

# Vaccine Development beyond TPP



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I declare no conflict of interest associated with the presentation.

All the views expressed in this presentation are personal opinions and do not convey any institutional view.

# Impact of the TPP on vaccine development in Japan

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**Q: Does Provisions on IP Rights of Pharmaceutical Products have any impact on vaccine development in Japan?**

**A: NO**

- Because the following provisions related with Extension of IP Rights of Pharmaceutical Products are consistent with the existing regulations in Japan.
  - (1) Data exclusivity on biologics and other pharmaceuticals
    - biologics : 8 years
    - other pharmaceuticals : 5 years
  - (2) Patent term extension
    - 20 years + max 5 years

# Outline

- 1 Impact of the TPP on vaccine development
- 2 Convention on Biological Diversity and the Nagoya protocol
- 3 Nagoya protocol and influenza vaccine development
- 4 Strengthening global security through Vaccine development

# Convention on Biological Diversity(CBD)



The Convention on Biological Diversity has 3 main objectives:

- The conservation of biological diversity.
- The sustainable use of the components of biological diversity.
- The fair and equitable sharing of the benefits arising out of the utilization of genetic resources.  
: (Access and Benefit Sharing (ABC))

\*The convention entered in to force on 29 December 1993.

\*\*By February 2015, it has received signatures from 196 countries/regions.

# Example of Drug Development Raising ABS Issues

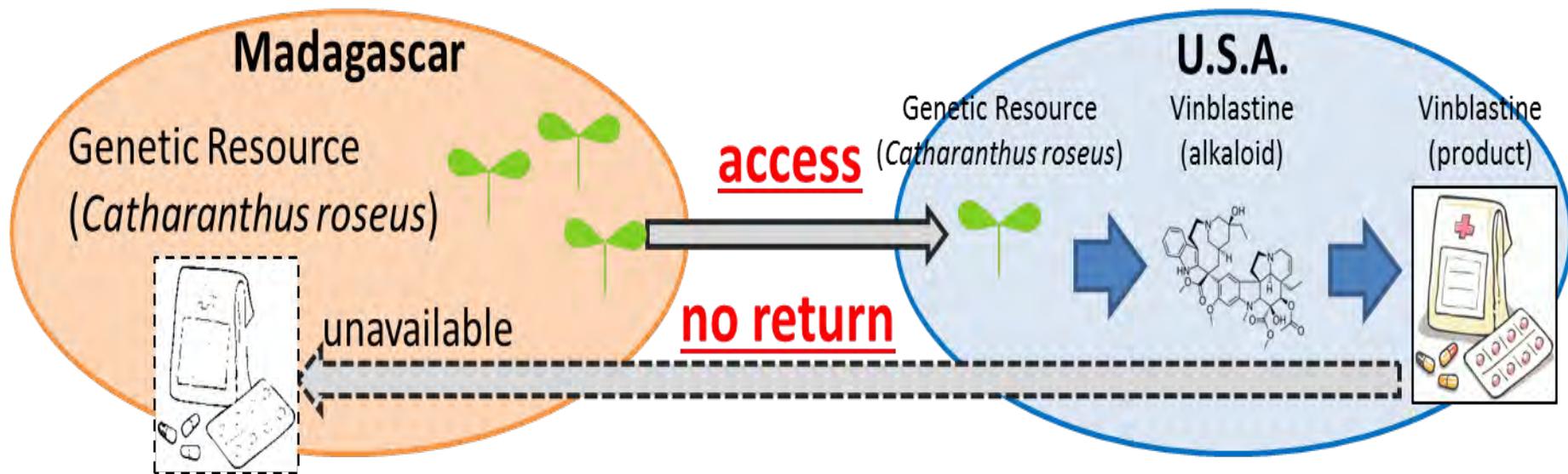
1950s': A drug company started research on *Catharanthus roseus*, which was used as a traditional medicine for diabetes in Madagascar.

1961 : The drug company extracted an alkaloid from *Catharanthus roseus*, and developed a drug for leukemia.



