



midwinter
Your Clinical Supply Solutions



▶ White Paper

Balancing Comparator Spend and Supply Risk in Global Clinical Trials



► Contents

Introduction	03
Where low-cost comparator strategies can create hidden exposure	04-05
What does good comparator value really look like?	06
Reducing comparator risk	07
Key questions for smarter comparator decisions	08
Summary	09



Comparator spending has always come under scrutiny for companies running clinical trials, and rightfully so, as it often represents a very significant portion of a budget. If you are operating in oncology, rare diseases, or autoimmune diseases (amongst others) then you are likely no stranger to biologic therapies that run into hundreds of thousands of dollars per patient, per year.

Multiply that by even a moderately sized modern Phase II trial design and cost quickly becomes a significant factor. An indicative Phase III budget can cause even the hardest Financial Controller to break out in a cold sweat.

Price sensitivity is always necessary, but unit cost alone seldom captures the true impact of a comparator strategy, and whilst the stars do occasionally align and the cheapest comparator can be the best choice, we still need to ensure we are making the right decisions for the right reasons. The objective of this white paper is to discuss, and highlight, where the opportunities lie for reducing comparator cost... but not at all costs.



Where low-cost comparator strategies can create hidden exposure

The temptation is always very real. Both drugs are commercially licensed and in stock, and they fit the profile of what you need, but one is significantly cheaper.

“Well... that’s all I need to know then, I’ll take the cheap one please!”

Risk is not always directly related to cost, but when we see a lower cost alternative, we need to understand ‘why’, so that we can properly assess risk. If we compare exactly the same products, i.e. the same manufacturer, same brand, same pack size and strength, same origin, and the only difference is the cost, then there is a good chance you are making an astute and financially savvy purchase. The risk exists when we find an alternate product more attractive, based solely on price.

Apparent savings can be offset by clearly visible factors such as shorter shelf life and longer lead time, but the more impactful factors can be hidden just out of sight; the track record, service levels and reputation of the manufacturer, and the product’s history with disruption or shortages, are key considerations to a successful long term comparator strategy.



The origin of the pack is also worthy of consideration. For example, whilst low-cost markets (certain parts of Europe and APAC) do exist, those advantages can be offset by lower product availability due to a smaller patient population when compared to larger and more established pharmaceutical markets.

The length of a manufacturer's supply chain, whilst not a deciding factor on its own, can add weight to a decision-making process. If generic 'A' is manufactured under a third-party agreement and done so in a country that would necessitate a long transit before the drug can be released, it may represent more risk than generic 'B' which is manufactured, packaged and released wholly under the license holders' own, in house, operations.

The risk is often not the product itself, but the fragility of the route which is used to manufacture and distribute it.

What does good comparator value really look like?



Good value in a clinical supply chain could be defined as 'price + continuity + operational fit'.

Whilst flirting with oversimplification with that equation, what would be true with any equation is that price is only one part of it, and we must strive to maximize all elements. A strong comparator choice is one which gives us confidence that changes shouldn't be needed as the study progresses.

We have touched on this in previous White Papers which address trial complexity, comparator selection, and protocol design; the true cost (and headache) of a poor strategy is when Clinical Supply professionals have to go back to the drawing board halfway through a study.

The costs attributed to these changes are not clearly listed on a quote so that can be overlooked by the holders of the purse strings, but they exist in the form of waste, protocol amendments, re-filing, new label designs, and re-supply pressures. All of this results in precious working hours being lost in processes and paperwork, and a long-term loss of value.

Achieving a comparator strategy that gives you the best chance of not adjusting your approach mid-study, of not risking stock levels depleting and creating patient risk, and of not encountering regulatory push back when trial data is being reviewed, should all be factored in when considering if 'value' has been demonstrated.



Reducing comparator risk

Society has done a comprehensive job of creating countless proverbs, sayings and maxims that underscore the wisdom of valuing quality over price. The short but sweet **“You get what you pay for”**, the slightly more rounded **“Good tools aren’t cheap, and cheap tools aren’t good”**, and the downright elegant **“Quality is remembered long after price is forgotten”**.

As enjoyable as they are, the cynical among us will still group them with the spiel of an accomplished salesperson. The one that I think fits most nicely in our world of Clinical Supply Chains doesn’t treat price as the focal point... **“Measure twice, cut once”**. The emphasis moves away from treating price as the primary factor, and helps us focus on thorough planning, long term efficiency, waste reduction, and thoughtful decision making. This is true whether we are supplying a global clinical trial or attempting some home DIY.

There are opportunities to reduce risk throughout clinical supply chains, and these can be identified and interrogated independently of cost. It is then prudent to overlay the cost with your risk profile, so a well-informed decision can be made.

The key factors in reducing risk are extensive, but as a starting point attention should always be given to the track record and reputation of a manufacturer, data relating to sales and shortages and the length and complexity of the supply chain. What must also not be overlooked is the service level, communication, and reputation of your direct vendor, as they play an integral role in not only the strategy, but also the physical delivery.

In essence, your vendor needs to be measuring twice, so that you as the sponsor at least have the opportunity to only cut once.



Key questions for smarter comparator decisions

Not all of planning can be done in house, and much of the insight necessary to make informed decisions needs to come from your vendor. These are the people that are plugged in to commercial pharmaceutical supply chains on a daily basis.

Here is a selection of questions that can be posed to your comparator vendor, to help you form a picture of 'cost vs. value'.

- What is the track record of this manufacturer/product?
- Can you give me any insight into the capability of this supply chain? Is our demand level impactful, or are we comfortably within the likely limits?
- What is the difference in cost between Plan A and Plan B (this is most important when working with generics and pricing fluctuates greatly)?
- Is this approach a well-trodden path, and what type of regulatory evidence might I need to support this comparator?

It is good to take this one step further, by engaging with your CDMO and CRO, to understand the likely downstream cost in the event of comparator delays, changes, or waste.

- Understand the cost of delaying or cancelling packaging slots in the event of late deliveries
- Question if there is greater Regulatory involvement needed such as more document reviews or further product releases
- Consider scenarios that involve new label and packaging designs, should a comparator strategy need to be changed



► **Summary**

Even in clinical roles, we live in a commercial world and the organizations we work for have the responsibility to be cost conscious across all operations. This, however, needs to be balanced between true long-term value and simple unit prices. The best decisions any of us can make need to consider risk, continuity, and operational realism, as a well-judged comparator strategy doesn't just protect the comparator budget, it protects the entire study budget from downstream risk.

Those responsible for comparator purchases often bear the weight of managing very significant dollar values, where both risk and opportunity are magnified. Ensuring that unit price is treated as only part of the equation enables us to focus on the bigger picture and make the most informed decisions we can.

Please feel free to reach out to me at ben.everington@midwinter-solutions.com with any questions, or to further the discussion.

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