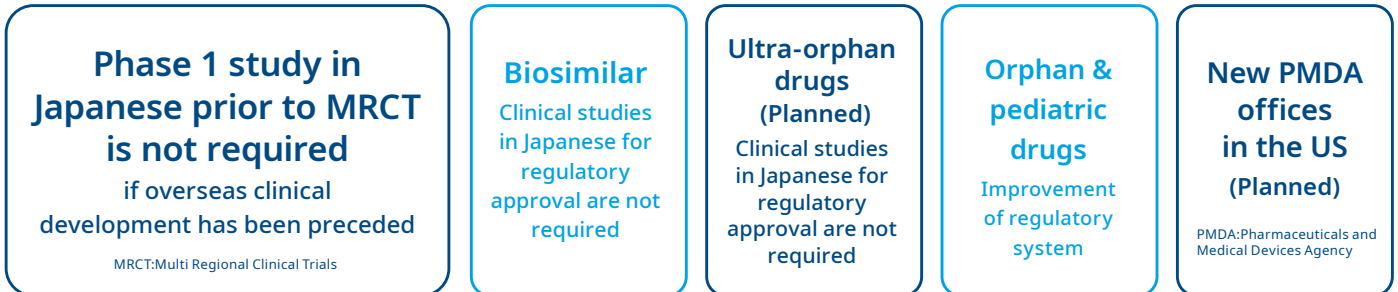


# Regulatory Renaissance in Japan

## Leading the Way for Pharmaceutical Pioneers!

The recent evolution of drug regulations is expediting new drug / clinical development & product launch in Japan. Don't miss this opportunity!



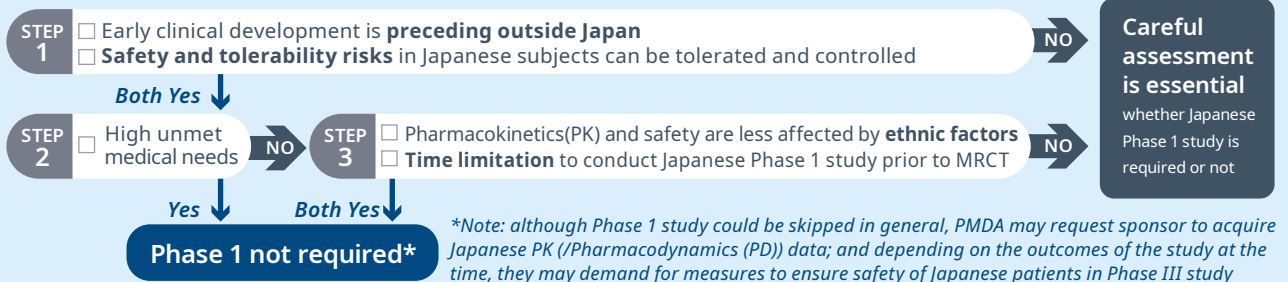
PMDA/MHLW consultation is recommended to apply these regulatory changes. IQVIA Japan regulatory consulting experts will assist clients with the consultation to promote the most effective clinical development plan

MHLW: Ministry of Health, Labour and Welfare

### 1.1 Phase 1 in Japanese Requirements prior to Multi Regional Clinical Trial (MRCT)

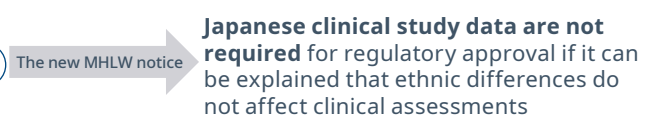
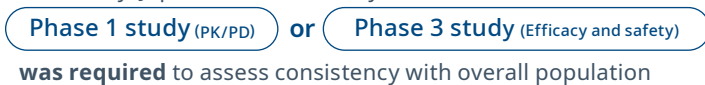


**Decision Tree:** The decision-tree was originally created by IQVIA Japan based on the new guidance issued by MHLW for the reference



### 1.2 Biosimilar

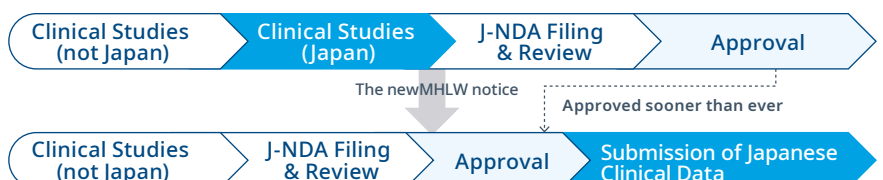
Previously, Japanese clinical study such as



### 1.3 Ultra-Orphan Drug (Planned)

The drug may be approved without Japanese clinical data if:

- ‡ The drug is for treatment of a very serious disease and is **already approved overseas**
- ‡ The expected number of Japanese patients is **less than 1,000**



## 2.1 Improvement of Orphan Drug Designation (ODD) System

New guidance to allow ODD at an early stage of study development and to broaden the scope of designation

Review system for ODD (No updates in the new MHLW notice)

Orphan Disease  
: No. of Pts < 50,000

Clinical Trial  
(Exploratory)

Clinical Trial  
(Confirmatory)