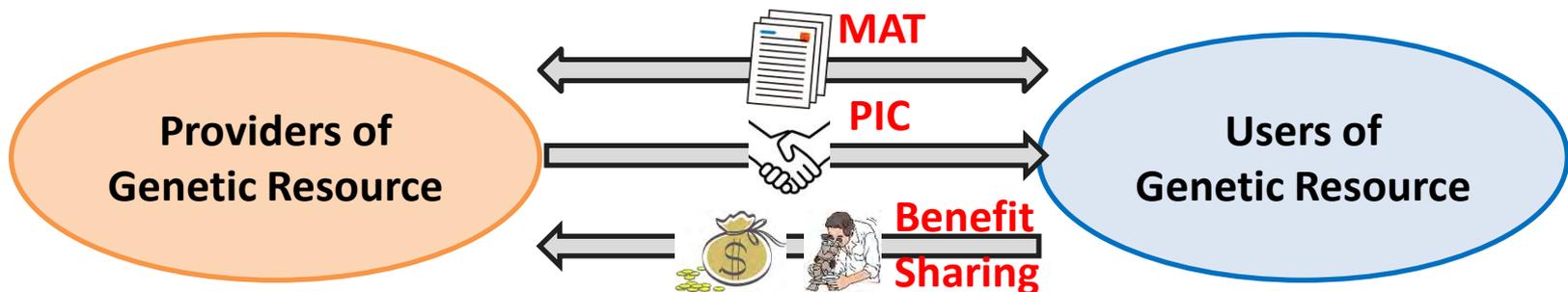
1988~: The United Nations Environment Program (UNEP) started to work on CBD.

1992 : NGO's reported the problems of sharing benefit to the UNEP.



# The scheme of Nagoya Protocol on ABC

- Fair and equitable sharing of benefits\* from the utilization\*\* of genetic resources based upon mutually agreed terms (MAT).
- Access should be subject to prior informed consent (PIC) unless otherwise determined by the Party with the genetic resource.
- A similar benefit-sharing regime with respect to “traditional knowledge associated with genetic resources” held by indigenous and local communities.
- Parties to the Nagoya protocol are to establish national legislation or regulation addressing these issues.



\*Benefits may be monetary or non-monetary such as royalties and the sharing of research results.

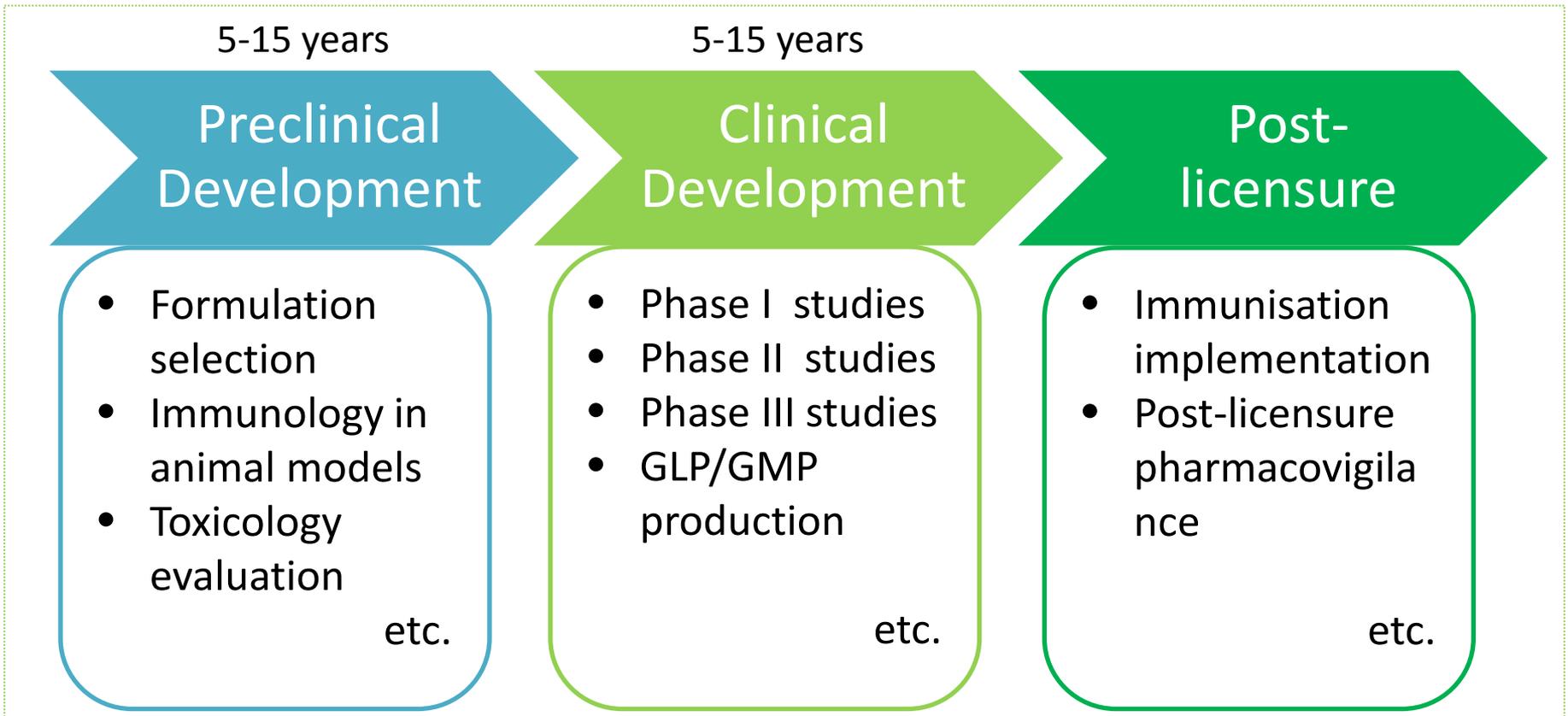
\*\*Utilization includes research and development on the genetic or biochemical composition of genetic resources, as well as subsequent applications and commercialization.

