

Top 10 Core Key Risk Indicators:

# Quality Oversight and RBM Starter Kit

A graphic element for the TRi logo consisting of a thin grey curved line with five dots of varying sizes and colors (grey and red) positioned above it.

**TRi**

*The Risk-based  
monitoring company*



# Why Did We Create This Document?

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Through our many discussions with customers, prospects, industry groups and business forums, we have observed three consistent themes amongst the small and mid-sized Pharma and CRO community:

- A genuine desire to improve quality oversight and decision making during clinical trials
- Confusion as to where, when and how to start
- A misconceived perception that quality oversight tools and services are too expensive and so it remains the domain of big Pharma and CROs.

At TRI, we care about helping move the industry forward and so wanted to share some simple insights into KRIs we are seeing being used successfully across the industry for quality oversight, and ultimately, as a first step in risk-based monitoring.







We really hope it helps you start your journey.....

*Duncan Hall, CEO Triumph Research Intelligence*









# How To Use This Document

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 An icon representing categories, showing three stacked rectangular boxes labeled 'A', 'B', and 'C'. Box 'B' is highlighted in orange, while 'A' and 'C' are grey.	CATEGORY – This tells us the indicator category, and allows us to group indicators according to purpose
 A blue circular icon with a white lowercase letter 'i' in the center, representing information or a description.	DESCRIPTION – How is the KRI derived?
 An icon representing data requirements, showing a 3D structure of blue cubes with white binary digits (0s and 1s) on their faces.	DATA REQUIREMENTS – What data is needed for the KRI and how are the calculations performed?
 A blue magnifying glass icon, symbolizing search or investigation.	WHAT ARE WE LOOKING FOR? – What is the KRI telling us in real world terms?
 An icon representing additional comments, showing two overlapping speech bubbles in blue and white.	ADDITIONAL COMMENTS – Is there anything else we think you should know?
 An icon representing companion KRIs, showing two hands, one blue and one grey, shaking or holding each other.	COMPANION KRIs – Are there any other KRIs we recommend using in conjunction with this one?

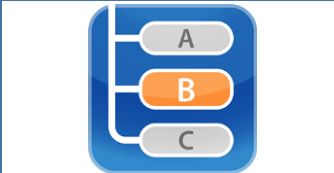


# 1: Screen Failure Rate

	Recruitment
	<p>% of total screened subjects who fail screening compared to study population, normalized by number of weeks since activation</p> <p>*activation is the date that the site was able to begin enrolling subjects</p>
	<p>Per site, total number screened and total number screen failed</p> <p>Can count from subject data in IxR and/or EDC. Count number of subjects screened and number of subjects with screen fail status</p> <p>* screened subject is a subject who has consented and attended screening visit</p> <p>Total time, in weeks, since activation</p>
	To identify sites with higher or lower screen failure rates - are they screening correctly?
	Could also be run-in failures as applicable
	<ul style="list-style-type: none"><li>• Early Termination (ET) rates</li><li>• Enrolment Rates</li><li>• Screen Failure (SF) reasons</li><li>• ET/SF Ratio</li></ul>



# 2: Early Termination (withdrawal) Rates



Recruitment



% of enrolled subjects who terminate from the study early compared to study population, normalized by total time on study.



Calculate per site, total number of subjects that terminate early.  
Need to identify eCRF visit (usually Study Completion visits) and visit date  
Count number of subjects that have Completed Study Visit but not completed all subsequent visits.  
Cumulative total time on study for all subjects.









Identifies sites with subject retention issues and also sites that have near perfect completion rates.



- Screen Failure (SF) Rates
- Enrolment Rates
- Early Termination (ET) Reasons
- ET/SF Ratio



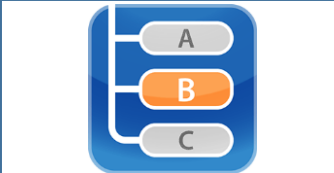
# 3: Data Entry Timeliness

 An icon representing data quality, showing three stacked rectangular boxes labeled 'A', 'B', and 'C'. Box 'B' is highlighted in orange, while 'A' and 'C' are grey.	Data Quality
 A blue circular icon with a white lowercase letter 'i' in the center, representing information.	Median number of calendar days from subject visit date to data entry to eCRF page entered in the EDC system, normalized by total data entered
 An icon showing a 3D structure of blue cubes, some of which are numbered with '0' and '1', representing data or binary information.	Per site, all subject visit dates, all EDC data entry date/time stamps, a count of all data entered, by site
 A blue magnifying glass icon, symbolizing search or investigation.	Is the site keeping on top of the data entry? Are we getting data when we require it for remote monitoring. Indicative of lack of process/delegation of responsibilities
 An icon of a blue speech bubble with three horizontal lines inside, representing communication or messages.	Can also plot as % compliance with contracted timelines e.g. 5 days from subject visit date
 An icon showing two hands shaking, symbolizing agreement, partnership, or compliance.	<ul style="list-style-type: none"><li>• Subject Visit Compliance</li></ul>



