Welcome!

Predictive "Quality" for Patient Safety

January 22, 2021
11am-12pm ET

XAVIER HEALTH

Inspiring collaboration. Leading innovation. Making a difference.

Sponsored by:

Webinar Leaders

Larry Mager
Principal and Founder
Mgmt-Ctrl

Marla Phillips
Director, Xavier Health
Xavier University

Xavier Health Mission

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Leading Innovation

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CONFERENCES

- FDA/Xavier PharmaLink Conference
- FDA/Xavier MedCon Conference
- Xavier AI Summit
- Xavier Combination Products Summit

INITIATIVES

- Xavier Artificial Intelligence Initiatives
- Xavier YoPros Network
- Xavier Peer Pros Network - **New!**
- AI World Consortium - **New!**
- Xavier AI Experts Network - **New!**

DEVELOPMENT

- **Predictive Quality Webinar - Free!**
- 510(k) Workshop
- EU MDR Workshop
- Avoiding Top Landmines When Launching AI
- Predictive Capabilities for Unpredictable Times
- Device: Addressing and Preventing Recalls
- Design and Development Webinar Series

Making a Difference

WITH YOU

ACT Sheet

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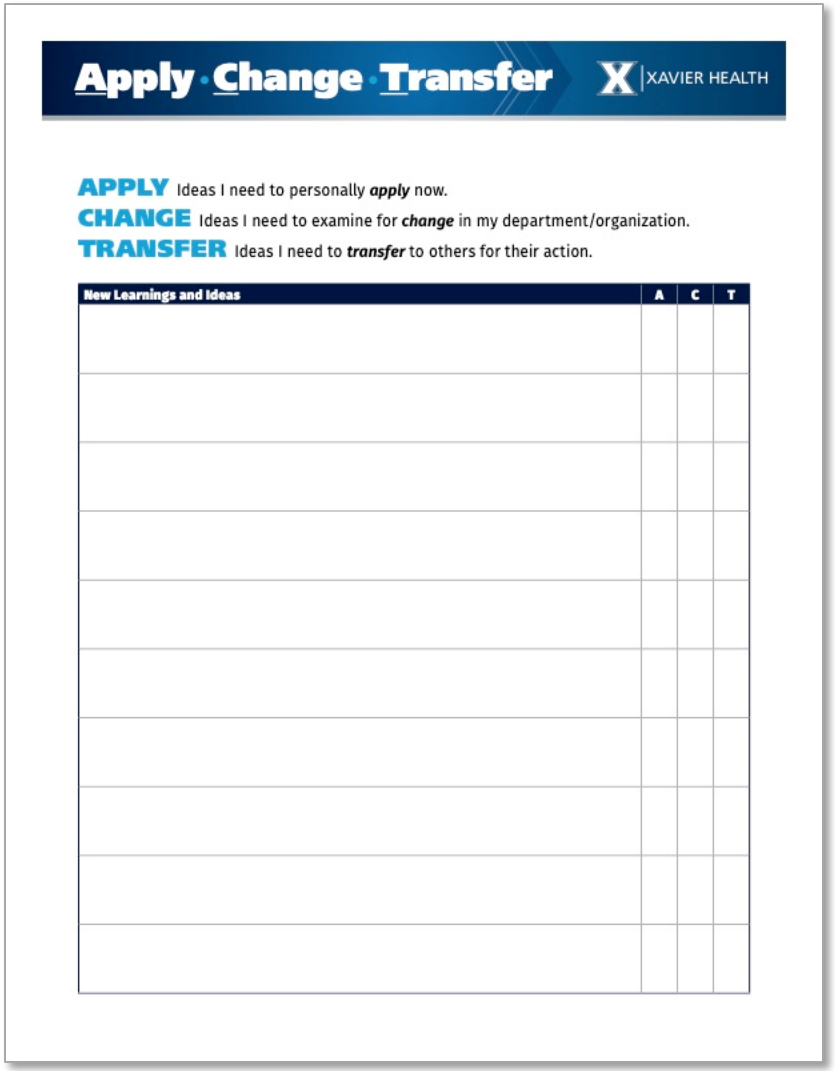
- **Apply**
  - Ideas I need to personally apply now
- **Change**
  - Ideas I need to examine for change in my department/organization
- **Transfer**
  - Ideas I need to transfer to others for their action



Apply · Change · Transfer XAVIER HEALTH

APPLY Ideas I need to personally ***apply*** now.
CHANGE Ideas I need to examine for ***change*** in my department/organization.
TRANSFER Ideas I need to ***transfer*** to others for their action.

New Learnings and Ideas	A	C	T

Action Plan

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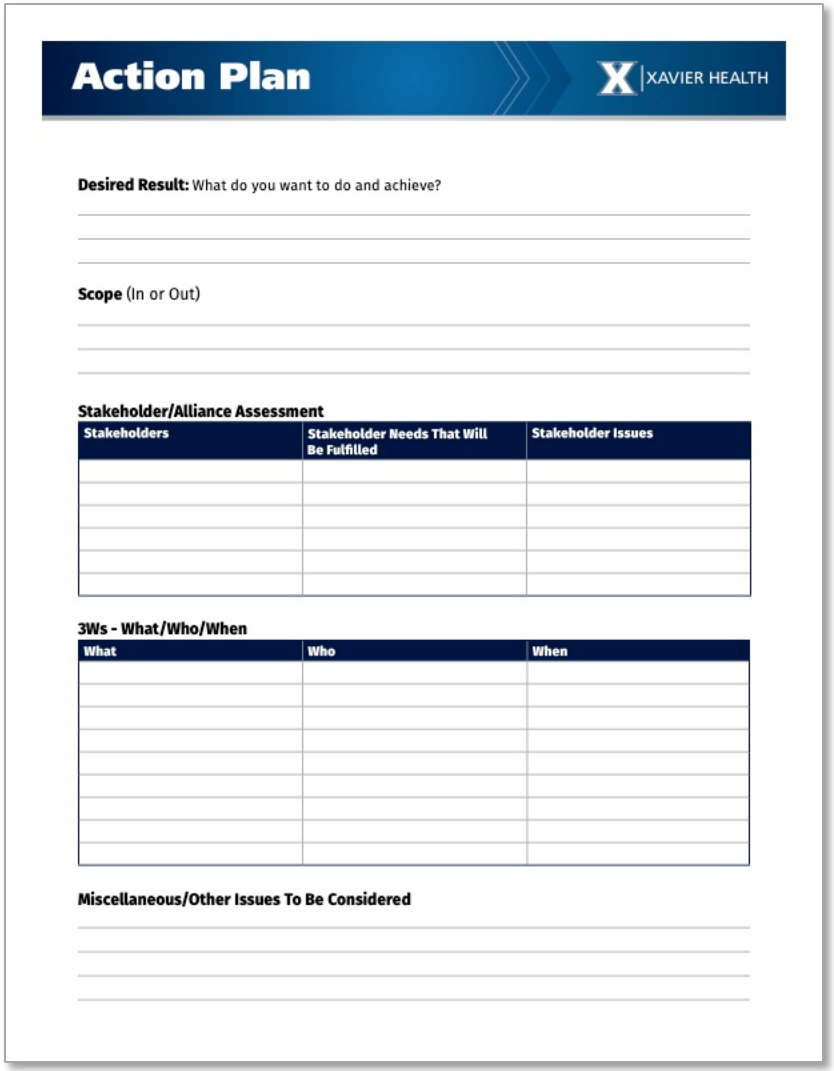
This sheet will help you:

- Formulate desired result
- Figure out scope
- Assess stakeholder/alliance
- Determine what, who, when



Action Plan

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Desired Result: What do you want to do and achieve?

Scope (In or Out)

Stakeholder/Alliance Assessment

Stakeholders	Stakeholder Needs That Will Be Fulfilled	Stakeholder Issues

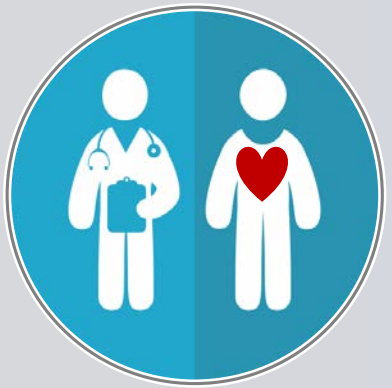
3Ws - What/Who/When

What	Who	When

Miscellaneous/Other Issues To Be Considered

For the Patients You Serve

Predictive *'quality'* for Patient Safety



What is predictive 'quality' for patient safety?

Predictive *'quality'* for patient safety is focused on the management and reduction of *'unreasonable'* and/or *'unacceptable'* patient harm that is associated with the use of a medical device or combination product.

Risk Management *- ISO 14971:2019*

A.2.10 Production and post-production activities

It cannot be emphasized too often that risk management does not stop when a medical device goes into production.

Therefore, the manufacturer needs to ***collect and review production and post-production information and evaluate its relevance to safety****. The information can relate to new hazards or hazardous situations, and/or can affect their* ***risk estimates*** *or* ***balance between benefit and overall residual risk****.*

Overall Residual Risk

Guidance on the application of ISO 14971
ISO TR 24971:2020; 8.1 – General considerations

The companion guidance document to the 3rd Edition of the ISO 14971 risk management standard refers to an updated approach to the evaluation of ***overall residual risk*** as a "***difficult and challenging task***", *further stating…*

"There is no preferred way for evaluating the overall residual risk. The manufacturer is responsible for determining an appropriate method."

'State of the Art'
Benefit of Patient Safety

The 'state of the art benefit' of patient safety is established through an understanding of post-market device 'quality' and is achieved when the ***overall residual risk*** *provided with any specific device is aligned with the level of risk that is inherently experienced with the use of competitive devices.*

This is a criteria/policy that should be relevant and obvious to all stakeholders associated with the life sciences industry.

Risk Management

Uses for the *residual risk' technology solution*:

1) *The 'residual risk' technology solution can be utilized during **design control** to quantify the overall residual risk of the product failure modes associated with the targeted market segment.*

2) *The 'residual risk' technology solution can be utilized to establish an understanding of the 'benefit' of patient safety that is associated with the use of **currently marketed medical devices**.*

Risk Management

Uses for the *residual risk' technology solution*:

1) *The 'residual risk' technology solution can be utilized during design control to quantify the overall residual risk of the product failure modes associated with the targeted market segment.*

Today's focus…

2) *The 'residual risk' technology solution can be utilized to establish an understanding of the 'benefit' of patient safety that is associated with the use of* ***currently marketed medical devices****.*

The pathway to predictive 'quality'

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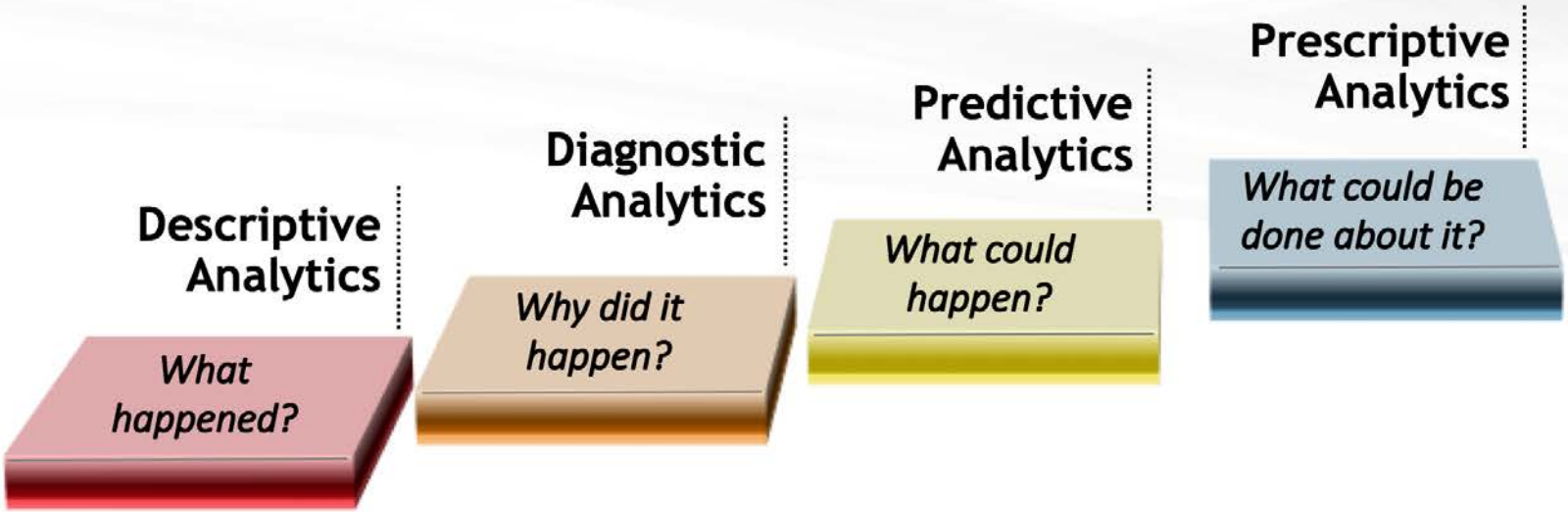
Analytical pathway…



…to retrospectively achieve the capability of ***predictive 'quality'*** for improved patient safety

