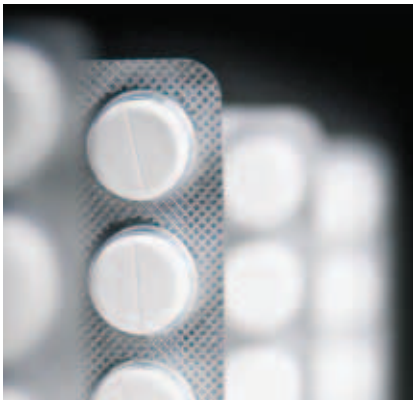

MYODERM WHITE PAPER

Alleviating the Pain of Independent Site Sourcing

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When sponsor companies require clinical trial sites to source commercial drugs and ancillary supplies independently, it can impact the outcome of clinical trials. Sites often lack the expertise, time, resources and processes for efficient and effective supply chain management. It is critical that sponsors evaluate these challenges and optimize their sourcing strategies to minimize risk and maximize success.

Identifying the Risks

Independent site sourcing can be challenging. Trial sites, especially in emerging markets, oftentimes lack the trusted supplier network to source the initial and ongoing supply of commercial drugs and ancillary products. And, the opportunity for volume cost savings is lost.

The risk of not obtaining these products leaves trials in jeopardy of disruptions and delays due to missed doses or dropped patients. Even when supply is successfully sourced by independent sites, trial integrity is at risk due to lack of standardization from site to site.

Ensuring product integrity is crucial. Sponsors need to understand sites' storage capabilities and capacities, and clearly communicate expectations. Storage at clinical sites is often at a premium, especially for cold chain products.

Ongoing inventory management at clinical sites can be challenging as well. Relying on sites to ensure proper supply levels is only one piece of the puzzle – products stored at the sites require staff to monitor expiration dating and recalls, handle those recalls, and keep detailed records for lot traceability.

Centralization for Simplification

The complexities involved with independent site sourcing pose an obvious threat to clinical trials. But there are alternative solutions that can alleviate these challenges and minimize risk.

Pooling commercial drugs and ancillary products at a central warehouse is one option. This takes the burden of sourcing off the individual sites and places the responsibility with an experienced sourcing specialist, giving sponsors control over purchasing and approval.

Centralization mitigates the risk of not being able to obtain the product needed and reduces costs by taking advantage of a specialist's volume purchasing power. Consolidated storage and shipping provides additional cost savings.

Utilizing centralized storage improves inventory management. With established resupply levels, trial sites can be supplied on an ongoing, as needed basis, throughout the length of the trial. And the standardization of products from site to site, with the centralized monitoring of expiration and recalls, protects trial integrity and enhances patient safety.

Choosing an experienced sourcing partner is integral to the success of a centralized sourcing program. Larger IMP distributors do not typically have the streamlined processes and capabilities, which is why it is important to identify a sourcing and distribution specialist with deep expertise.

The value of centralized sourcing is clear. The benefit it provides, along with the risk it eliminates, is why an increasing number of sponsor companies around the world are using this option.

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Matthew Voicheck plays an integral role in managing CentralSource, Myoderm's revolutionary drug sourcing, distribution, and management service for clinical trials. Matthew has over a decade of industry experience helping global pharmaceutical and biotech companies, as well as CROs, implement distribution and sourcing solutions for more efficient and effective clinical trials. A graduate of Kutztown University, he holds a B.Sc. in Psychology.

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Myoderm is a global leader in sourcing, distribution, and management of commercial pharmaceutical products and supplies for clinical trials. With our deep expertise, customized solutions, and personalized service, Myoderm provides the optimal drug supply solution for clinical studies around the world.

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