

Using Data Analytics for Enhanced Compliance Monitoring

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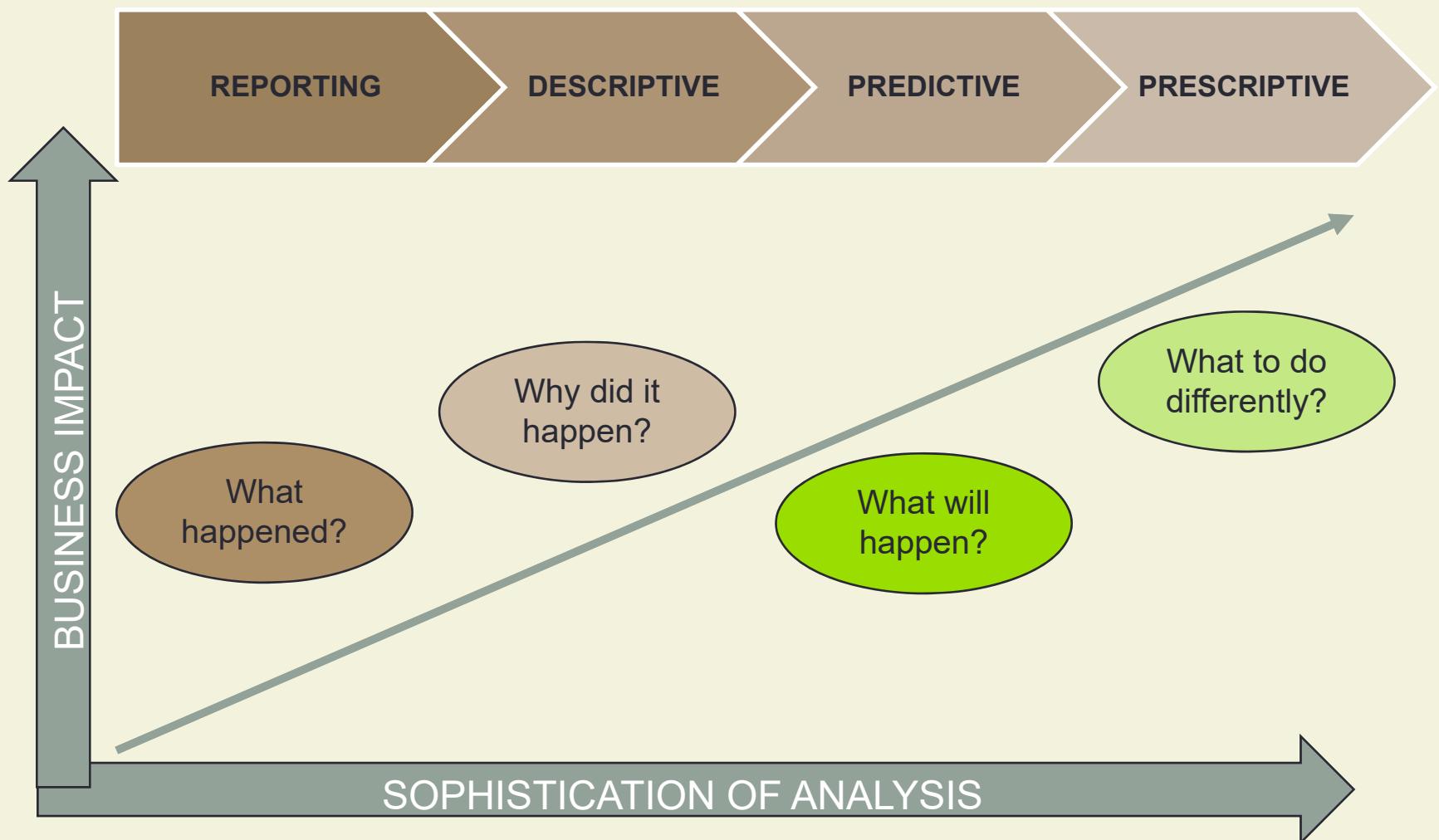
Introductions