MAA

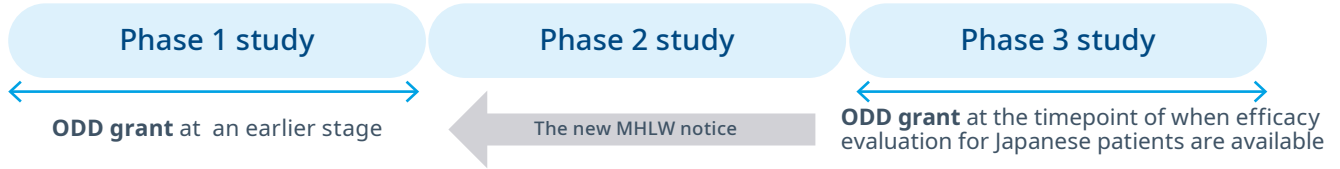
MA

Review 9 Month

MAA: Marketing Authorization Application  
MA: Marketing Authorization

Re-examination Period:  
(Exclusivity Period) 10 years

Timing of ODD grant may be at an earlier stage of study development

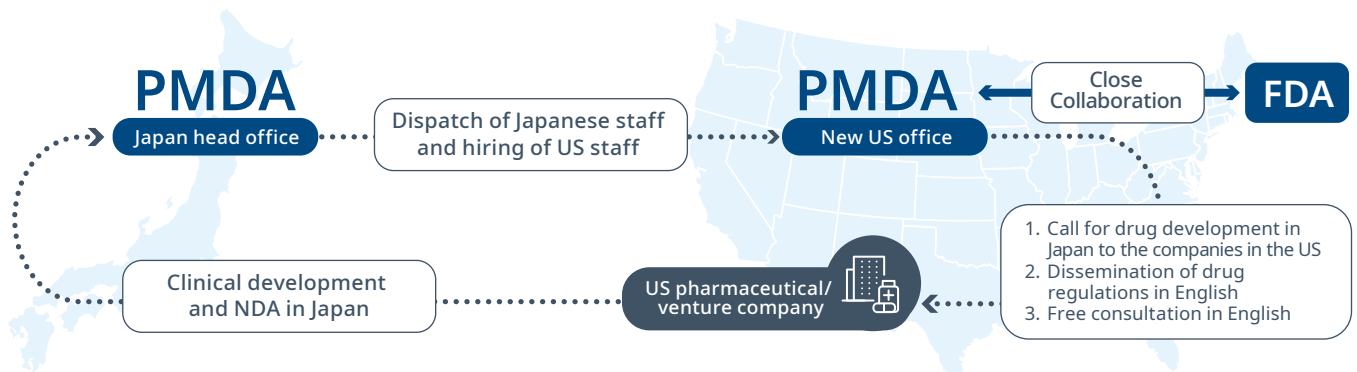


## 2.2 Promoting Pediatric Drug Development

Building a development plan for pediatric use at the time of adult drug development is now desirable for new drugs

- Dissemination of existing incentives
  - Extension of reassessment period by 2 years (maximum 10 years) for pediatric drug development
  - Addition to drug price
- Establishment of new incentives

## 3 Start-up of PMDA US Office (Planned) MHLW/PMDA intends to actively promote drug development in Japan by building relationship with the companies in the US



## IQVIA Japan Regulatory consists of expertise that lead successful pathway for your products!

We propose an efficient regulatory strategy for drug development plan / J-NDA submission according to the new guidance

### Regulatory Consultation Experience in IQVIA Japan

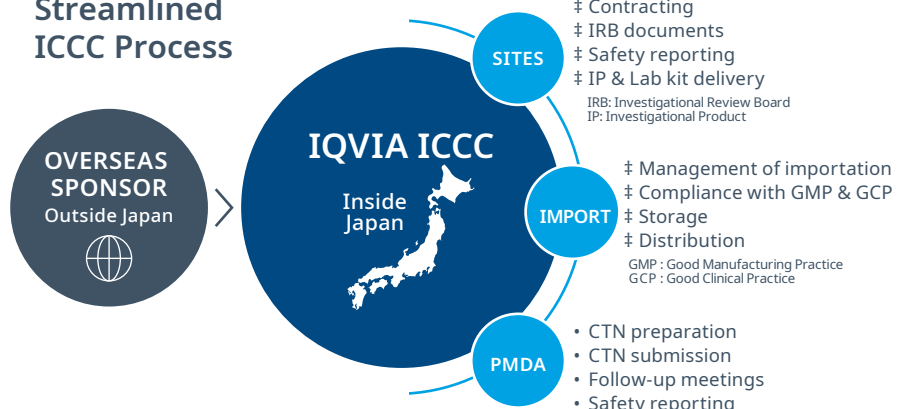
>80 PMDA Consultation

>70  
\*Including Gap Analysis, NDA related activities, Orphan Drug Designation, KOL management, etc.

Study Development >20

ICCC Experience >140 protocols  
IQVIA Japan successfully passed all inspections and contributed to getting Sponsor products approved for marketing

### Streamlined ICCC Process



The In-Country Clinical Caretaker (ICCC) is the representative of the company who sponsors the clinical study and ensures that procedures are followed as per regulations