IQVIA TECHNOLOGIES

White Paper

Routes to Sponsor of Choice: From Shared Pipelines to Streamlined Payments

Introduction

This whitepaper summarizes a discussion with George Kourtsounis, Senior Director for Clinical Trial Contracts and Grants at Bristol Myers Squibb; Casey Orvin, Chief Commercial Officer at CenExel Centers of Excellence; and Jim DiCesare, Senior Director of Study Operations for IQVIA Clinical Trial Payments, a third-party site payments provider that operates independently of IQVIA's contract research organization (CRO).

Increasingly, sponsors are competing for clinical trial sites and want to distinguish themselves from their peers to become sites' first choice for partnerships. To this end, companies are creating "sponsor-of-choice" initiatives that look for ways to improve site-sponsor relationships. Investing in a clinical trial payment solution that ensures sites get paid reliably and efficiently is one of the most important ways to be a sponsor of choice.

Clinical Leader and IQVIA Technologies recently explored this issue in Trends in Sponsor-of-Choice Initiatives: Consolidating Site Payments in a Multiple CRO Model. Kourtsounis, Orvin, and DiCesare's perspectives and experiences varied, but they agreed that paying sites on time is vital to becoming a sponsor of choice for sites.

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Bristol Myers Squibb's Sponsor-of-Choice Initiative

As a drug development leader, Bristol Myers Squibb (BMS) is committed to being a sponsor of choice. Kourtsounis agreed with Orvin that it's a difficult term to define, but it centers on the association between sponsors and sites. BMS has a team of site relationship managers dedicated to this process.

"At BMS, we've been at the forefront of cell therapy and oncology, so our needs are complex," explained Kourtsounis. "We work with many large academic institutions, so communication between our medical team and the principal investigators within each department or therapeutic area is primary."

Kourtsounis added that from a study start-up perspective, it can be challenging to communicate clearly with representatives from large institutions to negotiate contracts and budgets. BMS has a three-pronged approach to becoming a sponsor of choice. First, they have over 200 master clinical trial agreements to leverage previously negotiated terms. Second, they offer non-binding rate cards, which can increase study start-up efficiency but with added flexibility.

"Our third pillar is a singular clinical trial payments model. We had six different ways to make site payments at the beginning of 2019, and we are

migrating to IQVIA CTP as our single payments model across the enterprise."

"We've been acquiring organizations and expanding our business, so we needed a singular payments model to have consistency in application across the board and to get as many of those master clinical trial agreements and rate cards in place."

Kourtsounis explained that becoming a sponsor of choice requires a multilayered approach that looks at start-up times, patient enrollment and retention, and clear communication with sites. Consolidating the systems and processes by which they get paid into one reliable provider helps sites negotiate and contract with BMS with more confidence, which benefits both parties.

What Does "Sponsor of Choice" Mean To Sites?

The honorific "sponsor of choice" is not clearly defined, but it's an ideal to which many sponsors aspire. Considering that increasingly there are more clinical trials than sites can manage, the definition is ultimately up to the sites themselves. Orvin, who has devoted his entire career to clinical research sites, explained that a sponsor of choice is defined by how openly it communicates.

"We begin by asking, 'Do we have access to the sponsor's pipeline?'" explained Orvin. "If we do and have an established connection, that's where it starts. We want sponsors to say, 'Here's our pipeline, here are the studies you can be successful in, and here are the results of similar studies we've done.' Many sponsors may think they have a good relationship with sites, but are they truly collaborating with them? Are they sharing detailed information that the sites couldn't get elsewhere?"

The importance of sponsor-site relations has risen dramatically in recent years, and sponsors and contract research organizations (CROs) now have departments that focus exclusively on sites. But Orvin explains that establishing trust doesn't just mean chatting casually on the phone once a week. It means considering sites' needs and capabilities.

For example, sponsors should consider in what therapeutic areas sites have experience and consider them for similar studies. Sponsors' goals and pipelines should match site capabilities to accelerate the study-building process and have confidence that sites will deliver the right number of participants, screenings, and randomizations. Sites often prefer sponsors who work with master service agreements, too. These dealings help lessen the study start-up phase and shorten the enrollment timeframe, which benefits both sites and sponsors. Investing in site-sponsor collaborations improves efficiency, which benefits both parties.

"As sites, we should ask ourselves, how can we better collaborate with sponsors?" added Orvin. "I'm excited to be chairing an initiative at SCRS to advocate for better payment practices in our industry."

