PCF Analytics Workshop

Asking the Right Risk Questions to Power Your Advanced Analytics Strategy

November 7, 2018

pwc

Welcome!

19th Annual Pharmaceutical and Medical Device Compliance Congress
Preconference IV

November 7, 2018

Washington, DC

Today's Objectives

Today's Agenda

Data Analytics Working Session	
Introductions	8:00 AM – 8:15 AM
In-room survey - Your stage in the analytics journey	8:15 AM - 8:45 AM
Defining the right risk questions for your analytics strategy: Table Activity Intro	8:45 AM – 9:10 AM
- **Risk Area 1**: Third Party Risk	9:10 AM – 9:35 AM
- **Risk Area 2**: HCP Spend	9:35 AM – 10:00 AM
Break	10:00 AM – 10:20 AM
Taking analytics to the next level - Advanced Techniques	10:20 AM – 10:50 AM
Industry Perspective on Operationalizing Analytics	10:50 AM – 11:30 AM
Questions and Close-out Session	11:30 AM - Noon

Introductions

Our Presenters Today

Katherine Buckley, PwC, Pharmaceutical & Life Science Risk Advisory

Christina Woods, PwC, Pharmaceutical & Life Science Risk Advisory

Anthony Greco, PwC, Pharmaceutical & Life Science Risk Advisory

Vahan Minassian, Pfizer, US Promotional Monitoring Lead

Joe Lake, BMS, Lead, Compliance & Ethics, Monitoring & Analytics COE

Audience Survey

Text **PCF2018** to **22333** to Join the Poll!

Benchmarking results will help us understand your experience with Compliance Analytics and topics of focus for today's session

Question 1:

What best describes the type of organization you work for or clients you serve?

A. Pharmaceutical / Biotechnology
B. Medical Device
C. Both
D. Other

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Question 2:

What best describes the overall maturity of the use of data analytics in your organization's compliance program?

A. Emerging (i.e., little to no processes or data enabled analytics)
B. Defined (i.e., informal/ad hoc processes and data analytics used)
C. Managed (i.e., formal processes and data analytics used)
D. Optimized (i.e., established KRIs and structured data analytics processes)

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Question 3:

In what aspect(s) of your compliance program are you utilizing data analytics? Select all that apply.

A. Risk Assessment
B. Ongoing data monitoring
C. Transaction monitoring sample selection
D. Reporting
E. Other
F. Not using analytics

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Question 4:

Which best describes your compliance program's data analytics resources?

A. Fully Outsourced to a third party
B. Shared service model (internal team with outsourced execution)
C. In-house, dedicated data science / analytics resource(s)
D. In-house resources developing analytics "part-time" while balancing other responsibilities
E. No data analytics capabilities at this time

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Question 5:

If conducting data analytics in-house, how many resources are dedicated to data analytics?

A. Fewer than 5 FTEs
B. 5-10 FTEs
C. 10-20 FTEs
D. Greater than 20 FTEs

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Question 6:

What data sources does your compliance program consider when conducting data analytics? Select all that apply.

A. Enterprise Resource Planning (ERP) system
B. Time and expense (T&E) system
C. Transparency data
D. Internal audit data
E. Issue management system
F. HCP engagement or meetings / event system
G. Third Party Engagement system
H. Grants Management system
I. Contract Management system
J. Other
K. None

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Question 7:

What best describes the scope of the data sources your compliance program uses to conduct data analytics?

A. Global
B. Regional
C. US-only
D. Other

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Question 8:

If your compliance program is using data analytics, which risks / activities are you monitoring?

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Defining risk questions for your Analytics Strategy

Introduction to Data Analytics

What do we mean by "data analytics"?

Data analytics is the outcome of collecting, transforming, and modeling data to draw conclusions and supporting decision-making.

What do we use data analytics for?

We use data analytics to help us identify directional insight into where our organization bears the highest risk.

How do we get there?

We develop a series of risk signals that allow us to identify trends and outliers, visualize the results, and determine what to follow up on.

Types of Data Analytics

There are multiple types of analytics that can be used to enhance your company's monitoring program

Descriptive

Descriptive Analytics uses data aggregation and data mining to provide insight into the past and answer:

What has happened?

Traditional compliance analytics approach with emerging technology leveraged to enhance insights.

