Case Study

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Streamlining Clinical Trials with Direct-to-Participant Shipments

How Perceptive IRT/RTSM Helped Sponsors Maintain Momentum During Disruption, and Beyond

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Challenge: Navigating uncertainty in China during COVID-19

When COVID-19 first emerged in China, clinical trial teams faced unprecedented disruption. With little time to prepare, sites and depots struggled to maintain regular dispensing schedules. Historically, Chinese New Year caused minor delays of a few weeks, but during the pandemic, it took over **12 weeks** to return to acceptable levels of on-time dispensing.

In contrast, other regions fared better. Sponsors who had already implemented **Direct-to-Participant (DtP) shipment strategies** were able to maintain continuity, ensuring participants received their medications even when site visits were impossible.

DtP: More than a crisis response - a smarter way to run trials

While DtP shipments proved invaluable during the pandemic, their true value lies in **efficiency, flexibility, and participant-centricity**. By enabling medication delivery directly to participant's homes, sponsors can:

- Reduce site burden
- Minimize missed visits
- Improve participant retention
- Accelerate timelines

This approach isn't just for emergencies, it's a scalable solution for modern trials.

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Key Considerations for Implementing DtP Shipments

Regulatory Compliance

Sponsors must navigate country-specific regulations to ensure DtP is permitted and properly executed. Key questions include:

- **Can participants be treated at home under local law?**
- **Who is authorized to dispense medication?**
- **What documentation is required in the protocol and informed consent?**

Participant Privacy and Data Protection

Protecting participant confidentiality is critical. Sponsors must:

- **Share participant details with couriers without exposing them to the sponsor**
- **Prevent disclosure of health data**
- **Ensure trial participation remains confidential**

Operational Best Practices

To streamline DtP implementation, sponsors should:

- **Update protocols to justify DtP as a safety and efficiency measure**
- **Revise informed consent forms to include shipment details and data protection clauses**
- **Use IRT systems to manage dispensing, track shipments, and maintain accountability**

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Perceptive IRT/RTSM: Enabling Seamless DtP Shipments

Perceptive IRT/RTSM supports both site-to-participant and depot-to-participant models, offering flexibility based on study needs.

Site-to-Participant Shipments

- Investigator dispenses via IRT as usual
- Courier collects and delivers kits to the participant
- Delivery confirmation is recorded in the eCRF
- Recommended: Extend pack life to account for transit time

Depot-to-Participant Shipments

- Investigator assigns kits from depot-reserved stock
- Depot arranges courier delivery
- Site is notified upon successful delivery
- Kits are tracked and reconciled via IRT

Automation and Integration: Making DtP Effortless

Perceptive IRT/RTSM simplifies DtP logistics with:

- **Stock Reservation:** Depots can ring-fence inventory for specific sites
- **Automated Notifications:** Real-time alerts keep sites and depots aligned
- **Proof of Delivery:** Couriers can update delivery status directly in IRT or via system integration
- **eCRF Integration:** Ensures accurate tracking and reporting

Conclusion: Future-Proofing Trials with DtP

Direct-to-Patient shipments are no longer a contingency plan, they're a **strategic advantage**. By integrating DtP into trial design from the outset, sponsors can improve operational efficiency, enhance participant experience, and reduce risk.

Perceptive's IRT/RTSM experts are ready to help you implement DtP solutions that work, whether you're responding to disruption or proactively streamlining your study.

Contact us today: **hello@perceptive.com**

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