Research Professionals-CRO Case Study:

Accelerating Early Phase Studies with a Central and Eastern European (CEE) based CRO

Research Professionals (RP) is a leading GCP compliant CRO based in Hungary (EU Member) with operations in CEE countries including Poland, Czech Republic, Romania, and Bulgaria, serving customers from across Europe and the globe. www.rp-cro.com

Introduction:

Partnering with the right CEE-based Clinical Research Organization (CRO) to manage a new drug product through phase I/II clinical studies is critical to successfully advancing early-stage products. Finding CROs with the specific knowledge, experience, and capabilities that can help guide sponsor companies through the unique challenges of early phase studies, while staying on time and on budget can be a challenge. Whether you are a global pharma or a new biotech start-up, navigating the many pathways through phase I/II clinical studies requires a high-quality CRO partner with the capabilities to move studies forward quickly while maintaining global quality and regulatory standards.

Background:

Phase I/II clinical study data can serve as the basis for decisions to fund the next phase of development or support product valuations for exit strategies, such as the license or sale of the product. Whether conducting phase I (First In Human - FIH) dose escalation studies focused on safety or phase II studies assessing preliminary efficacy of the investigational medical product (IMP), tolerability and basic pharmacokinetics (PK), sponsors need to choose a CRO that understand each customer's specific needs for early phase clinical study services. One of the most common challenges for early phase clinical studies is timely recruitment, even though the studies require a small number of viable subjects.

Phase	Number of Subjects	Purpose
Phase 1	10-100	Healthy subjects - safety
Phase 2	100-300	Subjects with condition of interest - safety & efficacy
Phase 3	300-3000	Subjects with disease - therapeutic effect
Phase 4	thousands	Post marketing - long-term effects

Figure 1 – Clinical Study Subject Requirements

The other factors that should be considered when selecting a CRO for early phase studies is their experience in managing phase I/II studies, ability to maintain tight budgets, advanced quality systems, and the availability of phase specific regulatory support. Some markets are saturated with many competing clinical studies vying for the same subjects. Others may offer small subject pools via limited Principal Investigator networks, all of which can slow recruitment and reduce the CRO's ability to complete the early phase studies on time.

Strategies & Solutions:

Research Professionals CRO (RP-CRO) brings significant experience managing phase I/II studies to every customer study. RP-CRO's operations are in CEE countries within the EU. They are adept at managing studies to EU regulatory standards, which are recognized and accepted by other leading

regulators including the U.S. FDA. RP-CRO engages PIs with access to modern clinical sites and large patient pools for faster recruiting potential. The CEE states contain patient populations that are generally more open to clinical trial participation and may have lower density of similar clinical studies thus reducing competition for viable subjects. These factors combined with the CEE offering some of the largest population driven patient pools found in Europe can help the PIs within RP-CRO's network to recruit enough subjects to start trials on time. Although most Phase I/II studies are single country, with 1-2 sites, RP-CRO can quickly expand recruitment to other CEE countries in order to enroll even the most difficult to find patient pools.

RP-CRO's Early Phase Study Advantages

In addition to rapid recruitment options, RP-CRO can provide CRO services that make a measurable difference to customers large or small. RP-CRO operates in compliance with the latest in EU regulations (CTR) that can streamline the single application (CTIS) process, which is accepted by other major regulatory bodies such as the U.S. FDA. With extensive early phase clinical management experience, RP-CRO can provide realistic protocol, timeline and budget guidance to customers. RP-CRO's well established quality systems and SOPs are designed to meet the strictest quality standards and produce submission-ready results for early phase studies. RP-CRO customers receive all of this within a cost competitive budget when compared to most major clinical research countries. All combined, RP-CRO can complete early phase clinical studies in the shortest timeframe possible so that customers can make robust data-driven decisions about their product's future development path.

Research Professionals CRO – Early phase I/II Clinical Study Experience

RP-CRO has successfully supported 15 early phase clinical studies, including phase I, phase II and FIH medical device studies through its CEE network of operations.

Phase	Number of Studies	Scope
Phase 1	10	Drug product trial protocols
Phase 2	5	5 protocols managed in 28 clinical sites
Phase X	7	FIH medical device study in 16 clinical sites

Figure 2– Research Professionals CRO Phase I/II study management experience

Key Points

- RP-CRO has successfully managed 10 phase I clinical trials to completion with accelerated recruitment and competitive budgeting.
- RP-CRO has proven ability to prepare phase I/II study submissions for regulators aligned with current requirements.
- RP-CRO has completed seven studies that are eligible to move on to the next clinical phase. with three drug studies and three MedDev trials ongoing.

Conclusion:

As an EU regulated CRO, with operations in the CEE, RP-CRO is uniquely well positioned to support the needs of biotech start-ups to global pharma companies with clinical management services that produce accelerated recruitment, quality results, regulatory compliance, in a cost-effective package designed just for early phase clinical trials.