

The 11th

Asia Partnership Conference of Pharmaceutical Associations

Building a platform and delivering valuable innovation for the peoples in Asia

- Next decade of APAC

aUHC Session: "Toward the achievement of true UHC in Asia."

-UHC in Asia beyond the Pandemic- Lessons Learned and Future Perspectives

Tuesday, April 5, 2022; from 18:30-18:50

Keizo Takemi

Member, House of Councillors, Japan

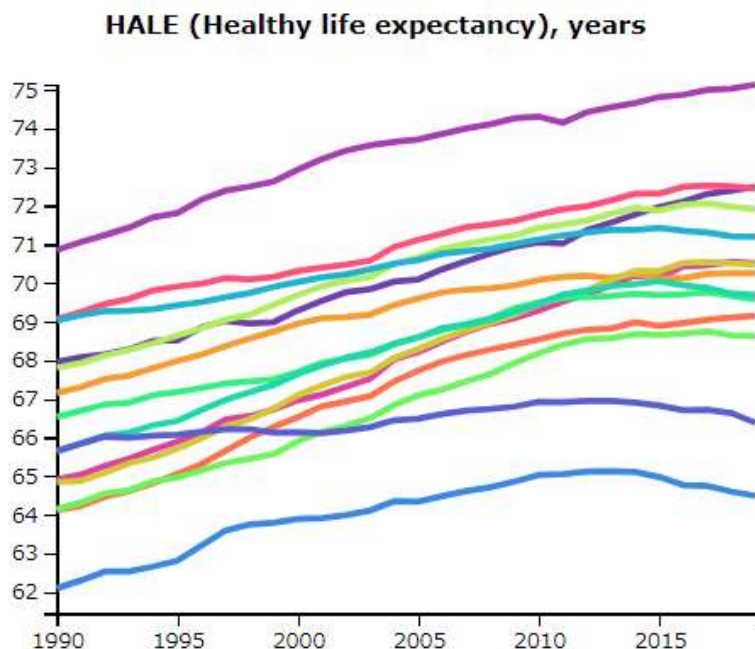
Chairperson, Special Committee on Global Health Strategy, LDP

WHO Goodwill Ambassador for UHC

Japan has Comparative Advantage Internationally in the Health Sector

Japan's Motive (1)

- After the **Second World War**, Japan knew that the task of **rebuilding a nation** would require **investments** not only in new **infrastructure** but also in **human capital**
- Japan made a **political choice**: a choice to **invest** in the **health** of its population through **universal health insurance**
- Today, Japan has the world's **longest life expectancy** and the world's third-largest economy. In **2021**, Japan celebrated the **60th anniversary** of its **UHC**
- **Accessible, effective, efficient, available to all citizens and affordable**



Japan, Males, All Ages	72.49
Japan, Females, All Ages	75.13
France, Males, All Ages	70.50
France, Females, All Ages	72.44
Germany, Males, All Ages	69.15
Germany, Females, All Ages	70.25
Italy, Males, All Ages	70.47
Italy, Females, All Ages	71.91
United Kingdom, Males, All Ages	68.62
United Kingdom, Females, All Ages	69.58
Canada, Males, All Ages	69.69
Canada, Females, All Ages	71.19
United States of America, Males, All Ages	64.48
United States of America, Females, All Ages	66.37

High-Level Advisory Panel for a Special Report on Human Security

Japan's Motive (2)

The Search for Future-oriented Pacifism
Organizing the Concept of Human Security

Human Security

- The concept of human security was first publicly addressed in UNDP's Human Development Report in 1994.
- It was subsequently discussed under the Commission on Human Security established in 2001 and co-chaired by former UN High Commissioner for Refugees **Ms. Sadako Ogata** and **Professor Amartya Sen**. In 2003, a report entitled "Human Security Now" was published.



Millennium Development Goals (MDGs): Goals and Targets

Japan's Motive (3) From International Health to Global Health

The MDGs were universal development goals that integrated the United Nations Millennium Declaration, which was adopted at the United Nations Millennium Summit in New York in September 2000. There were 8 goals, including eradicating extreme poverty and hunger, that were to be achieved by 2015.



1

1 Eradicate extreme poverty and hunger

•Target 1.A

Halve, between 1990 and 2015, the proportion of people whose income is less than \$1 a day.

