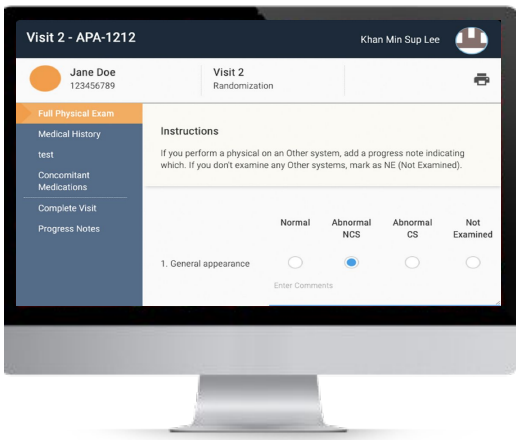
Case Study

617-302-9845
sales@clinicalresearch.io
www.clinicalresearch.io

WASHINGTON UNIVERSITY IN ST. LOUIS: USING CRIO AS A QUALITY TOOL IN CLINICAL TRIALS

OVERVIEW

At Washington University in St. Louis, Tarisa Mantia currently serves as the Manager of Clinical Research in the Division of Allergy and Immunology. Tarisa is responsible for ensuring that all studies within that division utilize the best clinical practices. To help achieve this mission, her division has now implemented CRIO's eSource on their industry-funded protocols, conducting an average of 20-30 industry-funded studies annually. Tarisa has witnessed firsthand how CRIO is improving quality across these studies, reducing data errors, enhancing patient safety, and simplifying PI oversight through its accessible workflow.



CHALLENGE

Tarisa was "drowning in paper" and was often struggling to obtain PI sign off in a timely manner due to the busy schedules for many of the investigators. She knew there had to be a better method of conducting research, and she had been looking for an electronic solution in clinical research for more than 10 years.

SOLUTION

Tarisa received a recommendation for CRIO from a study monitor that was working with another site who was using CRIO. After extensive internal security and compliance reviews, Tarisa received approval to implement CRIO on clinical research trials in the Division of Allergy and Immunology.

> No one wanted to have a 600-page source document or even a 40-page source document. Today, we are able to put detailed instructions into CRIO....now we have much clearer instructions to follow.
>
> *Tarisa Mantia, Manager, Clinical Research Division, Washington University in St. Louis*

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OUTCOMES

Going Paperless

CRIO's eSource provides Tarisa the freedom from binders that she had always envisioned. But eSource unlocked much more than the benefit of cutting down on paper use. Going paperless meant she now had freedom to design source forms without limitation from the finite size of a few pieces of paper.

"We no longer have to try to fit cliff-note instructions so each procedure would fit onto one piece of paper," says Tarisa. "No one wanted to have a 600-page source document or even a 40-page source document. Now we are able to put detailed instructions into CRIO. And this is especially helpful for more complicated procedures like the eDiary entry so that now we have much clearer instructions to follow."

Not only is it now less of an endeavor to format the source forms, but coordinators are also better equipped with the detailed instructions to conduct visits properly to ensure data quality and patient safety.

Improved Data Quality

Tarisa reports personally seeing a significant improvement in the data quality. She says her favorite part about CRIO is how eSource significantly "cuts down on errors and messiness". The built-in alerts and checks in the system, for example, prevent coordinators from entering the wrong date or year. And when changes are made in the source, CRIO provides a clear audit trail with documentation with the reason for change, in conformance with ICH-GCP. She and her staff are able to customize the eSource for study visits by modifying CRIO templates in order to match the protocol and/or eCRF guidelines exactly, which cuts down on follow-up items generated at monitoring visits.

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PI Oversight

The remote flexibility of eSource allowed for PI oversight from anywhere despite the PIs' busy schedules. Working with PIs who also have clinic days and conferences lined up back-to-back, Tarisa recalls how difficult it was to obtain PI signatures in a timely manner. While the PI is always reachable by phone or text, the actual signature is the key part of oversight documentation. Paperwork awaiting signature would pile up while PIs were out of town, at different locations, or over holidays. Investigators had to stay extra late after research visits and clinic in order to sign lab reports in anticipation of being out of the office. Now with CRIO, she just needs to upload the lab reports into CRIO, and the PI can review and sign the reports any time from anywhere.

How CRIO Helped with Implementation

Using a new system takes time and effort getting used to. Tarisa attributes her willingness to continue navigating through the change to the excellent support staff at CRIO. The Livechat support staff are available 24 hours a day, 7 days a week, 365 days a year, allowing her to complete eSource design builds even in severe time constraints and over the weekend.

"Compared to previous technology solutions whose support staff usually have no idea what you're talking about," Tarisa explains, "I can just send them a link to what I'm looking at and they are able to see exactly what I'm talking about."

Tarisa went on to explain how patient and knowledgeable CRIO's staff are. And even when "[the staff] needed time to find out about something that I was asking about on a Sunday night, he got back to me at 7 in the morning just in time for my subject visit the next day at 8AM. I couldn't believe it, I definitely didn't think he would."

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Looking Ahead

While she and her staff are still getting used to eSource, she already can tell that it will allow research visits to be much faster. Once their site has many studies in CRIO, building out the source will become faster because they can simply reuse procedures from their own library of templates.

Only halfway through her implementation, Tarisa is already realizing value from the system and envisions a more effective and efficient research site in the near future.

ABOUT THE PROFILE

Tarisa Mantia is a clinical research manager at Washington University School of Medicine in St. Louis, Division of Allergy and Immunology. Tarisa is a graduate of Washington University in St. Louis, where she earned a Master's of Science in Clinical Research Management. Tarisa is also a Certified Clinical Research Coordinator (CCRC) equipped with over a decade of clinical research experience.