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The Ultimate Guide to Scenario Planning Clinical Supply Decisions

Bringing crucial medicines to those who need them, faster.

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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.

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

About 4G's RTSM

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

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

Purpose

Many facets of a clinical trial are unpredictable. Patient enrollment can vary widely within regions, countries and sites due to competitive enrollment and other variables such as discontinuation rate, titration probabilities, weight or Body Surface Area (BSA) of patients which directly impacts dispensing. It is also not uncommon for protocol amendments to add new treatment arms, countries, or introduce changes to the depot/supply network.

This unpredictability increases the complexity of clinical supply planning.

Think about all the key assumptions that are made at the onset of a clinical trial surrounding packaging design, sourcing/manufacturing and distribution. What if those assumptions shift? Do you know with a certain level of confidence how changes in those assumptions impact the clinical supply strategy? Would you be able to show your operations or financial counterparts the impact of those decisions in a timely and efficient manner?

This is why scenario planning is so valuable, and critical to help manage the variability in clinical trial supply decisions. Scenario planning puts the power back into your hands to explore possible outcomes based on specific combinations of events. Simply put, it enables you to find the best strategy while balancing risks and costs as well as gives you the ability to arm your internal stakeholders with impact assessment data based on plausible scenarios.

However, the value of scenario planning is not just comparing two detailed data sets. To be meaningful for the decision maker, scenario planning must enable a high-level impact assessment of the key parameters of the trial, and even to the compound and network level.

By following the guide below, you will have the in-depth information needed to inform your clinical demand and supply planning (D&SP) strategy.

Key Facets of a Clinical Trial to Apply Scenario Planning

Packaging Design Strategy

What is the optimal packaging design? Should you use single-unit or multiple-unit packs in case of repetitive or weight-based or response-based dosing titrations?Package design has a direct impact on shipping costs, expiry management as well as storage on the site.

Sourcing/Manufacturing Strategy

What alternative manufacturing plans do you have in case of alternate enrollment and distribution strategies? Are you at risk of waste due to expiry from slow enrollment? Another consideration is in-sourcing vs. outsourcing, where each approach has variability in lead times, flexibility in schedule changes, etc.

Distribution Strategy

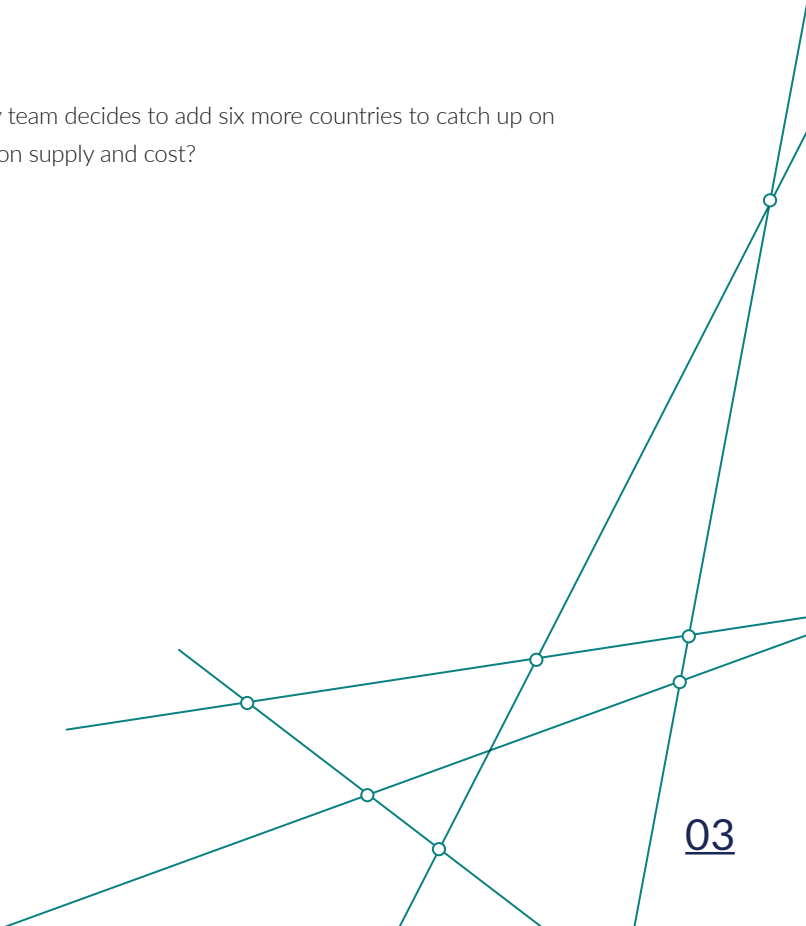
What is the optimal distribution network? Do I need a global depot or can I work with regional depots only? What countries do I need local depots due to import complexity or local comparators? Other key questions to consider include impact to changes in shipping frequency? Or should I apply different strategies to expensive drug product, scare drug product, etc.? What happens if I simplify my depot network after enrollment is completed and demand is more predictable?

Crisis Management

Crisis management should not be overlooked. However unlikely the scenario, there needs to be contingency plans in place. Using scenario modeling is a useful tool to prepare for the worst. Examples can include losing a manufacturing batch due to quality. What is the impact on the current supply strategy? Should the depot/site supply strategy be adjusted to offset the limited supplies until a new batch arrives?What are the risks?

Protocol Changes or Uncertainties

What happens when your clinical study team decides to add six more countries to catch up on enrollment delays? What is the impact on supply and cost?



Now that we've focused on the five major areas to apply scenario planning, let's shift the focus to the value of having this data in real-time. Here are the top 3 benefits of leveraging scenario modeling to inform clinical supply decisions.

Benefits of Real-Time Clinical Supply Scenario Planning

Balance Risk and Cost

At the onset of this guide, we touched upon the purpose of scenario planning to choose the best strategy for the organization based on the information available to you today. Not all risks or costs are visible unless you can model various scenarios that each manipulate different variables. The ability to model many scenarios with speed and accuracy can give decision-makers the tools to move down the best path.

Increase Collaboration Between Supply and Operations

Clinical supply and operations departments in many cases have competing priorities. Scenario modeling can help drive a dialogue between the two groups and ultimately end up with a better result. Ideally, 1-1.5 years prior to study start, there is a conversation discussing the protocol. Having that information, the supply manager than can suggest changes (such as in dispensing plan) based on the key facets discussed within this guide that can reduce cost or increase efficiencies in the study.

Meaningful Data for Better Trial Decisions

Scenario planning is not as valuable if it takes weeks to build models. Changes to trials occur rapidly, and the ability to shorten that cycle to one working day (vs. 2+weeks) allows for faster, meaningful data to review with stakeholders to ultimately make better decision makers.

Conclusion

The technology now exists to enable real-time scenario planning. With the use of Natural Language Processing (NLP), supply managers have the power to model as many scenarios as needed to enable better decision-making, all within a single working day.

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:
Clinical Supply Planning Optimization

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

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