Developing Effective Supply Chain Strategies Utilising Forecasting Technology

Drug development has evolved considerably over recent decades, along with the clinical supply chains that underpin the continued advancement of human health.

In the 1980s, single-country clinical trials – where a single patient kit was provided to each study participant for the duration of their treatment period – was the standard. The introduction of Interactive Voice Response systems in the 90s ushered in a new era in patient randomisation and created more flexibility over supplies. This was followed by the increase of globalisation and emergence of biologics in the '00s, which gave rise to today's more complex clinical trials' landscape.

While this evolution has made the objective of providing the right drug to the right patient at the right time and temperature more challenging, forecasting technology is playing an increasingly important role in supporting sponsors to mitigate the additional complexity and risk and deliver future leaps forward in drug discovery.

Effective forecasting is the ability to align supply and demand for a trial or program of trials. Failure to meet this objective can quickly result in inefficient supply chain operations that heighten risk of stock outs, product waste, negative patient impact and, ultimately, compromise a study's commercial performance.

Leveraging supply forecasting and demand planning technology can support sponsors to develop optimised and effective supply chain strategies.

Understanding Supply

Harnessing forecasting technology to develop effective supply chain strategy requires a solid understanding of core supply-based factors, so that the supply chain can align with the clinical requirements, as defined in the protocol.

The first factor relates to patient need. This is dictated by the quantity of drug needed to support each patient anticipated to enrol in the study through their whole treatment period. The protocol synopsis provides crucial data to support effective forecasting of patient need, covering cohort, weight-based dosing criteria, visit schedules, and other study design factors.

Production strategy is the second port of call when establishing supply requirements. The timing of when drug is required informs production schedules, packaging design and expiry dating. Again, the protocol synopsis will inform production strategy and resupply events for expiry, along with providing visibility over bulk availability of products and lead times.

A final supply-based factor relates to distribution strategy and helps sponsors to understand the frequency of depot and site shipments, country-specific supply requirements and temperature management considerations.

Delivering Demand

Once supply requirements are understood, sponsors can focus on the demand factors. This begins with the clinical enrolment projections that allow sponsors to understand when patients are expected to enrol in a study. Understanding site activation and seeding events will also help align requirements within the forecast. For instance, establishing whether drug is needed on site prior to screening events or if supply should be conserved until the first patient visit. Another demand factor is patient dispensation events that will make up the visit schedule and dictate the timing of when drug is needed.

The depot and site inventory – resupply strategies and country-specific study approvals – also warrant scrutiny. Sponsors should work closely with IRT vendors to understand how the drug management section of the IRT has been developed, as this will play a key role in understanding the overall demand and associated implications. Order algorithms will inform look ahead windows for site shipments, how they will be raised and how the available inventory at site is considered against projected need for patients due for site visits.

Thoroughly understanding demand to effectively deliver it requires in-depth knowledge of expiry planning. The timing and quantity of new manufactured lots and expiry extensions will impact on timelines for sites to be reseeded. This is especially important as, in the early days of a study drug may only have six months shelf life so pre-seeded sites may be approaching expiry and need resupply. Exploring how to approach an expiry event – by pulling material into a traditional production run and relabelling it with an updated expiry date or harnessing Just in Time Manufacturing methods utilising an updated expiry date – will help develop the best course of action.

Treatment variations form the last piece of the demand puzzle. If dispensation and dose for patients remain unchanged through the total disease progression, then calculating overall patient demand is more straightforward. However, different titration, dose finding and studies with different cohorts or high dropout rates will require continuous examination to ensure demand is met and drugs are appropriately allocated.

Navigating the Ever-evolving Landscape

Evolution is a constant of drug development. When supply and demand factors are appropriately considered, forecasting solutions can be harnessed to build more robust and agile supply chain strategies that empower sponsors to better navigate and respond to change, while avoiding negative impact.

For instance, scenario planning tools empower sponsors to conduct 'what if' analysis that projects the impact to supply should a study experience accelerated or reduced enrolment or if there is an instance of bulk manufacturing failure. This insight helps to bridge the unknowns with calculated solutions; informing effective decision making and supporting sponsors to develop contingency plans that work to mitigate risk.

