

CLINICAL TRIAL PACKAGING

**INNOVATIVE,
FLEXIBLE AND
TIME-SENSITIVE
SOLUTIONS**

patheon

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Clinical trials: A constantly changing landscape

Medicine is an ever-changing field. As our knowledge increases and becomes increasingly refined, new treatments are developed that benefit more patients.

Standards of care change as already-approved medicines are used in new ways and new medicines are approved at increased rates, owing in part to the FDA's Breakthrough Therapy, Priority Review, and Fast Track designations.

Oncology drugs, for example, have seen approvals at record rates in recent years.¹ To succeed, pharmaceutical companies must remain vigilant, attending to every detail of the process, as well as the larger landscape around them.

Creativity and adaptability are key to successfully developing and commercializing new treatments. Companies must be flexible enough to anticipate and avert pitfalls and shift direction according to enrollment progress, trial results and releases by competitors. These changes often impact outsourced services, which requires suppliers remain equally flexible e.g. changes in dosage, increases/decreases in packaging volumes, expiry date changes, addition of new countries.

And time is of the essence: patients are eager to receive treatment sooner, and companies stand to lose financially with each day of delay in releasing a new treatment.

For the large pharmaceutical manufacturer, outsourcing non-core activities is a key strategy in support of streamlining operations.

They need suppliers that can be responsive, held to high standards, with a demonstrated ability to work across their organizational silos in order to get job done. At the other end of the spectrum, emerging biopharma companies simply do not have the internal resources and expertise to manage the range of activities required in support of a clinical trial. They need a trusted advisor that can walk them through the process, demonstrating proactive approaches to solve problems with excellent communication & project management skills.

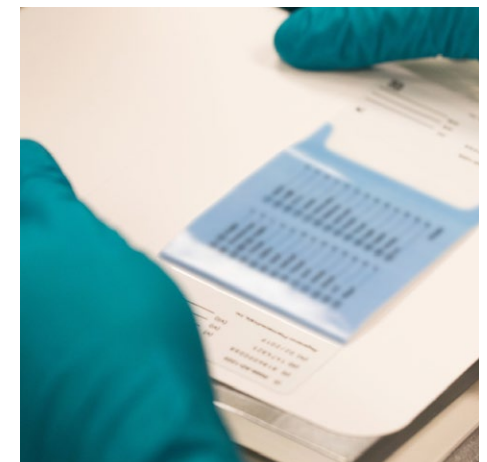
Whether large or small, clinical trial sponsors must have the assurance that their selected suppliers can meet their needs. Given the rapidly changing landscape of today's trials, timelines, flexibility and innovation are essential. Equally important is the project management expertise that ties everything together and keeps things on track.



A delay in launch can cost a company an average of \$15 million per drug, per day.²

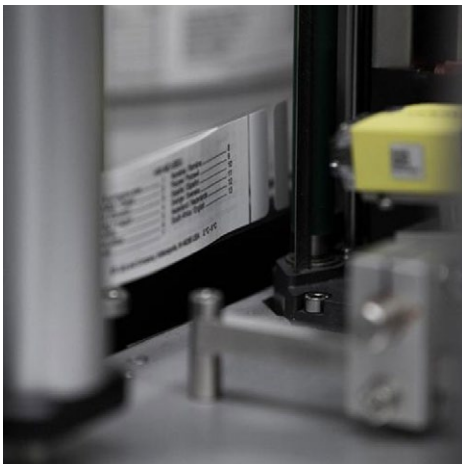
1. Zupnick, Andrew. "The Impact of Faster Drug Approvals on Oncology Clinical Trial Design." Applied Clinical Trials Home, 2 May 2018, www.appliedclinicaltrials.com/impact-faster-drug-approvals-oncology-clinical-trial-design.

2. Noffke, Tim. "No Time To Delay." Pharmaceutical Executive, March 1 2007, www.pharmexec.com/no-time-delay



Case study: Packaging innovation enables breakthrough results

Developing new drugs is a complex process, but challenges at each step offer opportunities for creativity and innovation. A large pharmaceutical company was planning to conduct an infectious disease trial for the treatment of Hepatitis C. The global trial would cover over 40 countries and require the labeling and distribution of more than 250,000 pre-filled syringes over the course of the study.



The investigational drug also required strict 2°C to 8°C temperature and handling protocols. Only one comparator drug was suitable for use in the study, and it was available as a pre-filled syringe in four dosages and included a needle-stick protection device. The sponsor faced 2 significant challenges: the comparator had to be blinded using a label that met the exact dosage specifications of the branded product, and the sponsor had to match its own investigational product packaging and labeling to the comparator, including the same size syringes and labels with similarly precise dosing regimens. Having completed an extensive study of supplier capabilities, they found none had existing capabilities that would meet their needs.

Having previously worked with Fisher Clinical Services, the sponsor engaged their project management team to discuss solutions. A global team of engineers was assembled to design a solution to include high-precision labeling equipment and labels that would meet the exacting dosage requirements of this trial, as well as future trials that required precision dosing graduation.