•Target 1.B

Achieve full and productive employment and decent work for all, including women and young people.

•Target 1.C

Halve, between 1990 and 2015, the proportion of people who suffer from hunger.



2

2 Achieve universal primary education

•Target 2.A

Ensure that, by 2015, children everywhere, boys and girls alike, will be able to complete a full course of primary schooling.



3

3 Promote gender equality and empower women

•Target 3.A

Eliminate gender disparity in primary and secondary education, preferably by 2005, and in all levels of education no later than 2015.



4

4 Reduce Child Mortality

•Target 4.A

Reduce by two thirds, between 1990 and 2015, the under-five mortality rate.



5

5 Improve maternal health

•Target 5.A

Reduce by three quarters, between 1990 and 2015, the maternal mortality ratio.

•Target 5.B

Achieve, by 2015, universal access to reproductive health.



6

6 Combat HIV/AIDS, Malaria, and other diseases

•Target 6.A

Have halted by 2015 and begun to reverse the spread of HIV/AIDS.

•Target 6.B

Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it.

•Target 6.C

Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases.



7

7 Ensure environmental sustainability

•Target 7.A

Integrate the principles of sustainable development into country policies and programs and reverse the loss of environmental resources

•Target 7.B

Reduce biodiversity loss, achieving, by 2010, a significant reduction in the rate of loss.

•Target 7.C

Halve, by 2015, the proportion of the population without sustainable access to safe drinking water and basic sanitation

•Target 7.D

Achieve, by 2020, a significant improvement in the lives of at least 100 million slum dwellers.



8

8 Develop a global partnership for development

•Target 8.A

Develop further an open, rule-based, predictable, non-discriminatory trading and financial system.

•Target 8.B

Address the special needs of least developed countries.

•Target 8.C

Address the special needs of landlocked developing countries and small island developing States.

•Target 8.D

Deal comprehensively with the debt problems of developing countries.

•Target 8.E

In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.

•Target 8.F

In cooperation with the private sector, make available benefits of new technologies, especially information and communications

Japan's Key Milestones: Major Global Health Meetings

日本の国際保健外交における主要な国際会議

- July 2000 G8 Kyushu-Okinawa Summit
- Sep 2000 UN Millennium Summit
- July 2008 G8 Hokkaido Toyako Summit
- Sept 2013 68th UNGA68 Post-2015: Health and Development
- Sep 2015 UN Sustainable Development Summit 2015
- Dec 2015 UHC Conference in Tokyo
- May 2016 G7 Ise-Shima Summit
- Dec 2017 UHC Forum 2017
- Oct 2018 Global Conference on Primary Health Care
- Jun 2019 G20 Osaka Summit
 - Finance Minister and Health Minister's Meeting
- Aug 2019 TICAD7
- Sep 2019 74th UNGA UHC ULM
- Oct 2019 G20 Health Ministers' Meeting in Okayama
- Dec 2019 World Health Summit
- Jan-Feb 2020 PMAC2020 UHC2020
- Sep 2020 Finance and Health Ministers' Symposium
 - ADB, WHO, Japan
- Jun 2021 COVAX AMC Summit
- Dec 2021 Tokyo Nutrition for Growth (N4G) Summit 2021
- 2023 G7 JAPAN Summit
- Sep 2023 78th UNGA UHC HLM

MDGs

SDGs

Hosted by Japan

HIV/AIDS, Malaria, TB

MDG4, 5, 6

Health System Strengthen (HSS)

Universal Health Coverage (UHC)

SDG3.8: UHC

Public Health Emergencies & UHC

Accelerate efforts to achieve UHC

Mobilizing domestic funds for UHC

UHCファイナンスに関するG20財務大臣・保健大臣合同セッション Joint Session of Finance and Health Ministers' Meeting on UHC Financing



G20 Shared Understanding on the Importance of UHC Financing in Developing Countries —Towards sustainable and inclusive growth— (June 6, 2019)

