

Customer & Market Due Diligence Of Clinical Trial Packaging Manufacturer: Establishing Growth Outlook And Competitive Positioning

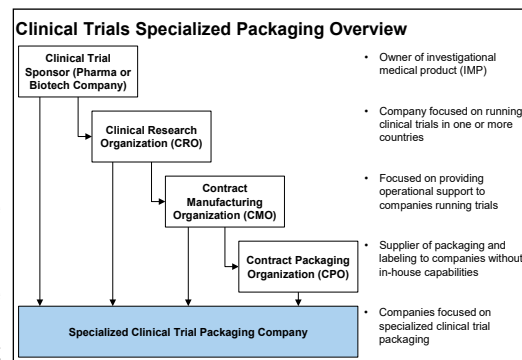
The Challenge: Our client, a leading private equity firm, was looking to acquire a specialized packaging company serving the clinical trials market. Attracted by the target's positioning as a market leader in a high-margin niche with limited competition. The client wanted a clear view of addressable market size and growth rate, and potential competitive risks. Gotham conducted a customer & market due diligence to: (1) establish market size/growth outlook; (2) understand insourcing risks and substitution threats; and (3) establish the target's reputation/competitive positioning.

Robust Clinical Trials Market Assessment: To deliver a comprehensive and fact-based view of the market and competitive dynamics, Gotham:

- Conducted 26 interviews with clinical trial sponsors (pharmaceutical and biotech companies) and with Contract Research (CROs), Contract Manufacturing (CMOs), and Contract Packaging (CPOs) Organizations to gain insights into: demand drivers for clinical trial packaging; in-house production capabilities and outsourcing drivers; substitution threats; vendor selection and purchasing criteria; and target's reputation/competitive positioning
- Assessed substitution threats by establishing technological innovations, country-specific regulations, and country-level adoption feasibility
- Identified and profiled key clinical trial packaging competitors, with profiles including detailed differentiating information on company size/presence, packaging capabilities, and value-added services
- Established clinical trial growth outlook by analyzing the drug pipeline, trial success rate, and R&D spend projections
- Built a bottom-up market sizing model based on individual clinical trial level details, including drug type, trial phase, participation, end points, and number of countries.

Increasing Complexity of Clinical Trials Driving Growth in Packaging Demand

Gotham established that clinical trials are becoming increasingly complex, driven by growth in the number of trials, participants, countries, and endpoints, as well as a shift to Biologics (which require more complex trials than Pharmaceuticals). Currently, Biologics account for ~13% of Phase II and III clinical trials. However, they account for ~40% of total R&D spend and are expected to grow to ~50% of spend over the coming 4 years, with Pharmaceuticals/Biologics combined R&D spend expected to grow at ~5% CAGR over the next 5 years. Gotham estimated that this underlying growth in the number and complexity of clinical trials will drive a 4+% CAGR growth in the clinical trial packaging market as packaging requirements become increasingly complex (e.g., Phase III trials involve an average of 8.4 countries, requiring complex packaging to meet country-specific regulations). Clinical trial packaging customers (i.e., sponsors, CROs, CMOs, and CPOs) have in-house production capabilities for simple packaging but mostly outsource packaging for more complex clinical trials as it requires specialized equipment and international regulatory expertise.



Trusted and Long-term Relationships Critical Due to High Cost of Failure

While clinical trial packaging is only a small cost component of the drug development process, the cost of packaging failure is very high. Clinical trial packaging must be accurate, consistent, and adhere to regulatory requirements for all countries in which the trial is conducted. Inaccurate packaging can extend lead times and delay or even invalidate a trial. Furthermore, there are last-minute changes in trials that affect packaging design. Due to the high cost of failure, customers are extremely risk averse and choose packaging vendors based on quality, service, and responsiveness. Once a vendor establishes a trusted relationship, customers tend to come back to the same vendor and will only consider other vendors if the primary vendor does not have available capacity.

Target Is Well-positioned in a Specialized Niche with Strong Performance Reputation

Given the complexity of clinical trial packaging, only a small number of companies have the specialized knowledge and production capabilities required to meet rigorous industry standards. Gotham established that there are only 4 companies, including the target, that participate in this niche market. Of the three other key competitors, two were recently acquired by larger companies – one by a CRO and the other by a diversified packaging company with a minor clinical trial offering and a poor reputation. These acquisitions provided an opportunity for the target to capture market share as customers were somewhat hesitant about using a competing CRO for their packaging needs and/or were concerned about the diversified packaging company's ability to maintain quality, service, and responsiveness of the acquired business. Gotham determined that the target is a well-established player with longstanding relationships at the clinical trial sponsor, CRO, and CMO levels, enabling it to provide service across the clinical trial value chain. These relationships were built through high levels of service and responsiveness to customers' last minute change requests, enabling the clinical trials to move forward accurately and on time.

The Outcome: Gotham's comprehensive, fact-based assessment of clinical trials growth outlook, the niche clinical trial packaging market, target's competitive positioning, and potential insourcing/substitution threats provided our client clarity on the target's growth opportunity as well as its downside exposure, enabling them to move forward with confidence and successfully close the transaction.