Injecting agile production methodologies into clinical trials

Why labeling within the supply chain holds the key

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White Paper

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In recent years, the clinical trial sector has been going through unparalleled change. Overnight, the industry had to adjust its way of working as Covid-19 wreaked havoc across the world, and the wider clinical trial supply chain had to adjust to fit a new paradigm. This report looks at how the industry has shifted its approach to how clinical trial supplies are managed and as a result made the industry more patient centric.

Theory becomes reality

While the pandemic no longer dominates the headlines, many changes brought in have become a permanent part of the clinical trial landscape. Adaptive designs, decentralized models and direct-to-patient dispensing were known to have value but struggled to gain traction. However, it was the onset of the pandemic that finally provided the impetus for adoption. The clinical trial industry was faced with the simple choice of either hitting the pause button on studies or adapting. The sector rose to meet the challenge and along the way realized that adaptive design, decentralization, and direct-to-patient supply models were also patient centric.

The shifting landscape

At the heart of the shifting landscape around the clinical trial industry was the need to accelerate trial processes for Covid-19 vaccine candidates. This was achieved through proactive and collaborative innovation at all stages of the supply chain. Everything needed to be sped up, including labeling and booklet production, which historically would often have a three-month lead time. That simply wasn't good enough; these essential printed materials needed to be produced, ideally, on-demand/Just In Time (JIT) and there was a scramble to find labeling solutions capable of doing this in a GXP (Good x Practice) environment.

"One third of global clinical trials were disrupted in 2020, affecting some $3 billion in new product revenue" — Frost and Sullivan, Post-Pandemic Global Healthcare Market Outlook

There are several important reasons why JIT labeling is an attractive model:

- Firstly, JIT techniques remove the logistical costs of dealing with expired products or having to relabel and reallocate products across multiple sites.
- Secondly, a JIT approach reduces the risk of introducing manual errors during production and ensures the small-batch printing of packaging labels can be delivered in a timely and cost-effective way.
- Thirdly, the drive towards patient-centricity has added an additional component to planning and production as sponsors demand more convenient and accessible ways of distributing products to patients. JIT opens new possibilities for connecting with and supporting the patient in a more sophisticated and personalized manner.

Instilling agility in trial management

While the vaccines might have been in the spotlight, more agile approaches to trial management were being adopted to support studies already underway. Even when patients could travel to a trial site, many of them justifiably had concerns for their safety considering they were potentially more vulnerable to the virus due to pre-existing conditions. It was only by sending trial packs directly to patients that some clinical trials were able to continue.

It is likely we would have seen this shift in approach as new clinical trial regulations have also influenced how many organizations handle clinical trial supplies. Since the introduction of the EU Clinical Trial Regulations and Annex VI requirements, changes to the expiration date may need to be physically reflected on the primary drug. This is where on-demand/JIT packaging and labeling is key. Ensuring that you have the very latest protocol details and expiry dates included at the time of shipping reduces the likelihood of needing to modify the pack at a later date.

This is particularly relevant when you consider the rapid rise of biologic studies. In a previous era, sponsors might routinely overload sites to help reduce the potential for shortages, but this approach is cost prohibitive. For example, if you are overseeing a phase III cancer trial with a budget of $60 million just for the comparator, you cannot afford to use a delivery model which could easily result in 50 to 75% of drugs being wasted. Understandably, there is now considerable pressure throughout the supply chain to minimize drug product and comparator waste, plus the uncertain stability data of biologics already makes it more likely that expiration dates will need to be updated, requiring relabeling if you are not printing labels on-demand.

Label production holds the key

Previously, the 'industry norm' was that label design and print took months. Ultimately, once sponsors discovered that the slow and clunky way 'we've always done it' was not the only option available, clinical trial service partners are expected to accelerate many aspects of the trial process as standard. Consequently, CROs (Contract Research Organizations),

CDMOs (Contract Development and Manufacturing Organizations), and CSOs (Clinical Services Organizations) are now seeking to standardize or operationalize these new agile production models that allow them to be much more reactive.

