PharmaSUG China 2018 – Paper MA-37

USER EXPERIENCE or DATA DRIVEN – the life of Metrics

Charan Kumar, Ephicacy Lifescience Analytics Pvt. Ltd., Bengaluru, India

ABSTRACT

Mission Possible - is Metrics. In today's data driven world, metrics plays a key role in every business. In clinical domain, metrics is key in all aspects - research, development, market and user experience too. A measurement is concrete, usually measures one thing, and tends to be quantitative. A metric describes qualities and requires a measurement of baseline characteristics. A key performance indicator (KPI) is the next improvement in measurement. A KPI is a metric that is deemed to be a critical evaluation of the success of a process. A balanced scorecard is the collection of KPIs that look at the health of your organization from multiple different perspectives at the same time. Maintaining each of these KPIs within their desired range maximizes the health of the organization. There may be many measurements and metrics that are useful regarding that process, but there should only be one or two KPIs that provide a high-level, quick evaluation of the performance of that process. The balanced scorecard was a concept first discussed by Robert S. Kaplan and David P. Norton. What are our mission-critical domains? What are the most significant KPIs to measure within each domain? These are the questions which metrics tries to answer.

The question also to be answered - should be driven by raw data alone or should there by reliance on user experience related data too? The era of social media and integrated workspaces have made metrics rely on user experience too apart from the normal way of monitoring KPIs. If yes, should this be part of organization culture? If this is part of organization culture, what are the challenges in inducting and monitoring this culture and possible ramifications of it. This paper tries to decipher - should we rely on raw or readily available data or data based on user experience with respect to managing metrics.

INTRODUCTION

Metric – the word has its origin from French ‘metrique’ from metre. Most historians agree that Gabriel Mouton, the vicar of St. Paul’s Church in Lyons, France, is the “founding father” of the metric system. ”What gets measured gets done,” the old saying is valid in the current era too, stressing the importance of measurement and monitoring.

Information is the key for any performance be it a human tissue or organ or an extraordinarily big business conglomerate. What is this information? How is it important in a biological function - a cell or tissue or organ level? Interestingly, this is the data we look for in the performance of our drug – the vital parameters with a predefined range. And based on this data, we come up with the outcome related to the performance of our drug; infact performance of the human body system and any discrepancy will trigger alarms about functioning of our body system pushing the rest of actions. Each individual need to be informed about the performance of our own body system to lead a healthy life. The performance is based on parameters defined medically.

Similar is the case in an organization comprising several functions. Each function is supposed to co-ordinate, deliver based on pre-defined set of timelines, quality parameters to their customers. And the customers need to be satisfied about the delivery. Here too, companies, organizations need to be well-informed about their own business to pave way for success. Hence METRICS DRIVES BUSINESS and INFORMATION DRIVES METRICS. INFORMATION could be in any from – the age-old method of utilizing the RAW DATA or the advent of technology leading to new form called – USER EXPERIENCE DATA.

NEED FOR METRICS

Metrics are used to drive improvements and help businesses focus their people and resources on what’s important. The range of metrics that companies can employ vary from those that are mandatory – for legal, safety or contractual purposes – to those that track increases in efficiency, reductions in complaints, greater profits and better savings.

Overall, metrics should reflect and support the various strategies for all aspects of the organization, including finance, marketing, competition, standards, or customer requirements and expectations. Metrics indicate the priorities of the company and provide a window on performance, ethos and ambition.

Ultimately, metrics will help tell the organization:

- Where it has been
- Where it is heading
- Whether something is going wrong
- When the organization reaches its target

BENEFITS OF METRICS

To derive the most benefit from metrics, it is important to keep them simple. Defining a metric is similar to telling a joke – if you have to spend too much time explaining it then it will not work. Employees need to understand the metric, how they can influence it and what is expected of them. For example, it is clearer to state that a metric's target is to reduce complaints down to two per month than have a 50 percent reduction per month. This communication element is a detail often overlooked, but it is important that employees have a good sense of what success might look like.

