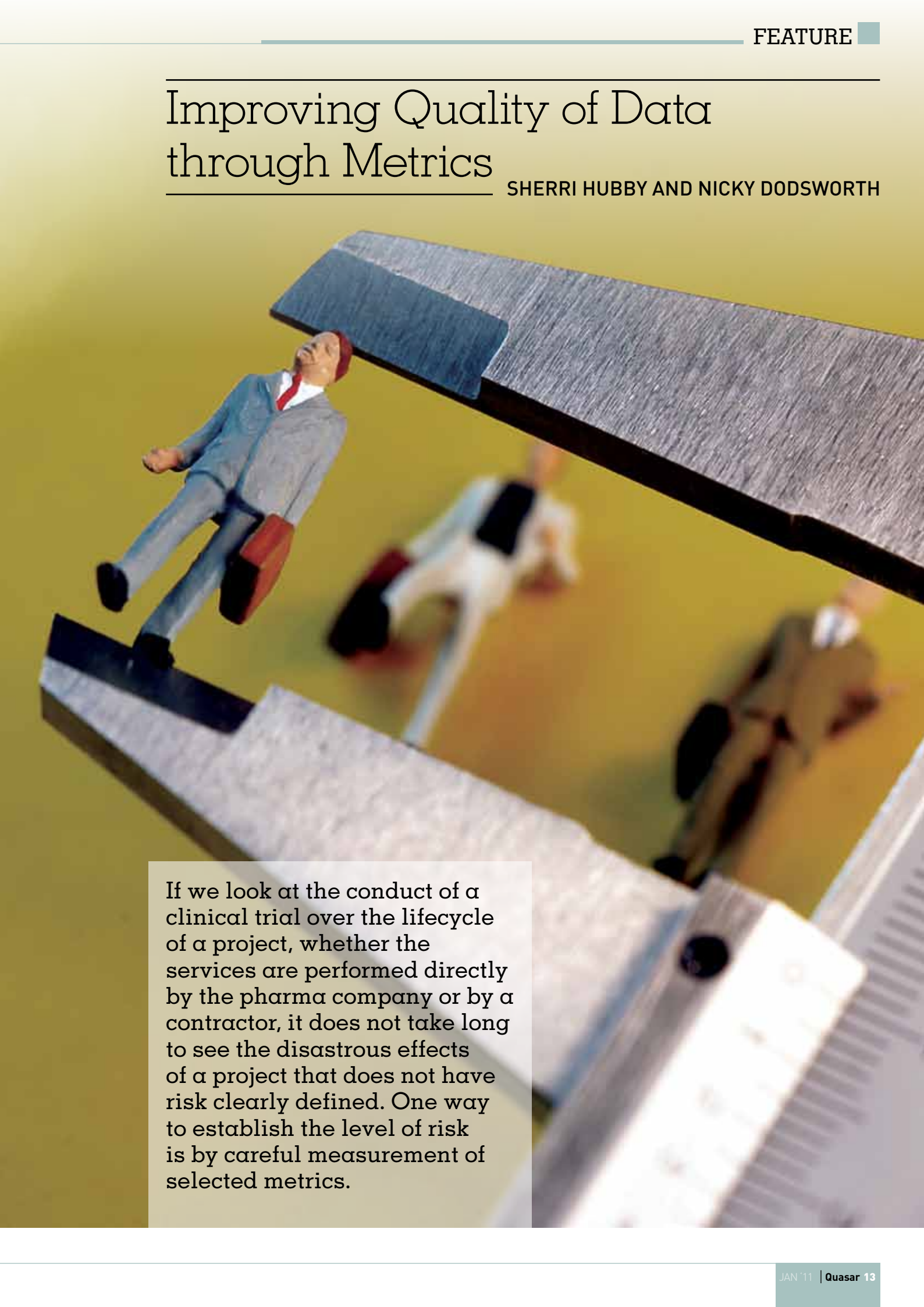


# Improving Quality of Data through Metrics

SHERRI HUBBY AND NICKY DODSWORTH

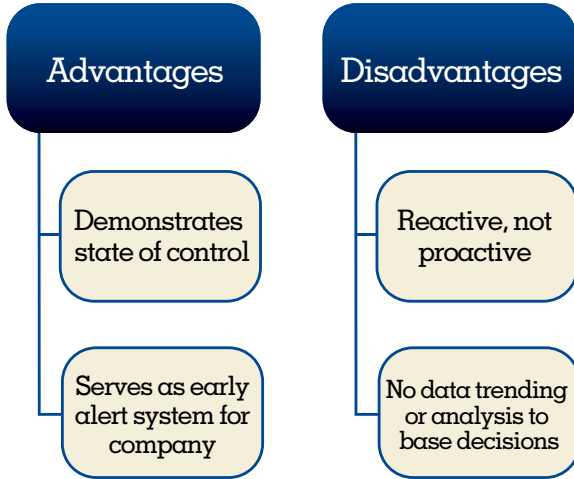


If we look at the conduct of a clinical trial over the lifecycle of a project, whether the services are performed directly by the pharma company or by a contractor, it does not take long to see the disastrous effects of a project that does not have risk clearly defined. One way to establish the level of risk is by careful measurement of selected metrics.

Metrics are useful to establish operational benchmarks for performance of the organisation/department and have been seen to improve performance. As Lord Kelvin said "If you cannot measure it, you cannot improve it." It is important that the metrics chosen have meaning to the organisation/department, are objective and, most importantly, need to be measurable.

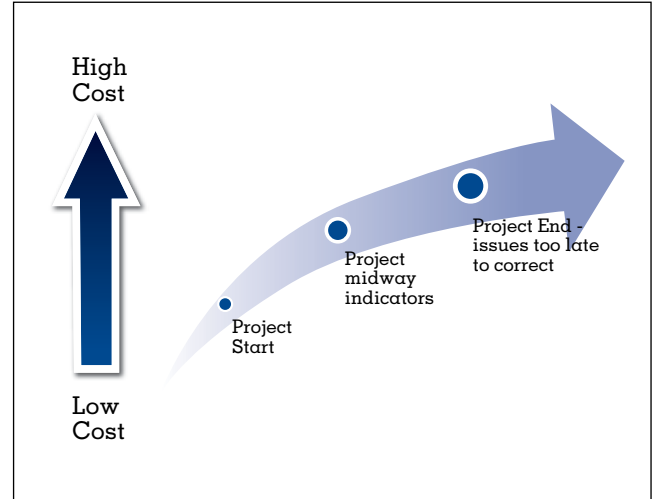
**Improving Company Performance**

In order to objectively evaluate whether improvements have taken place within a company, potential risk areas for the company must be identified and measured. These areas are not stagnant and may change over time. In setting up your metric system, it is important to look at the strategic relationship between the sponsor and contractor. The table below gives you some valuable insights to consider in implementing quality metrics.



