

Research Professionals-DCT Case Study:

RP-DCT Oversight Through Sponsor-Driven Vendor Changes in a Paediatric Trial

Research Professionals (RP) is a leading GCP compliant clinical research service provider based in Hungary (EU Member) with operations in the pan-European region, serving customers from across the globe. <http://rp-dct.com/>

Introduction: Ensuring continuity of home-health services is paramount in decentralised paediatric trials, where treatment adherence and trusted clinical relationships directly affect patient safety and study integrity. This case study demonstrates how RP-DCT preserved uninterrupted delivery in a multi-country neuromuscular disorder trial despite a sponsor-mandated change of the global home-care provider.

Background: The sponsor conducted a global, multi-centre paediatric trial to evaluate the safety and efficacy of an investigational product (IP) administered via weekly intravenous infusions at home, using either a peripheral venous catheter or an implanted port. The protocol demanded hospital-grade standards in a family living room, maintaining both patient safety and comfort and data integrity.

In late 2022, the client engaged RP-DCT to build, staff, and manage this decentralised clinical trial infusion programme in Hungary. Each of the enrolled families was supported by a micro-team comprising a primary Research Nurse, a back-up Nurse, and a Country Coordinator, ensuring every visit was safe, punctual, and fully aligned with the protocol. After twenty months and 104 incident-free home visits in Hungary, the client expanded the assignment to Poland in mid-2024. More than twice the initial number of patients were added, validating RP-DCT's scalable one-nurse-per-patient model and cementing trust among investigators, pharmacists, and families.

In November 2024, stability was threatened when the sponsor announced that its master home-care vendor would be replaced by a new global provider as of 1 January 2025. Although RP-DCT was a preferred subcontractor to the incoming vendor, continued involvement – especially in Poland – was uncertain. A patchwork approach risked unfamiliar staff, tangled communication, and missed infusion windows at the height of winter. For vulnerable children relying on familiar faces and precise timing, even brief disruption risked missed treatments, additional hospital visits, and potentially compromised data quality. Preserving continuity of care, local expertise, and established relationships became an urgent, non-negotiable priority.

Strategy: Upon learning of the impending vendor handover, RP-DCT enacted a forward-leaning plan to lock in continuity:

- 1. Rapid Risk Mapping** Within 48 hours, our operations team mapped every contractual, operational, and regulatory dependency threatened by the transition.
- 2. Knowledge-Sharing & Collaboration** We led a focused session with the incoming global provider, positioning RP-DCT as the bridge for operational continuity. By transferring study-specific know-how and lessons learned, we turned the handover into a collaborative effort centered on patient safety, underscoring the clinical and emotional cost of replacing trusted nurses and accelerating contracting.
- 3. Data-Driven Negotiations** Our track record anchored every discussion. Over five years, RP-DCT completed nearly 2,000 high-quality home-care visits across Hungary, Czechia, Romania, Poland, and Switzerland with virtually zero missed doses and no unplanned hospitalisations. Field

personnel logged over 160 hours of study-specific training; Country Coordinators then trained local nurses in their native languages, ensuring protocol compliance and cultural alignment. We achieved a 99.6% mean venous-access success rate – exceeding typical hospital performance standards – and travelled 55,981 km in total to reach patients. This spared families a combined 229,182 km of travel, 928 lost school days, and corresponding parental work absences. Electronic source notes maintained a 100% audit-readiness score, demonstrating operational reliability, regulatory compliance, and patient-centred value.

Key Points

Four differentiators secured RP-DCT's continued involvement rather than replacement during the vendor transition:

- **Continuity of Personnel** Over 300 home-care visits by the same paediatric nurses fostered trust, improved protocol adherence, and reduced emotional stress for children with a progressive condition.
- **Country-Specific Expertise** Bilingual Country Coordinators had already resolved port-flushing protocols, IP temperature-controlled shipping, and other site-specific challenges, providing the transition team with a toolkit of field-tested solutions.
- **Integrated Logistics & Quality Controls** Unified scheduling, route optimisation, and real-time temperature monitoring upheld GxP integrity for Direct-to-Patient shipments without extra validation steps.
- **Robust Quality Management** Our ISO 9001-aligned system ensured full traceability of corrective and preventive actions, supporting high operational quality with multiple internal checks.

Collectively, these assets translated into quantifiable risk reduction, faster study start-up, and demonstrable cost avoidance for the incoming vendor.

Results:

- **Rapid Contracting** The transition contract was signed within 15 business days of receiving the initial template, ensuring every New Year infusion proceeded on schedule. The full handover was completed in three weeks.
- **Uninterrupted Delivery** By August 2025, RP-DCT had delivered 515 visits across Hungary and Poland – over 2,800 hours of professional home care – while preserving a zero-deviation record.
- **Stakeholder Confidence** Investigators reported no service disruptions; parents expressed ongoing confidence; and the sponsor avoided an estimated three-month timeline slippage worth over €1 million in forecast market delay.
- **Patient-Centred Impact** Most importantly, vulnerable children continued to receive life-altering therapy from nurses they already knew and trusted. This outcome underscores how proactive strategy, robust performance metrics, and a clear value proposition can safeguard continuity through major organisational change.