

COVID-19 vaccine Pharmacovigilance: TFDA's experiences

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Outline



Actions against the COVID-19 Pandemic



Accelerating COVID-19 Vaccine Development



Safety Surveillance for COVID-19 Vaccines in Taiwan



Actions against the COVID-19 Pandemic



DRUG SUPPLY

- Drug Supply Database Platform
- Guidelines



SANITIZER PRODUCTS

- Maximize Production
- Restrict Exportation



CLINICAL TRIALS

- Protect Right and Safety of the participants
- Recruitment Registration Platform

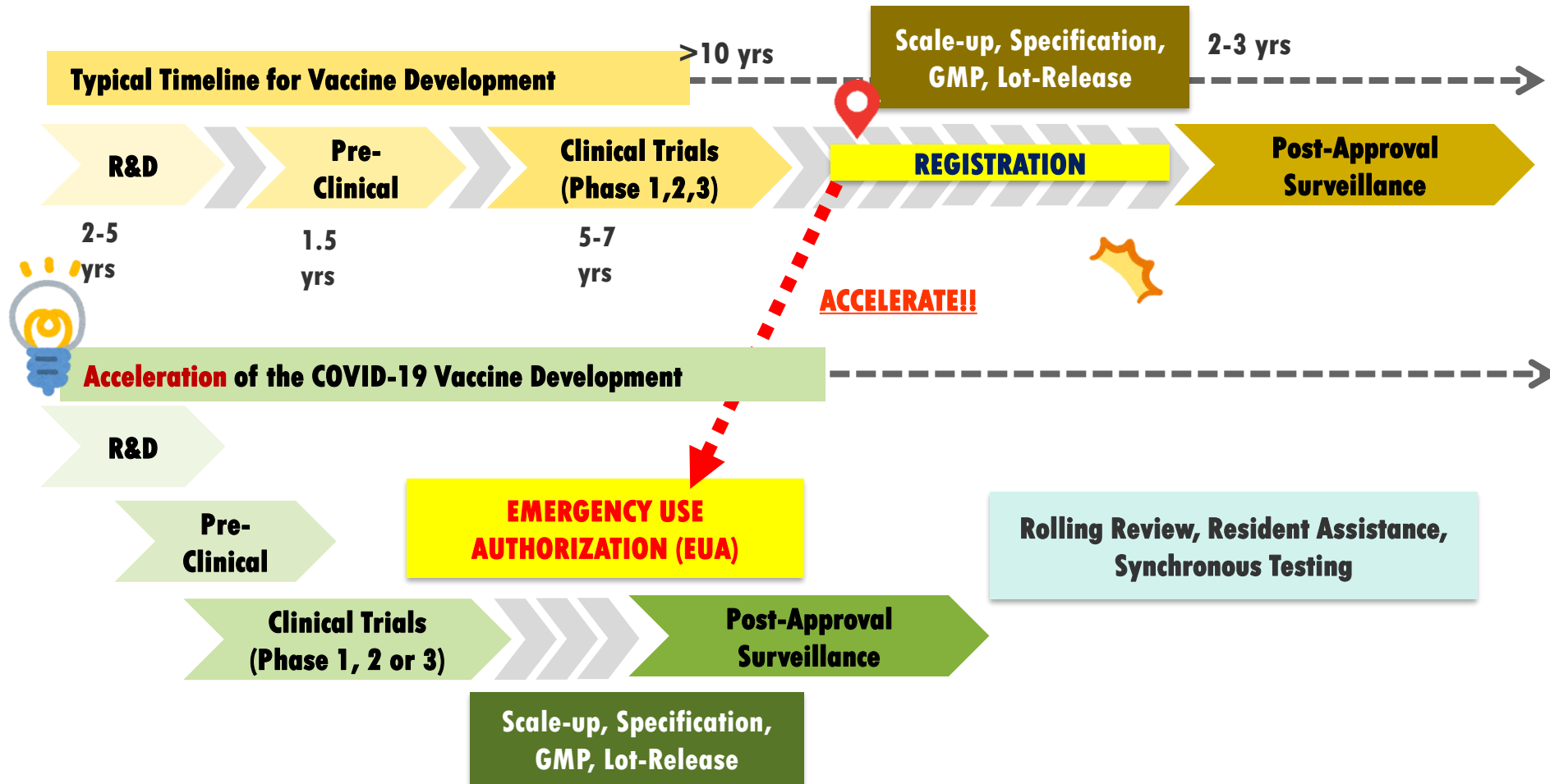


COVID-19
Vaccines

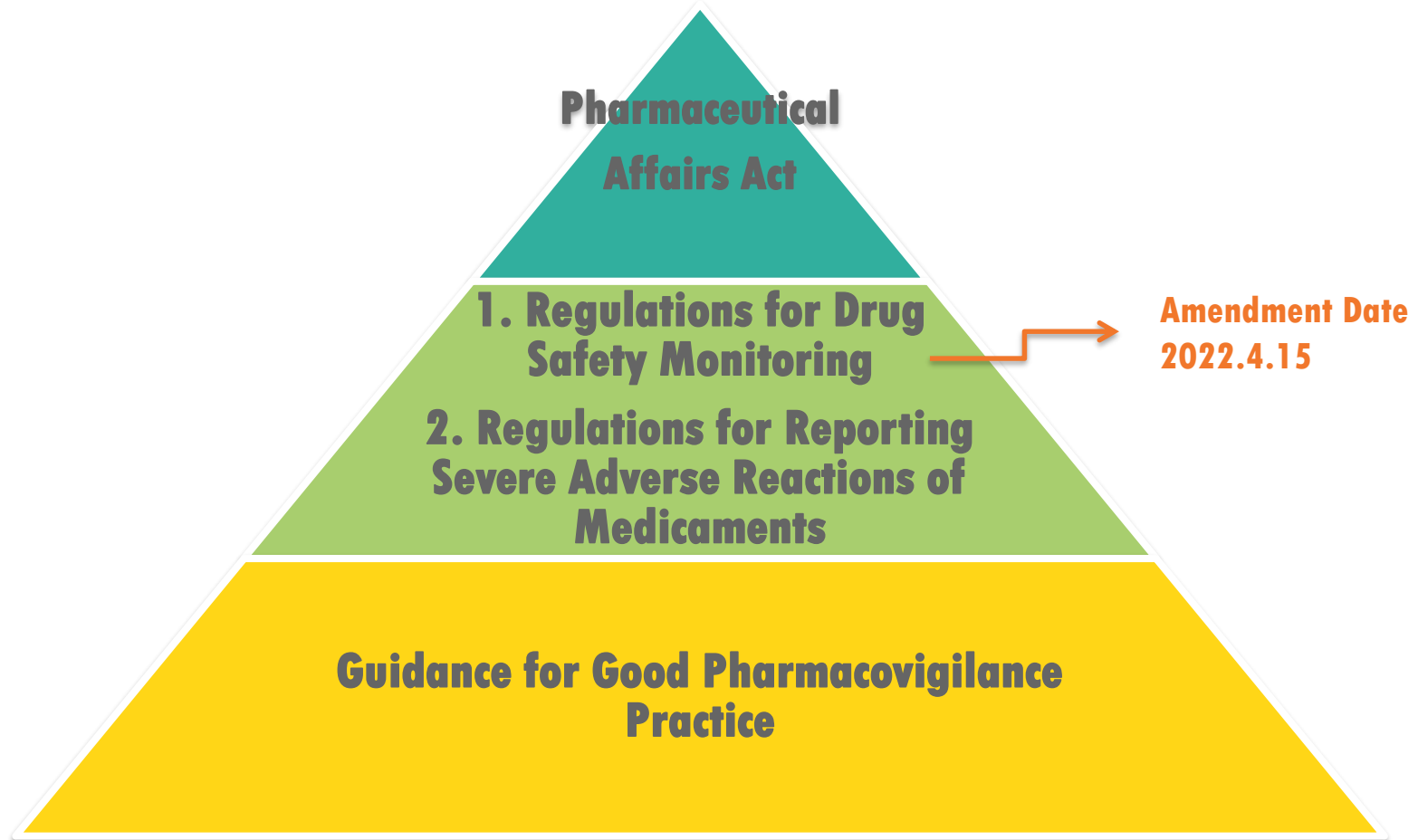
DRUG DEVELOPMENT

- EUA
- Consultation Team
- Rolling review
- Technical and Financial Support

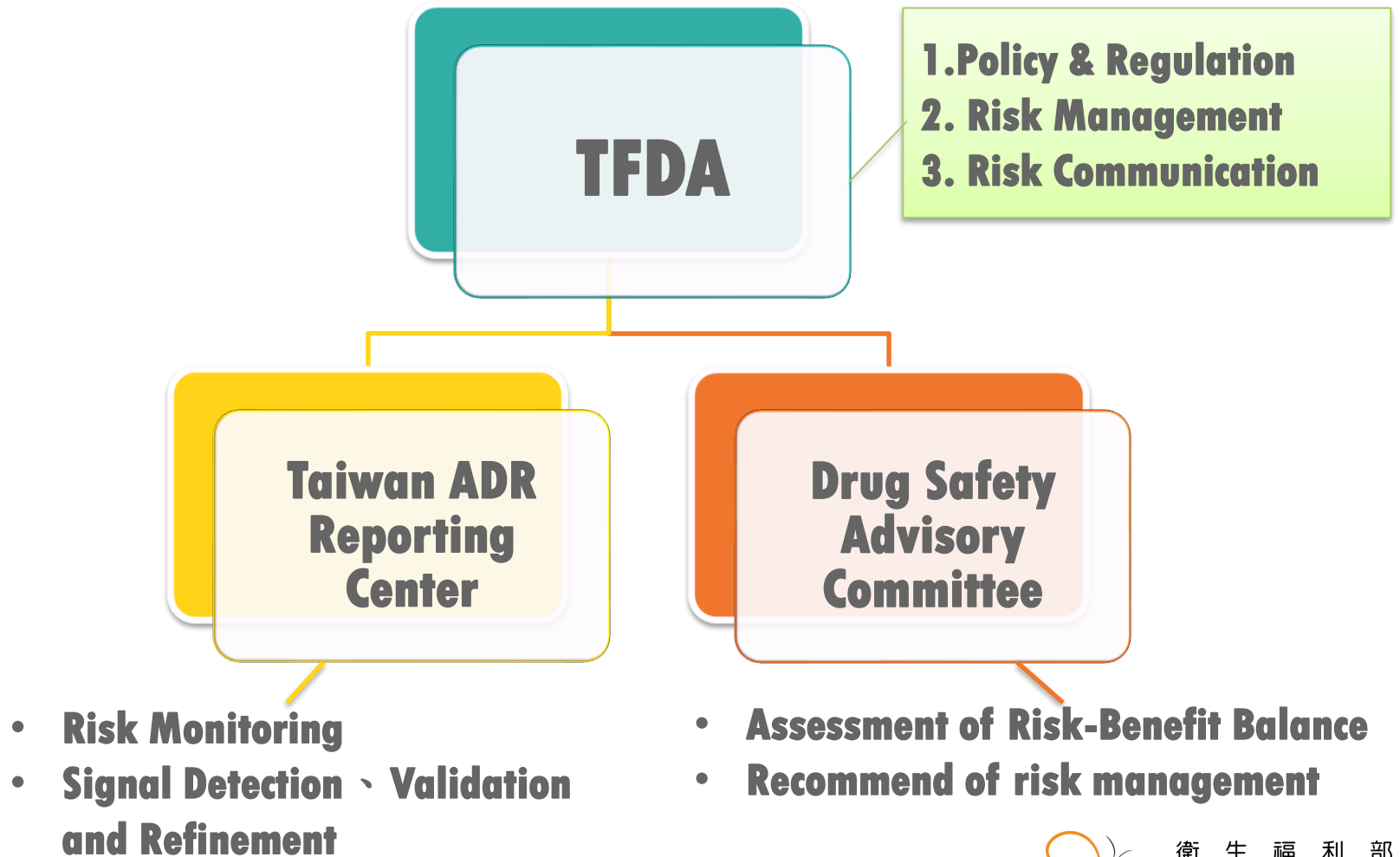
Accelerating COVID-19 Vaccine Development



