BioSpectrum the business of Bio & Health Sciences ASIA EDITION

# APAC on the Rise: Developing multinational clinical trial success

02 June 2017 | Analysis

**With drug sponsors increasingly challenged to recruit sufficient numbers of patients to run complex, global clinical trials in key therapeutic areas, and to conduct those trials efficiently and cost-effectively, the Japan and the Asia-Pacific region (APAC) offers an expanding array of opportunities for clinical development and commercialization activity.**

Sebastian Bather President, APAC and Japan at inVentiv Health

With drug sponsors increasingly challenged to recruit sufficient numbers of patients to run complex, global clinical trials in key therapeutic areas – and to conduct those trials efficiently and cost-effectively – the Japan and the Asia-Pacific region (APAC) offers an expanding array of opportunities for clinical development and commercialization activity.

A major driver of market attractiveness for launch of innovative drugs is the oft mentioned, continuing trend of increased

healthcare spending by a growing middle class in the region. When combined with improving trial infrastructure and more experienced investigators and related resources, means trial outcomes in APACare showing less variability and greater reliability. Korea and Taiwan, in particular, have proved themselves able to concentrate infrastructure and resources for clinical trials in aneconomical way—which is very appealing to multi-national trial sponsors.

Despite the vast opportunity that exists in including APAC sites in global clinical trials some nonAPAC based companies remain hesitant about running trials in APAC. This hesitation isoften due to several factors includingtime zone changes, regulatory heterogeneity, language challenges and lack of understanding of the cultural nuances at play in each of the countries in the region.For those considering the value in running trials in this region, this article will provide an overview of the challenges and opportunities for orchestrating a trial across APAC.

**A Balancing Act**

To fully leverage the opportunities that APAC offers, sponsors can turn to contract research organizations (CROs) that fully understand that “globalization” of the research enterprise involves a careful balancing act between understanding local practices and customs and the imperative for consistent methodologies driving and reliable outcomes on a global scale. For instance, while the general concept of good clinical practice (GCP) is increasingly well established throughout APAC, how GCP is interpreted can vary among countries, among regions and even among clinical trial sites within a region.

An often quoted example is Japan’s investigators expectations of higher face-to-face time with monitors and sponsors. This drives a need for additional site visits; the associated costs of which can cause challenges in putting together a cost-effective trial strategy. An understanding of local nuances like these is necessary to successfully run globaltrialsin partnership with other trial sites around the world. CROs also must rise to the challenge of coordinating across APAC markets while at the same time being part of a complex global trial. inVentiv, a 15,000 strong global company, is able to fulfill these needs for clients by combining our therapeutic expertise and best practices on a global level with on the ground expertise and investments in resources that make a difference for our clients. For example:

- Invested in enhanced capabilities for cross-border project management, clinical monitoringthat understands the individual country nuances and regulations.
- Provideon the ground feasibility resources, on top of the standard globally-available data-bases, and in our ability to hone our insight into specific clinical trial sites and principal investigators in key therapeutic areas such as oncology, respiratory and central nervous system disorders.
- Established dedicated study start-up teams in key markets to bring local expertise to bear in tandem with our global methodologies, and to move more rapidly through feasibility to study initiation and to accelerate patient enrollment timelines.

**APAC Markets Getting Bigger**

While the big APAC markets of Japan, Korea, Australia, Taiwan and China are attracting more complex clinical trials there are nuances to each market. Partnering with an experienced CRO can provide sponsors with insights that can help anticipate the differences between countries and regions. Several items to consider when expanding into a new APAC country include:

- Japan

Japan is investing heavily and systematically in developing open data and common standards for health technology assessment. Improving compliance and the quality of post-marketing surveillance is also a focus of attention. In general, needs are shifting from commercial resourcing to clinical oversight and resourcing. However, constraints on clinical trial resource availability are still posing challenges and there are opportunities for CROs to provide cost-effective alternatives.

- Korea

Korea attracts a very large number of global studies, partly because of sustained investment by public authorities in high quality, costeffective clinical trial infrastructure. The Korea National Enterprise for Clinical Trials (KoNECT) that was established by the Korean government in 2007 to foster clinical research in the Republic of Korea. KoNECT focused on developing infrastructure for clinical trials in Korea but since then its mandate has grown to include promoting the country’s capabilities for clinical trials and the wider recognition of Korea as a hub for world-class clinical research. Patient recruitment takes a degree of local knowledge and insights in the market along with an understanding of the historical trial data available. KoNECT works closely with CROs and sponsors to ensure they optimize trial design and have access to up-to-date information to in support of trials In Korea as well.

- Australia

Australia offers sponsor experienced and well-established clinical research sites, principal investigators and research nurses. Given that the industry is wellestablished there is also much experience and talent in the clinical research employment sector. However, the competition for clinical research talent can still be fierce and we are finding that, similar to other countries in the region, career and leadership development is an increasingly important “draw” for key talent.

- China

China presents some unique opportunities and challenges. The country is achieving positive momentum in approvals for drugs meeting urgent needs even as some data quality and compliance issues are still being worked out. The approval timeline remains long and highly variable (9-18 months). These timelines could decrease as the current backlog of medicines awaiting approval is clearing. Unlike their Korean or Australian counterpart, the infrastructure supporting clinical trials in China is not as advanced, so the “human element” is critical for fostering connections among clinicians, clinical monitoring and project management staff. China can still seem a bit daunting to some, but with early engagement, broadbased feasibility analysis and flexible resourcing modelsthese and other challenges can be overcome.

**Avoiding Silos Across the Region**

Indeed, the ability to adapt to different requirements in different geographies with competitively priced models – avoiding a silo’d approach at all costs – is key throughout APAC. At inVentiv, effective solutions are therefore about taking the BEST approach (Blended Efficient Sustainable Team). What is BEST is what works, allowing for strategic needs that move faster than a current partner set-up can keep apace of. BEST models integrate different partners as well as different models of delivery that range from resource augmentation, through project-based outsourcing to high accountability joint-investment partnerships.

**The BEST approach is all about being:**

- Blended. A mix of Sponsor and Partner, multiple deliverymodels and systems, adapting quickly to changingdevelopment needs of all stakeholders and regions.
- Efficient. Achieving more with no more; it is more than ameasure of operational productivity and cost, thecritical factor is unlocked value.
- Sustainable. Value created this year becomes the baseline fornext year, the onward drive continues throughinvestments in innovation, or the ecosystem’sability to shift shape to increase the amount ofchallenge it addresses.
- Team. Clarity that advances further than the usual notionsof RACIs and task matrices to work aligned to valueoutcomes, made easier when some elements can still be delivered in sponsor systems under sponsor control.

As these markets grow, an expanding list of stakeholders needs to be engaged in competition for the most advantageous sites. They can provide the local knowledge and insights required to identify the sites and investigators where the potential for rapid initiation and recruitment is highest.

**Becoming Truly Global**

We are at an exciting time in the history of clinical development in this region. APAC is increasingly seen as being integral to global trial success, and markets such as Japan are more often being considered in the first wave of launches for innovative drugs. With the help of globally-scaled CRO’s that have deep local insights to bring to design and execution of clinical trial studies, efficiency and effectiveness of trial outcomes are improving greatly. This progression has been long in the making. The reality is that this is a journey on a twoway street, one that requires effort from all parties including sponsors, CROs, regulators and investigators across oceans, time zones and geographies. A highly evolved understanding and openness to working with differences across countries as diverse as China and Japan, for example, implies not just knowing the context in which all teams operate, but how to be mutually-adaptive to the need for both local sensitivity and global consistency.