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Your Clinical Supply Solutions

White Paper

Choosing the right generic/biosimilar for a clinical trial

Discover how to choose the right generic or biosimilar for your clinical trial.

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Generics, and the subsequent emergence of biosimilars, have played a positive role in reducing the cost of global healthcare and, in turn, the cost of comparators for clinical trials.

When the patent protection of a branded pharmaceutical ends, it is open season for generic manufacturers to create copies of that drug. Each branded drug will invariably be copied by multiple generic manufacturers, and as these companies clamour for market share it is that competition that will drive down the price.

The clinical trial space is typically well-versed in the use of biosimilars and generics, and for those sponsors that aren't using them in trials, we would strongly recommend that they be given further consideration. In this paper, we will address some of the key considerations in choosing the right product for your study, and whilst cost does play a part, it isn't the only benefit that the right biosimilar/generic can provide.

If your vendor isn't volunteering the information below, then here are the questions that you could be asking to make sure your selection is informed and as beneficial as possible.

1. Are all biosimilar/generic manufacturers created equal, or are there advantages to some over others?

As with all supply chains, there are differences, and these differences can be impactful.

The first thing your vendor should be able to guide you on is which manufacturer has a strong reputation for a robust, reliable supply chain, and a good attitude towards supplying their drugs to clinical trials.
When a branded drug is under patent protection, it is not uncommon to see a manufacturer protect their asset by controlling its supply to the market or by simply not working with clinical trial suppliers to get their drug into studies. Manufacturers of generics and biosimilars are often much more cooperative, primarily because they don't need to protect their molecule in the same way – what matters most to them is increasing sales and market share. This makes sales into clinical trials more desirable to them.

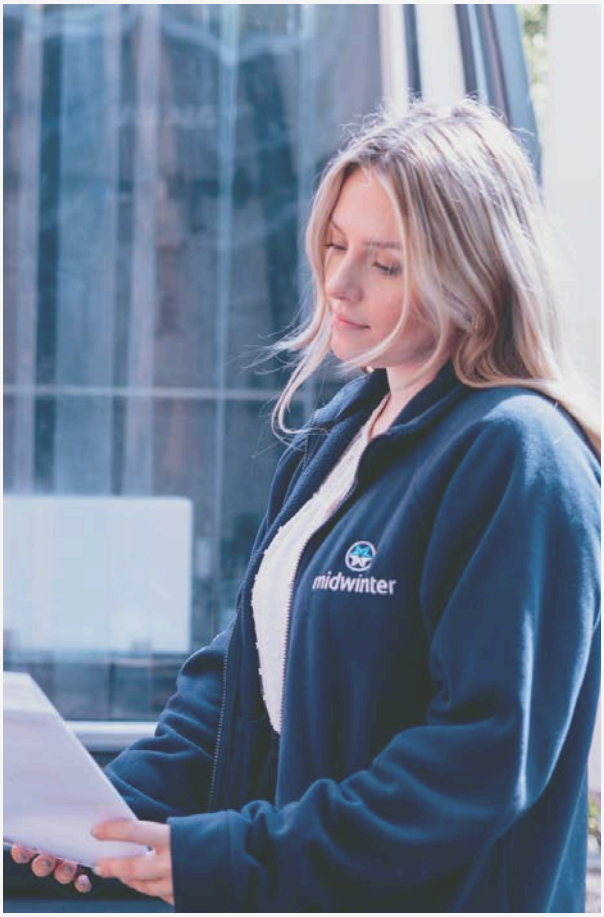
Identifying a manufacturer that recognises this is important as they will be more open to providing lower prices, better expiry dates, more documentation and even temperature stability data. It's also important to realise that one manufacturer's strength may be another one's weakness. Just because one manufacturer has a strong pipeline of biosimilar 'x', they may not have as much success with biosimilar 'y', which, again, your vendor should be able to advise on.

2. Is there a biosimilar that is approved in all my intended trial countries?

Whilst the market for solid dose generics is typically more fragmented, with a lot of smaller generics manufacturers present in each country (and not necessarily having global presence), we are seeing that the biosimilar space is occupied by some larger pharmaceutical companies. With their deep resources, some of the biosimilars that they produce are licensed and marketed all around the world very quickly after launch.

The benefit to this is that you could select a comparator that is marketed in most or all of your intended trial countries, which will reduce regulatory hurdles and filing criteria.

3. What is my cost saving likely to be?

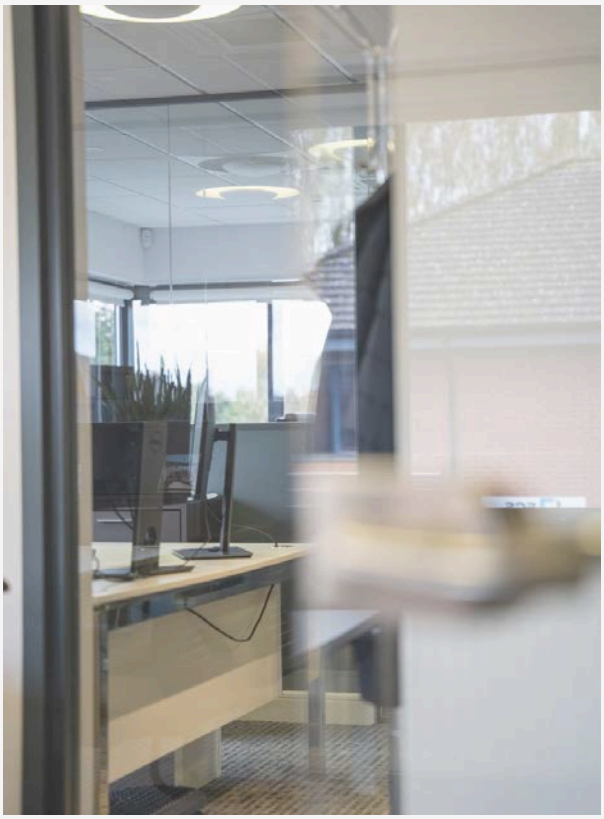


This depends very much on the drug in question, the manufacturer you select and the territory you purchase from. In short though, there will be a saving, and that saving should only increase over time.

