Ask RxSource

What do I do when a drug goes into shortage in the middle of a trial?

Drug shortages. Two words no clinical trial supply manager wants to hear in the middle of a clinical trial, with a global resupply pending in the next few weeks. How do we mitigate against this and ensure that if drugs are in short supply, we can still continue to support our patients?

We always recommend that clients involve us/their drug-sourcing partner while their trial is still in the planning phase. This enables us to get a good idea of the likely demand for commercial product over the course of the trial. It also allows us to develop the best sourcing strategy. For example, if demand is high and single lots of product are desirable, we may advocate sourcing directly from the manufacturer. Conversely, if drug need is spread over multiple months/years, and is within country/wholesaler quota levels, an open-market sourcing strategy may be preferable. Early involvement also allows us to evaluate other options – for example, if there is a risk that enrolment could be slower than expected, can we reserve stock and reduce orders at short notice without financial penalties? Starting discussions early also allows us to develop back-up plans. For example, while some markets may offer products at competitive pricing, in our experience product may be in limited supply in those countries, so it makes sense to have a back-up plan that supports sourcing from larger markets, even though these may result in higher unit prices.

Drug sourcing partners can also provide insight into current market demand for specific products, which may develop into shortages. This can be a combination of assessing the number of inquiries we are seeing for a particular product (naturally, respecting client confidentiality!), and use of public/subscription websites and databases that we use to evaluate demand across the wider market.

Using simulation software to predict demand before a trial starts, and using simulations to recalculate demand during a project can also reduce the risk of drug shortages impacting trial supply. We work with partners who can provide this service if clients do not have this capability in-house.

We also recommend that clients avoid writing specific drug sources into protocols – for example, writing 'EU-sourced comparator' rather than 'Italy sourced comparator'. If there is a chance that a back-up market will be required to support projected demand, we recommend seeking approval from regulators to use 'foreign' sourced material during submissions, not after a drug shortage has happened.

Finally, trust your partner! If your provider warns that wholesalers or manufacturers are warning of impending shortages and early ordering is essential to secure stock…this is not a sales tactic to obtain an early commitment (at least, not always!). Focus your sourcing efforts on trusted partners, with a proven ability to supply. We have seen occasions in the past where Sponsors have approached multiple wholesalers with the same request. These in turn have each approached the manufacturer, creating artificial demand in the market – to avoid this inflated demand impacting on supply to their core market, manufacturers can drastically reduce, or even shut down, supply to clinical trials.

Final Words

In summary: Start discussing your sourcing needs with your partner(s) as early as possible. Partners with a global footprint can research product availability in multiple markets, helping mitigate against future shortages. Also, ensure that your discussions with regulators, and any regulatory submissions, support sourcing from a back-up market in the event that supply from your preferred market is exhausted.

Contact us

www.rxsource.com

solutions@rxsource.com

Canada I USA I Ireland