



# Supply on Demand

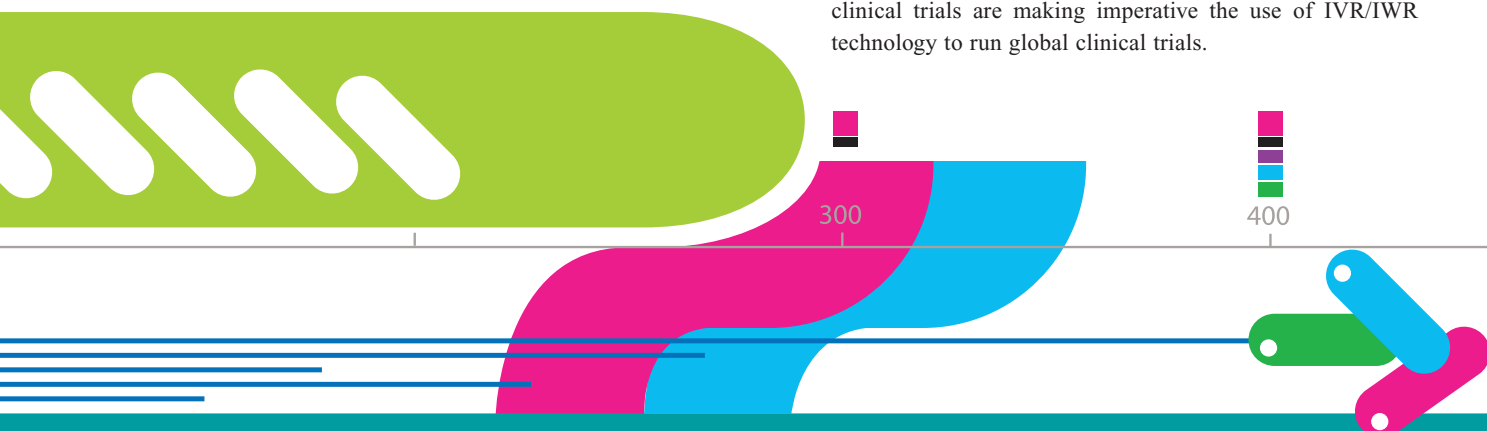
**Hugh P Levaux and Jaime Lau at UBC assess the benefits of leveraging interactive voice/web response technology to power clinical trial globalisation in Asia**

Tighter FDA regulations in recent years have resulted in a call for more complex protocols and extended clinical trials, while at the same time, the search for patients has led to an increased globalisation of trials – in Asia in particular. As a result, industry pressure to bring drugs to market through cost reduction efforts, such as streamlining the supply chain, has increased. That need is exacerbated by the increasing cost of biotechnology products. One tool that could aid in these efforts is the interactive voice or web response system (IVRS/IWRS) technology, which has been a ubiquitous tool in clinical trials for the past decade. Initially used for patient randomisation, IVRS/IWRS not only collects and stores patient and study data, but also translates the information into usable inventory counts that, when combined with the system's automated inventory management functionality, will mitigate the new challenges, optimise global trial operations and maximise savings.

## CLINICAL TRIAL OPERATIONS

Clinical trials use investigational drugs and biotechnology products that require careful assignment to patients, as per pre-determined protocols and, most of the time, in blinded fashion. Patients are randomised to particular treatment arms and a visit schedule determines titration schedules. For the past few years, IVR/IWR technology has facilitated patient allocation and management of patient visits, along with their associated titration regimens. Recently, the technology has been extended to facilitate complex drug supply and inventory management strategies.

In addition to technological developments, geographic developments are also increasing the need for IVR/IWR technology. Asian markets are growing and, concurrently, several Asian countries have revved up their capabilities for participating in and delivering clinical trial patients and data. Regulatory developments – such as upgrades to Japan's good clinical practices in 2008 – have facilitated clinical trial operations and the set-up of regional 'depots' from which investigational supplies can be sent to local sites in the region. As such, the combined effects of technological improvements and the growth of Asia as a destination for clinical trials are making imperative the use of IVR/IWR technology to run global clinical trials.



