pci CLINICAL TRIAL SERVICES

Delivering the Full Value Chain for Oncology Clinical Trials

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Tim brings over 22 years of experience in clinical packaging. He has been successfully leading and building PCI's Global Clinical & Manufacturing Sales Team for the last three years, and before this led its UK Clinical Operations. He has made a significant and positive impact on team members, Clinical business results and most importantly PCI's client base. Prior to joining PCI, Tim delivered strong results within similar healthcare solution providers focused on sales, program management and operations leadership roles.

The incidence of cancer is increasing across the globe, and pharmaceutical companies are responding with a pipeline of novel therapeutic candidates. Oncology clinical trials are always challenging, and clinical approaches and the needs for supportive services continue to evolve. Partnering with the right contract services organization that is committed to putting patients first is critical. To ensure the right patients get the right doses of the right medicines every time, even for the most advanced and complex next-generation clinical trial materials, those partners should also continually invest in innovation and have a demonstrated track record of performance, the necessary specialized expertise and capabilities, and a global distribution network.

Development of Cancer Therapies Continues Apace

Worldwide, the cancer rate has increased to the point where this disease is now the second leading cause of death, behind cardiovascular disorders.[1] It is predicted that the number of global cancer cases will rise from 18.1 million in 2018 to 29.4 million by 2040.

In 2020, oncology drugs were estimated to account for approximately 30% of the pharma industry pipeline and 25% of pharma industry revenue.[1] The global oncology drugs market was valued at $141.33 billion in 2019 and is projected to expand at a compound annual growth rate of 11.6% to reach $394.24 billion by 2027.

Fortunately, scientific understanding of the causes of cancer and their associated disease mechanisms is advancing rapidly, leading to the continued development of novel and more targeted therapies.

Personalized treatments, particularly immunotherapies, are becoming the norm, with the development and application of traditional chemotherapies declining.[2] Checkpoint inhibitors, T cell–engaging bispecific and multispecific antibodies, antibody–drug conjugates, and chimeric antigen receptor (CAR-T) and other cell therapies are examples of novel drugs that have reached the market.

Unfortunately, these drugs are expensive to develop. Oncology costs continue to rise at unacceptable rates and are predicted to exceed $240 billion globally by 2023.[2] With over 12.5 million new cases of cancer identified worldwide each year, improved diagnosis and treatment is essential, yet oncology clinical research remains complex, demanding, and continually evolving. Despite these challenges, developing and commercializing sustainable, cost-efficient treatments remains paramount.

Every Dose Counts

A primary driver of those high costs is the complexity involved in conducting oncology clinical trials. Each drug candidate and clinical trial is unique, from the patient populations involved to the diagnostic tests required and with respect to the nature of the clinical trial materials.

Trials for rare cancers may involve only a few patients scattered around the world. Those for more common cancers may include tens of thousands of participants. Regardless, with oncology trials, there are no placebos, and successful results at phase I can lead directly to a phase III trial.

Despite each project being unique and the nature of novel oncology treatments rapidly evolving, the patient must always come first. Trials can only be successful when the delivery of GMP-compliant clinical trial materials, whether more traditional or next-generation, is guaranteed to be on time and in full and always of the highest quality.

In the evolving oncology clinical arena, increasingly complex and sensitive drug products, notably including cell and gene therapies, are putting new strain on temperature-controlled logistics, including packaging, storage, and distribution. With many products requiring strict cold-chain (and even ultra-cold) handling from packaging through administration to patients — made even more complicated in decentralized trials where drugs are supplied directly to patients' homes — temperature excursions of any kind are not acceptable. To ensure the integrity of every valuable dose, clinical trials sponsors need to rely on outsourcing partners with impeccable track records of temperature control and many crucial links in the value chain — or integrated partners capable of supporting the entire journey.

A small number of missed doses can disrupt the choreography of large, complex clinical trials. More importantly, however, even one missed dose can be fatal to a patient who has staked his/her life on the clinical trial. Every dose counts, crucially more for oncology clinical trials than in other therapeutic areas. Every participant must have the right dose at the right time, every single time; there is no room for second chances. Clinical trial material providers must have the global facilities, capabilities, expertise, and commitment to ensure that those materials reach the right patients when they are needed without fail.

Outsourcing Partners Crucial to Clinical Research Success

In addition to each oncology trial being unique, constant internal and external pressures make it difficult to sustain traditional approaches to drug development. Increasingly, pharmaceutical companies are relying on partnerships with outsourced clinical trials organizations to achieve their goals.

Contract development and manufacturing organizations (CDMOs) with demonstrated track records of success and the necessary specialized expertise provide support across the entire drug development life cycle. When it comes to provision of oncology clinical trial materials, the best partners like PCI Clinical Trial Services leverage advanced technology solutions and innovative supply chain models to ensure optimal drug delivery. These CDMOs are committed to innovation and quality, evolving with the industry to provide ongoing delivery of both conventional and next-generation oncology therapies.