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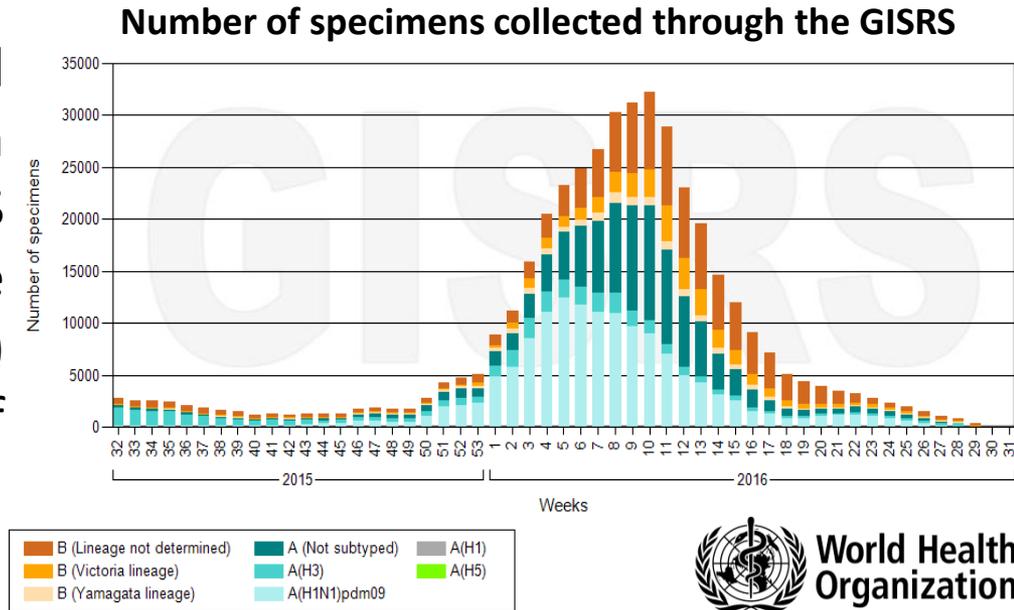
# Vaccine Development

- Vaccine development is a complex multistep process.
- Identifying pathogens responsible for diseases are the starting point for new vaccines.
- Clinical and epidemiological studies indicate that benefits of vaccines clearly outweigh the risks of adverse effects.



