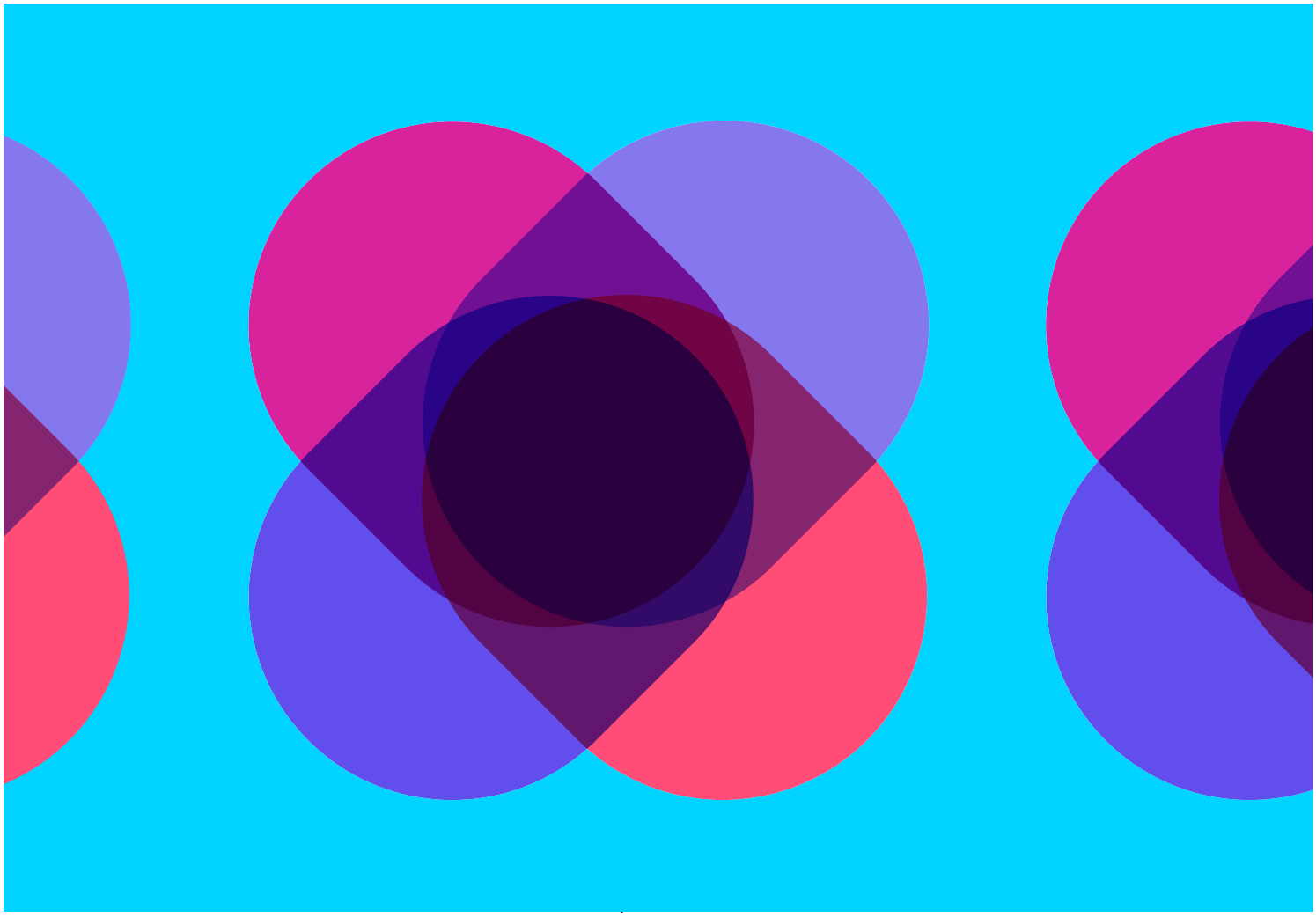
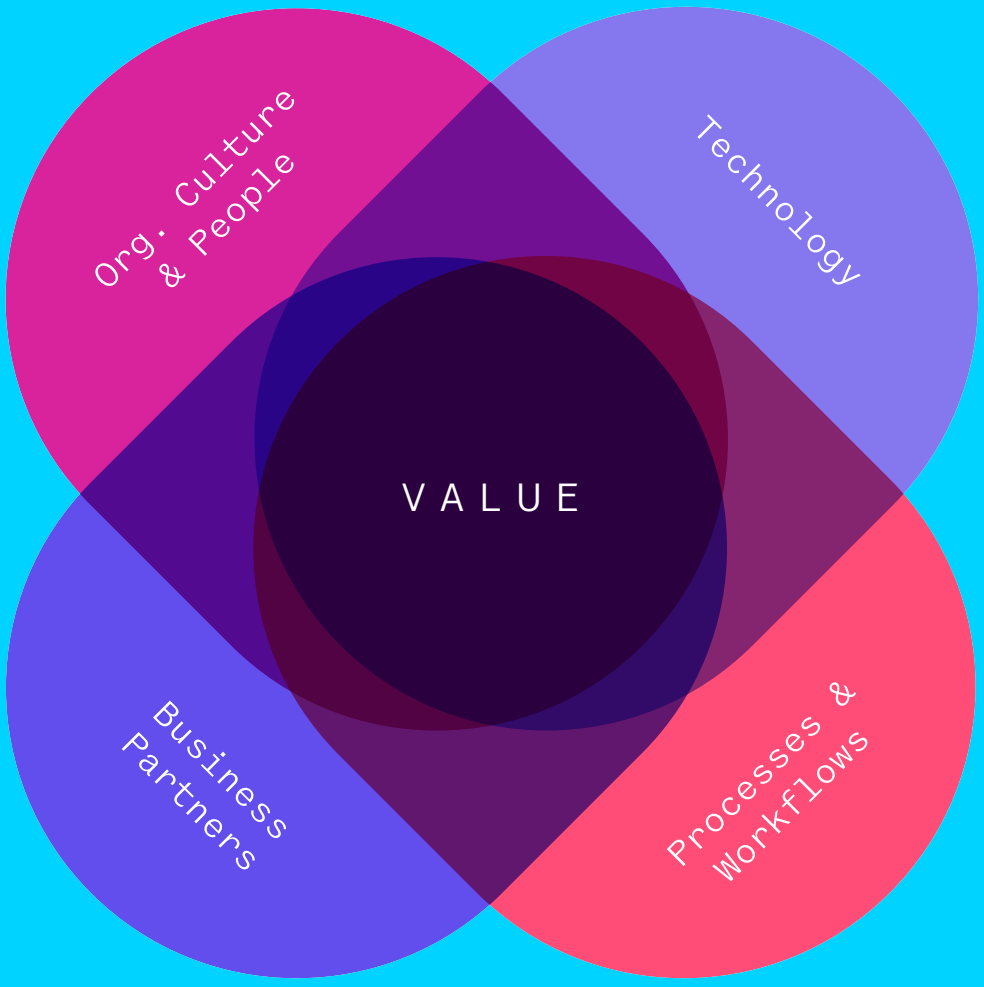
Run Your Site Like a Business: A Framework for Success