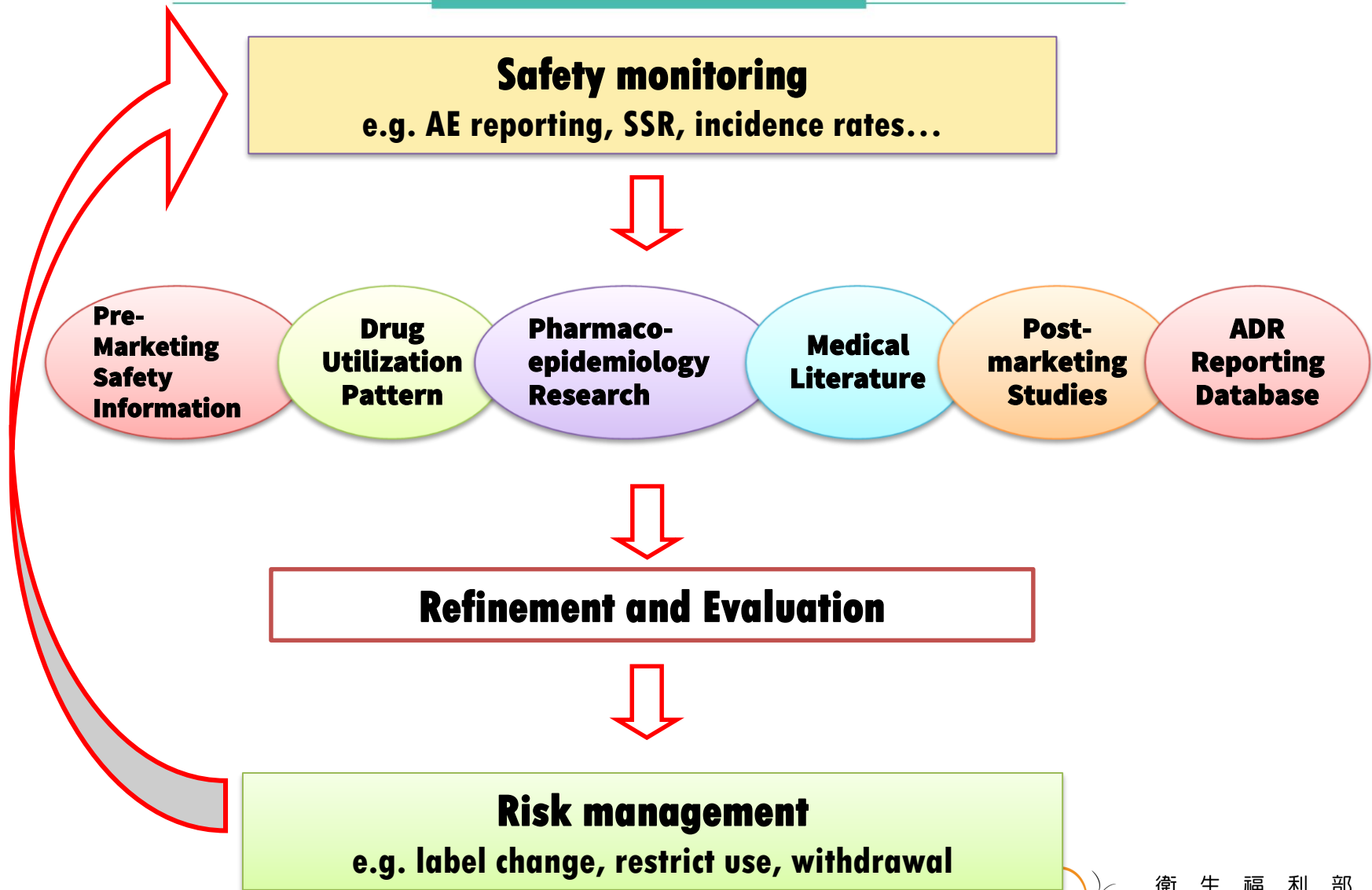
Regulations of Pharmacovigilance in Taiwan



