4G CLINICAL

Mitigating Supply Chain Risks

From Unpredictable Demand

Knowledge Sharing Series

Mitigating Supply Chain Risks from **Unpredictable Demand**

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Clinical trials have both predictable and unpredictable demand. Predictable demand accounts for known patients that are enrolled in the trial, have been assigned a Treatment Group, and have a defined visit schedule. Supply chain complexity is introduced primarily due to the unpredictable demand, which can stem from shifts in the expected enrollment rates as well as the ripple effect from protocol amendments throughout the study.

For example, patient enrollment can vary widely within regions, countries and sites due to competitive enrollment and other variables, such as discontinuation rate, titration probabilities, and patient physiology, all of which directly impact site demand and resupply strategies. Protocol amendments may add new treatment arms, extend the visit schedule, and/or add countries, all of which impact the supply chain.

This unpredictability introduces risk into the supply chain. It is critical for Clinical Supply Chain Managers to be aware of these risks and understand how best to mitigate them within their trials.

Below, we highlight key areas of risk and how technology can help supply managers.

Three key supply chain risks include:

1. Not maintaining sufficient supply

Arguably one of the biggest supply risks within a clinical trial is not having drug available when a patient is at the site. Beyond being an inconvenience, this can be detrimental to the patient's health and the overall trial. Many clinical supply managers apply a significant amount of overage to the supply to account for any unknowns and offset this risk. Though this effectively prevents stock-out, this can lead to excessive–and avoidable–waste and cost.

Many companies would agree that the cost of the loss of a patient in their study is incalculable. But, because of the cost of some medications, it's not always feasible to simply increase the amount of overage needed for the study. There are better options available to ensure sites have sufficient supply for their enrolled subjects and a

buffer stock for their unknown subjects, but not a significant amount of excess sitting at the sites that may never be used. Using a predictive resupply strategy allows a randomisation and trial supply platform (RTSM, also known as Interactive Response Technology or IRT) to "see" the subjects' future visits and determine what kits will be dispensed at those times.

A "Buffer-Only" or "Min/Max" resupply approach keeps in consideration any of the subject's visits, treatment group assignments, or other parameters that would impact the demand. It serves to ensure that site stock is above the minimum buffer value, and is filled to the maximum (Ceiling) value once a resupply shipment is triggered.

As mentioned, the cost of some medications can limit the amount of overage added to a packaging campaign. By using a clinical supply forecasting tool, it is possible to determine where, when, and how much supply is needed. By using the protocol details and other study assumptions, the Clinical Supply Manager can make a more accurate determination of how much overage is truly needed.

In addition to cost, the shelf life of the study medication can also impact how much drug may be wasted. Using the shelf life in the supply forecast can help to plan additional packaging campaigns and ensure that only the required amount of drug is being packaged for each campaign and will be used before it expires.

2. Lack of agility in supply planning and distribution

The idea behind an agile supply chain is the ability to move quickly and change direction on a dime. However, one of the risks in doing so from a regulatory and quality standpoint is not having the infrastructure in place to make that change, such as the ability to add a new country, so that it does not negatively impact enrollment. In short, agility and infrastructure must go hand-in-hand.

Additionally, if your supply chain is not able to adapt in response to unpredictable demand, it creates additional risk of overage, waste and stock-out. For example, the enrollment rate can vary significantly by site, and not all sites will enroll the same number of subjects. Not being able to accommodate these differences can lead to a site stockout in some cases, or in contrast, wasted supply.

Mitigating Supply Chain Risks from **Unpredictable Demand**

Utilising the Resupply functionality in the RTSM can allow the Clinical Supply Manager to group sites into enrollment categories – low, medium, and high, for example -- and set a resupply strategy that best fits with each group.

The Low enrolling sites can be set with low Initial Shipment values and buffer levels while the High enrolling sites can receive a higher quantity of Initial Supplies and keep higher buffer values to accommodate a larger patient population.

3. The "ripple effect" of protocol amendments

When cross-functional conversations around the impact of protocol amendments are not had early enough, there may be unintended consequences on the supply chain. As mentioned above, adding countries that have complicated import requirements or long shipping lead times can delay enrollment, adding to timelines and budget.

Additionally, introducing new dose levels, visits, and cohorts can all have a similar ripple effect on supply and should be discussed upfront. Since many Clinical Operations and Clinical Supply departments operate in silos, it is not uncommon for last-minute shifts to occur.

