



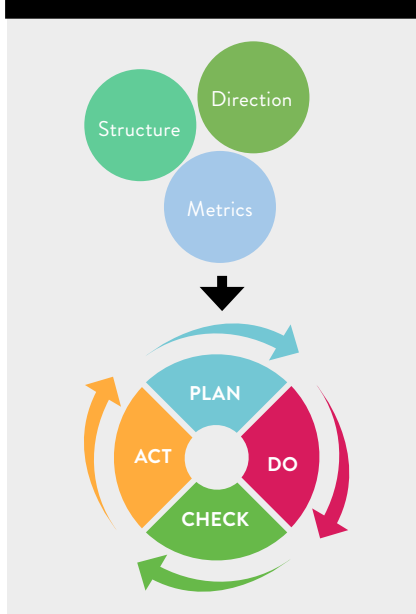
Michelle Manton

QUALITY ASSURANCE-BASED KEY PERFORMANCE INDICATORS

In November 2022, I had the pleasure of presenting the topic of Quality Assurance-Based Key Performance Indicators (KPIs) at the RQA International QA Conference in Brighton, alongside other members of the GLP Committee. This article is intended to capture the discussions and feedback received during that workshop with the intention of promoting reflection on how we in the quality profession use KPIs, what we hope to achieve and how we can use KPIs or similar metrics to drive continuous improvement – the heart of any robust ‘future-proofed’ Quality Management System (QMS).

Continuous improvement is generally driven by the 'Plan – Do – Check – Act' (PDCA) cycle, a continuous loop of planning, doing, assessing performance, and enacting changes and improvements where opportunities are identified (see Figure 1). Such assessments are often pointed in a set direction, be it general compliance with regulatory requirements or industry expectations, organisational objectives or to facilitate problem solving and change. Within a QMS structure, the PDCA model is useful for testing improvement measures before updating procedures and working practices. Therefore, the 'checking' stage of the PDCA model is a key component in continuous improvement – taking what we know and ensuring that information can be assessed as measurable data. And this is where KPIs, a type of metric often referred to as 'metrics', come into play as a potentially powerful tool.

FIGURE 1. CONTINUOUS IMPROVEMENT USING A PDCA CYCLE



The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring no.24 (position paper on Quality Improvement Tools and GLP) defines a KPI as 'a measurable parameter that demonstrates how effectively a process is performing. This can range from a measure of inspection response times or number of deviations raised, through to number of equipment issues within the test facility'. It clearly defines how measurable data can be used to determine effectiveness of a planned process and from this we can make informed decisions to amend or adapt, with the intention of improving processes.

It is worth noting also that the effective use of KPIs is not limited to the GLP environment.

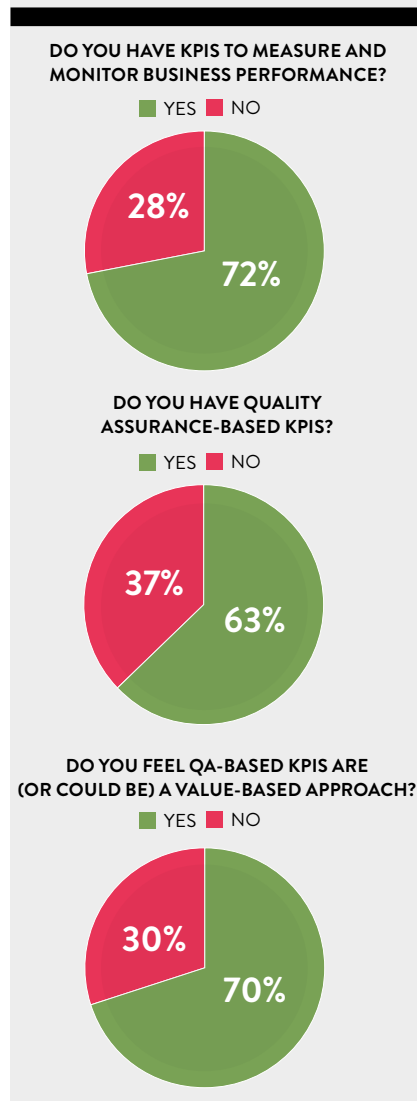
Improvements in quality can be applied to all environments where the performance data is measurable. In fact, the objective of monitoring and improving regulatory compliance is not a prerequisite for effective use of KPIs, which can be just as effective in a non-regulated research environment. Equally, use of KPIs is not limited to activity-based process change, but also product improvement and optimisation of deliverables. For example, in everyday life we may feed information into many such PDCA cycles as consumers, either when providing customer experience feedback, completing satisfaction rate surveys by clicking on a range of emojis from a happy to a sad face, 'liking' or 'disliking' a thumb icon or selecting a number of stars to indicate levels of customer satisfaction from one to five. In doing so, we allow for that subjective information to be transformed into quantifiable measurable data points that may be used to assess improvement needs and subsequently to drive change in physical products or services.

