

Standardized Development **METRICS**

BY ROBIN ROBINSON

The use of standardized performance metrics by drug developers — CROs and sponsors — to reduce clinical development time and to improve deliverables **is more essential than ever for success.**

MALCOLM BOHM, TrialMetrics



Many companies have attempted to come up with ways to better manage the clinical-trial process, but there has yet to be an industry shift that has made a difference.

I **Imagine the confusion if every Major League Baseball team had its own way of calculating batting averages.** This fictional scenario is analogous to the real environment in which sponsors and CROs are currently operating.

With every company — sponsors and CROs — having its own set of metrics and tracking methods for clinical trials, across-the-board analyses and comparisons are major challenges. Metrics are crucial to keeping clinical trials on track and identifying weak spots that may impede success, but only a fraction of the industry currently uses standardized performance metrics, says Linda Sullivan, VP of operations at Metrics Champion Consortium (MCC). The nonprofit organization aims to develop performance metrics within the biotechnology and pharmaceutical industry

LINDA SULLIVAN, Metrics Champion Consortium



The purpose of the MCC metrics initiative is to establish a standard set of performance metrics that sponsors and service providers can collect and review together to understand where there are opportunities to improve the clinical-trial process.

will be requested to ensure that the metrics are successfully measuring the information that they were designed to capture, resulting in actionable outcomes. Ms. Sullivan says modifications will be incorporated, as necessary, for future versions.

that will enhance performance, effectiveness, and efficiency, and set appropriate levels of controls for both sponsors and service providers.

These MCC Clinical Trial metrics are the fourth set of standards that the organization is initiating; it has also addressed laboratory performance, ECG performance, and medical imaging.

"This collaboration is intended to understand how metrics are measured and what's behind the numbers," Ms. Sullivan says. "Because there are so many metrics being used across the industry, the goal is to make sure everybody is measuring and talking about results in the same way."

Some experts are leery of the feasibility of standardized measurement across the board, and wonder if the metrics will be applicable to their own partnerships.

According to Ms. Sullivan, although data are coming out of CRO data systems, in some cases the data are tracking items that the CRO has no control over.

After an industry review of the metrics in April, the MCC will collect the feedback, and responses will be included in a working draft version. Once industry members have had an opportunity to implement the outlined initiatives into their operations, further feedback

The Impact of the MCC Metrics

PharmaVOICE asked experts in the CRO field to share their opinions on how the new Metrics Champion Consortium (MCC) objectives might shape the future of CRO and sponsor partnerships and processes.

BOHM. TRIALYTICS. The industry is crying out for a set of metrics that can be standardized to measure the productivity of solution providers and sponsor-driven programs. There is going to be universal interest in the MCC outcomes, but the details will be in the final criteria: for example, whether the proposed metrics are sufficiently aligned with sponsor metrics. There are a number of factors that drive the ultimate trial enrollment and the number of patients randomized over time. The challenge is that beneath this metric are a myriad of contributory factors, such as how productive are the sites and how quickly can sites be up and running. To the extent that the metrics drill down to the nitty-gritty operational levels and provide a bottoms-up approach to improvement, I think there will be a great deal of interest in the adoption of these metrics.

CORCORAN. STIEFEL. One of the biggest challenges between sponsors and CROs is establishing common standards. This is usually a