Good metrics will:

- Drive the strategy and direction of the organization
- Provide focus for an organization, department or employee
- Help make decisions
- Drive performance
- Change and evolve with the organization
- Produce good internal and external public relations

DEVELOPING METRICS

Metrics development needs several factors to be considered.

Few of the factors are:

- Align the metrics to organization vision and goals
- Develop measures along multiple dimensions
- Process performance to be measured
- Consider historical data and/or industry standard to set thresholds
- Take into consideration clinical site related inputs

Different types of metrics could be:

1. Leading indicator – provides information that one can act on immediately to get the trial/process back on track.
2. Lagging indicator – provides information that can be used as input for future trials or for baselining for process improvement efforts.
3. Cycle-time – Measures the time taken to complete the task
4. Efficiency – Measures the amount of resource required to complete a task or set of tasks versus that expected.
5. Quality – Measures how well an output from a process meets the requirements of the customer of that process.
6. Timeliness – Measures whether a milestone has been met.

IMPLEMENTING EFFECTIVE METRICS

The following five steps cover the basics for setting up organizational or process metrics:

1. Define the metrics
All metrics should be clearly defined so that an organization can benchmark its success. One way to keep metrics understandable is to use the SMART (specific, measurable, achievable, relevant, time-based) model. The Achievable step in this model is particularly important. It's important the metrics which are defined should be achievable; else the purpose of setting metrics would not be achieved.
Incase, the metrics are not defined clearly it could lead to chaos. For instance, a bus company with a metric based on how many buses complete routes on time could result in bus drivers speeding, jumping traffic lights, taking short cuts or missing skipping bus stops to make better time. Metrics should not encourage employees to take negative actions.

2. Consent from management and employees
The successful implementation of any new metric requires the approval and interest of both senior management and middle management. They must lead the culture change from the top. Using a new set of metrics to measure performance is a change that may well attract resistance from across the company, so high-level endorsement and open communication is needed to get everyone on board. Also, incentivizing compliance to metrics can be an effective way of achieving buy-in. For example, if the company's priority is information security and allocates less budget for bonus related to information security, then the purpose is not served.

3. Understand what data to be collected
It's not unusual for companies to set a metric, only to discover that either their processes or tools (or both) cannot generate the data they need. It could mean some investment is required but clarity is needed about how much the business will benefit from having the metric before spending money. Metrics need to be reliable and give out the same outcome despite different methodologies of calculating it. They also need to be standardized, with data being collected in the same way across single or multiple departments, facilities and offices.
To deliver real progress, everyone involved with the metric needs to be completely honest. Any untoward way of mismanaging metric will lead to negative consequence and instead efforts must be made to improve the existing metrics in every sense. But understanding the company's true position is the first step toward improving it.

4. Measure and share the results
Metrics must be manageable – it is better to have five meaningful metrics that the organization will use than having an exhaustive list of metrics that it won't.
Constant communication is important to know the pulse of the function, department. If the organization has multiple sites or divisions, leaders should set up regular meetings to review progress, share experiences and successes, and discuss problems.

5. Do not forget the "continual" part of improvement
When implementing metrics, its important for an organization to review and revise its metrics from time to time. The process is needed because businesses evolve, and changes will surface as time goes by. It is important to make sure that the metrics still measure what they intended to measure.

TRACKING THE METRICS

1. EASE OF RUNNING THE BUSINESS

Metrics give a clear picture of the health of the area or function. Are sales up? Meaning the sales team is performing. Are leads down? Meaning the marketing team has work to do. Are products being delivered on schedule? Then the fulfillment team is on track. And so on.

It is important that key functionaries in the organization have access to key metrics making it much easier to run a business. This will help in focusing on critical issues and allocating right resources.

2. PERFORMANCE

Metrics give employees a transparent scorecard. They tell them if they're doing well or not. For example, if your marketing manager is responsible for driving traffic to your website, they should own the metric "website visitors." And once they own it, and can see their performance, they typically perform better. With access to metrics, they can set goals, but are also held accountable for those goals.