## TRADITIONAL PROCESS

For any inventory manager, the goal of supply chain management is to get the inventory to its destination on time. Though a simple mantra, the process of doing so is actually a long one that involves many stakeholders and much coordination. With clinical trials, the process is made even more complicated: clinical trials by design are randomised, which is great for generating unbiased trial results, but for an inventory manager, randomisation translates into not knowing what patients will need and when they will need it. As a result, inventory managers would need to send medication to locations based on probabilities of patients randomising to specific treatments. Thus, not only does the inventory manager have to worry about shipping times, expiry dates, drug duration and shipping temperature ranges, he or she must now also be able to predict the future and send the correct medication to a site where a patient may or may not be randomised to that treatment. To complicate matters, nobody at the site knows what each patient is randomised to. There is a risk of sending either too much medication or too little to the site. At best this results in wastage of resources and money, at worst, if the system does not work, the wrong medication or the wrong dosage might be blindly administered to a patient.

## AUTOMATION

With an IVR/IWR System, the ambiguity is removed. Through its inventory management functionality, the system is constantly tracking the status of all shipments to sites as well as monitoring the status and levels of inventory at sites. Thus, the system is always 'aware' of site inventory at all times. Also, because all transactions such as shipment receipts and drug dispensation visits are recorded through the IVRS/IWRS, the system is able to keep an accurate account of the site inventory, increasing or decreasing site inventory quantities immediately, as necessary. In capturing up-to-the-minute data, the system eliminates the time delay introduced through manual processing and can precisely determine when resupplies are needed. To do so, the IVR/IWR System makes available multiple inventory resupply models, including expiry management, buffer, threshold and predictive.

## Expiry Management Model

With the expiry management model, an IVRS/IWRS is able to compare the expiration date of a location's inventory to the current date, in order to:

- ◆ Identify expiring medication for replacement
- ◆ Prevent expiring medication from being allocated to shipments
- ◆ Prevent dispensation of expiring medication to patients

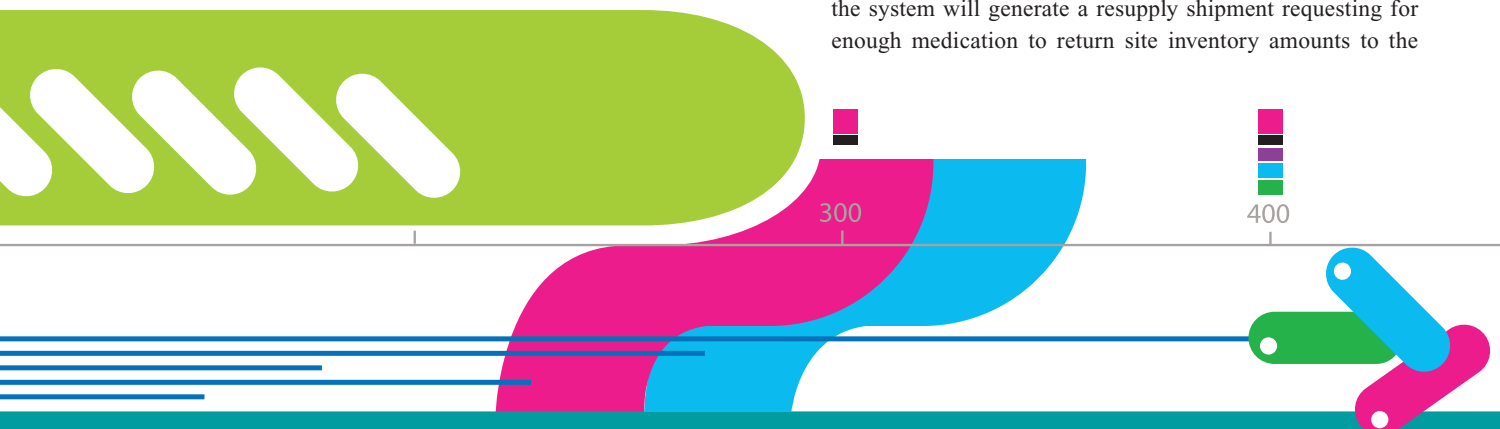
Through automation of this process, the system not only eliminates the need for constant monitoring, but also ensures that only the expiring drug is resupplied while leaving the non-expiring drug available at the location for distribution. As a result, the location is allowed to continue with business as usual while the system takes care of the resupply request.

## Buffer Resupply Model

Buffer inventories are normally provided to sites for emergency use. For example, if a patient loses their medication and requires a replacement, the site may opt to dispense from the buffer inventory. In the buffer resupply model, the system takes into account a buffer quantity when tracking site inventory levels. Once the buffer quantities are depleted or are low, the system will automatically generate a resupply request to replenish the buffer inventory. Similar to the expiry management model, this resupply will be controlled by the system and will occur behind the scenes so that the site can continue with business as usual, and will always have enough inventories of the correct quantities for emergency use.

