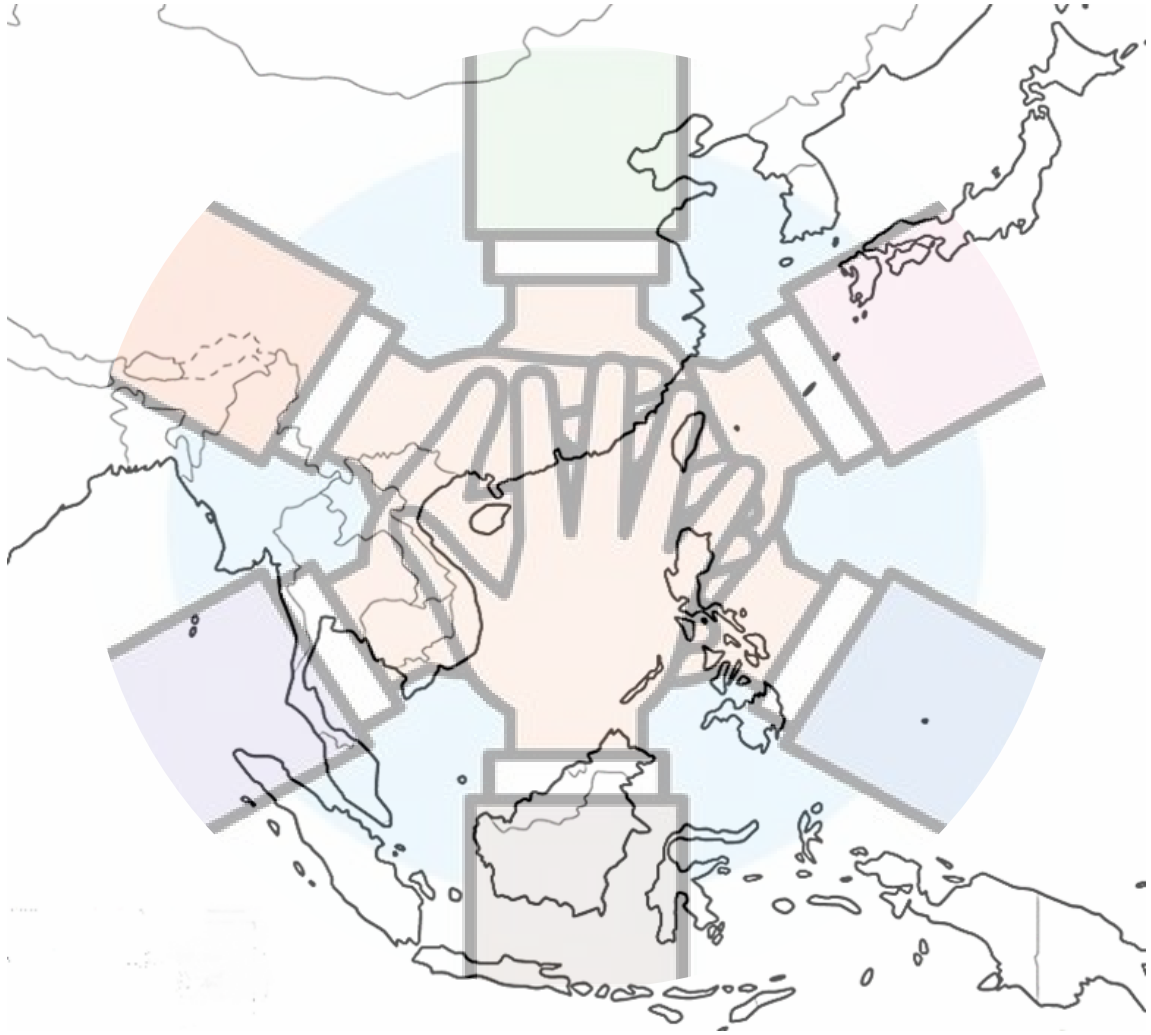
PMDA held Malaysia-Japan Bilateral Meeting together with National Pharmaceutical Regulatory Agency (NPRA) via the internet on November 17.

Key participants from PMDA included Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. UZU Shinobu (Senior Executive Director), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs) and Dr. SATO Junko (Director of Office of International Programs). In addition, from Ministry of Health, Labour and Welfare (MHLW), Dr. YASUDA Naoyuki (Director of Office of International Regulatory Affairs) participated. Key participants from Malaysia included Datin Dr. Faridah Aryani Md Yusof (Senior Director of Pharmaceutical Services Programme) and Dr. Hasenah Ali (Director of NPRA).

In the bilateral meeting, Datin Dr. Faridah and Dr. FUJIWARA made opening remarks and then measures against COVID-19 in Malaysia and Japan were shared. After that, any other topics of Malaysia-Japan cooperation concerned with pharmaceutical regulation was discussed by the participants. Although it is difficult to hold face-to-face events due to COVID-19 outbreak, PMDA and NPRA decided to continue the effective cooperation.

PMDA Updates December, 2020 **https://www.pmda.go.jp/files/000238352.pdf**

Working as “Team Asia”



Collaborative Activities

- PMDA-ATC
- Symposium
- Bilateral Meeting

Thank You!