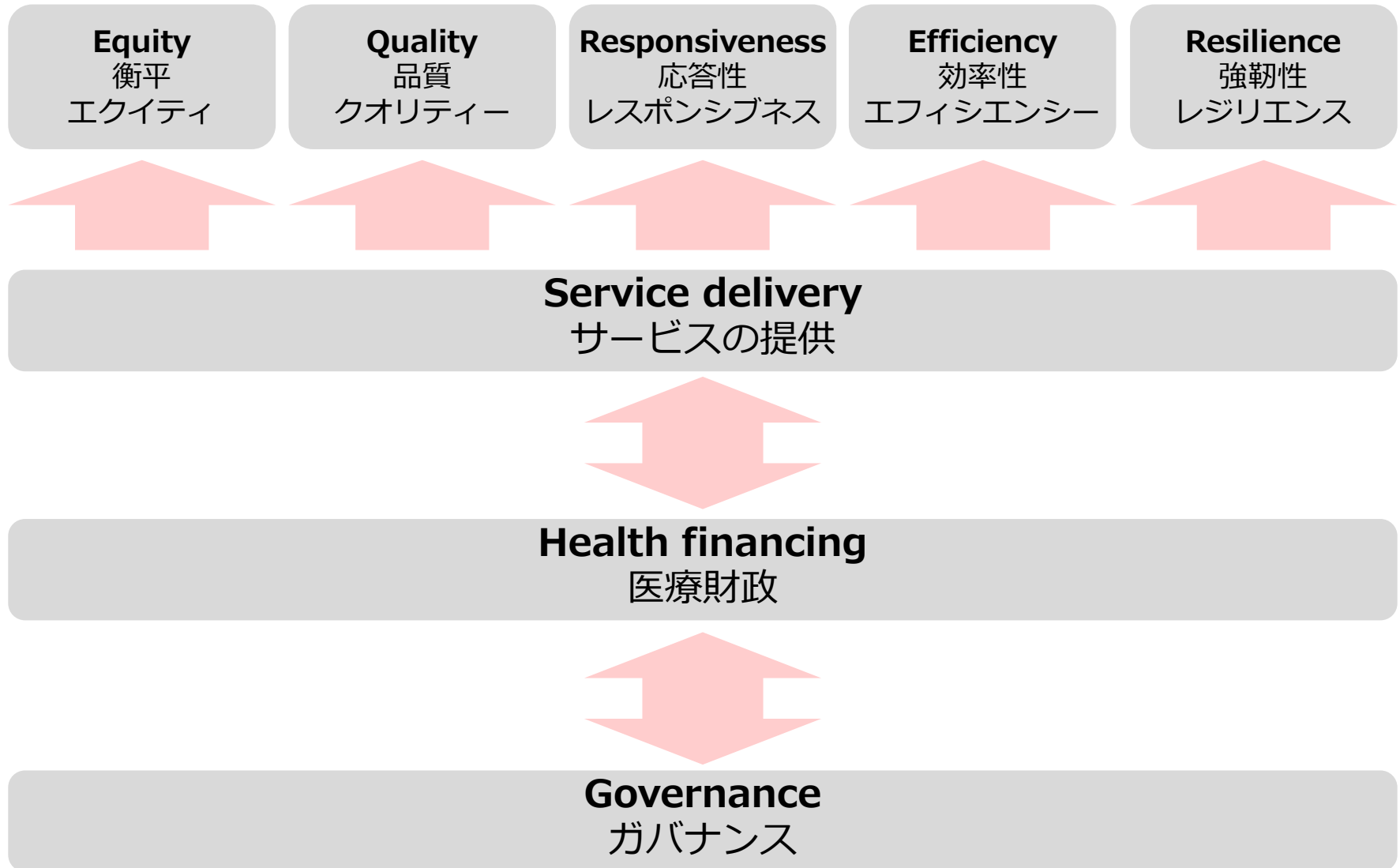
Key considerations for finance authorities

1. Power of an early start and preparedness for the future
 2. Prioritizing domestic sources in a fair and equitable manner
 3. External funding sources to complement domestic sources
 4. Cost-effective and equitable health systems
 5. Public health emergency preparedness and response
 6. Building institutional capacity
 7. Contribution of the private sector
 8. Finance ministries' roles and collaboration with health authorities
1. 経済発展の早い段階における取組の重要性
 2. 国内資金を主な財源とした保健財政制度の設計
 3. 国内資金を補完する形での国外資金の活用
 4. 費用対効果があり、かつ公平な保健システムの構築
 5. 保健危機への事前の備え・対応
 6. 組織的なキャパシティの構築
 7. 民間セクターの活用
 8. 財務当局の役割と保健当局との連携

