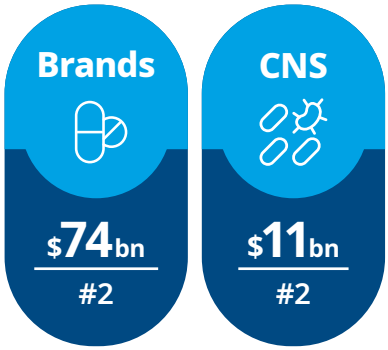
Clinical Development of CNS Products in Japan

The 2nd largest market for innovation

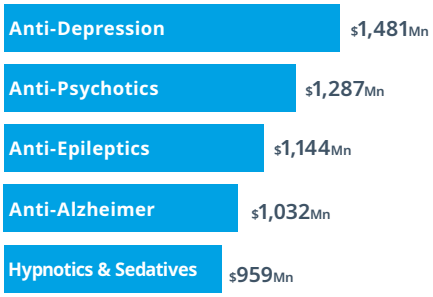
CNS market in Japan

Pharmaceutical market globally in 2020



Source: IQVIA MIDAS. IQVIA Solutions Japan, Japan Thought Leadership Team analysis

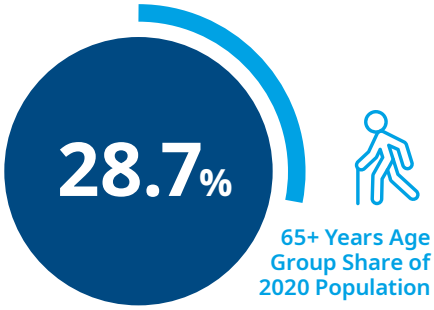
Sales for CNS products in 2020



($1 = 103yen)

Source: IQVIA Solutions Japan, Japan Thought Leadership Team analysis

Japan has one of the highest share of elderly (aged 65 years or older) and is expected to keep growing



Source: World Population Prospects: The 2019 Revision (United Nations)

Regulatory considerations in Japan

PMDA approval time

- Japan is now 2nd fastest for NDA approval time amongst all major regulatory agencies
- Average approval now down to ~10 months (twice as fast as 2010)

Source: Centre for Innovation in Regulatory Science (CIRS) , 2020, R&D Briefing 77

Trend for Japan to join multi-regional clinical trials (MRCT)

Being more efficient, cheaper and faster for getting approval,
>50% of clinical trials in Japan are MRCT compared to 15% 10 years ago.

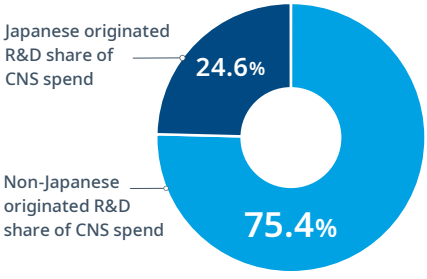
Typical clinical development strategy

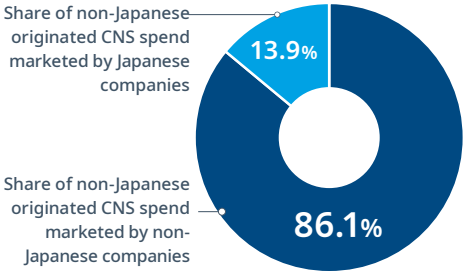
Phase I — **Global Phase II** (and or) **Global Phase III**

- ☑ Recommend including Japanese subjects as part of a global development plan. Japanese patients would be enrolled in a global phase II and/or phase III studies after Japanese phase I trial.
- ☑ Local development plan also possible but recommended to include Japan in a multi-regional development plan
- ☑ **Recently PMDA sometimes accepts Japanese patients directly enrolling in Phase III global study without Japanese Phase I data for diseases with high medical unmet needs**

R&D origin

75% of all CNS spend in Japan are from foreign discovered products and majority are marketed by non-Japanese companies.





Source:IQVIA Solutions Japan, IMSBase JPM (Japan Pharmaceutical Market) Oct. 2020

IQVIA - Your trusted partner for development of your CNS asset in Japan

IQVIA Japan has served >40 companies conducting >110 protocols acting as In-Country Clinical Caretaker (ICCC*).