Predictive

Predictive Analytics uses statistical models and forecasts techniques to understand the future and answer:

"What could happen?"

Pilot programs within Compliance are starting to emerge as companies invest in big data and technology.

Prescriptive

Prescriptive Analytics uses optimization and simulation algorithms to advise on possible outcomes and answer:

"What should we do?"

Beginning to be utilized by other functions, Compliance still challenged with how prescriptive analytics will be implemented.

Why do we use analytics?

Analytics incorporated into your compliance monitoring can promote compliance by creating a culture of accountability

Proactive Compliance Monitoring ***plus*** *Analytics*

- Gain a better understanding of dealings with healthcare community
- Reduce employee and vendor fraud
- Give management and the board a better sense of the effectiveness of and adherence to the company's compliance policies
- Establish credibility with regulatory bodies
- Reinforce compliance policies
- Alert employees to the commitment of management and the board to ethical business dealings

Establishing an Analytics Framework

Before implementing analytics, Compliance Teams should answer the following questions:

- Have I defined the **risks and specific risk questions** I want to answer with my analytics?
- Do I have a clear understanding of our **organization's current data environment**?
- How will I **use the insights** I am generating from my compliance analytics?

Asking the "Right" Questions

Questions can be targeted for each area of risk you want to evaluate with analytics

Example Risk Area	*Example "Right" Questions to ask*
Distributors involved in ABAC activity	• Do we have any distributors that receive a discount that is higher than other distributors in market / region?
Excessive payments or transfers of value to doctors	• Which doctors have received payments in excess to our average or exceeded our annual cap (if applicable)?
Use of Time & Expense / Corporate Credit Cards	• Are we seeing transactions that are outside of our policy for events with HCPs?

Assessing our current analytics environment

Understanding the data and analytics environment at your organization is important to inform your analytics strategy

Defining Key Risk Indicators (KRIs)

Risk Questions inform the KRIs you design for your compliance analytics

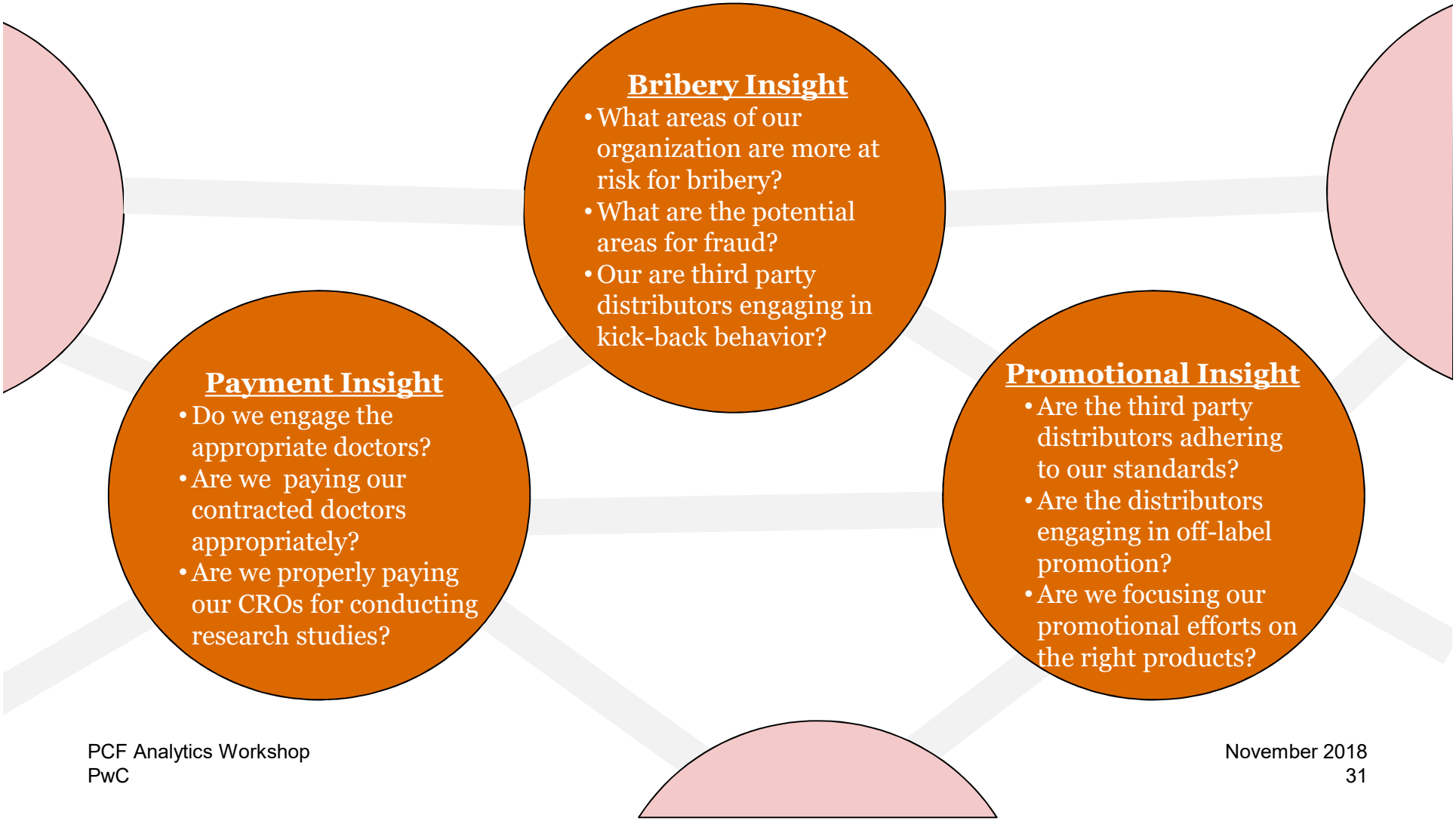
Example Risk Area	*Example "Right" Questions to ask*
Distributors involved in ABAC activity	• Do we have any distributors that receive a discount that is higher than other distributors in market / region?