Health systems strengthening towards universal health coverage

ユニバーサル・ヘルス・カバレッジに向けた保健システム強化

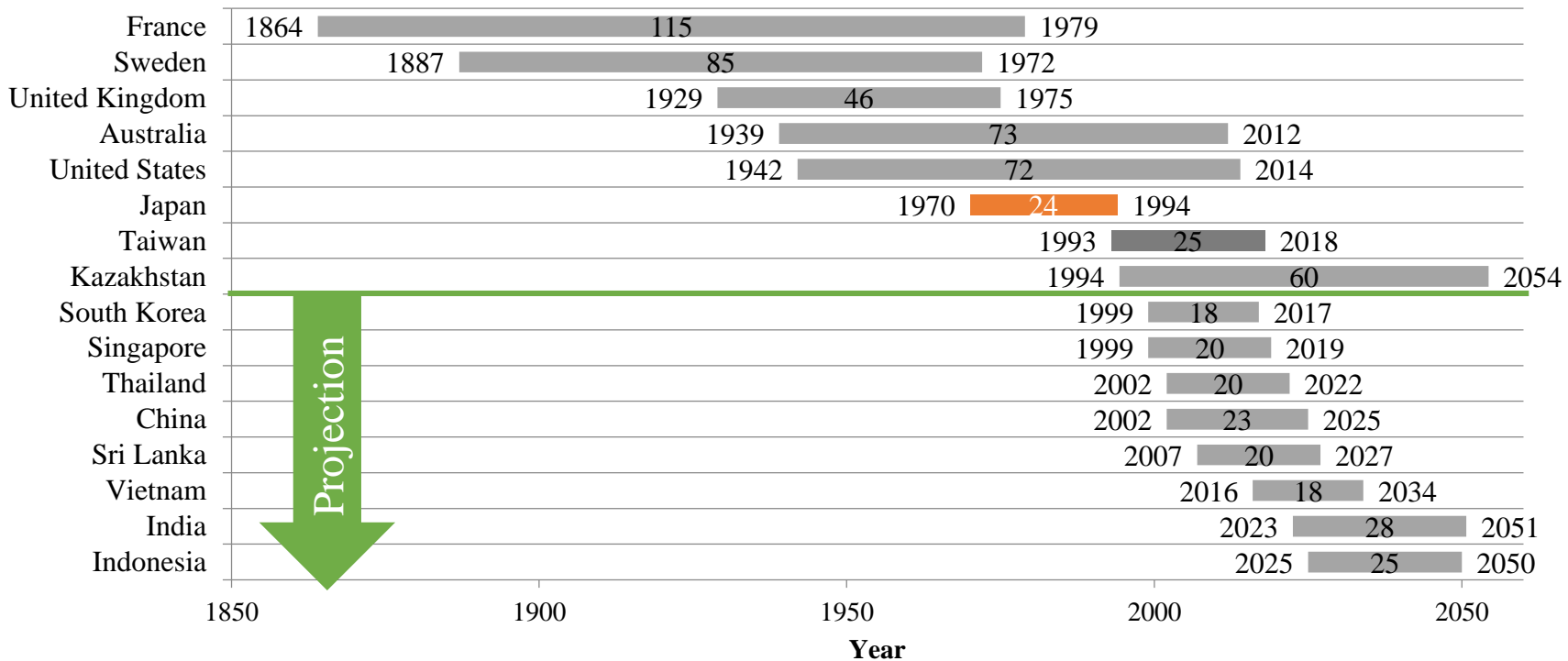
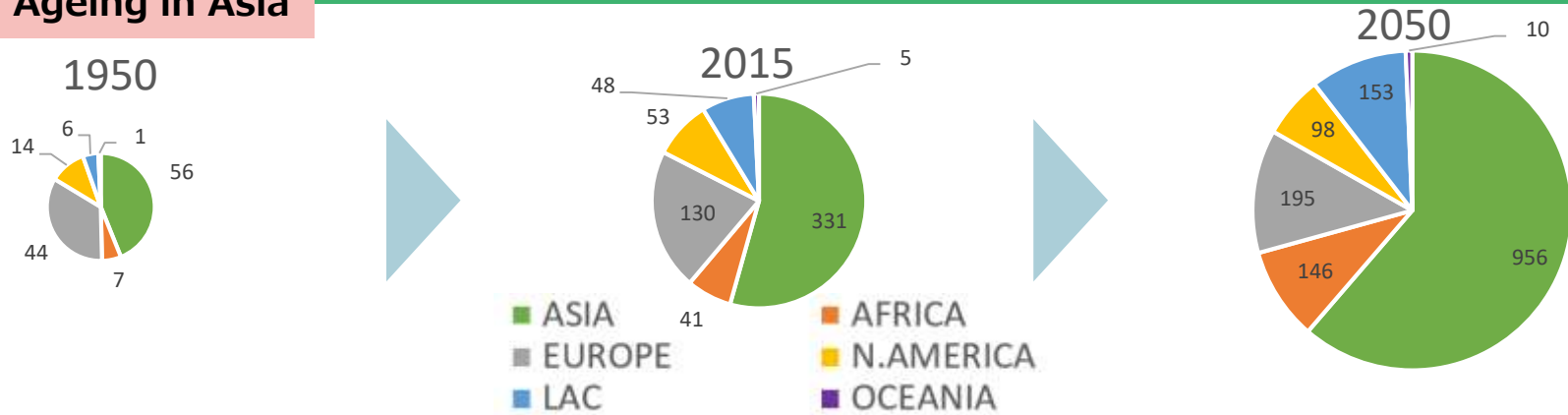
Priority Framework on UHC



