The Ins and Outs of Comparator Sourcing: How and Why to Choose a Provider

Chris Greco, director of comparator global services at Catalent, spoke with Pharmaceutical Technology *about comparator sourcing providers and how they support emerging, small, and midsize biotechnology and pharmaceutical companies by offering a tailored, one-stop solution.*

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PHARMTECH: With clinical trials becoming increasingly multiregional in scale, how should a sponsor go about choosing a comparator sourcing region for a particular study?
GRECO: It depends on several factors specific to the study in question that must be carefully considered. Some important questions to address include which countries are involved in the study, where the commercial product is manufactured and where the materials can be packaged. An important consideration when choosing a source region is to work closely with the comparator sourcing provider and share information about the plan for the entire study so that they can tailor and optimize the sourcing region and supply plan. Providing a copy of the study protocol for review, even if it has not yet been finalized, can be very useful during this initial evaluation, and it's highly recommended to discuss and develop the supply strategy with a sourcing specialist.

The comparator supply plan will consider several factors: import and export into certain countries or regions, different price points in different countries, if the commercial product should be sourced from inside or outside of a particular region or country, plus available lead time and expiry and any other factors known at the time the plan is being developed. These are all taken into consideration to build an optimized supply plan.

We strongly recommend that sponsors (or their CRO, if they are working with one) discuss the entire plan with their comparator sourcing provider. This is the time for sponsors to discuss preferences or concerns, as these might impact the sourcing strategy and will give their sourcing partner the opportunity to share helpful insights and supply considerations that are not obvious. For example, if the sponsor is planning on an additional study that will also use the same commercial product, a good provider will consider this information to build a suitable plan that fits the needs of the sponsor versus only offering a standardized or generic approach.

PHARMTECH: If a sponsor has unsuccessfully attempted to source the comparator on their own, or if they are already working with a sourcing provider and are not getting the level of service they need, how hard is it for a new sourcing provider to step in and help rescue the study?
GRECO: The first thing the new provider will need to consider is the specific issues the sponsor is having either with its own sourcing attempts or with the current provider. The nature of these issues will quickly reveal what is needed to rescue the study, assuming that it can be rescued without negatively impacting the timeline. For example, if the sourcing efforts to date have been unsuccessful due to a stockout or backorder, or if the commercial product has been discontinued, it can be challenging to step in and quickly overcome the issue. However, if the root cause of the sourcing trouble is a lack of internal expertise or resources, the current level of service from a provider is deficient, or another issue such as the sponsor looking at alternative supply routes, then it is often possible to improve quickly.

Again, the key is to work with a provider that knows the space well. By that, I mean they have established relationships with the manufacturers and their authorized distributors, they know the products and the region, and they have a good understanding of the nuances of supplying commercial products for clinical studies. If they do, then a robust backup plan can be established from the start to ensure that if something unexpected happens, the right contingency plan and the right strategy are already in place to make sure that there is a continuous supply throughout the study.

It is important to remember that the nuances and challenges of comparator sourcing aren't always immediately obvious. It is a complex and specialized service area and one that has many moving parts, any of which can derail or delay a study if discounted or not taken into consideration. Sponsors who are experiencing challenges sourcing the commercial products need to act quickly to find a solution, even if that means tapping into another sourcing provider to take over the project, as the future of their study is quite literally at stake if they are unable to procure the necessary products.

PHARMTECH: Considering all the comparator sourcing providers out there, including both large global companies and small regional ones, how does a sponsor determine the right partner to work with for their study?

GRECO: First, the sponsor needs to look at its own internal expertise and resources. If the sponsor needs a greater level of service and expertise than it can access internally, then it makes sense to outsource the work and use a partner, large or small, who knows the space well. These days, sponsors—especially emerging or small and midsize companies that are resource-constrained—will need to outsource and can benefit greatly from working with a single-source solutions provider who can provide end-to-end support. I'd like to point out that a single-source approach, in particular, can be an advantage for these smaller companies because having one provider versus having to manage and coordinate several is far easier. A large company with sufficient internal resources or a dedicated sourcing department might be able to effectively manage activities across multiple vendors, but this would be very challenging for a smaller company with only one or two people tasked with securing the necessary commercial products for a study.

As a result, you can see how the different parts work together with clinical supplies management, packaging, labeling, etc., and then reconcile that with the supply of comparators to get the right material with the right expert at the right time.

PHARMTECH: When assessing potential comparator sourcing providers, what are some key things that sponsors should keep an eye out for to fully screen and select a provider?

GRECO: It sounds obvious, but a sponsor should first be sure that the potential provider has access to the regions that are appropriate for the studies. For example, a provider that is only familiar with the North American market would likely be a poor choice for a study that requires sourcing from within the Asian market where a lack of established relationships and differences in regulations, language and business practices could all prove to be problematic. In addition to regional access, the sponsor should also verify the provider has the right regulatory compliance framework in place for each region in which they will operate, e.g., having the right processes in place to fully comply with the Falsified Medicines Directive (FMD) for decommissioning commercially sourced products and other activities within Europe, or be in compliance with the Drug Supply Chain Security Act (DSCSA) within the United States.

PHARMTECH: How involved are the comparator sourcing specialists throughout the entire clinical supply process from end to end?

GRECO: Closely, and that's where they can be most effective. Comparator sourcing as an activity tends to be more downstream because when sponsors are considering a clinical trial, there are a lot of things to think about. Comparator sourcing can seem like a simple piece compared to packaging and labeling, but it has its own nuances and challenges—its own details that need to be ironed out. Also, there are often crucial aspects related to comparator sourcing that must also be worked out in advance, such as how will the commercial product be blinded or masked and who will perform that work. At Catalent, we prefer to get the comparator sourcing specialists on our team involved from an early stage because there is important information that can be "upstreamed" to dictate the plan—to provide insights and guide the strategy. For example, long lead times for product delivery or documentation requirements for international shipments should be built into the sourcing strategy and study timeline; or if a product will be particularly challenging to blind, we will need to investigate the available options or develop a custom solution early on as to not delay the study.

The sourcing specialists monitor the process, making sure there are no issues along the way. If there are challenges, they have the expertise to quickly evaluate the problem and devise solutions to address them, whether it's getting unexpected documentation to facilitate importation into a country that was outside of the project scope, or reacting quickly if the product experiences a temperature excursion (then validating whether it is still usable or replacements are needed). It is important to note that there are downstream issues that can happen as well, so really, end-to-end support is needed. Additionally, for longer studies, comparator sourcing is not a one-time activity, as new lots might need to be purchased in the future, or a change in the presentation or availability of the commercial product might require a modification of the original sourcing strategy.