The Use of Predictive Analytics to Improve Quality in Clinical Trials Quality Assurance:

Independent or an Enabler – or Can it Be Both?

The impact of poor quality in a clinical trial, often discovered late in the process, can not only add costs to addressing the re-work necessary, but in some cases can lead to rejection from a regulatory authority. Using predictive analytics and scorecards throughout the lifecycle of a study can, in many instances, prevent a quality issue occurring or mitigate the impact in other cases. The need to apply this approach in Quality Assurance (QA) is becoming more important due to the increasing complexity of clinical research and the increased use of technology to capture patient data remotely, as is the case with decentralised and hybrid trials.

Quality Assurance – An Evolving Discipline

The traditional role of the QA department is to provide oversight of process and patient safety by way of audits. This approach involves an auditor looking at a sample of data in a process and making a judgement on if the process is robust and fit-for-purpose, or has gaps. The challenge with such an approach is that it is reactive and involves a deep assessment as to why the process isn't working or why there was non-compliance to the process, otherwise known as Corrective Action Preventative Action, (CAPA). However, too often we see repeat CAPAs with the same root cause and the same preventative action, i.e. retraining.

However, similar to how technology and the insights we can gain from innovations is changing and evolving many areas across the clinical trial process, there is a real opportunity to develop new and innovative processes in the area of QA.

The role of QA departments is moving beyond audits at a given point in time, and building processes and procedures that will enhance the value it delivers on an ongoing basis. Predictive analytics is one of the key approaches that is enabling this expansion of how QA departments support the clinical trial process. This, coupled with the use of scorecards in the appropriate settings, can prevent serious data quality issues occurring in a study. In this article we'll outline how using data analytics can deliver greater value and driving an expansion of the QA department's role.

What's Enabling this Evolution?

Predictive analytics is an approach that examines data, trends and content to answer the question, "What is likely to happen?" based on the data trends we are seeing. It involves looking for patterns and trends in real time throughout the lifecycle of a clinical trial.

In the field of clinical trials, we already have a vast amount of data available to us from external audits, regulatory inspections and internal audits. Putting the findings into agreed consistent categories before data mining is a critical step in being able to refresh the data in real time. Following this step, we can examine the root cause of each category with an experienced expert and data analyst. This allows the QA department to direct the business in the correct areas that lead to repeat findings. For example, it may be a sub-optimal process that is the issue, or a repeat human error in what can be an over-complicated process.

The development of scorecards can also bring considerable insight to the process. They are the product of a snap assessment of a process (or multiple processes) embedded in a study, providing a "score" or colour code indicating if a process is under control or out of compliance, even before a study has begun.

The Benefits of Predictive Analytics and Scorecards

Our experience has shown a number of clear benefits from the use of predictive analytics, not least the ability to assess risks both before and during a study, thereby allowing us to combine initial, inherent and operational risks.

It has allowed for timely conversations with clinical trial team members in advance of a process being executed. The approach steers the team in the right direction, thereby avoiding the need to perform root cause analysis explaining why something went wrong.

With more and more hybrid studies being implemented, there is a great need for early intervention of the QA department to evaluate the flow of data from the onset. Technology is and will continue to play a greater role in collecting patient data. The traditional role of the project manager has evolved, and now requires more technology-minded individuals who can identify the need for audit trails, identify the original source data and ensure that the data has not changed as it travelled throughout the various tools. Partnering with the QA department earlier will enable the project manager to implement controls, plans and enhanced communication plans across the study to ensure the data flow map is understood by all key stakeholders, with the critical end point data always as a priority. Ultimately, predictive analytics and early intervention provide a greater opportunity for clinical trial teams to implement a change to process at the right time, therefore preventing repeat errors occurring in the trial and potentially risking fatal errors being made that could impact the outcome of the entire study.

Embedding a QA Process Into the Clinical Trial Process

By way of example, let's look at how this expanded QA process can be embedded into the overall clinical trial framework.

It is critical that the QA department and clinical trial teams understand respective responsibilities and collaborate from the outset to ensure reduction of quality errors on a study. The QA department then assesses and determines the categories that require more attention as the study is being set up. The study can be evaluated against key risk indicators such as phase of study, patient populations, and this can also include data sources to be collected and mode of collection. If a study is considered a high risk study or is planning accelerated approval, the approach of a scorecard can be applied. The auditors in the QA department will evaluate, via a snap assessment approach, the planned processes put in place against regulations and compliances to approved internal processes. Each process will be assigned a rating of red, amber or green, with details behind the score indicating where the process is at risk.

