The Pharmacy Adjudicated Clinical Study Supply Process Decreases Risk, Cuts the Cost and Improves the Efficiency when Providing Subjects Unblinded Clinical Study Supplies

Purpose: A survey documenting clinical study supply chain management for unblinded supplies was undertaken to determine areas where a pharmacy adjudicated clinical study supply process could improve efficiency and reduce cost. The results could then be used as a potential means to reduce risk, costs and time in appropriate clinical study supply settings.

Design/Methodology: A survey was sent to one hundred clinical study supply administrators to measure the potential efficiency of a pharmacy adjudicated clinical study supply process within the clinical study supply chain for unblinded supplies. The pharmacy adjudicated clinical study supply process is sponsor-funded and allows subjects to acquire their unblinded clinical study supplies through the pharmacy network. The survey response was analysed to determine a need and benefit for such a clinical study supply service.

Findings: Clinical study administrators were supportive of this alternative as a means of overcoming issues related to clinical study supply shortages, time consumption and costs (both time and monetary) associated with clinical study supply management of unblinded medications, supplies and devices.

Value: This paper provides details of a novel means for decreasing risks, manpower and costs in supply chain management of unblinded clinical study supplies. This paper lays the groundwork for a new step forward in supply chain management of clinical study supplies. Additionally, this paper highlights the degree of complexity in clinical study supply chain management and the need for a potential solution.

Supply chain efficiency in the conduct of clinical studies is a critical factor determining part of the overall cost. When appropriate, unblinded clinical study supply optimisation can save money, time and resources, and decrease risk, by preventing costly delays due to supply shortages. The pharmacy adjudicated clinical study supply process is a sponsor-funded programme that allows subjects to acquire their unblinded clinical study supplies through the pharmacy network. As in all arenas, optimisation is the ideal and is rarely achieved in practice or with great efficiency. Various tools have been developed, attempting to improve forecasts of medication requirements for clinical studies, though many rely on deterministic calculations (or an applied set of sequenced calculations).[1] However, significant improvement is achieved via Monte Carlo simulation techniques.[2] Nevertheless, even with a more sophisticated supply strategy obtained via simulation, this approach remains limited and certainly not free of potential error when fully employed in the conduct of clinical studies. In order to minimise these issues related to unexpected gaps in the supply chain, another layer of protection is necessary for clinical study supply administrators. In the context of unblinded clinical study supplies, the expansion of available resources towards the pharmacy network (via a "pharmacy adjudicated clinical study process") has helped provide more efficient clinical study supply management. The net benefit has been preventing and minimising costs related to problems and delays with the traditional bulk purchase supply model, preventing clinical study delays. Typical hassles associated with the traditional bulk purchase supply model that can cause study delays and excess expense include vendor identification and validation, price negotiation, production and delivery timelines, packaging, labelling, storing, inventory management, shipping, reconciliation, reclamation and destruction. The pharmacy adjudicated clinical study supply process allows subjects to obtain their unblinded clinical study supplies through the pharmacy network without any subject out-of-pocket costs. This may aid compliance with unblinded components within a clinical study.

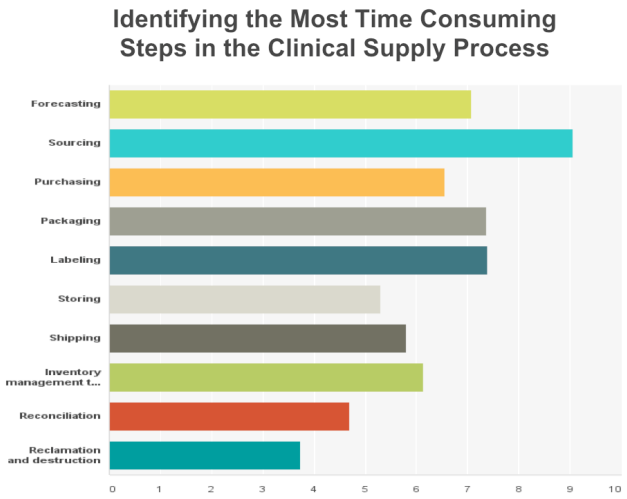
Given the high cost of research and development, supply chain-related expenses are one potential area of savings. In 2010, R&D expenditures amounted to roughly $67.4 billion. These issues are compounded when also dealing with the realities of limited product shelf life and uncertain supply demand throughout the study, further resulting in the destruction of unused clinical study supplies.[3] Deploying the use of a pharmacy adjudicated clinical study supply process reduces the overall burden on supply chain administrators to ensure that unblinded medication and supplies are readily available for study participants. This has the added benefit of reallocating human resources to where they are best suited and eliminated when they are deemed redundant.[4] Although best practices for supply chain management in other industries do not always translate well in the setting of clinical trials (and healthcare in general), there are many avenues of greater efficiency that warrant consideration.[5] It is that search for efficiency that gives birth to the possibility of employing a pharmacy adjudicated clinical study supply process for unblinded clinical study supplies.

