

## PerkinElmer Risk-Based Monitoring Solution

The PerkinElmer Risk-Based Monitoring (RBM) Solution provides several advantages in deploying a Risk-Based approach to clinical trial oversight.

Using the TransCelerate standards and guidelines, our RBM solution aims to enhance early, ongoing risk assessment by building Quality by Design (QbD) into trials. By using risk indicators and thresholds (Green, Yellow, Red threshold levels), our end users are able to focus on critical processes and data and adjust their monitoring needs accordingly.

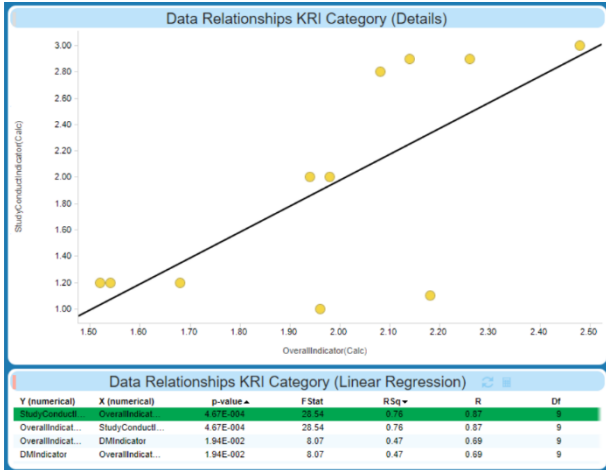
Key Risk Indicator (KRI)	Metric	Form
Total screened	Days since site initiation	Ratio
Total randomized	Days since site initiation	Ratio
Number of Subject Visits since last Monitoring Visit	N/A	Absolute Threshold
Visits entered late	Total visits per site	Percentage
Monitoring Visit Report Questions	Staff and Quality Issues	Ordinal
Protocol-specific labs (eg BP variability)		
Adverse event rates	Total visits per site	Ratio
Safety signals	Total visits per site	Ratio
Informed consent failures	Number of subjects per site	Percentage
Early withdrawal or screening failures	Number of subjects per site	Percentage
Events leading to discontinuation of treatment	Number of subjects per site	Absolute Threshold
AESIs, SAEs, deaths	Number of subjects per site	Absolute Threshold
Missing Labs	Total missing labs per site	Percentage
Queries late	Total late queries per site	Percentage
Query rate	Total queries per site	Ratio
Total number of queries	Total visits per site	Ratio
Protocol Deviations	Number of subjects per site	Ratio
Relative experience of the clinical investigator	N/A	Weighted Factor
Relative experience of the sponsor with the investigator	N/A	Weighted Factor
Site documentation	N/A	Weighted Factor
Training levels achieved by site personnel	N/A	Weighted Factor

Figure: RBM Approach- Identify Potential Issues via Key Risk Indicators (KRIs)

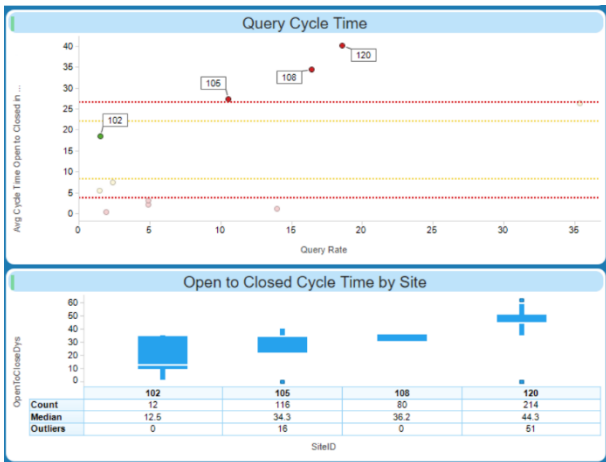
Below are some examples of the visual analytics included in PerkinElmer's Risk-Based Monitoring solution:



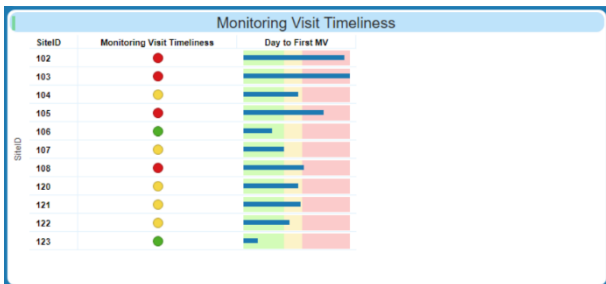
Risks, actions taken and their impact represented over time.



