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Driving the Performance of a Clinical Research Site with Metrics

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Effective organizations in other industries use metrics to measure activities and performance toward their goals, so it's time for more clinical research sites to follow their lead.

Sponsors have recently started compiling and sharing site "report cards" with the sites. These report cards include metrics about site performance that the sponsors compile and consider important. By developing their own metrics, sites can anticipate problem areas and make the case that the sponsor's metrics are anomalous or erroneous. For one thing, sites can collect more data than sponsors can about their own performance. They can also design metrics that more accurately reflect their performance and are more useful for internal management purposes. For example, sponsor metrics may not notice that the sponsor is the bottleneck in a clinical trial agreement negotiation or which data queries are the site's fault ("for cause").

Before deciding which metrics to use, an organization should first establish its goals. In clinical research, three goals might include:

- Increase number of studies.
- Meet enrollment commitments.
- Improve quality of data.

The above goals are qualitative. They require memory and judgment to measure performance subjectively. People may disagree on whether a particular goal has been achieved. Personnel may "game the system," for example, by starting studies that are unlikely to succeed. Metrics not only enable measurement of progress toward goals, they also enable creation of goals that can be measured quantitatively and objectively, for example:

- Increase number of studies from 20 to 30.
- Meet enrollment commitments in 80% of studies.
- Reduce average data query rate from 100 per study to 50 per study.

With the right metrics, the above goals could be further clarified to better produce the desired results:

- Increase number of studies from 20 to 30, with 80% of studies meeting enrollment commitments.
- Meet enrollment commitments in 100% of cardiology studies and 60% of oncology studies.
- Reduce "for cause" data query rate from 40 per study to 10 per study.

Goals based on clear metrics are more likely to cause actions that produce the desired results and achieve the organization's larger goals, for example:

- Avoiding difficult studies by applying the feasibility evaluation process more thoroughly.
- Increasing enrollment by performing daily chart reviews of scheduled patients.
- Reducing data queries by identifying and retraining study coordinators who generate the largest numbers of queries.

Collecting and analyzing metrics data is time-consuming, so it is important to focus on metrics that:

- Are objective
- Are practical and economical to measure and collect
- Accurately indicate progress toward the goals
- Minimize loopholes (usually ambiguities) that allow gaming of the system
- Are "actionable," i.e., point the way to do things better
- Are useful in communicating with study sponsors and other external parties

Clinical Research Site Metrics

Clinical research sites vary and their priorities can change over time, but the most common metrics are in the following categories:

- Resources
- Productivity
- Quality and Satisfaction
- Timeliness

The following metrics are just a few of the many ones that a site might find useful. Sites should select the metrics that answer the most important questions for achieving the site's goals.

Resource Metrics

Resource metrics are useful for managing internal operations. However, sponsors want to know whether adequate resources are available and if sites are up to the job.

Financial

Common financial metrics include lines in the financial statements like revenue, profit and accounts receivable. They also include ratios and other analytics like:

- Collection Period (accounts receivable/revenue/365 days)
- Revenue/Headcount (the most accurate measure of staff utilization and productivity)

Revenue/Headcount is a hybrid metric that consists of the ratio between a financial and a personnel metric. It can also be considered a productivity metric. It could thus be listed in any of these sections.

Personnel

Common personnel metrics include:

- Headcount (number of full-time-equivalent employees and contractors)
- Headcount vs. Authorized (actual headcount as a % of authorized headcount)
- Retention Rate (% loss)
- Active Studies/Headcount (initiating or enrolling)

Common personnel metrics also include training metrics:

- Human Participant Protection Training (% of requirements completed)
- Good Clinical Practice Training (% of requirements completed)
- Investigator Meeting Attendance (% of meetings attended)

- Certified Study Coordinators (% of total)
- Training Hours (actual)

All of the training metrics can be combined to create a single metric for the entire training program. The metric can be weighted based on the importance of different types of training or the amount of time each type requires.

Other Resources

Other resources include items like facilities, equipment (including safety equipment), and study supplies. Common resource metrics include:

- Space/Person (square feet of office space, including offices, exam rooms, and common space)
- Subject Visits/Exam Rooms
- Standard Operating Procedures (number current and actively used)

Productivity Metrics

Productivity metrics touch numerous points in clinical research. They are useful for managing internal operations and external interactions. Sponsors are very interested in productivity metrics. Numerous productivity metrics that count the number of activities per unit of time are not listed below.

