Beyond the Protocol

How can sites be empowered for optimum trial performance

In today's complex clinical trial environment, site success depends on more than protocol adherence — it requires targeted support that addresses the realities of site operations.

From managing complex eligibility criteria to balancing competing studies, clinical sites face unprecedented challenges that can impact recruitment, retention and overall trial performance.

In this Xtalks Spotlight interview, Dr. Rebecca Sayers, Senior Director, Global Head of Site Enablement Solutions at IQVIA, shares how sponsors and CROs can empower sites through smarter communication, tailored support roles and strategic planning to drive success across trial phases.

From tackling patient recruitment and retention challenges to reducing site burden and simplifying vendor interactions, gain actionable strategies designed to meet the realities of today's trial sites.

Discover how clinical trial educators (CTEs), monitors and targeted communication strategies can elevate the site experience — and why performance-based engagement is shaping the future of trial execution.

The realities of patient recruitment and retention

Patient recruitment has become one of the most challenging aspects of conducting clinical trials.

Sites are tasked with identifying eligible participants while contending with increasingly complex protocols and fierce competition for patients.

"The sheer complexity of eligibility criteria is a major barrier," said Rebecca. *"It just makes it quite complicated and time-consuming to identify those patients."*

Beyond managing prior medication exposures, specific medical events and lab values outside of standard care, sites must also navigate overlapping studies that target similar populations. This intensifies the pressure and extends recruitment timelines.

Retention presents its own challenges, particularly as trials lengthen and endpoints require extended follow-up. Ensuring that patients remain engaged and compliant over months or years adds to the site's operational burden. As Rebecca noted, *"That time investment and that retention is really critical."*

By simplifying trial designs, minimizing unnecessary complexity and providing tools that ease operational demands, sponsors and CROs can help sites devote more time to what matters most: identifying, enrolling and retaining the right patients for their studies.

Risk-based site communication: a smarter way to engage

In today's complex trial landscape, communication with sites needs to do more than check a box — it must be purposeful, timely and relevant.

Without a thoughtful approach, frequent messages and reminders can overwhelm sites, creating confusion rather than clarity.

> *"Time is a non-renewable resource for sites."*
>
> *— Dr. Rebecca Sayers*

"When we're just blasting the sites with email messages, phone calls... the sites are getting inundated with these kinds of messages, and it gets impossible for them to prioritize," explained Rebecca.

Generic or excessive outreach not only consumes valuable time but also risks disengagement, as site teams struggle to identify what requires immediate action.

A risk-based communication strategy can address these challenges by tailoring outreach based on site performance and study needs.

Rather than sending blanket reminders to all sites, targeted messages ensure that teams receive only the information most relevant to their situation at any given moment.

This approach requires careful planning and agility. As Rebecca said, *"What works well is when there's a really comprehensive plan that's set out at the beginning of the trial... making sure that the messaging that we send to sites is insightful. It gives them something of value that's really relevant to that study."*

Equally important is the ability to adapt, whether due to changes in the competitive landscape, protocol amendments or emerging risks.

Ultimately, risk-based communication not only improves trial efficiency but also fosters trust and satisfaction among site partners — setting the stage for stronger performance across the study lifecycle.

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Delivering a "concierge" site experience

As clinical trial complexity grows, sites need more than traditional monitoring to succeed. They need dedicated, personalized support that helps them navigate protocols, technologies and evolving expectations.

While clinical research associates (CRAs) play a foundational role in ensuring sites are trained and compliant, that alone may no longer be enough.

"The more complex we make it overall, we then transfer that complexity to the CRA that has to get the site up and running on that. And that's a challenge too," said Rebecca.

The increasing demands placed on CRAs can limit their capacity for deeper, more hands-on support.

This is where roles like CTEs come in. CTEs offer what Rebecca describes as a *"white glove experience,"* providing sites with tailored guidance that clarifies protocol requirements, explains system workflows and ensures that site staff truly understand why certain processes matter for trial integrity.

CTEs help reduce protocol deviations, improve site engagement and support smoother transitions when protocols change.

As Rebecca shared, *"What seems like a simple ask — hey, screen a patient on this study — can be really challenging if there's not someone there to help guide you, help explain why this has been set up this way, why it's important for the overall scientific integrity of the trial."*

By combining the operational rigor of CRAs with the personalized support of CTEs, sponsors and CROs can deliver a "concierge" site experience. This approach empowers sites, builds stronger relationships and ultimately drives more successful trial outcomes.

Supporting site evolution for future success

As trial designs and patient populations become more specific and complex, sites must evolve to stay competitive and sustainable.

This means rethinking traditional models, diversifying staff roles and adopting technologies that support more efficient operations.

"The sites that have really kind of leaned into a different way of doing things themselves and asking, 'Hey, now that we have this new technology... I'm going to change what I'm doing,'" said Rebecca.

"We want sponsors to engage creatively with us to introduce new roles and models at sites, improving efficiency. This shift will benefit the industry and speed up medicine delivery if we rethink our approach."

— Dr. Rebecca Sayers

By proactively adjusting their internal structures — for example, by assigning specialized staff to manage certain tasks or leveraging technology for remote visits — sites can operate more efficiently and take on additional studies without overextending their teams.

Sponsors and CROs have a critical role to play in enabling this evolution. From designing protocols that integrate home visits to offering tools and training that help sites rethink their business models, collaborative strategies can ease site burden while accelerating trial delivery.

Ultimately, empowering sites to innovate not only supports their long-term success but also helps bring therapies to patients faster.

This article was created in collaboration with the sponsoring company and the Xtalks editorial team.

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