SPOTLIGHT

The Difference a Step Makes

Signant Health explains why a purpose-built clinical supply chain platform is a must-have for 2020 and beyond

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It's a relatively calm and quiet Friday afternoon, until you hear it, the chime of a new email coming through your speakers. "Urgent: Class II recall of Molecule RFGH79245 – Lot XFD157899," the subject line reads. Now, in just a moment's time, what was once a quiet office environment has turned into a cacophony of conversations regarding vendor processes, systems, who has the latest Excel tracker, and more.

Regrettably, this is the scene of several pharmaceutical companies, moments after receiving a lot recall notice for a clinical trial. In fact, many organisations in trials lag behind their commercial counterparts in terms of trial supply sophistication and visibility. While manual systems and processes can work, they often present serious hurdles for those looking to accurately forecast, predict, and solve clinical trial supply issues. As the introduction illustrates, manual processes can quickly become an administrative nightmare any time there's a serious bump in the road.

At Signant Health, we categorise organisations that utilise manual processes as being 'stage one' or 'stage two' within the supply chain maturity process. Stage one organisations feature a high level of dysfunction and lack of standards, processes, and procedures. In other words, these organisations are a bit chaotic. Stage two organisations function well, have base level operating procedures and systems in place to ensure success, and generally do well with tactical trackers, phone calls, and email. However, what many stage two organisations come to realise is that while their current processes allow the business to run without issues, they aren't running nearly as effectively as they could be. In fact, stage two organisations would frequently fail regular 'stress tests', such as 24-hour mock recalls.

Thus, many stage two organisations look for an enterprise solution that allows them to manage the entirety of their clinical trial supply process while providing greater insight and allowing better flexibility. These tools, known as clinical supply chain systems, present stage two organisations with two large advantages over manual processes:

- The ability to view and aggregate all of the clinical supply and demand in one system
- Simplifying the process to understand, predict, and adjust clinical supplies
- Maintaining a licence to operate
- Many stage two organisations are unable to trace a batch in its entirety through their supply network within the 24-hour regulatory timeframe
- Clinical supply chain system customers can typically do this recall within minutes and prevent a potentially catastrophic event

While both reasons are key, there are several other reasons for moving a stage two organisation to a clinical supply chain system (and thus becoming a 'stage three' organisation).


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First, organisations gain instant access to automated information, such as drug supply numbers that pass through the system to everyone impacted by the clinical trial supply chain, including sites and patients. Second, they gain a single system for communication, reporting, and metrics, allowing users to communicate with each other, and where necessary, quickly ascertain the situation regarding trial supplies. Third, they eliminate the inefficiencies inherent in manual processes. Finally, they provide organisations with the ability to quickly and efficiently react to emergency scenarios. While each of these benefits is great in their own right, they combine to allow greater control and insight over an organisation's clinical trial supply.

Clinical supply chain systems also enable organisations to look at the problem of clinical trial supply management as a whole. Currently, stage two organisations must balance multiple silos, such as the management of drug supply forecasting, logistics, quality, supplies, etc., independently of each other. While each of these silos may be functioning efficiently, stage two organisations often cannot see the bigger picture, understand the downstream impact of changes to silos, react to quick industry changes, or scale their policies up and down. They also cannot effectively communicate in a quick or efficient manner in instances where communication is key, such as recalls. With a clinical supply chain system, these issues are no more, as changes made in one area or silo automatically impact the information contained in other areas of the system.

Clinical supply chain systems also allow organisations to standardise their clinical operating procedures across the entirety of their organisation, as opposed to within their individual silos. This allows study managers, programme leads, and other key leaders across multiple areas in the organisation to review upcoming studies, contrast them against supplies, and escalate or apply a plan as necessary. Done regularly, this is one of the best ways to utilise a clinical supply chain system as it allows organisations to see upcoming fluctuations and changes in supplies, formulate a plan, and contact those affected if necessary.

So, as we move into a new decade, and trials continue to expand in complexity, those looking for peace of mind with their clinical trial supplies should consider a clinical supply chain system – because no one wants to spend their Friday afternoon pulling their hair out when they could be pulling a single report instead.