CLINICAL INVESTIGATION

Pan-Asian clinical research coordination: challenges and opportunities

"We have collected ... key data showing what tactics work best depending on the type of study and the country it is conducted it, allowing better decisions to be made."

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Over the past 30 years, the landscape of Asia-Pacific clinical research has evolved dramatically – from a high-risk frontier to a low-cost location to its current state: an integral part of global drug development. Within the Phase I–III space, the volume of clinical trial and site numbers has been relatively stable since 2009. However there have been changes in geography, nature and therapeutic areas of the trials being conducted.

Mature clinical trial markets, for example, Japan, South Korea, China and Taiwan continue to be key destinations. Countries in growth mode, for example, Indonesia, Vietnam and the Philippines, are starting to increase their participation in clinical trials. There is also evidence of a trend toward an increasing number of local trials by local companies focused on developing drugs for diseases with a higher prevalence in Asia [1].

The Phase IV numbers look somewhat similar, with 1295 unique studies started since 2012 – the largest proportion taking place in China, South Korea, Australia, Taiwan and Japan [2].

Access to potential clinical research subjects has been one reason for including Asian countries, which account for about 60% of the world's population. In addition, there is high interest from Asia-Pacific physicians to participate in clinical trials [3].

Despite these attractive operational attributes, there have been challenges in site selection in Asia-Pacific. Horsburgh describes how inexperienced sites are being systematically excluded from clinical trials in favor of experienced sites in oncology clinical trials. It is postulated that this could be due to perceived inability to deliver [4].

Horsburgh further describes how this might not be the case: there is evidence that inexperienced sites do just as well as experienced sites [5]. Innovation is a driving force in Asia and changes are occurring in site selection as a result of sophisticated data analysis. Turning the process upside down has yielded valuable insights about a country's potential to conduct trials, as demonstrated in Saldanha's work of mapping all the healthcare facilities in a country prior to protocol development versus waiting for protocol then looking for the sites [6].

The emergence of new technology and systems are providing opportunities to address the challenges of running pan-Asian trials, helping realize benefits while mitigating risks. In particular, these developments take advantage of mobile and data analytics to improve productivity, quality, data capture and consistency of processes that ultimately lead to enhanced decision making.

Improving monitoring productivity is a priority, as time-savings in processes allows more time for the team to work on the complexities of a regional study. Technology is proving to be a valuable tool in improving productivity, in particular mobile technology as monitoring teams are frequently on the road at sites with so-called dead time during travel and waiting at sites for access, personnel and other gate keepers.

We have begun to create simple apps for deployment in Asia that maximize the use of this dead time as well as address other repetitive processes including subject visit

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scheduling, IP accountability and essential document acquisition. The digitization of some of these processes through apps has shown in early field testing to achieve time savings of up to 30% on these activities – potentially freeing up time to devote to other essential tasks. We are also in the process of assessing the impact that they have on improving the quality of these processes with data expected later in 2015.

Careful management of monitoring quality in Asia-Pacific is important because the region's highly competitive job market contributes to industry-wide turnover (and subsequent staff transitions). Other contributors to quality, such as line manager oversight, are also important targets for intervention.

Our app to allow more consistent conduct of accompanied site visits, a key process for manager oversight, enables easier data collection, storage in advanced 'data factories', and improved data analytic possibilities that can be reinvested into further improvements.

These improvements, coupled with sophisticated data analytics drawing on Clinical Trial Management Systems, allow better oversight of the study and risk areas from data points such as queries, action items and source data verification backlog to be tracked. These risk areas can then be acted upon with processes such as the accompanied site visit as described above. The ability to now track and monitor a study at various levels of the project team in near real-time, on both our mobile devices and laptops, enables earlier more educated decisions to be taken.

Another process we are developing an app for is proactive site inspection readiness, combining monitoring staff qualitative assessments with quantitative data from the systems described above. The end result is a holistic 360-degree view of a site in a project, enabling even more educated decisions and actions to be taken at all levels of a project team.

Effective knowledge management is vital to ensuring that pan-Asian trials progress smoothly regardless of staffing changes that occur over the life of a project. Robust knowledge management systems and processes ensure that important information is retained and key actions taken, regardless of changes in personnel. We are in the process of taking the management of study progress to the next level through effective task management and use of reminder tracking technology that maximize mobile and desktop devices.

Profiles of individuals in projects are created with key tasks populated and over time, new ones loaded. These profiles will be passed on to new staff preventing tasks from being lost in transitions. In addition, centralization of these key tasks will be located in a dashboard to provide an additional fail safe that management can intervene with.

With this in place, critical tasks such as regulatory/ethics approvals and safety updates will be reassured.

Simple knowledge management systems now also allow us to track and effectively manage the heterogeneity of regulatory, ethics and other local processes in each country. This enables staff to act more quickly, accurately and consistently in complex pan Asian studies.

Recruitment is another challenge in large studies that is often targeted in an *ad hoc*, individually based manner. We have developed a patient recruitment and retention tool available in both app and desktop forms for various site facing staff. This allows better understanding and education of the various recruitment tactics as well as earlier planning, execution and tracking.

We have collected through our network, key data showing what tactics work best depending on the type of study and the country it is conducted it, allowing better decisions to be made. For next steps, we will integrate these with our study management tools enabling earlier intervention as well as more accurate and timely assessment of these lead measures of recruitment. The use of these tools will further collect additional data points on the effectiveness of these tactics and put us into a virtuous cycle of continuous improvement.

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