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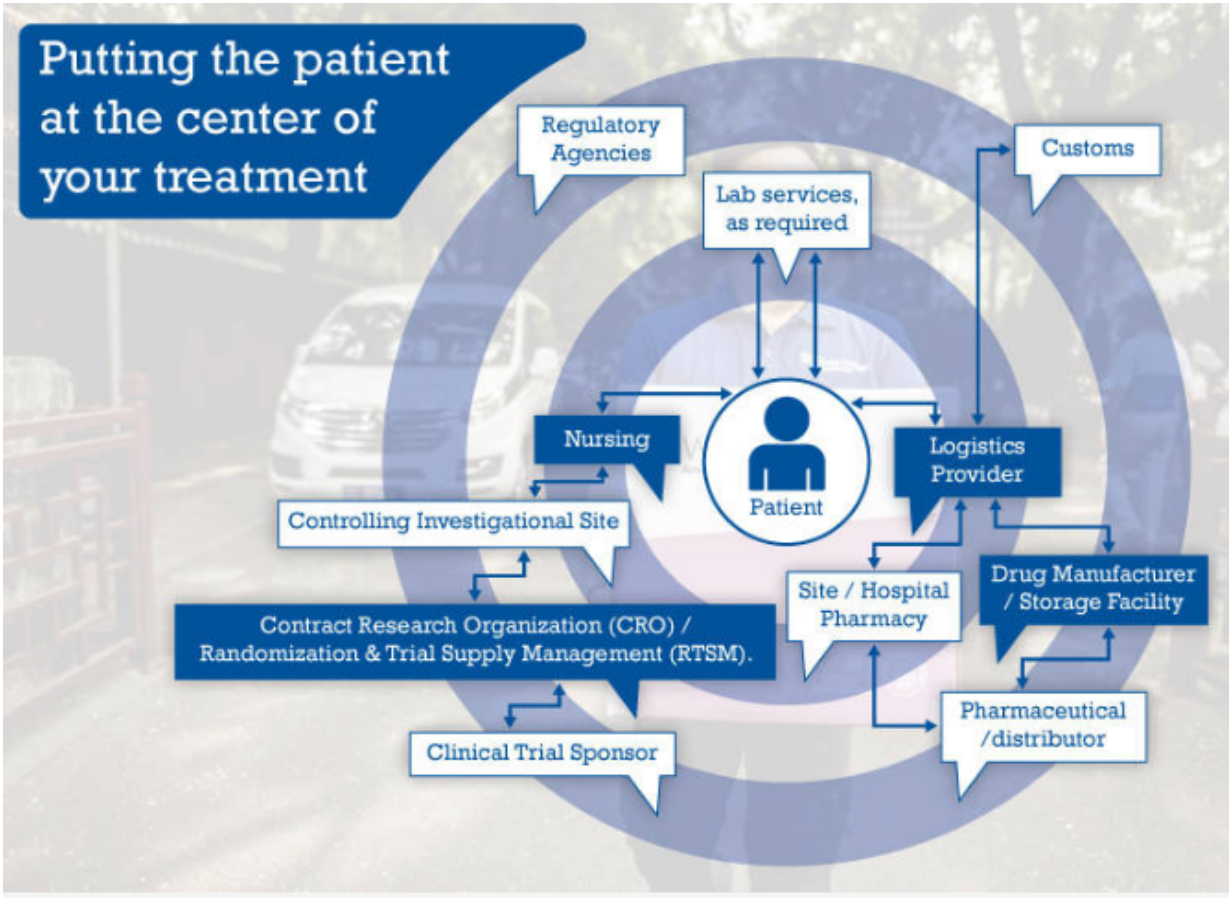
The Challenges of Direct-to-Patient Logistics

By Mike Sweeney

In a decentralized, virtual or hybrid clinical trial, study participants should seldom or never have to travel to a research site to obtain the study drug. Direct-to-Patient logistics (DtP) employs an integrated supply chain system that enables study participants to receive study drug in their own home or place of work. DtP also eliminates the need for research sites to store, dispense and track study drug.