# Annual Recommendations on Seasonal Influenza Vaccine Strain Selection

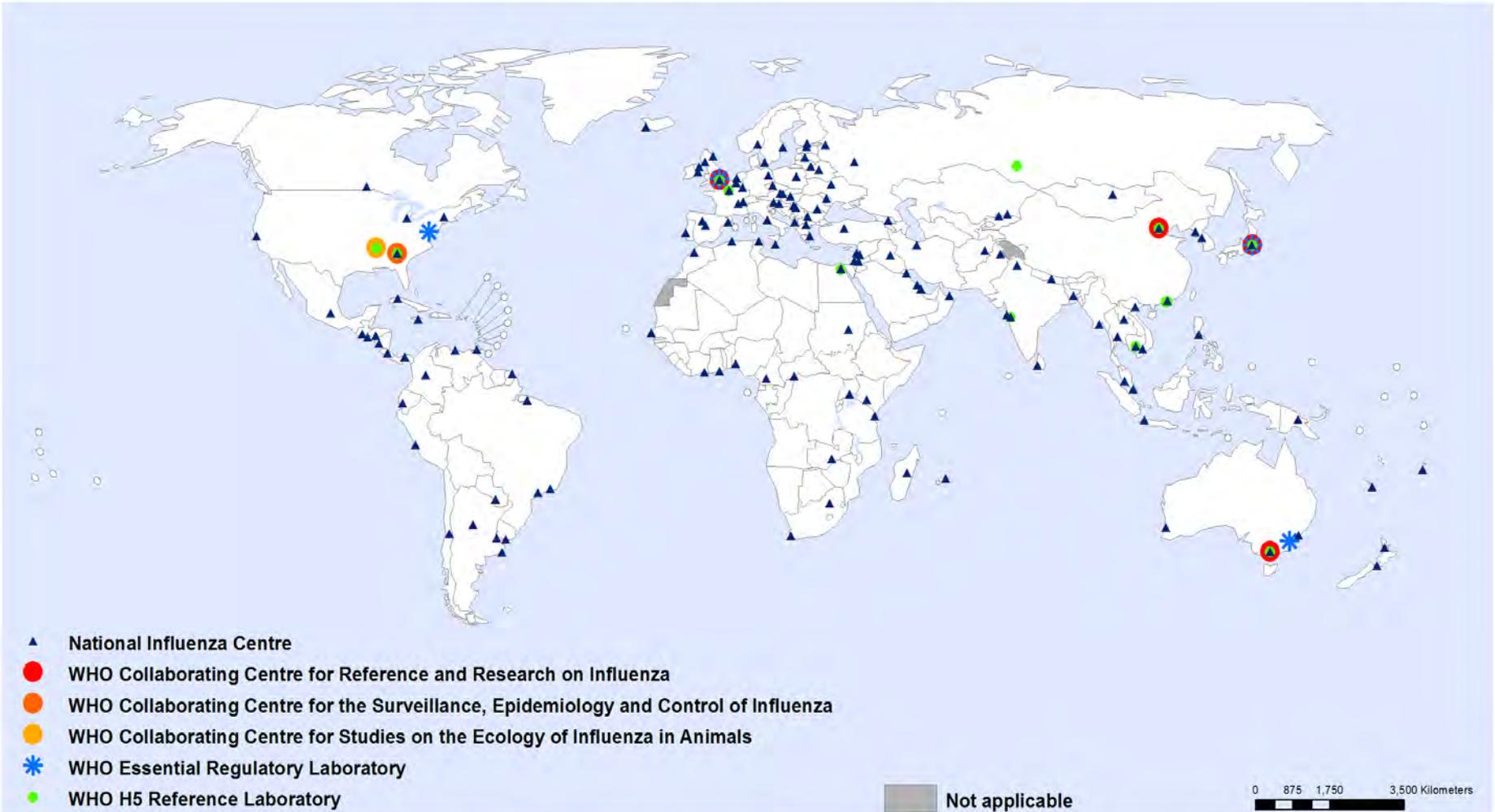
- Global influenza virological surveillance has been conducted through WHO'S Global Influenza Surveillance and Response System (GISRS) to monitor the evolution of influenza viruses.



- Annual seasonal flu vaccine production is dependent on international collaboration on surveillance and exchange of influenza viruses to select best candidates for vaccine composition.
  - Geographically representative and comprehensive
  - Timely
  - Easy

# WHO Global Influenza Surveillance and Response System

28 September 2015



- WHO Collaborating Centre:  
Atlanta Centre(US CDC), Beijing Centre(China CDC), London Centre(FCI),  
Melbourne Centre(VIDRL), Memphis Centre (St Jude), Tokyo Centre(NIID)
- ▲ WHO National Influenza Centre: 143 institutions in 113 WHO Member States



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# Nagoya Protocol and Seasonal Flu Vaccine

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## Potential impacts

➤ Requirements of Nagoya protocol may have a potential impact on sharing use of pathogenic samples:

- Reluctance to send or receive pathogenic samples
- Hesitation to risk use of candidate pathogens

