

AmerisourceBergen

World Courier

Comparator sourcing efficiencies

How to shorten the clinical trial supply chain

Managing an increasingly challenging ecosystem

The top 10 pharmaceutical companies collectively spend more than \$20 million a year on comparator sourcing services, according to the Tufts Center for the Study of Drug Development (CSDD).¹

With this investment comes four challenges that sponsors may encounter when accessing comparator drugs for use in clinical trials:²

- 01 Manufacturer approval is a lengthy process**, with many having restrictions in place.
- 02 Comparators must be sourced from a single manufacturing lot**, so large quantities can be difficult to source.
- 03 Comparator drugs are often expensive** and may exceed budget expectations.
- 04 Comparator sourcing services are sought late in a clinical trial**, rather than at the initiation of study design development.

COVID-19 has only amplified these factors. Regional lockdowns may reduce the accessibility of some medications and reduced operations at distribution and transportation centers impact shipments to clinical trial sites.

At a time of increasing restrictions and pressure on the clinical trial supply chain, it's important for trial sponsors to turn to reliable, timely, and ethical sources for their comparator drug and clinical trial supply needs.

Balancing innovation and competition

Manufacturers of approved pharmaceutical products are not incentivized to supply their medicine for clinical trials that are evaluating a future competitor. So gaining access to biosimilars and investigational drug products from manufacturers relies on proven relationships – that's when a comparator sourcing solution is vital to keep clinical trials on track.

When evaluating a comparator sourcing provider, make certain that they:

- **Have established relationships to access necessary supplies for research and development**—including hard-to-find drugs.
- **Can collaborate on strategic plans**, including assessing the requirements for clinical trials in detail and addressing regulatory restrictions.
- **Demonstrate expertise to establish specifications for storage, distribution and transport**, as well as develop contingency plans in case adjustments are needed during the trial.

"It gives me confidence in our provision of service to our clients that every medical product that we procure from World Courier is sourced directly from manufacturers, it is delivered within the manufacturer's specifications, correct quantity, dosage form and packaging, and with full pedigree. Through our strong partnership with World Courier, we're able to provide a first-class service to our clients."

Chairman, Global Clinical Sourcing Company

Four ways the right partner can support with comparator sourcing challenges

01 Expert partnership

Stable, long-term affiliations with pharmaceutical manufacturers mean that comparator sourcing providers can offer optimal cost management, even for products that are difficult to source. Sponsors should start to source comparators as early as protocol development, ensuring they have time to identify risks, explore options and secure supplies by the start of the study.

Identify a partner that demonstrates ethical behavior and has a transparent business model. They must meet all of your manufacturer-specific and FDA requirements for comparator drugs, ensuring product integrity throughout the supply chain, while taking full accountability.

How World Courier can help:

- **As part of AmerisourceBergen, World Courier is a wholesaler with a dedicated specialist comparator team.** World Courier's comparator sourcing solution removes the need for manufacturers to source products from several places—allowing clinical trials to progress with efficiency and speed.
- **World Courier leads the industry with commitment to quality and fully documented quality control (QC) system.** Our team employs the highest standard of excellence to ensure both comparator product integrity and patient safety during clinical trials.



02 Expansive network

Comparator sourcing providers have access to multiple potential sources of drugs. They also understand product manufacturing schedules. Additionally, they often have knowledge of upcoming formulation changes with the ability to forecast market shortages. This awareness mitigates risk, enabling secure, sustainable supplies throughout the clinical trial.

How World Courier can help:

- **World Courier purchases products directly from the drug originator.** Through AmerisourceBergen's established sourcing network, we can provide cost-effective and transparent pricing that helps our clients better manage the costs of trials.
- **AmerisourceBergen is an Authorized Distributor of Record (ADR)** for nearly all commercial drugs and is the second largest wholesale drug distributor in the world. We buy direct to ensure product integrity and patient safety for clinical trials.
- **Leveraging AmerisourceBergen's wholesale portfolio,** World Courier may be able to obtain on-the-market drugs that may not be available through other comparator sources.



03 End-to-end logistics

For most clinical trials, comparator materials must be sourced from a single manufacturing lot, which can be challenging—especially if a large quantity is required.

Comparator sourcing partners provide project managers and coordinators to simplify communications and streamline end-to-end logistics. They manage the supply chain and logistics process to reliably deliver comparator drugs to clinical trial sites.

How World Courier can help:

- **World Courier provides an integrated, closed loop comparator solution.** We ensure comparator drugs are stored and transported in temperature controlled environments, meeting all manufacturer specifications, to maintain product integrity. With a short supply chain, especially if the biotech innovator is using our third-party logistics services, World Courier reduces the possibility for delays in trial completion while ensuring product security.

04 Exceptional commitment and responsiveness

When choosing a comparator sourcing provider, ask how they handle quotes and RFPs.

How World Courier can help:

- **World Courier's comparator sourcing team ensures a fast, predictable response time to quote requests—within 48 hours.** In many situations, product availability for specific lots and expiration dates is confirmed immediately.

Leveraging proven comparator sourcing efficiencies can shorten the clinical trial supply chain

In summary, as the effects of the global pandemic continue to pressure the supply chain, clinical trial sponsors seek reliable, timely, and ethical sources for their comparator drug and clinical trial supply needs. To overcome supply chain challenges, sponsors will seek partners with extensive expertise, access to an expansive network of manufacturers, a proven end-to-end logistics solution, and an unwavering commitment to client service.

World Courier is such a partner:

- **World Courier's comparator sourcing solution has a proven track record of service delivery for more than five years.** We work with pharmaceutical manufacturers to understand their specific needs, ensure full transparency throughout the sourcing process, and provide advanced logistics services.
- **As the 100% dedicated specialist comparator sourcing solution, World Courier** enables pharma manufacturers, biotech innovators, and CTMO's to acquire comparator drugs and ancillary items for clinical trials research with greater confidence, speed, and efficiency.

To learn how World Courier's Comparator Sourcing team can help increase speed to market for your clinical trials, please visit worldcourier.com/solutions-comparator-sourcing

¹ "A Look at the Comparator Drug Sourcing Market." GEP. 13 May 2019. <https://www.gep.com/blog/mind/a-look-at-the-comparator-drug-sourcing-market> ²<https://www.pharmasalmanac.com/articles/evolving-needs-for-comprehensive-clinical-comparator-sourcing-strategies>