DtP services can include dispensing the study drug, transporting it to the study participant, and storing it in the home in a temperature-controlled appliance. The return of unused drug and patient sample collection can also be called "Direct-from-Patient (DfP)." Studies that employ DtP are also likely to employ DfP, and the term DtP sometimes also encompasses DfP services.

The premise of the DtP model is straightforward: Investigational medicinal product (IMP) is delivered to and taken or administered in the study participant's home. However, the execution can be complex because it requires the study sponsor, CRO, research sites, home nursing services, labs, specialty couriers, pharmacies, drug storage facilities, and packaging companies to focus their work on individual study participants rather than research sites.



DtP services for standard medications typically employ standard postal or express courier services. However, specialty courier services are required if the medication requires a temperature-controlled environment or a higher level of physical control and tracking (e.g., for a controlled substance).

DTP is complicated by the following three challenges:

Challenge 1: Regulatory Requirements

A study that employs DtP must comply with the regulations of each governmental jurisdiction where study participants are located. As a relatively new model, DtP might be subject to closer scrutiny by regulatory authorities than traditional distribution models. The study protocol should clearly detail any DtP elements and are subject to pre-approval from each health authority.

Regulations that are applied to DtP typically did not envision clinical trial DtP scenarios. For example, Israel's regulations that govern deliveries from online commercial pharmacies also apply to clinical trial DtP.

Import regulations, procedures, facilities and timelines vary widely by country and can be subject to change on short notice.

Regulations governing home healthcare and DtP drug distribution vary by country, state and province. Several countries have regulations concerning drug dispensing for in-home use. Typically, these regulations cover in-country distribution. However, in some situations, exceptions are allowed for "out of country" deliveries. Exceptions, such as shipping across EU country borders, are normally approved as part of a clinical trial protocol in the country where patients are treated, potentially with oversight by authorities in both countries.

Challenge 2: Timing and Temperature

DtP demands that pick-ups and deliveries happen within a predetermined and often extremely tight timeframe, and potentially over long distances. As with any pharmaceutical shipment, the integrity of the cold chain is essential. Consider the impact should any of the following events occur:

- The drug arrives late or is lost in transit.
- The drug has expired.
- The drug has been exposed to damaging temperatures, e.g., in a customs facility, a nurse's car, or a study participant's home.
- The study participant is not available when the nurse arrives.
- The nurse is unavailable to administer the drug on schedule.
- Replacement drug is unavailable or costly.
- Study participant or nurse frustration causes non-adherence or drop out.
- Cultural norms prevent a nurse from visiting the study participant's home or interacting with the patient (e.g., a male nurse and a female study participant).
- Any of the above problems create a protocol deviation or serious adverse event.

Challenge 3: Patient Confidentiality

Most countries and sometimes states or provinces require compliance with HIPAA, the General Data Protection Regulation (GDPR), or other privacy laws. DtP requires providing personal information, e.g., names and home addresses, to various people and companies. Those within the supply chain that need this information might include the dispensing

pharmacy, home-visit nurses, couriers, and anyone else involved in coordinating or making deliveries to patient homes.

Most participants consider their participation in a clinical study private information. Your DtP plan must address these privacy issues, especially when confidential information passes from one service provider to another, and might be exposed to third parties, e.g., customs officials, delivery personnel, and neighbors.

Conclusion

DtP is an essential ingredient in many virtual, decentralized and hybrid clinical studies. Such studies often require DtP coordination with other home services, such as physical examinations and blood draws. DtP is subject to regulations, distribution channels, and cultural norms that vary by geography and might be problematic. A study sponsor contemplating a DtP clinical study must therefore ensure that experienced and capable people plan and conduct the DtP elements of the study.

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