

# Developing a Proactive Compliance Monitoring Program

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# Compliance Monitoring Defined



- Monitoring is the ongoing, near-time analysis of traditional and non-traditional data sources, related to targeted business activities and controls, to proactively identify, trend and respond to potential compliance “signals” and to be predictive of customer behavior
- Monitoring is considered distinct from auditing, which is typically retrospective and often limited by time, frequency and scope
- The primary focus of Pfizer’s current compliance monitoring efforts is:
  - ✓ Promotional activities
  - ✓ Financial transactions
- Monitoring results inform corrective action plans, including full-scale compliance investigations, policy changes, enhanced training and communications, additional monitoring, focused audits and other programmatic responses

# Regulators Continue to Focus on Monitoring



- As Corporate Integrity Agreements (CIAs) continue to evolve, the OIG is placing stronger expectations (and obligations) for companies to demonstrate that they have effective means of monitoring compliance with high risk areas
- Pfizer's new CIA requires execution against several monitoring programs, including:
  - ✓ Headquarters
    - Consultant Arrangements
    - Publications and authorships
    - Medical Education Group Activities
  - ✓ Field Force Monitoring → ***Focus of PQA***
    - Tablet PC Detailing Monitoring (controls around starters, MIRs, detail materials)
    - Ride Along Observations
    - Records Reviews (three products with elevated risk identified through RAMP)
    - Speaker Programs (live speaker monitoring)

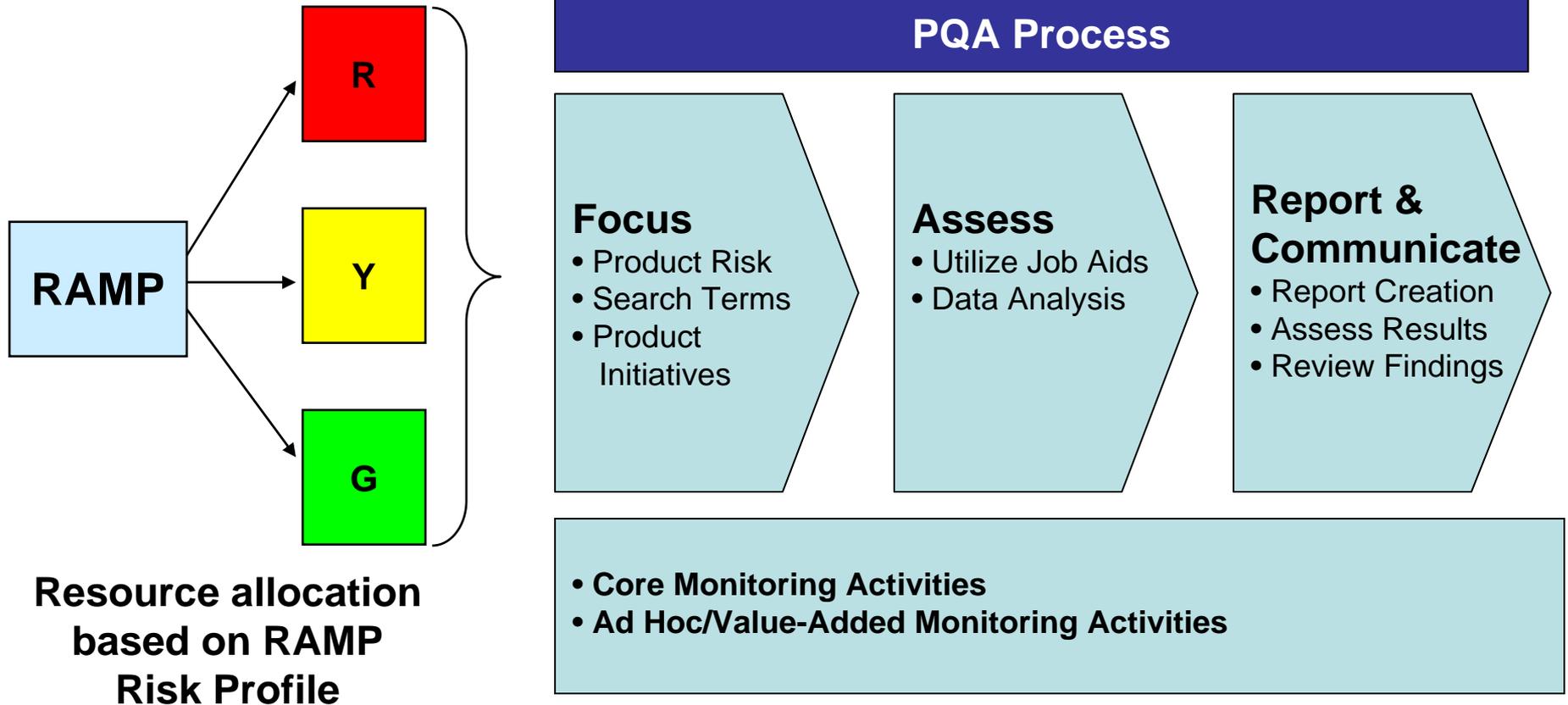
# Promotional Quality Assurance (PQA) Program Objectives