Predictive Quality Management

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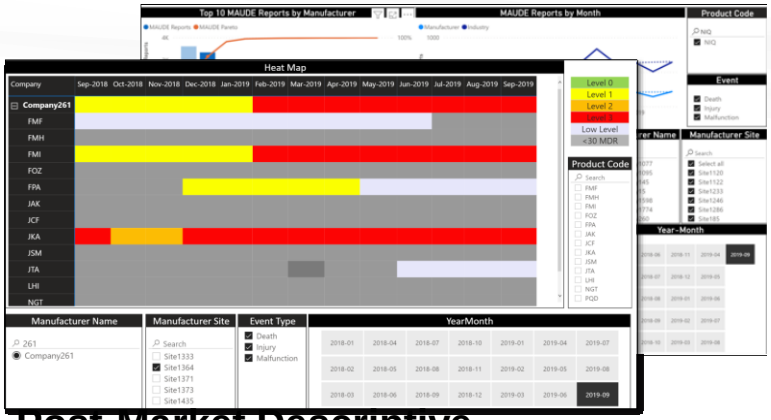
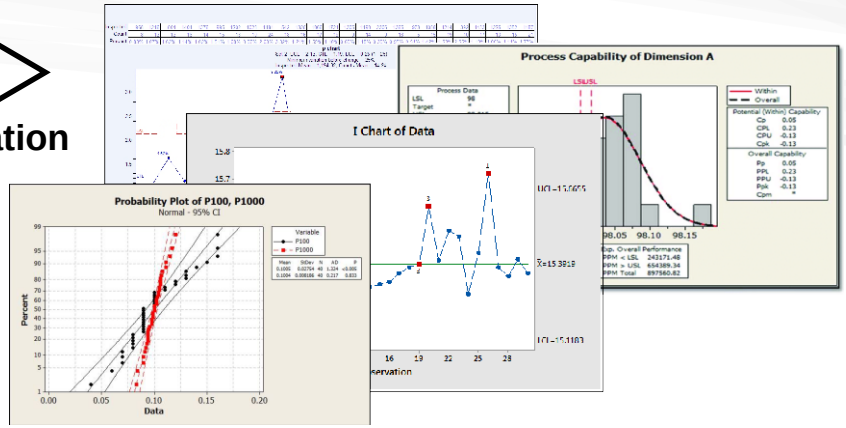
Patient Safety within the Healthcare Market



Post-Market Descriptive Analytics

Correlation

Risk Control Measures within the Production Environment



Production Capability and Variation

Measure - Monitor - Analyze - Report - Review - Manage - Improve - Sustain

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Predictive *'quality'* Pathway

Descriptive Analytics
What happened?

Diagnostic Analytics
Why did it happen?

Predictive Analytics
What could happen?

Prescriptive Analytics
How can we control it?

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FDA MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

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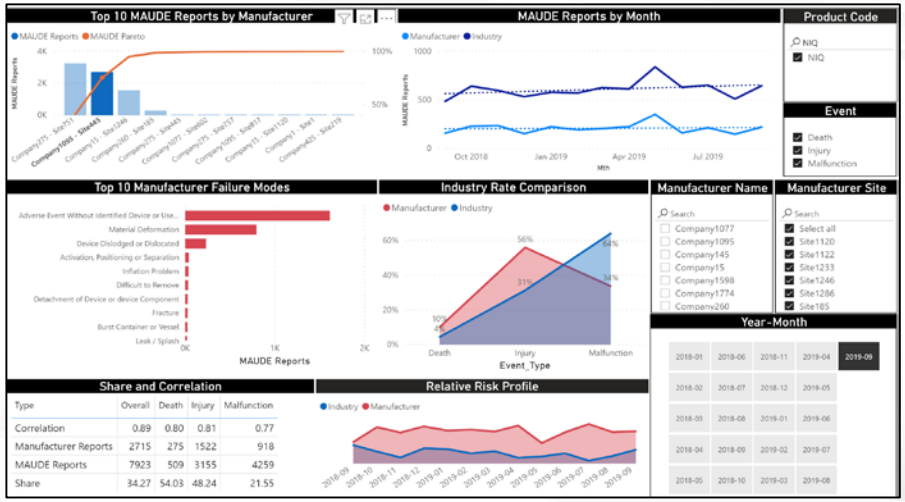
Post-market datasets are transformed into information that people can use.

Product Portfolio Heat Map

FDA MAUDE
post-market data

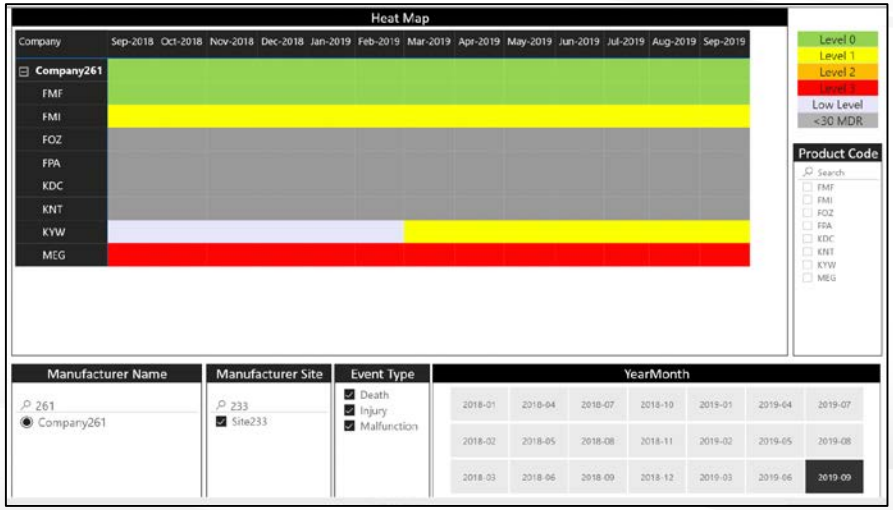
Statistical Indication Report

Company 261 | Site 1364 | Product Code ABC



Descriptive Analytics

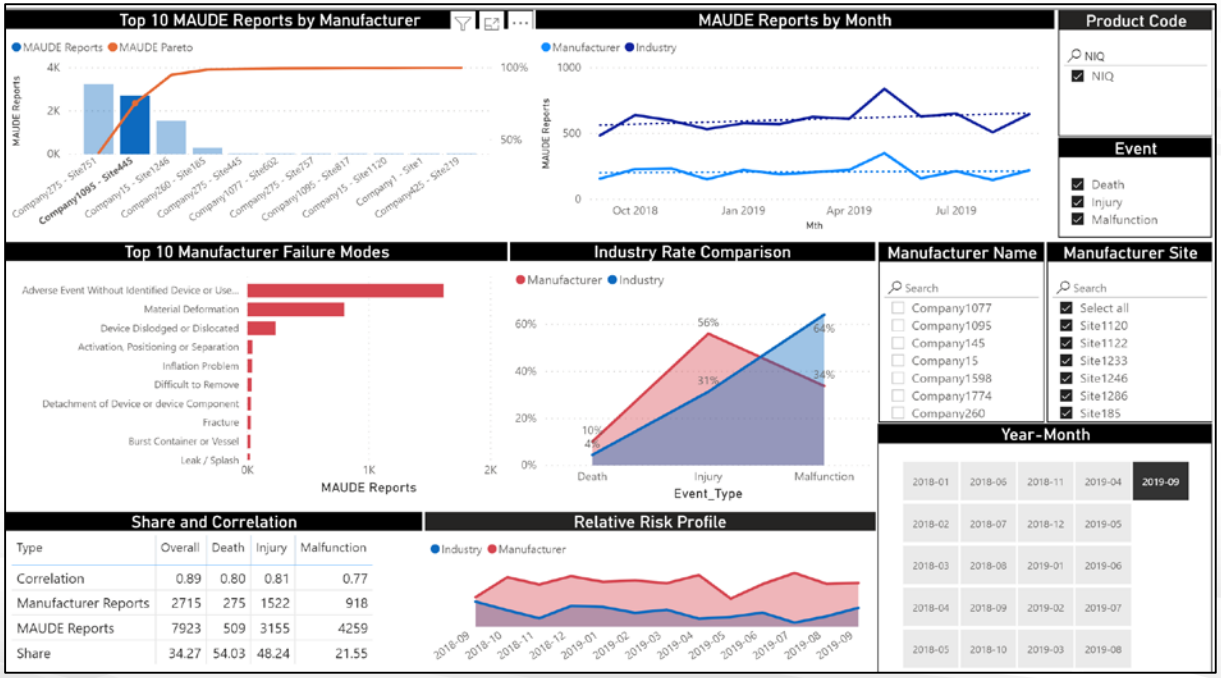
Capability to understand the status of the *‘quality’* of a product portfolio utilizing a high-level heat map…



Descriptive Analytics

Utilization of a *Statistical Indication Report* to identify any underlying potential concerns of product *'quality'*.

Company 261
Site 1364
Pro Code ABC



Statistical Indication Report

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Company 261
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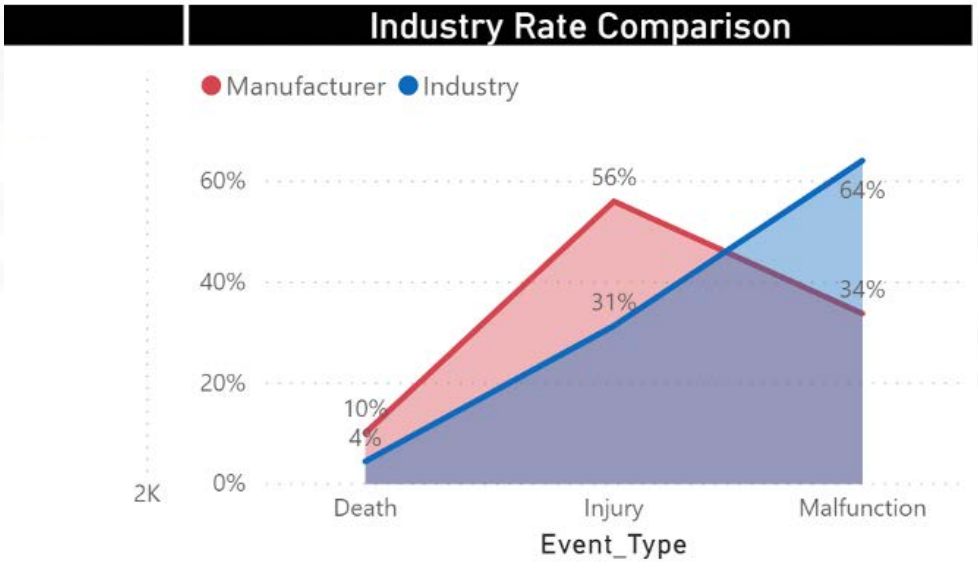