3. HIGHLIGHTING THE PROBLEMS

A company reviews results at the end of the month only to realize sales declined. If they had their "command center" and had been tracking other key metrics, such as number of leads, they would have noticed three weeks earlier that new leads had decreased. They could have fixed the problem earlier and had a solid sales month, but because they didn't track this metric, performance suffered greatly. Similar is the turn around time for AE/SAE related communication; unless this metric is tracked on an ongoing basis, it would be difficult to meet the regulatory requirements and the sponsor might lose out opportunity to work on the key pain points of the drug.

4. FOCUSING ON CERTAIN METRICS

By selecting and tracking certain metrics, you can ensure your whole company focuses on the right things. Do you want to be known as having the best customer service in your industry? Then track multiple customer service metrics such as returns, response times, and customer satisfaction surveys etc.

5. IMPROVEMENT

What is improvement? Level X to Level Y – here what is Level X? unless we have a measure of Level X, we wouldn't know what Level Y is. The saying "you can't improve what you can't measure" talks about how tracking a metric is important to know if you're improving. Conversely, if you are tracking it, you can methodically improve over time.

METRICS IN CLINICAL DOMAIN

All organizations have generic and standard metrics used across the globe irrespective of the domain they serve – clinical, IT etc. These organizations have certain generic metrices such as:

- Financial metrics
- Process related metrics
- Project metrics
- People metrics

Clinical organizations too utilize the above metrices; and apart from the above-mentioned ones, here are the few metrics normally used by these organizations as part of their business. Key performance indicators (KPIs) that bridge the gap between strategies and results are integral to ensuring efficiency.

CLINICAL STUDY
Time
Cost
Quality
Compliance
Planning
Performance (trial/drug)
Employee/Staff feedback
Subject feedback
Site feedback
Performance of innovative measures

Table 1. Metrics in a clinical study

USER EXPERIENCE or DATA DRIVEN – the life of Metrics, continued

Time:

- Award to Executed Contract
- Data Systems Available
- Site Activation Time – contracts and essential docs
- Major milestones achieved
- DB lock
- Query response time
- Issue closure time
- Submission time

Cost

- Budget (Planned vs actual)
- Payment timeliness
- FTE ratio
- Unit costs (per visit, per site, per month)
- Deviations/Change requests impact

Quality:

- Patient recruitment
- Patient retention
- Documentation
- Organization quality systems – goals and objectives
- Audit findings – internal/external
- Deviations
- Incidents
- Database unlocks
- Change requests implementation

Compliance:

- AE/SAE reporting compliance
- SUSAR reporting compliance
- Protocol deviations / Site compliance to protocol
- Training compliance
- Project management plan

Planning:

- Planned sites vs Actual
- Enrollment plan

Performance:

- Drug supply
- Protocol amendment
- Shift in timelines
- Subject drop-outs

Employee/Staff Feedback:

- Overall satisfaction survey

Subject Feedback:

- Subject satisfaction survey

Site Feedback:

- Investigator satisfaction survey

Performance of innovative measures:

- Idea and its performance

These metrics are ideally the clinical related metrics which is relatively important with respect to regulatory and statutory needs. While sponsors and contract research organizations (CROs) have made targeted efforts to establish KPI programs that help optimize clinical trial processes, costs, and timelines, the efforts at research sites have largely been sporadic and unsystematic.

METRICS DRIVEN BY DATA

The defined metrics needs to be applied on data which acts as input to the defined rules or observing parameters.

A measurement is concrete, usually measures one thing, and tends to be quantitative. A metric describes qualities and requires a measurement of baseline characteristics. As an example, the amount of gas in a car can be measured and the distance traveled also. The number of miles driven per gallon (MPG) of gas used is a metric and is far more valuable than simply knowing the individual measurements that went into it. A key performance indicator (KPI) is the next improvement in measurement.

A KPI is a metric that is deemed to be a critical evaluation of the success of a process. There may be many measurements and metrics that are useful regarding that process, but there should only be one or two KPIs that provide a high-level, quick evaluation of the performance of that process. Is it doing well, or is it doing poorly?