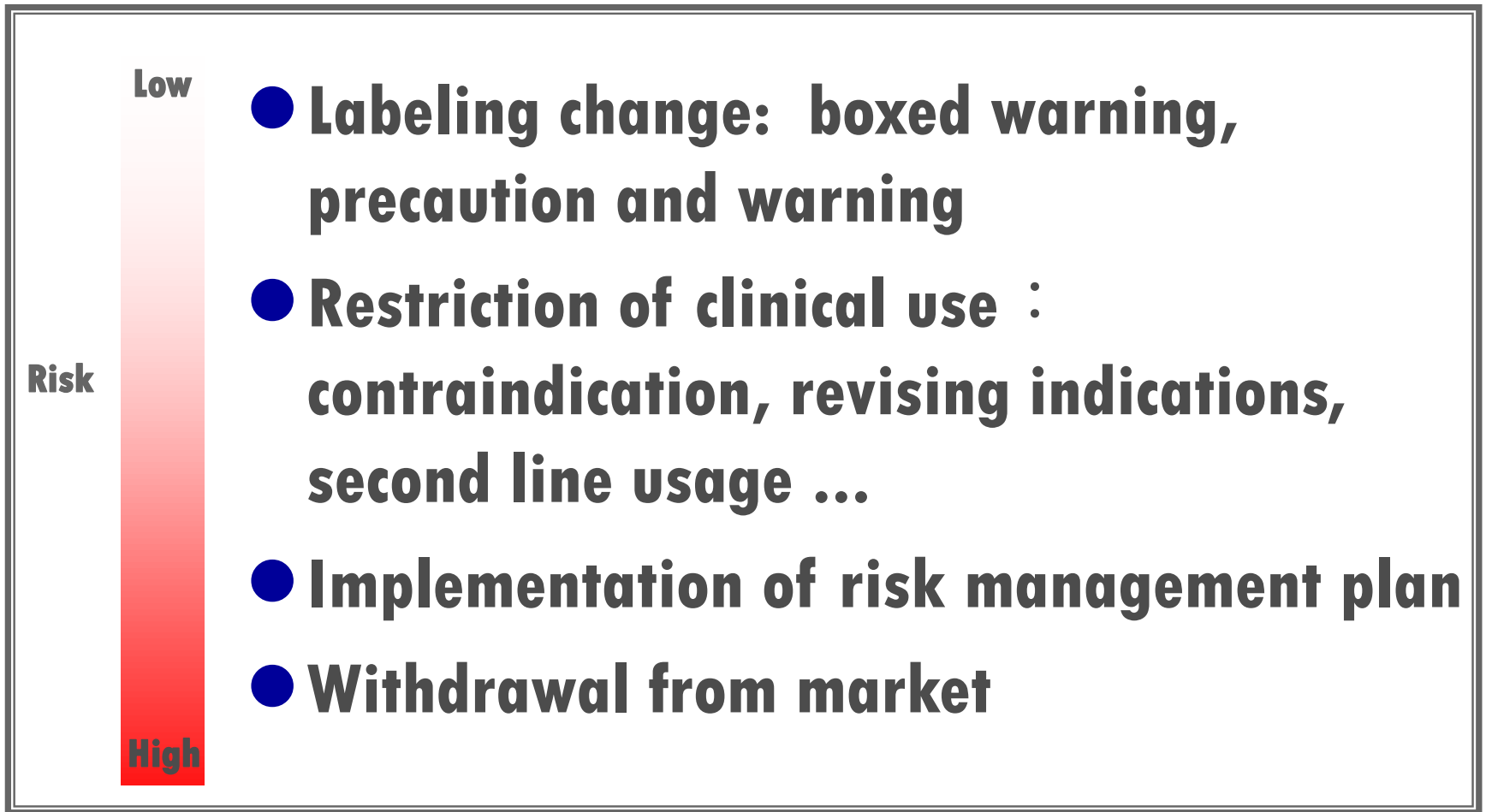
Organization for Pharmacovigilance



Pharmacovigilance system in Taiwan



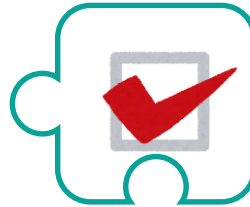
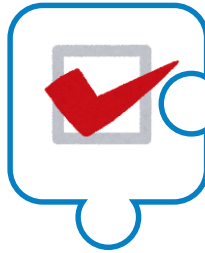
Strategies of Risk Management



Safety Surveillance for COVID-19 Vaccines

Summary Safety Report (SSR)

Applicants shall collect safety information and regularly provide it to TFDA .



Global Safety Information Monitoring

AE reports

Accept the event that a vaccines causes a severe adverse reaction from medical care institution.



Active Assessment of National Health Insurance Database

Local background incidence rate of Adverse Event of Special Interest (AESI)

Establishment local background incidence rate to compare the vaccines incidence rate.



