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Pharmacists Unbound

RxE2 Direct-to-Patient IP Dispensing for a Dose-Ranging Phase 1/2 Decentralized Clinical Trial

Introduction

In an innovative approach to improve clinical trial outcomes, RxE2 pioneered the **integration of pharmacy practices** into clinical trial workflows. This case study examines our collaboration with a large Contract Research Organization (CRO) working on behalf of a mid-sized pharmaceutical company, facing the challenge of executing a cost-effective, **direct-to-patient solution for a complex Phase 1/2 clinical trial protocol**.

Study Background and Challenges

The CRO, known for its extensive experience in managing intricate clinical trials, required a flexible solution adaptable to the evolving nature of this dose-ranging Phase 1/2 protocol. The complexity of this trial demanded a novel approach to ensure timely and accurate study medication delivery to patients, irrespective of geographical constraints. The complexities of this protocol included:

- **Placebo-controlled** and **open-label** extension periods
- Investigational Product (IP) which required **ancillary supplies** for administration
- Commercially available **concomitant medication**
- **Refrigerated IP,** and temperature control required for storage, shipping, and handling
- **IP formulation changes** which introduced frozen storage requirements

Solution, Deployment and Timeline

To address the trial's challenges, we mobilized **RxE2's Central Pharmacy** which handles millions of drug shipments annually. This solution provided the agility needed to rapidly adapt to the trial's changing needs and supported a seamless process from material receipt to patient dispatch. Our **Precision Dispensing** solution was tailored to the trial's unique requirements captured in **RxE2's project-specific Dispensing Manual** – a client-approved, comprehensive operational guide – incorporating the following key elements:

- Prescription templates for products involved in the trial
- Detailed shipping logistics, including requirements for both dispatch and return
- A robust returns process to manage unused or expired medications effectively

The entire system was **designed and deployed within a 3-week timeframe**, ensuring readiness to ship medications within three days of receiving the IP at the central pharmacy. This rapid turnaround was critical in maintaining the trial's momentum, especially given the unpredictable nature of manufacturing schedules and patient appointments.

Benefits of the RxE2 Solution

Our approach provided significant benefits for the CRO and the trial at large:

- Managed complex protocol requirements, including multi-period phases and **diverse medication types**, with precision
- Ensured stringent compliance with refrigeration and handling requirements for temperature-sensitive medications **and end-to-end supply chain accountability** including returns processing
- Aligned medication shipments with scheduled visits from traveling nurses, **optimizing patient convenience** and trial efficiency
- Demonstrated exceptional agility in adapting **to frequent dosage adjustments** and changes in medication quantities

Client feedback underscored the high level of satisfaction with RxE2's efficiency, reliability, and adaptability.

Results and Challenges Overcome

The integration of our pharmacy practices into the trial workflow led to remarkable outcomes:

- Increased patient enrollment, and **added multiple doses** and **new formulations** with **zero disruptions** to the supply chain
- **Over 700 successful medication shipments** across 18 months
- A **dispensing accuracy rate of 99.9%** and an **on-target shipment rate of 98%**
- Achieved multiple instances of **same-day IP processing and dispatch**, ensuring patient adherence to dosing schedules and maintaining the integrity of the trial

Conclusion – Lessons Learned and Looking Ahead

This trial presented unique challenges, including the introduction of a new medication requiring frozen storage. The expertise and flexibility of **RxE2 Pharmacy Operations** were instrumental in overcoming these hurdles, maintaining trial integrity, and ensuring patient safety.

This case study illustrates the tangible benefits **of incorporating RxE2 pharmacy practices into clinical trial workflows**, demonstrating a fit-for-purpose solution for Direct-to-Patient trials. Our ability to manage a wide range of product types from a central pharmacy sets a new standard in clinical trial management, offering a scalable, efficient, and patient-centric approach to complex trial protocols.

Building on the success of this solution, RxE2 is committed to exploring further optimizations and enhancements to our pharmacy practices, particularly in leveraging technology to streamline processes and enhance patient engagement in clinical trials.

