Challenges to Clinical Trials During a Pandemic

Challenges

There has been difficulty with patient recruitment if patients are homebound or reluctant to go to clinics, or clinics allowing only essential or critical visits or refusing to take part in trials. Also, obtaining informed consent for trial participation has typically taken place face-to-face, but with this not being possible due to COVID restrictions, the industry should attempt to move to electronic consent methods.

Vendors and contractors have sometimes been unable to meet certain obligations, such as delivering drugs to certain sites due to limited flight availability/delivery options in-country being subject to local restriction, or limited availability of thermal packaging caused by the global increase in demand. All CT stakeholders need to ensure there are robust end-to-end supply chain processes in place to mitigate any risks in supplying CT material to patients.

Preparation and training – preparation of standard operating practices (SOPs) and training/guidance documents for staff not familiar with decentralised methods for trial conduct will help facilitate a smoother transition in the face of potential further disruption. Creating formalised, structured methods of conducting telemedicine will help in gathering consistent reliable data. If direct-to-patient supply of the investigational medicinal product (IMP) is appropriate, sponsors should consider any training or information the research staff and trial participant will need to allow self-administration of the IMP at home. If self-administration is not feasible, the sponsor should consider the logistics of home visits and how to capture data from remote patient monitoring visits. In preparation for moving to a decentralised model of trial conduct, sponsors should begin to set up vendors and conduct due diligence on providers, including home care providers.

Hybrid Clinical Trials

The pandemic required the rapid adaption to decentralised clinical trial models. What's more is that the regulators (FDA and other agencies) worked closely with pharmaceutical sponsors to provide guidance on how to continue to clinical studies within the realm of the new COVID world. Although decentralised clinical trials and patient-centricity were already trending themes pre-pandemic, the trajectory of frequency has been significantly accelerated. Therefore, we expect to see future clinical trials build decentralised trials into their clinical study protocols. These clinical supply chains will require careful planning to ensure that proper resources, such as conditioned temperature-controlled packaging, is provided to several distribution locations utilised in these hybrid clinical trial models. These distribution locations will include facilities like clinical sites (for site to patient distribution) or central pharmacies, that do not typically have significant resource to support conditioning of temperature-controlled packaging with freezers and refrigerators. As a result, we anticipate that pharma sponsors/CROs will seek cold chain support from their thermal packaging partners.

Technology

The pandemic also spurred the increased utilisation of technology in clinical trials. Virtual clinical trials which include telemedicine visits, remote monitoring, and wearable devices, have become part of the norm. As the pharma industry seeks to leverage additional data from technology, we also anticipate that technology will also be further leveraged in pharma supply chains. The pandemic cast a spotlight on the need for end-to-end supply chain visibility, and we believe the industry expectation will be that crucial investigational and commercialised therapies will be tracked with real-time tracking devices and integrated into holistic supply chain platforms.

Frozen Temperatures

The race towards a rapidly authorised COVID-19 vaccine brought about interesting new challenges related to frozen temperature control. As these vaccine candidates were developed at "WARP Speed", condensing what normally takes upwards of 10 years of research into one year, it necessitated transport of research and ultimately emergency authorised vaccine at temperatures colder than most distribution facilities can accommodate. In working with our customers, we supported "exotic" frozen temperature ranges that included: -30°C to -40°C, -40°C to -50°C, -60°C and colder.

With the deep-frozen temperature demand, it also created surging demand for dry ice. With a dual concern of sufficient dry ice supply and dry ice offload potential for air freight, pharma companies turned to phase-change refrigerants as an alternative to dry ice. These phase-change materials do not require dry ice to support frozen product temperature requirements, and they help avoid the risks associated with dry ice supply and air transport.

Ben Singleton

Ben Singleton is Senior Business Development Manager at Peli BioThermal. Ben has worked for Peli BioThermal for over 12 years and is responsible for a number of key accounts in the Pharmaceutical, Clinical, and Specialist Courier industries. Prior to joining Peli BioThermal, he held a variety of Customer Service, Operational, Sales and Commercial Management roles during 10 years at a worldwide logistics company.

Email: ben.singleton@peli.com

James Klingelhoefer

James Klingelhoefer Director of Sales Americas, has over 12 years experience in various leadership, sales and customer support roles having worked closely with pharmaceutical sponsors, CRO's, CMO's, packaging/labeling providers, and other life science organizations to leverage supply chain efficiencies and identify risk mitigation opportunities. As the former North America Sales Director at World Courier he was responsible for sales operations and clinical operations teams.

Email: james.klingelhoefer@pelican.com