Q&A: Global sourcing for optimized cost and supply in clinical trials

Based on our experience of implementing comparator sourcing strategy to meet studies' increasing complexity, Oximio held a webinar to explore this topic further and provide actionable insight for our participants.

Below is a short summary of the questions asked by our audience, and Oximio's answers. You can also access the webinar on demand to listen to the session in full.

Q: Which parties need to be included in technical agreements with suppliers to ensure regulations are met for use of the product within clinical trials. Is there a role for the sponsor?
A: The Technical Quality Agreement (TQA) is usually signed by the Supplier of the Commercial product and company with a wholesale license ability (e.g.: Oximio).

There can be a role for the Sponsor, but this needs clarity on where the product is being released. For example, if the product requires blinded packaging (which is a more complicated procedure with no simplified QP release) the TQA needs to be signed by ALL parties in EU (supplier of commercial product; Oximio, sponsor, facility for blinding and QP).

Therefore, it is crucial to understand this at the time of supply or re-supply request. The connection is required from the QP release from the manufacture to any future releases of product for the clinical study.

Q: What is the process for product recall, if there is an incident?
A: At the time of the sourcing request, our procurement team will verify we have a process for product recall and can track and trace. This should be included as confirmation from the supplier in the supply agreement. It is important to have this process in place as if the clinical study is ongoing and a temperature excursion or incident occurs, the distributor may not want to share any information regarding product stability.

Therefore, the sponsor must have agreement from manufacturer prior to any purchase of comparator of the product on the clinical study.

Q: What is the key documentation available when sourcing comparators? Does this differ per country sourced from, and is it always available?
A: The manufacturer can routinely provide full pedigree documentation reflecting the chain of custody from the source to your designated point of delivery along with full product documentation, including certificates of analysis, certificate of conformity, package inserts, GMP compliance, equivalency data and material safety data sheet documentation.

However, the availability of these documents is not always guaranteed when sourcing comparators via wholesalers, putting a company at risk in terms of meeting regulatory requirements. While a wholesaler may be able to offer the lowest product cost, the lack of robust relationships with manufacturers and supply quota restrictions may result in an unreliable supply of comparator throughout the course of a trial, ultimately leading to a much higher total acquisition cost.

Q: How much does price play a factor in comparator sourcing? How do you go about negotiating price margins and building strong relationships?
A: Focusing on cost, not value, can exacerbate these challenges by leading companies to take financially motivated decisions that ultimately make it harder to quickly source enough comparator products while complying with regulations and quality requirements.

Region-to-region differences in the challenges of comparator sourcing. For companies working in North America, cost is the main challenge, reflecting the high prices of drugs in the US. It is cheaper to buy medicines in other parts of the world, but these regions tend to be less homogenous, creating a different set of problems. Respondents cited customs as a challenge in Europe. In Asia, language barriers and doubts about drug quality are among the biggest concerns.

Q: What is your average turnaround time from product request, to confirming availability and then shipping the product?
A: We aim to provide the sourcing schemes as quickly as possible for our clients to be able to make the decisions they need.

Confirming availability and shipping to the end destination also depends on whether the product requires labelling or if the product is to be shipped to multiple locations or if a single batch is not available at the time of sourcing and this may require analysis of the manufacturing process timelines. But Oximio always provides transparency during all steps of the process.

Q: Can you expand upon some of your specific experiences in countries like China and Russia?
A: One of our most interesting recent projects has been supplying medication for oncology treatment across Southeast Asia. We were buying directly from the manufacturer in 3 different countries, keeping some drugs in the country and, in some cases, shipping them direct to the site, and also to other distribution centers Oximio has acted as the central hub for all order processing and approvals of those goods. This means the sponsor had one simple interface to procure those drugs and we used our global network to ensure success.

Q: How does Oximio mitigate the risk of sourcing from unauthorized channels/the grey market?
A: The last thing a sponsor wants to do is procure a product for a comparator that is either counterfeit or hasn't been stored properly. What we bring to the marketplace is expertise of what has to be done. We have a network of suppliers across the globe. That network has been established and includes audited, approved wholesalers and suppliers.

They must meet our tough quality standards and financial and legal due diligence. And that, combined with relationships with manufacturers and major pharmaceutical companies, also allows us to buy direct from manufactures for sponsors willing to divulge trial information.

The gold standard in comparator sourcing is to source directly from the comparator's marketing authorization holder/originator, through a partnership with a procurement/clinical supply chain specialist that benefits from an established relationship with the manufacturer. Through this partnership, sponsors may obtain visibility over what is available in each market (based on the different formulations, presentations, strengths and brands) and create enhanced insight over access and availability (expiration, lead times and licensing) to streamline and safeguard supply.

Q: Can you comment on the conflict of interest that Sponsors require collaboration from Comparator companies in sourcing comparators e.g providing COA, product availability often the cause of trial delays which is not in interest of the patients.

A: What is important to note is that the risks associated with comparator sourcing can increase without a well-planned supply strategy. When procurement teams are tasked with sourcing comparators at short notice, wholesalers or suppliers must be quickly identified and appraised; a process that can be challenging in a compressed timeframe.

The major risk it presents is that there can be great variability in supply and no security to deliver in time. Wholesalers may not be able to provide large single-lot batches with long expiration dates. The trial sponsor may have to buy the comparator in multiple lots, leading to clinical inconsistency. This can create significant operational challenges, as well as more paperwork to address audits or even recalls.

Additionally, wholesalers may not be compliant with sourcing regulations and the logistics necessary to deliver the comparator to sites worldwide. Suppliers should know the import and export requirements for each country, as well as the specific handling criteria necessary for each type of delivery (i.e. cold chain requirements, controlled drugs requirements, special nature of the sources).

Most of the time, a short lead time may prevent sponsors from sourcing directly from the manufacturer through a sourcing specialist, a process that takes more time than usual. Therefore, robust relationships between sponsors and suppliers should be built to address this complex process.

Q: With Covid-19, pharmaceutical industries are moving forward with decentralized clinical trials model. How do you manage global supply of ancillaries and other devices used in drug trials for measuring outcomes to comply with local legislation?

A: Centralized or decentralized supply is confirmed at the beginning of the project, and the set-up can work for some countries but not with others (e.g. can work with Georgia and cannot work with Israel). We have an Import/Export Function which is dedicated to resolve and discuss any such issues. We would welcome any further discussions if required.

Q: Do you support JIT labeling in your local markets to meet local labeling requirements?

A: Yes, we offer this service.

Q: How do you strike a balance between price of comparator and quality of product supplied (including accuracy and availability of all Chain of Custody documents)?

A: Budgets are agreed in advance of any purchase with distributors or manufacturers and costs are managed by having a clear scheme of work with a sponsor e.g. different countries, different regions, negotiation specific to a country. But we never under-deliver on quality.

We have pharmacy depots which are licenses in each of our locations and each depot has QP individuals who critically oversee each stage of the process.