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Clinical supply optimization:

Digging for the true cost of clinical supply

Pharmaceuticals are a small part of this company’s overall business and its team was relatively new to clinical supplies. In their first discussions Thermo Fisher Scientific team revealed they were extremely worried about losing an investigational biologic due to temperature excursions in the cold chain process.

The clinical trial protocol required that patients receive two vials of the drug during visits to the clinical sites. Because each vial was worth about \$1,000 in this multinational Phase III trial, the client planned to send each one in a separate cold chain shipment carton. They reasoned that if an excursion happened then only one vial would be lost. Controlling waste was especially important because enrollment was expected to be difficult and expensive. To recruit about 400 patients, the client planned to open 100 sites.

The distraction of temperature excursions

When presented with the client’s favored packaging option, our Thermo Fisher Scientific Supply Optimization team began to dig a little deeper. Using robust risk analysis, the team found that there had been several temperature excursions in Phase II, but that none of these had actually damaged the study drug.

Next, our team examined the true cost of the client’s packaging design, including the need for two labels and additional packing components. The team also considered the strong possibility that the client would lose patients to competitor trials. Several drugs were in development for the same indication and site personnel might hesitate to enroll for any trial that required two trips to the pharmacy for one dose.

Compelled by lower risk and costs

Presented with this compelling risk profile, the client team members began to reconsider their original plan. They agreed that the relative risk of wasting drug due to temperature excursion was nothing compared to the risk of losing patients or sites. Now on board with the concept of packing two vials in one carton, the client was further impressed by our package design that held both vials but was the same weight and dimensions as the original single-vial shipper.

Besides the projected benefit to patients, going from two boxes to one box made sense in another important way. Thermo Fisher Scientific reduced the overall study costs by nearly 20%, cutting the client's expense by \$200,000. Satisfied with this first project and now further up the learning curve, the client expanded its relationship with the Thermo Fisher Scientific team, inviting us to work on six subsequent clinical supply projects.