

Transform clinical trials with innovative services

With a rapidly changing landscape, optimising clinical trial processes and procedures is essential for everyone involved. **CSM** has the expertise and services needed in clinical supplies and biological sample management to support and ensure clinical trial success.

As with any industry, those working in clinical trials are having to deal with challenges, ranging from patient recruitment to adoption of technology, and regulatory requirements to spiralling costs. Delivering trials on time and within budget is becoming increasingly difficult.

Looking at clinical trials in new ways can help pharmaceutical and biotechnology companies to adopt a new approach and meet the complex clinical supply challenges they face.

The impact of Brexit

At this time, no one knows exactly what will happen once the UK leaves the EU, but with most experts predicting a hard Brexit, the risk of disruption is great. Clinical trials could become more complex and costly after 30 March 2019, when EU laws will cease to apply to the UK.

Companies need to act now to determine where they are going to source Qualified Persons (QPs), who certify each batch of a medicinal products before they can be released for use, and the impact that changing QPs may have on the supply chain. They also have to prepare for potential import or export duties related to the movement of drugs between the UK and the EU, and VAT being applied to drug products manufactured in the UK. To anticipate those and other changes, it would be beneficial to choose a provider of clinical trial services with established facilities in the post-Brexit EU.

Changing traditional thinking

Successfully managing clinical trials that are streamlined, connected and more engaged with the patient in a rapidly changing landscape may require making some changes. Introducing innovative services can decrease timelines, improve quality, reduce costs, and help enrol and retain more patients. It could also help companies to position themselves to operate in the post-Brexit EU and avoid derailing the development of a new drug.

On-Demand supply method

The effective management of drug supplies – choosing the right packaging and labelling processes, for example – is crucial to the success or failure of a study. While traditional clinical supply management methods may be appropriate for some companies, others, such as those developing expensive and limited supply medicines, can greatly benefit from on-demand packaging and labelling.

With company's On-Demand method, which was invented by CSM's founder, Gerald Finken, clinical supplies are packaged



Delivering trials on time and within budget is no easy task, but CSM provides solutions that help companies increase flexibility, and save time and money.

and labelled after the receipt of the shipment request, saving time and money, and increasing the flexibility of the study.

Direct-to-Patient platform

When dealing with homebound patients, an orphan indication or a dispersed patient population, a customisable solution per patient and per protocol can help improve patient enrolment and retention. The company's Direct-to-Patient platform is a patient-centric approach to clinical supplies in which the medicines are prepared, packaged, labelled and then shipped directly to the patient's or caregiver's home.

When used in conjunction with On-Demand packaging and labelling, CSM is able to dispense daily dosing for a product that has a very short shelf life.

With the stakes so high for the development of a new drug and the effect these can have on patients' lives, it is important to choose the right clinical supplies partner and have the right solutions in place. CSM delivers trusted processes and creative services that produce outstanding results. ■

Further information

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