The purpose of the SCRS Payments Initiative is to create a fair state where sites are paid 100% of earned revenue, payment terms are monthly rather than quarterly, and clinical trial volunteers are not penalized through tax.

According to Orvin, two-thirds of sites have less than three months of operating cash on hand. Without timely payments from sponsors, sites can't operate. When sponsors take 60 or 90 days to make payments or expect withholdings, it puts unreasonable financial burdens on sites. Orvin encourages sites to insist on 30-day payment deadlines and negotiate for 0% withholding to improve the relationship with sponsors.

Payment Systems Can Help or Harm Sponsor-Site Relationships

Orvin and Kourtsounis agreed that payment problems harm sponsor-site interactions. Given current economic conditions, sites may be struggling with cash flow and resources, and sponsors can support them by paying efficiently and effectively.

Kourtsounis explained that when there are payment delays, sites and investigators may stop enrolling patients or deprioritize a sponsor's trial. This disruption slows drug development and underscores how timely and accurate payments are a key competency that sites look for in sponsor partners. One thing BMS has done to retain goodwill is eliminate withholding in their site contracts.

"At the end of the day, if the money isn't coming in for the resources that you're allocating, especially during a period where everybody is resource-strapped, late payments is a trigger that can undo a lot of the goodwill from a relationship management perspective, a pipeline management perspective," stated Kourtsounis. "Because if you can't continue to operate, then you can't execute the trial. Site payments are a crucial indicator that you must get right to ensure the goodwill of the sites. If we weren't getting a paycheck to come to work every day, we would stop working too."

BMS: Streamlining Payment Processes for the Global Economy

Sponsors need to consider the site experience in their clinical trial payments strategy. Sites manage multiple trials, and when payment systems are complex and require training, it creates a burden for staff. Choosing a streamlined, standardized payment system helps sites invoice and receive payments efficiently.

"Managing several payment systems overburdens sites," Orvin commented. "Every time a sponsor asks us to use a new system, we have to take time to train our staff on that system. And when we're overseeing ten or more studies, that time burden multiplies. A sponsor that uses a single payment system standardizes the process and increases efficiency."

Likewise, when sponsors are working with multiple CROs, site payments become complicated, and compliance reporting is more difficult. Companies like BMS that are working to become a sponsor of choice avoid the trap of relying on the study's CRO for payments processing and instead adopt a standardized payment system across their studies enterprise wide. Standardizing the process globally is key to navigating multiple currencies and cultures.

"We need to have a global approach but account for local standards and nuance," explained Kourtsounis. "When we didn't have a standardized reporting and transparency process, we had a lot of resource and administrative burden on internal staff. And when we acquired other companies and increased our scope, we needed to find a faster, more efficient system. The best solution was to make IQVIA CTP our single payment provider. It has put us on the forefront of the industry in terms of understanding that economic conditions change, business conditions change, but we have the global reach and capability to adjust and pivot on the fly."

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— George Kourtsounis, Senior Director for Clinical Trial Contracts and Grants at Bristol Myers Squibb

Kourtsounis admits that changing payment systems in the middle of inflight studies is a bold move and a byzantine project that involves many stakeholders; but in the end, the gains are worth the effort. The global market shifts daily, and sponsors need agility to keep up with local inflation, political changes, and other economic factors. Standardizing site payments provides stability in difficult times and maintains positive relationships between sponsors and sites.

"Having listened to our sites and working to be sponsor of choice, we knew we needed to move to a single-provider model," explained Kourtsounis. "After an exhaustive search, we found that IQVIA CTP system was the best system to work with, and it has lived up to our expectations. No one expected a global pandemic that would cause our industry to pivot in various ways, but our overarching goal is to deliver to our sites and give them what they need. Improving our technology and developing new connections has allowed us to create a better system today than before the pandemic."

IQVIA CTP Benefits Sponsors and Sites

"IQVIA CTP helps sponsors that employ multiple CROs converge into one payments solution, giving sites a single, standardized approach that stabilizes cash flow," DiCesare explained.

IQVIA CTP uses a Six Sigma methodology to find and fix the root cause of any late payments and remove inefficiencies. BMS reports significant gains from its work with IQVIA CTP, including standardization of information and a single source of truth. This allows BMS to improve forecasting, cash flow management, compliance, and transparency.

"Every time I look at the IQVIA CTP dashboard and can see all the payments that we've executed and have outstanding, from a metrics perspective, it gives me the information I need," Kourtsounis explained. "We're not poring through Excel spreadsheets with thousands of lines of information that we must sort manually. Having that easy visibility allows us to address issues with sites quickly and transparently."

