

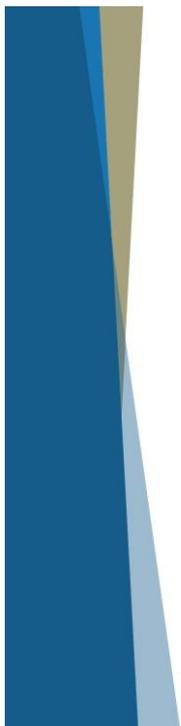


Metrics for Compliance Program Effectiveness

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HCCA Indianapolis Regional
Healthcare Compliance Conference
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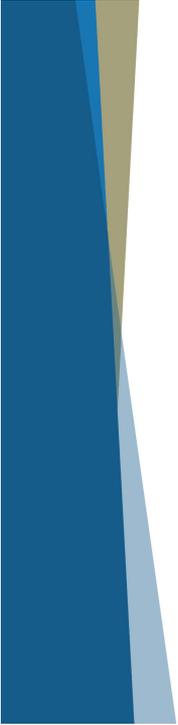
Compliance Today – September 2019

Interview with Matthew Tochow, Chief Compliance and Business Integrity Officer,
Veterans Health Administration, U.S. Department of Veterans Affairs

- Q&A: "...how do you see compliance evolving over the next five to ten years?
 - I believe that the ethics, culture, and "people" part of our jobs will remain constant. Human nature will continue to be human nature, and we will need to continue to inspire people to behave with integrity.
 - However, **technology will impact us greatly** for good and bad. I worry about the ability of people to use technology to commit fraud and to **manipulate data** maliciously. At the same time, I believe that we will be able to **use big data to help mine and visualize risks** in a more advanced fashion and, therefore, aid out efforts to be proactive, to get ahead of and mitigate emerging or hidden risks, and detect and remediate others."

SUNHAWK 2

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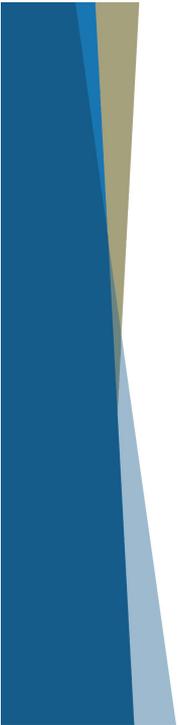


Compliance Program Effectiveness – Today's Discussion

- Evaluation of compliance programs should factor into your metrics.
- Measuring outcomes not just activities is key to regulatory expectations.
- Perfection is not the expectation – but authentic measurement and reasonable mitigation that builds regulatory trust.



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Department of Justice – Evaluation of Corporate Compliance Programs

- Is the Company's Compliance Program Well Designed?
- Is the Company's Compliance Program Being Implemented Effectively?
- Does the Company's Compliance Program Work in Practice?
- Where do metrics and data analysis fit into these DOJ questions?

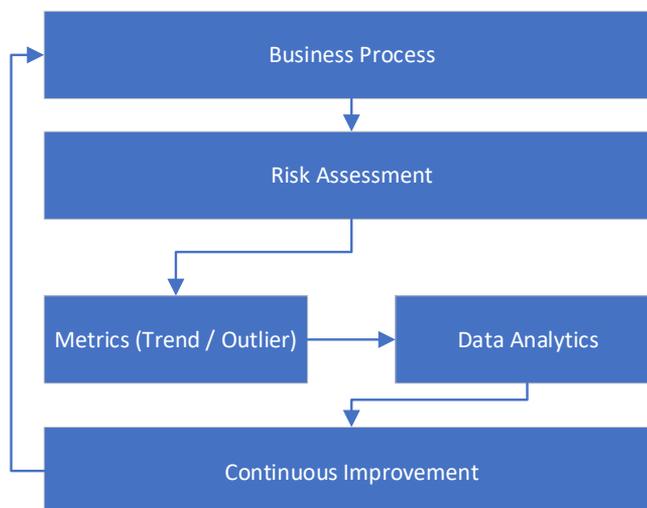


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Department of Justice – Evaluation of Corporate Compliance Programs

