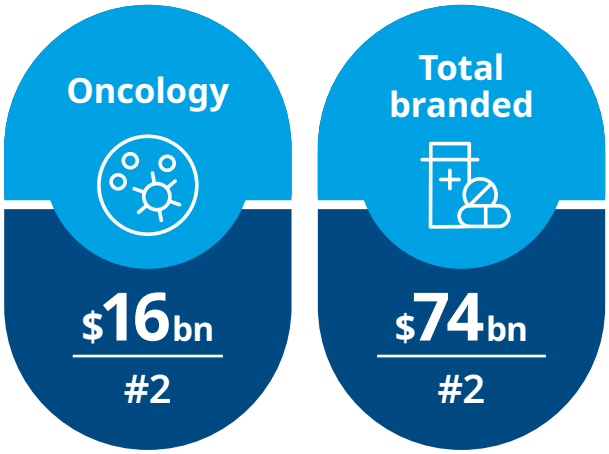
Clinical Development of Oncology Products in Japan

The 2nd largest market for innovation

Pharmaceutical Market in 2020– Japan portion



Source: IQVIA. IQVIA MIDAS Quantum. Japan Thought Leadership Team analysis

Cancer incidence trends in Japan

Cancer incidence surpassed 1 million in 2020 and is expected to keep growing due to continued increase in ageing population

Regulatory considerations

PMDA approval time

- Takes 8-10 months for J-NDA approval (twice as fast as 10 years ago)
- Japan now 2nd fastest for approval (FDA fastest)

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

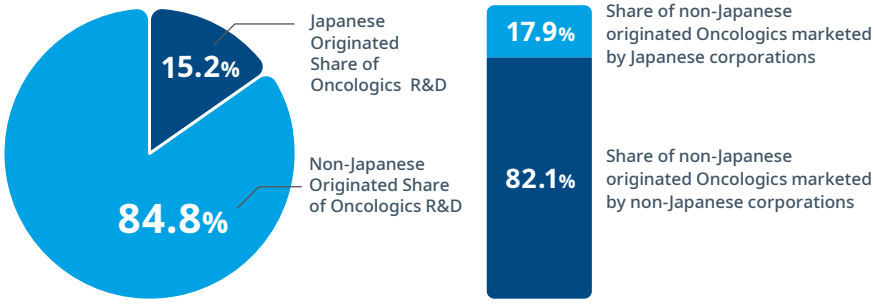
Being more efficient, cheaper and faster for getting approval, >50% of clinical trials in Japan are MRCT compared to 15% 10 years ago.

Typical clinical development strategy for anti-cancer drugs

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 accept Japanese patients directly enrolling in Phase III global study without Japanese Phase I data**
- ☑ **IQVIA's Regulatory Affairs team in Japan has experience successfully supporting Sponsors with such aggressive regulatory strategies**

R&D origin



Source:IQVIA Solutions Japan, IMSBase JPM (Japan Pharmaceutical Market) December 2019

***85%** of oncology products in Japan are foreign discovered & majority of those products are also marketed by non-Japanese corporations.*

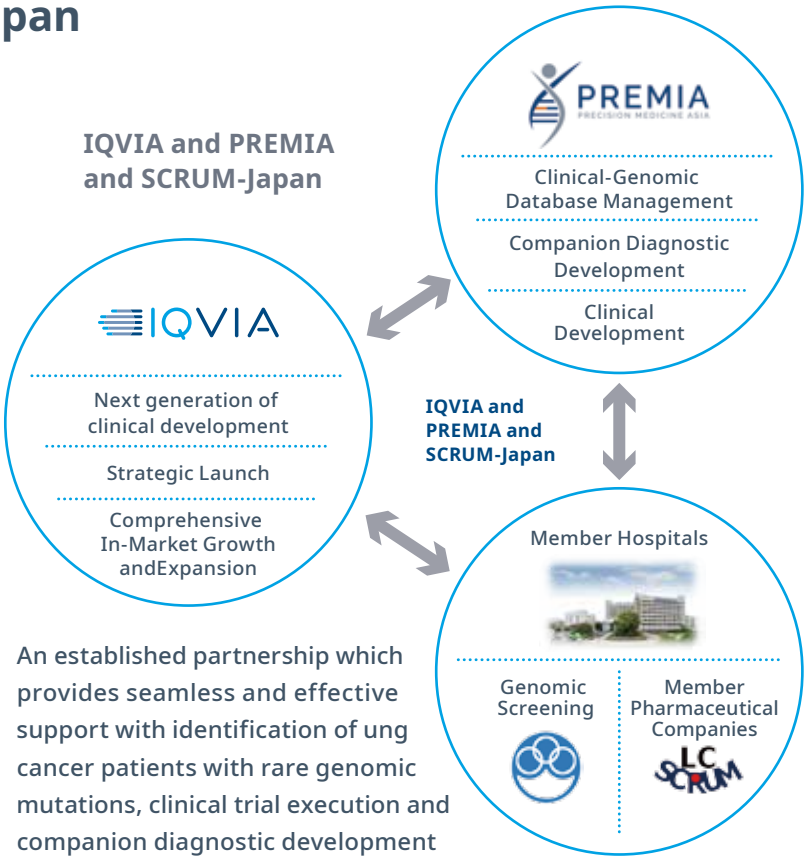
IQVIA - Your trusted partner for development of your oncology asset in Japan