Example Key Risk Indicators

- ***High Ratio of Discounts to Sales Volume*** - Identify Sales-related third parties with outlier ratios of discounts to sales volume* (> 2 Standard deviations above average ratio)
- ***Sold below Cost*** - Identify transactions where sold price is below Company cost
- ***High Ratio of Total Incentives to Sales Volume*** - Identify Sales-related third parties with outlier ratios of incentives to sales volume (> 2 Standard deviations above average ratio)

Delivering Compliance Insights

The right risk questions and KRIs can help deliver Compliance insights to the organization



Revisiting our Data Analytics Framework

Framing question

What risk do we want to evaluate?

What questions are we trying to answer?

What relevant data do we have available?

What data points might lead us to that answer?

What do the KRIs tell us?

Will this result in an investigation, inform future monitoring, etc.?

Table Exercise

Practice applying the analytics framework and asking the right risk questions

The challenge

Your team is tasked with **discussing two (2) risks** and the **considerations for developing an analytics approach** for monitoring each risk.

The format

- 60 minutes total (2 risks, 30 minutes per risk)
- 10 minute small group discussion
- 15-20 minute large group discussion

The approach

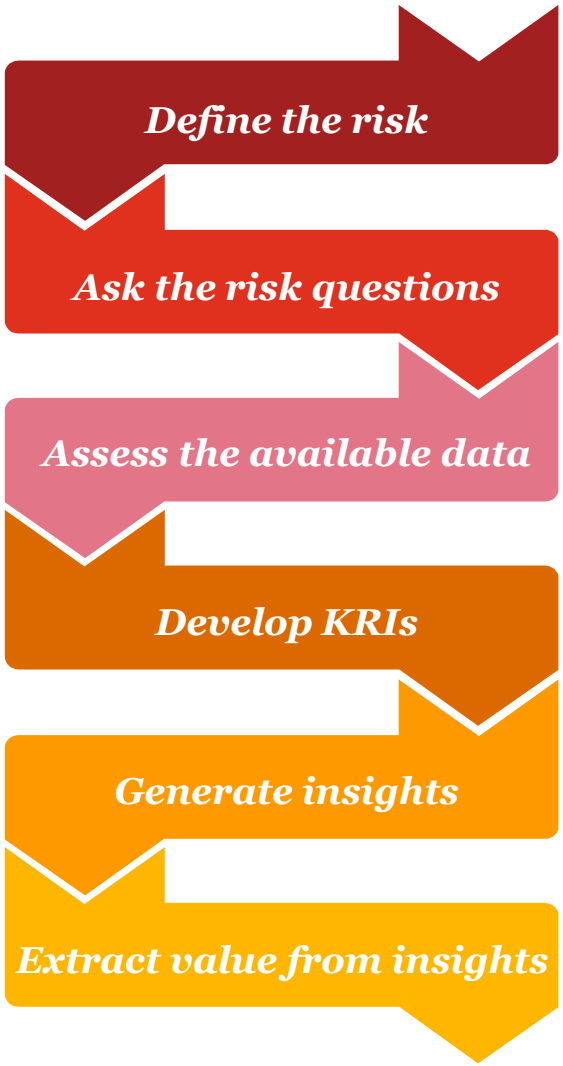
Consider the following questions during your discussion:

