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Water Cooler Chat

Clinical Supply Distribution Strategy – Planning & Adapting

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PCI Clinical Trial Services hosts a weekly virtual ***Water Cooler Chat*** series, where our subject matter experts host informal discussions around a number of clinical supply hot topics.

Clinical Supply Distribution Strategy – Planning & Adapting

Neil Fox, PCI's Clinical Supply Manager, recently discussed how to effectively plan your distribution strategy and the importance of early planning. In this article, he covers how to ensure your distribution plan is robust and the information needed to plan your distribution strategy, how to best determine your depot requirements, how to efficiently adapt to study changes, as well as how COVID may impact your distribution planning.

What is the goal of a good distribution strategy?

Correct Kit, Correct Location, Correct Condition - to ensure that when a subject requires a kit it is there, ready to be dispensed. From an overall study objective we want to avoid enrolment constraints due to supply availability. To achieve these, we must establish compliance with GMP, GDP and GCP and be mindful of all these aspects in early planning. We then must manage and control risks and budget alongside this.

What is the most important aspect in ensuring a robust distribution plan?

Alignment and understanding between your clinical operations and clinical supply chain teams is vital. Agreeing and understanding the limitations of your available supply; country, site and subject supply lead times as well as your overall supply strategy can make or break even the best planned studies.

Your clinical colleagues under recruiting in one country and enrolling those subjects elsewhere is expected, but when

TIP

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considering limited supply and a global study, the timing of this can be critical in ensuring continuity of supply. Your distribution capability and flexibility will determine whether it can be achieved and how much you can support a multi-faceted and changing enrolment environment.

What are the main drivers when considering distribution strategy at a high level?

While international harmonisation and improving processes continue to simplify planning to a degree (labelling and import requirements consistent across Europe for example), a large number of country specific regulatory and customs challenges still remain. Understanding drug sourcing and labelling, regulatory as well as import requirements early will help you to understand quickly which options are feasible when determining depot needs and deciding on depot locations. For some countries there won't be a choice due to cultural or business expectations, e.g. Japan.

At what point should you be gathering information to help define your distribution plan?

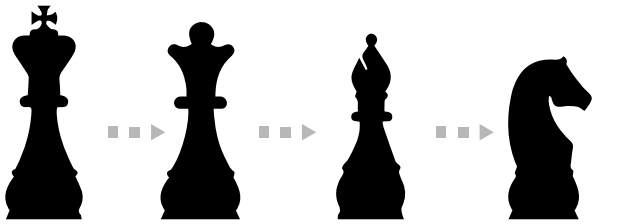
If you have a draft protocol you can start asking questions to drive better planning and changes to the protocol that may greatly affect all of your downstream activities. Kit design, visit windows and dispensing quantities will all affect both your supply flexibility and distribution budget. What will really allow you to determine your depot requirements will be the information gathered during site feasibility.

What information, in addition to the protocol, would you require to generate a distribution budget or spend forecast?

For a basic budget; enrolment projections, site feasibility info/start up timelines and quantity of available drug should allow the clinical supply manager to generate a high level budget forecast and plan. Understanding courier routes, transit times and having agreed depot locations and shipping plans would allow this to be much more accurate.

What aspects do you think are most often overlooked when planning distribution strategy?

Typically, clients tend to consider each aspect of clinical trials in siloes. Where functional areas are planned and decisions made in a linear fashion aligned to the overall typical project plan of a clinical supply study.



In reality these tasks are inherently interdependent and touch on many functional areas at each step and times in-between. Clients should begin with the end in mind and consider their IRT vendor, build and functionality when agreeing a kit design. Likewise, kit design, depot proficiency, country selection and enrolment capability are all factors in trial feasibility assessments at both country and site level.

What factors are good to consider as a starting point when determining depot requirements?

		Direct to Site (Central Depot)	Local or Regional Depot
No of subjects per country	High		✓
Available Drug	Low	✓	
Shipping Timelines	Long		✓
Regulatory & Customs	High Costs, Long lead time, Import License Restrictions		✓

In assessing whether a depot is required or not there are some factors which, solely or in combination with one or 2 others, will make that decision for you. Some of these potential decision making factors are outlined above. Additionally cultural expectations and geographical challenges can also enforce the need for an in country depot. The best approach is to gather as much information as possible and assess the benefits from both a flexibility and budgetary perspective.

What is the key to adapting quickly to a change in your study?

Understanding how your projected patient activity, shipping frequency and depot lead times affect supply availability is critical. The best way to assess this is to consider these subjects alongside your IRT parameters. Ask the questions; how long can I continue to supply my sites? What is the projected stock out date at the depot? What is the lead time to resupply the depot? Then consider protocol specifics; screening windows, visit windows and dispensing quantity and adjust your IRT settings to centralise supply. This will give you flexibility to engage your CMO and distribution partners to resupply your depots based on the answers to the questions above.

How has COVID-19 impacted distribution planning?

The challenges seen pre-covid in maintaining standard shipping lead times have been further exacerbated by the impact COVID-19 has had on global travel and logistics. In reality, the majority of couriers operate using hybrid models, using their own aircraft and routes alongside both commercial and passenger airlines. With half of the worlds global fleet grounded during the pandemic, the capacity within the network to meet clinical shipping requests diminished. Now more than ever, assessing your outgoing supply chain is critical to ensure that your shipment size, temperature condition and need by date can be accommodated, given the new logistics reality. This may mean increasing depot resupply frequency or adjusting IRT parameters to ship earlier to meet expected patient need.

When planning your distribution strategy, it is important to start planning early and in conjunction with all aspects of your clinical trial to ensure harmonization. By understanding the country specific regulatory and customs challenges as well as the key factors to have in place, including critical alignment and understand between your internal teams, a clinical trial sponsor's distribution strategy can be more robust.

About Neil Fox, Clinical Supply Manager, PCI Pharma Services

Neil Fox has 9 years' experience in the pharmaceutical industry working in clinical diagnostics, veterinary pharmaceuticals and for the past 7 years, clinical trial supply. In his current role, Neil forms part of the PCI SMART team and responsible for supporting clients in the design, management and oversight of their clinical trial supply chain across a range of study phases and therapeutic areas.

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