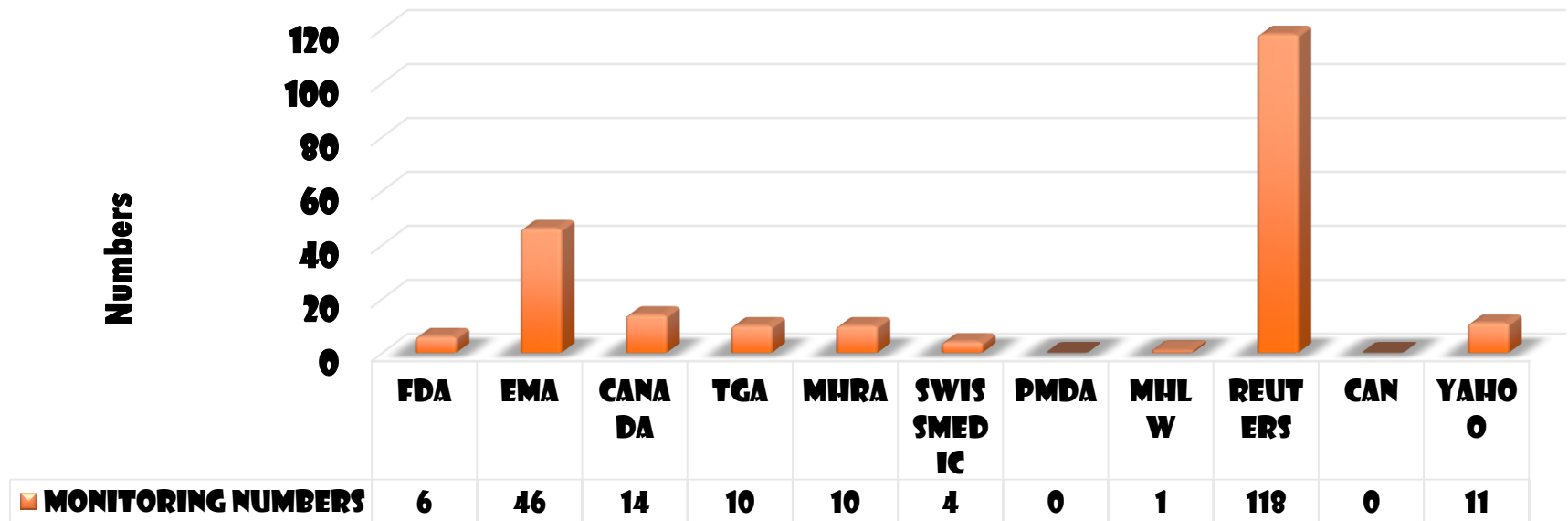
Summary Safety Report

- **Applicants shall collect the following safety information :**
 - Update of global safety experience
 - Evaluation of benefit-risk balance about new or changed information.
- **Up to 19 September 2022, TFDA reviewed 44 SSR reports from COVID-19 vaccines.**