- What risks do we want to evaluate?
- What risk questions would we want to answer with analytics?
- What relevant data do we have available?
- What data points (KRIs) might lead us to that answer?
- What insights do these data points tell us?
- What would you do with the insights generated from the analytics (additional monitoring, investigation)?

The result

Thought-provoking discussion points to bring back to your organizations that may inform future approaches to data analytics for various risk areas

Example Risk: Hospitality



Framing question	*Example answer*
What risk do we want to evaluate?	Anti-Kickback (US) / Bribery (Global)
What questions are we trying to answer?	We've increased our meal budget to support a new launch, is this budget being used appropriately?
What relevant data do we have available?	T&E / travel vendor extract (expenses), ERP extract (payments)
What data points might lead us to that answer?	- Attendees with meal expenses > 2 Standard Deviations above average - Keyword analytics for in scope expense and attendee types
What do the KRIs tell us?	Meal spend that exceeds average appears to be localized to 2-3 regions.
What would you do with the insights generated from the analytics?	Perform detailed transaction testing within the identified Regions, initiate training for teams in higher risk areas

Risk 1: Third Party Vendors

10 min. small group discussion

Challenge: Developing an analytics approach for monitoring Third Party Vendors ("TPVs").

Framing question

What risk do we want to evaluate?

What questions are we trying to answer?

What relevant data do we have available?

What data points might lead us to that answer?

What do the KRIs tell us?

What would you do with the insights generated from the analytics?

Risk 1: Third Party Vendors

20 min. large group discussion

Sample: Developing an analytics approach for monitoring Third Party Vendors ("TPVs").

	Framing question	*Example answer*
Define the risk	What risk do we want to evaluate?	Anti-Bribery
Ask the risk questions	What questions are we trying to answer?	How do we know if certain Distributors have excess margin that could support bribery activity?
Assess the available data	What relevant data do we have available?	ERP extracts (discounts and payments)
Develop KRIs	What data points might lead us to that answer?	High Ratio of Total Incentives / Discounts / Credit Memos to Sales Volume
Generate insights	What do the KRIs tell us?	Noted 5 Distributors that have discounts in excess to our average for those markets / products
Extract value from insights	What would you do with the insights generated from the analytics?	Initiate Distributor audits, update / change pricing contracts with at risk Distributors

Risk 2: HCP Payments

10 min. small group discussion

Challenge: Developing an analytics approach for monitoring HCP Payments (e.g. Consulting Arrangements, Speaker Programs, Advisory Boards).

Framing question

What risk do we want to evaluate?

What questions are we trying to answer?

What relevant data do we have available?

What data points might lead us to that answer?

What do the KRIs tell us?

What would you do with the insights generated from the analytics?