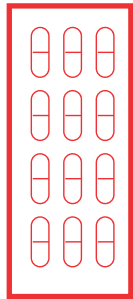
In collaboration with the sponsor, acceptable precision standards were defined and extensive testing was conducted to ensure compliance. The complete system was ultimately qualified according to the co-developed precision standards. Working with the sponsor to meet stringent requirements, the Fisher Clinical Services team was able to develop a first-in-industry capability that is now available to all sponsors requiring varying levels of precision dosing graduation on labels.



Innovative design yields high precision labeling solution for pre-filled syringe within +/- 0.7mm tolerance level, with integrated automated quality assurance to ensure exceptional results.

Case study: Creative design delivers flexibility and time savings

Product packaging is a detailed task that requires both creative thinking and flexibility to realize the greatest gains. Designing with an eye toward versatility, involving the right experts and completing appropriate testing can result in time and cost savings, and lead to success far beyond the original project.



A small, emerging biopharmaceutical company developing an oncology Investigational Medicinal Product (IMP) had been working to blister-pack capsules in a 12-pack strip. Over the course of 3 to 4 months, the requirements changed multiple times, impacting production scale and the packaging process. The team saw that they needed a solution that provided greater flexibility to meet the changing needs and avoid waste. The supplier's project manager pulled together a team of experts from operations, engineering, design, and quality to create a package design that was scalable as needs changed through various phases of the trial.



Their CAD team created a 3-dimensional proof-of-concept which was used to further refine their solution—a blister pack with perforations in strips of 3 with a single outer wallet. Adopting perforated blister packs offered the flexibility required to support multiple dosing strategies

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Using one wallet design across all studies reduced storage and costs; only the inside card needed to be changed



Applying a single-panel label with multiple languages enabled small batch print on demand runs vs. the more costly booklet production



Packaging re-work was eliminated delivering time and cost savings



Design was fully scalable through all phases of the trial



Flexible design results in decreased waste and, due to the scalable approach, eliminates re-design throughout multiple phases of trial.

Case study: Remaining nimble allows rapid respond to unexpected needs

From drug development to production to patients, there are a host of stakeholders, experts, processes and requirements that come into play. Success requires the ability to communicate across all of these groups to build collaboration, communication and consensus that guides swift action. Proactive project managers are trained to leverage their years of clinical trial expertise to anticipate and prevent errors from occurring. Unfortunately where multiple suppliers are involved, issues can arise that require swift action to save a trial that might be in jeopardy.

Sometimes a small error can have a significant impact on clinical trial timelines and even patient safety. This was the case for a small biopharmaceutical company as it prepared to begin a trial. The study preparation had run smoothly but, during the final stages before the clinical trial, the sponsor realized they had made an expiry dating error. The sponsor had inadvertently submitted the wrong expiry date for a particular lot of investigational drug. As a result, the labels had been approved with a shelf life of 48 months instead of 30 months. This required immediate attention as there was a significant risk to meeting dosing timelines.

Realizing they could not remedy this issue on their own, they turned to the supplier their consultant recommended to facilitate an emergency relabeling process. Reaching out to the relevant teams, the supplier's project manager saved time by simultaneously requesting a quote for relabeling the drug with the correct expiry date, conferring with the packaging site to facilitate speedy relabeling, and requesting permission to start the re-work pending quote signature by the customer. The project manager received the green light to begin the relabeling at risk because patients were at risk of not getting their required dosage. Ultimately, the customer was able to complete all required documentation prior to the start of relabeling. The teams were able to work closely, communicate effectively across all parties, and respond with speed and flexibility in order to keep the trial on track and keep patients safe.



Quick action and clear communication allows emergency relabeling due to sponsor error to commence within 5 days of quoting the job.

Case study: Project management experience is essential for quality results

Having a dedicated partner with the expertise to help guide your team can mean the difference between making it to market first and having to take a step back or begin again. There is a methodology to addressing client packaging needs that includes gathering information, setting timelines, presenting options and delivering quality results. Suppliers that collaborate with sponsors and engage their own internal subject matter experts can deliver the best outcomes for trial sponsors and their patients.



A large biopharmaceutical company had an injectable drug in the field, but in limited supply, which placed a heightened focus on minimizing or eliminating rejects. They requested an unconventional packaging process: instead of applying a plunger rod to a syringe before snapping on the backstop, they requested that operators apply the backstop first, then push the plunger rod through the backstop while ensuring minimal movement to the rubber stopper.

The supplier's project manager gathered a team of subject matter experts from engineering, packaging, operations and quality to brainstorm and create custom tools that would facilitate the assembly process while ensuring optimal quality. Team leads from each discipline worked to prepare a batch record, which was then tested in a simulated packaging room. Test operators were briefed on the client's expectations and given the draft batch record to guide the process. Gowns and gloves on, the team proceeded to assemble the syringes, working to refine the process and procedures as they worked. A process engineer was a key member of this initiative, revising the batch record in a way that was easily understood by those performing the work.

When the production job was ready to run, the client came on-site to observe. Because the team had conducted a detailed simulation in advance, the production run was completed with no delays and with minimal rejects. By creating a clear timeline and engaging the right experts, the project manager was able to deliver a solution that exceeded the client's expectations.

Project Management leadership delivered a proactive timeline and plan that eliminated change orders, provided a solution that minimized waste, and avoided costly downtime or delays due to comprehensive advance testing.

