

# Direct and agile

Clinical trials, and the patients that participate in them, face an unprecedented set of challenges in the time of Covid-19. An agile approach, and the use of direct-to-patient logistics services, can alleviate the pressure on both the trial sponsor and patients. With its dexterous global capabilities and expertise, **CSM** is committed to helping mitigate the impact of the pandemic on clinical trials and supporting patients.

**W**hile the Covid-19 pandemic is still disrupting life as we know it, countries are slowly moving into the recovery phase. However, many precautionary measures remain in place, and experts warn of a possible second wave. Adopting a different approach to running clinical trials that are vital to the health of citizens worldwide can help ensure that trials are still able to be completed successfully.

So how can direct-to-patient (DtP) positively impact the clinical trial process and the lives of patients?

A DtP platform is a patient-centric approach to clinical supplies, in which the supplies are prepared, packaged, labelled and then shipped directly to the patient's or caregiver's home. Choosing to work with an experienced clinical supply management provider will ensure that products are delivered at the right time, at the right temperature and within the right guidelines.

*“A DtP platform is a patient-centric approach... in which the supplies are prepared, packaged, labelled and then shipped directly.”*

An agile service provider can adapt ongoing studies with DtP services, and turn traditional clinical trials partly or completely into DtP trials. Working with a supplier, especially with experience in shipping the medication directly from the drug depot to the patient's home, mitigates the impact on sites such as hospitals that may be under pressure during the current crisis. Being able to provide site-to-patient shipments, and adapt a trial quickly, is also an asset. Agility ensures that the service provider can meet the needs of the trial sponsor, site and the patients.



With the scope of trials diminished during the pandemic, direct-to-patient may be the best way forward.

Choosing the DtP method enables patients to receive the medication on time and avoid the risk of being exposed to Covid-19 at clinical trial centres. While

covers supplies, storage and distribution has never been more important.

### For the greater good

Working with an experienced global clinical supplies partner with agile managerial and operational systems, and the ability to provide innovative solutions can make the difference. Introducing DtP brings the product to market faster, minimises disruptions and expands patient take-up.

With over a decade of experience working together with trial sponsors, couriers and clinical sites managing DtP studies, CSM has delivered over 5,000 DtP shipments to trial participants. As part of Clinigen Group, CSM has the global footprint to deliver large international phase-III studies the agility to give every trial personal attention and customise the service solutions as needed, even in these challenging times. ●

DtP shipments have limitations in Europe, some restrictions have been lifted because of the pandemic. DtP investigational medicinal product (IMP) delivery from site to trial participant is now accepted in several EU member states. Even DtP from depots to patients has been accepted by authorities in rare cases, when justified.

While there were already many factors to take into account when conducting international trials, such as changing regulations and importation requirements, the Covid-19 pandemic has introduced a new dimension. Having a detailed plan that

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