Projection of the global population aged 65 years and over & the proportion of older people has increased from 7% (Ageing Society) to 14% (Aged Society)

Period required for an increase to 14% (Aged Society)

Rapid Ageing in Asia



From Japan to Asia Pacific region



Provision of Services by Specific Businesses

Building of Foundations Necessary for Healthcare



※Healthcare service: Services related to prevention of diseases and maintenance of good health, etc. provided in Japan mainly uninsured

Promotion of Asian Pharmaceutical and Medical Device Regulatory Harmonization

From AHWIN to Regulatory Harmonization

Basic Principles of the Asia Health and Wellbeing Initiative (AHWIN, established by the Headquarters for Healthcare Policy of Japan in July 2016; revised July 2018)

- In order to contribute to resolving the 'drug lag' between Japan and Asia, Japan will **promote harmonization efforts to make pharmaceutical approval systems and safety regulations more effective and rational** by ensuring interoperability in Asian countries/regions of data used for approval of pharmaceuticals.

Situation surrounding Asia

Economic growth

Population increase

Aging



Increasing public interest in high-quality pharmaceuticals and medical devices
Expansion of pharmaceutical/medical device market

Issues of access to pharmaceuticals and medical devices

- Access to innovative pharmaceuticals and medical devices is insufficient in Asian countries/regions.
- Access to pharmaceuticals and medical devices is a complex issue related to research and development, regulation, securing of intellectual property, etc.
- Globalization and diversification of products mean increasing regulations and heightened importance of international cooperation



Work together to harmonize regulations and handle related matters by having the competent ministries and agencies through concrete measures to the AHWIN

Goals

Develop a borderless Asian market for pharmaceuticals and medical devices
Contribute to healthy and active aging in Asia as a new Japanese initiative

From Regulatory Harmonization to **NCDs** Clinical Trial**PURPOSE**

- Establish **Asian Cancer Trials Network**
 - Facilitate early drug development and genomic medicine together with Asian countries
- Conduct multiple international trials under the ATLAS project
 - Initially focus on academic clinical trials
 - Encourage industries to utilize the ATLAS network

Asian Well-being Initiative (AHWIN)

- Asian Pharmaceutical and Medical Device Regulatory Harmonization
 - **NCDs: ATLAS Project**
 - Communicable Diseases: ARISE Project

Part of **GOVERNMENTAL POLICY on UHC in Asia**

- Promote regulatory harmonization
- Establish the infrastructure for clinical trials

BUDGET

- NCC has received **15M USD** from the Japanese funding agency

NCC Asian Partnerships Office @Bangkok

- Strengthen local ARO (Academic Research Organization) function for Japan-led international trials at lower cost
- Reinforce local site management & on-site monitoring function
- Reduce CRO (Clinical Research Organization) costs and achieve low-cost Asian collaborative studies
- Strengthen network with facilities, regulators, government, etc.



