

The Right Resources and Local Knowledge of Pharmacovigilance in Japan




PPD-SNBL provides a dynamic, robust and effective approach to a full range of clinical trial and post-approval pharmacovigilance services in Japan.

Global Capabilities with Japan Expertise

Our dedicated PPD-SNBL pharmacovigilance team is comprised of physicians, pharmacists and other medically trained professionals who bring nearly 20 years of experience to ensure maximum success for your program. Our experts are based in Tokyo and Osaka and have extensive knowledge of regulations in Japan. They adhere to globally established standard operating procedures and quality standards. Our experienced team members are fluent in both Japanese and English, allowing them to facilitate direct communication with global and local customers, along with the ability to review safety data in both languages. We have comprehensive experience in ArisGlobal's LifeSphere Safety MultiVigilance (formerly ARISg) and Oracle® Argus safety databases. Through these capabilities we ensure consistency, accuracy and confidence with our services in Japan. The PPD-SNBL Japan service offering is further strengthened by our established pharmacovigilance hub in Shenyang, China. This team of nursing and pharmacy healthcare professionals are fluent in both Japan and English affording them the ability perform Japanese data entry, and thus giving our customers a cost-efficient solution to support their Japan case processing needs.

End-to-end Pharmacovigilance Services

We offer global solutions and exceptional quality to successfully navigate Japan's clinical trial and post-approval environment, including re-examination management.

- Global and domestic (Japan-originating) individual case safety report (ICSR) processing
- Local and global literature review
 - Research reports
- Measures take overseas for medicinal products containing the same active pharmaceutical ingredient
- Safety reporting to the Pharmaceuticals and Medical Devices Agency (PMDA) and Japan investigators/ heads of institution
- Safety writing
 - Japanese development safety update report (J-DSUR)
 - Japanese periodic safety report (J-PSUR)
 - Periodic report for unexpected and non-serious adverse drug reactions (ADRs)
 - Re-examination applications
 - Japan risk management plan (J-RMP)
- Good vigilance practice (GVP) manager support
- Drug safety system that captures Japan-specific data elements for all case types

PROVEN QUALITY AND COMPLIANCE



In country clinical caretaker (ICCC) for 25 medicinal products across over 35 clinical trials in Japan



Processed and submitted more than 23,000 ICSRs to the PMDA with a year-on-year PPD-SNBL compliance of greater than 99.8%



Reviewed approximately 230 full-text literature articles and over 14,500 abstracts (Japanese and English language) related to research reports



Authored 65 Japanese DSURs with a PMDA submission compliance of 100%

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