Clinical Trials: Industry Challenges and How to Overcome Them

How to future-proof the supply chain with on-demand labelling

The regulatory landscape between countries is shifting, as is the unpredictability surrounding Brexit, with the effect this will have on clinical trial regulation uniformity across Europe still unclear. The traditional clinical trial model is being challenged, yet ensuring that Brexit does not distract organisations' ability to plan for broader changes is essential. Therefore, preparing for the indirect and direct implications that may be in store for the clinical trial supply chain is the only way that sectors can progress forward and blossom in times of uncertainty.

Due to the growth of drug innovation and targeted therapies, the clinical trial industry is constantly expanding, and with this so are the efforts towards tackling safety and ineffectiveness. However, these come with many challenges. From diversity to exports, recruitment and many more, challenges affecting the clinical trial supply chain are profuse. Especially in light of prevailing disruptive technologies, planning for any uncertainties requires greater resource.

Simon Jones – VP of Global Products, PRISYM ID, highlights the key challenges and outlines how best to overcome them.

Increase in Demand

As a result of IoT, the growth of the internet and the readily available nature of products and services, patients are increasingly demanding faster drug development and a more on-demand approach. And with the pressure on for organisations to shorten the time to market for new drugs and medical devices, it means generating quicker clinical trials. A more efficient method is required in order to cut down these times as well as manage the accumulating number of medical devices and pharmaceuticals being created for clinical research. Although clinical trial supply chain professionals have continued to focus on stock overage, this solution is not ideal. Instead, new thinking and reconfiguring the packaging and labelling design process is required.

The current process that many clinical trial companies adopt is batch production. However, this is a solution that struggles to offer the speed or flexibility that an on-demand solution can provide. Rather than forecasting in advance, an on-demand solution offers the process of packing, labelling and shipping IMPs to be undertaken in response to patient demand. As a result, lead times can become shorter and orders can be drop-shipped to clinics so that they reach patients in time for appointments. Although it is a significantly different production model which requires changes for any supply chain based on a traditional 'batch production' model, it can aid to minimise stock wastage. Delaying the printing of labels until required to ship will also help ensure that the latest expiry dates or dosage instructions can be used, thereby increasing patient safety.

Patient-focused Trials

Patient-centricity has become a topical issue within the pharma industry, with many requiring and demanding services and processes to be updated to become more patient-focused. There has been a noticeable decline in clinical trial patients, and therefore these challenges need to be tackled. Making the clinical space more patient-centric should be a priority, not just from a commercial perspective, but also an ethical approach. Making the patient journey simpler does not only stimulate positive involvement, but also makes leaders appear forward-thinking. Due to this, simpler and clearer packaging for IMPs which are patient-administered is a solution which is increasingly gaining traction within the industry. Unfortunately, the desire for clearer labels with less information on them is often in conflict with the amount of information that regulations stipulate. Not to mention, booklets with several pages are created to provide information in many languages, yet they are also frequently considered unhelpful for the patient experience.

As pressure to increase efficiency within clinical trial management rises, the pharmaceutical industry will need to look towards creating more patient-centric clinical trials. This style of trial won't just enable more accurate results, but ultimately, a rise in patient retention, reduced delivery costs, more valuable data; overall forming a more efficient study. Due to this, patients aren't the only individuals that will benefit from the change of packaging, but it is a transition that will also work in the favour of stakeholders. For this reason, patient-centricity combated by packaging alterations should be prioritised within the healthcare sector.

Language and Cultural Barriers

Clinical trials across multiple countries are becoming increasingly common, and a focus point for many regulators who seek to improve the quality of results which can come with spanning over numerous countries. Emerging market countries offer access to a more diverse patient population, which in some cases can be the critical differentiator when it comes to the development of rare disease drugs, and due to this it becomes an attractive move. Research by the Medical Research Network (MRN) found that as of June 2016, there are commercial clinical trial sites active in 140 countries around the world. However, these types of trials face additional challenges as they come with linguistic, cultural and regulatory differences.

In multinational trials, there are many areas that demand compliance, from translations, to the formatting and inspection of the different language text on labels. Pre-agreed and pre-approved language transitions accessed through language and phrase management tools are a way of solving these challenges, as they have the ability to remove language barriers through ensuring that clinical trial-specific phrases and terminology are maintained across medical devices and pharmaceutical packaging.

Changing Regulations

Different regulations apply to different countries, which becomes even more challenging in light of increasing multi-site trials as well as packaging and labelling regulations. Even with many of the emerging market countries catching up with the levels of regulation which are already in place for Western countries, there are still many differences and discrepancies. With new EU regulations being implemented, Brexit has created great uncertainty on the effect it will have on clinical trial regulation uniformity across Europe, leaving the UK and EU questioning how or whether to continue cooperating with clinical trials.

Meeting requirements is vital. Not addressing and ensuring compliance with each regulator's specification could affect the import of IMPs into a country, and the supply to clinical sites. One way that this can be combated is through the use of label software that utilises a data-driven approach. Holding the latest data, this solution can ensure that at the time of print, the label is populated with up-to-date data, which also helps tend to specifics such as IMPs for specific countries. Ensuring quality translation is also an ethical imperative, a task which can be helped through content and design management. This is also necessary in light of adaptive trials and protocol changes, which are frequently-faced challenges. Protocol changes can occur at any time, which may include adding countries mid-trial or altering the expiry dates of a drug. A data-driven approach can eliminate the need for introducing overhead as well as changing or creating new labels in regional depots.

Biologics

The growth of biologics and biosimilars has also created significant change within the clinical trials industry. As a consequence of increasing biologic trials, IMP costs have suddenly grown, which in turn has had a knock-on effect on stock control, making the management and control of this at its most critical. At a significantly greater cost in comparison to chemical IMPs, the stock overage and wastage of these has a large effect on clinical trial budgets; enhanced by the fact that they often require a cold supply chain with close monitoring in case of any temperature excursions. This means that a shortage of drugs can be the repercussions of a mismanaged cold chain.

Although there will always be a need for a certain amount of necessary overage to cover safety stock on sites, on-demand packaging and shipping can be used to tackle and reduce any unnecessary overage and waste. In order to save money and time when shelf-life and dosages are not accurately known at the start of the trial, stock will more likely require re-labelling in preference to being destroyed. In light of this, an 'on-demand' supply chain can be seen as the logical solution. This would allow for IMPs to be packaged, labelled and shipped in response to real patient demand. Instead of forecasting, this method would enable deadlines to be met, and not compromised, allowing the process to become more agile and flexible.

Conclusion

With clinical trials becoming more complex, forecasting is crucial. The challenges explored highlight the overarching decision that the clinical industry faces: confront and adapt or risk failing to meet the growing demand for new drug candidates. By virtue, supporting on-demand packing and shipping as a service is a feature that is increasingly expected to be adopted, as is providing both country-specific expertise and the latest label requirements. This move doesn't mean the total removal of 'batch production' – as for many this is still important – however, an on-demand approach will help streamline the design and approval process of labels. This in turn will help companies get closer towards their undeniable goal: a 'future-proofed' supply chain.

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Simon Jones is the Vice President of Global Products for PRISYM ID with responsibility for managing the end-to-end lifecycle of the company product portfolio. Simon has 20 years of experience in delivering product strategies and product positioning which address market opportunities effectively. He is a subject expert in clinical trials labelling, researching this market, discussing the industry challenges with the PRISYM ID customers and remaining up to date on market trends, regulatory changes and technology alternatives.