Significant amount of ICCC experience includes CNS studies

*ICCC = It is mandatory for a pharmaceutical company based outside of Japan intending to perform clinical studies in Japan, to appoint an eligible partner (ICCC for Clinical trials) as their representative to clinical trial, to make sure the procedures are followed as per regulations.

Largest in-house medical doctors team in CRO in Japan with experience across all key therapeutic areas including 1 psychiatrist and 2 neurologists

Largest pool of CRAs in Japan and well experienced in CNS studies

Internal CNS advisory board supporting strategy and studies with CNS medics providing regular advice to project leads and CRAs

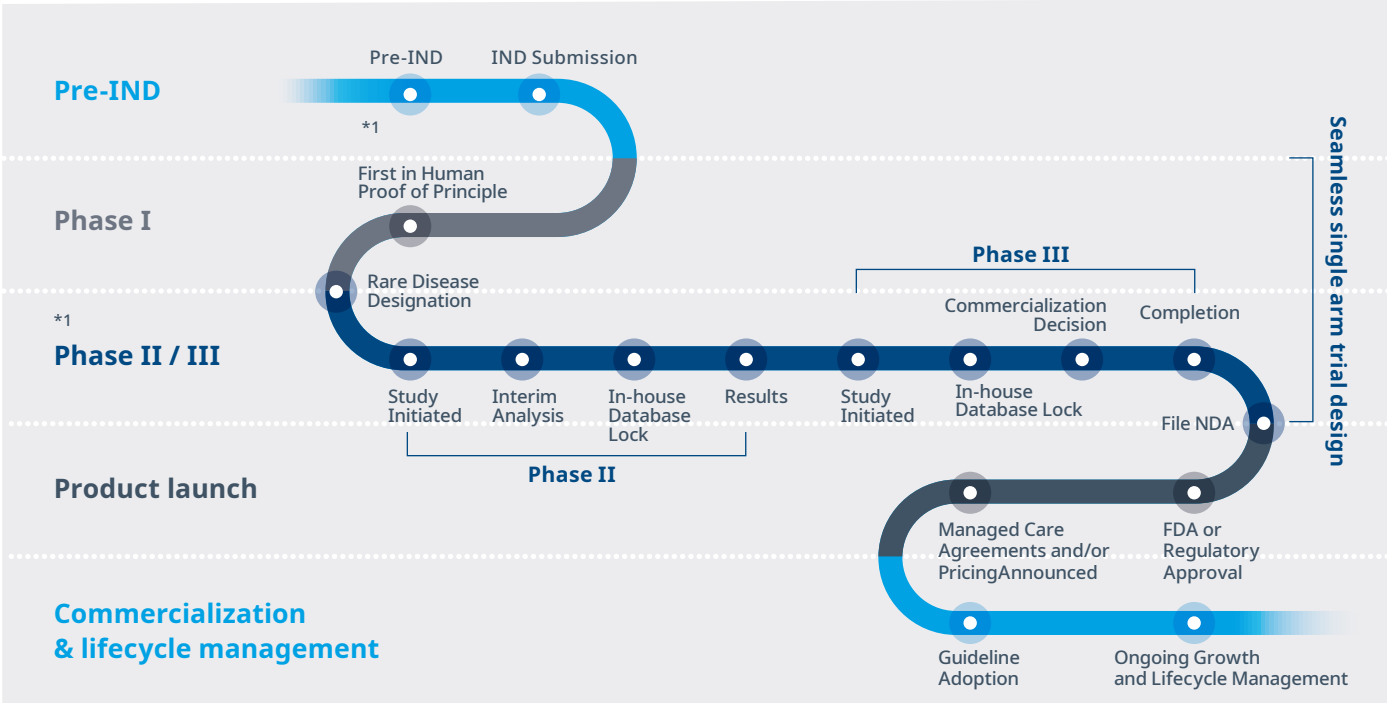
Faster and better recruitment leveraging IQVIA CORE™

IQVIA CORE is our innovative way of integrating **Unparalleled Data, Transformative Technology, Advanced Analytics**, and **Domain Expertise** to power solutions to discover better and faster path to success.

IQVIA CORE can **identify sites and recruit patients faster** in Japan. It is a powerful tool in studies with populations such as rare disease and pediatric studies.

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.

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