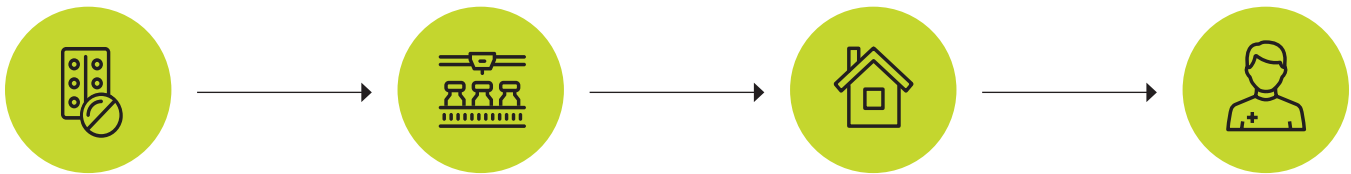# Medidata Rave RTSM for Direct-to-Patient

As the healthcare industry continues to deepen its focus on patient-centricity, the popularity of Direct-to-Patient (DtP) services in the clinical trial setting has grown significantly. The DtP approach brings investigational medicinal products (IMP) directly to a patient's home, bypassing the need for the patient to travel directly to a site. The benefits of this 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 success of clinical trials

Randomization and Trial Supply Management (RTSM) solutions play a crucial role in the success of a Direct-to-Patient trial. Because drug supplies are being managed and shipped from distribution facilities directly to patients' homes, a sponsor must have a high-quality system in place to accurately track the chain of custody, ensure patient-blinding and handle other logistical challenges, while ensuring that **the right treatment reaches the right patient at the right time**.
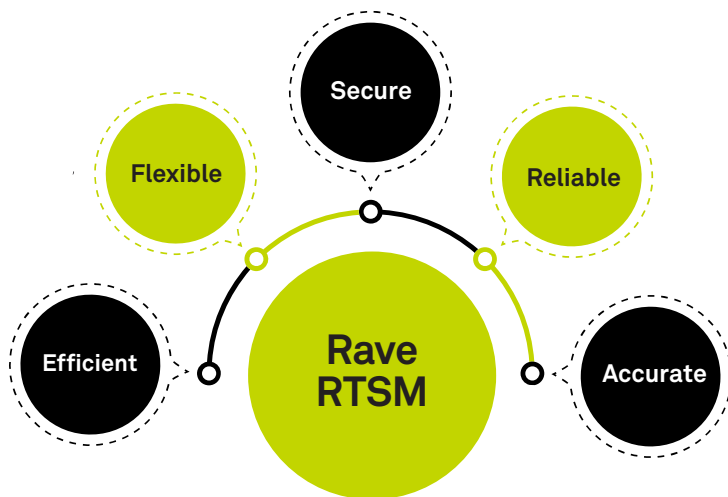
Given the changing dynamics of clinical trials and the demand for more patient centric approaches, Medidata now supports Direct-to-Patient (DtP) shipments. With Medidata's Rave RTSM, sponsors and CROs can manage DtP shipments for clinical trials or medical device trials, all while maintaining patient confidentiality since patient addresses are never stored in Rave RTSM.

Since virtual or DtP trials require agility in visit scheduling, **visits may be marked in the study configuration as home visits and/or at the site, so that kits can be sent directly to the patient using the Depot/Central Pharmacy inventory.** 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 including the Subject Identifier so the depot can ship or courier the items to the patient.

Key features of Rave RTSM for DtP are:

- Use in new and existing studies

- Flexibility in making mid-study changes

- Ability to set individual visits to Direct-to-Patient through the Treatment Schedule

- Configurability on the visit and site level

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- Dispense from site or directly generate a shipment from depot

- Manual dispensations can be sourced from site inventory

- Sites can be configured to follow the DtP visit schedule, or to dispense from site inventory, supporting a trial combining virtual and physical sites

- Full life cycle view of DtP shipments and dispensations (e.g., depot to patient, site accountability, site to destruction depot)

Robust Capabilities	Streamlined Workflows	Unified with Rave EDC
Timely dispensation from Depot to Patient	Minimum manual changes associated with site to patient shipments	A connected platform suite of solutions enables more robust data insights in multiple dimensions
Comprehensive capabilities for sites to work remotely as needed	Efficient dispensation from site or shipment from depot	Driving shorter timelines, improved quality, and faster decision-making

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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