Research Professionals-DCT Case Study:
Integrated Clinical and Decentralized Approach to Accelerate Clinical Trials

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: An emerging U.S. based life science company with operations in Europe was seeking to restart and expand their stalled clinical trial came to Research Professionals for assistance. Research Professionals (RP) had built a reputation as a leading high-quality clinical research service provider with clinical management capabilities in both conventional in-clinic studies and more recently Decentralized Clinical Trials (DCTs). As a result, the sponsor came seeking a time-sensitive solution that could get their study moving forward and compliantly completed under the pandemic related travel restrictions. The sponsor had encountered some challenges with the study protocol submission in one country combined with overall recruitment shortfalls. The study was halted as a result. The sponsor then went in search of an innovative clinical research service provider that could alleviate these challenges and complete the study under tight timeline requirements.

Background: First, the sponsor required a CRO with the regulatory and technical expertise to support the timely completion of the protocol review by an Ethics Committee (EC) and manage the approval process with the Regulatory Authorities (RA) in both countries. Ethics Committees are required to review the protocol and study documents to ensure they are ethically designed and provide the subjects with the information required for subjects to give their informed consent to participate. Once this is achieved the study must be reviewed and approved by the overseeing regulatory authority so that the clinical study protocol can begin. Delays in either of these steps can result in significant study delays.

The study sponsor had received EC and RA approvals for their clinical study in Hungary, but not yet in Poland. The study was launched in Hungary and RP started to manage the newly added DCT operations under the original CRO. The regulatory submission from the original CRO ran into challenges in Poland with the regulatory authorities, so the sponsor sought a new clinical research service provider who could successfully manage the clinical operation process in both countries. The new clinical research service provider also needed the knowledge and capabilities to run a DCT study arm that could provide wider recruitment pools and to get the study timelines back on track. The new clinical research service provider was expected to overcome challenges and quickly complete the study in compliance with applicable regulations. Once the sponsor received required approvals in Poland, the new clinical research service provider's next challenge was to support the clinical sites and quickly recruit the appropriate subjects for the study. The new clinical research service provider's staff would have to complete the study as designed with shortened timelines. Research Professionals (RP) had the required experience in managing both in-clinic studies and DCTs. They also had established professional knowledge and relationships with ECs and RAs in both countries to achieve these objectives.

Strategy: Research Professionals was managing the DCT arms of the study and were subsequently engaged by the sponsor to take over management of the Hungarian based in-clinic study and manage four additional clinical sites in Poland. Research Professionals (RP) immediately worked with the client to prepare submissions for the Ethics Committee and Regulatory review in Poland. Once the study approvals were secured, Research Professionals were in charge of managing the trial, monitoring sites and providing home nursing services in both Poland and Hungary. This decentralized approach delivered enough top-tier Principal Investigators (PIs) with the reach to rapidly recruit qualified subjects in the required numbers. Research Professionals' teams coordinated with their established in-clinic and DCT teams to move the clinical study forward quickly. RP also had the staff, training, and systems in place to handle the clinical operations from submission to the close-out for the total of 23 patients managed in 8 sites.

Post Study Conduct Integrated Approach Timeline Metrics

Dates	Business Days from LPLV	Activity
February 25, 2021	-	Last Patient, Last Visit (LPLV)
March 26 – April 2, 2021	36	Data Base Lock (DBL)
April 30, 2021	64	All sites closed
May 31, 2021	95	Inspection ready Trial Master File (TMF)

Key Points

- RP utilized its experience, network, and regulatory expertise to solve a major problem for its sponsor customer.
- Because of RP's success with the DCT arm of the trial, it was then engaged to manage, expand, and coordinate the in-clinic part of the study.
- RP was able to go from LPLV to having the TMF inspection ready in only 95 days demonstrating accelerated study management capabilities.
- RP had the critical processes, quality systems, and trained staff already in place to manage clinical operations and support rapid recruitment and DCT/Clinical study conduct in two EU countries.

Results:

RP applied an innovative strategy to the sponsor's study that combined its well-established clinical trial capabilities and its innovative DCT competence. RP initiated the study using a DCT approach in Hungary but was also later engaged to expand and manage in-clinic and DCT study operations in both countries. RP integrated the in-clinic and home nursing operations so that they met the required ethics and regulatory requirements needed. By using both their traditional in-clinic and high-quality DCT capabilities, they were able to accelerate recruiting and shorten overall study timelines. RP seamlessly managed the dual approach study across two countries and was able to complete post study activities in record time. They were able to go from Last Patient, Last Visit (LPLV) to inspection ready Trial Master File (TMF) in only 3 months. This is an excellent example of RP's achieving high-quality results, through innovation and flexibility, in less time using both its established in-clinic and Decentralized Clinical Trial (DCT) study models.