Risk 2: HCP Payments

20 min. large group discussion

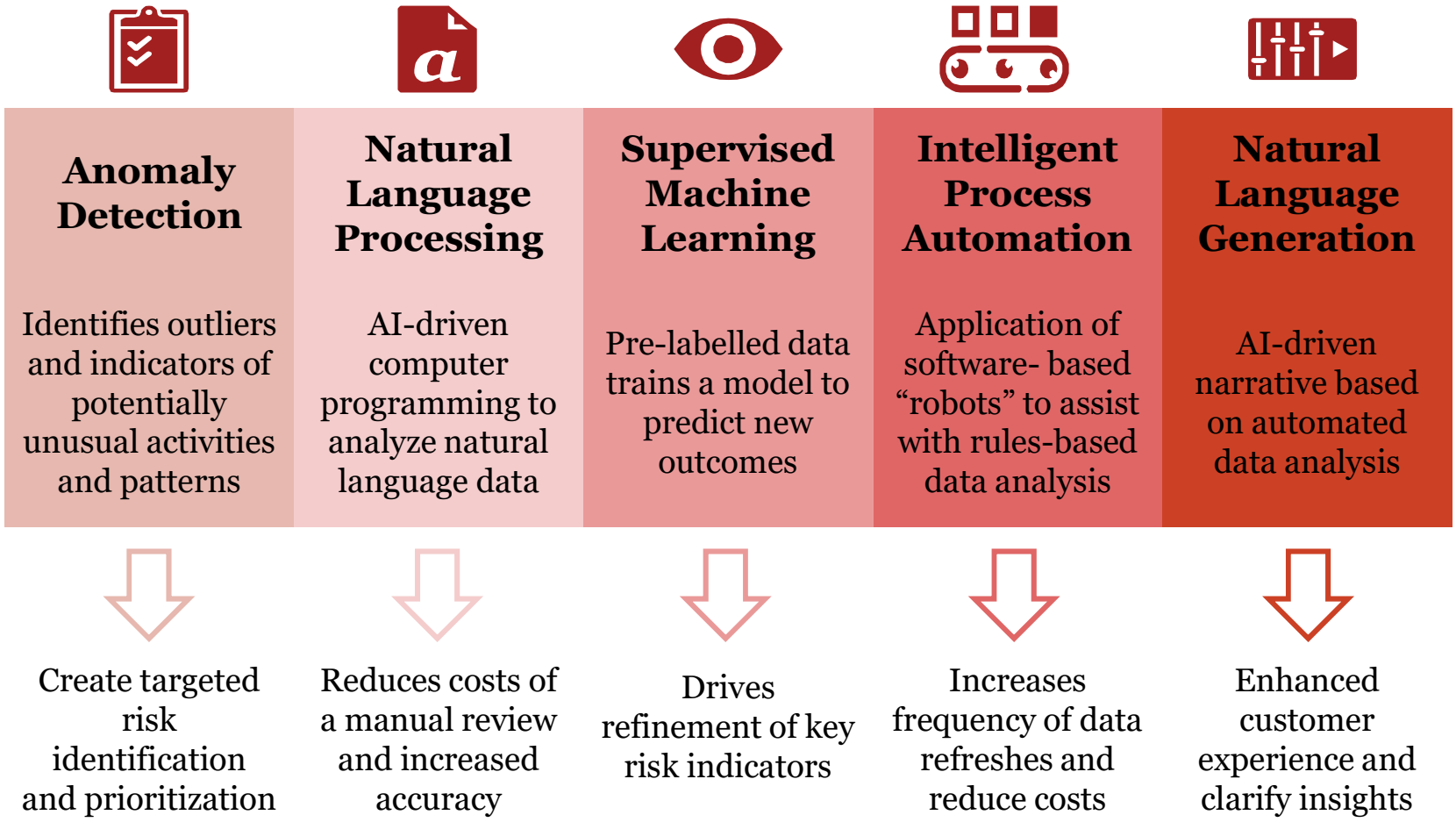
Sample: Developing an analytics approach for monitoring HCP Payments (e.g. Consulting Arrangements, Speaker Programs, Advisory Boards).

	Framing question	*Example answer*
Define the risk	What risk do we want to evaluate?	Anti-Kickback
Ask the risk questions	What questions are we trying to answer?	Do we see any KOLs that with excessive payments across payment types?
Assess the available data	What relevant data do we have available?	ERP extract (payments),HCP Engagement Management System, Spend Transparency
Develop KRIs	What data points might lead us to that answer?	Excess Payments, HCP/ HCO Payment Outliers (Industry or External)
Generate insights	What do the KRIs tell us?	Several KOLs total payments have increased significantly over the last 12 months
Extract value from insights	What would you do with the insights generated from the analytics?	Perform detailed transaction testing and implement increased controls around KOL spend management

Taking analytics to the next level - Advanced Techniques

Advanced Analytics Techniques

Utilizing Advanced Analytics and Emerging Technology can power your compliance analytics strategy

