ALMAC

Partnering to Advance Human Health

Guide

How to develop comparator sourcing best practice for your clinical trial

As drug development becomes increasingly competitive, many sponsors are turning to comparative trials to demonstrate a study drug's enhanced efficacy and tolerability over the best performing, commercially available alternative.

Yet the potential on offer can quickly be lost if comparator sourcing is not given the care, attention and expertise it warrants.

With recently published data revealing that 60% of sponsors surveyed identified comparator sourcing as a key stumbling block for losing time and money in clinical trial supply, and with the number of clinical trials comparing two active drugs rising[i], there's never been a better time to get to grips with how to design a best practice approach to managing supply for comparative trials.

Here are a few tips to get started.

Plan upfront

Start the comparator sourcing conversation at the earliest possible opportunity and factor in requirements during the trial's planning phase. This should include the sourcing of co-medication and ancillary supplies, like infusion kits, needles, tubing, oral dispensers, sharps provisions, syringes and adaptors.

Treating comparators, co-medication and ancillaries as an afterthought or attempting to organise mid-way through an otherwise established supply chain may limit options and risk both delay and heightened costs.

Consider all options

It may seem logical to source comparators from a country where a study is taking place (referred to as a local sourcing strategy) but it isn't necessarily the right or most cost-effective option.

Comparators can often be found at a lower price point by looking further afield and adopting a central sourcing strategy. This involves the procurement, packaging and labelling of comparators in one single country for distribution to/use within all countries participating in a clinical trial. However, it's worth bearing in mind this approach may require additional compliance-based paperwork or confirmatory testing to ensure drugs meet the trial's protocol requirements.

A hybrid approach can deliver the best of both worlds but will need to be managed with precision and expertise.

Expect the unexpected

For a variety of external reasons, from general shortages to mid-study export bans, the goal posts move and sponsors must adapt quickly or risk bringing supply chains to a grinding halt.

Moving goal posts or delays during a study can risk budget for a sponsor, especially when it comes to expiry dates of comparators.

If sourcing when supply is low, it can take some time for the drug to become available. It's also vital to ensure expiry dates of available drugs are sufficient to accommodate the planned packaging campaigns.

Avoid the risk hot spots

There are several aspects of comparator sourcing where the additional complexity associated with assuring supply to patients can introduce increased risk.

Examples include the need to secure an appropriate placebo, encompassing identical components, to 'match' the comparator drug and blinding comparators to create an identical appearance, without impacting weight or dissolution rate.

Regularly auditing sources and conducting testing to demonstrate traceability and prevent counterfeit products entering the supply chain is another essential task required to reduce the risk burden, as is access to bulletproof country-specific regulation and import/export information and the ability to effectively forecast demand vs. availability.

Keep an eye on costs

The cost of delaying the launch of a product by just one day is estimated to be approximately $8 million in lost sales.

It's therefore important that sponsors have access to reliable lead time estimations for larger volumes, informed by market intelligence, that enable them to select effective sourcing strategies that keep study timelines on track.

Utilising generics is another way sponsors can minimise costs in what can be an expensive exercise. However, this should be approached with caution and considered against the bigger picture to avoid realising a false economy.

Select the right partner & approach

There are several options available to sponsors looking to undertake comparator sourcing activity. Occasionally it's possible to source direct from a manufacturer. Wholesalers and specialist sourcing companies are also possible avenues.

Each option brings its own pros and cons, but the safest bet is to partner with an established clinical supply chain management vendor, like Almac.

With decades of experience, Almac can not only identify suitable comparator medication, along with the optimal source to procure them, but provide expert guidance relating to available options, market limitations and lead times.

Almac can also leverage relationships with manufacturers, suppliers and wholesalers to define and deliver a best-fit sourcing strategy that assures supply to patients, while minimising the risk of delays, shortages, product waste and spiralling costs.

To find out more about developing a best practice sourcing strategy for your comparative trial, visit www.almacgroup.com.

References

[i] www.pharmalogisticsiq.com/logistics/news/sharper-comparator-collaboration-needed

[ii] Lionbridge LIFE SCIENCES; Bairu et al 2014; Metadata Solutions 2013

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