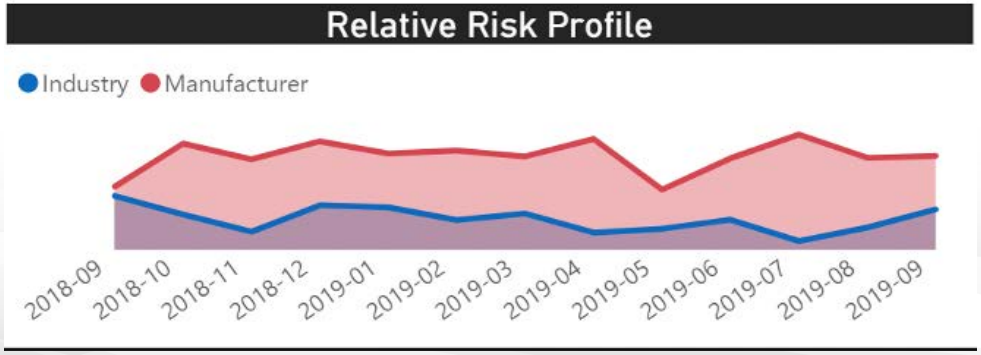

Descriptive Analytics

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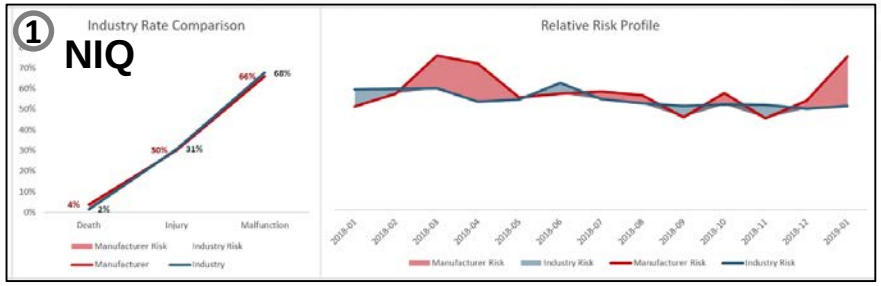
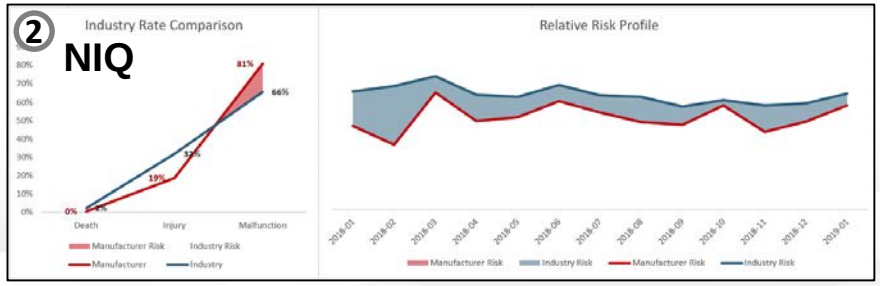
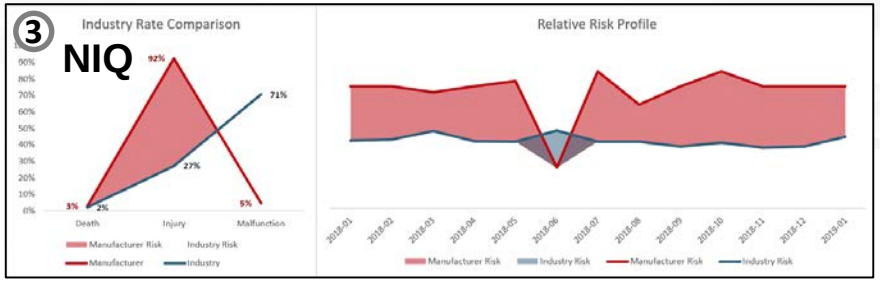
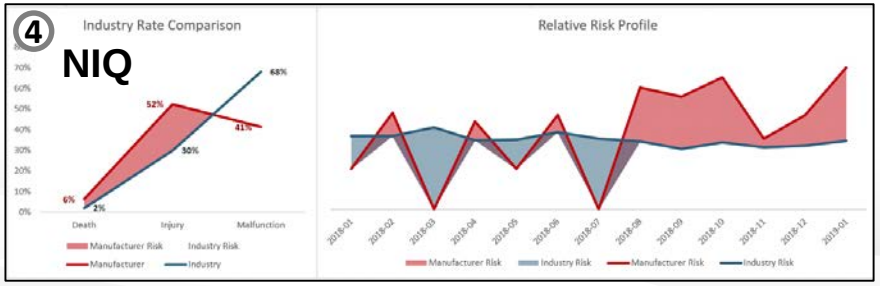
This solution has the capability to measure and compare *'patient safety'* between competitive products.









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Predictive *'quality'* Pathway

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Diagnostic Analytics

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SOTA, a risk-matrix, establishes the **risk thresholds** that are *inherent* within a specific product market.

Industry rate of harm established in risk-matrix

Rates	Risk Evaluation	Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
0.00001	Improbable					
0.0001	Remote				0.000035	
0.001	Occasional		0.000188	0.000452		0.000160
0.01	Probable	0.002406				
	Frequent					

Color coding added to risk matrix

Rates	Risk Evaluation	Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
0.00001	Improbable					
0.0001	Remote				0.000035	
0.001	Occasional		0.000188	0.000452		0.000160
0.01	Probable	0.002406				
	Frequent					

SOTA Matrix establishes inherent risk and acceptability

Rates	Risk Evaluation	Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
0.00001	Improbable					
0.0001	Remote					
0.001	Occasional					
0.01	Probable					
	Frequent					

Diagnostic Analytics

Risk acceptability is established with a *'SOTA Matrix'* to quantify the *overall residual risk* of a product.

Rates	Risk Evaluation	Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
0.00001	Improbable					
0.0001	Remote					
0.001	Occasional					
0.01	Probable					
	Frequent					

Rates	Risk Evaluation	Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
0.00001	Improbable					
0.0001	Remote				0.000035	
0.001	Occasional	0.000675	0.000278			0.000209
0.01	Probable			0.001252		
	Frequent					

Indication of unreasonable harm

Diagnostic Analytics

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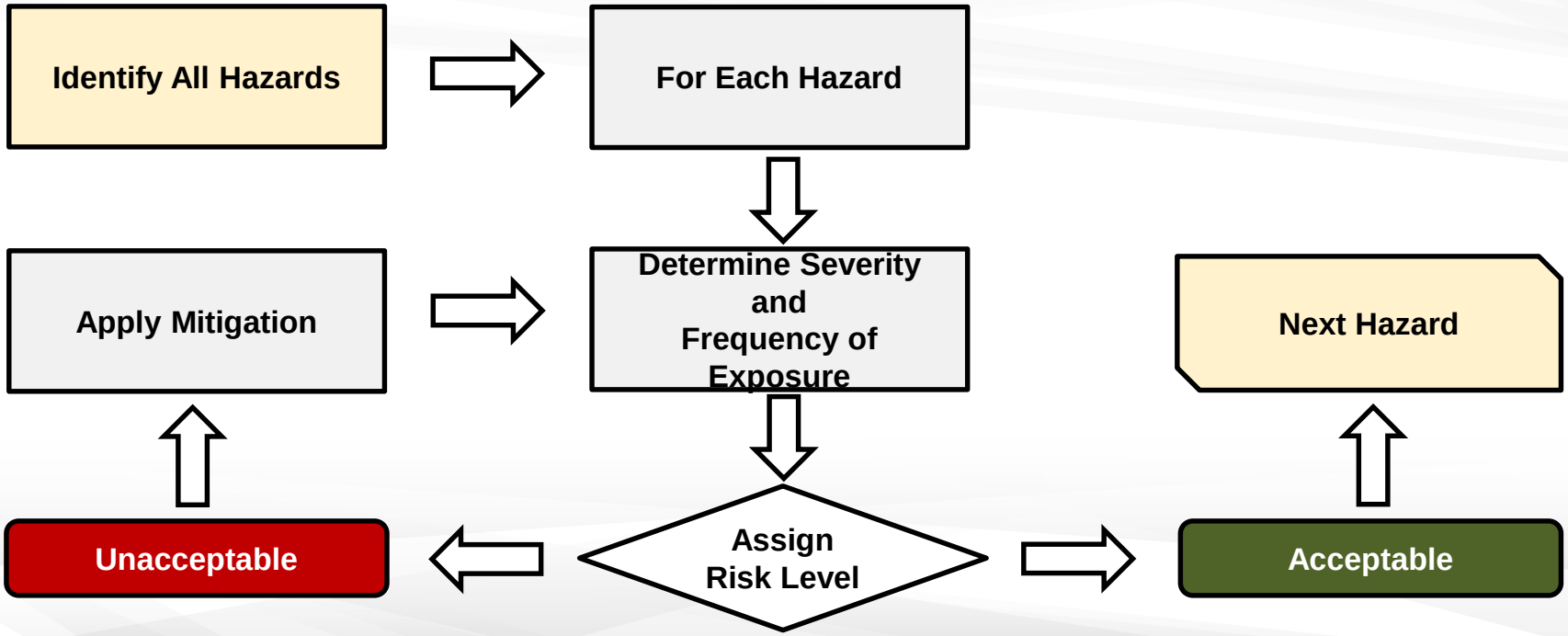
Hazards and harms are identified through a Hazards Analysis, used to investigate the indicated harm.



Diagnostic Analytics

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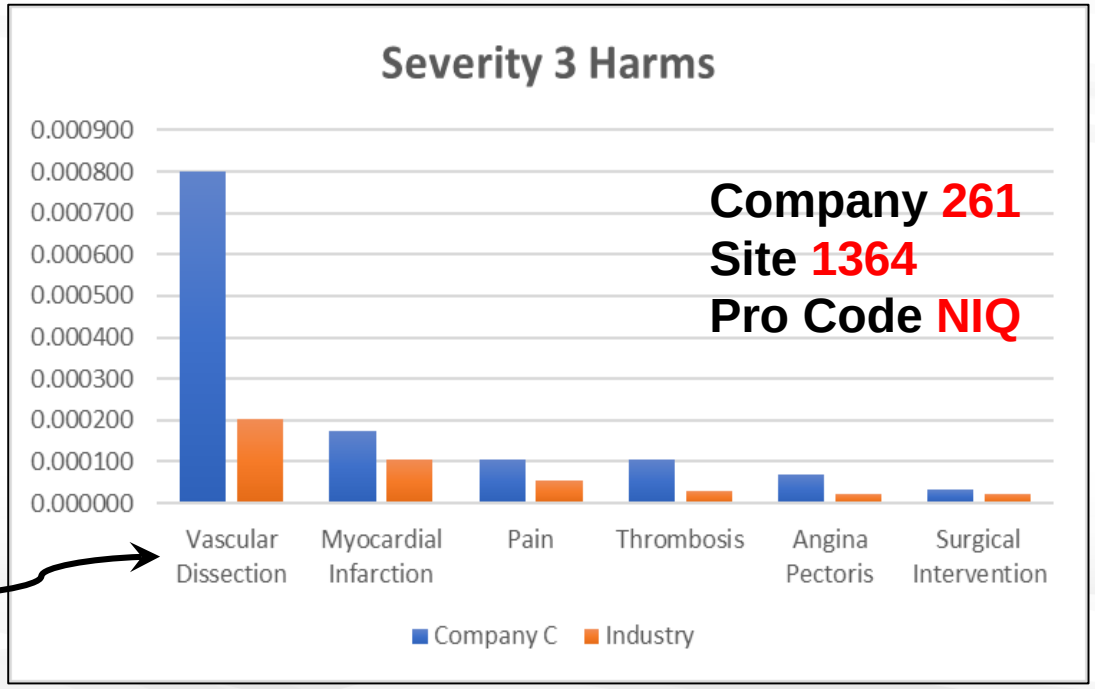
Individual harms are evaluated through a pareto of the '*rate of harms*', contributing to the overall residual risk.



Egregious or unreasonable individual harm identified

Diagnostic Analytics

'SOTA matrix' is established to assess *residual risk* of **individual harm** against risk acceptability.

Rates	Risk Evaluation	Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
0.00001	Improbable					
0.0001	Remote					
0.001	Occasional					
0.01	Probable					
	Frequent					

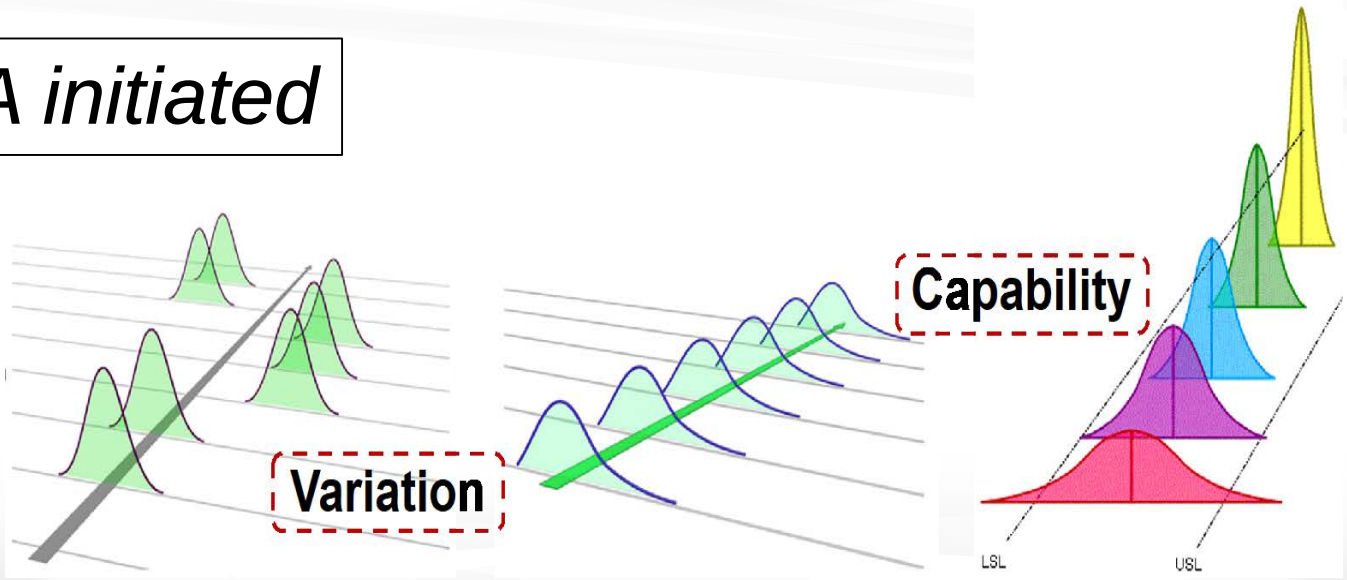
Indication of unreasonable *individual* harm

Rates	Risk Evaluation	Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
0.00001	Improbable					
0.0001	Remote	0.000070	0.000070			
0.001	Occasional					0.000209
0.01	Probable			0.006642	0.003852	
	Frequent					

Diagnostic Analytics

Investigation is required to address inadequate or missing **risk control measures** associated with individual harm identified.

CAPA initiated



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Predictive Analytics

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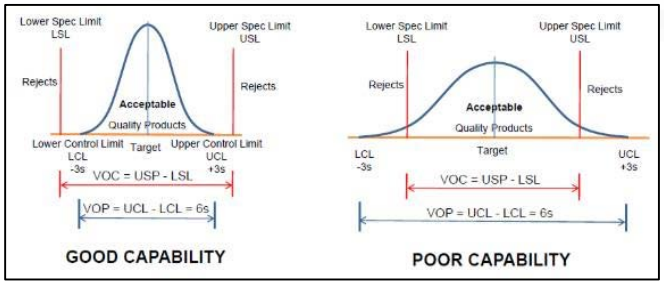
Analysis is required to identify level of improvement of risk control measures required to achieve SOTA.



