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Partnering to Advance Human Health

Fuelling the engine

How to use technology to power your clinical supply chain

Fuelling the engine: How to use technology to power your clinical supply chain

To accommodate the scale and complexity that modern clinical trials entail, the physical supply chain (the network of manufacturing facilities, warehouses, trucks, planes and people through which drugs are produced and distributed) must be underpinned and powered by a series of systems that form the digital supply chain. These include Material Resource Planning (MRP), Interactive Response Technology (IRT) and Temperature Management Software (TMS).

Leveraging technology to power your clinical supply chain requires an integrated, best practice approach, along with an understanding of the role individual systems play in assuring compliant, timely and cost-effective supply to patients.

So, let's take a look at the core digital systems used to capture, store and disseminate data that powers, monitors and tracks ordering, movement and administration of clinical supplies.

Material Resource Planning (MRP)

A fundamental task in developing effective clinical supply chains is understanding requirements for material and production planning. MRP systems, defined as a production planning, scheduling, and inventory control system used to manage manufacturing processes, play an intrinsic role in facilitating this objective.

By analysing demand-based factors, such as country ramp up, site activation and enrolment by region, as well as supply factors, like expiry limitations and drug procurement timelines, By analyzing demand-based factors, such as country ramp up, site activation and enrollment by region, as well as supply factors, like expiry limitation and drug procurement timelines, MRP systems can capture the necessary data to support the creation of precise forecast. This supports the development of accurate production campaign schedules that effectively accommodate all patient considerations and demand constraints, while reducing the risk of stockouts and overage.

MRP systems also assist with purchasing and delivering activities by making sure goods and materials are where they need to be, when they need to be there, that the correct materials are available for production and that products are available to sites/patients when they are needed.

At the click of a mouse, a robust MRP system will be able to provide you with a holistic view over drug supply and demand; highlighting when demand will be satisfied, when stock will run out, and when a replenishment order needs to be released or completed.

Forecasting Technology

Through utilising real time data, forecasting software creates a supply forecast that factors in key information from the protocol, assumptions provided by the clinical team, as well as details related to pharmaceutical development. This study design and site activity data, combined with enrolment forecasts, creates accurate supply predictions. It also supports sponsors with enrolment, discontinuation and drug usage information, while automatically adjusting forecasts based on drug usage data. Most systems will also issue automated comparison reports to provide visibility of forecasted vs. actual usage to aid continuous improvement.

By taking an integrated approach to technology infrastructure that makes up the digital supply chain, several processes can be automated thanks to a seamless flow of data. One such process is the mapping of forecasts directly to MRP systems to inform inventory management and production planning in real time.

One way to achieve this level of integration and optimise production and distribution strategies is to opt for a single, multi-purpose system, opposed to a series of standalone applications that require excessive programming in order to share and received data. Almac's SupplyWise™ encompasses demand forecast functionality to calculate clinical supply and demand over time, MRP technology to drive production and capacity planning and IRT to provide real-time inventory and patient enrolment data.

Interactive Response Technology (IRT)

IRT helps to automate randomisation, enhance blind protection, facilitate precise patient tracking and reporting and provide site performance and supply data visibility in real time.

IRT also enables sponsors to capture and track patients and kits and automatically calculate drug assignment based on kit availability at site and the treatment arms patients have been randomised to.

Expiration is more easily managed too, as IRT is programmed to recognise when kits are due to expire, assign product in expiration order and avoid assigning product that doesn't possess adequate shelf life.

Inventory management is further bolstered via IRT's enhanced methods of medication management and intelligent stock level functionality. This enables the system to automatically analyse site inventory - in addition to kits in transit - to establish levels. If they fall below pre-set triggers, the system will alert users and calculate requirements before placing a replenishment order.

IRT can harness patient data to tailor types of medication to send to sites in advance of patient visits by automatically projecting how much product patients will need and when they will need it, before breaking it down into short and long distribution windows. This helps consolidate shipments to optimise efficiencies and ease the burden at site.

Almac's range of IRT solutions – from 'off the shelf' configurable software to fully customisable systems – can optimise a trial's productivity, regardless of study scale or complexity.

Temperature Management Software (TMS)

DUnderstanding how temperature sensitive drugs need to be processed, creating the right operating procedures and environments and selecting capable materials are vital components in shaping the physical side of an effective cold chain.

TMS provides a digital mirror of the physical cold chain operation: collecting temperature data at each stage of the process – from production through to administration – in order to mitigate excursions and demonstrate compliance with a range of legislation, including cGXP and GDP.

TMS provides this holistic view by receiving temperature data from numerous monitor brands at each step of the journey from production line to patient, uploaded into a single database. Such systems also allow any stakeholder in a sponsor's clinical or commercial supply chain to upload temperature monitor data and record planned and unplanned excursions at a lot or serialised level.

Almac's TempEZ™ system empowers sponsors to build a complete temperature history for a product, establish a controlled quality-approved process for adjudication, expedite the removal of out of specification drugs, run analytics across key performance factors and make changes to improve internal and vendor performance.

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