Likewise, forecasting technology also supports more effective program level planning, as the demand feeds into bulk forecasting

and highlights the impact of any additional scope of work on the overall drug supply. This means sponsors have visibility over how much additional product needs to be allocated to Phase IV, while Phase III is ongoing. The same is true for production planning and distribution strategy.

It is important to remember that leveraging supply and demand factors and harnessing forecasting technology will only create an effective supply strategy if good data is made a priority. This requires sponsors to ensure full and accurate data is used to create a supply forecast and places an onus on continuous evaluation throughout the life of study.

The Benefits of System Integration

As clinical trials become more complex – and IMP more expensive – the margin for error decreases, while the need to promote data integrity, reduce risk and streamline processes increases. Resultingly, system integration is quickly becoming a prerequisite for successful clinical supply management and forecasting technology has a critical role to play.

This is because dedicated clinical supply forecasting technology provides visibility of bulk product and finished goods and generates projections (or several for comparison) detailing material needs within specific periods of time based on factors, including enrolment rates, site and country ramp up, safety stock requirements, dropout rates, medication type and visit schedules. Another key benefit of forecasting technology is its ability to receive patient and drug order data, such as enrolment, discontinuation, and drug usage information, directly from an IRT so that forecasts can be automatically adjusted based on drug usage data and reports produced to compare what was initially forecast vs actual usage.

However, this optimised forecasting capability would not be possible without integration within the wider supply chain technology eco-system. Sponsors rely on multiple systems – from ERP and Temperature Management software to IRT and forecasting tools – to support different aspects of the supply chain. Considering the data housed in each of these systems is interconnected, creating a closed loop, comprehensive linkage is necessary to streamline efficiencies.

To develop effective supply chain strategies utilising forecasting technology integration between systems must be prioritised to enable data flows that promote automated and optimised processes, while lowering overall supply chain risk.

With integration, study 'actuals' can be incorporated into forecast management to drive continued supply chain accuracy as studies progress. For instance, inventory oversight, provided by an ERP, enables a proactive approach to drug supply management and fosters the ability to adjust production plans and distribution strategies for a study or program of work with precision and ease. The risks associated with a reliance on manually updating forecasting tools, such as Excel and manual patient dispensation trackers, with study 'actuals' is also removed when data flows seamlessly between core systems.

Other examples of how data flows between these core systems can optimise processes and lower risk can be found in the inventory release process, drug order process and patient and medication event data exchanges. When the inventory release process is aligned with QP processes, sponsors can be assured that drug released to the IRT is matched within the ERP system for allowable countries product can be shipped to. Similarly, when drug orders are raised in an IRT and sent to the distribution team, when picked and dispatched, this information is shared through to the IRT before the order is dispatched to site and order details (complete with temperature monitor information) shared to the Temperature Management System. Finally, when patient and/or medication events take place, IRT systems can automatically pass vital information to the forecasting software, which can in turn harness it to inform updated and relevant forecasting adjustments.

Drug supply forecasting encompasses many moving parts. The key to successful clinical supply forecasting – and the successful delivery of modern clinical trials – can be found in timely and accurate data that is achieved via system integration, dedicated resources to support the development of the clinical supply strategy, and continuous evaluation and oversight of that strategy. Expert application of forecasting systems, that are integrated effectively within the wider supply chain technology eco-system, are critical components in successfully bringing an investigational product to market in what is an increasingly complex and competitive drug development landscape.

Caitlyn Clauss

Caitlyn Clauss is Supply Chain Solutions Manager at Almac Clinical Services where she is responsible for enhancing and supporting the Almac Supply Chain Management consultation service. Her main responsibilities include ensuring cohesive delivery of new services and products, maintaining positive and collaborative partnerships among supply chain stakeholders, and leading improvement efforts to ensure optimal service quality and client experience. Caitlyn graduated from Bloomsburg University of Pennsylvania with a Bachelor of Science focused in Business Management and Supply Chain Operations.