IQVIA CTP's global reach and site-focused customer service allow clients like BMS to rely on them for analysis and help address problems with any site, worldwide. Additionally, IQVIA GrantPlan helps BMS build budgets based on market benchmarks. These tools ensure sponsors invest their capital in the best possible way, with the flexibility needed to adapt to changing markets.

"The ultimate goal of this industry is to get new drugs to the most people that we possibly can in the shortest and safest way possible," added Orvin. "Efficiencies, standardization, and technology play a key role. So, as a site network, when we have 10 different studies from BMS using IQVIA CTP, it makes us so much more efficient and gives us resources we need to run more trials. Any time we can improve the process and shrink the time it takes for drugs to be approved, the better it is for all of us."

About the contributors

GEORGE KOURTSOUNIS, JD
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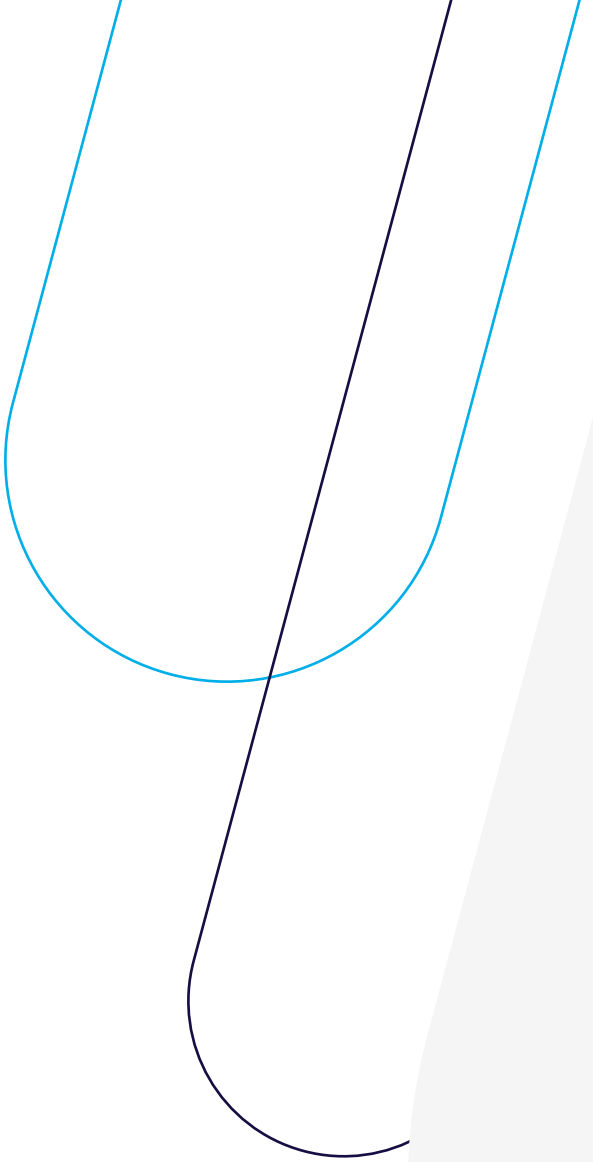
George Kourtsounis is a strategic thinker whose passion for patients and the business aspect of what we do merge in his role at BMS. His role at BMS has him responsible for Site and Investigator contracting in the United states as well as being accountable for all site and investigator payments worldwide. With over 10 years experience as both a lawyer and a contract negotiator, George's expertise touches all aspects of the lifecycle of a clinical trial and beyond.

JIM DICESARE
Senior Director, Study Operations,
IQVIA Clinical Trial Payments

Jim DiCesare is passionate about delivering innovative site activation and site payment services to clinical trials. With over 25 years of industry experience leading clinical operations teams at Merck, DrugDev, and now IQVIA Technologies, Jim has expertise across the contracting, budgeting, and investigator grant payment management continuum. He is a frequent speaker at industry conferences and has written for a variety of publications. He has a B.S. in Accounting from Kutztown University.

CASEY ORVIN
Chief Commercial Officer (CCO)
at CenExel Centers of Exellence

Casey has a long and exemplary career history in pharmaceutical research services and currently leads the business development efforts for CenExel, now the U.S. leader of independent clinical research sites. Prior to joining CenExel, he served as President of the Society for Clinical Research Sites (SCRS), a global organization representing nearly 10,000 clinical research sites in 47 countries within the pharmaceutical industry.



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