The program objective was to establish the organizational model, supporting processes, and leverage technology, data and the resulting analytics to:

- Apply a risk-based approach to monitoring US promotional activities
- Proactively identify *potential* regulatory compliance issues before they become *real* issues
- Report and escalate findings to relevant stakeholders
- Address certain external reporting obligations
- Support continuous improvement of their promotional activities
- Inform internal certification protocols

# Promotional Quality Assurance (PQA) Standard Operations

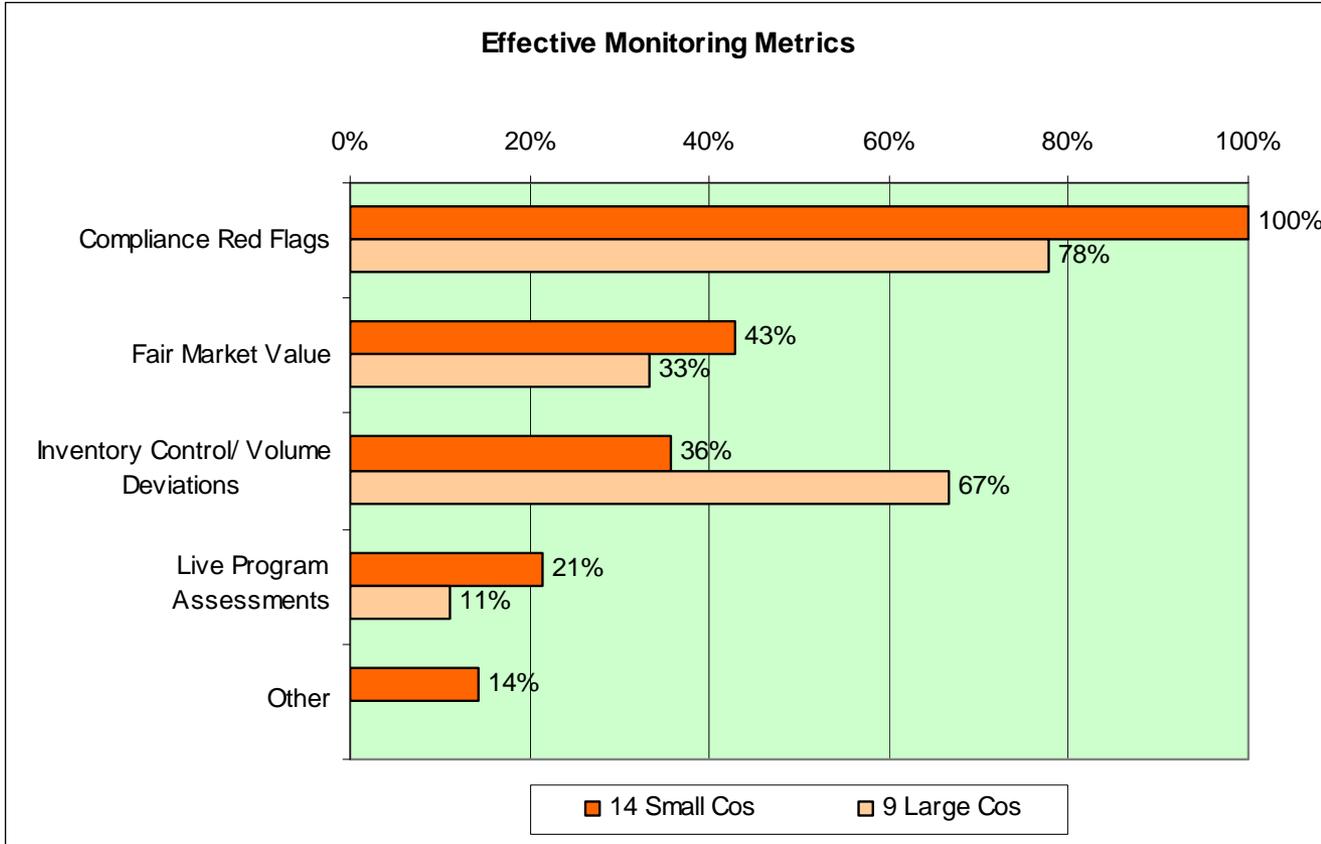


# PCF Survey Results: Effective Monitoring



## Compliance Monitoring: PCF Survey Data

*Please describe the monitoring metrics you find effective:*



