

# 16<sup>th</sup> Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

## Getting Ahead of the Game – Utilizing Data and Other Operational Indicators to Identify Potential Compliance Issues Early



October 21, 2015  
Washington, D.C.



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# Traditional Auditing & Monitoring Plan Development - Potential Risk Area Sources

- ◆ Industry Corporate Integrity Agreement Compliance Monitoring Requirements
- ◆ Industry Government Investigations/Settlements
- ◆ OIG Annual Workplans
- ◆ OIG Fraud Alerts
- ◆ Industry Compliance Conferences
- ◆ Compliance Hot-line Submissions

# Potential Compliance Related Data Analytics – Key Benefits

- ◆ Supplements/helps prioritize auditing & monitoring activities
- ◆ Early detection of *potential* regulatory compliance issues to further investigate
- ◆ Leveraging of data already being collected for regulatory/operational purposes
- ◆ Early detection and potential explanation of publically available data and other operational anomalies potentially identified or targeted by enforcement agencies
- ◆ Early detection of potential business reputational risk

# Potential Compliance Related Data Analytics – Key Benefits (Cont.)

- ◆ Key approach to demonstrating an effective compliance program in today's compliance focused environment
- ◆ Monitoring adherence to internal Policies & Procedures
- ◆ Certain indicators a potential benefit to the business side of the organization

# Potential Compliance Related Data Analytics – Example Data Sources

- ◆ Meals & Entertainment
- ◆ Education Grants & Sponsorships
- ◆ Samples
- ◆ Speaker Programs and Related Payments
- ◆ Research Payments
- ◆ Consulting Arrangements/Payments
- ◆ Employee Social Media Activity
- ◆ Medical Science Liaisons Activity
- ◆ Publications/Reprint Activity
- ◆ Rebates & Discounts
- ◆ Service Fee Arrangements/Payments
- ◆ Sales Activity by Employee, HCP
- ◆ Call plans
- ◆ Medical Information Requests (MIRs)

# Potential Compliance Related Data Analytics – Example Data Indicators

- ◆ Correlation of fees paid to HCPs (consulting, speaker programs, research, etc.) against sales activity (amount and timing)
- ◆ Correlation of HCP reimbursed meals & entertainment against sales (amount and timing)
- ◆ Increased sales force interaction with HCP's who do not traditionally treat approved product indications
- ◆ Correlation of increased MSL activity against sales (amount and timing)
- ◆ Correlation of increased service fees paid against sales (amount and timing)



# Potential Compliance Related Data Analytics – Key Risks to Consider

- ◆ Potential inaccurate conclusions based on missing data sets or incorrect/incomplete data
- ◆ Too much focus on the data analytics collection/process/"tool" – focus can be lost on basic "blocking and tackling" of auditing & monitoring
- ◆ Determining Internal distribution or access rights to compliance related data analytics dashboards/reports
- ◆ Inaction on identified/internally distributed anomalies and/or potentially concerning trends

# Potential Compliance Related Data Analytics – Key Risks to Consider (Cont.)

- ◆ Balancing appropriate coordination with the business side of the company
- ◆ Coordination Between Compliance Department/General Counsel Office when inquiring/analyzing further anomalies and/or potentially concerning trends
- ◆ Coordination with Internal Audit initiatives



# Potential Compliance Related Data Analytics – Other Considerations

- ◆ Government enforcement agencies' increased use of data mining/data analytics during investigations
- ◆ Plaintiffs Bar's increased use of data mining/data analytics during Qui Tam litigation
- ◆ Requests of certain manufacturer HCP data by Healthcare institutions
- ◆ CIA compliance certification requirements

# Potential Compliance Related Data Analytics – Other Considerations (Cont.)

- ◆ DOJ Individual Accountability for Corporate Wrongdoing memo (“Yates Memo”)
- ◆ Responsible Corporate Officer Doctrine
- ◆ New DOJ Compliance Counsel position

# Audience Q&A

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