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Founded in 1983, BBK Worldwide is a marketing consultancy firm specializing in patient recruitment for clinical R&D segments of the pharmaceutical, biotechnology, and medical device industries. In June 2015, the company had set-up a new office in Tokyo, Japan. An email interview by *Anusha Ashwin* of BioSpectrum with Toshio Mori, Managing Director of Operations, Japan, BBK Worldwide, explains about his responsibilities in establishing and growing the company's new Japan office.

Could you give the readers a small bio about yourself and the new office in Japan?

I was born and raised in Tokyo, Japan and I have worked in the medical device and the pharmaceutical industry for the past

25 years; work which included leading marketing operations for a top Japan-based medical device company. Early in my career, I worked in Germany and for an American medical laser device manufacturing company, which gave me the global experience to handle this new role at BBK Worldwide.

The new BBK office in Tokyo is located in close proximity to major pharmaceutical companies, and we're excited about the opportunities the new location offers to collaborate with our clients. My goal is two-fold: strengthen our relationship between BBK and Japan's local clients and vendors, and second to expand our footprint in Japan to create new partnerships and opportunities.

As a newly appointed MD for BBK Worldwide, what would be your role and how do you plan to steer the company to success?

My role at BBK is focused on business development and managing clients in Japan. The landscape is evolving, and I believe we are uniquely suited to help. Together, with the corporate team headquartered in Boston, Massachusetts, USA, we are committed to understanding all aspects of the clinical research ecosystem in Japan so that we can most effectively support clinical research through our suite of patient recruitment and retention services and solutions.

BBK Worldwide was founded in the year 1983. The company has been a close witness to growth of the CRO industry for more than two decades. Can you explain how it has grown, especially in Japan?

The pharma corporate culture in Japan is unique. Sponsors must conduct and submit results of clinical trials specifically in Japan with Japanese patients to have any of their drugs approved for market in Japan. To some extent, this makes growth difficult as many foreign CROs are often hesitant to make big investments in Japan. However, in recent years with government health reforms and greatly reduced drug approval timelines, business for CROs and SMOs has been changing. To date, BBK has worked with 8 of the top 10 Japanese pharmaceutical companies and their interest in us continues to keep pace with increased demand.

What is CROee? How has its collaboration with BBK Worldwide brought out a difference in Japan?

CROee is a Japanese CRO focused on patient recruitment. They own a patient database and a call center that is at the core of their patient recruitment offerings. The collaboration with CROee helped BBK better understand the market and business culture in Japan, while helping CROee sophisticate their infrastructure and their recruitment strategies by sharing BBK's 30+ years of experience.

What are latest technologies and apps adopted by BBK and how have these technologies helped in patient recruitment in Japan?

BBK's clinical trial management software, TrialCentralNet (TCN) streamlines, organizes and provides on-demand analysis of all recruitment and retention data, processes and activities. This secure system enables clinical study teams to make better project management decisions throughout a clinical study's life cycle. Using TrialCentralNet while preparing materials for IRB submissions in particular helps speed up the approvals in Japan and rest of world.

In addition to TrialCentralNet, BBK is working to incorporate mobile apps for patient and site engagement in Japan. Mobile engagement for both sites and study patients is increasingly important today and it's increasingly important to ensure that these communications channels are available to the Japanese market.

What is the major difference between CRO market in US and Japan? How has BBK addressed this difference?

CROs have traditionally had a smaller role in Japan compared to the US, and the role of SMOs in Japan is much more prevalent in clinical trial management. Many Japanese sponsors are used to developing much of their clinical trial services in-house but that's changing. Of late, increasingly Japanese sponsors have started following the US model in choosing preferred vendors instead. Working in collaboration with SMO, CRO, Sponsor and creating deeper relationships with all three to give consult on what's the best way to execute a study has proven the most effective for BBK, especially in Japan. BBK is helping educate the market on the options for certain aspects of clinical trial management and teaching the same using a Functional Service Provider (FSP) model in which BBK would be used as a patient recruitment specialty vendor.

The company has fostered novel ideas in managing patient recruitment, what are these ideas and how far have they been successful in Japan?

Yes! Innovation is a continuous process at BBK. The company recently launched RSG Arrive, a full-service concierge

program created to fully support clinical trial patients and operationalize travel for pharmaceutical companies, where recruitment of patients extends well beyond the area of the site, often in different countries. The program has designed to optimize the millions of dollars spent on study-related care annually and support the demands inherent in today's growing personalized approach to research.

RSG Arrive manages all travel-related logistics - operational and financial - for trial patients and sites. From car and shuttle booking, to international flight and accommodation management, RSG Arrive ensures that patients get to and from study visits as simply and seamlessly as possible. RSG Arrive leverages BBK's cloud-based patient recruitment platform all travel logistics are linked to individual patient and study visits and are updated and available in real-time, providing clarity and saving study teams valuable time, budget and resources - all within a secure and confidential environment.

At BBK, we believe that patient recruitment must follow an adaptive model; that planning for change, and adapting as you go based on real-time data and analytics is a core part of every successful plan. Once a patient recruitment strategy is approved and is set in place in Japan, that approved strategy is usually set in place for the rest of the recruitment period. We understand how in Japan the need to 'adapt' could be perceived as a 'failure' or 'short-coming' of the original strategy, and we are working to change that perception.

To what extent has information technology (IT) helped in clinical trial management and why?

There are two major ways in which IT has helped in clinical trial management. First, IT has helped to eliminate waste and redundancies. IT replaced paper processes and put electronic data capture (EDC) and case report forms in place. Easily accessing all this data in an instant has paved the way for enhanced analytics to build better strategies. Second, IT has enabled accuracy in clinical trial management in the operations side. Operational enhancements using IT have made data readily available for everyone. Everyone is able to work from the same data set and decisions are made more accurately, efficiently and on time with the correct data set. Much of this process used to be hand written manually without insuring the best recruitment activity. Today, we have the ability to leverage technology for everything from feasibility and study start-up to patient recruitment management.

What is your opinion about The Japan Vision: Healthcare 2035? What is BBK's contribution in supporting this vision?

The Japan Vision: Healthcare 2035 recognizes Japan's commitment to the future of healthcare, and offers ideas to help promote engagement and foster innovation. BBK will be well-prepared to support Japan in these efforts, many of which are at the center of BBK's work around the world. Ensuring that all clinical trial stakeholders are engaged - physicians, patients, sites, researchers - is critical when creating a patient recruitment strategy. I'm excited to help support this vision and integrate BBK's best-in-class technologies where we can help to healthcare in Japan.

Could you please outline the company's strategic financial plans for the period between 2015 and 2020? Would there be any M&As and collaborations?

As our office was set up in June 2015, I would consider these days as early! We're in the midst of finalizing the roadmap, but it's an exciting time to be a part of clinical research and within patient recruitment and engagement in particular.