- Is the Company's Compliance Program Well Designed?
 - Risk Management Process: What methodology has the company used to identify, analyze, and address the particular risks it faces? **What information or metrics has the company collected** and used to help detect the type of misconduct in question? How have the information or metrics informed the company's compliance program?
 - Confidential Reporting and Investigations: Are reporting and investigating mechanisms sufficiently funded? How has the company **collected, tracked, analyzed and used information** from its reporting mechanisms? Does the company periodically **analyze the reports or investigations findings for patterns** of misconduct or other red flags for compliance weaknesses?

Compliance Program Metrics



- Can you trace your metrics back to your risk assessment?
- Can you show how your data analysis drove business process improvement?

Department of Justice – Evaluation of Corporate Compliance Programs

- Is the Company's Compliance Program Being Implemented Effectively?
 - Autonomy of Compliance Department: Do compliance and control personnel have the appropriate experience and qualifications for their roles and responsibilities? Has the level of experience and qualifications in these roles changed over time? Who reviews the ***performance of the compliance function and what is the review process?***
 - Incentive System: Has the company considered the ***implications of its incentives and rewards on compliance? How does the company incentivize compliance and ethical behavior?*** Have there been specific examples of actions taken (promotions or awards denied) as a result of compliance and ethics considerations? Who determines the compensation, including bonuses, as well as discipline and promotion of compliance personnel?

Compliance Program Metrics

Performance of the Compliance Function

Activity / Process Metrics

- Years of experience – compliance function / industry
- # of high-risk areas reviewed
- # of compliance issues initially detected – by compliance
- Benchmarks on above – peers, industry

Outcome Metrics

- # of compliance issues initially detected – externally (by regulators, outside auditors, customers)

Compliance Program Metrics

Incentives

For any metric tied directly or indirectly to an incentive or recognition program – what actions could potentially happen if the incentive was a “\$5 million” bonus?

Assume a Value Based Health Environment

- # or % of additional eligible diagnosis codes identified
- % of charts with fully eligible diagnosis codes
- % of charts which are accurate regarding diagnosis codes
- What compensating controls or metrics would you put in place depending upon the other metrics which are tracked?



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Department of Justice – Evaluation of Corporate Compliance Programs

- Does the Company’s Compliance Program Work in Practice?
 - Continuous Improvement Periodic Testing and Review: What is the process for determining where and **how frequently** internal audit will undertake an audit and what is the rationale behind that process? Did audits occur and what were the findings? How often does internal audit conduct assessments in high-risk areas? **What testing of controls collection and analysis of compliance data** and interview of employees and third-parties does the company undertake? **How often** has the company updated its risk assessment and reviewed its compliance policies, procedures, and practices?
 - Analysis and Remediation of Any Underlying Misconduct: Payment Systems: Were there prior opportunities to detect the misconduct in question? What **specific changes has the company made to reduce the risk** that the same or similar issues will not occur in the future?



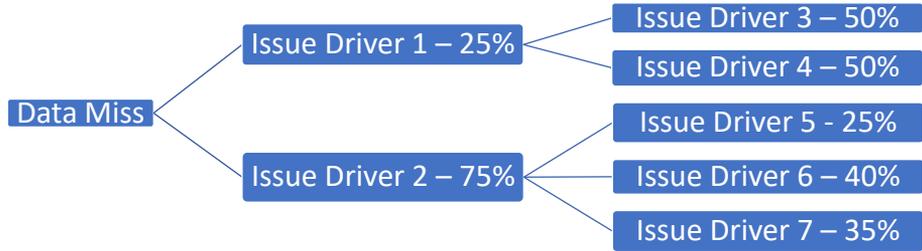
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Compliance Program Metrics

Periodic Testing and Analysis of Data

- # of Audits by Type
 - Low Risk Areas
 - High Risk Areas
- Finding Analysis – Compliance Related Business Metrics



- Root Cause Methodologies: 5 Whys / Six-Sigma
- Process Improvement: Automated Controls / AI