**PQA Focuses on “Compliance Red Flags” and Potential Signals**

# Promotional Quality Assurance (PQA) Program Approach



- 1. *Better Leverage of Data*** - Leverage technology and data to detect potential compliance issues
- 2. *Enable Short-Term Monitoring Program*** - Provide necessary analysis to product attorneys and compliance professionals to support proactive management of potential issues before they become widespread
- 3. *Develop a Long-Term Monitoring Architecture*** – design and implement a sustainable solution that consolidates information and provides robust analytics and reporting for greater insight, flexibility and timeliness

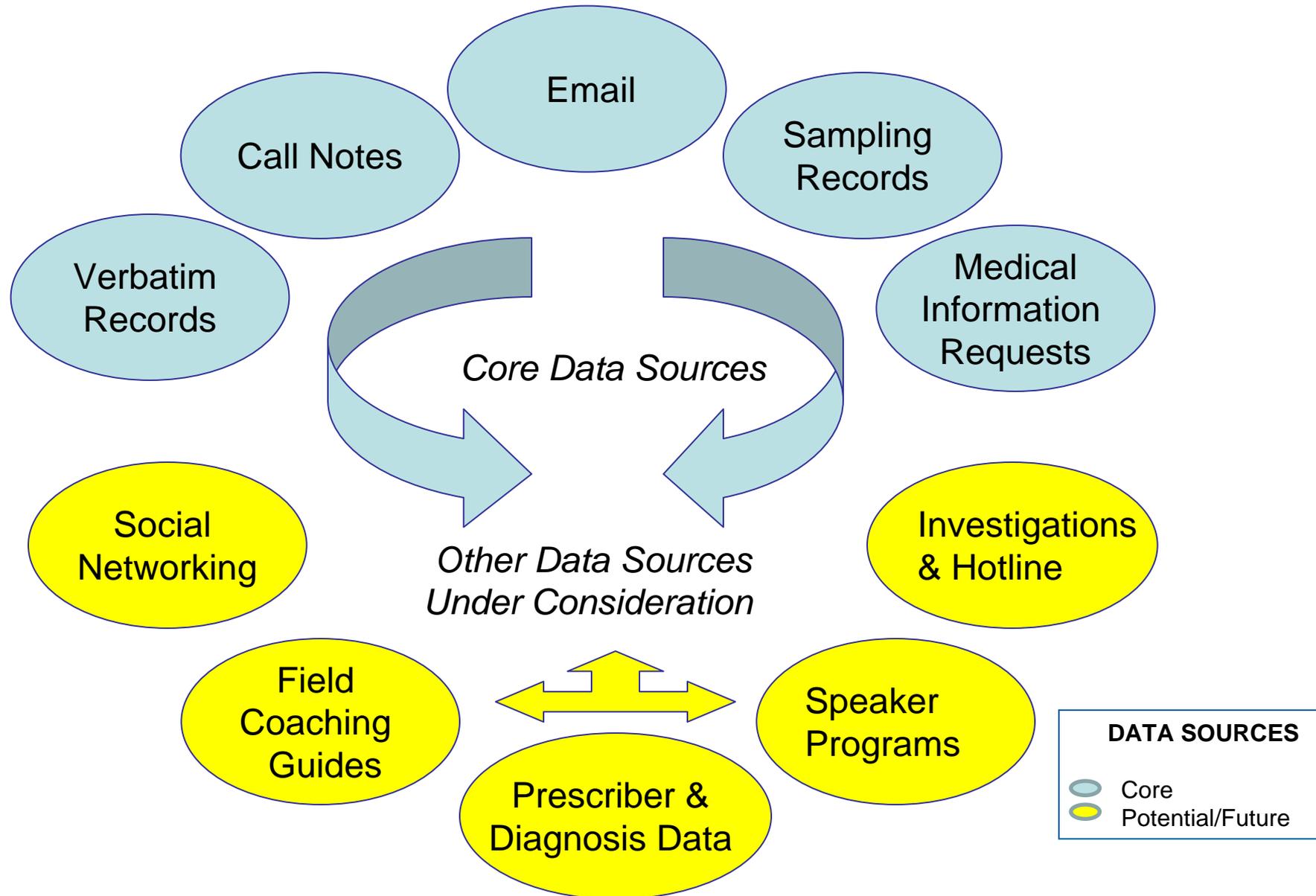
# Promotional Quality Assurance (PQA) Program Approach