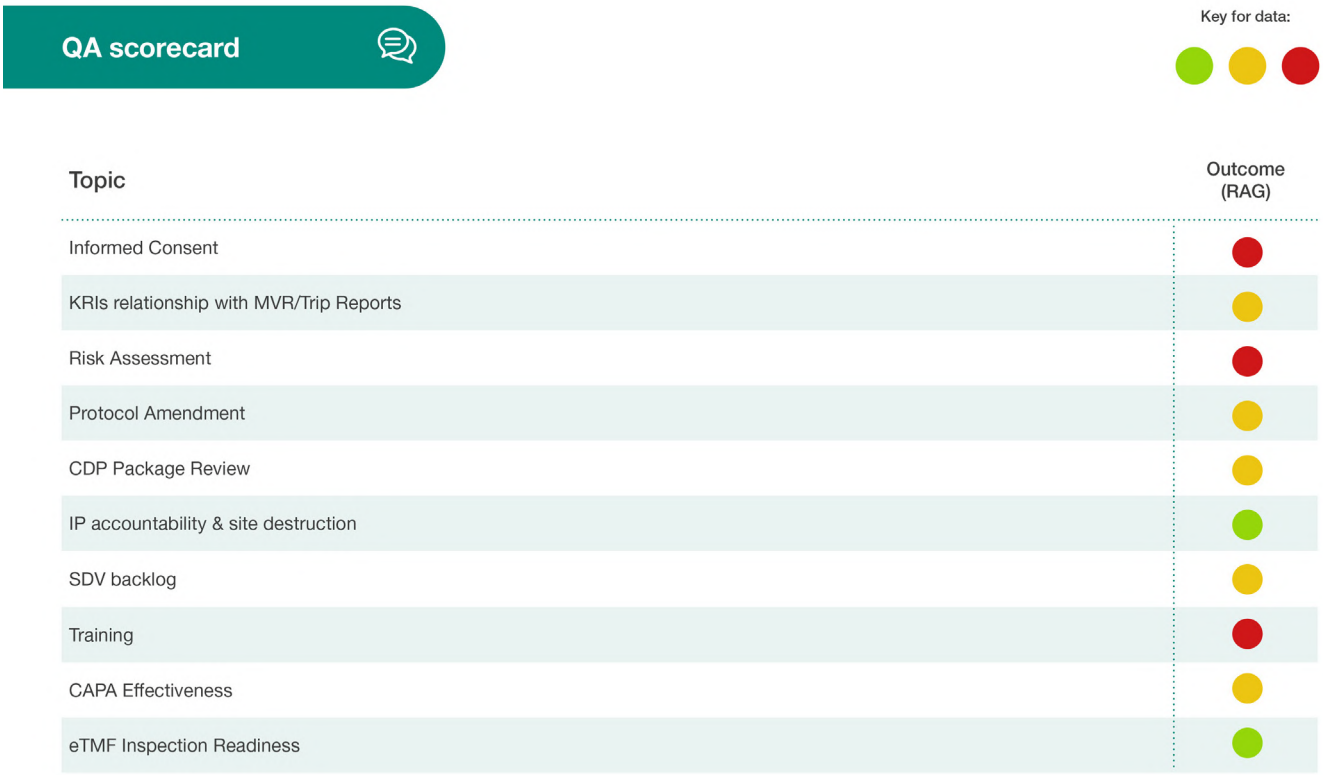

Figure 1: Example of a QA scorecard

The clinical trial is then empowered with the data at the right time and is required to address the gaps/risks identified in real time. The QA department can and should, at a later stage, conduct the standard independent audits or inspection readiness as would be routine. The reduction of average critical or major findings per audit is a measure of how successful the team embraced the data provided.

Key Considerations When Using Predictive Analytics

There are a number of considerations that should be borne in mind when implementing QA processes using predictive analytics.

When building the QA process, after identifying the correct data points and root cause information, consideration needs to be given to whether there is enough data to accurately represent the relationship between root cause and the potential outcome, should no intervention be taken. Data should be refreshed regularly to ensure the risk profile is kept up to date. Internal data sources are best for internal root causes such as employee behaviour and inadequate processes, for example. External data sources should be used as best-fit for risks driven by the external environment such as regulatory changes and new data sources e.g. remote patient monitoring or new technologies that enable decentralised trials.

In addition, a commitment to change management by the clinical trial teams is critical to them embracing the concept of "potential risk" and willing to invest time up front in the preventative activity. This speaks to the culture of quality within an organisation and whether it is willing to prevent rather than fix the issues, thereby embedding quality into the study design up front.

Conclusion

Predictive analytics and early intervention is becoming a necessity for QA departments. As the pressure continues to get much-needed drugs to the market to meet the needs of patients, there is a need for real time quality assurance support throughout the study to address/prevent any delays due to quality concerns. At this time of transformation in clinical development there is a significant opportunity to be innovative in the qualitative assurance approach to increase the quality and integrity of data throughout the trial. This allows for more enhanced insights and more timely corrective actions and reduces waste in re-work at the end of a clinical trial. Becoming a partner to clinical trial teams by providing predictive data enables the QA department to both be an enabler of high quality while still maintaining diligent independent oversight.

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In her role as Executive Vice President, Quality and Compliance at ICON, Rose leads an international team of experts who are specialised in Quality and Compliance. Rose provides leadership and strategic vision for the implementation and management of a quality and compliance infrastructure and a global Quality Management System at ICON. This involves proactive engagement with ICON operational service line leaders to advise and support on regulatory compliance and operational excellence.