Case Study

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CRAS FAVOR CRIO OVER PAPER BY 3:1 MARGINS ON KEY DIMENSIONS

One CRA discovered the benefits of the CRIO system and introduced it to other sites on the trial. The CRAs favorable impressions were confirmed in a subsequent survey of CRA users of the CRIO system, who favored CRIO over paper on promoting data integrity, compliance, and rigorous QC by a 3:1 margin.

A site on CRIO

Sin Park is a CRA for MOE Therapeutics, a small device manufacturer running a Phase 3 trial. Of his six sites, he noticed something different about one of them, which also happened to be the highest performer: Instead of the usual paper binders, this site was using the Clinical Research IO (CRIO) eSource system to collect data.

“I can log in any time and see the data,” said Sin. “I know exactly what is going on with the site. If I have any questions or comments, I can leave a query, and I know the site will see it. I don’t have to write a sticky note and wonder if it is going to get read or not.”

Remote monitoring was especially helpful because it meant he didn’t have to travel as often to the site. “If all my sites were on CRIO, I could do a lot more of my work from a central location, and that would save significant cost for the sponsor, and time for myself,” said Sin.

Not only was there value in the transparency and remote access, but the site’s data quality was substantially better than at the other sites. Sin later learned from the site that this was due to the edit checks and other quality safeguards built into the system. “The way the template was laid out – it was very easy for me to follow the workflow, confirm compliance, and review the procedures and results.”

Convinced of the system’s value, Sin worked directly with CRIO to have tablets, the software and the template given to two other sites. When two new sites were brought on, they came on agreeing to utilize the CRIO system.

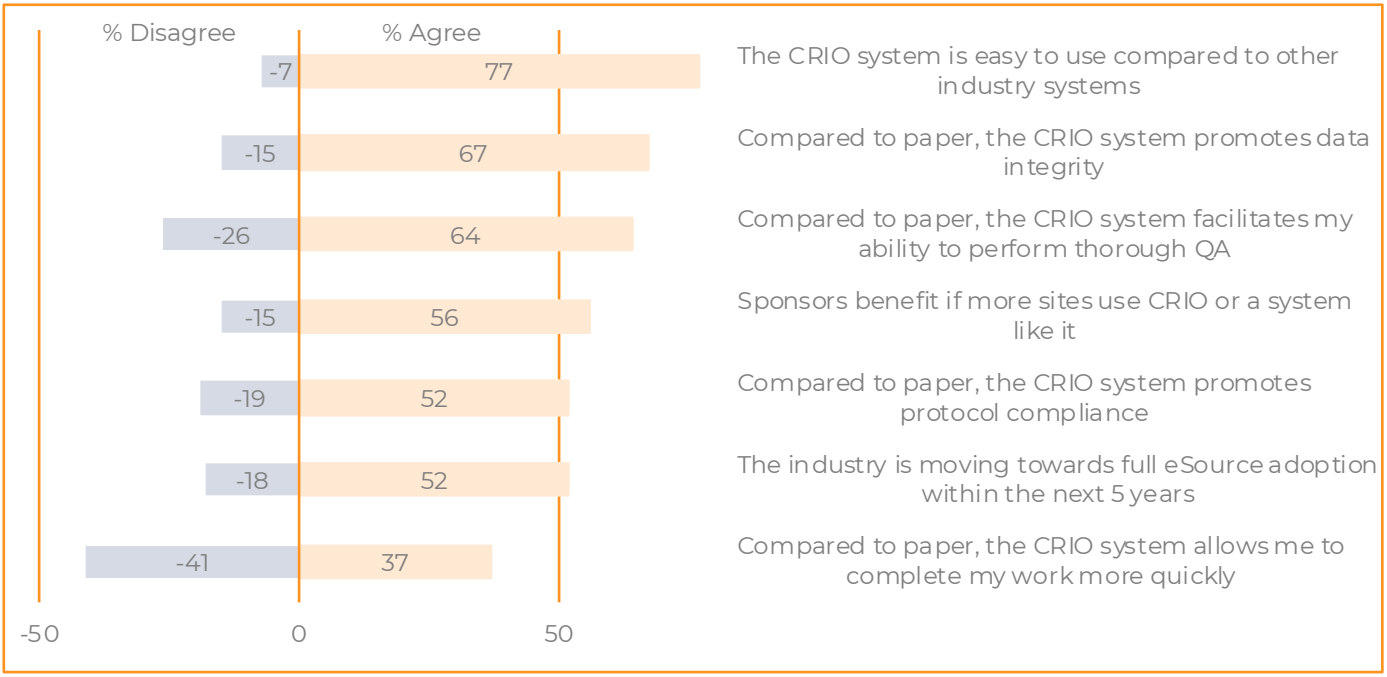
“If I were starting a trial today,” said Sin, “I would choose only sites that are using or are willing to use the CRIO system.”

CRAs favor CRIO over paper by 3:1 margins

Sin's experience is not unique. Clinical Research IO commissioned a third-party market research firm to survey its CRA users on their experience working with the system, and those results reflected widespread favorability to the system.

On several key attributes, CRAs reported CRIO as being superior to paper binders by margins of 3 to 1.

Responses of CRIO CRA-users



On the question of what better promotes data integrity, CRAs favored CRIO over paper by 67%-15% (4.5:1 margin). On the question of which facilitates rigorous QC, CRIO beat paper by 64-26 (2:5). On the question of which promotes protocol compliance, CRIO beat paper by 52%-19% (2:7).

The only question where the two systems were at parity was the one on which was faster to work with "I attribute that to the fact that CRAs are used to working with paper binders, and haven't had as much experience with our system," said Raymond Nomizu, CRIO's Co-Founder. "The fact we're at parity at all is pretty good."

eSource as the future

Two results in particular were telling. First, 56% of CRAs agreed and only 15% disagreed with the statement that "Sponsors would be better off if more sites used CRIO or a system like it." Second, 52% agreed and only 18% disagreed that "eSource will become the predominant mode of collecting data in the next 5 years."

Taken together, it reveals that CRAs as a whole believe eSource is not only beneficial to sponsors, but that the industry is headed in that direction.

Conclusion

Sin is not surprised by the results. "I supposed there are many CRAs who haven't given much thought to eSource and I'm sure many might be hesitant with it when presented as a concept," said Sin. "But when a CRA is exposed to CRIO, I can't imagine why they wouldn't embrace it, and this survey shows that."

ABOUT THE PROFILE

Sin is an engineer at MOE Medical Devices. His educational background is in biology, mechanical engineering and biomedical engineering. After working in academia, he now works for a medical device startup as the mechanical engineer, microbiologist and CRA for clinical studies. He a technophile and spends a good amount of time trying to optimize his productivity.