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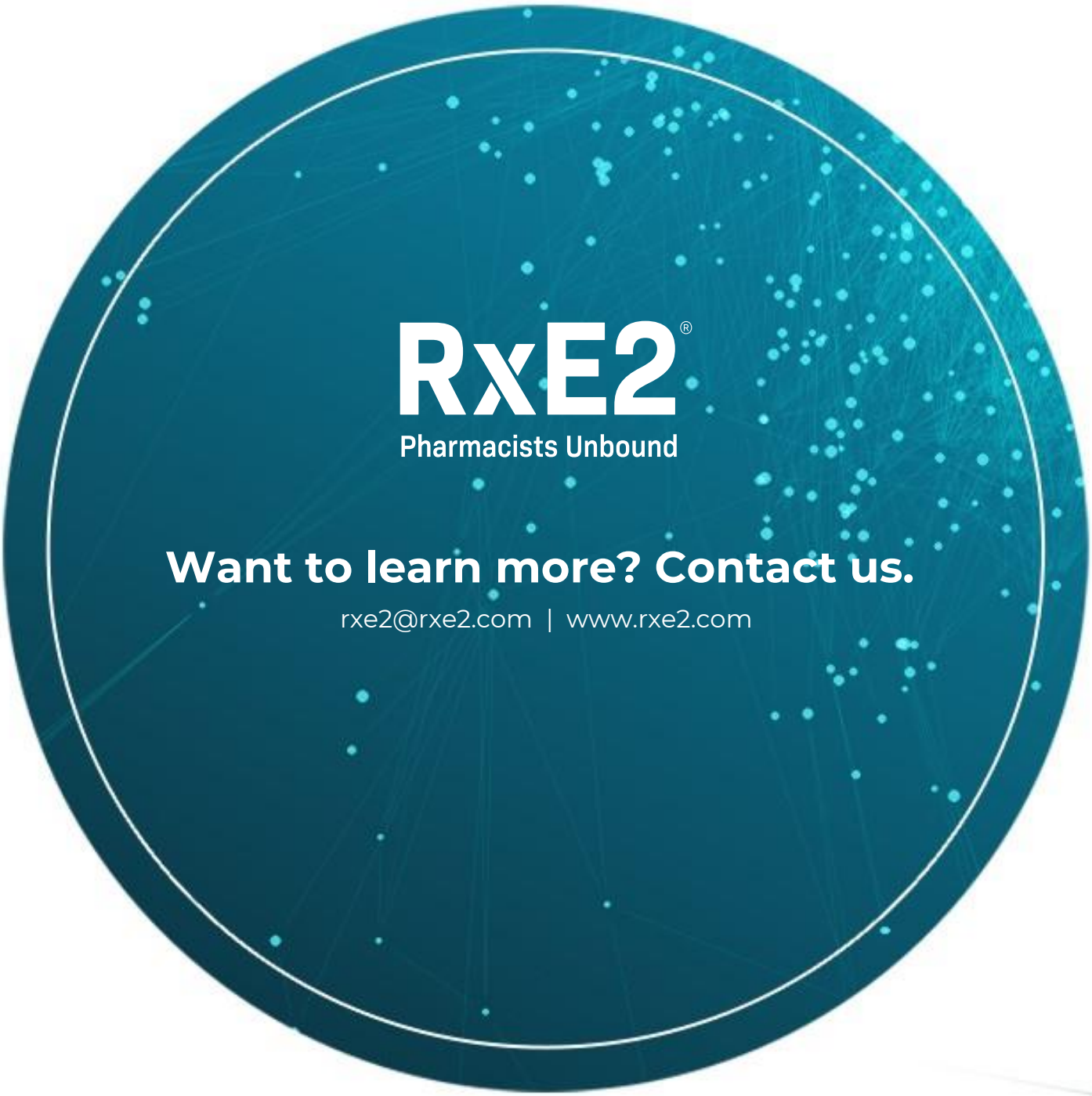
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