

# Advanced Issues in Auditing & Monitoring Introductory Discussion

**11<sup>th</sup> Annual Pharmaceutical Regulatory and Compliance Congress**

**October 21, 2010**

**LIFE SCIENCES ADVISORY SERVICES**



# Today's Speakers

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# The Evolution of Auditing and Monitoring

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## Significant Focus Area of Current Corporate Integrity Agreements

- The OIG has a significant focus on imposing auditing and monitoring provisions within the CIAs of many recent settlements.
- The auditing and monitoring provisions are broad and range across both promotional and non-promotional activities.
- Some CIAs have provision of risk based selection of programs and activities to be audited or monitored.
- Requiring “needs based” annual planning for many promotional and non-promotional programs.
- The concept of “comprehensive” field force monitoring program (“FFMP”) is being used more frequently to address interactions with healthcare professionals (“HCPs”) and healthcare institutions (“HCIs”).

# “Level-Setting” Auditing vs. Monitoring

## Significant Focus Area of Current Corporate Integrity Agreements

### Auditing



Typically characterized by the retrospective examination of records and data to assess the implementation, performance, and controls of a process against a set of pre-defined criteria. In general, audits provide an organization with a level of “assurance” that a process or system is working in accordance with defined policies and procedures.

### Monitoring



Typically characterized by the ongoing, “near-time” analysis of data, signals, inputs, or other business information that is designed to proactively identify, trend, and respond to potential non-compliance with a defined process or procedure. In some circumstances, the monitoring activity may be focused on a specific control within a process.

### COSO Framework on Internal Controls

1. Defining the Control Environment – outline the policy and tone for the organization on the policies and procedures.
2. Risk Assessment – the systematic identification and analysis of risks
3. Information and Communication – structured identification, capture, and exchange of information related to risks
4. Control Activities
5. Monitoring

# The Breadth of What the OIG is Imposing in CIAs

## Key Auditing and Monitoring Focus Areas

### Promotional

- ☐ Field Ride Along
- ☐ Call Note Review
- ☐ Speaker Program Monitoring
- ☐ Sales Call Planning
- ☐ Incentive Compensation Review
- ☐ Physician Verbatims

### Non-Promotional

- ☐ Needs Assessment Process Development
- ☐ Consultant Payment Review
- ☐ Advisory Board Monitoring
- ☐ Research Payment Review
- ☐ Publication Monitoring
- ☐ Research Monitoring

Sample for Discussion Purposes

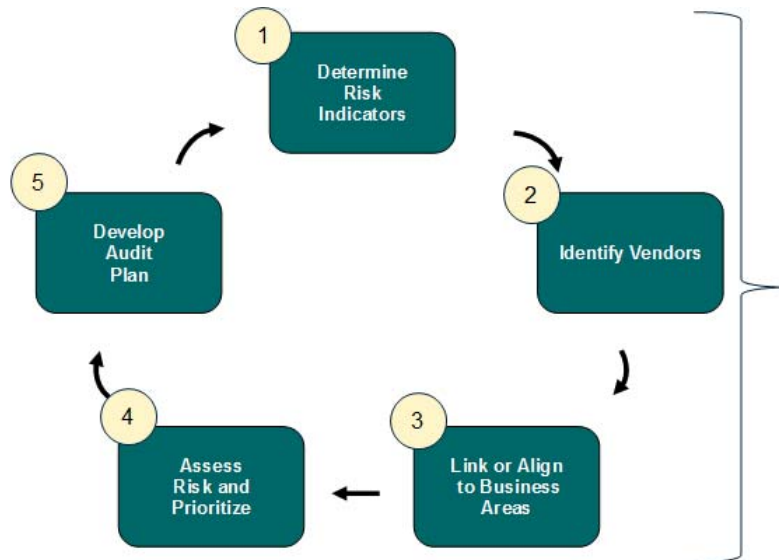
## Common Themes Across Recent CIAs:

- 1.Focus on non-promotional activities
- 2.Use of a “needs assessment” of “business justification” process.
- 3.Risk based targeting
- 4.Annual planning process for use of consultants
- 5.“Live” monitoring of a wide range of events

# Auditing Typically Requires Structured Planning

## Use of a Risk Assessment to Focus Auditing Resources

- Auditing resources are typically limited and may require specialized resources.
- The execution of an audit generally requires planning and coordination with the business process owners.
- The audit may be proactive as part of a structured risk management plan or may be directed as a result of a compliance “red flag” or other risk related need.
- A comprehensive auditing plan generally has some type of risk assessment component or risk based selection of audit focus areas.