However, for the purposes of the RQA Conference workshop and subsequently this article, the focus of KPI use here is targeted towards the GLP Test Facility environment and more specifically, how these can be utilised to assess the performance of the Quality Assurance Unit (QAU). We kickstarted the discussion with a benchmarking exercise to determine if Quality Assurance KPIs are in use currently, and to ascertain the perceived value-add of such metrics, see Figure 2.

The poll results indicate that KPIs are commonplace within many test facilities, but with over a quarter of those in the workshop confirming KPIs are not utilised in their work environments, it is clear that whilst common, the use of metrics is not currently an embedded standard industry approach for assessing performance across the board. Where KPIs are applied, 37% do not include any metrics for assessing the performance of the Quality Assurance Function and 30% question the value-add of such an approach. Discussions with the audience covered various contributing factors, including challenges in identifying processes that could be measured and determining a mechanism or system for processing the metrics data. As discussed in the introduction of this article, direction and structure are key components here. Metrics for 'metrics sake' is not a value-adding initiative.

Direction and purpose? What direction are you looking to take? What do you want to achieve with the KPIs? Are you looking to assess general performance across the board to gather benchmarking information or are you wanting to target specific areas of potential improvement? What level of QA process performance are you hoping to achieve? What will you do with the metrics data? Structure? How will you gather the information and ensure it is measurable?

FIGURE 2. DELEGATE BENCHMARKING POLL RESPONSES



What data sources are available? How will the data be processed and metrics produced? When it comes to setting the performance targets, what are the acceptance criteria? At what point do the metrics confirm satisfactory performance and when should improvement initiatives be proposed?

When discussing what measurable information is available to QAU in relation to their processes, the noticeable consistent theme was time. Time taken to perform audits and write reports. Time required to review Standard Operating Procedures (SOPs). Time taken to capture audit responses and finalise reports. Time taken to track corrective and preventive actions (CAPA) to completion. Within the audience it was clear that time is considered a precious resource to be spent wisely and a measurable of particular interest in any potential KPIs. But there are possibly other factors to be taken into consideration that could provide insights into the conduct of processes and potentially also facilitate improved time management. For example, how many draft versions of a document, be it a study plan, experimental report, or SOP; are QA

willing to review before they are considered of acceptable quality for finalisation? Have acceptance criteria been set for the quality expectations of draft documents before the QAU perform their audits? Multiple review cycles are resource heavy and potentially places the onus for quality on the 'Quality Assuring' personnel and not the functions responsible for ensuring an acceptable quality standard is set and met. The approach of rejecting poor quality drafts as opposed to spending time highlighting all deficiencies is more likely to drive improved quality in the long term and further preserve the resource of time. If effective, the metrics could demonstrate both a reduction in number of rejected drafts and a reduction in time spent auditing draft documentation.

Another theme that came through in the discussion was personnel resource. The OECD Principles on Good Laboratory Practice (number 1) require Test Facility Management to ensure there is sufficient designated personnel available to implement a Quality Assurance Programme and assure that the QA responsibility is being performed in accordance with the Principles of Good Laboratory Practice. Personnel resource and throughput of QA tasks are certainly measurable if the data is available. For example, how many SOPs are pending review until QA resource becomes available? How much time would be required to complete any forecasted audits and, based on the number of personnel available, how long is actually required to complete these audits? For example, a QAU may have personnel resource amounting to 120 hours per week; however, if the forecasted workload indicates 130 hours are required for auditing alone, plus training and any other responsibilities of the QAU, the metrics here could be used to demonstrate to Test Facility Management that workload and available resource are not aligned and the risk of delays is increased. This could also impact on client satisfaction where pre-agreed completion timelines are not met. An evidence-based assessment of the resource limitations and predicted impact on client satisfaction could provide Test Facility Management with the metrics they need to implement change, such as increasing resource or improving the flow of tasks into the QAU to prevent bottlenecks or delays.

Speaking of resource, there is no denying that initiatives such as designing and implementing KPIs do require some effort and do impact on available resources. And so, it is imperative that this and any quality initiative adds value to the organisation whilst being implemented with minimal impact on resource. The KPIs should align with the direction and objectives of the organisation or function seeking improvements in performance. So what structure is available for the embedding of a metrics-based initiative? If the QAU already captures data pertaining to number and time

taken to complete tasks for example, then this data can be employed and presented in a metrics-based format, then subsequently analysed and used for informed decision making. Another potentially useful data source identified within the workshop was company timesheets, often used to track personnel hours on a task or project basis.

