



SEPTEMBER
2022

DIRECT TO PATIENT

A SOLUTION TO BE CONSIDERED IN
YOUR CLINICAL DISTRIBUTION PLAN

STUDY
CASE #2

Managing Direct To Patient shipments in a decentralized clinical trial

WHAT IS DIRECT-TO-PATIENT LOGISTICS?

Direct-to-Patient (DtP) is an integrated supply chain system that enables patients to receive treatment in their own home.

DtP also includes patient sample collection and return management. These services are often required in parallel and might be considered Direct-from-Patient (DfP) solutions.

IMPs/IPs can be shipped from an investigational site or from a depot.



SITE TO/FROM PATIENT

IMP(s) are sent by CREAPHARM to the hospital pharmacy. Then, CREAPHARM arranges the pick-up & IMP(s) delivery to the patient, sometimes located several hundred miles from the investigational site.

IMPs/IPs returns or sample shipments can then be arranged from patient's home to the hospital pharmacy and central labs.



DEPOT TO/FROM PATIENT

IMP(s) are directly shipped from the warehouse* to the patient's home, office or vacation destination. Returns are arranged from patient's home to the warehouse*.

* CREAPHARM or one of its 40 partner depots

#MAKE YOUR TASK EASIER



"Selecting the right carrier solution is critical. Dedicated transport is strongly recommended to ensure efficient delivery to the patient"

Jérôme Haro

Project Leader Distribution
at CREAPHARM CLINICAL
SUPPLIES



"A local depot partner is necessary while dealing with regulatory challenges varying worldwide"

Sébastien Terrier

Depot Manager
at CREAPHARM CLINICAL
SUPPLIES

CHALLENGES WHILE MANAGING DTP LOGISTICS

While DtP has proven its advantages, it remains a complex logistic pathway, requiring expertise and flexibility

Regulatory compliance

The Dt/fP distribution strategy must be described in the submission dossier and authorized by Competent Authority(ies).

Patient must have consent to disclose his/her personal contact details for delivery purpose

Regulations governing DtP vary worldwide. For instance:

- authorization for operating DtP in the country
- clinical labeling specificities are required while handling DtP distribution in some countries (ie: Israel).
- a prescription form issued by the investigational site should have to be provided to the carriers (ie: Australia)



Maintaining Patient Confidentiality

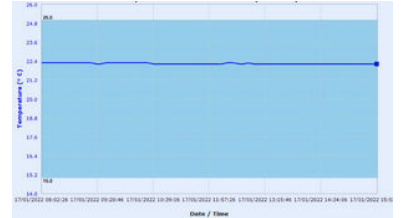
When IMP/IP are sent from site to patient home, patient confidentiality is ensured by the hospital and carrier. CREAPHARM or any depot only manages a unique patient number.

Managing a Depot to Patient shipment means dealing with a shipment without knowledge of the patient address.

Once again, local regulation impacts data confidentiality management. The carrier must be compliant for data preservation and destruction operations.

Full Traceability

Good Distribution Practices apply when managing Direct To Patient shipment. Thus, temperature monitoring is handled through the supply chain to guarantee cold chain management and consequently IMP/IP integrity.



**About Clinical Trial Decentralization
Capgemini Invent Report 2022 (1)**

As of 2020, only 0.5% of clinical trials conducted worldwide were decentralized (~1,000 to 2,000 DCTs). While drug-based interventional DCTs only experienced a 7% CAGR between 2014 and 2019, most of the trials turned into DCT in the course of 2020, due to the obvious constraints. The COVID-19 pandemic significantly accelerated the adoption of DCTs, with an increase in trial activities conducted remotely and in participants' homes.

The global DCTs market size is projected to reach Bn 9,1 USD in 2026, from Bn 1,8 USD in 2021, at a CAGR of 38.5% during 2021-2026.

(1) https://www.capgemini.com/fr-fr/wp-content/uploads/sites/2/2022/04/PoV_DCT_Def.pdf

QUICK FACTS

01

SPONSOR CHALLENGES

Giving Patient access to investigational drugs while staying at home

Reducing costs and storage at clinical sites

Increasing patient enrollment and retention

Gaining access to a wider patient population

Reducing patient trips to clinical sites

02

CREAPHARM'S APPROACH

#1challenge1solution
Providing each sponsor with tailor-made solutions for both packaging & logistic operations

Patient centricity

Deadline commitment to meet the patient needs

Full Traceability to guarantee patient safety by IMP/IP integrity

03

CREAPHARM'S SOLUTION

The **right logistics solution** for clinical distribution in each clinical trial

Efficient & reliable logistic pathway

Regulatory advice shared by the CREAPHARM's experts and partners.

A strong depot network bringing **local support** for operations and regulatory country specificities

A **dedicated Clinical Supply Manager** supported by specialists