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Partnering to Advance Human Health

Connecting the dots

How to harmonise your clinical supply chain with people, processes and technology

Connecting the dots: How to harmonise your clinical supply chain with people, processes and technology

Digital systems including Material Resource Planning (MRP), Temperature Management Software (TMS) and Interactive Response Technology (IRT) are vital components in managing the complexities of modern drug development.

If designed and integrated effectively, these systems power the supply chain engine and underpin the physical infrastructure to assure efficient, compliant and cost-effective supply to patients.

Yet without a connected approach it is impossible to effectively manage site activity, optimise drug supply, adjust future demand and provide a complete chain of custody, from production to accountability, reconciliation, returns and destruction.

To achieve a harmonised clinical supply chain, people, processes and technology must combine to connect the dots and deliver patient-focused, compliant and cost-effective operations.

There are several ways to help champion this ideal. Let's take a look.

Prioritise integration

Systems operating in silos will cause more problems than they solve so it's imperative that sponsors seek guidance from clinical technology and supply experts to create a fit for purpose, integrated digital supply chain.

Integrated technology can streamline processes and manage risk. Moving through the steps towards the end of a drug's lifecycle, when it comes to drug assignment, system integration is also key in bringing people, processes and technology together and maintaining the bigger picture.

For example, when patient data is entered into the IRT, the system determines the patient's appropriate strata and assigns them to a treatment group, based upon the randomisation list. If weight-based dosing is applicable, IRT will intuitively determine the optimal combination of kits to achieve the correct dose, before assigning kits from the site's inventory in the protocol's priority.

Blinding medication numbers will be provided to study personnel so doses can be prepared, and kit statuses changed to 'assigned'. This removes the kit from the site's inventory and triggers a resupply algorithm. The IRT will then send a shipment request to the MRP and push to the relevant supplying depot, where the cycle begins again.

All patient and drug usage data collected is shared from the IRT to the MRP's forecasting module, which updates and adjusts its future demand predictions based on real time data.

Let automation do the heavy lifting

Over reliance on manual intervention slows down processes and increases risk of human error. Embracing digital systems, capable of automating essential processes, will create faster and more precise operations that, in turn, will facilitate a harmonised supply chain.

To achieve this, integration is again key. MRP, IRT and TMS must be able to share data securely between system servers to pave the road for holistic process automation.

An example of integration and automation best practice can be found in the ordering process. When orders are placed in an IRT, data is seamlessly transferred to the MRP to raise drug orders automatically. Likewise, when packaging material is released from the MRP, the updated kit status is passed to the IRT so that parallel data sets exist in both systems. In this scenario, the IRT would then update virtual kits with information such as lot number, expiration date and physical locations, before altering the kit status to 'available' to indicate readiness for use.

Automation isn't limited to digital systems, by working with clinical technology experts and designing fit for purpose applications, the physical supply chain is also optimised to create a sense of supply chain harmony.

For instance, once a site is activated, clinical teams can select the site's supply strategy based upon projected enrolment so the IRT automatically raises a shipment according to the selected supply strategy to the MRP. This changes the status from 'available' to 'in transit'. The MRP will then flag the order in the appropriate depot and generate shipment details and associated documentation, enabling personnel to compile a compliant job pack for the processing centre for pick and pack.

Automation further supports harmonisation, as inventory is selected based on protocol design and material is warehoused in the same order. Kits are then e-verified against pick and pack lists and packed and stored at site in kit number order.

Leave reactionary management in the past

Taking a reactionary approach to supply chain management was less of a gamble before clinical trials grew in scale and complexity. Modern drug development, typically involving global studies and/or high-value or unstable products, significantly reduces the margin for error.

Sponsors are now compelled to anticipate and mitigate risk with a pro-active approach in order to achieve bigger picture visibility of performance and create harmonised operations.

Temperature management is a core discipline where a proactive approach, underpinned by a connected supply chain strategy and powered by technology, can pay dividends.

To put this into context, imagine temperature-controlled drugs en route to clinical sites. With a proactive, technology-enabled strategy in place, once shipments arrive at site they can be inspected and reconciled against the packing list. To avoid false excursion recordings, site personnel can quickly access the temperature monitor and press the stop button.

Site personnel then register shipments within the IRT and select the appropriate status. If monitors are alarmed, drugs may be registered as compromised and the status set as 'quarantined' in the IRT. At this point, sites are instructed to upload temperature monitor data to the TMS, which triggers an alert to relevant personnel to review logs against the drug's stability data. Temperature management specialists will then confirm if supply is acceptable or change its status to 'damaged' in the IRT.

Once material is cleared for use, it is stored within the site's pharmacy until needed, while inventory status and expiry are tracked in the IRT. As most temperature excursions occur during this phase, sites can pro-actively utilise technology by continuing to upload temperature data to the TMS to provide a real time overview. Information collated supports supply chain harmonisation by helping to resolve site-based excursions, track cumulative experience and automatically update the status of materials impacted by temperature events within the IRT.

Aligning your efforts

The clinical trials landscape is evolving in both scale and complexity. However, by building a data-driven supply chain model, and aligning the physical network used to produce and distribute IMP with interconnected digital systems – along with unified teams of supply and technology experts - supply chain harmony can be achieved. In doing so, safe, streamlined, compliant and cost-effective operations can be realized.

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