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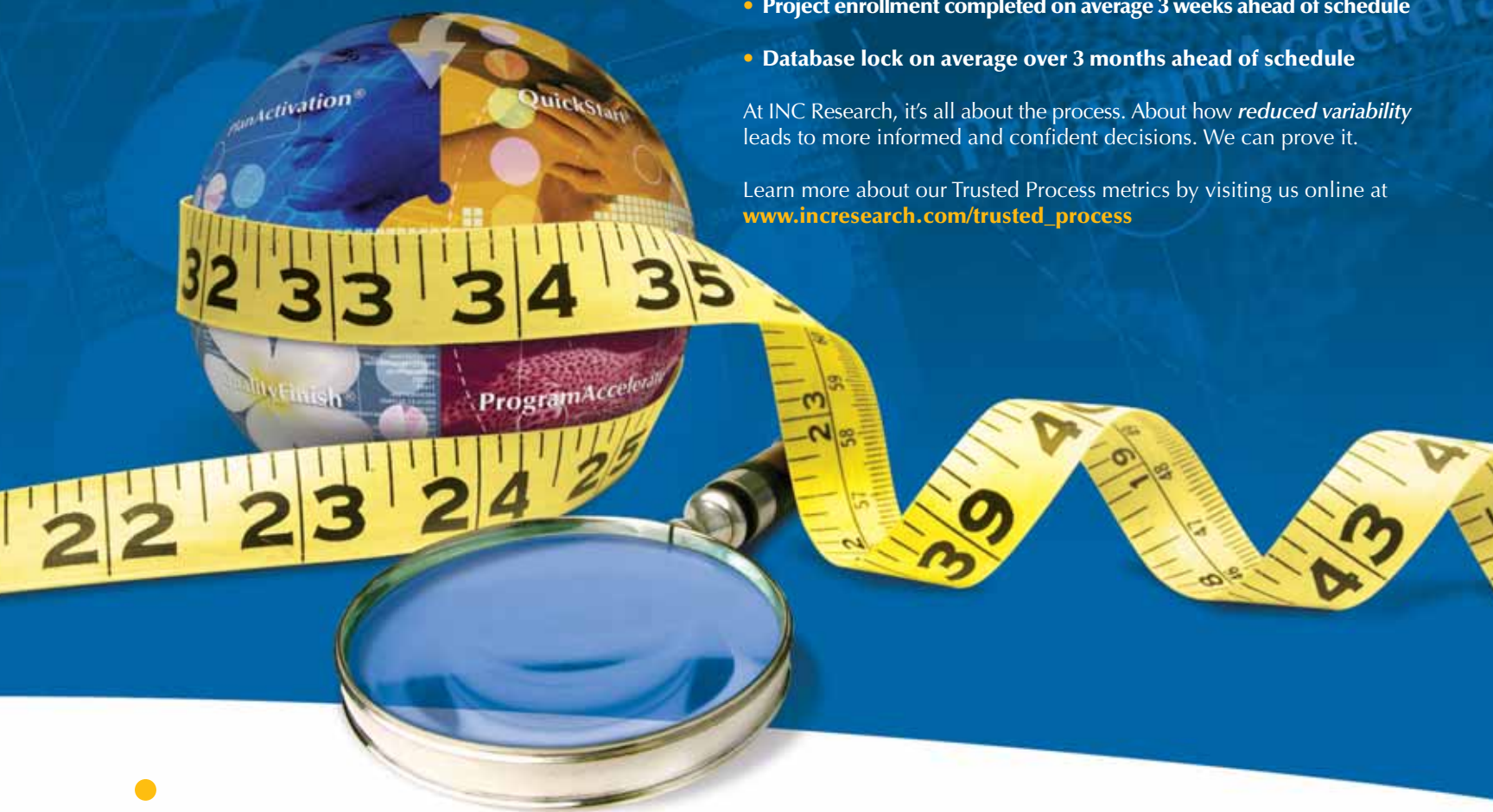
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Standardized metrics will pave the way for sponsors to raise the bar of excellence in execution and realize real value from the relationship.

big part of a study start up, especially for new partnerships. Having well-accepted standards will provide a reference and a starting point for these interactions.

DEARHAMMER. *i3* STATPROBE. The new metrics will deepen the appreciation for CROs, the talent they have, and benefits they bring as customers compare CRO metrics with their own. CRO selection will be based on value rather than price.

KUEFFER. *INC RESEARCH.* By its very nature, this collaborative process undertaken between sponsor companies and CROs — the result of which is a set of standardized performance metrics — will enable a new level of partnership within the industry to bring drugs to market. The introduction of standardized performance-based metrics acts to reduce the high degree of uncertainty and perceived risk traditionally associated with

selecting a CRO partner, and thus tangibly benefits the overall quality of the clinical-trial process.