AMEDアジアがん臨床試験ネットワーク事業

ATLAS Project (Asian clinical Trials network for cAnCerS)

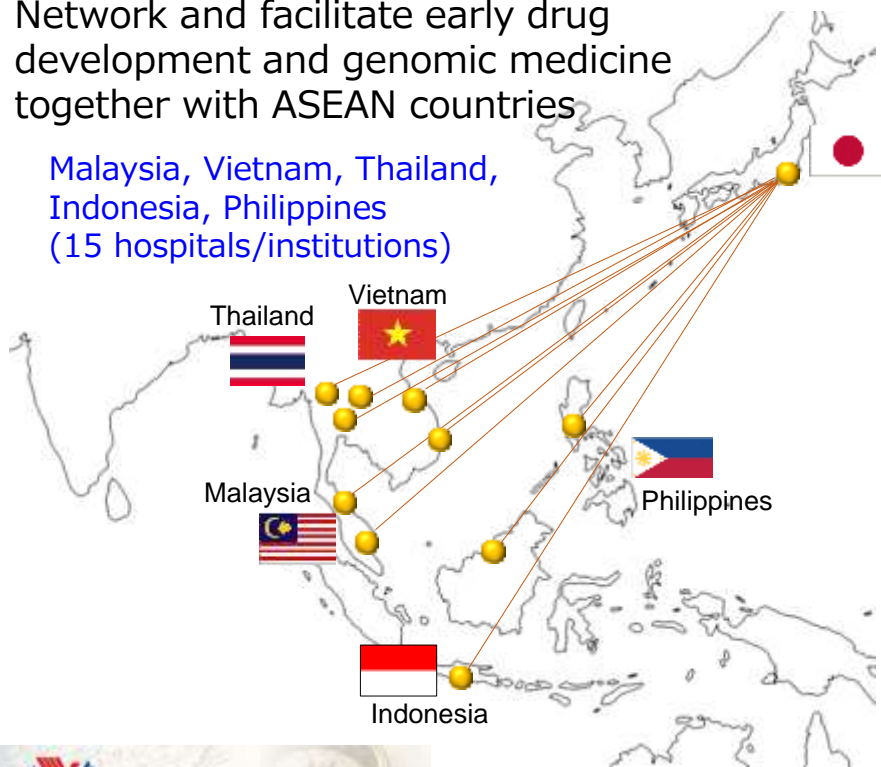
From Regulatory Harmonization to **NCDs** Clinical Trial

Existing networks with highly advanced Asian countries (Korea, Taiwan, Singapore, China (HK))



Establish and expand the Asian Cancer Trials Network and facilitate early drug development and genomic medicine together with ASEAN countries

Malaysia, Vietnam, Thailand, Indonesia, Philippines
(15 hospitals/institutions)



Strength in Asian networks:

- Population growth, economic development, aging society - increase of cancer patients, more needs for high-level treatment
- Little ethnic differences - genetics, physiques ...
- Reasonable cost in conducting clinical trials
- Area-specific cancers
 - liver, heat & neck, stomach etc.



ATLAS project

- Building infrastructure & clinical trials networks
- Capacity building programs
 - clinical trial procedure & genomic cancer medicine
- International clinical trials under ATLAS
 - MASTER KEY Asia, A-TRAIN study, TEAL trial



Goals of ATLAS:

- Establish the infrastructure for clinical trials in Asia
- Introduce genome-based medicine in Asian
- Obtain/expand drug indication simultaneously in Asia promoting regulatory harmonization with PMDA



From RH to Infectious Disease Clinical Trial

VISION

ARISE contributes to enhancing health and reducing illness and disability by promoting a network of AROs in the Asian region.

MISSION

ARISE will establish a network of **international joint clinical research and trials** together with **Thailand**, the **Philippines**, **Indonesia**, **Vietnam** and other countries that are actively seeking to promote clinical research and development in the Asian region in the future. Through this network, ARISE aims to **develop research and development in the Asian region** by conducting investigator-initiated clinical trials/company clinical trials to apply for regulatory approval.

1. Promotes the integrity, safety, ethics, and quality of **investigator-initiated clinical studies**.
2. Contributes to developing innovative medical products to **address unmet health needs and diseases** of public health significance in the region.
3. Contributes to **improving the resources and capacity** of clinical study sites in the region.
4. Accelerates clinical studies and **improves timelines and processes for authorization**.
5. Promotes **Public-Academic-Private-Partnerships (PAPPs)** in the region.
6. **Bridges the gap between sciences and policy for health**.

