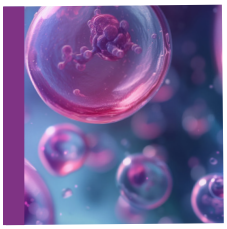
ELIQUENT
LIFE SCIENCES

Case Study

Supporting a Japanese Pharmaceutical Company developing a product licensesd abroad

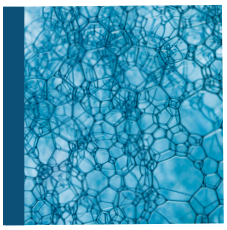


Stage 1

ELIQUENT Japan prepared the initial assessment report for the client's program—the program was not yet in-licensed by the client. The report demonstrated possible development scenarios in Japan for the client, and that led their decision-makers to move to in-license the program.

Stage 2

ELIQUENT Japan led the implementation of a PMDA consultation to confirm the development plan for the program in Japan. Due to the available data package from overseas, only minimal additional clinical and non-clinical data were required for the program to proceed in Japan.



Stage 3

ELIQUENT Japan collaborated with the client to select and manage CROs and testing sites. ELIQUENT Japan then implemented the additional studies for the Japanese regulatory requirements and led the selection and management of well-suited Key Opinion Leaders (KOLs) in the specified disease area.

Stage 4

ELIQUENT Japan leveraged both in-house and external resources to prepare a comprehensive eCTD for Japanese submission. Working closely with the client, ELIQUENT Japan managed all inquiries (CMC, Non-Clinical, and Clinical) from the PMDA through to complete product approval.

Japan Regulatory Solutions

ELIQUENT Japan partners with innovators to develop a synchronized, global go-to-market approach that unlocks the full potential of the Japanese market.. Learn more at **ELIQUENT.com**