Methodology

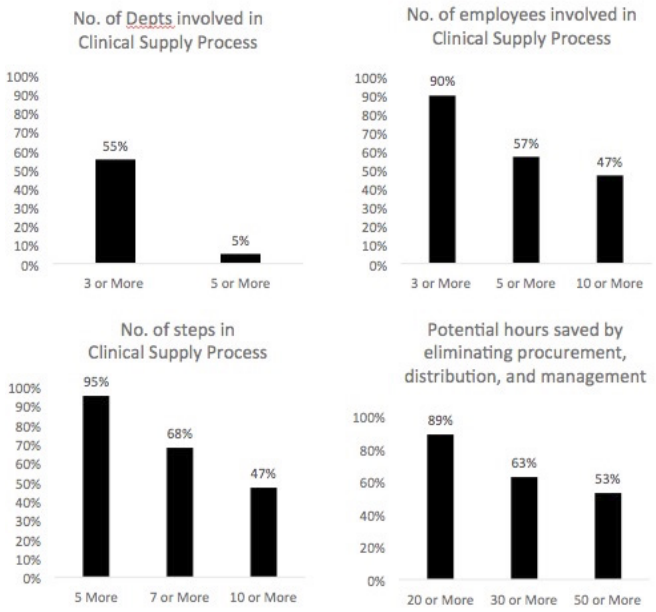
A survey to measure the efficiency of a pharmacy adjudicated clinical study supply process within the clinical study supply chain for unblinded supplies with clinical study supply administrators. There were one hundred surveys distributed and thirty-seven total respondents. These one hundred supply chain administrators were selected sequentially from a proprietary database. The survey was completed by administrators who have a working knowledge of the clinical study supply sourcing and procurement process for unblinded clinical study supplies (i.e.- comparator medication, rescue medication, co-medication and ancillary supplies). The majority of respondents were employed by either pharmaceutical manufacturers or contract research organisations (CROs). The response rate (thirty-seven per cent), was well within the typical rate of response for surveys collected from individuals (median of 52.7 with a standard deviation of 20.4) and just above the average response rate from institutions (median of 35.7 with a standard deviation of 18.8).[6]

Survey Response

Surveying clinical study supply administrators revealed that almost fifty per cent of the companies had ten or more of their staff, in multiple departments, involved with sourcing, procuring, packaging, labelling, storing, managing inventory, shipping, reconciling, reclaiming and destroying unused clinical study

