BioSpectrum ASIA EDITION
the business of Bio & Health Sciences

What is needed for a successful trial supply management service in APAC?

16 September 2015 | Opinion | By BioSpectrum Bureau

What is needed for a successful randomization and trial Supply Management Service in APAC?

Singapore: Today there is true growth potential in the Asian clinical trials market. Read any market report and this is obvious. With this growth there are ever expanding opportunities for eClinical technologies as their use is embraced by local and global biopharmaceutical companies in the region. While systems such as Electronic Data Capture (EDC) have been established for some time, other systems like Randomization and Trial Supply Management (RTSM) - also known as IRT (Interactive Response Technology) - are now beginning to see increasing adoption in markets such as China, Japan, South Korea and Taiwan.

RTSM involves the activities associated with real-time processing and monitoring of enrolment, treatment allocation, dosing, dispensing and clinical supplies tracking. The RTSM market size in Asia-Pacific (APAC) is expected to reach US$46.4 million by 2018 (a CAGR of 19.1 percent, compared with a worldwide estimated CAGR of 13.2 percent between 2013-2018).

To succeed in these markets and drive their adoption of RTSM, it is essential to not only rely on strategies that have worked in other markets but to also adapt to the unique needs of Asian markets. It's important to understand that building sustainable RTSM services in Asia cannot be achieved overnight and can be challenging to execute effectively in markets that are rapidly evolving and changing. Some of the unique challenges in applying the benefits of RTSM in these countries, include providing the following:

1. Local project services and support teams with domain expertise
2. User interface and end user documentation in local language
3. Service, system and process capabilities adapted for local markets
4. APAC market knowledge and applying global expertise where necessary
5. Cost-effective implementation, maintenance and operations

Local Project Services and Support Teams with Domain Expertise

It is often said the best way to learn about a region or country is to visit, to meet the people and to have in-person meetings. When it comes to providing RTSM services in Asia, the best approach is to utilize in-region project services and support teams that are subject matter experts. Developing and maintaining expertise in the region is critical to ensure success. However, there is a very limited pool of in-region resource with RTSM domain expertise and therefore one must invest in a long-term plan to build operations and achieve a knowledgeable critical mass. Resources need to understand patient transactions, unblinding to treatment and medication management functionality due to the criticality of ensuring each patient is randomized to the correct treatment and receives the correct drug (and dose) at every visit.

User Interface and End User Documentation in Local Language

Imagine trying to enter data or read end user documentation in a foreign language. When sites are trying to randomize and dispense medication in real-time without keeping patients waiting, they require an RTSM system and supporting documentation that can help them to achieve this easily and quickly.

For a site enrolling and dispensing medication to patients on a clinical trial in Asia, it is essential to have both an interface localized to the local market needs and user documentation describing the different RTSM system transactions in the local language - as not every end-user speaks, reads and writes English. While this may seem relatively straightforward, it can be very challenging and lead to confusion at sites, unless those translating the user interface and end user documentation into the local language understand the industry specific terminology associated with clinical trials. Direct translations from English to Mandarin or Japanese and Korean do not always work in the context of clinical trial terminology. For example, something as simple as 'Monitor' when referring to a Clinical Research Associate could be translated to a 'monitor screen' or something similar, which obviously has nothing to do with a CRA.

Service, System and Process Capabilities Adapted for Local Markets

One of the key advances achieved in the evolution of RTSM services in the last five years has been the move to more standardized development approaches . This has allowed vendors to implement RTSM systems using reusable building blocks while focusing more on custom client requirements. With the adoption of RTSM in Asia it is important to adapt and respond to local market needs while maintaining global integration and standardization.

For example, there are normally two dates associated with the arrival of medication shipments sent from depots to sites, the actual date the medication shipment arrived at the site and the date that site staff entered the medication shipment into the site inventory in the RTSM system. These two events may not happen on the same day as a medication shipment might arrive at a site and not get entered into the RTSM system until a subsequent day. In Japan there is a requirement to capture the actual date that medication physically arrived at the site in the RTSM system, whereas globally, it is normal to just capture the date that site staff entered the medication shipment into the site inventory in the RTSM system. Also, in Japan user documentation should include screenshots whereas this is not a requirement in other countries in the region or globally. Across all Asian countries there is a need to build in more process steps around the validation and addition of translations to both the phone (IVR) and web (IWR) interfaces.

APAC Market Knowledge and Applying Global Expertise where Necessary

The APAC market is a large non-homogenous region, with study teams and site staff that don't have the same extensive experience with using RTSM technology as in other regions, where it is almost ubiquitous on clinical trials since being introduced in the 1990s. Therefore, it is critical to manage both dimensions appropriately: the ability to strike the right balance between global expertise and responsiveness to local market needs. The breadth of global and local service experience - whether it's providing functionality that meets the requirements of complex evolving regulations or support for busy investigator sites unfamiliar with using RTSM systems - is extremely important for successful delivery.

Some of the most important considerations applicable to all regions include:

â€¢ Mitigating risks when implementing complex randomization methods or supply strategies

â€¢ Managing limited, expiry-bound supplies to minimize wastage and the risk of stock shortages

â€¢ Safeguarding trial integrity and patient safety

â€¢ Sourcing accurate study progress information on which to base decisions

The ability to rely on a local team in-region that either has the required information, or can tap into global resources to provide the randomization, supply chain and statistics input needed to design appropriate RTSM solutions for the protocol, cannot be understated. For example, explaining something as complex as dynamic randomization or randomization look-ahead is much simpler in Mandarin than English when talking to a Chinese person. There is less possibility for confusion or eliciting the incorrect system requirements.

Cost-effective Implementation, Maintenance and Operations

RTSM solutions can be challenged to meet local budget expectations in the APAC region. For companies with limited budget for eClinical technologies it is important to be able to provide cost-effective RTSM implementation and services throughout the lifecycle of a study. There are options to use manual paper-based solutions or call center solutions but these don't offer the advantages of a fully automated RTSM solution, such as integration with other systems like EDC, reporting on study progress, and automated control of randomization and medication management. One way to provide cost-effective RTSM is through flexible and configurable systems, which can be delivered and amended in shorter timelines.

Instead of collecting requirements at an initial kick-off meeting and returning weeks later with the final version of the system, a modern RTSM service provider can take the basic requirements to create a demonstrable version of the system ready for the kick-off meeting. This process makes it easier for the client to understand what has been implemented and provide robust feedback. The service provider, in turn, can move toward a final system much faster. In addition, given the flexibility of the configurable system, changes can be made quickly either pre- or post-go-live without significantly disrupting the study start date or progress of the live trial. Compared to the 12 to 16 weeks systems previously required to go live, the modern RTSM system can be delivered in four to eight weeks, depending on the specific study requirements. Any variations in this timeline typically are due to the creation of novel protocol parameters or custom integrations with proprietary eClinical systems.

Conclusion

To overcome the unique challenges in applying the benefits of RTSM systems and to meet market expectations in APAC, it is essential to provide an 'in APAC for APAC' service. Without this specific focus, it will be difficult to overcome communication and service barriers to achieve the benefits RTSM can offer in the region. To ensure the most effective delivery, it is best to develop in-region subject matter experts who understand what it takes to delight APAC customers. Continued focus on the benefits of RTSM will prove instrumental in driving further adoption on a sustained basis so that it too becomes ubiquitous on clinical trials in APAC.