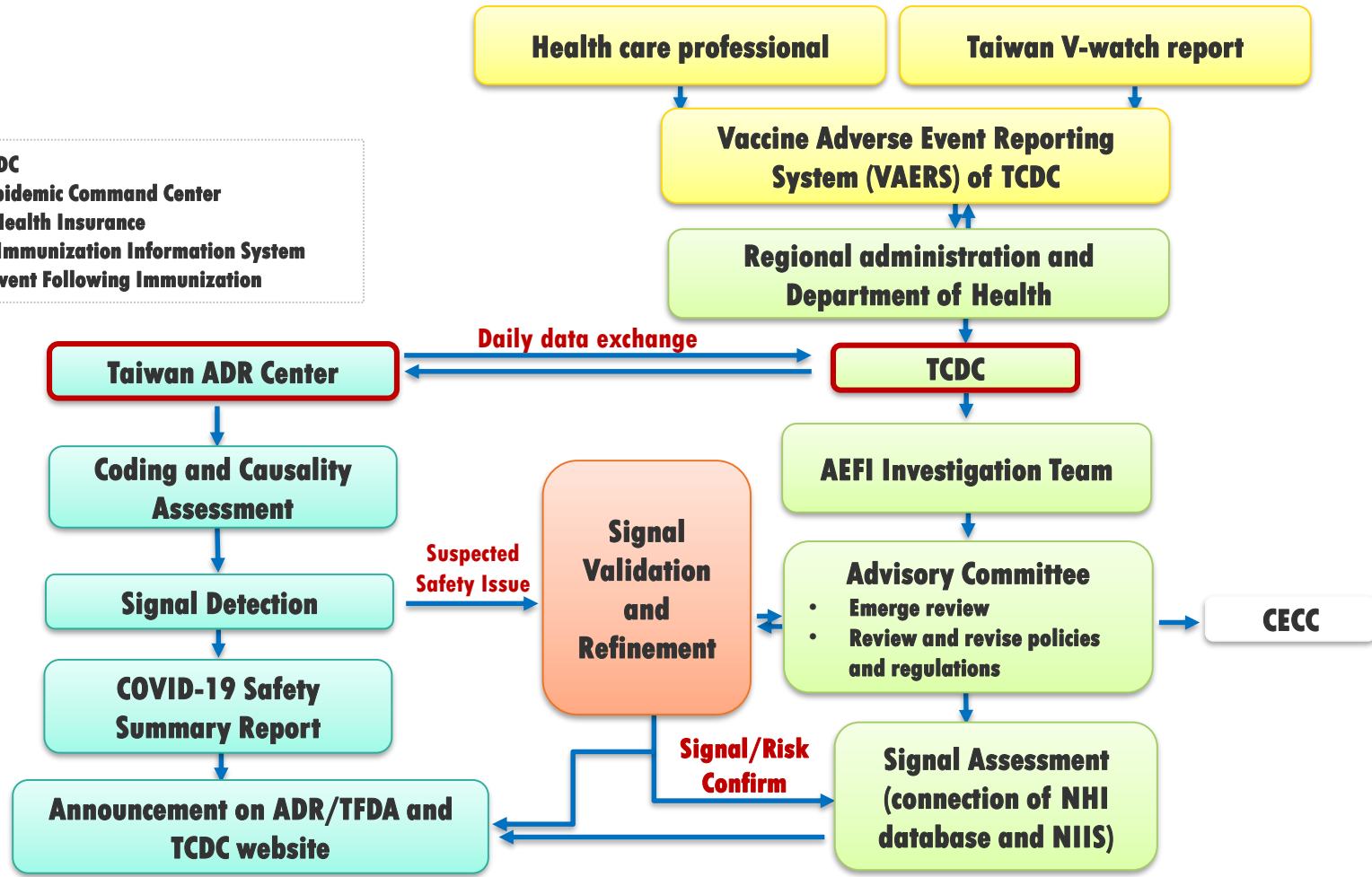


Global Safety Information Monitoring

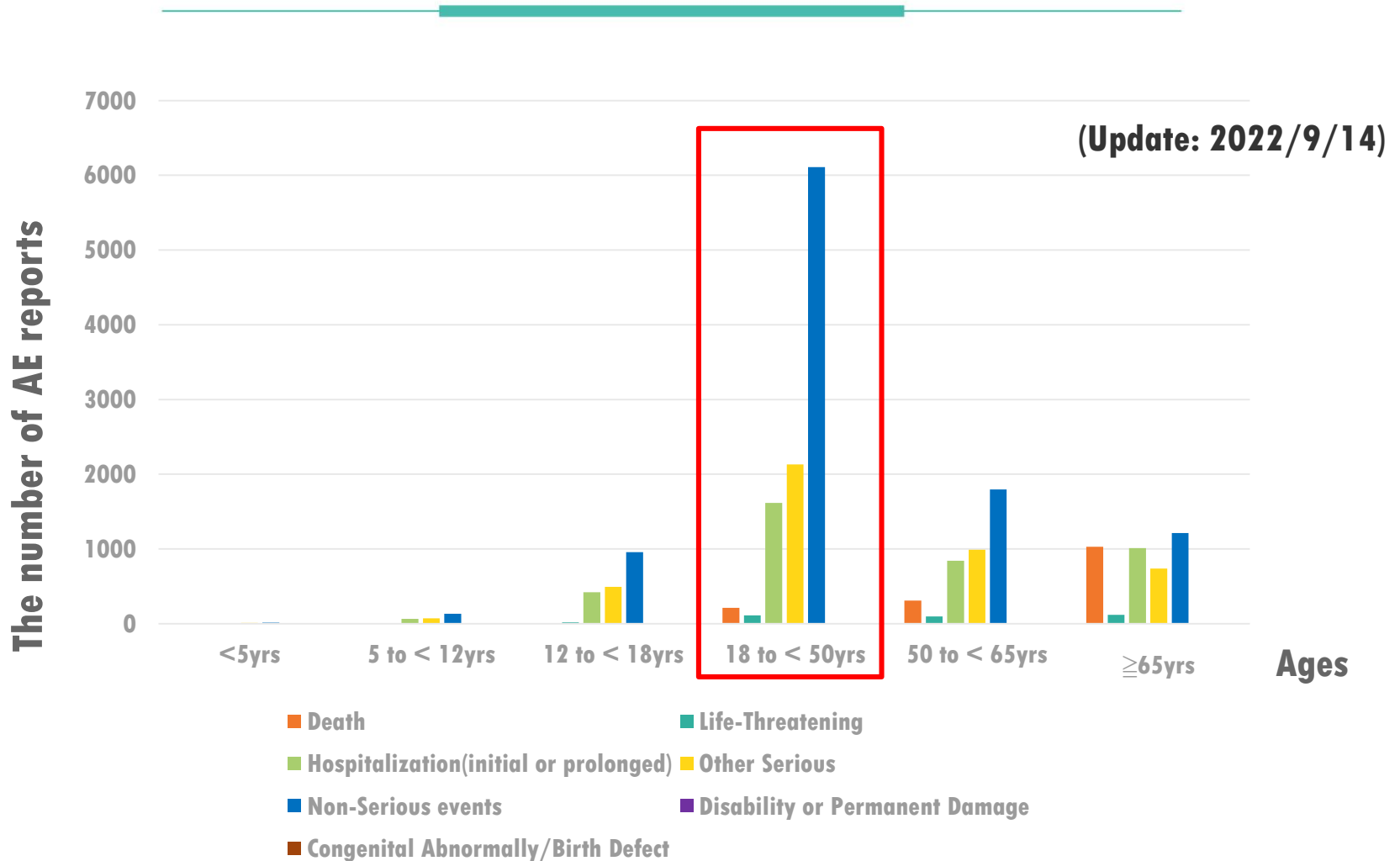
- Actively Monitor Global Safety Information and news daily.
- If there is a suspect safety signal, we will deliver risk communication letter and start drug safety re-evaluation.
- 220 alerts in 2021