Asian Well-being Initiative (AHWIN)

- Asian Pharmaceutical and Medical Device Regulatory Harmonization
 - NCDs: ATLAS Project
 - **Communicable Diseases: ARISE Project**



*ARO: Academic Research Organization

Health Politics: Rise of Middle Power

Governance Approach

- A new diplomatic space has emerged in the global governance crisis
- Rise of middle power countries, mechanisms, and collaborations
- Filling the gap of lack of leadership and challenges classical norm

May 29, 2020,

- President **Donald Trump** announced the USA would sever its relationship with WHO and redirect funds to US global health priorities.

July 6, 2020

- The US administration **officially notified** UN Secretary-General António Guterres of its intention to withdraw from WHO membership.

ACTaccelerator
ACCESS TO COVID-19 TOOLS

COVAX

BILL & MELINDA
GATES foundation



TheGlobalFund

CEPI



Access to COVID-19 Tools (ACT) Accelerator

Governance Approach

"The Access to COVID-19 Tools (ACT) Accelerator, is a groundbreaking global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines."

BILL & MELINDA
GATES foundation



The Global Fund

CEPI



診断 Diagnostics

The diagnostics pillar, co-convened by the Global Fund and FIND is focused on bringing to market 2–3 high-quality rapid tests, training 10,000 healthcare professionals across 50 countries and establishing testing for 500 million people in Low and Middle-Income countries by mid-2021.

Led by FIND and Global Fund.

治療 Therapeutics

Therapeutics can play a role in all stages of COVID-19 disease: to prevent infection; suppress symptoms and spread of infection to others; treat or prevent symptoms; as a life-saving treatment for severe symptoms; and as a treatment that can speed up recovery. The aim in the next 12 months is to develop, manufacture and distribute 245 million treatments, helping COVID-19 sufferers to recover from the disease.

Led by Unitaid and Wellcome.

ワクチン Vaccines

The vaccines pillar, convened by CEPI, Gavi and WHO, is speeding up the search for an effective vaccine for all countries. At the same time, it is supporting the building of manufacturing capabilities, and buying supply, ahead of time so that 2 billion doses can be fairly distributed by the end of 2021.

Led by CEPI, GAVI and WHO.

医療制度 Health systems

The health systems connector pillar, led by the World Bank and the Global Fund, is working to ensure that these tools can reach the people who need them.

Led by World Bank, Global Fund and Global Financing Facility.

COVAX

Governance Approach

*"With a fast-moving pandemic, **no one is safe, unless everyone is safe**"*



What is COVAX

COVAX is the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator

COVAX is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO. Its aim is to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world.

Financing & Procurement

COVAX has two main strands: the COVAX Facility and the COVAX Advance Market Commitment (AMC).

- **Higher-income economies participating in COVAX** ('self-financing economies') pool resources through the COVAX Facility, which functions both as a funding mechanism and a central purchasing office.
- **Low- and middle-income eligible economies** get vaccine doses through the COVAX Facility by means of financial support from the Gavi COVAX AMC.

As of March 3, 2022, donors have provided an estimated **\$11.0 billion in financial assistance to the COVAX AMC** for vaccination efforts and **pledged to donate 2.1 billion doses to COVAX**, other multilateral entities, and bilaterally

Financial support to the COVAX Facility

- Japan co-hosted the COVAX AMC Summit on 2 June 2021, and announced an additional contribution of US\$ 800M, which brings the **total contribution of US\$ 1 billion to the COVAX AMC**.

Donation of vaccines

- Japan has been providing vaccines since early June. Japan has allocated approx. 42M doses so far.



