KNOWLEDGE SHARING SERIES

4G CLINICAL

Clinical Supply Planning Optimization

Addressing Gaps in People, Process and Technology to Drive Supply Chain Efficiencies

Bringing crucial medicines to those who need them, faster.

4GClinical.com

About 4G Clinical

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 revolutionized RTSM (randomization 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.

About 4G's Clinical Supply Forecasting

4G's clinical supply forecasting solution enables you to make decisions based on business need rather than relying on complex calculations. As the world's first integrated RTSM and clinical supply forecasting solution, supply planners employ real-time visibility and leverage scenario planning to control supply decisions.

"Supply planners no longer have to build excel sheets or have the knowledge base to decode complex algorithms to inform supply decisions."

Purpose

This white paper provides a comprehensive overview of the current supply planning landscape, identifies gaps which are inhibiting supply professionals from optimizing their supply chain and delves into solutions for driving efficiencies from a people, process and technology perspective. This paper also serves to inform supply chain professionals how to make immediate improvements in their strategy as well as discuss the need for a holistic end-to-end approach to supply planning.

Supply Planning Landscape – Contextual Overview

Supply Chain Planning is the process of coordinating assets to optimize the delivery of goods, services and information from supplier to customer, balancing supply and demand. The integrated Supply Chain Planning model includes a hierarchy of planning cycles which aggregate up and down between operational, business and strategic planning. Each of these cycles have their own focus and purpose.

Operational Planning

During the operational planning cycle, decisions must be made on timing and quantity of sourced materials, manufacturing and shipping at all levels ranging from raw materials to drug substance, drug product as well as packaged and labeled finished product. These decisions are driven by demand forecast inputs and are primarily unit-focused. Available budgets are monitored closely to ensure financial compliance.

Business Supply Chain Planning

Business Supply Chain Planning is focused on mid-term (1-3 years before study start) financial opportunity planning and making trade-off decisions aligned with the company's strategic direction. Phase-in/out, market share development, new market penetration, product/service evolution are planned in the context of available resources. Demand aggregation is typically at the product group level and expressed in monetary and volume terms. Sales and Operations Planning (S&OP) is the central business process that connects Business Planning and Operational Planning. Leadership from sales, manufacturing, logistics and finance make decisions in support of the mid-term strategy.

Strategic Supply Chain Planning

Strategic Supply Chain Planning is focused on the company's long-term objectives related to product/service-mix, customers and markets. Decisions are to be made on major investments related to manufacturing or distribution resources for expansion of existing capabilities and future new capabilities. The focus is mostly on financials with high-level volume assumptions coming from the business planning cycle.

Commercial vs. Clinical Supply Planning

In a matured commercial environment, advanced automated planning solutions are implemented to assist in efficient planning in each cycle as well as aggregating between them. Scenario planning is generally conducted within each cycle of the planning hierarchy and the ability to aggregate up and down to the different levels is critical to the quality of the decision.

How Does This Translate to Clinical Supply Chain Planning?

The advanced automated planning solutions from the commercial environment are not transferable to clinical. The world of clinical trials is increasingly complex and with unpredictable enrollment and study design changes the same tools are unable to support both short and long-term planning with the same level of accuracy.

The tools that have been developed specifically for clinical supply planning do not aggregate between the levels of operational, business supply chain and strategic but rather enable supply planners to focus primarily on study-level planning.

Navigating the Complexity of Clinical Supply Planning

Early-Stage Planning (24-12 months to study start)

Best practice, in an early stage of protocol development, the supply chain function is consulted for assessments on supply capabilities. These are typically high-level feasibility and risk assessments and often requires multiple What-If scenarios. The clinical supply planner (CSP) seeks input from clinical operations to understand critical study assumptions such as number of patients, treatment schedule, number of sites, countries, enrollment plan, etc. Combined with product characteristics and supply network assumptions, the CSP builds a high-level model and calculates rough-cut product volumes overtime. As margin of error on the assumptions at this stage are generally high, an overage of 50% and often higher is added in the feedback to clinical operations and manufacturing.