MOORE. *CHILTERN.* I expect that the use of the new metrics will provide benchmarking standards for performance on specific trials and will enable the identification of opportunities for process improvement. The standardized metrics may also be used for quality risk management purposes. Hopefully, this will result in enhanced transparency and trust between sponsors and CROs, which will promote increased customer satisfaction.

SULLIVAN. *MCC.* The MCC plays an important role in the industry, as it is a place where sponsors and service providers can work collaboratively in groups to develop metrics. The shared learning experience of participating in the metric development process is very valuable for both sponsors and service providers. When we ask sponsors and service providers involved in the consortium what their takeaway is about the process, they often report it's the value they find in participating. Some companies have taken a wait-and-see attitude, but the consor-

One of the biggest challenges between sponsors and CROs is establishing common standards.

tium is not just about a list of metrics. It's about what can be learned in the work group sessions and developing a consensus around the metrics. When people from both sides can sit at a table and discuss how and why they do certain processes, everyone learns from one another. Sponsors are increasing their understanding of the CROs; CROs get a good opportunity to hear from sponsors about what's going on behind the scenes. Both sides come to appreciate the value each brings to the table.

WADE. *LIONBRIDGE.* The discussion around the proposed metrics is being driven by the need for sponsors and their suppliers to change the dynamic of their relationship from that of "supplier" to one of "partner." Currently sponsors outsource certain functions to suppliers, often without mapping out each other's internal processes and expectations. We live in one of the most regulated and complex vertical markets. This requires clearly defined expectations and responsibilities in terms of deliverables.

Improving Relationships

Our experts anticipate that the standardized metrics will have a positive effect on the relationships between sponsors and CROs.

CORCORAN. *STIEFEL.* As metrics get used more often and the comfort level grows, it could be a great help in shortening timelines and increasing efficiency of clinical research. We are committed to operational excellence in our research activities and these standards are likely to help us further that goal.

MALCOLM BOHM. President, Trialytics, a site selection and patient recruitment company specializing in applying advanced analytics of healthcare data to clinical-development strategies to optimize protocol designs, mitigate the risks of site selection, locate the right patients, and drive patient recruitment at the local level through primary-care pathways. For more information, visit trialytics.com.

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world. For more information, visit stiefel.com.

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MARK WADE. Global Practice Leader, Life Sciences, *Lionbridge*, a provider of globalization, development, and testing services. For more information, visit lionbridge.com.

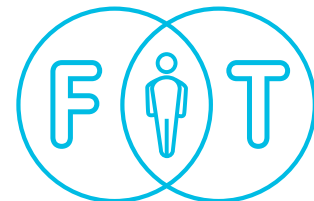


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THE METRICS CHAMPION CONSORTIUM'S (MCC) PROPOSED CLINICAL-TRIAL METRICS ARE NOT YET CAST IN STONE; THEY ARE IN THE BETA PHASE WAITING FOR FEEDBACK FROM THE INDUSTRY. THESE ARE THE GUIDELINES BEING USED BY THE CONSORTIUM TO IDENTIFY THOSE MEASUREMENTS THAT SHOULD BE USED IN THE STANDARDIZED SET.

THE MCC METRICS WILL

Measure performance in terms of

- **Timeliness:** Measures whether a milestone was achieved on time
- **Cycle time:** Measures how long it takes to complete a task
- **Quality:** Measures the number of errors in completing a task
- **Efficiency:** Measures the resources required to complete a task

Include lagging indicator metrics that

- Measure what has already happened; for example, percentage of sites closed after activation and before study closeout
- Measure what can be used for project-over-project improvement
- Predict future performance; for example, cycle time from final approved protocol released to CRO to first patient-first visit
- Aid in avoiding or mitigating problems on the current project

THE DIFFERENCE BETWEEN MCC METRICS AND OTHER METRIC INITIATIVES

Not strictly supplier-customer

- Success of both parties required
- Team-based
- Relationship-based

Decision driven vs. transactional

- Lots of interim decisions that affect the project direction

Each project is unique to some extent

- Not a "cookie-cutter" solution

Source: The Metrics Champion Consortium.
For more information, visit metricschampion.org.