Doses for at least 20% of countries' populations



Diverse and actively managed portfolio of vaccines



Vaccines delivered as soon as they are available



End the acute phase of the pandemic



Rebuild economies

ICMRA (International Coalition of Medicines Regulatory Authorities)

About ICMRA:

The **ICMRA** is a voluntary, **executive-level, strategic coordinating, advocacy and leadership** entity of **regulatory authorities** that work together to

ICMRAは、規制当局による自発的、ハイレベルな支援組織であり、戦略的調整および指導的な役割を担っており、協働して以下の目的に取り組む

- address **current** and **emerging** human **medicine regulatory** and **safety challenges** globally, strategically and in an on-going, transparent, **authoritative** and **institutional manner**

ヒト用医薬品の規制と安全に関する既存ならびに新規の課題に対し、その権限と制度上の方法を以って、グローバルかつ戦略的に、透明性の高い方策を講ずること

- **provide direction for areas and activities** common to many regulatory authorities' missions

多くの規制当局のミッションに共通する分野や活動に対し、方向性を示すこと

- **identify areas for potential synergies**

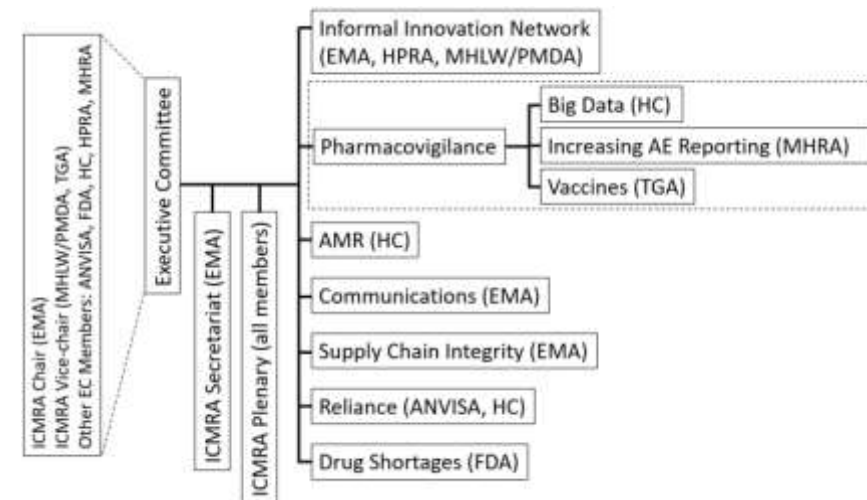
相乗効果を生み出せる可能性のある分野を特定すること

- wherever possible, **leverage existing initiatives/enablers and resources**

可能な限り、既存の取り組みやリソースを活用すること

ICMRA Member:

Australia (TGA), Brazil (ANVISA), Canada (HPFB-HC), China (NMPA), Europe (EMA and DG-SANTE, EU), France (ANSM), Germany (PEI), Ireland (HPRA), Italy (AIFA), **Japan (PMDA and MHLW)**, Korea (MFDS), Mexico (COFEPRIS), Netherlands (MEB), New Zealand (Medsafe), Nigeria (NAFDAC), Singapore (HSA), South Africa (SAHPRA), Switzerland (Swissmedic), Sweden (MPA), United Kingdom (MHRA), USA (FDA) etc.



WHO Hub for Pandemic and Epidemic Intelligence

WHO パンデミック・エピデミック・インテリジェンス・ハブ



WHO Global Biomanufacturing Training Hub

WHO グローバルバイオマニュファクチャリング・トレーニング・ハブ



WHO Academy

WHO アカデミー



WHO UHC Centre

WHO UHCセンター

Towards the 2030 SDG target year, considerations will be initiated on the establishment of a UHC Centre in Japan, in collaboration with WHO, for the achievement of UHC worldwide and the sustainability of UHC in Japan. The two possible functions required of a UHC Centre are as follows.

1. **Research and promotion functions for new UHC appropriate for modern society**, taking into account the **megatrends** of the 21st century (**changes in population and disease structure, use of digital technology and large-scale data, etc.**).
2. **Country support functions** to support the introduction and implementation of UHC according to the actual situation in each country.

From 2022, a task force will be established jointly by the Government of Japan and WHO to study the establishment, and to discuss the functions and mode of operation, with the aim of launching the task force in 2023.



WHO Global Centre for Traditional Medicine

WHO伝統医学グローバルセンター

Future Message

Global Health Governance Changes

- ACT-A
- COVAX Facility
- 100 Days Mission on Vaccine Development, Regulatory Harmonization, Mass Production and Allocation

International Mile stones for 2023

- Japan will host G7 Summit
- UN High Level Meeting on UHC

Medical Products as one of the Major Building Blocks for UHC

Private Sectors Role

- Investment on research and development
- Providing evidence to support more innovative regulatory harmonization and approval
- Public and private partnership for next pandemic preparedness and resilience for ASIA and Pacific Region