Japan

Seizing opportunities in the second largest innovation driven pharmaceutical market globally

Japan Global Position 2020

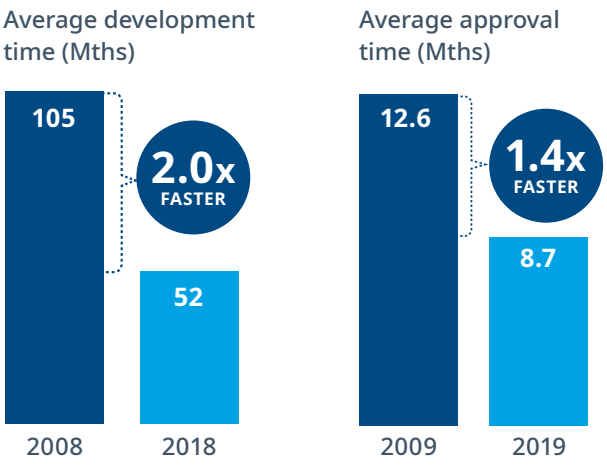
Japan continues to be the 2nd ranked pharmaceutical market for R&D driven companies across major product segments

Brands	Specialty	Biologics	5Yr NAS*	Oncology
$74bn	$35bn	$23bn	$19bn	$16bn
#2	#2	#2	#2	#2

Source: IQVIA, MIDAS Quantum. IQVIA Japan, IMSBase JPM. Japan Thought Leadership Team analysis.

*New Active Substances launches 2016 ~ 2020

Japan Health Ministry and other initiatives to reward Innovation have directly improved patient access to more effective therapies faster than 10 years ago



Introduction of PMDA consultation services to support clinical development contributes to faster timelines

2nd fastest behind USA

Source: Various. IQVIA Solutions Japan. Japan Thought Leadership Team analysis.

Japan has an accelerated review system that targets investment in innovation and unmet medical needs offering expediated timelines and additional protection

☑ Priority review
Products indicated for serious diseases or with efficacy/safety superior to existing products

☑ Conditional early approval
Confirmatory trials are difficult to conduct due and clinical trials other than confirmatory trials have shown efficacy and safety

☑ Products targeting orphan diseases
Number of patients is less than 50,000 or designated as intractable disease based on low possibility of development

☑ Sakigake system
Innovative products indicated for serious disease having prominent effectiveness and development and NDA in Japan ahead of, or simultaneously with, other major markets

IQVIA Japan

Leading CRO in Japan among both local and global CROs

Providing all functions and services for sponsors to successfully navigate the regulatory processes and perform high quality clinical development in Japan

4,900+ employees

25+ years experience

6 strategic locations

Data driven innovative Clinical approach to **site selection** and **patient recruitment**

99% Data coverage

>50 PMDA Consultations

Established very experienced **regulatory affairs team in** Japan helping sponsors successful negotiate the most efficient regulatory pathway with the PMDA for approval in Japan. Over 50% of clients are non-Japanese English speaking biotech

In Japan, IQVIA has served

>40 Companies **>110** Protocols

while acting as **In-Country Clinical Caretaker** for our sponsors clinical studies with successfully passed all inspections and lead sponsors to get marketing approval.

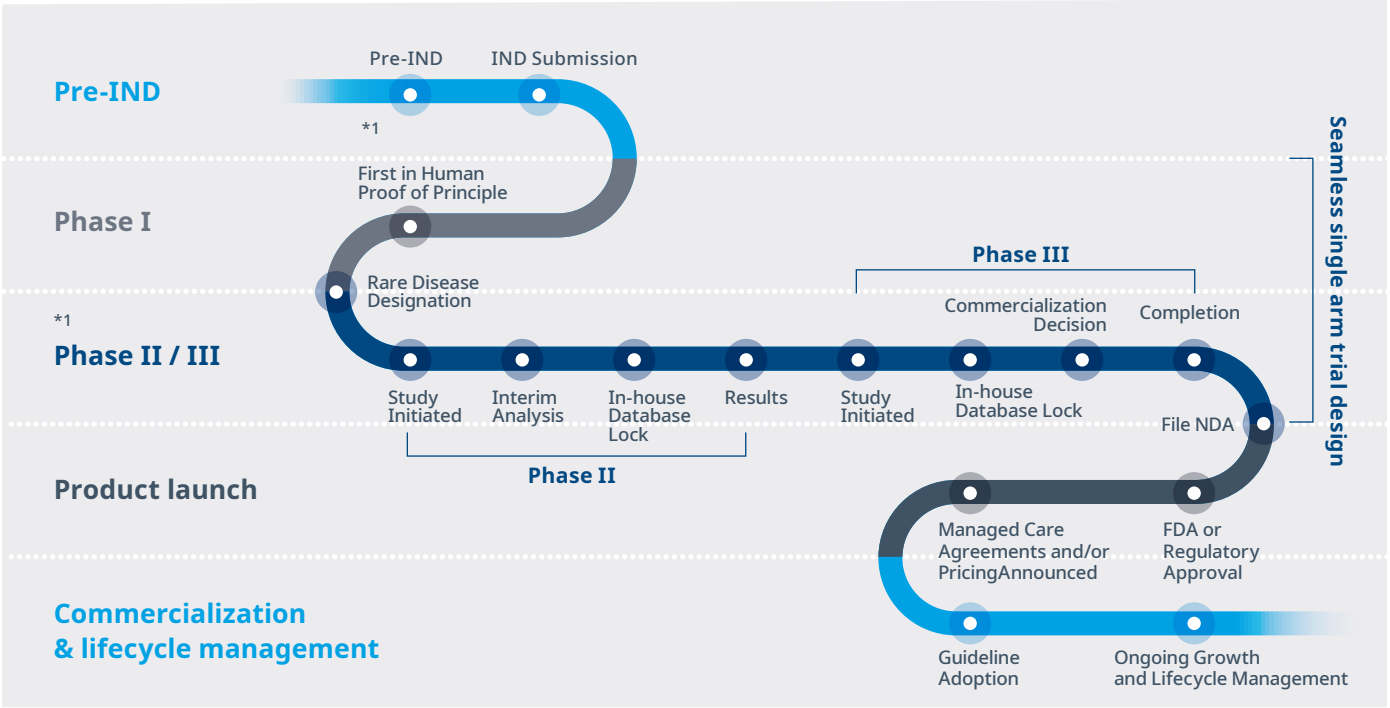
Largest medical team in Japan with experience in

>205 Projects in the last 5 years

Leveraging **personal network** to support sponsors identify appropriate KOLs

IQVIA Japan capability

From molecule to market – IQVIA's end-to-end support in Japan



*1 In Japan CTN (Clinical Trial Notification) application is required.

CONTACT US

IQVIA Japan Group

Keikyu Dai-1 Bldg., 4-10-18 Takanawa, Minato-ku, Tokyo

E-mail : Japan@iqvia.com URL: www.iqvia.co.jp