

# WorldPharma

Clinical Trials Insight

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## On point

**Gulam Jaffer**  
on how Yourway can  
protect clinical trials in  
the wake of Covid-19

**YOURWAY**  
THE BIOPHARMA SERVICES COMPANY

Direct-to-patient • E-consent • Real-world evidence • Supply chain agility



# The new normal in clinical trial protection

In an unprecedented time of worldwide disharmony amid concerns for supply disruption, **Yourway** can help navigate the critical supply chain journey for all stages of a successful clinical trial. It manages this through its development, execution and conclusion. Gulam Jaffer, president of Yourway, explains how.

In this ongoing global pandemic, which has levelled economies and curtailed research and development, launching or continuing trials represents a major hardship and challenge. As impacts from the novel coronavirus, or Covid-19, become more extensive, a major concern raised throughout the industry and the public is whether critical supply chains and clinical sites will be interrupted. This creates apprehension about whether patients can depend on a reliable supply of medicine, for treatment and ongoing clinical trials.

This is on top of the fact that nearly 80% of conventional clinical trials do not finish on time, with 20% delayed for six months or longer; for a major drug, each day a trial is delayed amounts to a revenue loss of approximately \$8m, and about \$600,000 per delayed day for orphan drugs.

Those concerns may be allayed by working with a global leader in providing direct-to-patient (DTP) and direct-from-patient services (DFP) for decentralised/virtual trials, ensuring the pathways of supply and delivery are clear, efficient and reliable. Yourway has been a pioneer in this service platform for years, and has a global network and substantial know-how to ensure continued and uninterrupted human clinical trial execution and fulfillment.

DTP models of clinical trials have been proved to positively impact efficient pharmaceutical development, as it improves patient retention, expands the ability to reach a dispersed population, and also bolsters patient satisfaction.

## Better than the rest

Yourway's experience, in supporting various and complex protocols, provides

a trial with reliable solutions to initiate rescue projects for DTP/DFP services in areas where other providers have not been able to operate. It also facilitates the implementation of DTP/DFP protocols to support sponsors seeking to transition from traditional centralised or virtual clinical trial models to decentralised or virtual models, allowing immunocompromised subjects to remain at home while continuing to receive therapy.

While Covid-19 is threatening to impede research progress, Yourway has demonstrated operational resilience during this unprecedented pandemic through its robust global network; experience with domestic and international logistics; strict adherence to good manufacturing practices (GMP) and good distribution practices (GDP), including detailed business continuity



Yourway's integrated project management, of having one coordinator of planning and execution services, is more important now than ever before.

programmes; as well as its extensive experience in the clinical trial space.

Despite all the disruptions that Covid-19 has created, Yourway has maintained its operations by navigating to overcome all challenges globally. In addition to the strict GMP and GDP cleaning requirements that already govern its facilities, vehicles, equipment and employee personal hygiene, Yourway has additionally taken internal measures to further augment these procedures.

*“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.”*

The company is monitoring the situation and the implementation of solutions during the ever-changing conditions created by Covid-19. These measures have allowed it to continue to efficiently support several ongoing global clinical trials, while also protecting the integrity of the investigational product and ancillary products being stored and transported.

With the current shelter-in-place recommendations, clinical trial sponsors are seeking avenues for the delivery of care to their immunocompromised patients, who require continued therapy. To mitigate this challenge, several centralised studies currently in place are being converted into decentralised/virtual

studies to afford patients the ability to continue to receive treatment at home.

The current experience should increase the number of sponsors that will utilise the decentralised/virtual model for their studies, and incentivise faster adoption of the same model for more studies moving forward. Yourway has and will continue to assist organisations seeking to make this transition.

Most decentralised/virtual trials require in-home care services in both pandemics

and epidemics. From the onset of every project, Yourway designs solutions based on the needs of patients, sponsors and the healthcare professionals performing in-home care. As a result, the DTP solutions implemented by Yourway are always based on patient-centricity, while offering safety, protocol and regulatory compliance, cost-efficiency and operational excellence.

Most recently, the number of requests for Yourway's DTP courier services has increased significantly. It continues to expand its ability to quickly review the requirements of each study protocol and create, present and deploy the most adequate, efficient, safe and

reliable solution, with a disciplined focus on patient-centricity, caregiver requirements, regulatory/quality compliance and privacy requirements.

### Under pressure

On the patient side, the company understands exaggerated stress levels and the fears of trial interruption. The home care experience needs to be one of respectful sensitivity, of knowing how to provide comfort and reassurance to patients and their loved ones, who are additionally coping with stress associated with the treatment.

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

This necessary shift towards DTP trials presents additional supply chain complexity, requiring the coordination of various systems and stakeholders to reach patients at the right time – and at their preferred location. The presence of a DTP/DFP expert enables researchers and drug developers to launch promising therapies. The DTP/DFP model also promotes the maintenance and compliance of patient populations by providing materials and appropriate care in a manner that is convenient and safe for them.

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. Yourway continues to excel at meeting its requirements while providing customised solutions to support the missions of its clients.

Everyone at Yourway embraces its tasks with great dedication, regardless of project size or scope.

The company provides the best customised solutions to support its clients in the noble mission of improving the outcomes of important studies. It also knows that all these collaborative efforts will help improve the quality of life of patients enrolled in each study, and of many other patients once the therapy is approved and launched commercially. ●



Direct-to-patient delivery methods are fast-becoming the most effective means of continuing trials.

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