You can think of a KPI as having your finger on your pulse. If during a normal part of the day, pulse is between 60 and 100, then it's probably doing just fine. However, if the pulse (a KPI in healthcare) is outside that range, then it's time to dig deeper with more measurements and metrics to determine the cause. This is the same way you should measure the health of your organization.

A balanced scorecard is the collection of KPIs that look at the health of your organization from multiple different perspectives at the same time. Maintaining each of these KPIs within their desired range maximizes the health of your organization. (See Table 1* for a summary of terminology related to this article.)

It's important to note also that metrics, KPIs, and the components of your balanced scorecard can be either leading or lagging indicators. If your metric is a lagging indicator, it's providing you with information about what happened in the past without any remaining time to intervene and improve performance (leaving the opportunity to affect change in the future only). A leading indicator is a metric that is providing you with current data that are predictive of future outcomes.

Your leading indicators can provide you with an opportunity to intervene and impact performance before it is too late. Leading indicators give you the opportunity to affect change actively.

Examining how to design a balanced scorecard for a research site is an interesting activity.

Mission-critical domains:

It's important to identify mission critical domains. These domains need to consider all stakeholders and the site's strategy. After choosing the domains, you should be able to confidently state that a balanced strategy to win in all the domains chosen maximizes your success. If you can still come up with a scenario where you can fail at your strategy, then consider whether you have chosen a balanced collection of domains.

Most significant KPIs to measure within each domain:

To choose your KPIs, first consider what the functional areas touching this domain are in your operating model. Next, decide what result or outcome you wish to achieve in each area, and think about the activities or actions that drive that result. Finally, identify the measurements or metrics that let you know that the right activities are being performed, and that the right outcomes are resulting.

As stated at the beginning of this article, research sites are hired by sponsors and CROs to do one thing and one thing only—produce high-quality data. To produce data, sites need to recruit patients, and it is mission-critical that customers be served well. Therefore, the customer perspective should be part of the balanced scorecard and should contain KPIs regarding enrollment numbers and data quality.

A sample KPI regarding enrollment numbers could be percent of time achieving sponsor goal enrollment, and a sample regarding the quality of the data would be the percent error rate. Now, the percent of time achieving sponsor goal is, by default, a lagging indicator, since you can only calculate that once goal enrollment was achieved. If the enrollment window closed prior to achieving goal enrollment, you no longer have any ability to intervene regarding that specific research trial.

Your percent error rate, however, can be tracked in real time. That makes it a leading indicator, allowing you to intervene and improve the quality of the data within an existing research trial prior to that research trial ending. For example, if you see that your percent error rate is unacceptably high in each research trial, that enables you to drill deeper into that trial and try to determine the reasons why. Are the error rates higher because of trial complexity? Is there confusion regarding interpretation of the protocol? Do the staff site members require retraining?

Additional KPIs pertinent to your customers could include total enrollment % of goal across all studies, % sponsor repeat business, or customer satisfaction rate. What is important is that you choose where you want to focus. You can't be all things to all people. How do you want to best serve your customers?

The financial domain is certainly necessary for a research site's balanced scorecard. Research is financially challenging for sites; ignoring this domain could be perilous. Repeat the process above to choose the KPIs you believe will maximize the financial health of your organization.

On the other hand, a research site only paying attention to its financial perspective can produce a very short-term view of performance. That site may immediately improve its gross revenue and net income by taking on as many trials as possible, and by processing as many patients as possible through those trials. That site may maintain a lean staff size to further enhance its financial profit, but it's reasonable to assume such a model would run the risks of increased error rates, lower subject satisfaction, and increased employee turnover due to the overly lean staff size. The long-term view of performance could therefore show that site's model as being ultimately flawed.

The internal perspective can't be ignored. It would include KPIs regarding employee engagement, payroll, or perhaps length of employment. If your business, for example, determines that your more senior research coordinators consistently produce higher quality data and higher levels of subject recruitment, then it would be reasonable to create a strategy for your business regarding methods to increase the number of senior research coordinators. Your KPIs regarding this strategy would fall into this internal perspective.