JEFF KUEFFER, INC Research



KUEFFER. INC RESEARCH. Standardized metrics will serve to further enhance the collaborative nature of the pharma and CRO partner relationship, as they will provide a defined set of objective criteria upon which to choose the right CRO partner for the pharma company's unique program requirements. Furthermore, this selection will be based on a platform of shared, defined expectations, thus reducing dissonance in the conduct of clinical trials.

MOORE. CHILTERN. Standardized metrics require a collaborative approach between pharma and CROs. Open communication and flexibility are key factors in maximizing the benefit from the use of standardized metrics. This process also will promote the use of steering committees between pharma companies and CROs working together on multiple projects, as this forum provides opportunities for regular oversight and shared goal development.

SULLIVAN. MCC. The purpose of the MCC metrics initiative is to collect data that a sponsor and a service provider can review together to understand where there are opportunities to improve the process. Our case studies show that metrics have helped strengthen partnerships in the other areas because they allow a more fruitful dialogue that works toward solving problems. They provide an effective way to track changes and how they are affecting the process. They also offer solid proof of what is happening. This is a much better way to manage a partnership.

WADE. LIONBRIDGE. The relationship between sponsor and supplier will evolve into a true partnership, one in which each party shares common goals and common pain points. Therefore, if one party is successful, both parties are successful. Many suppliers strive for partnerships with their sponsors from the outset. Upon achieving this mindshare, they embark on an advocate-type relationship where each party heralds the benefits of such a symbiotic

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relationship in the form of press statements and white papers. Clearly, a significant amount of professional collateral must be established prior to this form of public endorsement; partnerships require real sharing.

Save Time and Money

In addition to better relationships and an easier way to analyze data across companies and disciplines, our experts discuss how widespread adoption of the standardized metrics will enable better cost and time efficiencies.

BOHM. TRIALYTICS. The cost-efficiency drivers that are going to come out of this initiative are going to be very important. These efficiencies will allow the focus to shift to quality and time versus cost and quantity, something CRO partnerships are not usually focused on. From the manufacturer's perspective, the process of selecting the right provider across different solution variations using the same metrics makes for a better selection process and will foster more solid partnerships.

DEARHAMMER. I3 STATPROBE. The value of the metrics means CROs won't have to provide the same repetitive information in a multitude of formats. CROs will be able to show value to sponsors through data comparison versus competitors. Additionally, the metrics will clearly identify opportunities for improvement and best practices.

KUEFFER. INC RESEARCH. The biggest benefit will be eliminating variability from the clinical-trial process. Sponsors will have greater confidence that they are receiving the expected results time and time again.

MOORE. CHILTERN. Efficiency is presumed to be the largest benefit; the use of standardized metrics will facilitate a standardized approach to performance measurement across projects and sponsors.

WADE. LIONBRIDGE. I believe the most obvious benefit will result in a more collaborative relationship between sponsor and CRO. This will manifest itself in fewer errors and operational issues throughout each study. Moreover, each study will follow SOPs/metrics that both parties have agreed upon, which will result in speedier deliverables with less friction between sponsor and partner.



DR. SHARON MOORE, Chiltern

The greatest outcome of standardized metrics will be the potential for increased efficiency in performance measurement, but this is dependent on effective implementation.

Metric Resistance

Our experts discuss reasons for the chasm in the adoption of standardized performance metrics.