Handling Highly Potent and Biologic Trial Materials

Many oncology candidate therapies fall into the class of highly potent compounds that require specialized facilities and equipment and highly skilled and trained operators to ensure protection of workers and the environment and the purity and quality of the drug substance/product.

Next-generation oncology drugs, meanwhile, are often biologics or biologics conjugated to small molecule cytotoxic payloads. Biologics present their own set of challenges with respect to stability, with many requiring handling, storage, and shipment at low temperatures. Optimal CDMO partners have global distribution networks with established temperature-controlled infrastructure to enable delivery of biologic clinical trial materials to patients wherever they are located.

The PCI Way

The PCI Way is focused on looking to the future and seeing the potential that digitization and technology hold for the pharma supply chain. We specifically support small to medium-sized pharma and virtual companies who depend on their vendors for success and have a proven track record of being a trusted partner with best-in-class project management and quality teams. Clinical trial supplies are stored in facilities dedicated to investigational medicines, offering extensive environmental controls and monitoring, meeting full requirements for GMP and GDP.

PCI's solution-focused culture and combined capabilities in formulation and analytical testing, GMP clinical trial manufacturing and packaging and global storage, distribution and returns management enables us to provide seamless service throughout the development journey for even for the most complex supply chains.

We offer clinical manufacturing of solid oral dose, liquids and semi-solids, including highly potent products and biologics with cold chain with temperature ranges including refrigerated (2–8 °C), frozen (–20 °C, –40 °C, –80 °C) and cryogenic (–196 °C) for advanced medicinal therapeutic products, such as cell and gene therapies.

All of these services are linked to PCI's comprehensive global clinical supply chain that ensures on-time delivery of specialty medicines, including controlled substance

drug products, highly potent and cytotoxic drug formulations, temperature-sensitive biologics, and cell and gene therapies, safely and carefully to patients at clinical trial sites around the world. That network is always being improved through continuous investment in new technologies and capabilities. We recently invested $20 million to expand clinical and commercial packaging and release testing capabilities at our Biologics Center of Excellence (COE) in Philadelphia and cold-chain capacity at numerous global locations, expanded our primary and secondary packaging and labeling at the Clinical Services Center of Excellence in Rockford, Il, and. added a state-of-the art storage, logistics, and distribution center for clinical trials for the West Coast at our San Diego site.

Significant investments have also been made as PCI has traveled on its digital transformation journey with the goal of improving our processes, increasing both efficiency and transparency and effectively transforming the firm from a successful packaging and labeling company to a successful pharmaceutical supply chain company. We have implemented foundational front-office and back-office operations that are now integrated with digitalized core business processes, become a more collaborative organization and now leverage advanced data analysis and modeling tools to drive new insights that inform decision-making processes throughout the company.

Supply chain visibility is ensured via the pci | bridge digital solution, which provides real-time supply-chain information, including inventory, production, distribution and shipping data, to customers. This platform technology enables customers to make informed decisions based on real-time insights, collaborate more effectively, speed validations, create customized reports for greater efficiency, and do so knowing their sensitive project information and data is protected in a cyber-secured platform. The pci | bridge system is suitable for clients of any size and projects at any development stage and has been designed to be effective for very small clinical trial projects to very large-scale commercial products.

In addition to serving as a bridge to our customers' full supply chains, the pci | bridge platform serves as a bridge connecting PCI to patients in need of life-changing therapies by facilitating the manufacture and delivery of our customers' products and ensuring that every critical dose is delivered to patients in need.

Client- and Patient-Centric Services

PCI Pharma Services believes that, with our focus on client and patient centricity, we are an important bridge between our clients and the patients for whom they are developing novel, life-improving, and lifesaving medicines.

We are a market leader when it comes to clinical trial supply services, providing our clients the leading customer experience by delivering cost-effective, flexible, and unrivalled drug resources around the world. Our commitment to helping our clients improve patients' lives is proven daily with our uncompromising culture, which is focused on quality and excellence, our industry leading best practices and our solid regulatory position.

PCI Pharma Services is driven by the journey of the patient and passionate about working with oncology trial sponsors to extend and improve the lives of people dependent on the novel and often challenging and complex clinical trial materials and commercial drugs we manufacture. We truly understand that every dose counts and support the delivery of both conventional and next-generation oncology therapies with peace of mind.

References

1. *Oncology Drugs Market Size, Share & COVID-19 Impact Analysis... 2020–2027. Fortune Business Insights. Aug. 2020.*
2. "Emerging Oncology Trends: 2021 and Beyond." *Aptitude Health*. 8 Jan. 2021.