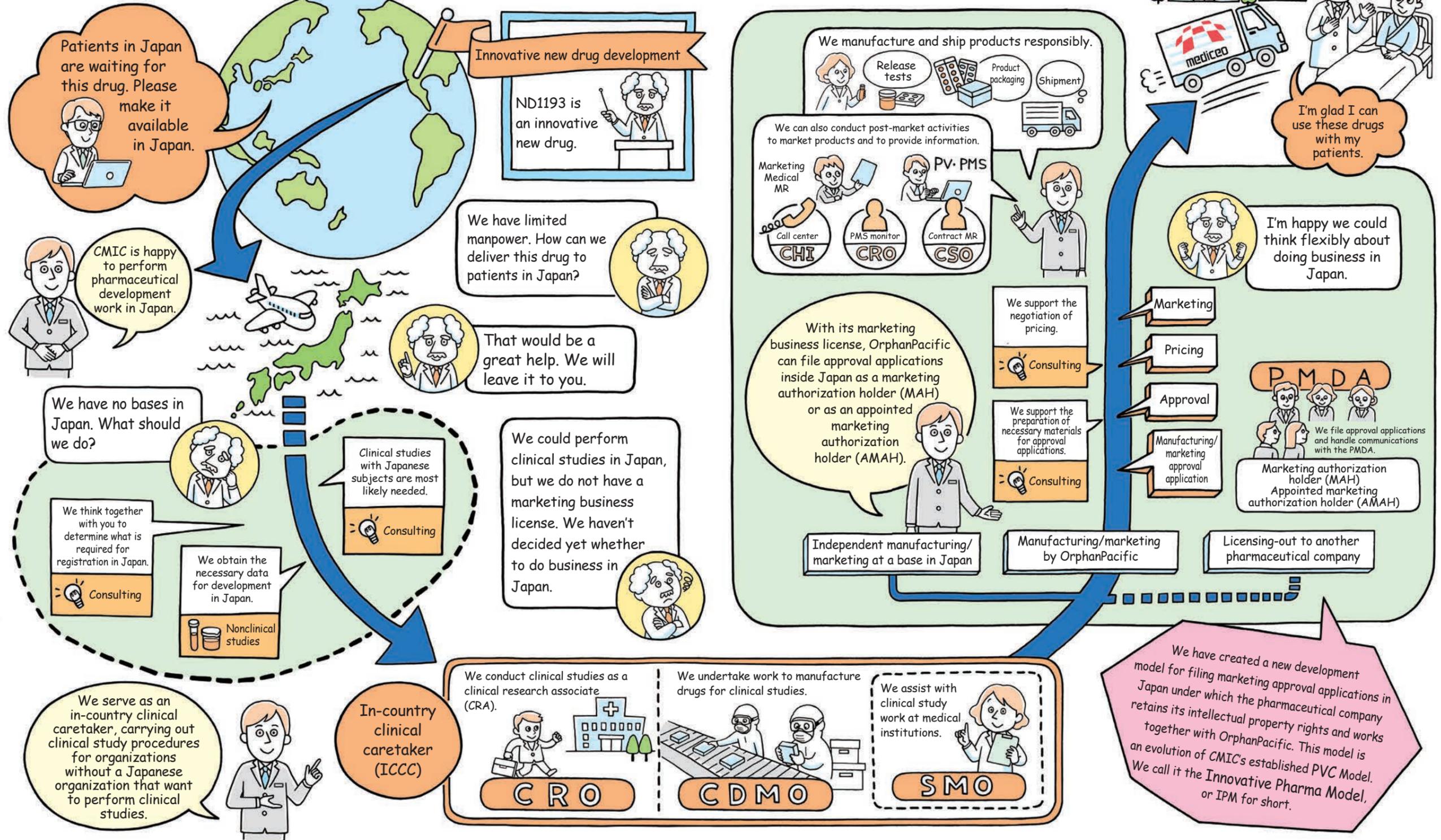
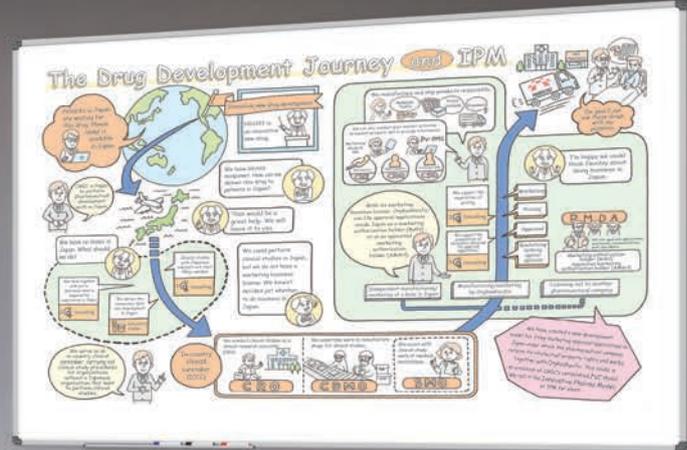


# The Drug Development Journey and IPM



# Innovative Pharma Model



## Q What is IPM? (How does it differ from PVC?)

The Innovative Pharma Model (IPM) is a scheme proposing a new business solution to pharmaceutical companies and other organizations to access the Japanese pharmaceutical market by combining OrphanPacific's manufacturing and marketing business license with the value chain (PVC) developed by CMIC Holdings. Overseas companies without any presence in Japan can conduct clinical studies by asking a Japanese CRO to serve as an in-country clinical caretaker (ICCC). However, overseas companies that do not have a

manufacturing and marketing business license for drugs and other products in Japan cannot file application, obtain approval, sell, or perform other activities for new drugs after completing such clinical studies. OrphanPacific serves as a marketing authorization holder (MAH) and supports such overseas companies in acquiring approval for manufacturing and marketing in Japan as well as in selling products. We call this business model IPM.

\* PVC: Pharmaceutical Value Creator

## Q Why is IPM unique to CMIC as a business model?

IPM is unique because OrphanPacific belongs to the CMIC Holdings platform. OrphanPacific holds the business license for drug manufacturing and marketing, enabling CMIC to extend the PVC to regulatory approval and commercialization of prescription medicine in Japan. OrphanPacific serves as the drug manufacturing and marketing license holder and closely collaborates with the relevant departments and companies within CMIC Holdings to cover all areas from optimizing development plans, conducting studies, and carrying out

regulatory filing all the way up to marketing. Only CMIC Holdings can achieve this model because we work in all areas of the pharmaceutical company value chain. OrphanPacific works together with its parent company CMIC Holdings—a leading CRO company—and a major Japanese drug wholesaler MEDIPAL Holdings under a structure that supports overseas companies which are looking to introduce new products to the Japanese market by performing appropriate work in drug development, regulatory filing, and marketing support.

## Q What are the benefits for pharmaceutical companies in entrusting work to CMIC Holdings through IPM?

Companies can think flexibly about doing business in Japan. Overseas pharmaceutical companies with no business license in Japan (e.g., a manufacturing and marketing business license for drugs) can obtain support for introducing products to Japan without conceding their marketing rights or intellectual property rights. Such assistance includes development, regulatory filing, drug price negotiations, marketing, and more. Also, if a company does not have a base in

Japan and cannot secure sufficient resources, or is unfamiliar with Japan's regulatory filing process, approval, drug price negotiations, distribution via wholesale businesses, and other areas, we can provide an optimum solution to suit the company's unique circumstances.