Optimizing Direct-to-Patient Supply Management: ClinChoice and 89Bio Case Study

PIVOTING TO PRESERVE CONTINUITY OF CARE

The CRO ClinChoice and the sponsor 89Bio were conducting a phase II, randomized, double-blind, placebo-controlled study to explore the efficacy and safety of investigational drug X in subjects with severe hypertriglyceridemia (SHTG). The companies needed to **pivot to a decentralized protocol during the pandemic or face trial disruption**.

Needing to maintain trial integrity during the COVID-19 pandemic, while prioritizing patients' safety and their continued participation in the study were key factors to initiating a Direct-to-Patient (DtP) solution. **This allowed the patient to choose to be dosed on site or at home.**

However, with 300 sites and 200 patients across both the US and Canada, the trial's hybrid approach needed to adhere to differing regulatory guidelines. It also required the ability to provide flexible dispensation preferences (i.e., home or site based on each dosing visit), and quick response to remote patient needs.

ClinChoice and 89Bio needed **a partner that could provide the ease and flexibility to rapidly execute DtP,** while ensuring Investigational Product (IP) supply management and optimization.

ClinChoice's longtime partnership with Medidata across multiple trials and different solutions earned their trust and confidence, and they engaged **Rave RTSM's DtP capabilities and professional services to ensure the clinical trial's success**.

RAVE RTSM: DIRECT TO PATIENT (DtP)

Delivers IP directly to a patient's home, bypassing the need for the patient to travel directly to a site.

What to Ask When Considering A DtP Solution

Can DtP manage different dispensation scenarios (site vs. patient home)?

How are shipments triggered by RTSM in those different scenarios?

Does DtP trigger dispensation prior to an upcoming visit?

Are roles assigned to designated personnel in the dispensation process?

Can action items be triggered in the dispensation process?

How will your team be trained and supported when adopting a DtP solution?

Considerations When Engaging in DtP

To succeed in implementing DtP in tandem with Depot to Site options, the IP Supplier, Clinical Operations, Data Management, and the Site would have to address challenges and considerations and collaborate to define processes to support what was for many their first experience with DtP capabilities.

The Learning Curve

Lack of experience and knowledge to determine DtP or Depot to Site dispensation options raised concerns about a steep learning curve.

Processes and Document Changes

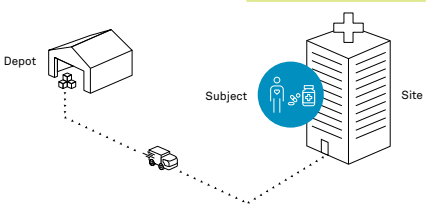
Thorough understanding of the advantages of using DtP rather than a traditional depot required an adaptive, creative, and decisive approach for successful implementation.

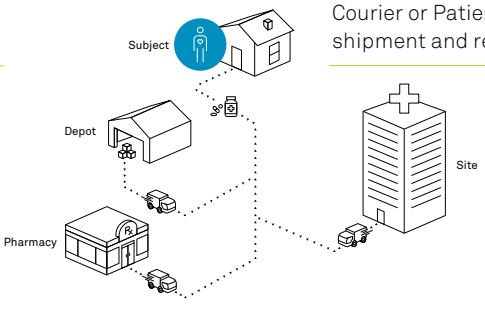
Policy Differences Across Countries

Management of dispensation in light of differing regulations (US allows DtP, Canada does not) required a flexible solution.

Differences between traditional Depot to Site and DtP

TRADITIONAL DEPOT TO SITE	DtP
Dispensation occurs on-site	Allows patients to choose on-site or at home
Resupply Prediction Algorithm runs daily	Daily Prediction Algorithm is not applicable
Site Shipping Address is stored in the system and embedded in Shipping Alerts	Patient Shipping Address is captured outside of Rave EDC/Rave RTSM
Site reports to temperature excursion, quarantine or confirm shipment	Courier or Patient to contact site to confirm shipment and report temperature reading





Keys to DtP Success

With guidance and training from Medidata's Professional Services team, the CRO and Sponsor/Site:

- ☐ Created a connected DtP workflow, providing step-by-step instructions to assign action throughout the DtP process, eliminating confusion and margins of error
- ☐ Received training and eLearnings prior to RTSM DtP setup to promote usability and compliance
- ☐ Created a dispensation source field in eCRF (electronic case report form), a critical data point to direct IP for a particular visit
- ☐ Assigned designated personnel to trigger dispensation prior to upcoming visits to accelerate data entry of dispensation source field
- ☐ Used Business Object© (BO4)'s daily ad hoc report with enhanced alerts to the study team to trigger dispensation, while also taking tracking responsibilities

A Comprehensive DtP Solution

The industry's leading RTSM provider, Medidata was a clear choice for 89Bio and Clinchoice in their adoption of DtP, allowing trial continuity and maintaining focus on patient centricity by alleviating the burden of patients who have to travel to the site.

Medidata worked with the Sponsor, CRO, site, and depot to integrate the DtP system across the entire supply chain. Its agility to be used in decentralized, hybrid, or on-site trials and **flexibility to offer a choice of dispensation scenarios**, whether at the patient or visit level, ensured it met both US and Canadian regulation requirements, and **supported accelerated processes by automating workflows**.

Rave RTSM enabled the study team to have a full overview of all shipments, including DtP shipments status updates for IP at each point. RTSM, like all solutions across the **Medidata platform, does not maintain patient identifiable data**, such as patient addresses. This information is kept outside the system and is managed via direct communication between the sites and the depot, removing an opportunity for a breach of patient identifiable information (PII).

In a changing global landscape, 89BIO and ClinChoice took advantage of the opportunity to explore the use of enhanced Rave RTSM DtP technologies, **accelerating their own digital transformation and increasing patient satisfaction**.