However, if you want to compete for research trials on cost, then perhaps you need to keep your payroll costs as low as possible and should choose different KPIs to help guide you in achieving your strategy.

All sites and all strategies are different. Therefore, site leaders cannot all use the same balanced scorecard and the same KPIs to achieve their strategies. You need to use the processes discussed to determine your balancing point, and how you will research your own outcomes to know with certainty that you are balancing your success.

The balanced scorecard allows you to bind your short-term activities to a longer view on performance. Once you've initiated a balanced scorecard in your organization, this scorecard will alter the foundations of how you run your business. Your scorecard translates your mission, vision, and strategy into operational metrics.

Your scorecard will alter what you speak about in your meetings. It will increase alignment throughout your organization, so that your entire team is rowing in the same direction at the same time. Your scorecard will affect business planning so that financial budgeting is in alignment with strategic goals. It will create a mechanism for

continuous improvement and your organization will have improved levels of learning. You will have achieved the ability to research your own activities as well as you research investigational products, medications, and devices.

METRICS DRIVEN BY USER EXPERIENCE (UX)

User experience metrics for any organization can be applied at two levels:

1. External
2. Internal

External UX would strategically focus on product related user experience; consumer or customer-based response.

Internal UX would focus on employee engagement related user experience; process or policy related user experience.

UX design follows the principle of focusing on USER, thus helping create a successful product.

In today's world, subject(patient)'s needs are changing and is important to know growing number of patients want to have more control over their own healthcare. Clinical research is adopting the principle where focus on patient centricity is the key. Designing a clinical trial around the needs of a patient, might lead to increase in patient enrolment and improve satisfaction quotient.

This is leading the sponsors, pharma majors focus on patient centricity. The user experience (UX) design approach uses disciplines like behavioral science, ethnography and service design to help companies understand their business's best path to people-centricity. User experience (or UX) design is a methodology that starts with the researchers immersing themselves in the world of the customer, or "user", of a product, service or system, to understand what they do, and how and why they do it. In a clinical trial context, this person is the patient. It is a qualitative approach, focusing not on how many people do or say something, but on the behaviors, emotions, cognition and culture that impact the way people experience a product or service. As a design approach for clinical trials, it involves the patient during the development of processes, methods and tools related to conducting trials.

User experience design integrates sociology, anthropology and psychology into design, to access the values, mental routines and aspirations behind people's behaviors, and to explore how to impact them through well-targeted innovation and strategy. Social media posts, blogs – these are natural resources for 'patient path leaders' who post information related to medical condition and gain attention due to which social media influencers can participate in spreading the user experience.

This leads to improvement in clinical trial design and trial participation could increase.

There are HEART and PULSE frameworks for reviewing the UX based qualitative data. Below table highlights few aspects of UX parameters during various steps in a clinical trial which could be part of the assessment and assessed, reviewed for improvement.

Pre-trial	Protocol design	Trial Planning	Participant enrollment	Data collection and analysis	Post-trial
Monitor patients' experiences with treatments, including non-clinical aspects (e.g. drug administration) online or through ethnographic methods.	Netnography research about patients' previous trial experiences.	Understand and model behavioral patterns of clinical staff, patients, and other stakeholders involved based on qualitative research.	Harness digital tools and existing communities to tap wider patient pools	Continuous monitoring of engagement levels, through quantitative and qualitative methods (e.g. contextual interviews) as trials go on.	Keep patients and patient communities engaged and trustful by sharing easy to understand results with participants and disseminating them to a wider audience
Partner with patients and physicians to access patients	Adopt participatory methods to enable patients and medical staff to provide input	Include cultural understanding and focus on	Design and implement patient-friendly and context-	Self-reporting and remote data collection	Inform patients on how they could get