Data quality can be difficult to measure objectively, but if metrics are clearly defined and agreed upon then data quality can be measured objectively. This can be even more challenging when sponsors and contract research organisations (CROs) have joint accountability for certain tasks. This is just one reason why it is vital to have roles and responsibilities carefully documented contractually.

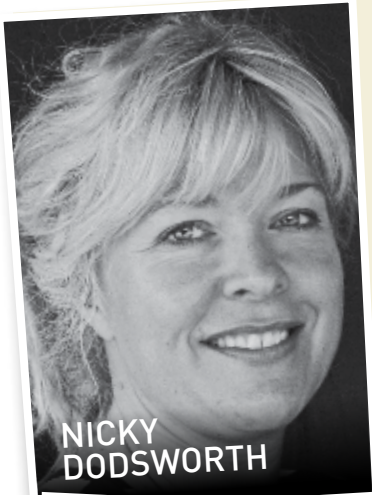
The results of quality without metrics can be seen in the graph below.



**'If you cannot measure it, you cannot improve it.'**

Quality metrics need to be established for every stage of the project/study. It is important to concentrate on important metrics early in the process. Measuring metrics at project end/late in the study is often costly and cannot be useful in helping with project oversight which needs to be conducted throughout the study. During project reviews, these metrics can be interpreted leading to detection of slippage and review of quality standards. This could highlight a more significant problem and the need to involve quality assurance (QA).