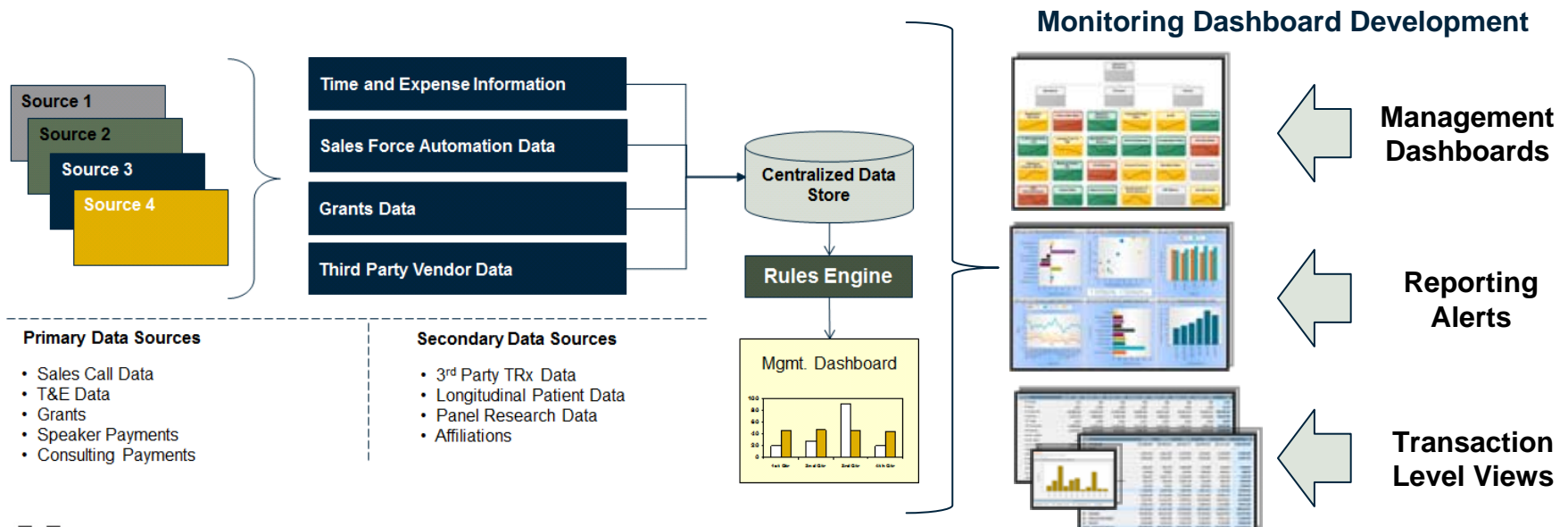
### Key Considerations

1. Developing a structured approach to assessing risk is a multi-step process requiring input from various process owners and stakeholders.
2. Each step of the planning and execution process should be iterative and consider key factors such as resources and timing.
3. Potentially review shorter-term and longer-term risk priority issues in developing a risk based auditing plan.

# Monitoring Requires Significant Data and Resources

## Infrastructure, Analytics, and Tools

- Monitoring typically occurs through either data analytics and reporting tools or through “live” monitoring of activities such as speaker programs, advisory boards, etc.
- A comprehensive monitoring strategy typically requires infrastructure investment in technology, tools, and support personnel.
  - Data must be integrated from source systems into an analytical architecture where rules and reporting dashboards can be configured to identify “outlier” or problematic activities/transactions.
- Through various aggregate spend data capture initiatives, manufacturers may have the ability to utilize enterprise level spend data for tracking and monitoring initiatives.



# Assessing Auditing and Monitoring Tools and Techniques

## Multiple Factors May Affect the Selection of Tools and Techniques

The use of any one tool is generally not sufficient to assess structural or operational compliance risks. A combination of two or more tools are necessary to develop a robust risk management framework. Organizations must consider the tools and techniques based on four broad criteria including: (1) Accuracy, (2) Predictability, (3) Difficulty/Disruptiveness, and (4) Cost.

Sample Tools and Techniques	Accuracy	Predictability	Difficulty	Cost
1. Rep “Ride-Along”	L   M   H	L   M   H	L   M   H	L   M   H
2. HCP Verbatim Services	L   M   H	L   M   H	L   M   H	L   M   H
3. Rep Call Note Analysis	L   M   H	L   M   H	L   M   H	L   M   H
4. Auditing (Transactional)	L   M   H	L   M   H	L   M   H	L   M   H
5. Monitoring (Data and Analytics)	L   M   H	L   M   H	L   M   H	L   M   H
6. Self-Assessments	L   M   H	L   M   H	L   M   H	L   M   H

Legend: L – Low | M – Medium | H - High

For Discussion Purposes



# Key Considerations in Auditing and Monitoring

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## Assessing Short-Term and Longer-Term Priorities

- Can enterprise level data be leveraged for auditing and monitoring purposes. Does the organization have an infrastructure that can be leveraged to detect potential compliance issues through data analytics?
- What are the organization's short-term objectives based on its current risk map and compliance priorities?
- What are the organization's longer-term objectives and what infrastructure needs should be considered in that longer-term plan.
- Is the organization's program focused on the U.S. or does it also include international affiliates and distribution partners?



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