registries data and collaboratively set research agendas	on protocols, such as evaluating which endpoints might be too onerous to measure.	geographical differences.	specific Informed consent forms and touchpoints for participant enrollment and engagement including dedicated contact person.	tools for patients.	involved in additional trials and/or other areas (e.g. become advocates and help recruit more patients).
	Gather feedback from regulators and/ or payers on existing protocol design weaknesses.	Define engagement monitoring practices in order to promptly identify and remedy disruptions (e.g. dropouts).	Adopt context-informed strategies to reach out to underrepresented groups (e.g. through local leaders).	Opportunities to provide feedback about the different aspects of trial experience (feeling supported, daily life etc.).	
	Design “inclusive” participatory methods for young, old, minorities, different nationalities, etc.			Hassle-free communication platforms for data sharing among the actors involved.	
	Participatory measures to learn about lifestyles/behaviors that could be included as part of the protocol.			Data visualizations to display insights derived from qualitative data.	

Table 2. UX in clinical trial

METRICS VS ANALYTICS

Metrics:

• Standardized measure to address a specific area

• Often have a defined start and end point or measures a unit or ratio

• Measured in a consistent manner to allow comparison over time as well as between entities

Analytics:

• Application of metrics to business questions

• Can use complex statistics

• Find patterns in data to address the business question and drive decision-making

The true value of analytics is to measure operational performance to improve internal processes. By objectively measuring key metrics, organizations can better identify and target areas of weaknesses and use that data to promote their strengths.

Individuals at all levels of an organization can benefit from a closer look at their research practices—from institutional leadership to principal investigators to study coordinators. Objective insights allow all stakeholders to bring data into conversations to inform and create efficient, effective processes that work well in the long term.

Tracking operational performance empowers PIs to make targeted decisions about their studies and ensure they are progressing in a timely and efficient manner. With performance metrics available to them, PIs can check in on

individual study performance to confirm they are meeting necessary milestones. They can also quickly identify delays and act to correct the problem.

Much like PIs, study coordinators can benefit from a glimpse at individual study performance to stay updated on progress and target timelines.

Study coordinators are also responsible for collecting many of the source metrics that will feed the analytic outcome, therefore it's important that they understand the value and required accuracy necessary when collecting study data. Once collected, they can use that performance data to have valuable conversations with other stakeholders involved and gain the resources they need to meet study goals.

Operational management benefit from actionable insights that allow them to manage their teams quickly and effectively. Operational performance metrics show them the progress of each study and allow them to react and prevent potential problems as needed. Viewing performance over past studies also helps these managers better delegate resources, such as staff workload, and determine the overall feasibility of a study upfront by proactively reviewing trends across protocols.

CONCLUSION

The current methodology of metrics-oriented data analysis is evolving to include user experience design too. The era of instantaneous result is prompting organizations to move towards individual or user or in this context 'subject's centric design. This is true not just in the case of a product or service however internally in an organization too. Organization's have been working towards designing their processes and policies to derive metrics based on user experience i.e., employee behavior, emotions and look for cultural fitness. In the millennial world, this new methodology throws its own challenges with respect to managing internal workforce. Externally, the need for a metrics design which couples both the native methodology of raw data-oriented and the user experience. Data analysis based on the collated data is showing promising results especially in the areas of predicting the market, trend analysis of population, age etc. Metrics, yet again proves that the results do help in forecasting and reviewing the current situation making the 'mission possible' in any given context. It is very important for any organization to move towards a metric-based approach to stay ahead in the game of business.

The role of technology in such metrics or user experience case is still in the nascent stages of development. Though predictive analysis yields probable results, yet there are chances that the prediction might not turn to be completely green as per the expectations. Parallel approach of analyzing data comparing both raw data-driven and user experience based could be tried to certain extent and then choose the right metrics to fit in either of the two methodologies. It is also important to focus on monitoring or reviewing the results of these metrics in an unbiased manner and devise the organization strategy based on the same.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Name: Charan Kumar K J
Enterprise: Ephicacy Lifescience Analytics Pvt. Ltd.
Address: No.6, 2nd floor, 2nd Main, Arekere, Bengaluru
City, State ZIP: Bengaluru, Karnataka, India 560076
Work Phone: 080-4146-3195/96
Fax: 080-4146-3915
E-mail: charan.kumar@ephicacy.in
Web: www.ephicacy.com
Twitter: @charan_kumar2