ThermoFisher SCIENTIFIC

CASE STUDY

UNITED WITH PARTNERSHIP & PLANNING

Clinical supply optimization:

Mid-size pharma rejects bulk, avoids shortage

Companies developing biosimilars are coming to partners like Thermo Fisher Scientific for assistance with forecast planning. This case study shows how these partnerships are paying off.

A midsize pharmaceutical company came to us prior to launching an ambitious Phase III clinical trial for a biosimilar product. It was planning four different four-year studies at 320 clinical sites, involving about 1,500 patients suffering from chronic kidney disease.

With only three members, including a contractor, the company's clinical supply team was not confident in their own capacity to forecast supply needs and manage them on an ongoing basis. They started to feel uneasy when the time was approaching to initiate the first trials. Because it was one of the company's first biosimilar studies there was a lot riding on the success of the trial.

Determining the packaging schedule was a challenge because dosing was variable and dependent on the clinical response of each patient. The Thermo Fisher Scientific team discussed this complexity with the sponsor and determined that the best route forward would be to create a series of assumptions based on Phase I data describing enrollment rates and patient dosing. Members of our Clinical Supply Optimization team would then fine tune these assumptions based on new data as they became available. Agreeing to this path, the sponsor released the raw data to our team then performed their own forecast calculations.

Conservative supply estimate embraced

Getting to the next step required applying statistical principles to the trial design. After just two weeks, our Clinical Supply Optimization team delivered a plan with estimates that were extremely close to the numbers the sponsor had developed. They calculated that patients would be coming to the sites for dosing three times per week on average; our figures showed that the average would be 2.8 doses per week.

Though the sponsor favored taking the more conservative route, our group was confident in its recommendation and argued against a strategy that could waste precious supply. They again emphasized that the initial estimates would be adjusted when the trial data began to accumulate.

Further discussion revealed continued uncertainty on the part of the sponsor's team who then decided to accommodate three doses per week.

Forecast meets the ultimate test

Enrollment began and the dosing data started flowing in from the 320 sites. In the early stages of the study, enrollment and dosing data were analyzed often and compared with the initial assumptions. During weekly meetings with the sponsor, the assumptions were adjusted and the forecast updated regularly. After a few months, the Thermo Fisher Scientific team was able to limit drug waste and maintain a sufficient supply cushion by decreasing the inventory levels to 2.6 doses per week.

A short time later our supply forecast met the ultimate test. We learned that the sponsor had rejected two batches of study drug due to quality issues. This was bad news because it meant throwing away a large amount of biologic at a crucial time in the trial. To make matters worse, the batches failed the sponsor's certificate of analysis during the holiday season when most everyone was out of the office.

Fortunately, our team was able to bring calm to the storm when they showed the sponsor that there was plenty of stock in the supply pipeline to keep the trial on track. Though we had saved money by lowering the forecast to meet a weekly schedule of 2.6 doses, the team retained enough slack in the supply chain to cover extreme conditions like this one. Despite losing the rejected bulk, there were no stock outs due to the lack of drug at the depots.

With that emergency behind them, the sponsor was more comfortable with their supply strategy. They moved meetings with the Thermo Fisher Scientific Supply Optimization team to a monthly schedule, down from weekly at study start. And now they can focus on their core competencies. "We really don't worry about the fate of our drug supply," the sponsor's team leader said. "We know we have a handle on it."

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