Approaching Study Start-Up (<1 year prior to study start)

Getting closer to study start, the CSP needs to start planning comparator sourcing, Investigational Medicinal Product (IMP) manufacturing and distribution. A model needs to be built at the appropriate detailed level to assess supply needs overtime at site, depot network and manufacturing levels. At this stage, it is critical to agree on a detailed set of assumptions to build the demand forecasting model and a matching supply plan. The complexity of the study determines the complexity of the model including but not limited to the following variables:

Study Design Variables:

- Open label versus blinded?
- Dose finding cohort studies?
- Fixed dosing or weight-based/dimensional-based dosing?
- Result driven titration?
- Fixed number of cycles or till disease progression dosing?
- Drop-out rates?
- Comparator or concomitant supplies required?
- What countries, how many sites?
- Enrollment plan at study level versus at country/site level?

Supply Variables:

- What are network lead-times?
- Any batch size limitations, either minimum or maximum sizes?
- Is the product temperature, light or humidity sensitive or hazardous material?
- Are you facing short expiry dates?
- What are your storage capabilities in your distribution network and sites?
- Cost of IMP, cost of comparators, cost of supply chain network, cost of scrap?

The CSP is expected to define how much inventory needs to be held at site level, at depot network level and at central storage level taking all these variables into account. The added challenge is that demand is extremely unpredictable.

Role of the Clinical Supply Planner (CSP) in Inventory Planning

Given the complexity mentioned above, what are best practices to set inventory strategies? There are three typical categories seen: worst-case, realistic and conservative scenario planning. Most clinical operations professionals lean towards the conservative model to reduce risk of stock-out, while manufacturing would lean towards realistic to reduce waste. Already, the CSP is handling competing priorities.

Additionally, it is not uncommon for trial design changes to occur after the CSP creates the initial model, including switching to a head-to-head study, changing treatment arms, adding patients, countries, etc. These changes put pressure on the CSP to provide an updated supply plan. Best case scenario, the CSP modifies the model. However, many times a new model must be built wasting time and resources.

Once the study starts, here are questions CSPs should consider:

- How well is execution in line with the assumptions?
- Are the assumptions unchanged or is enrollment slower, titration rates significantly different or randomization at site or country level significantly skewed?
- How often do you update the clinical supply plan?
- How easy can you get actuals from your IRT system and how easy can you upload them to your clinical supply plan?

Answers to these questions should inform internal discussions regarding process and technology. If the answers to these questions are not as favorable as you hoped, it is likely due to gaps and limitations in current supply planning solutions.

Gaps in People, Process and Technology:

Study-Level vs. Aggregate Demand Planning

The CSP spends so much time at the study-level there is minimum to no time left to aggregate or consolidate demand over time. Aggregation to the compound level is critical to make the right decisions, especially in the case where multiple CSPs manage studies using the same drug product.

Supply Planning Tool Limitations

- Almost every study design is unique and therefore each study demand and supply model is unique. As a result, there is not a high level of reusability of work from study to study creating labor-intensive processes – especially with tools such as excel.
- Existing web-based tools are extremely complex and most CSPs have difficulty verifying the outcomes based on the inputs. CSPs find themselves having to simply trust the tool without visibility into why the calculations are what they are.

Disconnected Systems – No Closed-Loop Feedback in Planning Model

Actual data is required to check assumptions on the inputs to the clinical supply plan. IRT/RTSM and planning/manufacturing systems are often disconnected. The CSP needs to gather data from multiple source systems and reformat to combine in self-created tools to track actuals versus plan and decide on required plan updates.

