**Clinical Ink**®
Confident Decisions, Faster

# A CRO's Road to ePRO Revenue

## Situation

A global, full-service clinical research organization (CRO) with nearly 20,000 employees, operating in more than 50 countries, and offering Phase I-IV clinical research services, eClinical technologies, and in-depth expertise, had looked at the increasing demand and expected growth rates for electronic patient reported outcome (ePRO) technology and determined that the opportunity for an ePRO offering would be significant.

While this company earned revenue for studies using paper-based patient reported outcome services, it lost revenue to an ePRO provider partner when clients elected to use a digital solution. Wanting to recoup this revenue, the CRO was searching for another way to include ePRO in its service offerings, take advantage of its benefits, and generate a new stream of revenue. The company also was hopeful of offering benefits to its sponsor clients, including a unified offering, a single vendor point of contact, a single invoice, and opportunities to improve the investigator and patient experience.
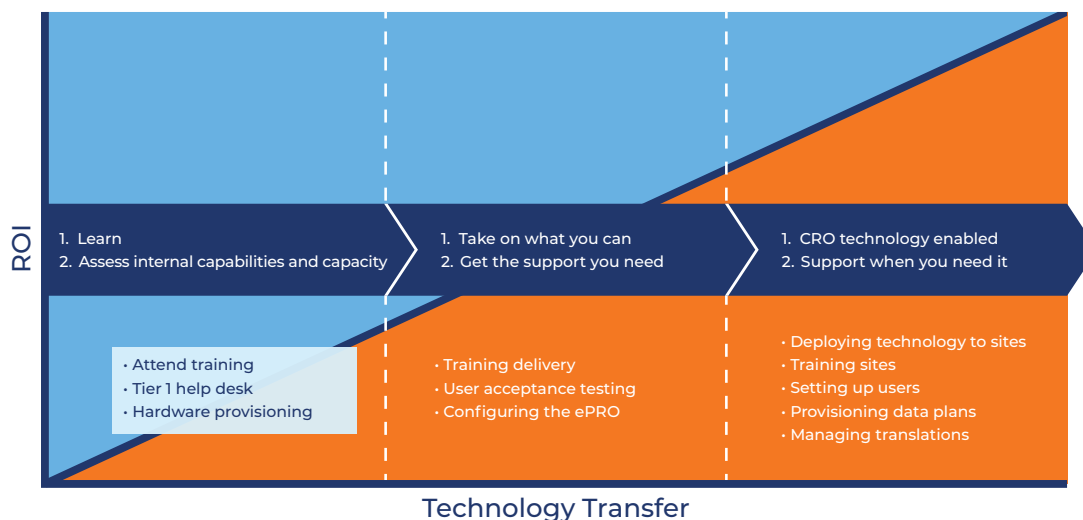
## The Goal

### Technology Enablement

Clinical Ink offers a traditional partnership model where it bids on business alongside a CRO; however, its technology enablement solution provides added benefits, giving CROs the ability to completely customize their role in implementing and deploying an ePRO solution over time. With this approach, CROs can take on some or all aspects of ePRO deployment, based on their internal capabilities and resources, and quickly begin to generate earnings from those services.

This case study describes how a global CRO successfully added ePRO to its service offerings and created a new revenue stream. Leveraging its unique delivery model, Clinical Ink followed a structured, step-by-step approach to transfer the technology, deploying a process similar to what the client had previously followed with EDC tools — an analogy that allowed the CRO to better understand the approach. The process was made up of three stages.

# The CRO's Path to ePRO Enablement



**ROI**

| 1. Learn | 1. Take on what you can | 1. CRO technology enabled |
| 2. Assess internal capabilities and capacity | 2. Get the support you need | 2. Support when you need it |

| • Attend training | • Training delivery | • Deploying technology to sites |
| • Tier 1 help desk | • User acceptance testing | • Training sites |
| • Hardware provisioning | • Configuring the ePRO | • Setting up users |
| | | • Provisioning data plans |
| | | • Managing translations |

**Technology Transfer**

## The Solution: Three Stages Toward Success

### Stage 1

For the client's first ePRO study, Clinical Ink completed all the work and delivered the entire solution, while a project manager and an innovation team member from the CRO observed and learned about the system. Unsure what functions it could comfortably take on, the CRO shadowed the Clinical Ink team, gathering the information necessary to assess its internal resources — all while confidently knowing that Clinical Ink would ably handle full deployment within this first study.