Sandy Smith, Senior VP for Clinical Solutions and Strategic Partnering, WCG



Clinical research is a business - a multifaceted and highly regulated one. To run it well, sites need to have a business framework in place.

We've developed a four-part framework; each element is crucial to success.



Each of these supports the value your organization provides to sponsors and CROs.

CULTIVATING THE RIGHT PEOPLE

It starts with culture. An engaged principal investigator and qualified, competent research team are, of course, essential. But success also demands effective communication, accountability and innovation. And that comes down to culture. Any successful organization should foster a culture based on a strongly held and widely shared set of beliefs that are supported by strategy and structure. Organizations not only educate and set expectations—they also empower the team and recognize members for demonstrating the organization's values.

The team leader is the PI. Ideally, the physician who will serve as PI has experience or a background in research. However, sites can create mentoring opportunities to help physicians become accomplished PIs.

The best investigators have the respect of their site leadership, physician colleagues and their team. They will devote the necessary time to the trial and attend the meetings, seeking leadership support and engaging with other physicians about the research.

This willingness to put in the time is vital, and it must start during study activation. Sites should involve the PI in the budget review and especially in coverage analysis. The PI is best able to distinguish between routine and nonroutine care. PIs also have insights that can inform the recruitment plan.

During the trial, the PI provides appropriate trial oversight and interfaces with the sponsor. But they also serve as the go-to expert for complex clinical questions, and need to be available to help underperforming investigators.

Supporting investigators in their early clinical trial experiences will be pivotal to whether sponsors will re-select them—and your organization—for future trials.

We are facing an unfavorable trend related to the number of experienced investigators. When we look at the profile of investigators who performed in trials in the past year, about 41% have been engaged in only one clinical trial. Two-thirds have performed in four or fewer. At the other end, only 13% have participated in 10 or more trials.

Finding the best staff may be even more difficult than securing a first-rate PI. Nearly half (49%) of all sites identify staffing as a top concern. The scarcity of research professionals certainly predates the pandemic, but the pandemic exacerbated it. Shortage or no shortage, you need a high-performing team. As you are recruiting staff, be clear about the characteristics you seek.

Once those team members are brought on board, outline expectations and make them aware of how their performance will be measured.

That's how your team members are going to expand in their role and end up being those people who identify opportunities for improvement within your research program, bring in best practices and allow your site to innovate. One last consideration vis-à-vis recruiting: Focus on diversity, equity and inclusion. Think about that in terms of staff recruitment, so that as you're trying to enroll subjects to clinical trials, they see that diversity in the research team members as well.

TECHNOLOGY AS AN ENABLER, NOT THE SOLUTION

Planned and executed correctly, technology can enhance efficiency and support growth, but it won't solve all site problems. Before making that substantial investment, consider how it will enable workflows and improve performance.

Start with a review of your current processes - financial, regulatory and operational. You must identify the problems before you invest in a pricey solution. Be strategic: Consider what you need today and what you will need five years from now. It's a tremendous investment not just in money, but in time and effort.