Disconnected Planning Cycles

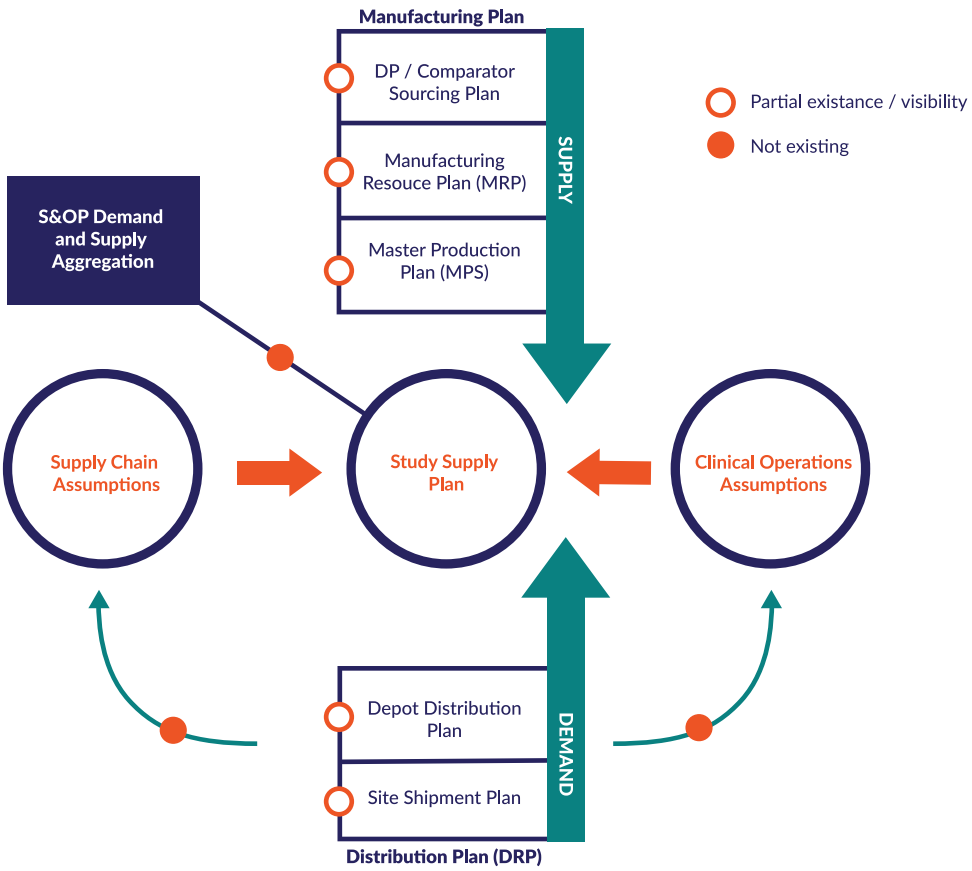
With focus primarily on demand, distribution and manufacturing planning at finished product (IMP) level, there is no visibility to full end-to-end supply chain impact of changes. As a result, drug product planning and drug substance planning are disconnected. With traditionally very long processing lead times, decisions can be made too late to initiate or postpone new drug substance or drug product campaign.

Missing S&OP Process

Complexity of internal organizational structure and responsibilities combined with the challenges to gather aggregated data complicates the organization of the clinical supplies S&OP process. As a result the Operations and Business Planning processes are best case partially connected but most often disconnected.

Human Error

Self-made models are often not validated. Any mistakes in formulas or incorrect linking of cells can cause an error in the output. Actuals from IRT and manufacturing systems are copied and pasted with a risk of error as well. Particularly when timing is critical and decisions need to be made fast, the potential of human error increases.



Change is Needed in Clinical Supply Planning – Addressing the Current Gaps

CSP Role

Clinical supply planners are typically not experts in statistical algorithms nor should they have to be. They shouldn't be forced to blindly accept forecasting plans from a tool they don't understand. There should be transparency into inputs and a direct correlation to its outputs. Actuals should be compared to forecast and used in future planning exercises. Simply put, CSPs should be able to modify the model as frequently as needed without effort. Decisions should be based on business need rather than relying on complex calculations.