"The biologics market was valued at approximately USD 302.63 billion in 2020, and it is expected to reach USD 509.23 billion by 2026. Extensive research and development activities taking place on biologics for the treatment of COVID-19 are expected to drive the growth of the biologics market in the near future". — Biologics Market - Growth, Trends, Covid-19 Impact, And Forecasts (2022 - 2027), Mordor Intelligence

In almost every case this involved gaining greater control over the label production process. Increasing numbers of clinical trial service partners are now dispensing with sub-contractors and moving their labeling functions in-house. This addresses problematic delays with label turnaround times and creates new revenue streams while boosting their margins. This has the added benefits of broadening their service portfolio allowing them to respond to sponsors' preference to work with a reduced number of service partners, by effectively providing a "one-stop-shop" for clinical trial services.

Of course, because of using the same procedures and processes for years, many organizations have not necessarily kept abreast of the latest technological developments and are now seeking to overhaul their way of working. As such, they are now eager to explore some of the purpose-built cloud-based clinical trial labeling solutions equipped with specialist functionality. These can help them streamline their operations, while maintaining compliance and ensuring they can respond to the ever-increasing demands of sponsors.

A case in point

To see the benefits of embracing technology, you need to look no further than global clinical trials specialist RxSource. By selecting Loftware Cloud Clinical Labeling validation ready platform, they were able to bring their labeling operations in-house within just five weeks. RxSource now has complete control over clinical labeling with the ability to design and print labels within 48 hours.

Investing in labeling capabilities

As highlighted, investing in clinical trial labeling capabilities and expertise in-house will significantly improve agility, pace, and capacity. Key elements that need to be looked for include:

- Label and booklet design
- Automated label and book design generation and approvals services
- Translation and phrase management
- Pack randomization
- Flexible production print capabilities including JIT/demand-led labeling print
- E-labeling
- Regulatory rules engine
- Default features to meet regulatory requirements such as FDA 21 CFR Part 11

Leverage technologies and services

To de-risk labeling platform implementations and operations, it is important to leverage vendor technologies, services, and expertise. There has been a huge uptake in the Cloud, making it a simpler and quicker way to implement and deploy regulated labeling capabilities. By adopting a cloud-based labeling solution, service providers can implement a validation-ready labeling platform within weeks.

The shift in industry from traditional custom/configured software, to implementing off-the-shelf label applications also reduces risk, as these are built to industry best practices and assures GxP compliance. Embracing automated testing as part of these labeling platforms also eases in-life upgrades, giving the ability to validate an entire system, while leveraging the system's vendor for objective evidence, functional specifications and test results required for compliance.

Conclusion

Unintentionally, the pandemic accelerated the adoption of technology, agility, and service excellence. Long gone are the skepticism and inertia that stopped organizations from embracing technology as an integral part of the process. The clinical trial supply chain has done well to adapt and will benefit from these changes now and in the future. Not only has it improved working practices for the industry, but more importantly it will benefit the patient experience too.

Embracing agility with Loftware Cloud Clinical Trials

Loftware Cloud Clinical Trials is an innovative label and content management solution that incorporates industry best practice and is designed to meet the complex regulatory requirements essential for clinical supply labeling.

The cloud solution is validation ready and is simple, standardized, and scalable. Its unique features include automated booklet design, phrase and translation management, and approval workflows, and flexible on-demand/Just-in-Time (JIT) print models.

Designed, tested, and delivered with a full validation documentation pack, Loftware Cloud Clinical Trials provides certainty that labels and booklets are produced accurately, efficiently, and compliantly to support today's complex, adaptive clinical studies.

Loftware™

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No matter what the challenge – digital transformation, time to market, or brand authenticity – Loftware can help you make your mark. We understand how global supply chains work and know that each item you produce, and ship is an expression of your company's brand. We can help you improve accuracy, traceability, and compliance while improving the quality, speed, and efficiency of your labeling. Our end-to-end cloud-based labeling platform helps businesses of all sizes manage labeling across their operations and supply chain and our solutions are used to print over 51 billion labels every year. Loftware also fosters supply chain agility and supports evolving customer and regulatory requirements, helping companies save over $200 million in fines annually. And with over 500 industry experts and 1,000 global partners, Loftware maintains a global presence with offices in the US, UK, Germany, Slovenia, China, and Singapore making us a trusted partner for companies in automotive, chemicals, clinical trials, consumer products, electronics, food & beverage, manufacturing, medical device, pharmaceuticals, retail/apparel and more.

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