## Threshold Resupply Model

Threshold inventories are similar to buffer, except that the intent for threshold levels is for future randomisations or enrolments. Hence, threshold quantities tend to be greater than buffer quantities. Much like the buffer resupply model, the threshold resupply model involves the system constantly monitoring site inventory levels and requesting resupply only when levels fall below a certain level. Thus, even if the site randomises or enrolls multiple patients, a resupply would not necessarily be generated. It is only when the site dispenses enough medication so as to fall below a threshold level that the system will generate a resupply shipment requesting for enough medication to return site inventory amounts to the



requisite levels. As a result, the quantity of medication distributed is minimised (by only sending the amounts needed), medication is sent only when needed, and shipping costs are reduced (single shipments as opposed to one for each dispensation).

### Predictive Resupply Model

With the predictive resupply model, the system calculates future inventory needs. The patient randomisation and associated visit schedule are stored in the central database of the IVRS/IWRS, thus the system is able to easily identify the patient's treatment assignment and determine the next expected visit date(s). It will then combine the information to determine the quantities and type of medication required for those visits. For example, assume a patient is randomised to active treatment and is expected to return for visits once a week for the next 10 weeks. At each visit, the patient is to receive two active kits. With a manual process, the inventory manager would send all kits all at once and not have to think about it again. In this case, the site would have 20 active kits for a single patient on site. For a site with 20 patients, that is 400 kits. Moreover, the risk of the kits expiring prior to dispensation in the 10th week is extremely high. Lastly, this is assuming that the inventory manager is unblinded to treatment and knows exactly what to send, which is not always the case. The alternative approach would be to time the distribution correctly – in other words, to send half of the medication now, watch the dispensations closely, and send the other

half when ready. This is time-consuming, error-prone and not ideal with a large scale trial. With IVRS/IWRS, these concerns are eliminated.

Using the same example, now assume that the IVRS/IWRS is configured to check every two weeks for patients who are coming for a visit for the next month (four weeks). What this means is that, in the predictive resupply model for this example, every two weeks the system must make sure the site has enough inventories available to dispense for all patient visits occurring within the next month. At week zero: the system calculates that a patient has four visits in the next month. With two kits at each visit, the system identifies that the patient is randomised to active, and therefore requests eight active kits to be sent to the site. By week two, the patient has another four visits in the next month, two of which were already supplied for during the week zero check. As a result, the system determines to request an additional four active kits (to supply for the remaining two weeks). Thus, at any given point in time, the site will only be holding a maximum of eight kits for a patient. For a site with 20 patients, that equates to 160 kits – a quarter of the amount of inventory calculated through the manual process. Not only is this a reduction in quantities of inventory distributed, but material is saved as well because the chances of medication expiring is minimised and the material being requested by the IVRS/IWRS matches exactly to the patient's randomised treatment. Lastly, if the patient prematurely discontinues from the study, the predictive resupply model automatically stops supplying for that patient, thereby preventing unnecessary medication from being sent to the site where it will most likely go to waste. Finally, and perhaps most importantly, the predictive resupply model would handle all calculations and requests behind the scenes as well, meaning the inventory manager may remain blinded to treatment because the system will take care of the requests independently.

### CONCLUSION

The IVR/IWR technology is the ideal tool for cost savings in the ever-changing world of clinical trials. Not only does it optimise the clinical trial process by automating patient data collection (randomisation and patient diaries), but it also streamlines the overall supply chain process. By providing the ability to record transactions via the IVRS/IWRS, the system is able to also provide up-to-the-minute, accurate inventory accounting. This in turn removes the time delay inherent with manual processes. Moreover, through the implementation of the various inventory resupply models provided by an IVRS/IWRS in conjunction with the patient and study data collected, the system requests only medication matching the patient's treatment and in quantities that will optimise usage and reduce wastage by 75 per cent. In conclusion, the IVRS/IWRS introduces efficiencies into the distribution logic that translates into a streamlined supply chain and maximised savings. Such savings facilitate the growth of an integrated global market for clinical trials and ease the integration of Asian economies into that market.

### About the authors



**Hugh P Levaux** is Senior Vice President, Strategy and Marketing Development at UBC and has 10 years of experience in clinical trial design and operations. He has held multiple positions in the life sciences, focusing on post-marketing activities and web-based technologies. He previously

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