Typical metrics to be measured to help improve data quality before a project starts, or very early in the process, include investigator recruitment rates, time to study start-up and time to first patient first visit (FPFV). However some of these metrics indicate speed of the process rather than quality. The number of revisions to a protocol can indicate a poorly designed or hastily developed protocol or it can indicate, for example, the variability in the quality of the reviews of Ethics Committees. There are a vast number of metrics that can be measured



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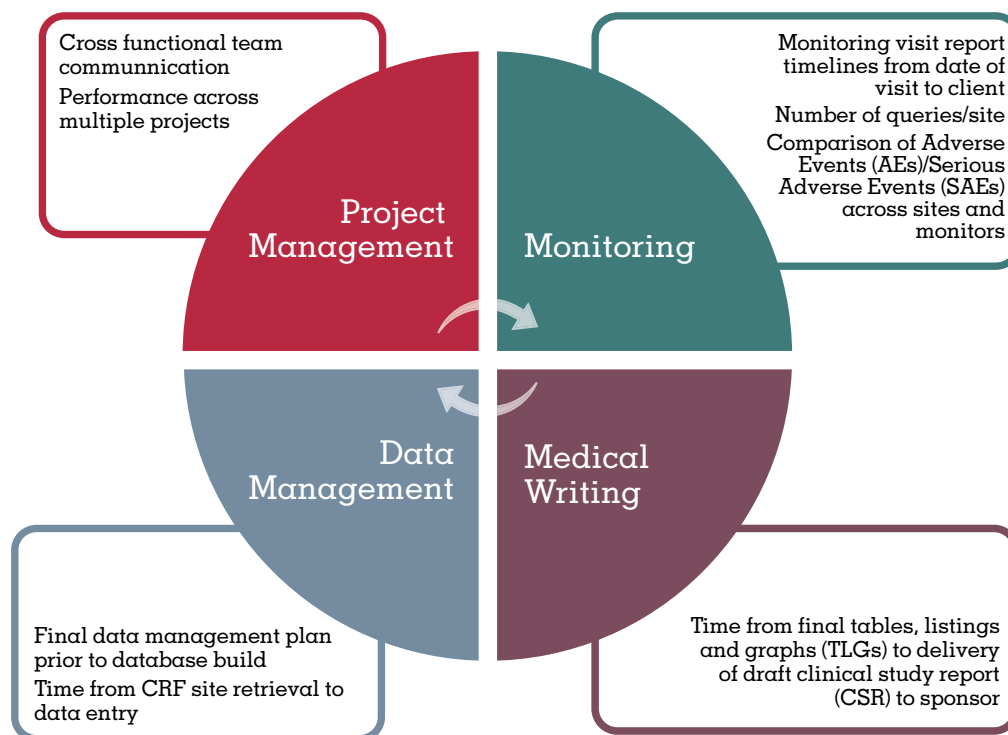
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## Examples of Key Indicators to Measure by Functional Group



during the course of a project. The types of metrics include the rate at which queries arise, the numbers of queries, ageing of queries etc. Query rates can result from poorly designed case report forms (CRFs) however, if query rates appear to be higher than normal it may indicate that there needs to be additional supervision/training at a particular site, an increase in monitoring visits conducted or even a need to introduce in-house secondary monitoring.

The time it takes for Clinical Research Associates to complete monitoring visit reports, post site visits, and the review time of the project manager or the time it takes to send these reports to the sponsor are frequently recorded metrics which can indicate a bigger issue if carefully assessed.

At the project end, QA can provide valuable assistance to operations by working with the teams to assess the project outcomes. It is particularly important that this type of assessment remains objective and targeted on process improvement rather than aimed at specific personnel.

In summary, no matter if you are a sponsor, CRO or site involved in support of the drug, biologic or medical device development process, performance quality metrics can be developed to improve any aspect of an organisation's operations.

In order to implement an effective system, companies must be prepared to identify risk. They must have a thorough understanding of their business processes and the critical quality attributes of those processes.

In the examples provided, metrics were developed as a baseline measurement for systems which could represent a regulatory or business risk. Metrics, when used properly, provide objective evidence that adequate controls are in place to improve performance, effectiveness, efficiency and appropriate levels of control for all involved.



## REFERENCES

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