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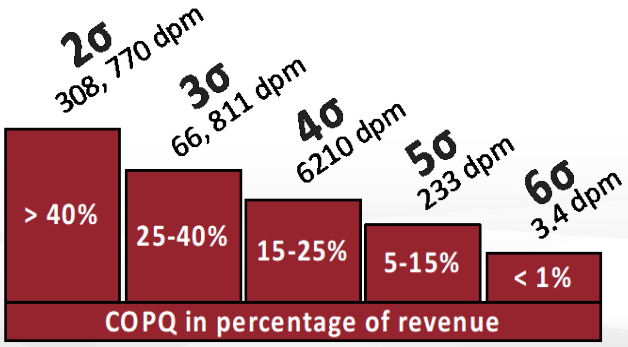
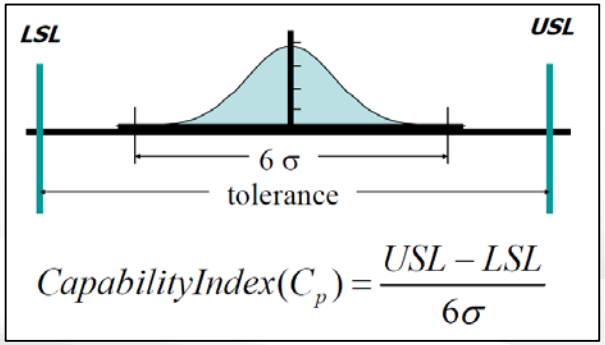
0.0001	Remote	0.000070	0.000070			
0.001	Occasional					0.000209
0.01	Probable			0.006642	0.003852	
	Frequent					

Capability → σ Level

Sigma Level	Defect Rate	Production Yield
2σ	308,770 dpm	69.10000%
3σ	66,811 dpm	93.33000%
4σ	6210 dpm	99.38000%
5σ	233 dpm	99.97700%
6σ	3.4 dpm	99.99966%





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Prescriptive Analytics

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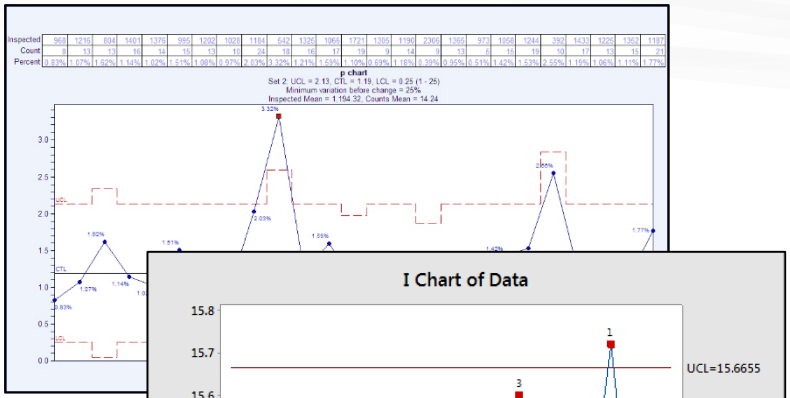
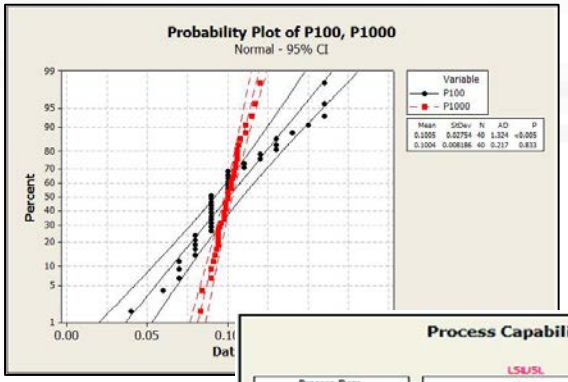
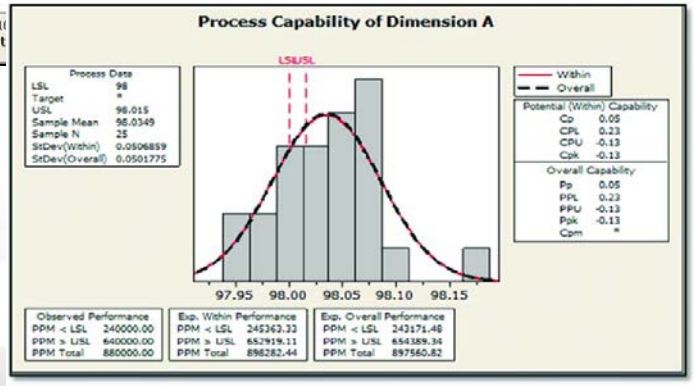
Risk control measures for individual harm and associated with what is *'critical to quality'* are targeted.







Predictive Quality Management

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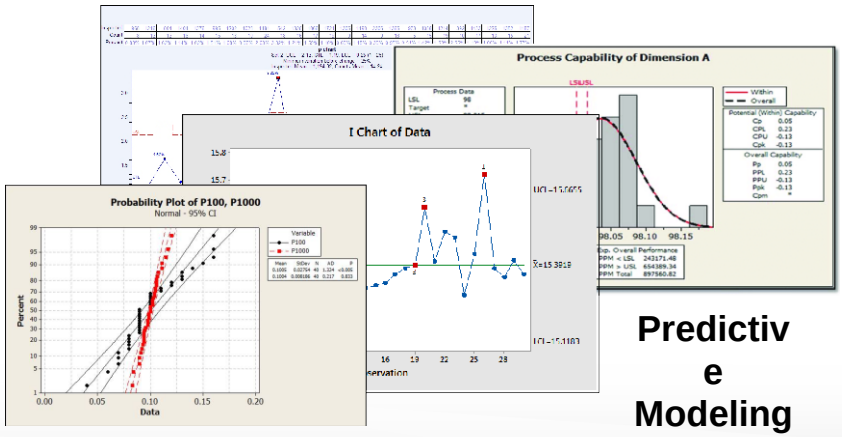
Risk Control Measures within the Production Environment

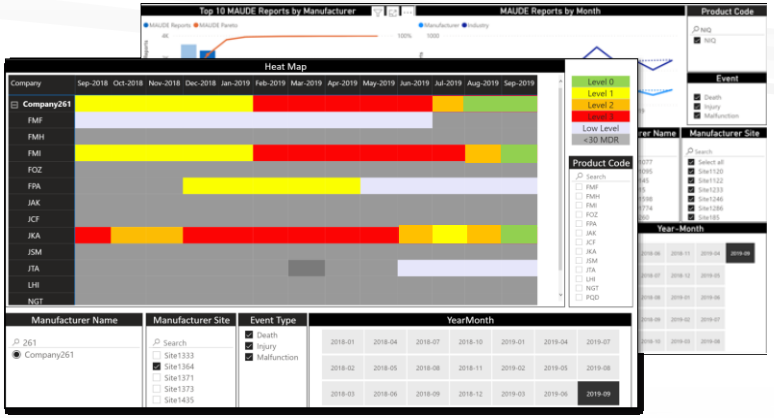
Capability and Variation



Predictive Modeling

Correlation

Patient Safety within the Healthcare Market



Measure - Monitor - Analyze - Report - Review - Manage - Improve - Sustain

The pathway to predictive 'quality'

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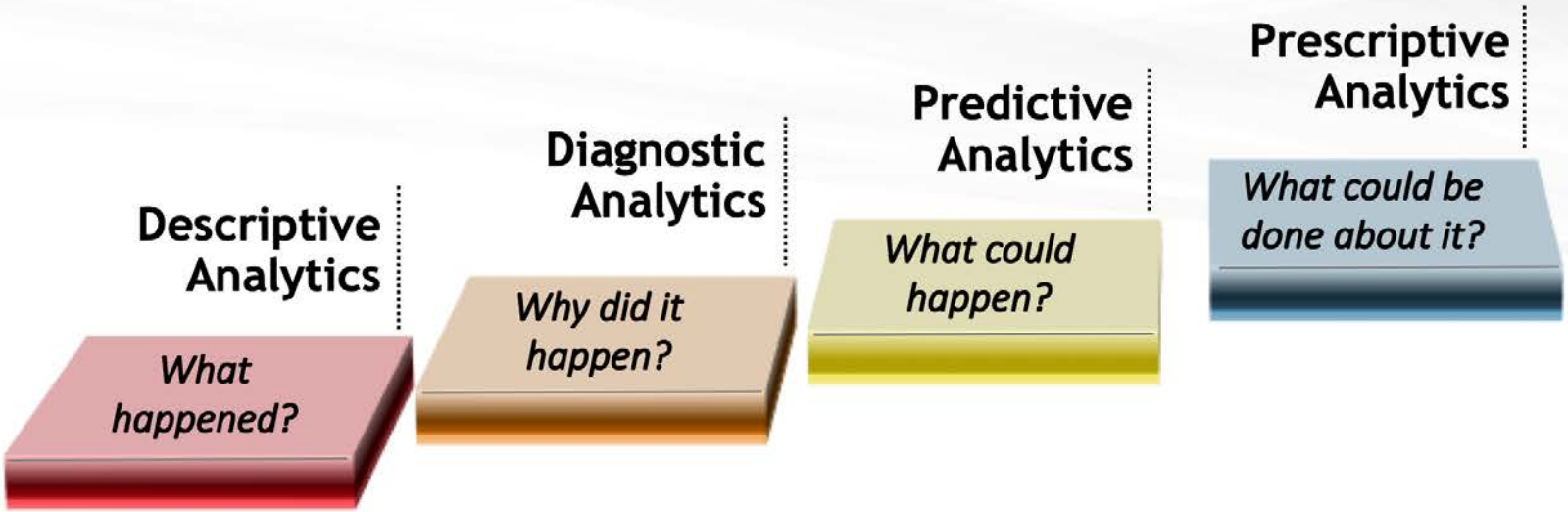
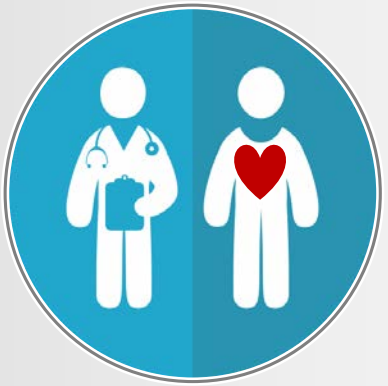
Analytical pathway…

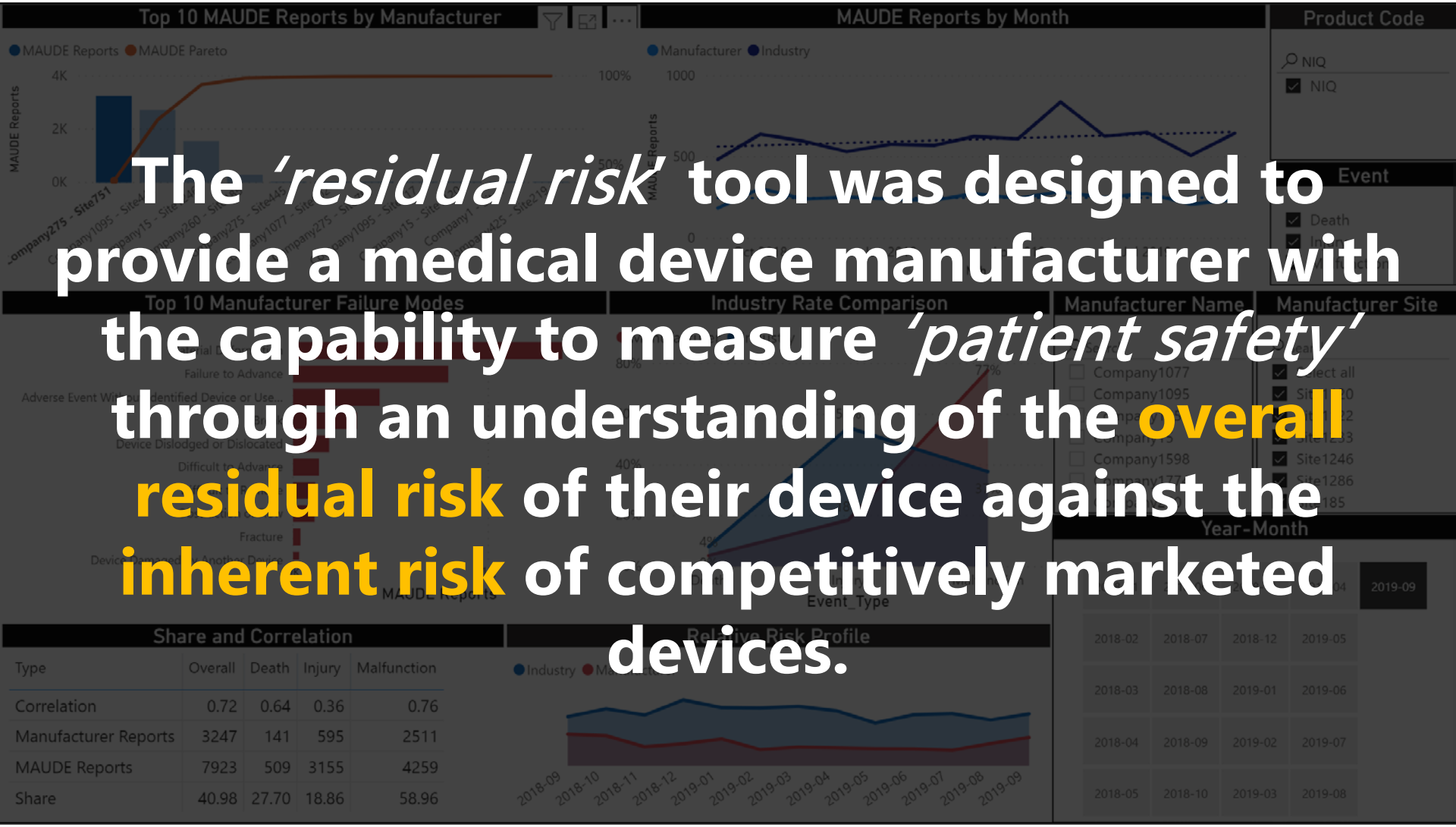


…to achieve the capability of ***predictive 'quality'*** for <u>managed</u> patient safety