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Evaluating Metrics

- Activity Metrics
 - Number of transactions with limited insight into the quality of those events
- Process Metrics
 - Assesses the overall process, but not the stakeholder needs
- Outcome Metrics
 - Directly tied to a desire of the stakeholder

Framework to Evaluate Metrics	1 - Good	2 - Better	3 - Best
Utility of Metric	Activity	Process	Outcome
Cost to Obtain / Maintain	Difficult	With Effort	Easy

Business “Compliance” Metrics

- By Process Area
 - Accuracy
 - Quality
 - Cycle Time
 - Completeness
 - Satisfaction
 - External Regulatory / Client Audit Results

	Activity	Process	Outcome
Billing / Claims	# Claims	% of Charts / Claims Audited	Accuracy % - Claims
	# Chart Audits	Auditor Validation Score	Accuracy % - Billing
Travel, Expense, Entertainment	\$ Paid / Employee	% High Risk Employees Reviewed	# Concerns Raised
Nursing	# Nurses # Nurses Hired	Average Staffing Levels	% of Hours Understaffed

Compliance Program Metrics

	Activity	Process	Outcome
Compliance Audits	# Audit	% of High-Risk Areas Reviewed	Audits Passed
Hotline Process	# Calls	Timeliness of Evaluation	Substantiated Calls
Training	# Staff Trained	Training Material Retention (test, quiz)	# Issues Related to Employee Knowledge

- Consider Metrics Across the Seven Elements
 - Written policies and procedures
 - Compliance governance
 - Effective training and education
 - Effective lines of communication
 - Process to respond to offenses
 - Auditing and monitoring
 - Publicized enforcement policies

Compliance Today – September 2019

Article on “The Quality and Compliance Partnership” – Paul Jesepe and Kristine Pelerin

- Discussion on the overlap of quality managers, risk managers and compliance officers.
- Noting how the different departments within an organization may be attempting to address the same issues without realizing the work of the other.
- Clarity on metrics helps align the strategy and resources, especially when the metrics embed compliance expectations within business metrics tracking.

Is there Alignment on Metrics to Monitor?

Governance Area	Financial Metrics	Operational Metrics	Satisfaction Metrics	Compliance Metrics
Audit	✓		✓	✓
Compliance	✓		✓	✓
Business Operations	✓		✓	?
Quality		✓	✓	?
Safety		✓		?
Risk Management	✓		✓	?
Executive Committee	✓		✓	?
Board	✓		✓	?

How is compliance monitoring embedded into all oversight groups?
How is compliance serving its role as the second line of defense?



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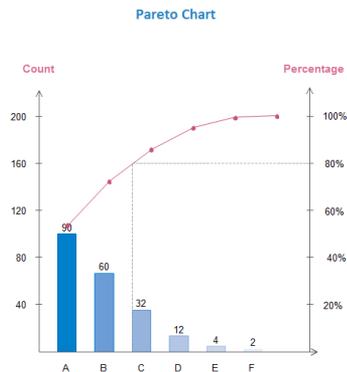


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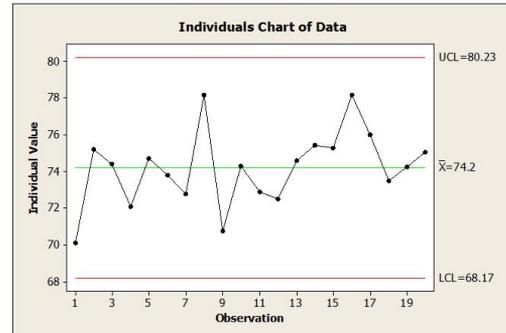
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Types of Metrics

- Can the reader assess the outcome without extensive interpretation?



Pareto charts assist in root cause analysis



Modified from Figure 10.8, *Integrated Enterprise Excellence Volume III - Improvement Project Execution: A Management and Black Belt Guide for Going Beyond Lean Six Sigma and the Balanced Scorecard*, Forrest W. Breyfogle III, BridgeWay Books/Citrus Publishing, Austin, TX, 2008.

