moving research forward.

Case Study

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MARCH 2018 | CASE STUDY

70% OF STICKIES ELIMINATED: QUALITY CLINICAL RESEARCH

After adopting the CRIO eSource system, Quality Clinical Research reduced their count of internal and external data quality findings by over 70%, resulting in significant efficiencies, more satisfied staff and CRA's, greater flexibility to recruit and expand, and a stronger business development pipeline.

Quality at Quality

Quality Clinical Research is an Omaha, NE based research site network with six Principal Investigators who recruit from the community. The site works with the individual PI practices for recruitment, and has five coordinators, four additional staff members, and two executives.

Tricia Harrison, Owner and President of Quality Clinical Research, had developed a robust internal QC process. After a coordinator completes a visit, she or he leaves the binder on the Principal Investigator's desk. The PI reviews and signs off, then hands the binder to Data Entry for EDC input, who then hands off to Quality Control for source data verification.

This process provided controls over data quality but was inefficient and often highly reactive. When a problem is discovered, for instance, the person reviewing it has to affix a sticky to the binder and pass it back to the Coordinator for troubleshooting. As a result, the cycle could take a long time, with multiple loopbacks.

"The basic problem with this approach," said Tricia, "is that we're correcting a lot of mistakes after the fact, instead of catching them upfront. We needed to find a way to prevent the errors from happening in the first place."

Workflow

When Tricia learned of the Clinical Research IO eSource system, her first thought was, "The sponsor should pay for it." But after one too many mishaps, she re-evaluated her initial reaction. When she and one of her senior coordinators saw the CRIO system at a conference, they decided to move forward.

CRIO's impact on operations

The system had an almost immediate impact on quality. "At first, we had to get used to collecting data in a different way," said Nicole Cureton, one of the senior coordinators. "But then we realized that the system was making our jobs so much easier. We were being more thorough with our visits and finishing up our source by the time the patient left."

Nicole articulates a lot of ways the system reduces errors and saves time during the visit:

- All signatures and dates for attribution are automated through the audit trail.
- Blank data fields are flagged for completion by the coordinator.
- Formulas are auto-calculated and current time-stamps are added with one click.
- Medication spellings are standardized.
- Procedures can be completed simultaneously by different people; for example, the Investigator could be performing the physical while the coordinator is completing IP compliance.

"I leave every night with a clean desk," said Nicole. "I no longer have nightmares of wondering if I had finished source or needing to double check it."

"Our monitors have really embraced this," continued Nicole, "because they can perform remote monitoring much more easily, and when they leave a comment, it's electronic so they can always see it. We used to get into disputes sometimes because they would say they left a sticky, but we didn't see it."

The same basic review process (coordinator → investigator → data entry → QC) still happens, but now it's done electronically, with no passing of binders. Using the system's Commenting feature, staff members communicate with each other without having to affix stickies. Because there is no longer a linear path for the binders – i.e., forward or backward – all stakeholders can work on their tasks iteratively and in parallel, meaning the entire cycle is compressed.