BOHM. TRIALYTICS. Up to 80% of trials are late and more than 80% of sites originally selected for a single study don't contribute close to the targets that were set. Only 7% of clinical-trial sites are meeting enrollment objectives. The costs to the bottom line in terms of time, resources, and productivity are tremendous; 93% of sites doing suboptimal work is a metric that has to improve. The proposed metrics have to capture the operational realities of conducting clinical trials, and I have yet to see that level of granularity in the proposed metrics.

DEARHAMMER. I3 STATPROBE. There are so many variables that go into performance metrics, many of which are out of the control of those held to the metric.

KUEFFER. INC RESEARCH. We operate within a highly competitive industry, one in which we are all bound to maintain strict confidentiality in our ongoing business practices. To establish industry standards that drive best practices, collaboration and transparency are necessary, but the process to do so proves more challenging given environment. Engineering variability out of the clinical-trial process by adhering to a standardized approach and incorporating continual process improvement is critically important. While historically the industry has been reluctant to embrace the use of standardized performance metrics, sponsors are demanding this change and CROs are responding to this need. Efforts to develop and execute on standardized performance criteria are a top priority among CROs, and collaborative efforts across the industry are taking hold.



GREGG DEARHAMMER, I3 Stat

Standardization will improve relationships by defining success with data rather than subjective, anecdotal evidence or personal perceptions.

MOORE. CHILTERN. At the current time, there is an unproven benefit from the use of standardized performance metrics, since the CRO clinical-trial metrics have not yet been finalized by the MCC. This process understandably requires much work to reach consensus on which metrics should be selected; how the metrics are defined; how often they should be reported; and what follow-up measures are needed to determine if the metrics selected are the most important to measure or whether refinements are indicated. Success depends on effective implementation.

WADE. LIONBRIDGE. I would not characterize the lack of standardized metrics as reluctance by the CROs or sponsors to improve the process. There is a commercial element that cannot be ignored and that is price versus value. The commercial conversations between sponsor and supplier do not intuitively lend themselves to that of a sponsor/partner relationship. The conversations themselves, by their nature, have historically been couched in terms of actual cost rather than actual value. Fortunately, strategic procurement looks at true value and the total cost of ownership rather than actual monetary costs. Indeed, the adoption of standardized metrics will pave the way for sponsors to raise the bar of excellence in execution and realize actual value from the relationship. ♦

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BY ROBIN ROBINSON

Building Partnerships Around Standardized Performance **METRICS**

The Metrics Champion Consortium (MCC) is an open, multidisciplinary, non-profit organization comprised of biotechnology, pharmaceutical, and service provider organizations.

Within the MCC, member organizations work collaboratively to develop and implement standardized performance metrics aimed at improving the efficiency and effectiveness of managing and tracking resources needed to successfully run clinical trials.

MCC's Mission

The mission of the MCC is to develop, through a collaborative process, performance metrics within the biotechnology and pharmaceutical industry with the intent to jointly encourage performance improvement, effectiveness, efficiency, and appropriate levels of controls for both sponsors and service providers.

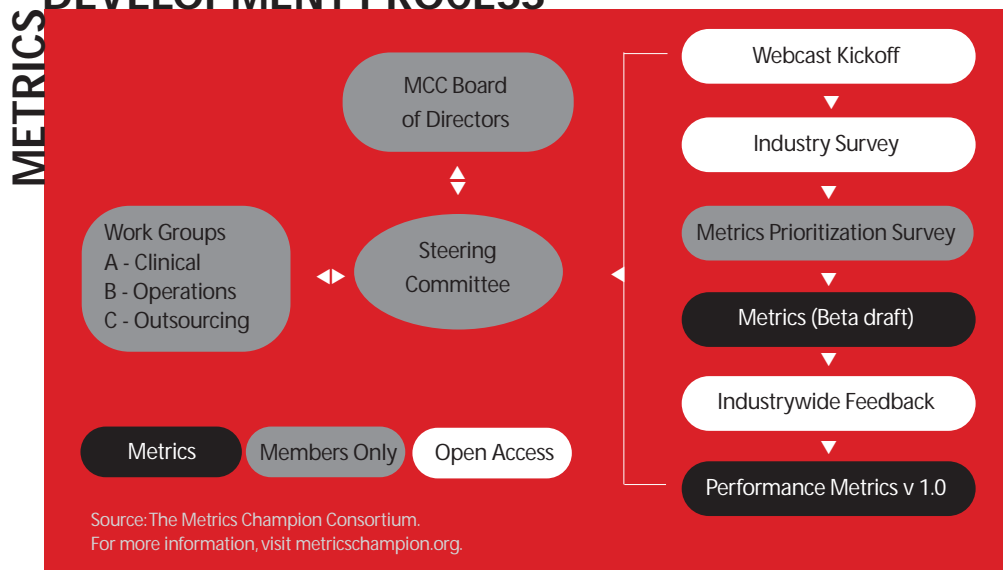
For CROs, the mission is to develop metrics to provide consistent, standardized performance measurement for research activities covering clinical, operational, and outsourcing/financial aspects of the sponsor, other CRO, and site partnerships.