Run charts assist in calibrating variability



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Types of Metrics

- Automated vs Manual
- Preventative vs Detective
- Number vs Percentage vs Per 1000/Per 100
 - 500 complaint calls
 - 5% of our patients
 - 5 / 100 patients
- Trends / Benchmarks / Year over Year Comparisons
 - This month's complaints were up 8/100 vs 5/100 last month
 - Year over year – complaints were same this month as last year at 8/100 due to seasonality of
- Actual to Goals / Upper and Lower Thresholds



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Types of Metrics

- Key Control Indicators – Generally activity metrics designed to identify when a control is no longer effective or meeting the control objective
 - % of claims audited
 - % of nurses meeting continuing certification requirements
- Key Risk Indicators – Generally process metrics that foreshadow a level of risk outside the organization’s risk tolerance
 - Average nurse absentee rate
 - Average experience of senior claims supervisors
- Key Performance Indicators – Generally outcomes metrics that identify a stakeholder needs
 - Claims billed accurately
 - Complaints resolved to patient / beneficiary satisfaction

Data Governance

- How can I trust my metrics?
- For key compliance related operational data – can I always trust the data?
- Does your organization have a Data Governance Committee?
 - Key data identification
 - Key data mapping
 - Source / extraction / transformation / loading / reporting
 - What are the touch points to the data?
 - Metadata management
 - Data steward identification
- Data validation audits
 - More than taking a sample of transactions and validating them
 - What data controls are in place?
 - How often do I need to repeat the data validation?

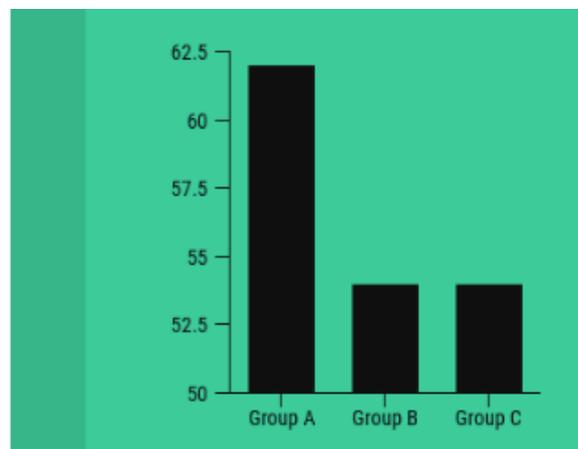
Reporting Your Metrics

- Exception Reporting vs Full Metric Portfolio
 - Lead with outcome exceptions / concerns
 - Show your work (your process) in the appendix
- Unit / Executive / Board Level
 - Why different?
 - Small issues / foreshadowing potential concerns
- Review for clarity
 - Have someone unfamiliar with the data look at the metrics and explain back to you what they mean.
 - Use thresholds, goal/budget/target to actual, benchmarks to show where metric is in relation to desired outcome.

Enhancing Metric Comprehension

Is your metric reporting authentic and intuitive?

Are the compliance issues across these groups the same?

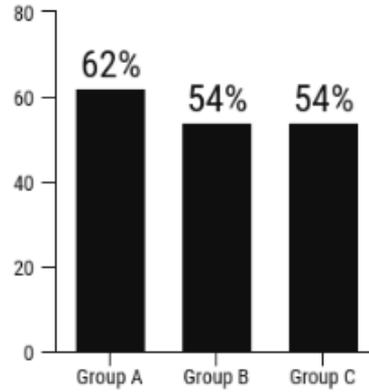


Examples from <https://venngage.com/blog/misleading-graphs/>

Enhancing Metric Comprehension

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Examples from <https://venngage.com/blog/misleading-graphs/>



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Enhancing Metric Comprehension

- Is your metric reporting authentic and intuitive?

1 OMITTING THE BASELINE

In most cases, the baseline for a graph is 0. But writers can skew how data is perceived by making the baseline a different number. This is known as a "truncated graph".

