

Bilcare Capabilities for Comparator Drug Procurement

Procurement of comparator drugs is often an extremely challenging aspect of implementing clinical studies - particularly studies that are conducted internationally and multi-nationally.

Because Bilcare has facilities in the US, EU, and Asia, procurement of comparator drugs can be very efficiently implemented on your company's behalf for studies around the world.

This is an informational sheet that addresses many of common questions about the exceptional capabilities of Bilcare's Clinical Study Drug Procurement Program.

Please contact any of Bilcare's global sites listed below to inquire about Comparator Drug Procurement for your important study.

Commonly Asked Comparator Sourcing Questions

1. How does Bilcare source comparator drugs i.e. directly from manufacturer, wholesalers, other? What percentage of spend goes to each option?

Bilcare primarily sources products through wholesalers and directly from manufacturers. The percentage of spend varies as we research which option is most competitive for our clients.

2. Please describe Bilcare's supply network (i.e. sole source, multiple wholesalers etc.)?

Bilcare's supply network consists of multiple wholesalers and manufacturers throughout the world.

3. Is Bilcare able to purchase comparator from market-specific EU/ROW¹ sources?

Bilcare is able to purchase any product from any region of the world market.

4. How can Bilcare's clients remain anonymous for comparator purchases? How does Bilcare proceed?

All product procurement activities that Bilcare performs on behalf of all clients are confidential. Bilcare will disclose information only if and when permission is given by our client.

5. How does Bilcare ensure optimal comparator expiry?

Bilcare cannot guarantee comparator expiry due to high levels of demand. We will negotiate with our providers to provide the product with optimal expiry dating.

6. How is VAT handled?

All stipulations on value added tax will be negotiated on a quote-by-quote basis or through a Master Services Agreement. We will attempt to eliminate any value added tax whenever possible.

¹ ROW = Rest of the World

7. Can Bilcare operate as the importer of record for purchases made outside of the US and manage import/documentation process?

Yes, Bilcare has the capability of operating as the importer of record. All stipulations on importer of record will be negotiated on a quote-by-quote basis or through a Master Services Agreement.

8. Does transfer of ownership occur upon delivery at final destination? If not, when does it occur?

Transfer of ownership is negotiable. All stipulations on transfer of ownership will be negotiated on a quote-by-quote basis or through a Master Services Agreement.

9. What is Bilcare's policy on insuring shipments?

All stipulations on insuring shipments will be negotiated on a quote-by-quote basis or through a Master Services Agreement.

10. What method of benchmarking does Bilcare use to verify comparator market price?

Our providers generally provide us with the most competitive pricing per our pricing agreements with them. However, we have extensive global references, indicators, and experience that provide us with insight during comparator inquiries and purchases.

11. Can Bilcare guarantee fixed pricing of an individual comparator drug throughout the course of a clinical trial if provided customer forecast?

Generally the market value of comparator drugs changes during the course of time, and we inform our clients accordingly. We can hold negotiations with our providers to explore fixed pricing.

12. Does Bilcare have the ability to return unused, unadulterated comparator drugs?

Generally, comparator drugs are non-returnable.

13. Does Bilcare have the ability to return expired comparator drugs?

Generally, expired comparator drugs are non-returnable.

14. Is Bilcare able to perform over-labeling, storage, and distribution of comparator drugs?

Bilcare has vast experience in the over-labeling, storage, and distribution of comparator drugs. We can also over-encapsulate, package, and perform formulation and analytical services. In addition, Bilcare can provide destruction services of unused clinical materials or expired materials. Destruction of all materials is certified.

15. What is Bilcare's target lead-time to respond to formal comparator product sourcing quotation requests? Can Bilcare meet a 48 hour turnaround time?

For most comparator requests, Bilcare can meet a 48-hour turnaround time in providing a quotation for the comparator services. Complex procurement orders may take longer depending on the nature of the request.

16. What is Bilcare's target lead-time from initiation of purchase until delivery?

Lead times for certain comparator products can vary as they depend on which world market the product is being sourced and the type of product (i.e. controlled, etc.). Bilcare coordinates extensively with all vendors to ensure that we obtain the comparator products requested within the most efficient and effective amount of time.

17. What is the minimum amount of time required to change or cancel an order? What are the penalties if any?

The minimum amount of time required to cancel an order is 48 hours. Any cancellation terms would be listed on a quote-by-quote basis or reference in a negotiated MSA.

18. Is Bilcare able to obtain and provide vendor certificate of analysis to the client before drug delivery for all drug comparator purchases?

Certificates of Analysis can be requested for each comparator purchase made.

19. Does Bilcare address temperature deviations upon delivery that may occur during transport? If so, what is the process and turnaround time for resolving deviations?

Bilcare can provide Temp-tale units with each shipment to monitor any temperature deviations during transport. We resolve all temperature deviation issues per internal SOPs, which are strictly followed under cGMP guidelines.

20. Please list all current licenses maintained to procure and distribute comparator drugs in US and ROW?

Bilcare can obtain all comparator drugs throughout the world market from various vendors. If a comparator product to be procured is a schedule I-IV controlled drug, we will inform you of the status of the procurement as the procurement may undergo an approval process from our sources.

Please contact your Bilcare representative for specific inquiries about the Bilcare's Clinical Study Drug Procurement Program.

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