IRB (Ethics Committee) Review

- IRB Applications Submitted (initial full review)
- IRB Submission Time (median days from receipt of regulatory package)
- IRB Response Time (% studies approved at first review)
- IRB Approval Time (median days from receipt of regulatory package)

Contract and Budget Negotiation

- Confidentiality Agreement (CDA) Initial Response Time (number of days after receipt)
- Clinical Trial Agreement (CTA) First Draft Response (number of days after receipt)
- Budget First Draft Response (number of days after receipt)
- Signed CTA (number of days after receipt)
- Adequacy of Budget (% of chargemaster fees)
- CTA Signature Rate (% signed and not abandoned)

Contracts and budgets may be tracked separately, depending on the workflow.

Study Conduct

- Subjects Enrolled
- Screen Failure Rate (% of subjects enrolled)
- Site Initiation to First Subject Enrolled Time (days)
- Subject Retention (% of enrollment)
- Last-Subject-Last-Visit to Last Data Submission Time (days, not including query resolution)

Quality Metrics

Quality metrics touch numerous points in clinical research. They are useful for managing internal operations and external interactions. Sponsors are very interested in quality metrics.

Protocol Adherence

Common protocol adherence (including regulatory compliance and subject protection) metrics include:

- Adverse Events (number of AEs and SAEs)
- Deviations and Violations (e.g., 1 deviation = 0.1 violation)
- Consent Issues (Number of problems identified by QA)
- EDC Completion (% of CRF pages completed within three days of study visit or other event)
- Queries (number of "for cause" data queries)
- Query Resolution (% of responses to "for cause" queries within three days of receipt)

Satisfaction

Study subjects, personnel and sponsors can be surveyed for satisfaction on multiple parameters. A combined score can be created for each group and tracked over time. Other metrics can be presumed to affect satisfaction.

Uses of Metrics

Once the data have been collected and compiled, metrics can be monitored and analyzed for numerous purposes:

- Communicate achievements.
- Recognize and reward successful performance.
- Identify and address problem areas.
- Provide evidence to support plans for changes that might otherwise meet resistance.
- Allocate resources, including management attention, to priority areas.
- Revise goals and metrics to reflect growing maturity of the organization.

Data Collection and Analysis

If only a small amount of data is to be collected, a spreadsheet is adequate, but organizations of any significant size will want to create a single, validated relational database with consistent data collection, analytics and reporting practices. One advantage of a single database is that unanticipated relationships between metrics can be analyzed easily.

Data collection processes should be designed to minimize the burden. It is far better to collect and error-check data contemporaneously than to try to reconstruct it later. It may be possible to piggyback data collection on other reporting systems. In the ideal case, the data can be loaded automatically from other systems.

Metrics are quantitative, i.e., measured with numbers. However, much of reality is qualitative: "I'm fairly happy with my experience in this study." Fortunately, it is not difficult to quantitate most metrics. For example: "On a scale of 1 to 5, with 5 being the best, my level of satisfaction in this study is '4.'"

Many metrics can be combined into ratios, potentially increasing the number of metrics exponentially. In some cases, an absolute number is more informative, in others a ratio. Discipline is required to prevent proliferation of metrics.

Metrics that include a timeline can be measured as the number of days to complete the item or the percentage of items completed before the deadline (which may be arbitrary).

If a metric cannot be measured exactly, estimates can still be useful. Sampling is a common way to estimate metrics. Another way is to ask someone's opinion. Recording the date of metric-worthy events enables sites to measure them within any time period. The amount of data in a short period of time, e.g., a month vs. a year, may not be adequate for meaningful analysis.

It is often hard to say whether a metric score is good or bad in an absolute sense. Is "4" an acceptable, outstanding or deplorable score? However, it is easy to say how scores look in a relative sense when compared to other metrics:

- Are other sites collecting the same metrics (in the same way)?
- Do other parties, e.g., sponsors and publishers, publish metrics for multiple sites?
- Have your metrics been collected (consistently) over a period of time ("longitudinally")?

The importance of metrics can change over time, so it may not be worthwhile to continue collecting data for a metric that has become unimportant. However, consider the long-term value of a longitudinal series before interrupting it. Another option is to adjust the sampling rate up and down to manage the cost.

Conclusion

Designing, collecting, analyzing and using metrics can be challenging. Management support and adequate resources are essential. There is no point in collecting data for a metric if it does not help achieve some goal. The good news that well-designed metrics easily pay for themselves in higher productivity, quality, timeliness and reputation.

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