MISLEADING 😞

- Starting the vertical axis at 50 makes a small difference between groups seem massive
- Group A looks much larger than Groups B and C

ACCURATE 😊

- Starting the vertical axis at 0 offers a more accurate depiction of the data
- The difference between the groups does not seem as dramatic

VS

Examples from <https://venngage.com/blog/misleading-graphs/>



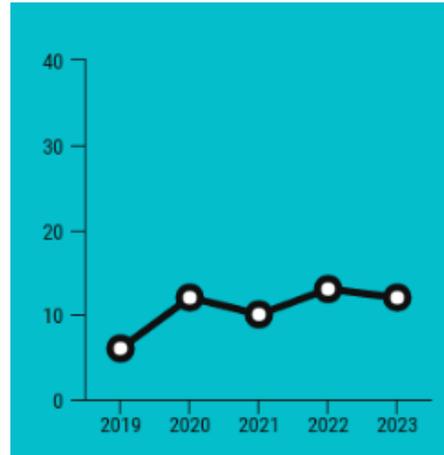
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Enhancing Metric Comprehension

Is your metric reporting authentic and intuitive?

Is the trend in the compliance issues a concern?



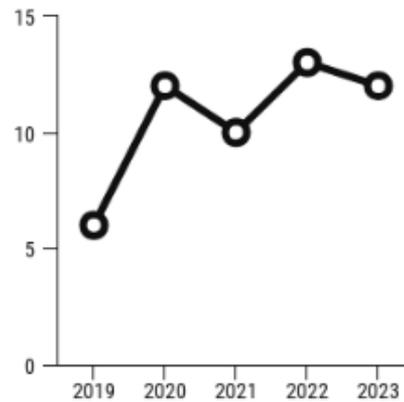
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Enhancing Metric Comprehension

Is your metric reporting authentic and intuitive?

Is the trend in the compliance issues a concern?

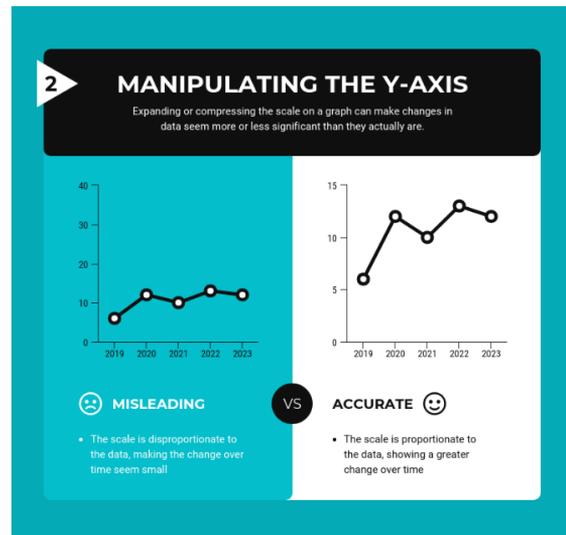
What if we had an upper threshold line?



Examples from <https://venngage.com/blog/misleading-graphs/>

Enhancing Metric Comprehension

Is your metric reporting authentic and intuitive?



Examples from <https://venngage.com/blog/misleading-graphs/>

Managing Your Metrics

- Desktop Software
 - Excel / PowerPoint
- Collaboration Tools
 - SmartSheet, SharePoint, TeamSite
- Business Intelligence Platform
 - PowerBI / Tableau
- Data Analysis Tools
 - Idea / ACL / SQL / Python / AI
- Governance, Risk, Compliance Systems
 - Logic Gate, RSA Archer, Metric Stream

Who Presents: Compliance or the Business?

	Business Leaders	Compliance Leaders
Compliance Related Business Metrics – Outcomes that Stakeholders Care About	✓	
Compliance Activity and Process Metrics		✓
Metrics Aligned with / Explaining the 7 Elements / DOJ Guidance Adherence / Overall Compliance Opinion		✓
Metrics Data Validation		✓

Case Studies

- Develop your own case studies / metric identification based on adverse events in your peer group.

