Advanced Issues in Commercial Compliance

Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum
November 11, 2009

Source Data for Monitoring & Compliance

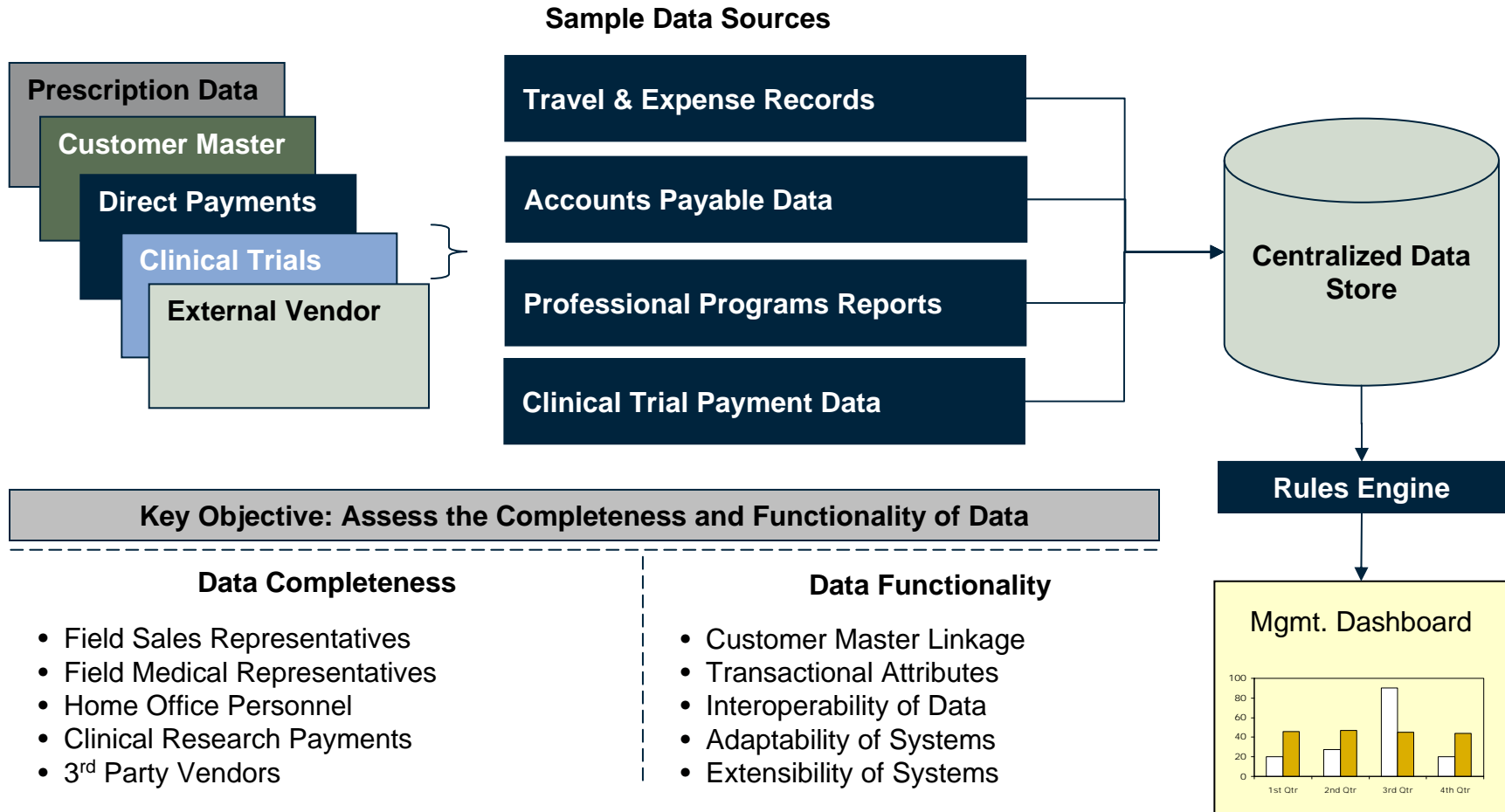## Using Core Transactional Data for Monitoring

Understanding the enterprise systems and the operational transactions across the various functional areas is critical to developing a monitoring strategy.