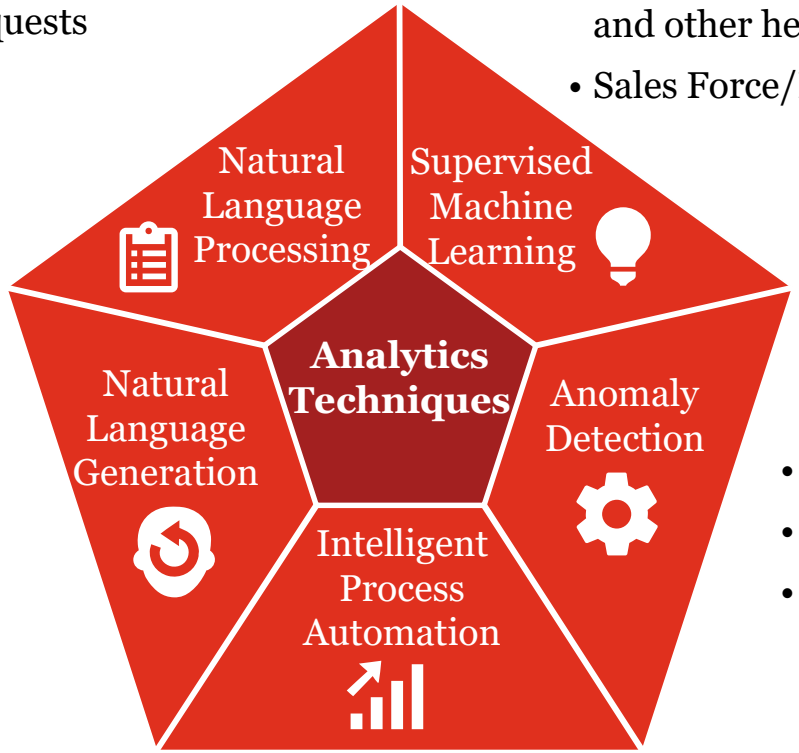


Advanced Analytics Techniques

Advanced Analytics and Emerging Technology can be utilized to address traditional and emerging compliance risk areas

- Medical Information Requests
- Contract Analysis

- Interactions with HCPs, Patients, and other healthcare stakeholders
- Sales Force/HCP Risk Profiling



- Analytics Dashboards
- Market Profile Risk Summaries

- T&E/Corp Credit Card
- Samples
- Payment related transactions (HCPs, Grants / Donations, Third Party)

- Samples Data
- Veeva Data

Advanced Analytics - Case Studies

The following techniques are often utilized to manage risks and can generate real value for its compliance program





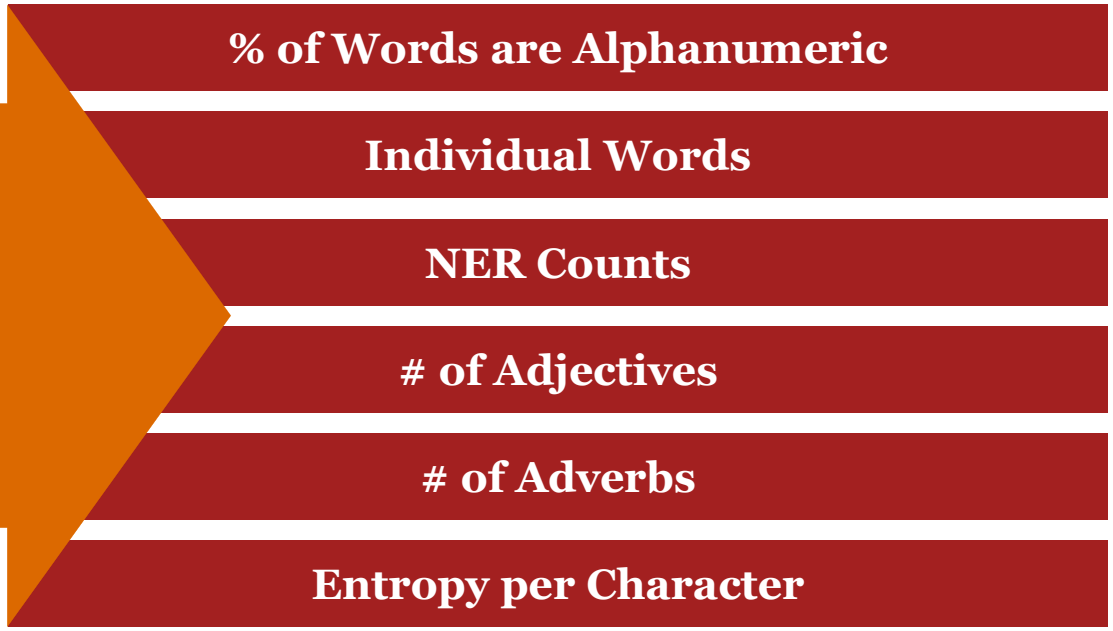
Anomaly Detection	Natural Language Processing	Supervised Machine Learning	Intelligent Process Automation	Natural Language Generation
Identifies outliers and indicators of potentially unusual activities and patterns	AI-driven computer programming to process and analyze large amounts of natural language data	Pre-labelled data trains a model to predict new outcomes	Application of software- based “robots” to assist with rules-based data analysis, transacting, and reporting	AI-driven narrative based on automated data analysis to drive broader compliance insights