Case Study: Pharmakon – Drug Compounding Facility in Noblesville, Indiana

- Licensed pharmacist convicted for distributing over and under-potent drugs, with some lots harming patients
- Evidence at trial indicated that the accused impeded FDA inspectors looking at pharmacy practices and failed to implement improvements noted in prior FDA inspections.

- METRICS
 - Quality reviews
 - External review findings
 - Finding remediation
 - Data validation efforts

Case Studies

- Develop your own case studies / metric identification based on adverse events in your peer group.

Case Study: September 4, 2019 Press Release

- Pharmaceutical company Mallinckrodt ARD LLC (formerly known as Mallinckrodt ARD Inc. and previously Questcor Pharmaceuticals Inc. "Questcor"), has agreed to pay \$15.4 million to resolve claims that Questcor paid illegal kickbacks to doctors, in the form of lavish dinners and entertainment, to induce prescriptions of the company's drug.
- The government alleged that, from 2009 to 2013, twelve Questcor sales representatives provided illegal remuneration to health care providers in the form of lavish meals and entertainment expenses to induce referrals resulting in a violation of the Anti-Kickback Statute and the submission of false claims to Medicare.
- METRICS
 - Conflict of interest / code of conduct attestations
 - Expense / entertainment levels per high risk employee
 - Audit results



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Considerations

- Not compliance's role to manage all data and metrics – just oversight on the metrics that matter.
- Consider throughout the remainder of the day:
 - What metrics would I implement for this area?
 - What can I leverage in my organization?
 - How does my organization collaborate on data governance and data quality?



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Metrics That
Matter

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Considerations for Metric Identification and Reporting

DOJ Metric Alignment Considerations

I.A: Risk Assessment Linkage

- Highest Impact to Stakeholders
- Highest Risk of Non-Compliance

I.B: Policies and Procedures In Place

- Percent of Policies with Annual Updates / Review

I.C: Training and Communication

- Attestations on Key Policies / Code of Conduct

I.D: Confidential Reporting and Investigations

- Employee Knowledge and Confidence in Investigations
- Level of Confidential Reporting to Benchmark

I.E: Third Party Management

- Percent of Third-Parties Monitored

I.F: Mergers and Acquisitions

- Percent of M&As with Compliance Due Diligence

II.A: Commitment by Senior Management

- Number of Private Sessions with the Board

II.B: Autonomy and Resources

- Experience of Staff
- Funding Benchmarks
- Last External Peer Review
- Number of External Regulatory Findings

II.C: Incentives and Disciplinary Measures

- Number of Disciplinary Actions by Level

III.A: Continuous Improvement, Periodic Testing

- Number of Audits / High Risk Audit Coverage
- Average Issue Remediation Cycle
- Frequency of Associate Engagement / Culture Surveys

III.B: Investigation

- Cycle Time of Investigations
- Last External Peer Review

III.C: Analysis and Remediation

- Number of Issues with Root Cause Remediation

Metric Development Considerations

Business Metrics – By Process Area

- Accuracy
- Quality
- Cycle Time
- Satisfaction Level
- External Regulator / Client Audit Results

Types of Metrics

- Activity / Process / Outcome
- Automated / Manual
- Preventative / Detective
- Number / Percentage / Per 1000
- Trended / Benchmarked / Year over Year
- Actual to Goal / Upper & Lower Thresholds
- Key Control / Key Risk / Key Performance - Indicators

Data Governance

- Data Governance Oversight
- Meta Data Management
- Data Validation Audits
- Change Control
- Data Steward Identification

Root Cause Analysis

- Data Issue Drivers
- Six Sigma / 5 Whys

Reporting

- Exception Reporting / Full Metric Portfolio
- Unit / Executive / Board
- Thresholds / Risk Tolerance
- Charts / Tables / Summaries
- Authentic / Intuitive
- PowerPoint / Azure / BI / GRC System
- By Compliance Leaders or Business Leaders

Contact Our Staff for Support on Your Metric Journey

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Discussion / Questions?

Thank you!

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