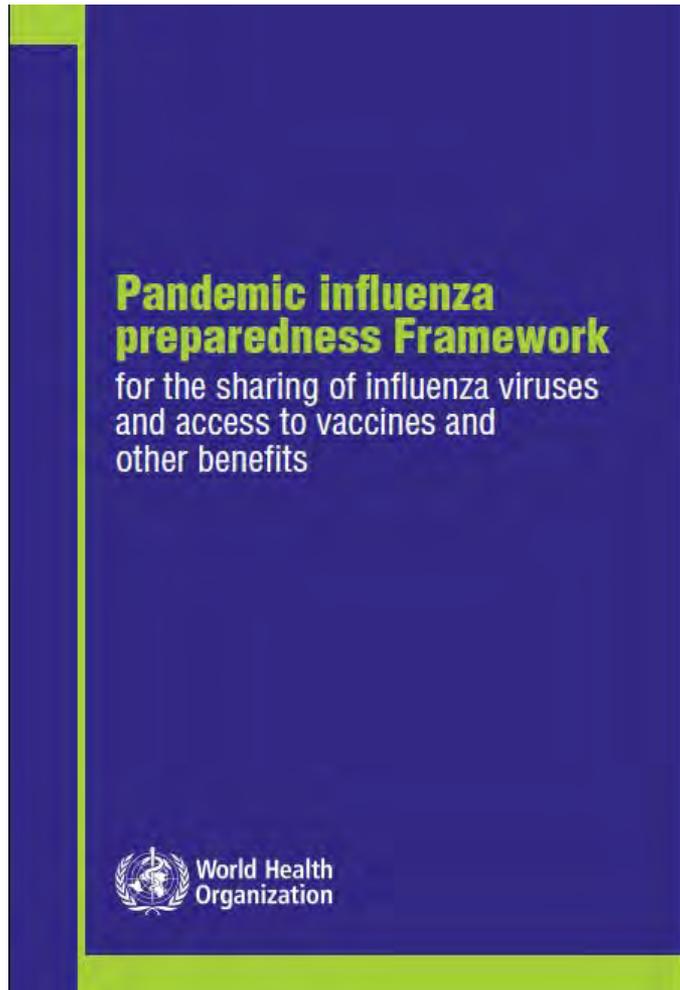
➤ Impacts on sample sharing may lead to:

- Reduced protection/production
- Delay in production
- Reduced preparedness for pandemic vaccine production



Negative impact to people in countries of origin and all.

# Pandemic influenza Preparedness Framework



- The Pandemic Influenza Preparedness (PIP) Framework brings together numerous stakeholders to implement a global approach to pandemic influenza.
- Its key goals include:
  - to improve and strengthen the sharing of influenza; and
  - to increase the access of developing countries to vaccines and other pandemic related supplies.
- PIP Framework is outside the scope of the Nagoya protocol for it meets the requirement of the specialised instruments of Article 4(4).

# PIP Framework: Implementation

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## ➤ Access to Vaccines/Technology Transfer

- Manufacturers who receive biological matters must commit to options (e.g. 10% donation of produced vaccines, technology transfer) under the Standard Material Transfer Agreement.

## ➤ Capacity Building

- The PIP Framework establishes an annual Partnership Contribution (PC) ( 50% of the running cost of GISRS: \$28 million in 2010) to be paid to WHO by manufacturers using the GISRS.
- The PC funds are used to implement activities such as:
  - ✓ Laboratory and Surveillance
  - ✓ Burden of Disease
  - ✓ Regulatory Capacity Building
  - ✓ Planning for Deployment
  - ✓ Risk Communication



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# For the future framework of Sharing Samples

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## The Challenges

➤ We still face substantial challenges in international sharing of non-influenza pathogens (e.g. MERS-CoV and Ebola)

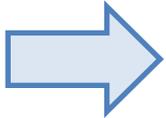
➤ The main issues related to sample sharing are:

- Policy issues  
e.g. : viral sovereignty and intellectual property issues
- Regulatory issues  
e.g. : import/export permits, lab certification
- Logistic issues  
e.g. : transportation documentation, international couriers, maintaining sample integrity

# Actions for Global Security beyond TPP

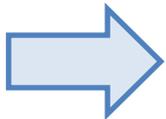
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## ■ Assessment on the Implementation of the Nagoya Protocol



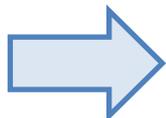
e.g. : Based on Member States request, the WHO is conducting a study to analyze how implementation of the Nagoya protocol might affect the sharing of pathogens.

## ■ Capacity Building and Incentives for Vaccine Development



e.g. : Several initiatives leading vaccine research and development (R&D) against pathogens with significant disease and economic burden.

## ■ Ensuring access to new vaccines



e.g. : Vaccine donation and other mechanisms for ensuring access to new vaccines for all.

Thank you for your attention.