What is Natural Language Processing?

Natural Language Processing is a machine-based process that allows for human-like interpretation of text.

Each document of interest is parsed into collections of distinct sentences

"Hello, I am a sentence that may or may not be about Product A."



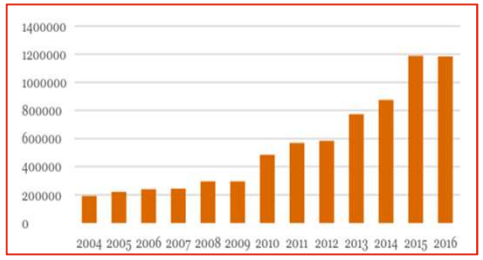
Each sentence is translated into a collection of distinct characteristics

Natural Language Processing – AE Case Study

Problem

There is a 15 - 20% annual growth in intake volume of *adverse event reports* driven by emerging economies, direct data entry, and increasing variety of reporting sources. These cases are typically manually interpreted and then manually entered into the safety database for regulatory reporting

Adverse events reported in FAERS



Advanced Analytics Approach

Adverse Event Reports

Intelligent Case Interpretation (ICI)
Automating Case Processing

Safety Database

Adverse Event Reports data is collected from multiple sources and hosted in a cloud data lake. Pre-trained machine learning and rule based models identify the key entities within the reports and interprets / analyzes them. The cases are sent to the safety database depending on the risk identified by the interpretation and verified by the user

Graph Data from FDA: FAERS

Advanced Analytics - Case Studies

The following techniques are often utilized to manage risks and can generate real value for its compliance program





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What is Supervised Machine Learning?

Training a computer to make predictions or decisions on new data based on what it has "learned" in the past

