

Express delivery

The Covid-19 pandemic has posed existential questions regarding clinical trials: namely, how they should be conducted under conditions of lockdown and social distancing. **Yourway** has led the industry in advocating and implementing direct-to-patient drug delivery as a method of safely and efficiently ensuring continued drug development.

The pandemic remains a globally disruptive entity that can impede the efficacy of clinical trials. But life must go on – especially clinical trials that continue to improve medicine and medical devices. With the sharply altered landscape, companies need to ensure their trial is safe from the travails that can impact at any point along the way from direct-to-patient (DTP) and direct-from-patient (DFP). Choosing the right partner helps you concentrate on obtaining optimal results from at-home populations.

Even before the pandemic, DTP models of clinical trials positively impacted pharmaceutical development because they increase patient retention, expand the ability to reach a dispersed population and bolster patient satisfaction. Now, DTP models are increasingly becoming the norm, and will likely be the typical way clinical trials are performed after the Covid-19 pandemic.

Before Covid-19, approximately \$2.28bn was spent by pharmaceutical and other companies recruiting patients. There was a staggering rate of failure of finishing on time (nearly 80%), and of retaining the number of patients through to trial conclusion (85%), according to the Office of the Assistant Secretary for Planning and Evaluation at the US Department of Health and Human Services.

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This was before the pandemic created severe impairments and hurdles in the clinical trial process. Before Covid-19, every day that a trial was delayed would puncture the bottom line by devouring hundreds of thousands of dollars – and



Yourway sits at the forefront of the rapidly expanding DTP drug delivery service.

of course, on the other end, potential revenue was lost by the product not being on the market.

For years, the industry has been gradually transitioning into decentralised/virtual clinical trial models. These create a more patient-centric experience, which has been reported to help increase patient retention, protocol compliance and data quality. During (and following) Covid-19, the patient-centric model has and will become, by sheer necessity, more dominant.

A global leader that knows how to navigate the complex field of

and clinical packager in the global clinical trials supply chain market, has been a pioneer in this service, and has constructed a global network and substantial expertise to ensure continued and uninterrupted clinical trial execution and fulfilment.

Delivery modulator

Despite the current global pandemic, Yourway is operating at 100% efficiency, and is continuously seeking ways to increase capacity to compensate for potential supply chain gaps created by changing travel restrictions and interruptions in the services of other providers. “Our DTP services are operating globally without interruptions,” Gulam Jaffer, president of Yourway, has assured. “Additionally, we have successfully initiated rescue projects for DTP services in areas where other providers have not been able to operate.”

Yourway also has protocols in place to facilitate customers seeking to transition from traditional centralised clinical trials models to DTP models, allowing immunocompromised subjects to remain at home but still receive therapy.

Paramount to Yourway's operational resiliency during this unprecedented pandemic is its robust global network, experience with domestic and international logistics, strict adherence to good manufacturing practices (GMP) and good distribution practices, including detailed business continuity programmes, and its extensive experience in the clinical trial space. In uncertain times, clients need to be sure of the quality and safety of clinical materials through the entire supply chain journey.

Yourway's abilities have both expanded and become fortified through strategic collaborations. For example, a recent key alliance with a notable niche service provider for patient-centric home healthcare provides coordinated supply and product deliveries, and administration services for virtual/decentralised clinical trials of all types and sizes. "The collaboration enhances others we have with specialised providers to better support patient retention and compliance, while also helping CROs and sponsors improve the efficiency of clinical trial management," Jaffer explained.

Clinical products and equipment are sent directly to the patient. In addition, collected bodily samples and other materials are shipped from the patient's home through a courier. In-home patient care is performed by an approved healthcare provider.

The current pandemic should increase the number of sponsors that will embrace the decentralised/virtual model for studies and incentivise faster adoption of the same model for more studies moving forward.

Creative solutions

Yourway's team of experts have proactively monitored the global pandemic situation and implemented solutions for changing conditions brought forth by Covid-19. All these measures have allowed Yourway to continue to efficiently support several ongoing global clinical trials, while protecting the integrity of intellectual property and ancillary products being stored and transported. As an example, with current travel and social distancing restrictions in effect, Yourway offers virtual audits to protect the health and safety of employees, clients and stakeholders, allowing auditors the ability to conduct full



The company provides both primary and secondary packaging of treatments.

audits with real-time access to Yourway's facilities and documents from anywhere they are located.

Challenges vary and can heavily impact a trial, even causing it to halt – especially in a pandemic. Yourway's capabilities should greatly reassure companies that make tremendous investments in trials. Yourway and its collaborative team perform:

- procurement of comparator drugs and ancillary supplies
- both primary and secondary clinical packaging
- translation services
- label and booklet printing
- Qualified Person releases
- Importer of Record and customs brokerage services
- specialised, temperature-controlled transportation and storage for all temperature ranges, from -180°C to $15-25^{\circ}\text{C}$
- temperature-controlled storage at one of Yourway's 21 global GMP depots, strategically located in all continents
- integrated in-home healthcare services
- returns and destruction services with full accountability.

Meanwhile, on the patient side, Yourway's team understands the intensified stress level and fear of trial interruption. The home care experience is approached with respectful sensitivity, and Yourway leverages knowledge of how to provide comfort and reassurance to patients and their loved ones, who are having to cope

with the additional stresses that are associated with their treatment.

"Attention to details such as the coordination of intellectual property delivery, to be executed exactly when the healthcare provider is arriving at the patient's home, is one of the numerous white-glove services provided by Yourway," said Jaffer.

Yourway assigns a project management team, including a project manager to each study; the team works closely with clients to analyse and understand the complexities and unique needs of the study protocol. The team creates solutions based on the needs of the patients, of the sponsors and of the healthcare professionals performing in-home care. As a result, the DTP solutions Yourway implements are always based on patient-centricity, while offering safety, protocol, regulatory compliance, cost-efficiency and operational excellence.

The convenience of having one service provider and one project manager assigned to coordinate the planning and execution of services is more important now than ever. This pandemic will eventually recede and be under control, but other epidemics will appear before they too are contained. Through it all, DTP studies will be ongoing across the globe, and Yourway will be there to ensure success. ●

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