The majority of the audience who use KPIs within their organisations tended to deploy a manual system for processing data and presenting metrics. Excel is a common tool in such an approach and requires personnel to input, format, organise and calculate data, which can be a resource-heavy approach, especially if the spreadsheet functionality is not used optimally. Whilst Excel or similar programs can be powerful data processing tools, striking the balance between resource input requirements and value-added outputs were a concern within this population.

Some audience members currently had, or have had experience of, specialist automated software systems that would process data inputted from audit activity, such as audits or documenting CAPA and generate metrics automatically. Whilst the launch of such automated software requires significant efforts, once embedded, the day-to-day use of these was considered substantially less burdensome. Factors such as the amount of data available, tend to impact on an organisation's decision to employ manual, automated or hybrid systems for data processing. Generally these systems have the primary purpose of providing oversight to Test Facility Management on all study or project activity but have the potential to drill down into details where learning or improvement opportunities are anticipated, facilitating the creation of metrics. Smaller organisations may be able to provide such oversight and data mining activities on a manual basis with minimal administrative burden, whereas larger or global organisations may decide that automated software is necessary to provide the oversight they require, with the benefit of being more agile and adaptable than a series of manually managed spreadsheets. But one fact we all agreed on is that the quality of the output metrics is driven by the quality of data inputted. The adage of 'you get out what you put in' was universally acknowledged in the workshop. A system can only produce a high-quality deliverable from high-quality processes and the same is true of generating KPI data. Therefore, it is imperative that you can rely on the data against which you make decisions that later impact on conduct of processes.

It is not only the size of an organisation that may impact on the KPI data processing capabilities and functionality available. A further variable that was identified was the maturity of the QMS in place. New quality management systems, either still in development or recently introduced, may

not have a sufficient data pool available for effective analysis but may have the advantage of increased flexibility at the design or planning phase of their KPI initiative. Plus, a new organisation or QMS would most likely implement a different set of KPIs than a more established organisation, looking to benchmark current performance and set future performance targets as opposed to addressing known risks or realised adverse events. Organisations with a mature QMS will of course have a greater and more powerful data pool and will have sufficient historical context to implement more experience or risk-based KPIs, but large datasets can present an extra administrative burden if there are multiple data sources or if some data transformation is required to generate useable and readable metrics. For these data sets, a degree of automated data processing is certainly an advantage. However, migration or translation of data into specialist software systems can become a project in itself and so it must be ensured that the desired KPI outputs are defined early on in the project. The system must be set up to ensure the resulting benefits far outweigh the impact.

The accessibility of metrics was also discussed and it was determined that the method of compiling KPIs can directly impact the availability of this information to your intended stakeholders. Those with automated systems had the opportunity to ensure such metrics were available at all times to those with software access, whereas the manual approach lends itself to periodic reporting, often supported by additional communication. See Figure 3.

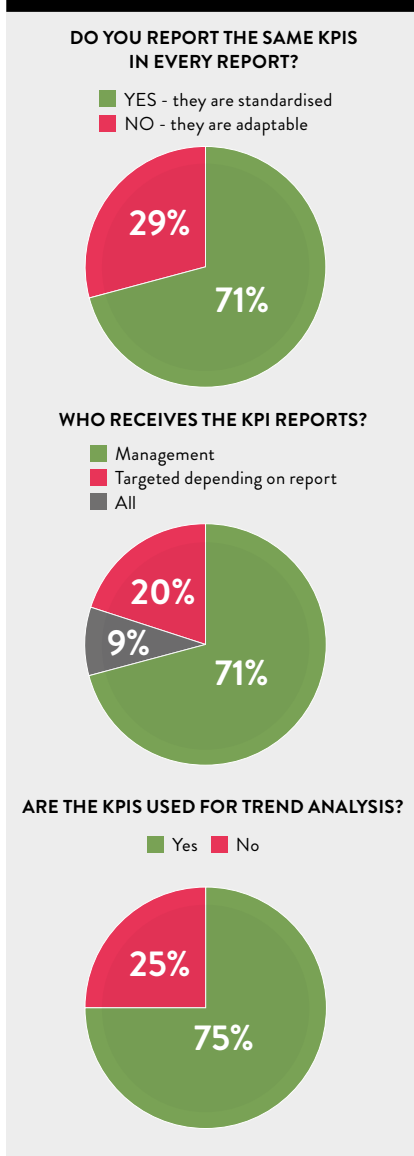
It was agreed that the way in which KPIs are communicated is integral to their success as a continuous improvement tool. The ultimate objective of the KPI is to identify opportunities for improvement in the 'check' phase of the PDCA cycle to facilitate the driving of change through the 'act' phase. Therefore, the method of reporting KPIs and engaging stakeholders is key in ensuring effort is dedicated to 'act' where risks or opportunities are identified and also ensuring the cycle does not come to an abrupt halt at 'check' – essentially resulting in the KPIs becoming 'metrics for metrics sake'. So how can we ensure we engage our stakeholders and facilitate onward continuous improvement, preventing the KPI initiative becoming a 'box ticking exercise' as opposed to an active continuous quality improvement process? First and foremost, the KPIs must be understandable and readable. There was unanimous agreement in the workshop that the message intended to come from the KPIs must be delivered in a format where it can be received and understood by its intended audience. Whilst additional communication such as meetings with key stakeholders was beneficial in promoting open discussion and providing context, it was felt that all KPIs must be fully understandable without