## 1. Better Leverage of Data

- **Inventory all promotional & information exchange activities across the organization. Examples include:**
  - ✓ Field Sales
  - ✓ Contract Sales & Alliance Partners
  - ✓ Marketing (Direct and Non-Personal)
  - ✓ Compliance
  - ✓ Legal
  - ✓ Finance
- **Prioritize these sources based on monitoring value and other considerations**
- **Evaluate both existing internal data sources and emerging external secondary health data sources**
- **Conduct preliminary statistical data analysis to identify insights that can be derived and options for consideration to proactively recognize potential issues**

# Promotional Quality Assurance (PQA) Program Approach



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## 2. Enable Short-Term Monitoring Program

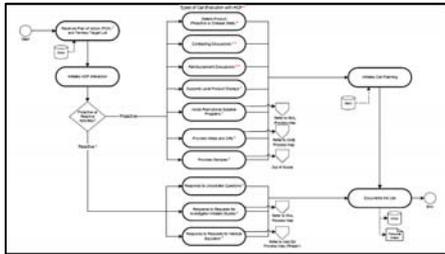
- **After prioritizing what to monitor, the organizational model, including roles and responsibilities, processes, and job aides were designed to:**
  - ✓ Define how to regularly review various sales and marketing activities
  - ✓ Identify potential areas of concern
  - ✓ Summarize and report information to appropriate stakeholders
  - ✓ Collaborate with other functions in designing corresponding protocols to escalate and resolve
- **Interim technology solutions were designed to assist the group in reviewing and reporting information across functions, geographies, and business units**

# Promotional Quality Assurance (PQA) Program Approach



## High-level Promotional Monitoring Process Flow

### Map Field Force Promotional Activities



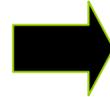
### Identify Available Data Elements



### Define Risk Indicators



### Mine Data



### Analyze and Trend



### Reporting and Remediation



*Activities are Informed by the  
Company's Product-Based Risk Assessment Program*

# Promotional Quality Assurance (PQA) Program Approach



## 3. Develop a Sustainable Monitoring Architecture

- **Leveraging current standards and business technology infrastructure, design and implement a future state scalable architecture for permanent, ongoing promotional monitoring across the product portfolio**
- **The longer-term sustainable solution:**
  - ✓ Integrates data directly from the source, eliminating duplicate creation/storage and manual loading processes
  - ✓ Consolidates data and information into a central organizational repository for better data aggregation and enhanced analysis
  - ✓ Creates the foundational framework for the enterprise that can be leveraged by other monitoring functions
  - ✓ Provides robust reporting and analytical tools to create more insightful standard reports and dashboards showing informative trends and patterns of activity over time

# PQA Success Factors



- Strong, regular collaboration with Compliance, Legal, and Business Colleagues
- Development of product-specific expertise
- Effective leveraging of existing technologies and data sources
- Continuous process improvement
- Transparency in communication
- More informed certifications

# Questions?