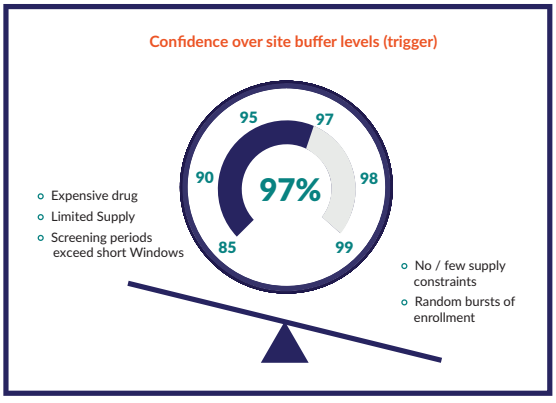
Supply Planning Tools

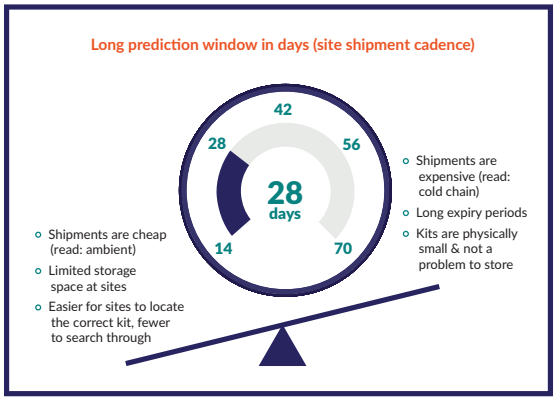
Clinical supply planning needs its own automated, end-to-end solution so CSPs can remove themselves from the siloes of study planning and view the portfolio in aggregate.

What Can Be Done Now?

In advance of such a tool, if CSPs were empowered with a good level of understanding what variables or information is critical to model supply planning (feasibility planning to study planning) they would be able to react and make decisions more efficiently.

Additionally, with the use of modern technologies and Natural Language Processing, it is now possible for those variables to be interpreted and configured into models. That way, the CSP no longer has to build excel sheets or have the knowledge base to decode complex algorithms to inform supply decisions.





"Decisions should be made on business need rather than relying on complex calculations."

Conclusion

Clinical supplies planning requires significant experience and effort, is at risk from both human error and a lack of understanding of complicated planning tools. Due to disconnected systems and planning cycles there lacks end-to-end visibility to the entire supply chain.

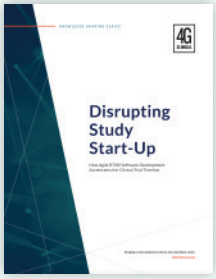
Technology should eliminate many of these challenges and enable the CSP to build an initial supply plan, ensure efficient supply management and enable sound business decisions. Modern supply forecasting technology allows the CSP to:

- Efficiently manage their work through an intuitive, simple user interface
- Compare what-if scenarios
- Modify study design changes
- View actuals versus plan
- Frequently update the plan
- Provide aggregated views at compound and manufacturing/distribution levels

With modern technologies such as Natural Language Programming (NLP), well chosen statistical methods, powerful reporting analytics and easy configurable integrations, this capability is on the horizon.

In the meantime, CSPs should base their study-level resupply decisions on tools that enable real-time visibility, scenario planning and control over supply decisions rather than blindly accepting outputs from complex tools they don't understand. For a more holistic end-to-end view, companies should continue to be conservative to prevent missed dosing/high level of waste until a modern technology designed to handle the complexity of clinical trials with the same level of automation as the commercial world is launched.

Featured Resources



Disrupting Study Start-Up
How Agile RTSM Software Development Accelerates the Clinical Trial Timeline

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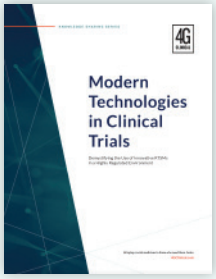

Modern Technologies
Demystifying the use of Innovative RTSMs in a Highly-Regulated Environment

DOWNLOAD

About the Author

Jan Pieter (JP) Kappelle, 4G Clinical Vice President of Strategy, is a Supply Chain Executive with 30 years of industry experience, of which 15 years were spent leading clinical trial supplies departments in global pharmaceutical and biotech companies. Trained as an Electronic and Quality Engineer, JP has a strong financial background and brings a methodical, analytical and process-oriented approach to his work. Coupled with his MBA and MSc in Supply Chain Management, JP has the unique ability to switch between strategic and operational discussions.

An energetic team player and trusted business partner, JP focuses on driving strategy and delivering results. JP also serves as the Global Clinical Supplies Group (GCSG) European Membership Officer and Master of Ceremony where he connects clinical supply professionals for the purposes of education, knowledge sharing and the development of industry best practices.

Download our White Paper: Disrupting Study Start-Up

Still have questions? Contact us today to start a conversation.

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