- J. Mark Farrar – Navigant (Moderator)
- Peter Andres – Baker McKenzie
- Amy Huang – Eli Lilly and Company
- Keith M. Korenchuk – Arnold & Porter LLP
- Maria “Maru” Quindimil – UCB Pharma

When Should You Use Data Analytics

- Monitoring for Instances of Fraud
- Commercial Insights / Business Enhancement
- Auditing and Monitoring
 - Consistent basis, e.g. quarterly to look for outliers, etc.
 - Risk Assessment based
 - Proactive vs Reactive
- Mandating reporting requirements (e.g. Transparency - Avoiding Penalties and Remaining Compliant)
- Litigation Support
- Measure against Key Performance Indicators (“KPIs”)

Types of Data Analytics



Polling Question

Where is your organization in the continuum of data analytics

- A) Reporting
- B) Descriptive
- C) Predictive
- D) Prescriptive

What Type of Data Should You Use

External Vs. Internal

External / Publicly Available

- * Social Media
- * Global Transparency
- * Publicly available reimbursement data
- * Clinical Trials

Internal / Company Specific

- * Meal and Call Interactions
- * Speaker Programs
- * Educational Materials
- * Finance / Accounts Payable
- * Previous Audit / Monitoring Results
- * Billing and Claims

Structured vs. Unstructured

Structured Data

- * Critical to integrate disparate data sets to maximize the effectiveness of the data analytics

Unstructured Data

- * Emails
- * Customer Relationship Management System Notes
- * Chat Messaging
- * Audio
- * Message Forums

Analytics Work Flow

Define the problem

Identify relevant data sources

Connect disparate data sets

Develop the logic

Presenting the analytics

MOCK CASE EXAMPLE

HCP Sponsorship

Case Study: HCP International Sponsorship

Fact Scenario:

- In 1Q, the local marketing team in Company A identified around 50 HCPs to be sponsored to different Congress and Symposia events for medical education.
- Several new products will be launched this year in Company A. There will also be newly published data on a new use for the Company's top selling product that will expand its use. One key objective of the sponsorships is to develop speakers.
- Several HCPs on the proposed invitee list are also on product review committees at some major hospitals.
- By 3Q, another 400 physicians are added to the list for sponsorships abroad to Congresses and Symposia. The total expenditure for sponsorships is increased to \$5M for the year.

Case scenarios are hypothetical and do not reflect actual events.

Fact scenario continues on next slide . . .

Case Study HCP International Sponsorship

Fact Scenario Continued...

- Internal emails between marketing team members refer to the potential increased prescription volume as one reason for the Company to sponsor the HCPs.
- When asked about these emails, the employees who wrote them explained that they expected an increase in prescribing as a result of the new knowledge acquired by the HCPs at the medical education meetings.
- One manager shared a spreadsheet that one marketing team had used in selecting sponsored HCPs. The spreadsheet listed HCP names, positions held, types of engagements with the Company, prescribing data and ranked HCPs for sponsorship.

➤What issues do you see?
➤What questions would you want to ask?

What risks do you see?

- What controls are in place to mitigate risks?
- What data would you use to test those controls?
- How would you assess the risk of the HCP?
- Discuss the FCPA risks? How would you mitigate this?

How would data analytics can help with this case?

- How would the issues of the 3rd party diligence or fraud detection be addressed with analytics?

HCP International Sponsorship

Fact Scenario Continued...

- An Internal review of documents found the following:
 - There were no itemized receipts from several of the agencies for HCP expenses abroad. The travel and meeting planning agencies only provided a one line invoice describing the services.
 - Documentation showed that the company had sponsored 7 HCPs to attend one congress. The expense records showed the following:
 - Lunch: US\$300 per person at a Hotel for 17 HCPs.
 - Another invoice showed lunch (during Congress meeting) at 'The Vineyards', a venue located 100km distance from the congress venue.
 - Transportation costs of US \$17,000 were charged to go from hotel to meeting venue and to airport. (A distance of less than 5 miles).
 - No proof of HCP attendance at the congress was provided.
- At year end, only a few of the sponsored HCPs had been used as speakers following sponsorship to the Congress/ Symposia.