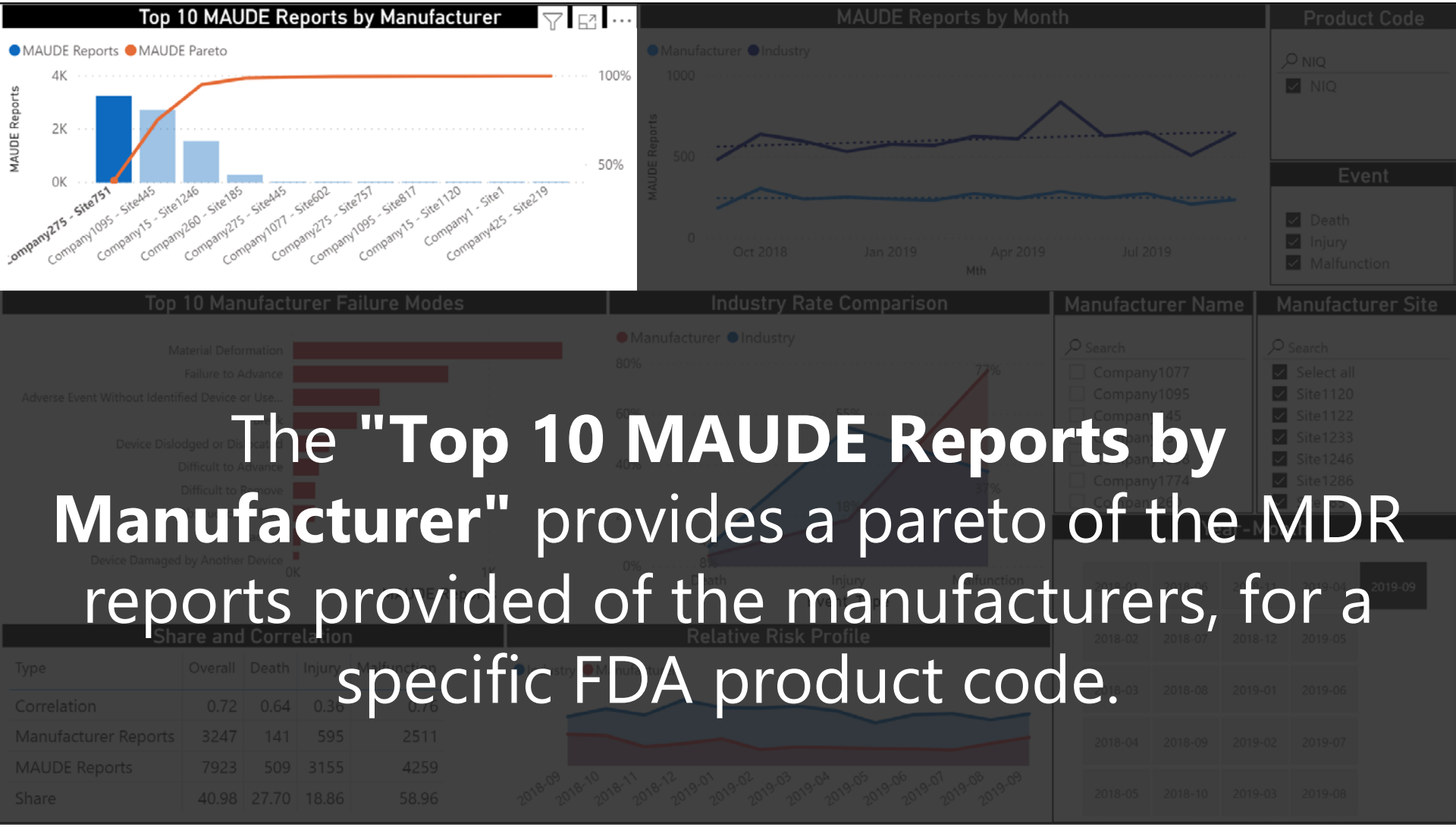
Features

‘Residual Risk Tool’

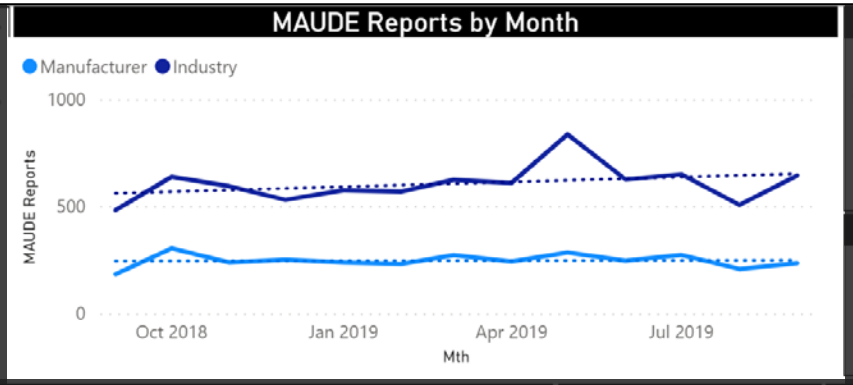




The *'residual risk'* tool was designed to provide a medical device manufacturer with the capability to measure *'patient safety'* through an understanding of the overall residual risk of their device against the inherent risk of competitively marketed devices.

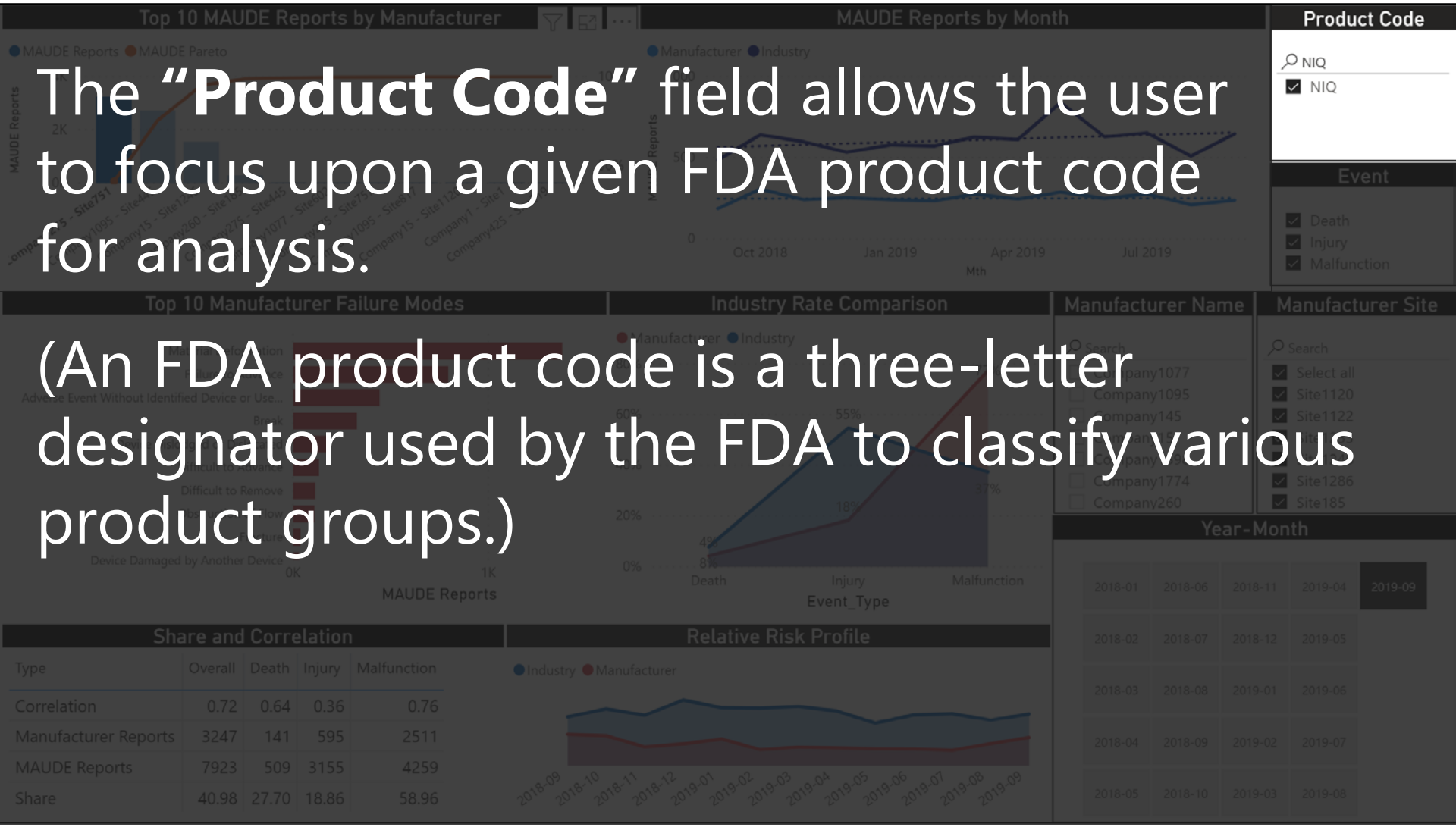


The **"Top 10 MAUDE Reports by Manufacturer"** provides a pareto of the MDR reports provided of the manufacturers, for a specific FDA product code.



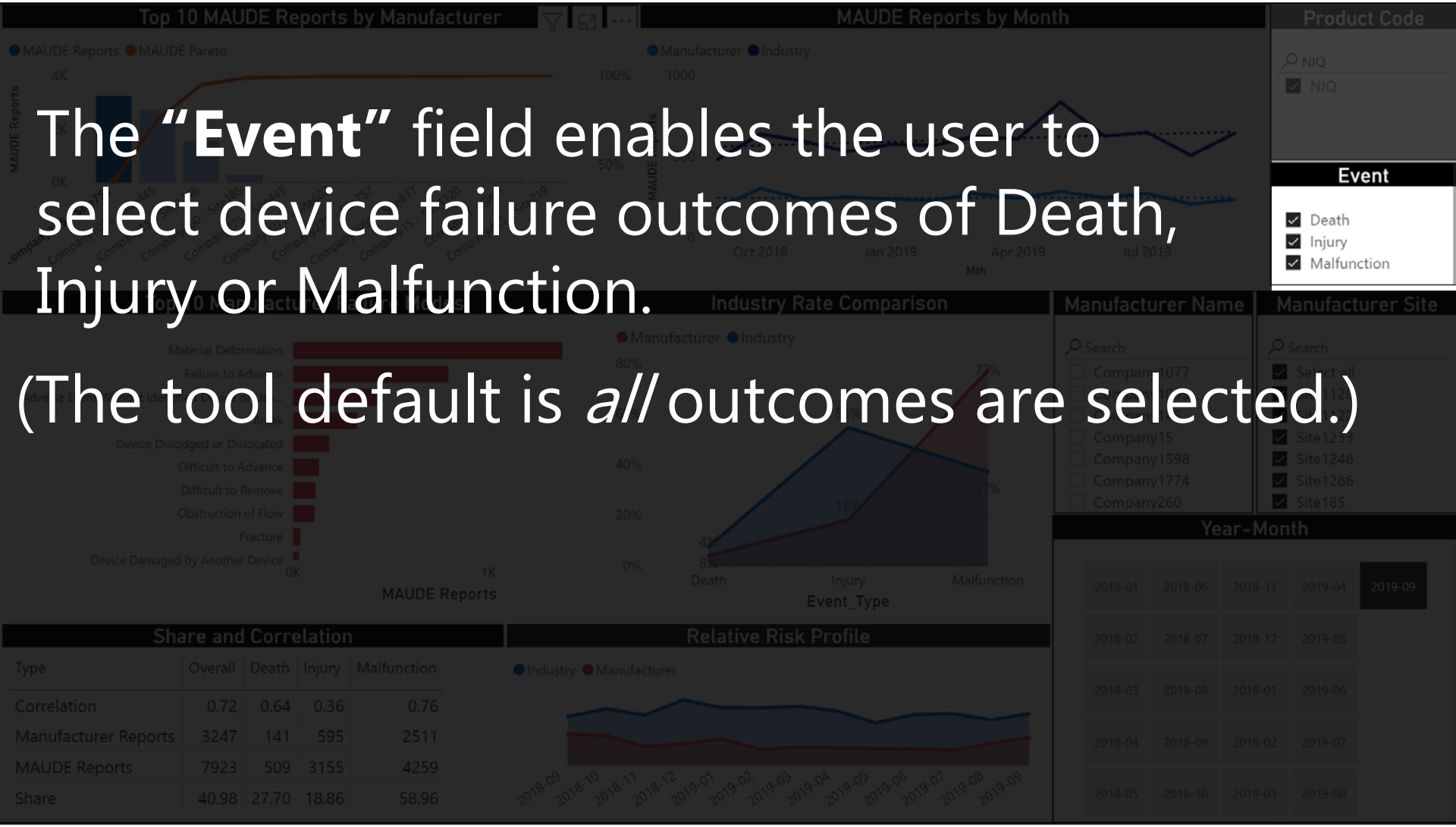
"MAUDE Reports by Month" is a run chart that outlines the industry MDRs for a given product code *vs* a company/site combination for that product code.