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Leveraging Advanced Planning and Technology to **Mitigate Supply Chain Risks**

To succeed, both sides need to align technology to bring clarity into supply planning.

As clinical supply complexity increases, there will always be risk. It is important, however, that clinical supply managers take proactive steps to mitigate these risks to prevent losing patients due to stock-out, while avoiding drug waste and unnecessary costs.

Some of this involves careful contingency planning such as building the infrastructure into a trial to support adding new countries from a regulatory, process and quality standpoint. Other strategies can be to encourage more frequent cross-functional collaborations between departments. However, one of the most powerful ways to mitigate unpredictable supply chain risk is through technology.

As mentioned earlier, clinical supply and operations departments often work in siloes. Planning tools can help promote dialogue between the two groups and ultimately achieve better results.

This means allowing clinical teams to easily determine how and when to launch sites, identifying the countries in which they're going to operate, and then making transparent decisions about supply needs through the software. transparent decisions about supply needs through the software.

Technology can enable clinical supply managers to accurately determine their resupply strategies, such as a Minimum Buffer (or Floor). This is one of the hardest variables to determine when it comes to unpredictable demand. Having a correct resupply floor value ensures you will have drug for an unpredicted patient's first dosing visit, but not at the expense of excessive product waste and cost.

Clinical supply forecasting tools also have the power to manage risk through more detailed scenario modeling. The ability to pressure test "what if?" scenarios can help inform everything from manufacturing capacity to enrollment projections. Today, supply managers can model as many scenarios as needed to visualise how different assumptions affect the clinical supply forecast.

These powerful visualisations can be used to facilitate cross-functional conversations between clinical supply, clinical

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operations, operations, and manufacturing to enable better decision-making.

These forecasting tools enable clinical supply managers to make informed supply decisions throughout the study lifecycle, from early-stage feasibility planning, all the way through to study completion. The systems can forecast the demand even when there are only limited details on the study and high-level assumptions are used – which then can be leveraged to forecast expected total demand, financial implications, and budgeting.

This technology can also be integrated with the RTSM to pull in real-time actuals. This allows study managers to compare study assumptions with the post go-live study data, helping them potentially uncover unexpected shifts in enrollment or other key variables.

The technology in an RTSM tells the Clinical Supply Manager where patients are enrolling and screening, allowing them to know in advance about where supplies are, and where they need to be. They are then able to initiate key conversations to determine if and how resupply and distribution strategies should be adjusted and whether additional production campaigns may be needed.

Conclusion

*There will always be **unpredictable demand** within a clinical trial and **mitigating risks** associated with it is a constant challenge.*

Supply chain agility in planning and execution are required to stay in step with clinical trial changes.

*To do so, leveraging **clinical supply forecasting** and **supply optimisation** software along with the RTSM can help surface potential risks and allow changes to be made to manage them.*

Meet **Laurel Ferenchick**

Laurel Ferenchick, is a Senior Forecasting Services Lead at 4G Clinical. She has 15 years of experience in Clinical Supply Management and Forecasting, holding various positions in Packaging & Distribution Management, RTSM Build & Maintenance, and Clinical Supply Forecasting.

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About 4G Clinical

We reduce the time it takes to commercialise vital medications by delivering validated, easily extendable RTSM capabilities to Pharma and CROs faster than anyone in the world.

4G Clinical is driven by a single purpose: bring crucial medicines to those who need them, faster. 4G Clinical believes that the way to accelerate clinical research is by disrupting the way trials are executed. That's why we have revolutionised RTSM (randomisation and trial supply management) and supply forecasting capabilities and services from the ground up.

4G Clinical is committed to helping sponsors and CROs follow the science, wherever it may lead, as quickly and as safely as we can. While we will not discover the next novel compound in the lab, we are doing our part by leveraging our extensive experience and technological innovations to bring speed and agility to clinical trials.

Prancer RTSM®

Our 100% configurable and agile RTSM is built for the clinical trials of today and tomorrow.

4G's RTSM platform, Prancer RTSM®, utilises natural language processing alongside integrated clinical supplies forecasting and management functionality to slash development timelines, increase operational efficiencies and offer exceptional quality.

Bringing crucial medicines to those who need them, ***faster.***

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