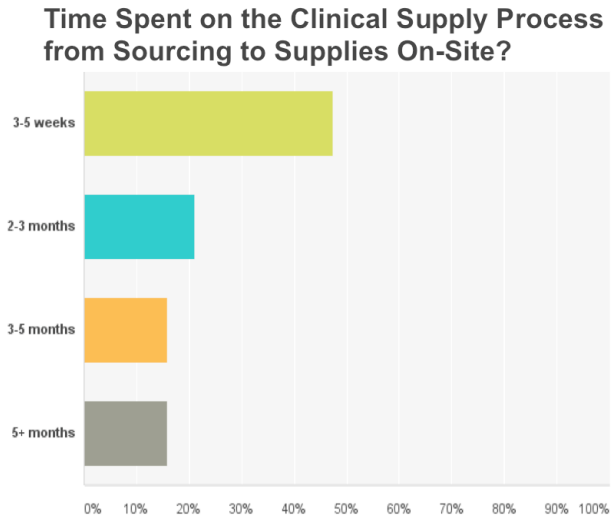


supplies. This effort combines to make more than seven different steps (often more than ten) in the entire clinical study supply process. Overall, clinical study supply administrators estimated that a significant number of hours could be saved over the life of a study if unblinded clinical study supplies did not have to be procured, distributed and managed by internal staff. Forecasting, sourcing, labelling, shipping and reclamation/destruction were typically identified as the most inefficient steps in the clinical study supply process, respectively. Supply sourcing was most commonly defined as the most frustrating step in the process, followed by forecasting, purchasing and shipping. It is in this mix of inefficiency and the distinct possibility that one of these vendors will fail at their task that the risk of costly study delays emerges. Decreasing this risk of a study delay is a major benefit of the pharmacy adjudicated clinical study supply process.



There are several identified factors that contributed most to the manpower and time spent on handling clinical study supplies. According to clinical study supply administrators, the most time-consuming activities were sourcing, labelling, packaging, forecasting and purchasing. Sourcing unblinded supplies via a pharmacy adjudicated clinical study supply process opens up internal resources to be deployed on other issues. In clinical study supply stock-out situations, staff were typically forced to seek replenishment from another supplier, while a minority directed subjects to a local pharmacy. However, over fifteen per cent of respondents indicated this usually triggered a delay in the study, clearly impacting the overall cost profile of the study. An added layer of frustration is often seen when dealing with comparator sourcing, particularly when the comparator is a key source of revenue for the manufacturer. The variability of comparator supplies also has the ability to trigger study delays, posing an additional layer of complexity when attempting to forecast their cost (as demand signals from sourcing managers have the potential to increase prices).

Time spent managing clinical study supplies becomes an even larger issue when considering the sequencing of activities. With nearly half of all survey respondents identifying ten or more steps, a delay of any length could have significant consequences for the clinical study. This contributes greatly to how long the entire clinical study supply process can take, particularly when accounting for the potential need to reorder supplies. Overall, the entire ordering process can typically take three to five weeks, though a larger majority of respondents identified time consumed by supply chain-related activities taking anywhere from two to five (or more) months. Another factor that could contribute greatly to time spent managing clinical study supplies are delays in supply production delivery dates (raw material shortages, increased trade demand and many other possible reasons). Taking this into consideration, a majority of survey respondents indicated expected delays of at least one month before a new production run could be utilised.



Discussion

This survey highlights a new step forward in the strategic management of clinical study supplies. Improving the efficiency of unblinded clinical study supply management enables clinical study supply administrators to use those resources elsewhere, fostering better outcomes with respect to supply management in general. The cost savings achieved by sourcing unblinded clinical study supplies through the pharmacy network has the ability to reduce the overall cost profile of a given study. The potential time-saving benefit of utilising a pharmacy adjudicated clinical study supply process would be substantial. The pharmacy adjudicated clinical study supply process may obviate any discount from bulk purchasing, however this is offset by the cost of labelling, packing, transportation, manpower usage, etc. A pharmacy adjudicated clinical study supply process is an added layer of protection aimed at minimising the risk/consequences of running out of medication, shifting away from perfecting an imperfect practice and focusing on a fail-safe solution that would not occur with a more transactional

approach to this supply management.[7] The pharmacy adjudicated clinical study supply process has the additional benefit of having a registered pharmacist reviewing the patient's prescription record for potential drug-to-drug interactions.

Conclusion

This survey of clinical study supply chain managers has shown the potential benefit of a pharmacy adjudicated clinical study supply process that allows subjects to obtain unblinded clinical study supplies through the pharmacy network without costs to themselves. These potential benefits include decreased risk, cost prevention of some unexpected delays, less manpower expenditures and added safety. While this will not affect all clinical studies (since many studies do not have an unblinded component) the pharmacy adjudicated clinical study supply process may be a significant factor in those appropriate studies to optimise the supply chain management and therefore reduce costs and risks.

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