This chart enables us to understand if a particular company is the significant driver of market variability, with respect to the MDR's for competitively marketed products within the industry.



The **"Product Code"** field allows the user to focus upon a given FDA product code for analysis.

(An FDA product code is a three-letter designator used by the FDA to classify various product groups.)

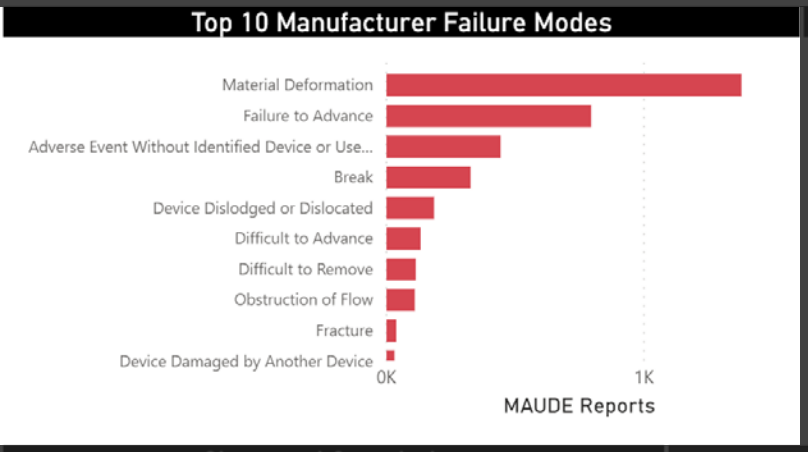


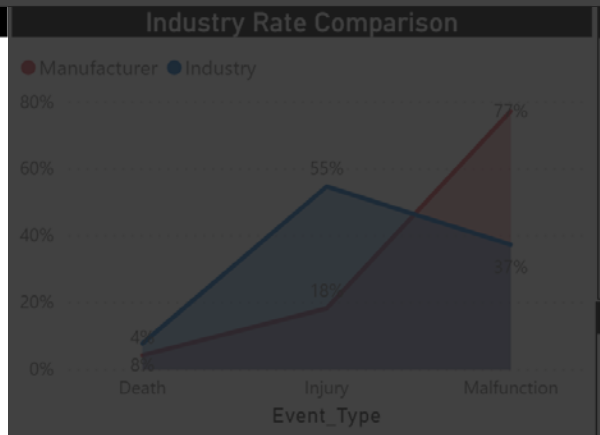
Type	Overall	Death	Injury	Malfunction
Correlation	0.72	0.64	0.36	0.76
Manufacturer Reports	3247	141	595	2511
MAUDE Reports	7923	509	3155	4259
Share	40.98	27.70	18.86	58.96

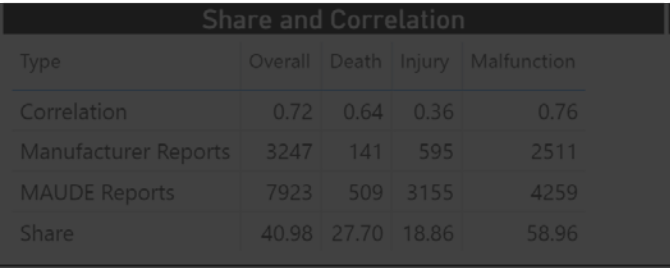
The **"Event"** field enables the user to select device failure outcomes of Death, Injury or Malfunction.

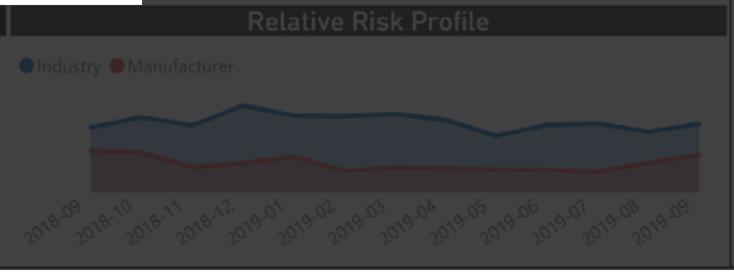
(The tool default is *all* outcomes are selected.)

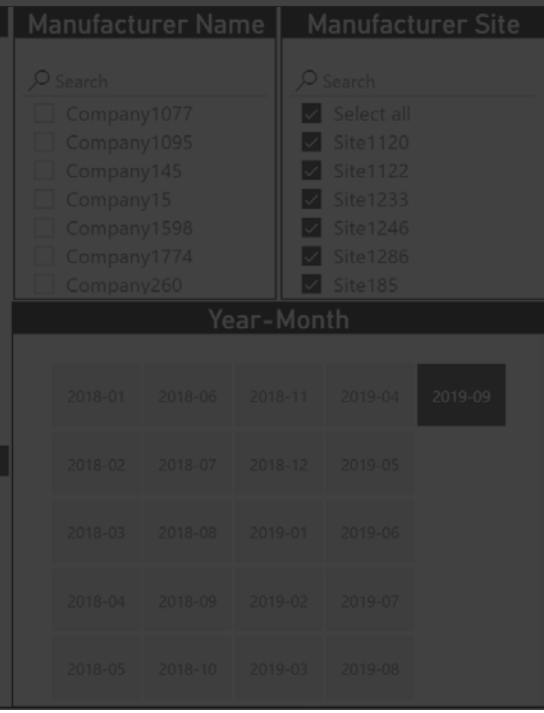
The **"Top 10 Manufacturer Failure Modes"** field show the failure modes of a specific company/site/product code combination.



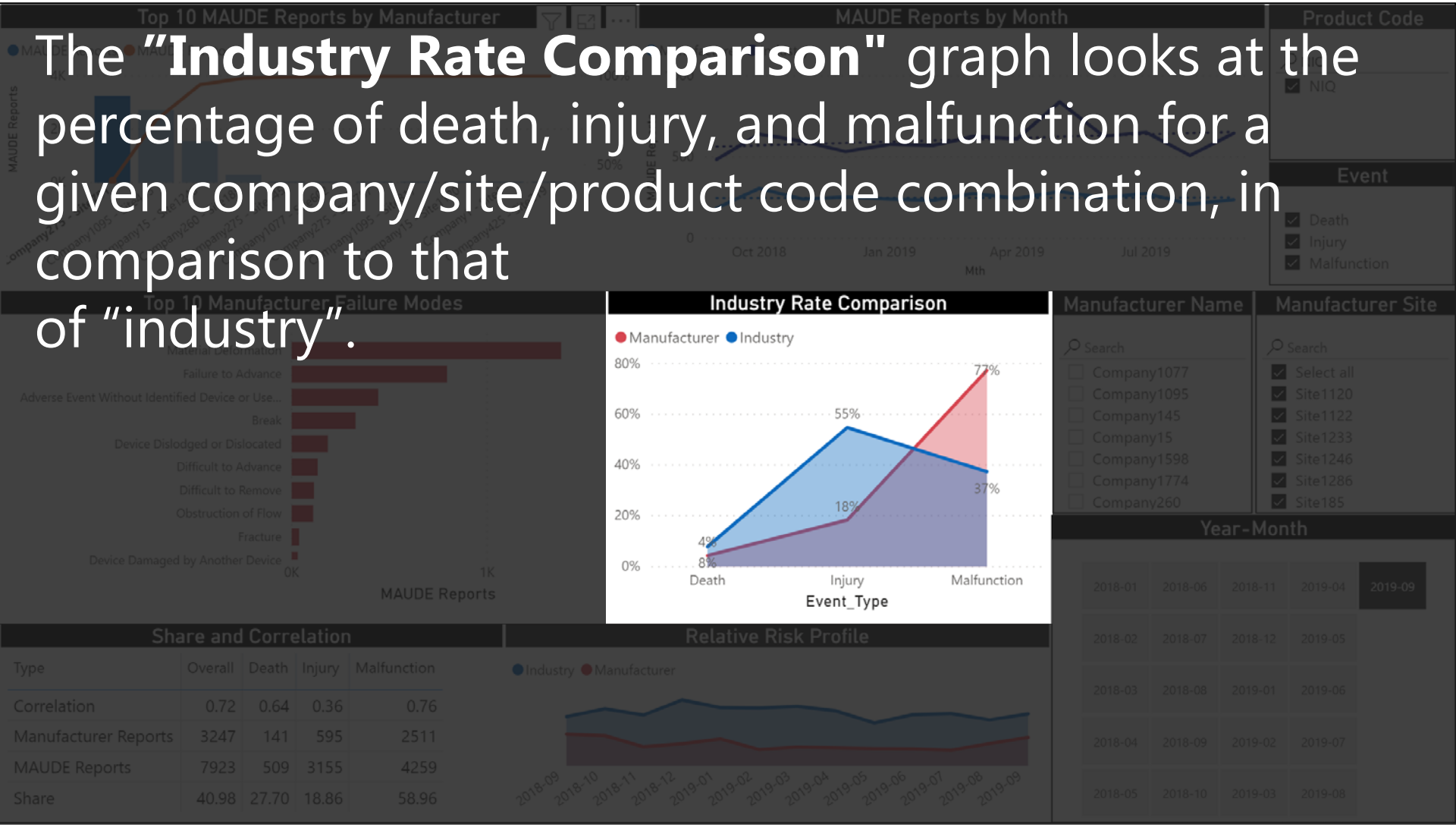


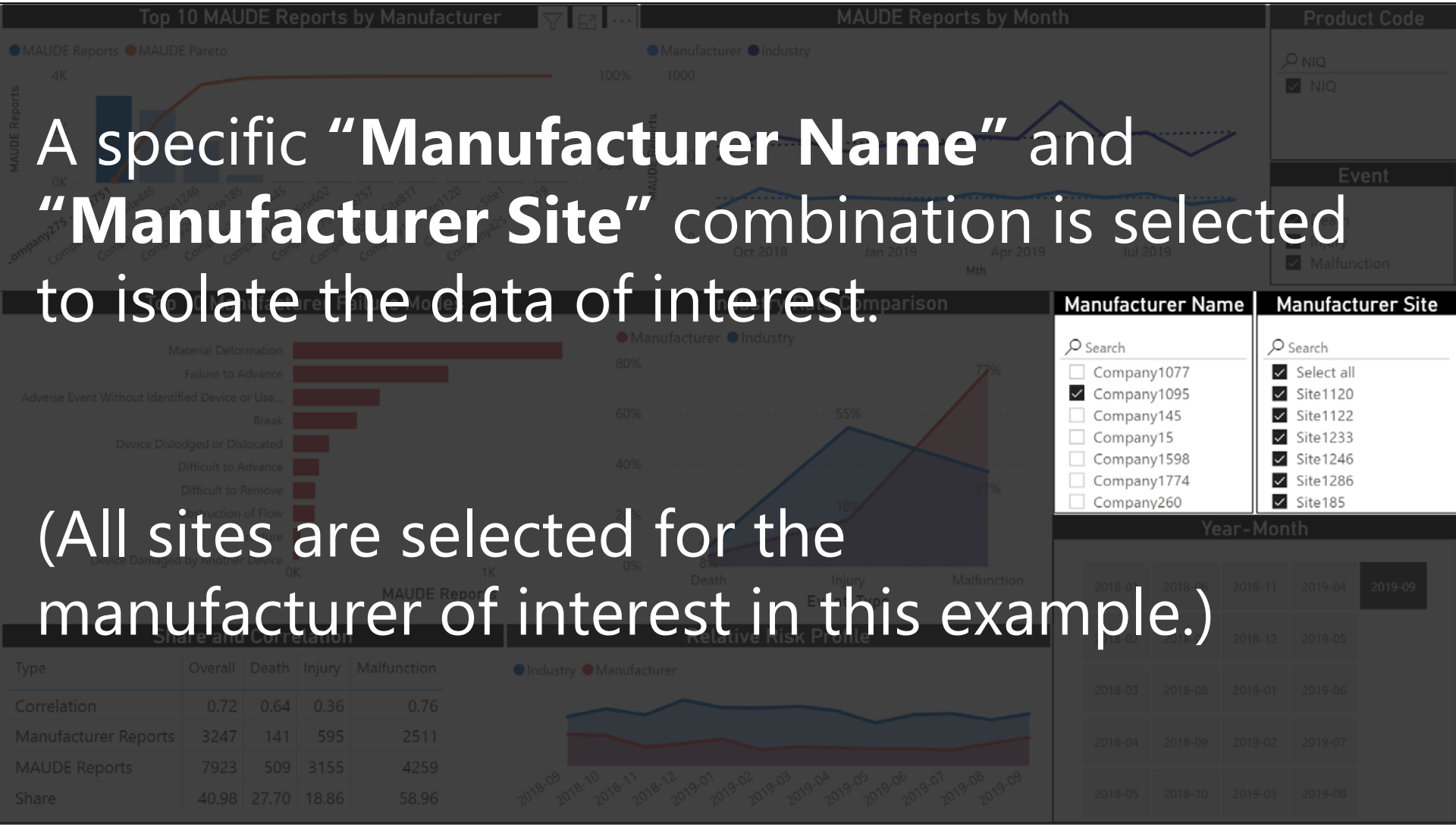






The **"Industry Rate Comparison"** graph looks at the percentage of death, injury, and malfunction for a given company/site/product code combination, in comparison to that of "industry".