AE reporting system of the COVID-19 vaccines



AE reports of COVID-19 vaccines in Taiwan by ages



The most concern of AEI reports in Taiwan(1)

(Update: 2022/9/14)

AEI	Reports cases
Anaphylaxis	49
Arrhythmia	57
Acute myocardial infarction	300
Myocarditis/Pericarditis	418
Cerebrovascular stroke	724
Facial palsy	233
Seizure/Convulsion	68
Transverse myelitis	4
Acute disseminated encephalomyelitis	9
Guillain – Barre ´ Syndrome	36
Neuromyelitis optica	6
Myelitis	6
Encephalitis	12

AEI	Reports cases
Aseptic meningitis	5
Optic neuritis	15
Acute pancreatitis	11
Acute kidney injury	10
Acute liver injury	23
Erythema multiforme	18
Vasculitis	27
Rhabdomyolysis	18
Arthritis	9
Spontaneous abortion	15
Stillbirth	15
Preterm birth	4
Idiopathic thrombocytopenic purpura	75

The most concern of AEI reports in Taiwan(2)

(Update: 2022/9/14)

AEI	Reports cases
Thrombosis with thrombocytopenia syndrome	63
Capillary leak syndrome	1
Multisystem inflammatory syndrome in children	1
Retinal vein occlusion	25
Retinal artery occlusion	10
Retinal vascular occlusion	5
Deep vein thrombosis	122
Pulmonary embolism	145
Cerebral venous sinus thrombosis	31
other thrombotic disorder	52

Incidence rate of AESI

- Establishment local background incidence rate to compare the vaccines incidence rate.
- Using National Health Insurance Database, including Ambulatory Care Expenditures by Visits, National Health Insurance Registry for Beneficiaries, Cause Of Death Data etc..
- Up to 6 September 2022, TFDA analyzes 28 AESIs.

<i>AESI</i>		
<i>Anaphylaxis</i>	<i>Transverse myelitis</i>	<i>Optic neuritis</i>
<i>Arrhythmia</i>	<i>Acute disseminated encephalomyelitis</i>	<i>Acute pancreatitis</i>
<i>Acute myocardial infarction</i>	<i>Guillain-Barre Syndrome</i>	<i>Acute kidney injury</i>
<i>Myocarditis/Pericarditis</i>	<i>Neuromyelitis optica</i>	<i>Acute liver injury</i>
<i>Cerebrovascular stroke</i>	<i>Myelitis</i>	<i>Erythema multiforme</i>
<i>Facial palsy</i>	<i>Encephalitis</i>	<i>Vasculitis</i>
<i>Seizure</i>	<i>Aseptic meningitis</i>

COVID-19 vaccines information release

Product information

Updated version

- PI of COVID-19 Vaccine which is received EUA
- Amends the safety information including warnings and precaution, post-marketing experience

COVID-19 Safety Summary Report

Weekly announcement

- Provides adverse event cumulative case reports and safety profile in domestic

Press News

Major events

- Issues an EUA for specific brand COVID-19 Vaccine
- Launches clarification regarding misinformation and fake news

Overall Safety of COVID-19 Vaccines in Taiwan

- Based on the current vaccine safety data, TFDA **doesn't find any new safety issues** and should require immediate action.
- TFDA will continue to conduct safety signal detection for vaccine adverse event reports to actively implement the drug safety monitoring mechanism to ensure the safety of COVID-19 vaccines.



Thank you for your attention

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