Quantifying impact

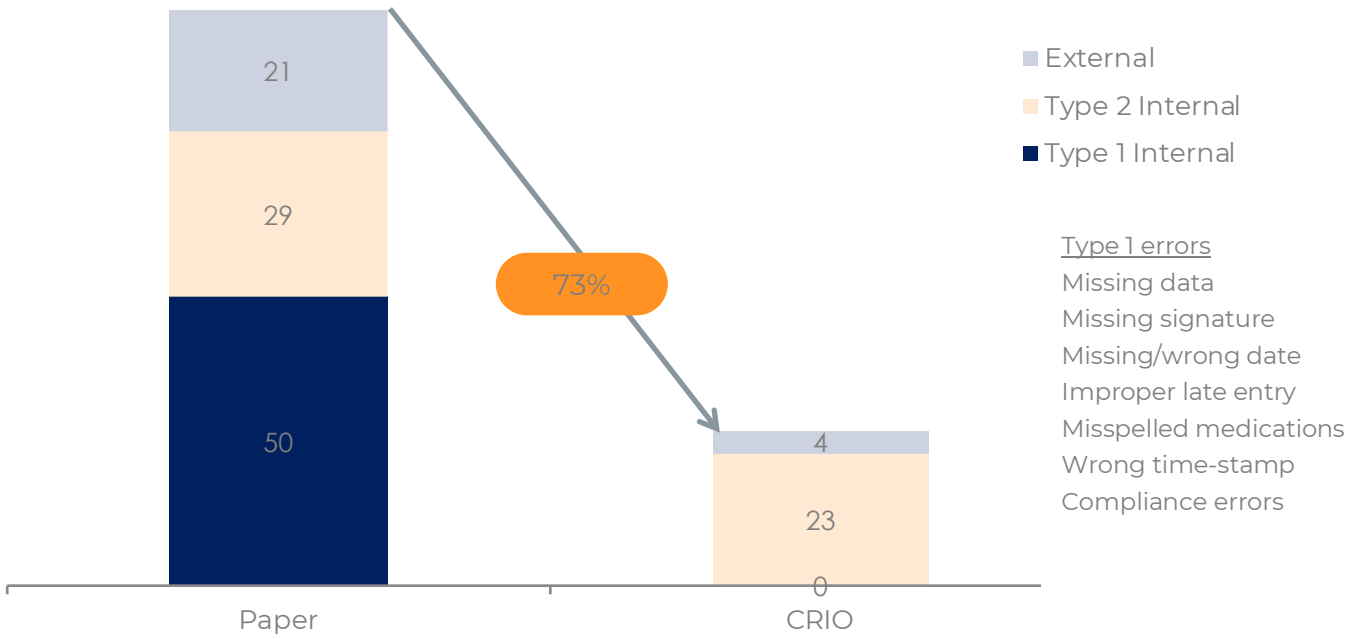
Tricia recently measured the impact CRIO has had in improving data quality. She compared the number of "stickies" on a set of studies conducted on paper vs. the number of comments (electronic stickies) on a set of studies conducted in CRIO. The pre- and post-CRIO studies were comparable in length and complexity.

She found an overall reduction of over 70% in stickies. This was in large part due to the significant decrease in errors associated with missing data fields, time-stamps, calculations, spelling mistakes and other easily automated items. These types of errors, which can be called "Type 1" errors, were eliminated *entirely*.

Other stickies are more judgment based, such as an inconsistency in observations across procedures, or the lack of a progress note to document a deviation. These errors, which can be called "Type 2" errors, still went down by 20% post-CRIO. Tricia attributes this decline to the fact that the PI's find it easier to review source online and are thus able to perform more thorough annotation and review before the electronic binders get reviewed by internal QC staff.

The impact didn't just end there. Tricia found that the number of *CRA* findings went down by80%, for many of the same reasons as outlined above. Her site has earned the praise of CRA's, many of whom have come to view the CRIO system very positively.

Decline in number of quality findings (indexed to 100)



Between the internal and external findings, Quality Clinical Research experienced a 73% decline in overall "stickies" per visit. This means substantially less re-work and clean-up, freeing up resources and allowing coordinators to focus more time on value-added activities such as patient recruitment or retention.

Translating to business advantage

Seneca Harrison, the site's CEO, puts CRIO's impact in business terms.

"First, we have been able to grow our operations with one less person than we would normally have had," he said. "Between the employee savings and the paper supply cost avoided, we literally come out ahead on a P&L basis. CRIO is not a cost item but a savings generator."

"Second, we've improved our standing with CRA's. We routinely get feedback from our monitors about how good our data is, and that increases our chances of winning future studies. It strengthens our pipeline."

"Third, this system has given us the flexibility to expand. We can now take on more PI's and indications easily, allowing us to diversify and grow our top-line."

Conclusion

Tricia summarizes her experience with CRIO this way: "I totally understand why someone would be hesitant to make the jump. I was very nervous at the outset, especially since I don't consider myself computer savvy, but in hindsight, I can't fully express how much the system has improved our operations and business. I don't think anyone can run a multi-specialty, growing site operation effectively without eSource, especially a system of the caliber of CRIO."

ABOUT THE PROFILE

As the owner and president of Quality Clinical Research since 2004, Tricia Harrison is both diligent in her practice and committed to the profession. Tricia has been in the medical field for nearly twenty years, attending both Metropolitan Community College and Creighton University in Omaha Nebraska. She was named "Woman of the Year" by the National Association of Professional Women in 2012 and is an active member of The Association of Clinical Research Professionals and the Society of Clinical Research Sites. She spends her free time volunteering with Habitat for Humanity, donating to several community organizations, mentoring youth girls, and spending time with her husband and their two children.