

### **INC Research Continues Focus on Growth and Delivery in Japan**

As a global contract research organization (CRO), INC Research Japan K.K. (“INC Research Japan”), has been working on “Japanization” of its global offerings and expertise to meet the needs of biopharmaceutical companies in the Asia/Pacific region, as well as globally.

Currently, the company is undertaking more than 25 projects, the vast majority of which are international clinical trials, and has organized a system to provide full support by their clinical development team. Senior Vice President, Clinical Development Miranda Porter Mann, PhD, pointed out the company’s development of a CRA recruitment strategy to support growth, saying that “increase in the number of clinical research associates (CRAs) is a rate-determining factor for growth; and Japan is showing the fastest growth for INC Research within the Asia Pacific region.” INC Research Japan’s primary challenge this year is maintaining our focus on continuous improvement in our delivery.

Entering the Japanese market in 2013, INC Research appears to have made a good start. Dr. Porter commented that the company is having an “exciting time” as the company grows in its business presence. As the number of total employees and CRAs in Japan increased to 148 and 82, respectively, the number of projects entrusted to them also increased. While most of the recently awarded projects are clinical trials of solid tumors, business in the fields of central nervous system disease, pain management, and ophthalmology has been increasing. The dedicated business units for each therapeutic area have been key in winning and delivering this business. Considering the growth scenario developed upon establishment of INC Research Japan, the progress so far is “more than expected.”

“When we decided to enter the Japanese market, we started from scratch, setting up a Japanese affiliate on our own rather than merging or acquiring companies. Experts said we cannot succeed in Japan because of unavailability of adequate CRAs. Historically, there has been a limitation in terms of recruitment for new entrants to operate their business,” Dr. Porter noted.

However, INC Research Japan has overcome the limitation by utilizing the company’s human resources personnel as well as staffing agencies to acquire employees with high English skills.

INC Research Japan conducts the Japanese components of international clinical trials entrusted to the company. INC Research combines local expertise with global therapeutic knowledge and processes in order to truly integrate the Japanese aspects into the global context of the clinical trial. This allows INC Research to promote bidirectional communication and lessons

learned (between our local and global teams and sponsor counterparts). This, in turn, helps to drive successes in the trial conduct within Japan. Since its beginnings in Japan, the company has utilized its global Trusted Process® project management methodology.

Japan is a country with a different clinical trial environment from that in foreign countries. This requires thoughtful consideration. To continue their process improvement efforts and ensure success in their clinical trial delivery, INC Research will soon implement Japan-specific enhancements to their Trusted Process®. The Trusted Process is the company's global project management methodology used to standardize operations, maintain quality controls, and ensure consistency in global project delivery. Via the enhancements to the Trusted Process®, INC Research is going to establish a risk management method adapted specifically to the clinical trial environment in Japan and integrate with the global risk planning for multi-regional clinical trials.

With regard to subject recruitment in Japan, achieving the target number of patients according to the schedule is more difficult as compared to foreign countries. INC Research Japan, however, has focused on developing the most appropriate approach for Japan and successfully completed enrollment of subjects as scheduled in the four global clinical trials that completed enrollment in 2016.

Dr. Porter stated that INC Research Japan has established a standardized risk management for pre-trial processes. "As for the study planning phase, we have completed 'Japanization' of the company's global Trusted Process®." She noted that "an organizational system and structure to enable continuous improvement in quality are required" in order to move from the "Plan" step to the "Do and Act" steps. INC Research Japan continues to prepare for regulatory audits/inspections, including such efforts as establishing risk-based quality assurance systems defined in the ICH-E6 (R2) guideline.

In order to utilize enormous post-marketing data guiding clinical development decisions and protocol design, INC Research Japan is entering the business of real-world data in the clinical settings. The company already has set up a dedicated department, and recruitment of experts has been started in Japan. Although the timing of program initiation is yet to be determined, the company is also building the team with expertise in the medical device field.