Among the many criteria to consider:

- Interoperability
- Good reporting functions
- eRegulatory/eSignature/eConsent solutions
- CTMS capabilities
- Research participant identification software to scan your EHR for eligible patients
- Remote monitoring capabilities to support remote and hybrid trials
- Financial management to manage site, investigator and patient payments
- Telehealth capabilities and the ability to gather patient data from wearable technology

Any technology must be integrated into a site's process and workflows.

PROCESSES AND WORKFLOWS

Trial activation may be the most critical process, and it may be the one that needs the most improvement. Currently, by any metric, it just takes too long. A Jan. 2021 paper in the Journal of Clinical Oncology found the median trial activation time at academic medical centers was 167 days. Contrast that to the ideal, 30 to 45 days. If you don't have a goal, set one and measure your improvement. We know the trial timeline is one metric that sponsors and CROs use to select sites.

When you are activating your trials, do you perform each step sequentially or concurrently? For example, are you working on your budgets, your contract and your IRB submission in parallel? That approach can cut your activation time by about half.

We'll now explore some of these workflows, beginning with financial management.

Financial management starts with the strategic plan and annual budget, but we're going to focus on the study budgets. One of the most important documents that will be created as you're preparing your study budget is your coverage analysis—this is especially true for complex studies as in oncology, where some items will be billed to the payer and some to the sponsor.

The coverage analysis serves as the basis for the study budget. It will provide insight into the true

costs of conducting a particular clinical trial and can serve as a billing guide to ensure compliant billing.

As you are creating the budget, include all the activities related to conduct of the study, including the following:

- **Time:** Time is frequently undervalued in budgets. The problem goes beyond physician or CRC time. For example, if a study engages a pharmacist or requires tissue collection, be sure to factor in that time. The same applies if you need to spend more time preparing for remote monitoring visits.
- **Infrastructure costs**: This includes technology, the associated licensing fees and cybersecurity insurance.
- **Inflation**: Especially now, this is a concern for multiyear studies. And if you're working on multiyear studies, factor in inflation, as that will help the financials for your program.

For each study, determine whether it is a good fit financially. If you're not going to be able to break even and you still want to do that study, go into it with your eyes wide open and knowing the risk.

Benchmark the time it takes to complete your processes related to study initiation activities. Budget development and coverage analysis should take about 38 days. In contract negotiations, we see a range of anywhere from 32 to 137 days. Putting master agreements in place can keep you on the low end because so much of the language will have already been negotiated.

Next, let's look at operational processes. We know that 68% of sites fail to meet their enrollment timelines. But published data suggests if you can enroll the first patient in the first 60 to 75 days after opening your trial, you're much more likely to hit your enrollment targets. So there's not only a speed factor with getting the trial activated, but also in getting that first individual enrolled. By the time you have a feel for the eligibility criteria, you've navigated all the details of the protocol, and that should set you up for success with subsequent enrollments.

Conduct a workload assessment. Given the volume of work, does your site have the right number of people? Trials have become more complex, with more endpoints and more amendments. Trial designs are changing. Does your site have the capacity to handle all this? To assess, look at a few metrics:

- Retention rate
- Screen failure rate by trial
- Enrollment by trial

You may find you need to supplement your staff.

PARTNERING FOR SUCCESS

Outsourcing is a word that makes some people uncomfortable because it suggests giving up control. But a site can keep control and partner with well-established organizations to support its research goals.

The endgame is to be a preferred site, to drive value for the sponsor and CRO and to exceed their expectations. So as you're evaluating business partners, look for those that can measurably contribute to predictable and improved site performance. Make sure that they are metrics-driven, and can show you their past performance and that they have expertise you seek.

Here are some situations when you might consider partnering with an outside organization over the long- or short-term.

- Your timelines are lagging.
- Your staff is relatively inexperienced in clinical research. Bringing in a business partner with more experience may help elevate their experience level.
- Your site has a high turnover rate.
- You need assistance with training and overall FTE management.

Although you may outsource some patient-facing functions, especially during recruitment, many background functions can be outsourced. Here are a few:

- Trial identification
- Administrative functions: Outsourcing administrative tasks allows your team to devote more time to participants
- IRB services
- Budgets and coverage analysis: Many organizations perform large volumes of these services with a dedicated team of experts who complete these tasks efficiently and predictably
- Claims review: Careful auditing ensures you are appropriately paid
- Data entry and query resolution
- Trial marketing/advertising
- Recruitment, enrollment and retention
- Regulatory tasks

These are just a few of the possibilities.

IT'S ALL ABOUT THE QUALITY!

A final word about metrics: You are being paid for quality data. So identify key performance indicators (KPIs) regarding your data entry, as well as your overall trial performance. When people understand what the KPIs are, and what's expected of their job, it gives them more accountability. As they say, an unmeasured process is an uncontrolled process, so if there's no measurement involved, then you probably won't have your eye on where you need to be.

At the end of the day, what you want to do is exceed the expectation of the sponsor and CRO so they're coming back to you for future studies.

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