Future-Proofing the Supply Chain

To accommodate the changes in the clinical trial industry and the challenges they face, an on-demand approach can help restructure the distribution network

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With the regulatory landscape between countries continuing to change and the uncertainty surrounding the changes that Brexit will bring to clinical trial regulations across Europe, it is becoming increasingly important to prepare for changes that might hit the clinical trial supply chain.

With the recent expansion of the clinical trial industry as a result of growing drug innovation and targeted therapies, efforts to tackle ineffectiveness and safety concerns are high on the agenda. From changing import and export regulations to temperature deviation, many challenges will affect the clinical trial supply chain. Planning for these uncertainties, especially in light of prevalent disruptive technologies, now requires more attention than ever.

Time to Market

The pressure for faster clinical trials demands advancement of the packaging and labelling design process. To facilitate the accumulating number of pharmaceuticals and medical devices being created for clinical research, a more efficient method is required. While stock overage has always been an area of focus for clinical trial supply chain professionals, it is not an ideal solution.

With packaging and labelling procedures currently being performed in batches, they struggle to offer the level of speed or flexibility that an on-demand solution can provide. Therefore, moving to an on-demand supply chain is the best answer, which means packaging, labelling, and shipping investigational medical procedures (IMPs) in response to real patient demand rather than initial forecasts. Shortening these lead times can be a big obstacle, but on-demand packaging and shipping can enable orders to be ready to dropship to clinics in time for patient appointments. Although it is a significantly different production model and 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 they are required to ship will also help ensure the latest expiration dates or dosage instructions can be used, thus increasing patient safety.

Patient Centricity

A noticeable decline in the amount of patients involved in clinical research,

challenges patient recruitment and retention. To combat this, patient centricity needs to be at the forefront of clinical research, not just from a commercial perspective, but also, an ethical approach. Simplifying the patient journey can stimulate positive involvement; therefore, clearer packaging and labelling for IMPs that are patient-administered is a change that is getting more attention. Unfortunately, the desire for clearer labels with less information on them is often in conflict with the amount of information that regulations stipulate.

The pharma industry is under pressure to find a new solution and increase efficiencies in clinical trial material management, thus making patient-centric clinical trials the core to their overall success, since more accurate information and results can ultimately lead to improved patient retention, reduced delivery cost, more valuable data, and, overall, a more efficient study. As a change that will benefit all stakeholders, patient centricity, combatted by packaging alterations, should therefore be seen as a priority within healthcare.

Multinational Trials

Many regulators are actively encouraging clinical research to span many countries to improve the quality of the results. This is an attractive move as many emerging market countries offer access to a more diverse patient population, which may be a critical consideration in the development of rare disease drugs. The Medical Research Network found that, as of June 2016, commercial clinical trial sites are active in 140 countries around the world. However, the more countries involved in a trial, the more language management overhead challenges they carry.

From translations to the formatting and inspection of the different language text on labels, ensuring compliance to the broad regulations is vital. Pre-agreed and pre-approved language transitions accessed through language and phrase management tools are a way of combatting these challenges. By ensuring clinical trial-specific phrases and terminology are maintained, language barriers can stop being a stumbling block to clinical trial success.

Regulatory Landscape

The regulations regarding clinical trials, and especially packaging and labelling, still vary between countries. Even with many of the emerging market countries catching up with the levels of regulation in place for Western countries, differences and discrepancies between regulations still exist. Many await with interest on what the effect of Brexit will be on clinical trial regulation uniformity across Europe, especially at a time when new EU regulations are being implemented.

Ensuring compliance with each regulator's specification is vital, as not meeting the requirements may affect the import of IMPs into a country and the supply to clinical sites. However, label software that utilises a data-driven approach can ensure that, at the time of print, the latest data populates the labels, tending to specifics such as IMPs for specific countries. Content and design management can also help with a number of shared global functions from translation to regulatory requirements. This is also necessary in light of adaptive trials and protocol changes, which are a frequently faced challenge. The changes to protocol may mean adding more countries midtrial or even changing expiration dates and storage instructions. Rather than introducing overhead and changing or creating new labels in regional depots, a data-driven approach is the solution.

Biologics

Another significant change for the clinical trial industry is the growth in biologics and biosimilars. The sudden increase in IMP costs, triggered by the growth of biologic trials, has made the management and control of both supply and stock at its most critical. At a significantly greater cost in comparison to chemical IMPs, the stock overage and wastage of these largely affect the budget for a clinical trial. This is enhanced by the fact they often require a cold supply chain with close monitoring in case of any temperature excursions, meaning that the mismanagement of the cold chain may lead to a shortage of drugs. The pressure to reduce the overage and waste can be tackled by adopting an on-demand packing and shipping model. Even if the shelf life and dosages are not accurately known at the start of the trial, it is more likely that the stock will require relabelling in preference to being destroyed, which can, in turn, save both money and time. Due to this, for many, moving to an on-demand supply chain is the best answer. Packaging, labelling, and shipping IMPs in response to real patient demand (rather than initial forecasts) offers the agility and flexibility required without compromising critical deadlines.

Future-Proofing the Chain

In light of the challenges explored, the clinical trials industry clearly needs to confront and adapt to maintain a growing demand for new drug candidates. The ability to support on-demand packing and shipping is increasing, as is the need for the latest label requirements and country-specific expertise.

Accommodating these demands does not mean completely scrapping batch production, but implementing an on-demand approach will help restructure the distribution network, as well as streamline label design and approvals, bringing companies one step closer to creating a future-proofed supply chain.

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