Interview: Sanjay Machado – Vice President of Global Operations and Integrations; Yohana Granados – Director of Clinical Operations Latin America, JSS Medical Research, Colombia



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Dr. Sanjay Machado, the Vice President of Global Operations and Integrations for JSS Medical Research Inc., (JSS) a Canadian based international Contract Research Organisation, elaborates on the rapid expansion of the company through strategic acquisitions, the full range of clinical research-related services of JSS and the company's vision to expand further through acquisitions in Latin America and in the US.

You both work at JSS, Yohana you were promoted post acquisition of Latam Clinical Trials in 2013 as the director of clinical operations for Colombia, and Sanjay you joined in 2011, now acting as Vice President of global operations and integrations. Could please both introduce yourselves and your role within JSS?

Sanjay Machado (SM): In September 2011, I joined as the executive director, global business operations for JSS. Five years later, I got promoted as the Vice-President of global operations and integrations. My role today primarily consists of managing the integration of the newly acquired companies while monitoring the consolidation of global operations for all the affiliate companies. Senior Management working at JSS remains very hands-on. As managers, we oversee most of the

on-going projects of the company at a high level, but we also attend clients meeting and regularly take on the challenges of delivering some of the tasks ourselves. Dr. Sampalis , our CEO and Founder, continues to reviews protocols, sample size calculation, statistical analysis, manuscripts and abstracts as an example of his hands on involvement and passion for science.

Yohana Granados: I used to work for LATAM Clinical trials, a company JSS acquired in 2013. LATAM clinical trials' activities were focused on vaccine studies for Colombia, Guatemala, Porto Rico, Panama, Peru and Venezuela. JSS acquisition has helped us build financial stability, broaden the range of services we deliver and thus, attract more clients as a full service CRO.

How have JSS's operations evolved along the years?

SM: Having successfully made an entry to Europe, Asia and Latin America, JSS is now a full-service international CRO. As of today, the company counts more than 350 employees around the world.

When I joined JSS in 2011, the company predominantly conducted post marketing observational and epidemiological studies, a niche service offered by JSS, while conducting early phase drug and device studies as well. Coming back to the early days of JSS: Dr. Sampalis founded the company in 1985. At the time, it was as small university based consulting firm providing medical writing and statistical analysis to the pharmaceutical industry. An independent CRO was established adding data management services. In 1997, services were expanded to provide quality assurance, clinical operations and IT solutions. In 2005, by adding monitoring, drug supply & storage, international alliances to the existing services, JSS became a full service CRO. Since 2014 until now, JSS has been focusing on international expansions by acquisition of established regional CROs in Colombia, India and Poland while expanding its capacity in Canada by acquisition of a local CRO.

[Featured_in]

As a fully integrated CRO, we offer a complete range of services from study design to results dissemination. We are truly a "One Stop Shop". Some of our services to note are conception, including gap analysis, study design, protocol development and CRF design; study setup, including regulatory, ethics, site selection, site initiation, document management & database development; study execution, including project management, data management, safety review, and monitoring; data analysis, including SAP development, biostatistical analysis, sample size calculation, and consulting; QA Program, including SOPs, software validation, training, and auditing; medical writing, including clinical study reports, abstracts, posters and manuscripts; reimbursement strategy, including market access strategy, core value dossier, and systemic review of literature; developing the submission, entailing medical writing, comparative effectiveness, health economics

analysis, and budget impact analysis; and finally submission specific to decision-maker with public and private payers.

We can also help develop the right approach to support our clients' market access goals with health economic evaluation, core value dossier and financial impact.

Our other services are investigator-initiated studies, epidemiology & biostatistics courses, in-sourcing mandates, clinical research consulting, and GCP training, among others.

How is the range of services you just told us about represented in Colombia?

SM: JSS Colombia now offers all the services mentioned above with the support from the HQ. All the regional activities are covered by our employees in Colombia. We have started recruiting employees in our regional offices with the required qualification for delivering services that are uncommon in the regions. We have a good mentorship programme where the new additions in the regional offices are supervised by our experts at the HQ increasing their experience and quality. By using this model, we are training a new set of resources in their regions to become the experts in providing our niche service offerings.

Which companies do you provide services to?

SM: We are currently working with 15 of the top 25 multinational pharmaceutical clients. Our services for the large pharmaceutical companies are mainly in the late phase including Health Economic Outcome Research. We work with many small to mid-size biotechnology and device companies in early phases of clinical trials.

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What motivated the decision to use Colombia as a regional hub for JSS in Latin America?

SM: JSS Medical Research discovered a gap that exist in Latin American countries to conduct real world evidence clinical trials. There are few if any, CRO in this region that has the experience to conduct these kinds of trials. Our existing clients referred us to their regional affiliates to provide them with the services they were looking for based on the work we have conducted for them. This is how we got started in Colombia. Colombia has a very good regulatory environment and most often if all the required documents are in order, you can expect an approval for the trial from the Ministry of Health (MoH) in three months. Colombia is one of the country in this region with the shortest approval time. More over the clinical sites that participate in trials are inspected and accredited by the MoH based on the requirements, training, and qualification of the site and site

personnel. Only site that are accredited by the MoH are allowed to participate in the trials. This allows for credible clinical data according to GCP and GDP.

What is the financial performance in Colombia and the special outlook of company?

SM: By expanding the service offerings in Colombia, JSS Latam was able to acquire new business in turn increasing the revenue. Post-acquisition, JSS was able to bring new business and financial stability to the office in Colombia. We have increased the number of employees since acquisition and are making strategic hires to consolidate our position as an leader in the market.

What are your strategic priorities in the next three to four years?

SM: We are looking forward to growing the business through organic and inorganic growth. Many of our US clients would like us to have our own offices in the US and therefore we are looking forward to doing the same. In the case of Latin America, we are already involved in many countries but we'd like to establish our own offices in Mexico, Brazil, Chile and Argentina.

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