New Input

"Real World" data is fed to the predictive model

Training Data

Predictive model is fed labeled examples of historical data

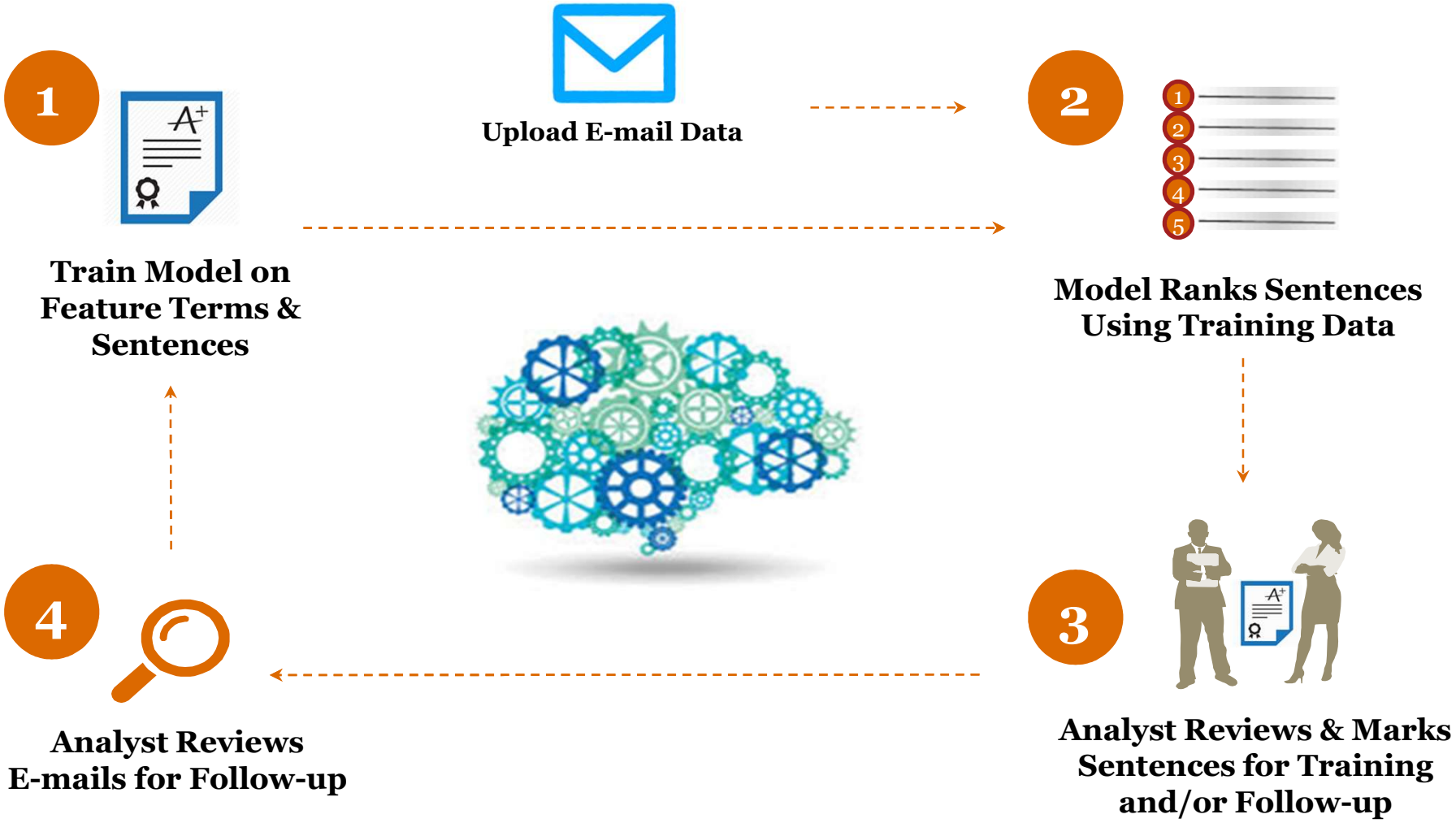
Predictive Model

"Real World" data is evaluated by Predictive Model based on training

Output (Prediction)

Theoretically, predictive performance continues to improve as more training data is produced.

Supervised Machine Learning – Example Use Case



How do we implement Analytics

Industry Perspective on Operationalizing Analytics

Operational considerations of implementing compliance analytics

How do we know the analytics work?

How do we continuously evaluate & improve the analytics?

What analytics do we need, and why?

How do we make the analytics part of our program?

Operational considerations of implementing advanced analytics

Key Drivers for Analytics Needs

- **Emerging compliance priorities - e.g. Risk Assessments**
- **Key business initiatives / operational challenges**
- **Business culture - "Blue Sky Thinking" & broader enterprise strategy**

Governance Structure & Process for Approving Analytics

Developing and Approving Business Case

Operational considerations of implementing advanced analytics

Developing a "Proof of Concept"

Pilot Scope & Design

Measuring Success of the Pilot

- **Improved efficiency**
- **Strength of insights**
- **Other operational considerations**
- **Salvaging Pilot / PoC failure**

Operational considerations of implementing advanced analytics

Technology Investment and IT support

Internal resource requirements

- **Specific tech/data SMEs at build and on-going maintenance**
- **Compliance and other SMEs ongoing time commitments**

Process Updates / Alignment

Data Management & Governance

Operational considerations of implementing advanced analytics

Ongoing Updates & Adjustments

Scaling & Expansion

- **Expansion of analytics scope**
- **Enriching outputs with additional data**
- **Connecting information with other analytics**

Wrap-Up

Recap of Today's Analytics Session:

Thank You!