As part of this first stage, Clinical Ink provided training on best practices for ePRO deployment including how to set up and run an electronic clinical trial. This enabled the CRO to take over some design and deployment functions to ascertain how it could stay on track and maximize the value of the technology. Because it was important that no task be left undone, Clinical Ink assigned a project manager and deployed a responsibility assignment matrix to clarify roles and responsibilities.

In addition to technical training, Clinical Ink trained the CRO on:

- Writing proposals
- Reviewing protocols
- Setting up and conducting internal and external kickoff meetings
- Configuring the system

- Conducting a user acceptance test (UAT)
- Identifying key workflows
- Deploying a study to sites
- Enrolling patients

### Stage 2

When the CRO won another study with ePRO, it was time to proceed to the second stage whereby the CRO takes on certain tasks, shadowed by Clinical Ink. In this case, to leverage its existing infrastructure and logistics experience, this client accepted responsibilities for basic help desk support and hardware provisioning. Most importantly, the CRO began to earn revenue for these services.

Meanwhile, the CRO assembled a five-member team to attend a four-day training session at the Clinical Ink facilities. The live, classroom, role-based training helped the CRO understand the optimal processes, procedures, job roles, and resources to maximize the technology. This included how to quote and sell ePRO, configure questionnaires, conduct UAT, and manage data, and understand critical success factors for successful deployment.

Over time, as the CRO grew its ePRO team, Clinical Ink shifted responsibilities to its client gradually as the CRO was ready. Training delivery and sponsor UATs were among the first tasks undertaken by the CRO. The CRO also soon assumed responsibility for building and configuring the ePRO, initially leveraging Clinical Ink's expertise for configuration testing and using Clinical Ink documents, then later using its own test documents.

Subsequently, the CRO took on deploying the technology to sites, training the sites, setting up site users, provisioning of data plans (through a partner), and managing translations, while Clinical Ink continued to provide data management and patient engagement services. With each task it undertook, the CRO earned additional revenue, as part of a shared revenue model, with Clinical Ink shadowing the CRO team.

With the CRO playing a larger role in deployment, it did so with expert assistance. Clinical Ink continued to support the CRO by shadowing its team members as they shouldered each new task. Throughout this stage, Clinical Ink's project manager supported the CRO team and also provided advanced help desk support via digital and phone communication if an issue was escalated.

> "By the second stage, Clinical Ink's unique model enabled its client to start generating revenue for its ePRO services."

## Stage 3

In the future, as the client takes on the remaining two activities — data management and patient engagement — it will enter the final stage. When it does, this CRO will become a completely ePRO technology-enabled organization, earning revenues for all the activities it performs in delivering an ePRO system to sponsors, sites, and patients. The relationship with Clinical Ink will move to a technology licensing model with support services purchased on an a la carte basis as needed. Today, the CRO offers this innovation as part of its routine service offerings and is well on its way to being completely ePRO-enabled.

### Keys to Success: Training and Support

- Clinical Ink enabled the CRO's success — with appropriate training, tools, communications, and support for both business development and operational teams.
- The model allowed the CRO to earn revenue that justified building out its internal team.
- The CRO's senior management saw value in an ePRO service offering and its growth potential.
- The CRO's innovation culture was supported by an internal innovation team that completed the ground work, developing internal workflows and enlisting a project manager to integrate ePRO into the company's broader product and service offerings.
- Within the CRO's team, there was an interest and some experience in ePRO. The team filled in its expertise gaps with external hires.

## Conclusion: Lessons Learned

This CRO had ambitious goals and initially sought a faster transition, but soon recognized it didn't have the required internal resources and expertise. Fortunately, Clinical Ink's delivery model allowed the CRO to transition in an orderly and step-by-step fashion. Enabling the CRO to gain experience necessary for informed decision-making while at the same giving it confidence that its clients received full ePRO coverage was key. But so was earning revenue. By enabling its client to generate revenue, Clinical Ink gave the CRO what it needed to justify further growth and investment.

Communication was essential between Clinical Ink and the CRO. Clinical Ink's team, particularly the project manager, ensured that responsibilities were clear so that ePRO provisioning remained seamless for the CRO's clients. Additionally, the CRO's internal communications were strong, which was a critical success factor due to the cross-functional nature of ePRO deployment: Both business development and operational enablement and mobilization are required for an efficient and successful ePRO implementation.

Clinical Ink's unique ePRO delivery model — backed by strong communications and nurturing support — made it possible for this client to add an ePRO service offering, generate revenue, and provide a unified service to its sponsor clients, all while enabling an innovative technology that significantly eases data collection for investigators and patients.

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