Monthly e-Newsletter
SCRS InFocus

SCRSConnects

SCRS recently connected with two executives from SCRS Global Impact Partner (GIP) Veeva: Nate Spilker, GM of clinical research solutions, and Jason Methia, VP of site strategy. We asked them about their pathways into clinical research, their perspectives on the struggles sites face today, and the solutions they envision.

Nate Spilker
GM of Clinical Research Solutions

Jason Methia
VP of Site Strategy

SCRS: How did you get into Clinical Research?

Spilker: I graduated from college as the dot com boom was igniting and I saw the immediate and disruptive impact technology can have on people's lives. Since then, my career has been focused on building easy-to-use technology to solve complicated business problems. While I have built software solutions for many industries, I became particularly drawn to the life sciences industry largely because its primary aim is to help people. Veeva presented me with an opportunity to contribute to an industry that I admire, and I jumped on it.

Clinical research is complicated. The dedicated, passionate research professionals who are working so hard to get treatments to patients are slowed by processes that can be significantly improved with technology. I am committed to delivering solutions that make the process better.

Methia: I started my career as a regulatory coordinator at the Dana Farber Cancer Institute, then moved to the pharma side with Wyeth Research, Vertex Pharmaceuticals, and now Veeva. Two thoughts remain with me wherever I go:

First, clinical research is personal. When you work with sites, you see the patient, you meet their family and you are personally impacted by their success and failure. As a result, researchers work hard to not only ensure trials are executed with speed and quality, but also to ensure a positive patient experience. This is one of the biggest reasons that working in the site space as a technology provider is rewarding – we get an opportunity to help the folks who help patients.

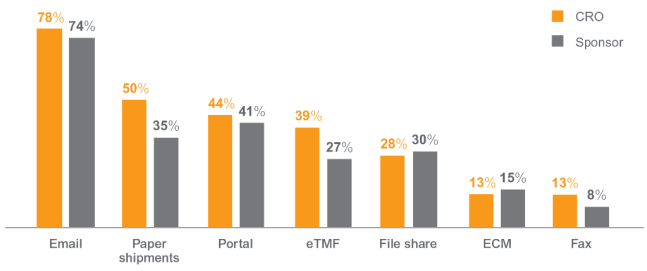
Second, clinical trial execution is broken. This is true at all levels, but you see the challenges first-hand when working with sites – problems like patients being held back from a trial or experimental medication simply because of a contract glitch. Seeing this highlighted the importance of rethinking legacy trial operations and business operations to bring focus to improving speed and quality. Helping sites improve their day-to-day operations and seeing practical results make a big difference in the lives of patients.

SCRS: What do you see as industry's biggest challenge right now within your professional spectrum?

Spilker: The industry is facing increasing clinical trial costs, complexity, and tightening timelines. As a result, it's getting harder and harder to get new treatments to patients that need them.

Methia: We are generating more data than ever before. Most of this information is shared and changes hands multiple times from sponsor to CRO to site, but the ability to share information easily remains a major challenge.

Veeva surveyed more than 450 clinical operations professionals from sponsors and CROs across the globe and discovered that 96% of respondents have significant challenges with the methods used to exchange information during clinical trials. Most information is exchanged via email, paper and portals. There is a critical need to improve information exchange across sites, sponsors and CROs.



What methods does your organization use to exchange trial data and documents with study partners? Select all that apply per row. (Q6)

The majority (96%) of respondents say they have significant challenges with the methods used to exchange information during clinical trials.

Source: Veeva 2019 Unified Clinical Operations Survey

Spilker: Clinical research sites are feeling the biggest impact of these challenges. They face a higher level of administrative burden than ever before and are spending an inordinate amount of time on manual processes and administrative work. Sites are struggling to make the investments in personnel and infrastructure required to keep up with the pace of change.

SCRS: What is your organization doing to address these challenges?

Spilker: Sites need to be able to remain focused on patient care and improving patient engagement, and they need better tools to conduct their research. Veeva is creating new ways to share and exchange information between sites and sponsors in a way that accounts for the site's workflows and resource capabilities. We're also adopting a "no site left behind" mindset by finding new ways to deliver technology to sites that don't otherwise have the resources to purchase a system.

In October 2019, we announced Veeva SiteVault Free, an eRegulatory (electronic binder) system built specifically for research sites. Providing SiteVault at no cost gives all sites access to high-quality technology to improve their studies, regardless of the sponsoring company. This helps sites eliminate slow paper processes and the need to manually send or resend documents to their study partners.

In 2020, sites, sponsors and CRO customers will be able to share documents and data with each other without the use of emails and portals.

Methia: Veeva is listening and working more closely with sites to build solutions that reduce their administrative burden. A site customer recently mentioned that their coordinators spend upwards of 70% of their time fielding emails and responding to queries. We are helping sites directly with administrative challenges like this. It's a collaborative win for both sites and sponsors.

SCRS: What do you see in the short- or long-term having the biggest impact on sites?

Methia: In the short term, improving awareness of and access to high-quality, easy-to-use technology will enable sites to manage studies with less effort.

In the long term, bringing all trial participants together will lead to higher-quality data, more efficient collaboration and faster trial execution. It will also help sites grow their business. Investigators will have more time to spend with patients, and trial participation will become more appealing to patients.

SCRS: How do you see SCRS helping to address this issue? What impact have you seen SCRS have on this conversation within the industry?

Spilker: SCRS is elevating the voice of sites and bringing industry partners together to improve collaboration. The open dialogue across sites, sponsors and CROs during the annual Site Solutions Summits has had a significant impact. SCRS is enabling alignment across stakeholders, and Veeva is proud to support this mission.

Methia: The mission of SCRS is to improve site sustainability, and we share this goal. SCRS listens to sites, advocates for their needs, and reliably provides unbiased information about new ways sites can run research effectively and efficiently.

About SCRS

Founded in 2012, SCRS is a global trade organization that unifies the voice of the clinical research site community to create greater site sustainability. Representing over 9,000 sites in 47 countries, SCRS membership provides sites with a community dedicated to advocacy, education, connectivity and mentorship. SCRS is an influential voice for sites and an active partner in industry-wide initiatives and dialogues focused on improving the clinical research enterprise. **Our Voice. Our Community. Your Success.** Join the community.