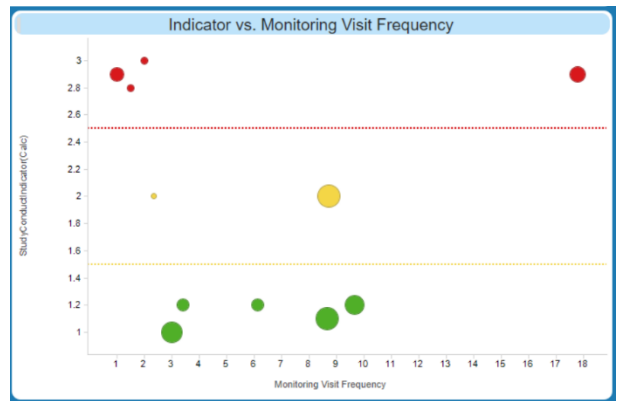
Correlation between pairs of KRIs.



Relationship between query cycle time and query rate per site.



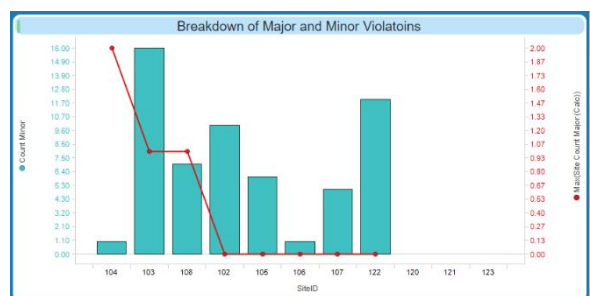
Days to the first monitoring visit per site, as a KRI.



Relationship between the study conduct indicator and the monitoring visit per site.



Query rate (number of queries per subject per months in study) per site.



Number of minor and major protocol violations per site (bar chart and geographic view).

## Appendix:

A comprehensive list of the visual analytics included in PerkinElmer's Risk-Based Monitoring solution. These visuals are dependent on the Key Risk Identifiers (KRI) Reference Library with TransCelerate's RACT (Risk Assessment categorization Tool) and include up to 20 KRIs.

The visual analytics in our RBM solution are fully customizable and can be extended to include additional Key Risk Indicators and visualizations.

### Visualizations available

#### Overview

Cover page with overall indicators per site and quick links to pages for specific personas (e.g. monitors, central monitors).

KRIs for all sites assigned to each monitor in the study.

Interactive report for monitors to update their actions, according to the overall indicator per site.

Geographical map showing the recommended actions for each site.

Overview of the recommended actions for each site and their status of completion.

Hierarchical map of KRIs, showing their weightings and their value at each site.

#### Model configuration

Modeler to specify the weightings for the individual and category indicators.

Selector of actions to be recommended automatically, according to the value of each category indicator.

#### Subject recruitment

Relationship between the enrollment ratio and the number of months in study, by site.

Detailed list of enrollment information by site.

Screen failure rate by site, with adjustable threshold.

Detailed screen failure ratio (number of subjects enrolled and screen failures).

Tabular information of screen failures.

#### Study conduct

Serum creatinine collection cycle by site.

Distribution of serum creatinine cycle time values by site.

Tabular details of serum creatinine data.

Number of days to first monitor visit per site.

Surgical procedures since last monitor visit per site.

Tabular details of surgical procedures data.

#### Adverse events

Adverse events rates (AEs per subject per month in study) by site

Relationship between the number of AEs and the number of subjects enrolled by site

Relationship between the number of minor protocol violations and the number of months in study by site.

Number of minor and major violations per site.

Geographic representation of the number of protocol deviations by site.

#### Data management

Query rate (number of queries per subject per months in study) by site.

Relationship between query cycle time (time between opening and closing) and query rate by site.

Distribution of query cycle times by site.

#### Fraud detection

Last digit indicator (based on the distribution of the last digit across all vitals values) by site.

Detailed distribution of last digits by site.

Detailed distribution of last digit by site and vitals test.

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