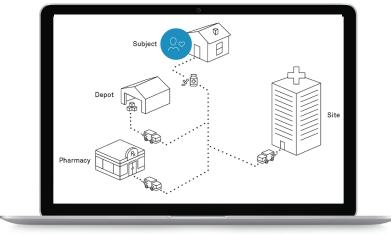
Rave RTSM Direct-to-Patient



As the healthcare industry continues to deepen its focus on virtual trials and patient-centricity, the popularity of Direct-to-Patient (DtP) services in the clinical trial setting has grown significantly.

Rave RTSM DtP (Randomization and Trial Supply Management Direct to Patient) brings investigational medicinal products (IMP) directly to a patient's home, bypassing the need for the patient to travel directly to a site.

Sponsors and CROs can manage DtP shipments for clinical trials or medicinal device trials. The benefits are:

- · Patients are able to access customized care and novel therapies from the comfort of their homes
- Biopharmaceutical companies are able to facilitate patient enrollment and increase patient adherence, which are central to the study's success

Rave RTSM Direct-to-Patient Benefits

Medidata RTSM Direct-to-Patient delivers solutions across many dispensation scenarios. Beyond responding to COVID-19 disruptions, DtP trials are an opportunity to address fundamental patient burden issues that affect drug development programs.

Flexibility

- Ability to set individual visits to DtP through the treatment schedule
- Configurability on the visit, site and country level
- Sites are empowered to determine if a patient visit should be DtP or sourced from site stock

Fully Decentralized

- Sites can be configured to follow DtP visit schedule or to dispense from site inventory
- Dispense from site or directly generate a shipment from depot
- No risk to patient privacy

Real-Time Visibility

- Full life-cycle view of DtP shipments and dispensations
- Depot to patient
- Site accountability
- Site to site destruction depot

Hybrid Model

- Sites can be configured to follow a hybrid model combining virtual and physical sites
- Manual dispensations can be sourced from site inventory or depot inventory
- DtP can be turned on or off for sites and countries

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Medidata & RTSM Support of Virtualization

The DtP approach brings investigational products directly to a patient's home, bypassing the need for the patient to travel directly to a site.

The native architecture of our Rave eCOA, and RTSM allows these products to seamlessly share and action data





The Medidata Advantage

Given the changing dynamics of clinical trials and the demand for more patient centric approaches, Rave RTSM supports Direct-to-Patient shipments. With Rave RTSM DtP, sponsors and CROs can manage DtP shipments for clinical trials or medical device trials, all while maintaining patient confidentiality.

Rave RTSM DtP plays a crucial role in the success of trial virtualization. When Direct-to-Patient dispensation is processed in Rave EDC, a shipment request is raised with the configured DtP depot to request a patient/visit specific dispensation.

Only Rave RTSM has the flexibility to define at a site/visit/patient level when to trigger a DtP shipment of an IMP or source it from site stock with no down time. The Medidata Clinical CloudTM makes it easy to set up Direct- to-Patient (DtP) shipments and the flexibility needed for the greatest efficiency.