FIGURE 3. THE ACCESSIBILITY OF KPIS



interpretation or through additional verbal or written clarification. Ideally the KPIS should be visually presented in a manner that clearly defines the acceptance criteria or performance targets against the actual performance metrics. The secondary objective identified at the workshop was engaging the audience. What do we want them to do with this information? What is the message? What will be learnt? What are the proposals for acting upon these metrics and what would you like to achieve? Ensuring the KPIS are in themselves an engaging media can be a challenge. A challenge which can be overcome by ensuring the KPIS are relevant to current risks and align with the direction of the organisation. Whilst producing information on the same metrics or measurables over a period of time is essential for trend analysis and forecasting, if the perception is that risk is low, then receiving the same information periodically is likely to reduce the level of stakeholder engagement. Conversely, reactive metrics that change with every issued metrics report may have the advantage of being ‘on topic’ and interesting but will omit opportunities to identify trends or creeping increased risks within a process that are not being detected in the short-term. It was felt that a combination of both approaches was valuable in engaging stakeholders and ensuring the

FIGURE 4. DELEGATE POLL RESULTS



KPI process was optimised. It was also agreed that variations in the periodic reports would encourage engagement, instead of providing all of the KPI information in every report issued. Focused reporting was certainly the preference and yet the workshop polls identified that in practice over 70% of those in the audience using KPIS would produce or receive a standard report with little variation on a routine periodic basis. See Figure 4. A further consideration raised was who are the stakeholders? Generally, KPIS are reported to Test Facility Management, such that they have oversight of the performance of their QAU and can demonstrate that they meet the requirements of the GLP Principles. But since QA are responsible for assuring the level of compliance for all regulated activity within the Test Facility, surely Test Facility Management are not the only stakeholders? Other stakeholders, such as Study Directors are also routinely excluded from KPI reports but rely on the effectiveness of the QA unit.

In some cases, the KPI information was not even fed back into the actual QAU – the process owners and source of the performance data. Such limited reporting may diminish the potential for lessons learned or opportunities to acknowledge improvements in QA processes. This approach may also be considered to not be reflective of a transparent and open quality culture, often being promoted by the QAU to the wider organisation.

KPIS can be a powerful process improvement tool when applied to the ‘check’ phase of the continuous improvement cycle and managed as a standalone process in itself. Understanding the objectives of the KPIS to be implemented and planning appropriately is key to ensuring they align with the direction of the organisation’s overall improvement objectives. Data sourcing and processing into constructive metrics should be conducted within a structure that supports optimised output with minimal administrative burden. Analysis of KPIS should be performed against clear acceptance or attainment criteria and presented in a manner which facilitates clear, informed decision making. And finally, to act upon the improvement opportunities identified within the metrics, you must engage all relevant stakeholders and promote the continuous improvement approach. Periodic review of the effectiveness of KPIS will prevent common pitfalls in this approach, such as the production of measurable data either by rote or as a ‘tick box exercise’ with no clear benefit to the stakeholders. It is also important to identify and celebrate the wins that emerge from KPIS, either from process or deliverable improvement, reduction in risks or adverse events, or maintaining a steady state of acceptable performance.

I would like to thank the GLP committee panel and the RQA conference delegates who participated in the workshop. Their proactive engagement on this topic ensured the workshop was a success and their contributions in the polls and open discussions allowed for this article to be written. Thank you.

PROFILE

Michelle joined Evotec in September 2021 with 17 years’ experience in Quality and is based in Milton Park, Abingdon. Her experience in quality is primarily GLP-based but she also has previous experience in GRP, GCP Lab, HTA and ISO, across both contract research and mid-size pharma organisations. Michelle is currently responsible for implementing a Good Research Practice based Quality Management System in the Drug Discovery labs at Evotec’s sites in Abingdon and Alderley Park.