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Partnering to Advance Human Health

Laying the foundations

How to build a fit for purpose clinical supply chain

Laying the foundations: How to build a fit for purpose clinical supply chain

Building an effective clinical supply chain that factors in the increasing challenge of getting the right drug, to the right patient, at the right time (and in the right condition) has never been so important.

To achieve this we have to link the physical supply chain (the network of manufacturing facilities, buildings, warehouses, trucks, planes and people through which drugs are produced and distributed) with the digital supply chain (the series of systems that capture, store and disseminate data to power, monitor and track ordering, movement and administration of clinical supplies). This integration helps to optimise operations, protect patients, mitigate risk and control cost.

Before this supply chain utopia can be realised, the foundations need to be prepared based on a clinical trial's unique requirements. To set off on the right foot and design a fit for purpose clinical supply chain strategy, four critical points should be considered.

Gather the right data (at the right time)

There is no one size fits all clinical supply chain strategy. To be effective, they must be designed to accommodate a study's unique needs and limitations. This requires intense scrutiny of the study's core data, which should take place at the earliest opportunity.

Some information that can be used to shape an effective supply chain strategy can be sourced from the study's title, including blinding and randomisation status, overarching objective, therapeutic area and use of comparator products.

More in-depth data can be found in the clinical protocol's synopsis, study drug and study conduct sections, including stratification factors, study design and visit schedules. This data will inform decisions surrounding kit design, production schedules and distribution.

The clinical team represents another key knowledge base; providing valuable insight into the number of participating countries, anticipated start dates, when individual sites will come online, enrolment rate projections and patient assumptions.

Finally, liaising with pharmaceutical development and comparator procurement teams will provide detail on drug characteristics, manufacturing timing and stability and flag any potential constraints. Collaboration with these teams provides clear visibility over the bulk manufacturing and fill finish plan and the kind of stability programme available to establish shelf life. They will also confirm if expiry extensions are planned, the required storage conditions and whether stability memos and time out of temperature data is available.

Establish supply and demand

Once key data is understood, it's time to focus on a fundamental task in developing effective clinical supply chains: understanding requirements for material and production planning.

This means creating a drug demand forecast, based upon enrolment forecasts. To create reliable enrolment forecasts, it's best to begin at country level and determine when each country will begin participation in the study. Next, consider how many sites are in each country and when participation is anticipated.

Although factors like discontinuation may complicate matters, by filling in these blanks, the enrolment rate (number of patients per site, per month) can be predicted.

When combined with dosing schedules and the amount of drug needed per dose, this informs a reliable demand forecast, which is used to create a supply forecast, utilising the forecasting module within an MRP system.

This last step enables effective planning of procurement and production, based on the timeline from the supply forecast. At this point various supply strategies, from bulk manufacturing to Just in Time, can be selected to safeguard against the risk of stock outs, while mitigating waste.

Understand packaging and labelling requirements

Packaging and labelling of clinical supplies are vital components of achieving overall supply chain success.

By utilising the protocol to design an appropriate kit configuration, drug supply can be maximised and waste reduced. Likewise, designing suitable labels helps uphold compliance and ensure smooth custom clearances.

Before deciding on packaging design, it's crucial to consider the drug's form requirements, the volume needed, temperature constraints (including freeze/thaw cycles and handling) and light protection factors.

For clinical sites to correctly identify drug products, and to be compliant with each country's regulatory guidelines, the Master English Label Text for the carton and vial must be consistent with Annex 13 guidelines.

Once complete, label text will need to go through extensive regulatory review for each participating country to ensure regional compliance. Translation into the local language for any participating country should happen once the label text is regulatory approved.

Sponsors should then select a multi-language booklet or country-specific, single panel label, depending on the nature of the trial.

Fine tune distribution

Distribution is the final step on the critical path towards a fit for purpose clinical supply chain. An optimised distribution strategy is one that places enough IMP (and ancillaries of the correct type), at the correct site, in an acceptable condition and in time to meet patient need.

This ideal is harder to achieve against the context of globalised clinical trials involving next generation pharmaceuticals. However, it can be made easier by harnessing key study data to inform an appropriate distribution model.

For example, central distribution facilities can be utilised for easy-to-reach countries, whereas local depots will normally remove the risk of shipping to countries with lengthy custom clearance lead times or complex import requirements.

Technology also has a core role to play in fine tuning distribution strategy. IRT systems, particularly the design and set-up of the drug ordering modules, will have a significant impact on distribution efficiency and cost.

Matching initial stock levels at site, trigger levels and resupply quantities and timings with stop-assign, stop-inventory and stop-ship, within the IRT, is an important part of distribution best practice.

Yet, the key to success lies not only in the set-up of such systems but in the monitoring and ongoing adaptation of the strategy to meet evolving needs and manage risk until the trial's completion.

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