It's worth noting that biosimilars in the US have, so far, maintained pricing much closer to the pricing of the original brand. There is a cost saving there, but it is much smaller than the EU.

In the EU, prices of generics and biosimilars tend to fall further and faster. Within a year of launch, it is not uncommon to see biosimilars at less than 50% of the price of the brand and then continuing to fall thereafter.

4. Are there ANY differences between generics/biosimilars and brands, and what should I be aware of?



From a clinical perspective, no; the drugs are interchangeable with consistent and acceptable levels of clinical performance. However, from a commercial perspective, there can still be differences in things like expiry dates and presentations.

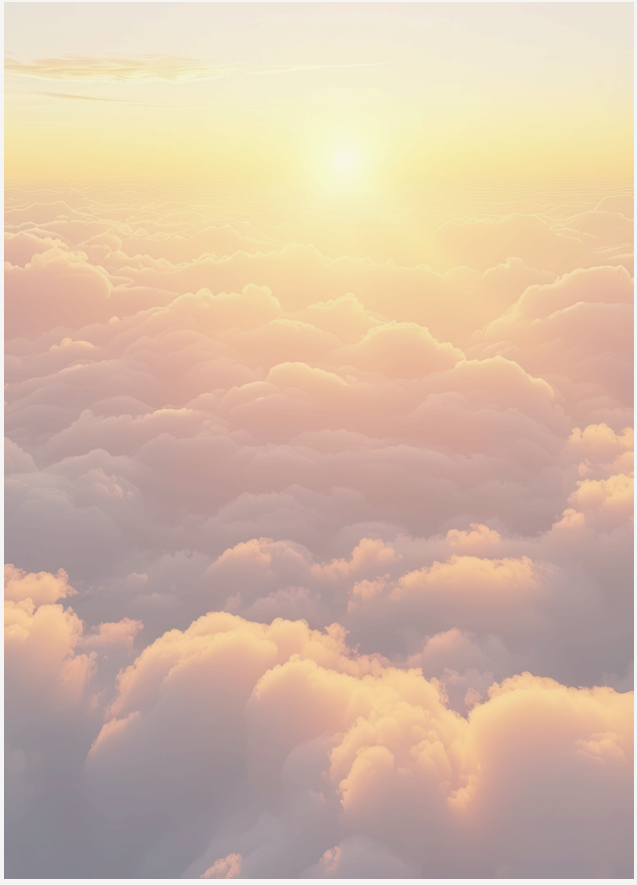
For example, a branded drug may be available as 50mg, 100mg, 200mg and 400mg. The biosimilar manufacturer may choose, based on projected sales and having finite resources, to focus their efforts on only the 200mg and 400mg. If your study needs all four strengths, then this is information that you need to know and that your vendor should provide. Whilst this scenario isn't common it does happen.

Similarly, not all generics have the same expiry date. Generic 'x' may look attractive based on price and availability, but it may have a shelf life of 18 months compared to generic 'y' having 24 months. Those extra 6 months may make your sourcing, packaging, labelling and dispensing timelines much more manageable. If your vendor hasn't shown you the complete picture, then be sure to ask.

5. Tell me again, why shouldn't I use the brand?

The brand can still be a viable option for comparator selection, but it's important to make that decision based on solid information. Historically, we have seen a lot of sponsors come to Midwinter with an initial request of supplying a branded drug simply because it has a longstanding reputation for being 'best in class'. But by definition, a biosimilar is identical to its predecessor, which quickly negates that reasoning.

Once biosimilars/generics come to market, they quickly win market share, and we seldom see a branded manufacturer reduce the price of their product. As a branded drug's market share decreases, so does its subsequent production, making the drug less and less available. When choosing a comparator, it is pragmatic to select one that is moving in the right direction, as ongoing availability is an important consideration.



We have seen instances of branded drugs being discontinued within a few years of the patent protection ending, which is a worst-case scenario. This forces the Sponsor's hand, making a switch to a generic/biosimilar inevitable. Of course, this can be a more orderly and considered process if your vendor has already advised you of that risk during the comparator selection process.

We should also consider the willingness of the biosimilar/generic manufacturers to support clinical trials. They are often more motivated to make sales in this area, so will not ask for a Sponsor's clinical trial details and will be more motivated to provide supporting documentation for their drug.

Summary

With any comparator selection process, there can be complexity and confusion, but this is only exacerbated when we start to look at drugs where there are several options for the same molecule.

More than ever, your vendor should be proactive in helping you make the right choice based on a lot of factors, and whilst cost is a very key factor, it isn't the only one. Selecting the right balance between cost and a robust supply chain is a collaborative process.

Midwinter Solutions can help and would be delighted to discuss your study plans.

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