



HELPING DELIVER LIFE-CHANGING THERAPIES



JAPAN EXPERTISE,
GLOBAL RESOURCES

STRONG LEADERSHIP IN JAPAN. THE RESOURCES NEEDED TO EXECUTE GLOBAL STUDIES.



When PPD and SNBL entered into a joint venture, the intention was to create a strong, singular clinical development team in Japan, combining the best of both worlds – the comprehensive technology and operational capabilities of a leading global CRO and the deep local knowledge and cultural understanding of an established Japanese company.

We understand the importance of having project leaders who are not only fully integrated globally on large trials, but who also have a deep understanding of the local clinical environment and cultural expectations in Japan to help ensure efficient operational performance and effective communication.

For studies conducted in Japan, PPD-SNBL's project leaders work alongside the PPD global team and ensure close collaboration with study teams in other regions.

Our local expertise allows us to drive better planning and efficiency of your Japan trials.

A LEADING CLINICAL CRO IN JAPAN

PPD-SNBL, one of the largest clinical development service providers in Japan, offers strong experience and capacities to support your clinical programs.

- + Comprehensive Phase I-IV clinical trial services
- + More than 720 staff in offices in three cities: Tokyo, Osaka and Kagoshima
- + Experience conducting more than 150 clinical trials in the past five years
- + Local leadership for Japan with more than 20 years of experience
- + Excellent track record of providing high quality services according to ICH-GCP standards
- + Recognized for staff retention success in a highly competitive recruiting market
- + Locally managed with extensive global capabilities, resources and standards



One of the largest full-service CROs in Japan
with more than 720 staff in three cities



THE COMFORT OF HAVING A TRULY LOCAL PARTNER

PPD understands the expectations of local regulators, sites and investigators, and has more than 20 years of experience working with our Japanese clients.

Our local expertise allows us to plan effectively and deliver greater efficiency for your studies to maximize investment in your trials.

MORE THAN 20 YEARS OF EXECUTING CLINICAL TRIALS IN JAPAN

PPD-SNBL was established when PPD, a leading global CRO, formed a joint venture with SNBL, a Japanese drug development company that has been conducting local trials since 1997.



FULL-SERVICE PHASE I-IV CAPABILITIES IN JAPAN



Clinical monitoring

Data management

Biostatistics

Medical writing

Regulatory affairs,
including PMDA
interactions and
ICCC services

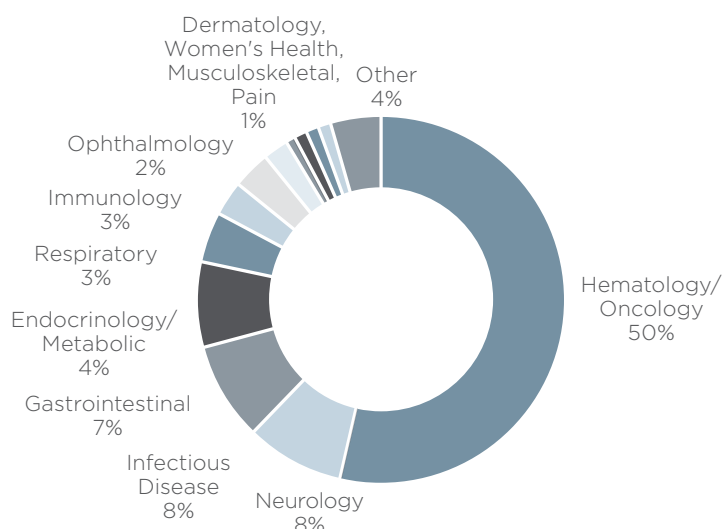
Quality assurance:
GCP audits and
clinical study site audits

Pharmacovigilance

EXTENSIVE CLINICAL DEVELOPMENT EXPERIENCE

In the past five years, PPD-SNBL has conducted more than 150 clinical trials across a wide range of therapeutic areas. This experience allows PPD-SNBL to offer full-service Phase I-IV capabilities and distinctive expertise in key functional areas in Japan.

CLINICAL TRIAL EXPERIENCE BY THERAPEUTIC AREA—PAST FIVE YEARS



REGULATORY AFFAIRS

Special consideration is needed to address PMDA requirements, enabling efficient conduct of clinical studies locally.

- + PMDA consultation meetings
- + CTN preparation and submissions
- + In-country clinical caretaker (ICCC) support
- + Local regulatory assessment and strategy development

CLINICAL DATA SCIENCE

PPD-SNBL's clinical data science team in Japan provides biostatistics, data management and medical writing services. This team of more than 60 experienced members has an average eight-year tenure with PPD-SNBL.

MEDICAL WRITING

- + Protocol development
- + CSR development
- + Investigator brochure
- + Proficient in Japanese and English

BIOSTATISTICS

- + Program development and regulatory submission planning
- + Protocol development and review
- + Randomization methods and schedules
- + Detailed analysis plans
- + Report tables and listings
- + Collaborative writing of integrated study reports and publications
- + DSMBs, interim analyses and annual safety updates
- + Regulatory submission-ready data delivery (including CDISC)
- + Integrated submissions and statistical sections

DATA MANAGEMENT

- + Global standards to ensure consistent high-quality data
- + Compliant with J-GCP and ICH-GCP requirements
- + Medidata Rave experience
- + eCRF/database development
- + EDC support
- + Data validation/query management
- + Medical coding
- + Manual listing review
- + SAE management

CLINICAL MONITORING AND INVESTIGATOR SITE SUPPORT

Investigator site selection and management is critical to the success of a study. PPD-SNBL engages an established network of site resources in Japan to facilitate strong enrollment and feasibility. With extensive on-the-ground experience with investigators and a deep awareness of investigator expectations in Japan, our clinical team:

- + Utilizes face-to-face communication and site visits as needed
- + Provides high-quality customer service and professionalism
- + Respects local culture and medical practices
- + Offers investigators customized training on clinical research methodology, biostatistics, etc.
- + Assists investigators with preparation of study documents

In addition, our team has multilingual capabilities and is well-versed in global best practices. PPD-SNBL provides staff with extensive, up-front training to help ensure the highest quality of conduct for studies where data is to be used for regulatory submissions in the United States, European Union or other markets.

TAKE YOUR TRIALS BEYOND JAPAN WITH EXTENSIVE REGIONAL AND GLOBAL RESOURCES



FULL SUPPORT FOR GLOBAL STUDIES

No matter where you are conducting your studies, when working with PPD-SNBL you will be supported by the innovative technology, processes, operational expertise and medical knowledge that you expect from PPD, a leading global CRO, including a global drug development team of more than 24,500 professionals in 46 countries.



For more information,
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