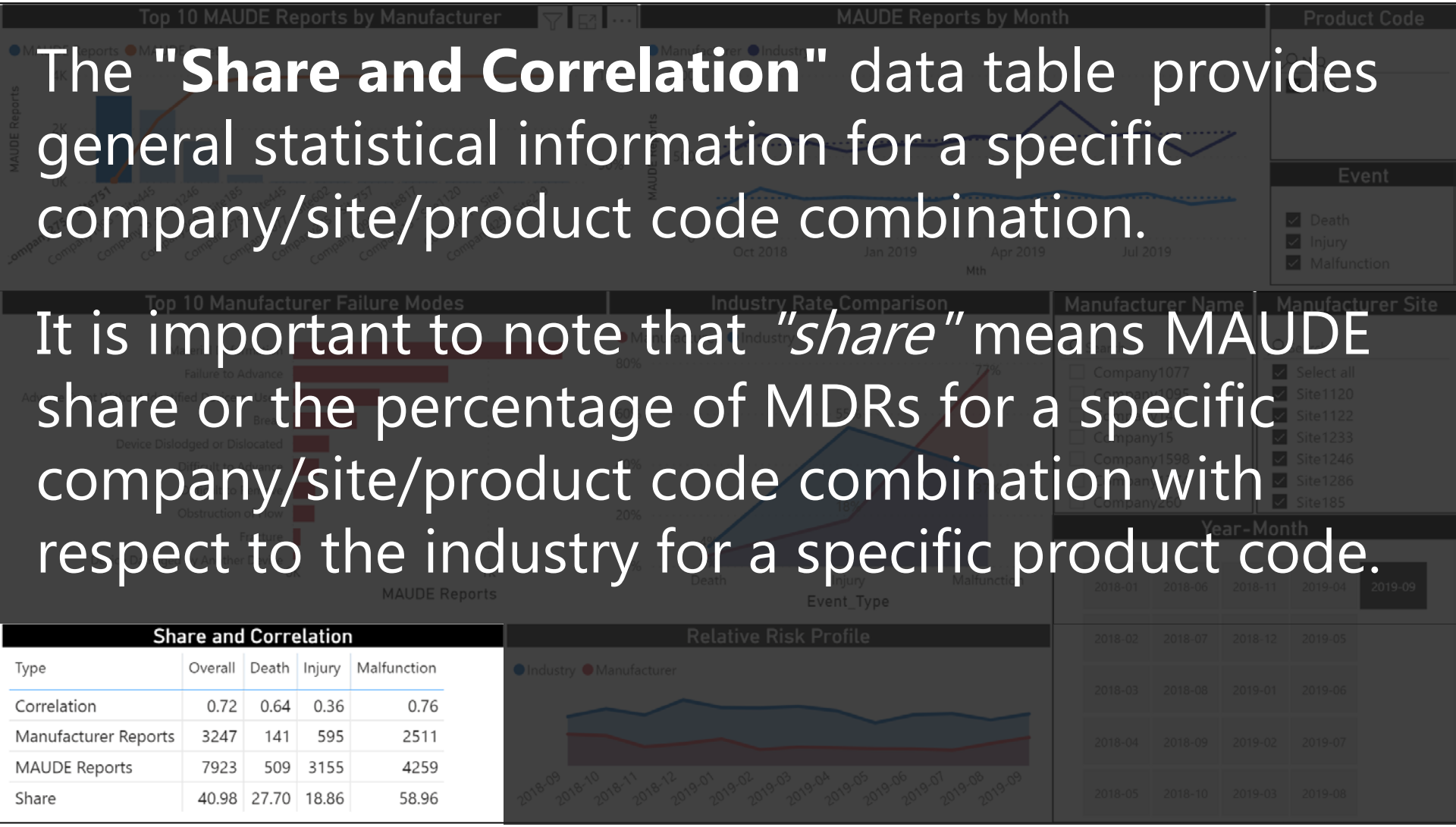


A specific **"Manufacturer Name"** and **"Manufacturer Site"** combination is selected to isolate the data of interest.

(All sites are selected for the manufacturer of interest in this example.)

The **"Share and Correlation"** data table provides general statistical information for a specific company/site/product code combination.

It is important to note that *"share"* means MAUDE share or the percentage of MDRs for a specific company/site/product code combination with respect to the industry for a specific product code.



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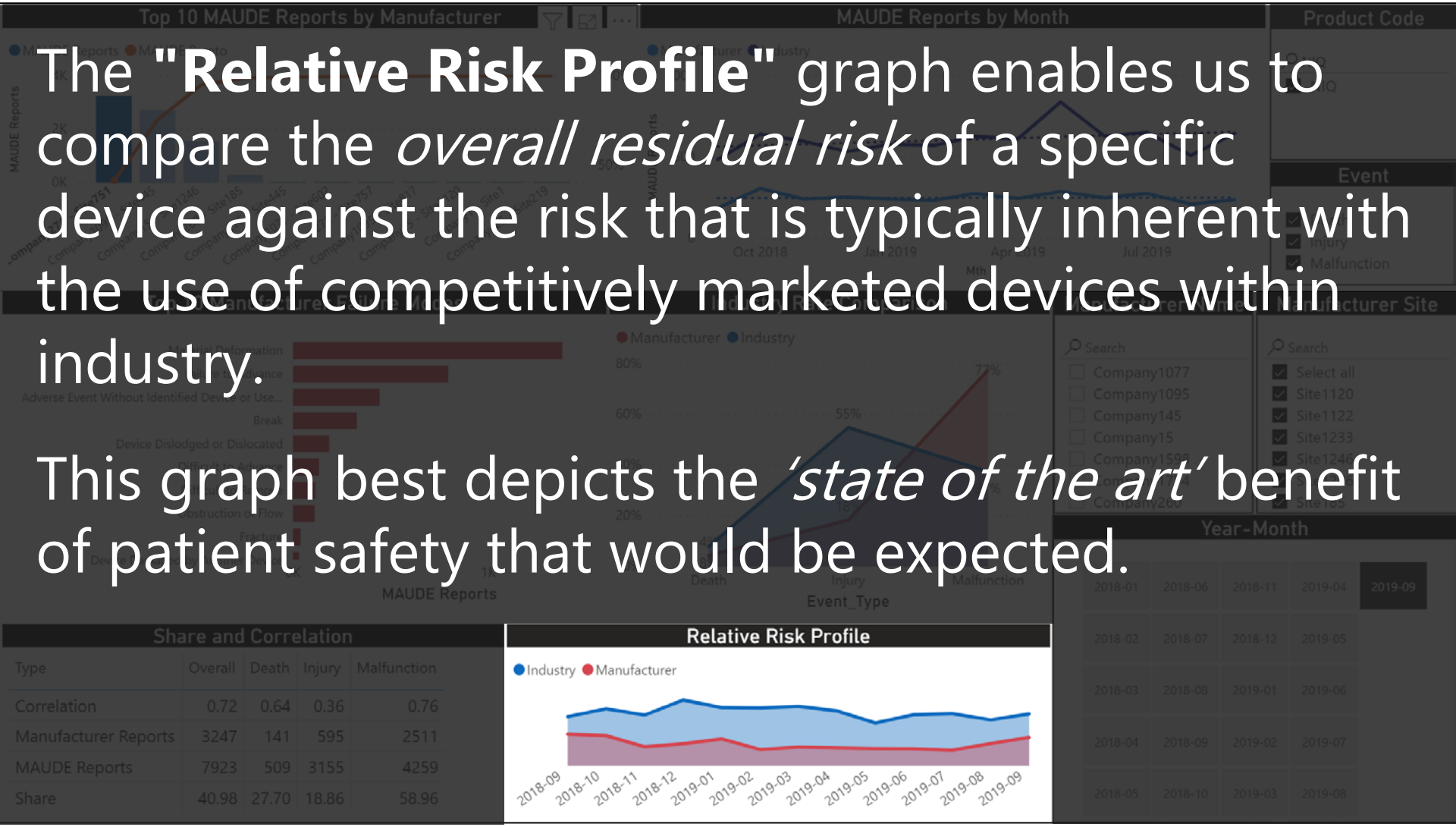
The **"Relative Risk Profile"** graph enables us to compare the *overall residual risk* of a specific device against the risk that is typically inherent with the use of competitively marketed devices within industry.

This graph best depicts the *'state of the art'* benefit of patient safety that would be expected.



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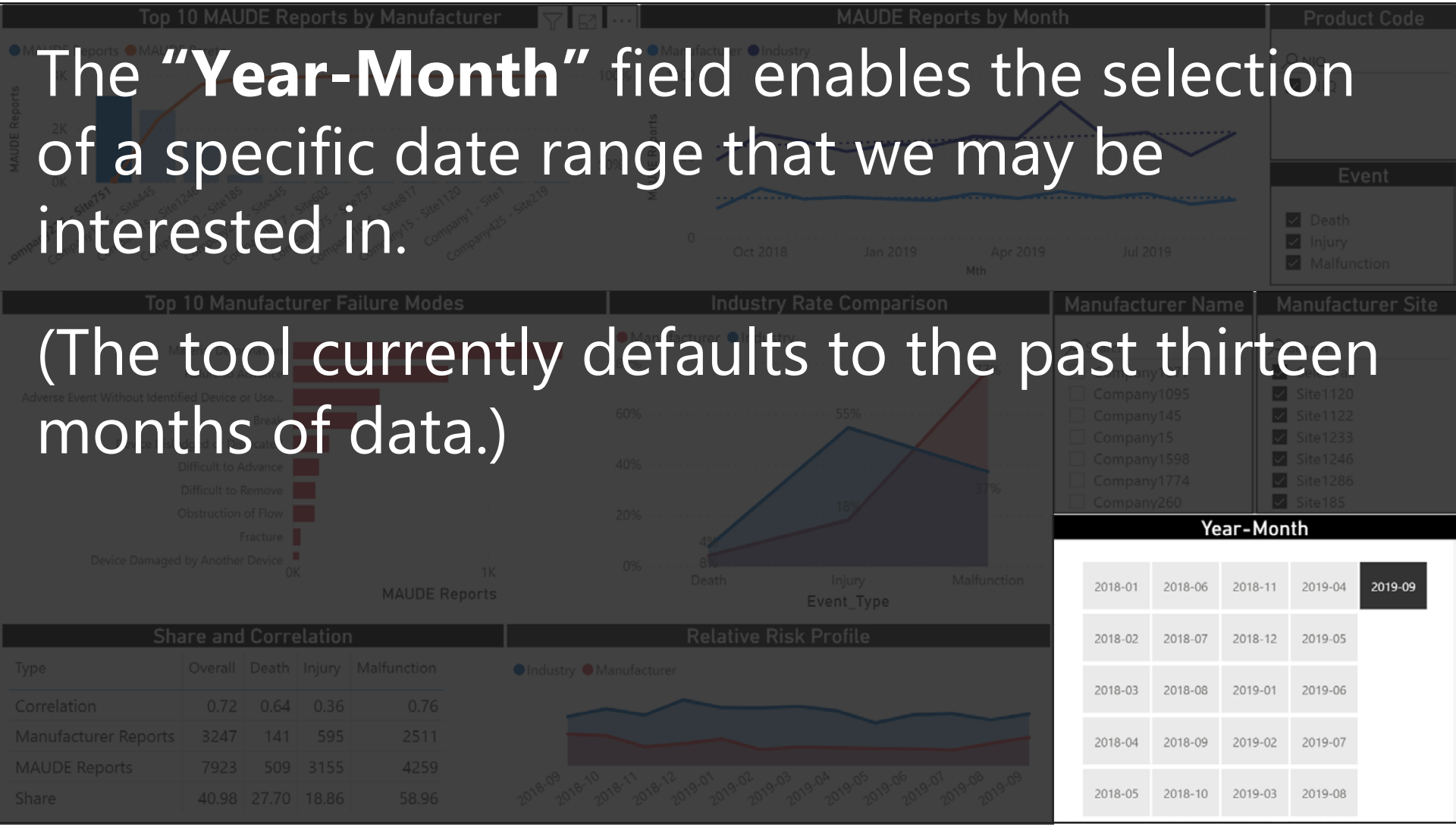
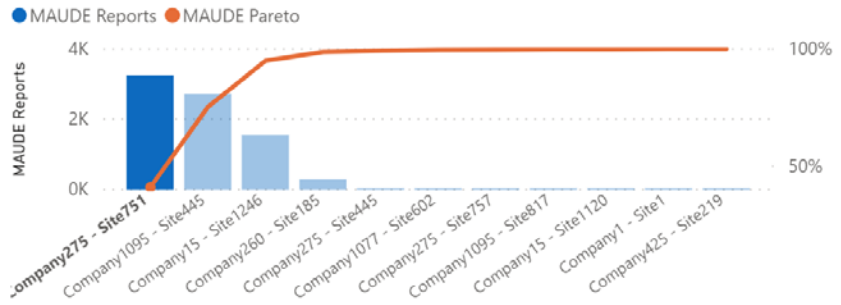


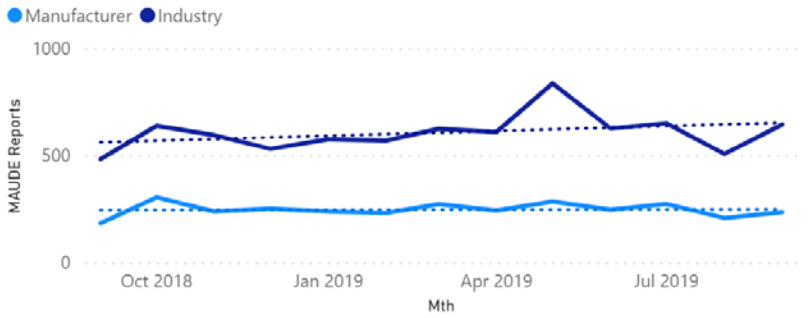
The **"Year-Month"** field enables the selection of a specific date range that we may be interested in.