Functional Dataset	Off-Label Monitoring Focus
• SFA System	▪ Analysis of HCP specialties and prescribing patterns
• Aggregate Spend Database	▪ Profile for HCPs that are frequently used by the Company for fee-for-service activities ▪ Changes in prescribing can "flag" HCPs for additional analysis
• Syndicated Prescription Data	▪ Rx activity of HCPs that haven't been detailed by the Company ▪ Prescribing behavior in relation to sales call details
• Diagnosis Panel Data	▪ Diagnosis panel data such as NDTI and PDDA to analyze off-label usage and "at-risk" HCP specialties
• Longitudinal Patient Data	▪ Specific analysis of patient level data with diagnosis codes can provide insight into specific prescribing and utilization patterns resulting from off-label promotions
• Requests for Medical Information	▪ Analysis of an individual rep's requests for medical information
• KOL Tracking Activities	▪ Company interactions with KOLs that have a focus in off-label thought leadership may provide insight into potential risk areas (affiliations with other doctors)
• Continuing Medical Education	▪ General trends in CME and Company sponsorship of CME may provide insights into potential off-label risk areas
• Investigator Sponsored Trials	▪ The nature and selection of the Company's ISTs can provide potential insight into off-label risk areas

Data Assessment and Review of Source Data Systems

Source Data Systems Required for Monitoring Purposes

Utilizing the data sources covered in the previous slides and coupled with promotional data, models can be created to now proactively monitor compliance as opposed to reacting to compliance challenges.

Sample Data Sources

Prescription Data

Customer Master

Direct Payments

Clinical Trials

External Vendor

Travel & Expense Records

Accounts Payable Data

Professional Programs Reports

Clinical Trial Payment Data

Centralized Data Store

Rules Engine

Mgmt. Dashboard

Key Objective: Assess the Completeness and Functionality of Data

Data Completeness

- Field Sales Representatives
- Field Medical Representatives
- Home Office Personnel
- Clinical Research Payments
- 3rd Party Vendors

Data Functionality

- Customer Master Linkage
- Transactional Attributes
- Interoperability of Data
- Adaptability of Systems
- Extensibility of Systems

Development of Monitoring Models

An Iterative Approach to Development and Implementation

| Develop HCP Level Decision Models at the Channel Level	Create Risk Curves Based on Specific Tolerance Thresholds	Roll-up Channel Models Into Strategic Risk Management Model & Optimize for Alerts	Providing Predictive Analytics to Address Key Monitoring Objectives
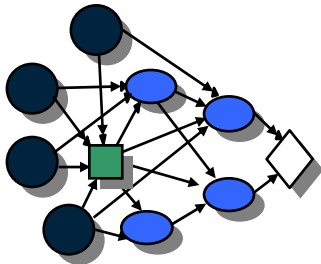
Determines risk sensitivity to channel tactics

Captures the action-reaction dynamic of activities that may influence HCP behavior
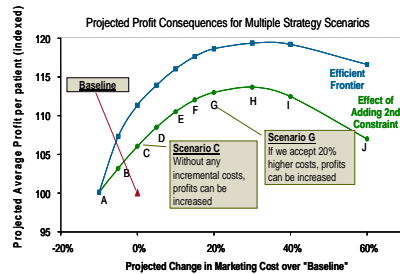
Map field and home office actions to identify potential risk thresholds

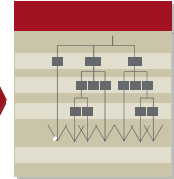Allows for the application of multiple factors on a weighted basis
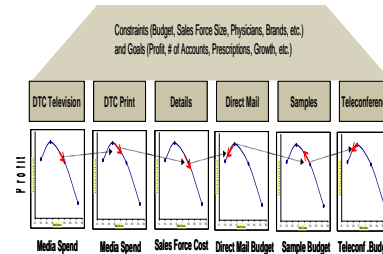
Captures interaction effects of channel tactics

Addresses carryover effect from various channels

Derives strategic - level activity reports

Strategic to tactical linkage enables guidance and optimization of Risk alerts

Creates optimized monitoring reports by objective

Dashboards Created for Compliance Monitoring

Creation of Various Dashboard Views Based on Technical Requirements

After creating models utilizing internal and external data sets, dashboards can be created to effectively monitor compliance and alert on suspicious activity.
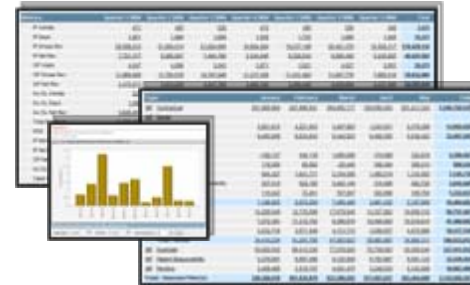
Strategic View
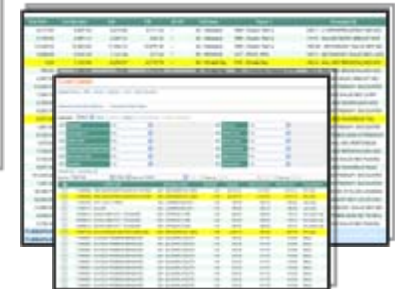
Executive Scorecards

Manager View

Personal Dashboards

Operational View

Root-Cause Analysis

Work List View

Transaction Detail