

Research Professionals-DCT Case Study:

Speed and Flexibility Delivered Through Decentralized Clinical Trials (DCTs)

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

Introduction: Research Professionals (RP) *clinical research* service provider was engaged by a European based global pharma sponsor to conduct two pediatric psychiatric clinical studies using their established Decentralized Clinical Trials (DCTs) approach, with home nursing led capabilities. Prior to engaging with RP, both of the studies had been running via traditional clinical site protocols that required subjects to travel to the study sites. In early 2020 the Covid-19 pandemic resulted in a series of lockdowns which blocked study subjects from traveling to the clinical sites. Sponsor companies then had two main options; canceling/delaying the studies or find a new solution that would allow the study to continue under these new and unexpected conditions. Decentralized Clinical Trials (DCTs) provided a unique option that allowed a range of studies to continue without the requirement for subjects to travel to physical clinical study sites.



RP's Decentralized Clinical Trials (DCTs) approach with home nursing led capabilities

Background: Since the beginning of the Covid-19 pandemic the importance of Decentralized Clinical Trials (DCTs) has risen sharply. DCT can include a range of remote activities such as remote monitoring, video call visits, remote data acquisition/processing as well as Home Care Research Nursing (HCRN) activities. Lockdowns and travel restrictions meant that clinical study subjects would no longer be able to travel to clinical study locations, and therefore the studies could not be conducted in a traditional manner. For those who had already initiated a clinical study, they faced the choice of either delaying the completion of the study for an unknown period of time or even worse having to stop the study and restart it from scratch only when conditions allowed in the future. Not only would the previously generated data be lost, but this would indefinitely pause the development of important medicines and delay the sponsor company's ability to get new medicines to the patients that needed them. The previously little-used option of a DCT approach for home nursing led studies had just become a potentially viable option for a wide range of studies moving forward.

Strategy: Some time prior to the start of the Covid-19 pandemic, Research Professionals (RP) had decided to strategically develop the ability to conduct Decentralized Clinical Trials (DCTs), including Home Nursing Led Studies in its countries of operations. RP had developed detailed processes and systems to support Home Care Research Nursing (HCRN) studies and had been conducting some smaller studies that tested the approach. When the Covid-19 global pandemic hit, RP was able to quickly respond to the European based Sponsor and quickly transition both of their pediatric psychiatric studies from an in-clinic format to a home nursing led format. Because RP had the foresight to build the infrastructure, knowledge and network of clinically trained home care nurses capable of conducting the clinical studies in the subject's home, they were able to **re-initiate the study only 17 business days** from first consultation with the sponsor. This was only possible because of the foresight and strategic planning of RP to develop a presence in the burgeoning DCT field.

DCT Project Transition Accelerated Timeline

Dates (2020)	Business Days	Activity
March 16	0	First consultation with Sponsor
March 17	1	Contract and budget plan provided
March 19	3	Vendor qualification process started
March 27	10	Contract signed with Sponsor
April 1	13	Full nursing team assigned
April 3	15	Nurse training completed
April 7	17	First home visit conducted

Key Points

- RP had already developed the critical processes, infrastructure and staff to transition the sponsor studies to a Decentralized Clinical Trials (DCT) – home care nursing model in 17 business days.
- RP's reaction to the emergency situation demonstrates its flexibility and responsiveness to customer needs, while providing the highest quality study management services
- RP has continued to expand its DCT capabilities and has deployed a retained nursing model across a number of regions of operation. This capability means that RP has specially trained clinical nurses as permanent staff, that are available to initiate home nursing-led studies without the delay of contracting and training new nursing staff.
- Sponsor was able to continue both of their pediatric psychiatric studies to completion through the Covid-19 pandemic with no loss of data integrity and minimal time delay for the transition process.

Results: RP was able to use its strategically developed DCT and home nursing study capabilities to quickly transition two sponsor studies from an in-clinic to DCT format. The results were that after a short two-week project transition process, the studies were both conducted to completion, despite travel restrictions and lockdowns during the Covid-19 pandemic. The sponsor did not lose any of its study data generated prior to the transition to a home nursing care model. After the short 17 business day transition window the two studies were able to stay within expected timelines. This case is an excellent of RPs quality and flexibility to adapt to challenging scenarios with innovative and compliant clinical solutions.