IQVIA Japan has served
>40 companies conducting >110 protocols acting as In-Country Clinical Caretaker.
30% of ICCC experience is oncology studies

Largest medical team in Japan with experience in **>205 projects in the last 5 years**

Vast experience over all common and **rare oncology** indications

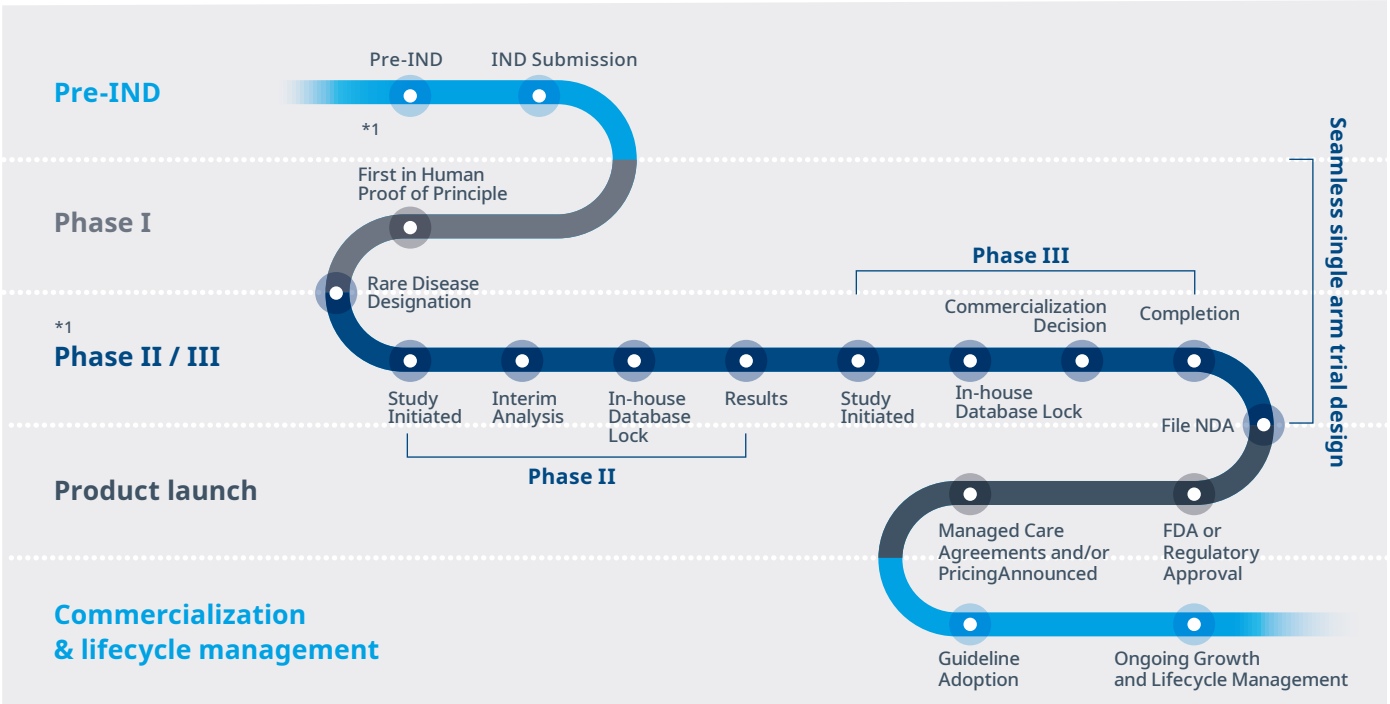
IQVIA and PREMIA and SCRUM-Japan



An established partnership which provides seamless and effective support with identification of ung cancer patients with rare genomic mutations, clinical trial execution and companion diagnostic development

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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