Consistent industry standard metrics will provide critical information for decision making and drive change. Specifically, they will identify the areas for process improvement and issue escalation for all of the stakeholders in terms of what works and what needs improvement. ♦

PARTICIPATING ORGANIZATIONS

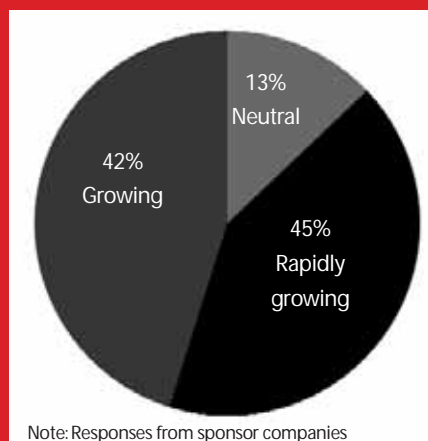
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DEVELOPMENT PROCESS



PERFORMANCE METRICS

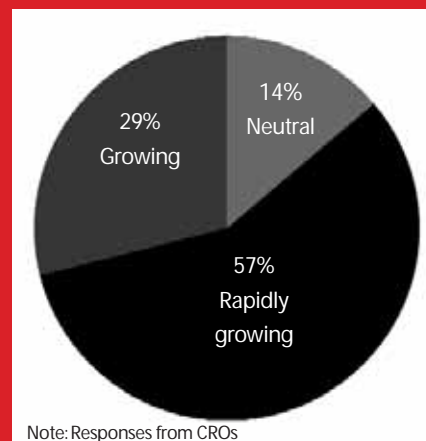
THE DEMAND FROM THE SPONSOR ORGANIZATION FOR PERFORMANCE METRICS IS



Note: Responses from sponsor companies

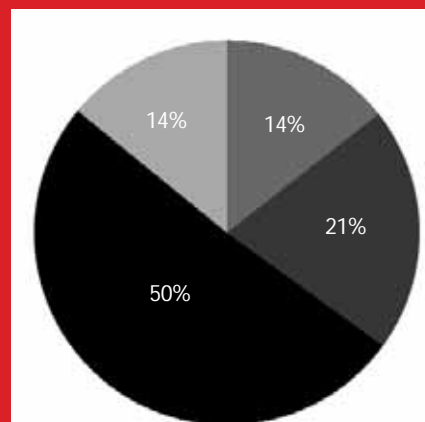
Source: The Metrics Champion Consortium.
For more information, visit metricschampion.org.

THE DEMAND FROM CRO SPONSOR PARTNER ORGANIZATIONS FOR PERFORMANCE METRICS IS:



Note: Responses from CROs

CRO PERCEPTION OF SPONSOR-REQUESTED PERFORMANCE METRICS IS:



- Sponsors request and review performance metrics to take effective action with CROs
- Sponsors request and review performance metrics but they do not use them to take effective action with CROs
- Sponsors request performance metrics but do not routinely review them with CROs
- Other

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