# 4: Query Rate

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Data Quality



Ratio of queries generated vs. the total number of data points collected per site, compared to study population, normalized by total data entered



Per site, total count of all data points, total count of all queries, and a count of all data entered, by site









Is the site providing good quality data?  
Is the site struggling with particular elements of the CRF or schedule of assessments?  
Can be indicative of lack of good process/delegation of responsibilities



- Subject Visit Compliance
- EDC Change History
- Deviation Rates








# 5: Site Initial Query Response Time

 An icon representing data quality, showing three horizontal bars labeled 'A', 'B', and 'C' within a blue rounded square frame.	Data Quality
 A blue circular icon with a white lowercase letter 'i' in the center, representing information.	Median number of calendar days from time query generated to initial query response on EDC system, compared to study population, normalized by total data entered
 An icon showing a stack of blue cubes with white binary digits (0s and 1s) on their faces, representing data.	Per site, total count of all queries and a count of all data entered Per query, metadata, query issue date and first response date
 A blue magnifying glass icon, symbolizing search or investigation.	Is the site managing their workload?
 An icon of two overlapping speech bubbles, one blue and one white, representing communication or messages.	Can also plot as % compliance with contracted timelines e.g. 5 days from subject visit date
 An icon of two hands shaking, representing an agreement or partnership.	<ul style="list-style-type: none"><li>• Query Rate</li><li>• Data Entry Timeliness</li></ul>










# 6: Subject Visits Schedule Compliance

	Compliance
	% of total randomized/treatment visits that are conducted out of the protocol visit window, compared to study population, normalized by total time on study
	Per site, subject visit dates, count of edit check on out of visit window If not edit check, identification of visit window to allow calculation at data processing Cumulative total time on study for all subjects
	Are sites demonstrating near perfect attendance and how does this compare to study population? Is site demonstrating lack of compliance with visit schedules, are there other compliance considerations, does this impact subject safety e.g. dosing regimens?
	<ul style="list-style-type: none"><li>• Deviation Rates</li><li>• Early Termination Rates</li></ul>









# 7: Deviation Rates

	Compliance
	Number of protocol deviations per time on study, compared to study population
	Per site, cumulative total time on study for all subjects. Count of number of deviations (from EDC or CTMS)
	Is the site being compliant with the protocol? Is the deviation rate too high, if site has been active for good period of time, compliance should improve.
	<ul style="list-style-type: none"><li>• Subject Visit Compliance</li><li>• EDC Change History</li><li>• Query Rates</li></ul>








# 8: Digit Preference

 An icon representing compliance, showing three stacked rectangular boxes labeled 'A', 'B', and 'C' from top to bottom. Box 'B' is highlighted in orange, while 'A' and 'C' are grey.	Compliance
 A blue circular icon with a white lowercase letter 'i' in the center, representing information.	% of BP readings ending in zero/ total number of readings per site, compared to study population
 A 3D isometric icon of a cube made of smaller cubes, with some faces showing binary digits (0s and 1s) in blue and white.	Per site, all BP readings
 A blue magnifying glass icon, symbolizing search or investigation.	Is the site accurately recording data? Is there sufficient variability in the data being recorded?
 A blue square icon with rounded corners, containing a white speech bubble with three horizontal lines inside, representing messages or communication.	Can perform similar assessment with other vital signs for leading/trailing digits e.g. Weight, Height
 A blue icon of two hands shaking, symbolizing agreement or partnership.	<ul style="list-style-type: none"><li>• Query Rate</li></ul>








# 9: Serious Adverse Event Rate

	Safety
	Number of SAEs per time on study, compared to study population
	Per site, cumulative total time on study for all subjects Count of number of SAEs
	Is the site under/over reporting on SAEs? Is there a country/region trend?
	<ul style="list-style-type: none"><li>• Adverse Event Rate</li><li>• Early Termination Rate</li></ul>



# 10: Adverse Event Rate

	Safety
	Number of AEs per time on study, compared to study population
	Per site, cumulative total time on study for all subjects Count of number of AEs
	Is the site under/over reporting on AEs. Is there a country/region trend?
	<ul style="list-style-type: none"><li>• AE Distribution</li><li>• Con Med Rate</li><li>• Medical History Rate</li><li>• Early Termination Rate</li></ul>



# Disclaimer

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The content of this document is based on our experiences and observations and should be used as guidance only. It is by no means a guarantee of quality improvements or cost savings.



## For More Information

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Please feel free to contact us for more information on quality oversight and risk-based monitoring techniques, technology and services – we'd love to hear from you.

**By website:**

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