(The tool currently defaults to the past thirteen months of data.)

Top 10 MAUDE Reports by Manufacturer



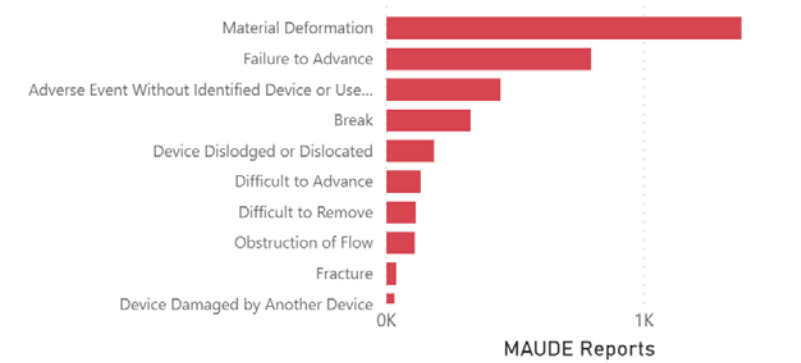
MAUDE Reports by Month



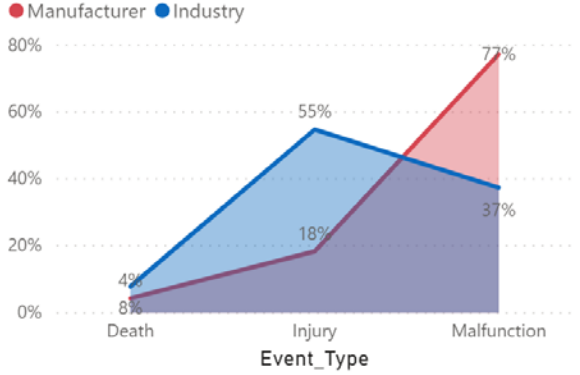
Product Code

Event

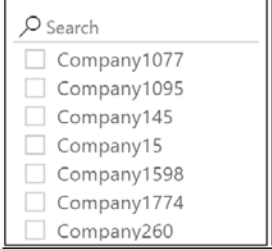
Top 10 Manufacturer Failure Modes



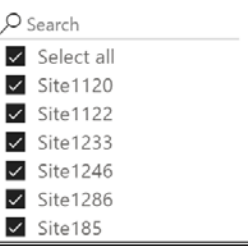
Industry Rate Comparison



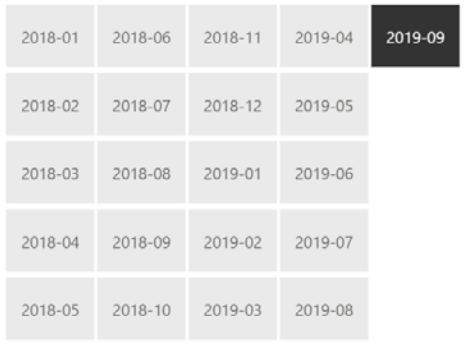
Manufacturer Name



Manufacturer Site



Year-Month



Share and Correlation

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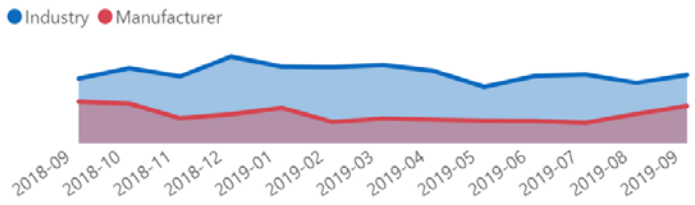
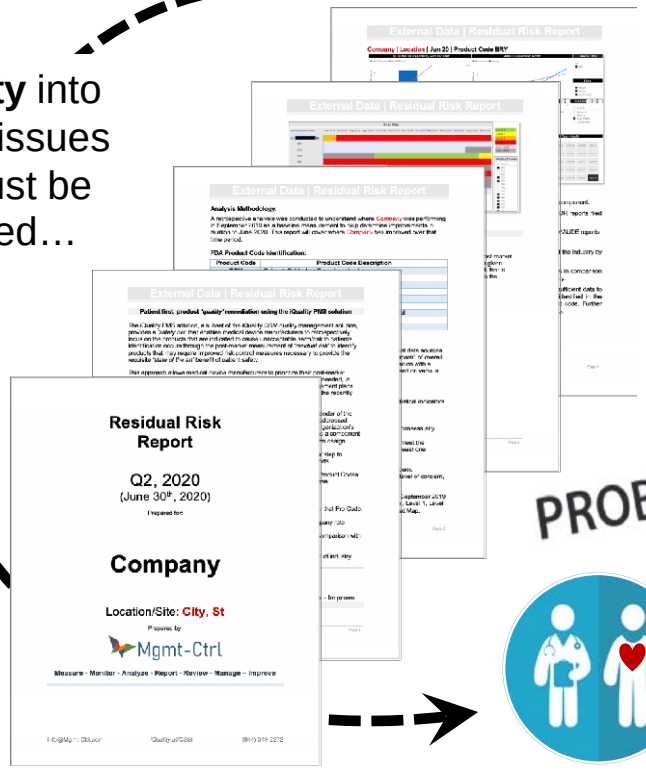
Relative Risk Profile



Quality Management Solution

Information for
Reporting and Review

Visibility into *'quality'* issues that must be resolved…



Data Management

SOLUTION

PROBLEM

ANALYSIS

Enterprise

Product *'quality'* Management

Risk Estimation

Post-Market Surveillance

iQuality
Analytics Platform

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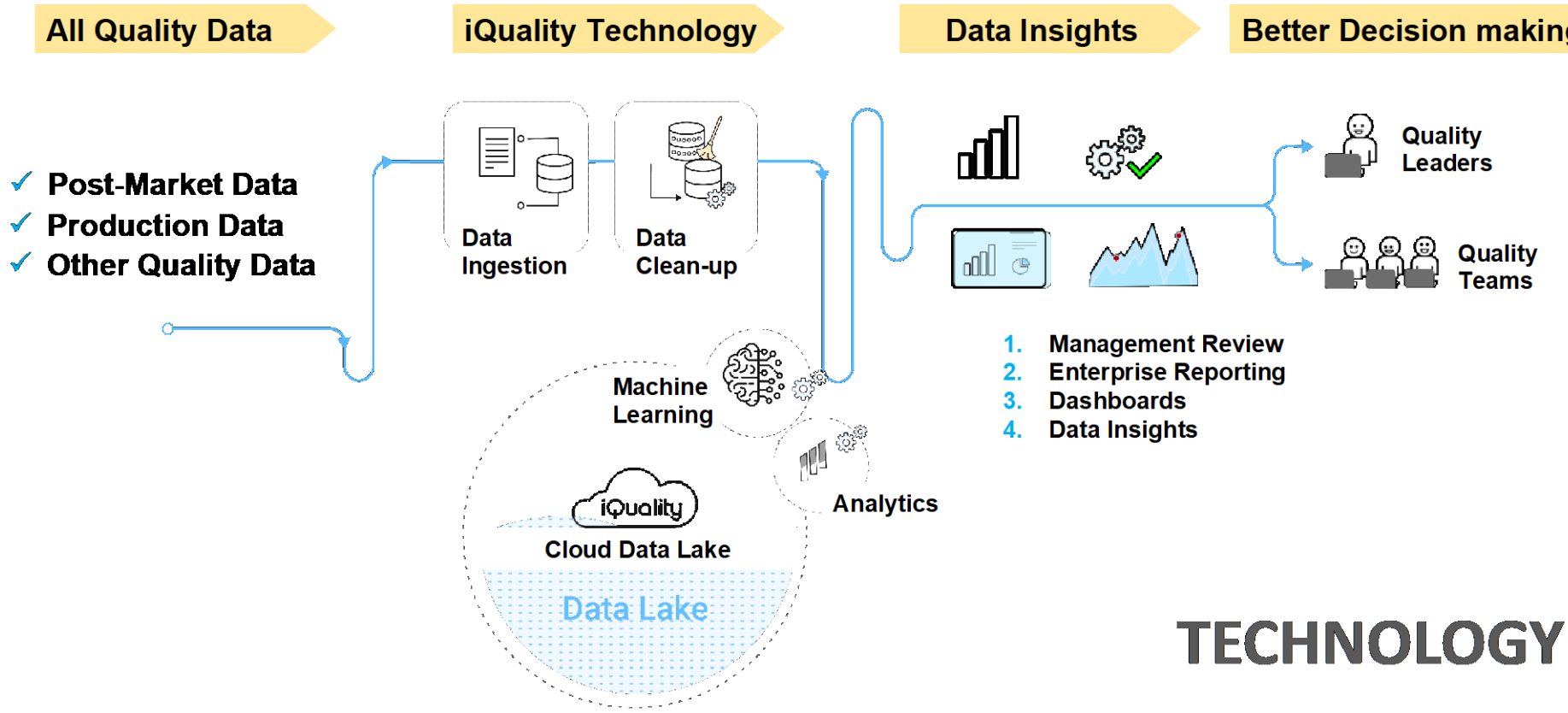

TECHNOLOGY

Platform Technology

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Completely built upon Windows Azure Technology

Azure's certifications
compliance with data protection standards and regulatory requirements

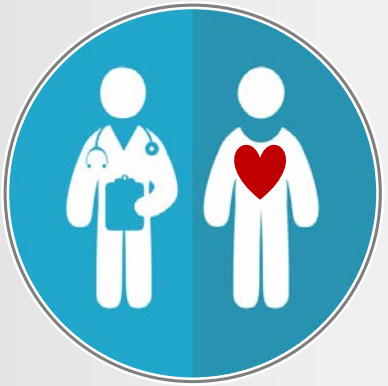
- **Service Organization Controls (SOC)**
- **International Organization for Standardization (ISO 27001)**
- **Federal Risk and Authorization Management Program (FedRAMP)**
- **PCI/DSS**

Use several cutting-edge Azure Services

- **Azure Data Factory**
- **Azure Machine Learning**
- **Azure Data Lake**
- **Azure App Service**
- **Power BI**
- **Azure Devops**

Demonstration

'Residual Risk Tool'



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METHODOLOGY

COMPLIANCE GROUP

TECHNOLOGY

It is our mission to support 'patient safety' by improving product 'quality' within the medical device industry.

Quality Management methodology within an AI enabled and cloud-based technology to…

Measure - Monitor - Analyze - Report - Review - Manage - Improve - Sustain

iQuality PMS

(844) 349-2272
Info@Mgmt-Ctrl.com

iQuality.ai/PMS

(847) 456-1796
Info@complianceg.com

Questions?

Larry Mager
Principal and Founder
Mgmt-Ctrl

Sponsored by:

COMPLIANCE GROUP

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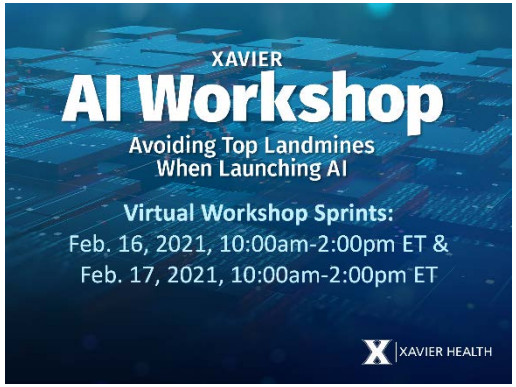
Xavier Health 2021 Events

XAVIER HEALTH