Collecting and Using 3rd Party Data for Effective Monitoring

Transparency and 3rd Party Compliance Requirements

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LIFE SCIENCES ADVISORY SERVICES




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The Unintended Consequences of Disclosure

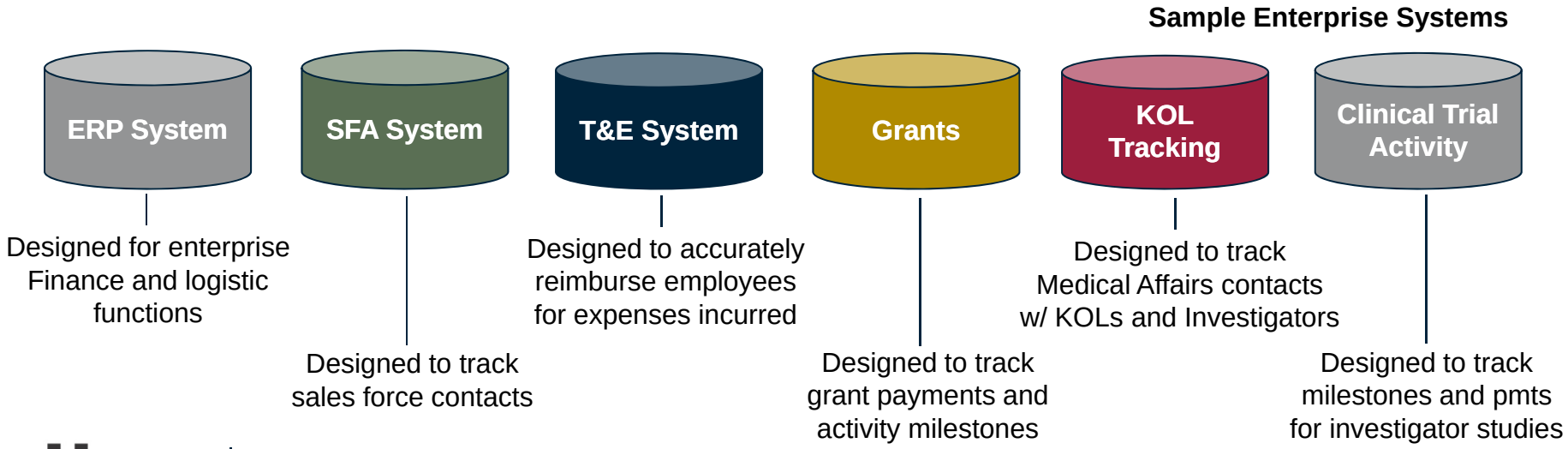
Understanding Your Data

- Disclosure is forcing the industry to assess its internal procedures for engaging and compensating healthcare professionals (HCPs).
- As enterprise level data on direct and indirect payments are collected and disclosed, manufacturers face potential scrutiny from various entities:
  - Regulatory Agencies
  - Enforcement Authorities
  - Customers
  - Business Partners
  - Public
- Manufacturers must preemptively analyze information before making disclosures:
  - Ensure accuracy and completeness
  - Identify potential business risk
  - Assess “downstream” compliance risk

Developing a Compliance Framework for Data

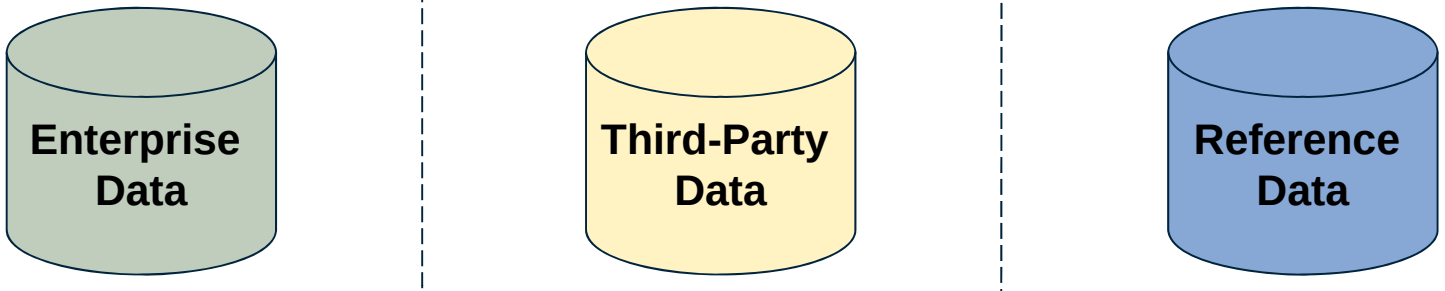
Implementation of Quality Standards

- Data can only be as good as the standards under which it was collected.
- Develop a **data governance** strategy for all enterprise systems, third-party systems, and reference data sources that has a focus on regulatory compliance requirements:
  - Availability;
  - Usability;
  - Integrity; and
  - Security.
- Identify the key stakeholders needed to support the initiative (e.g., Compliance, IT, Procurement, Marketing, Clinical, etc.).



The Data Landscape

Managing Your Data Sources

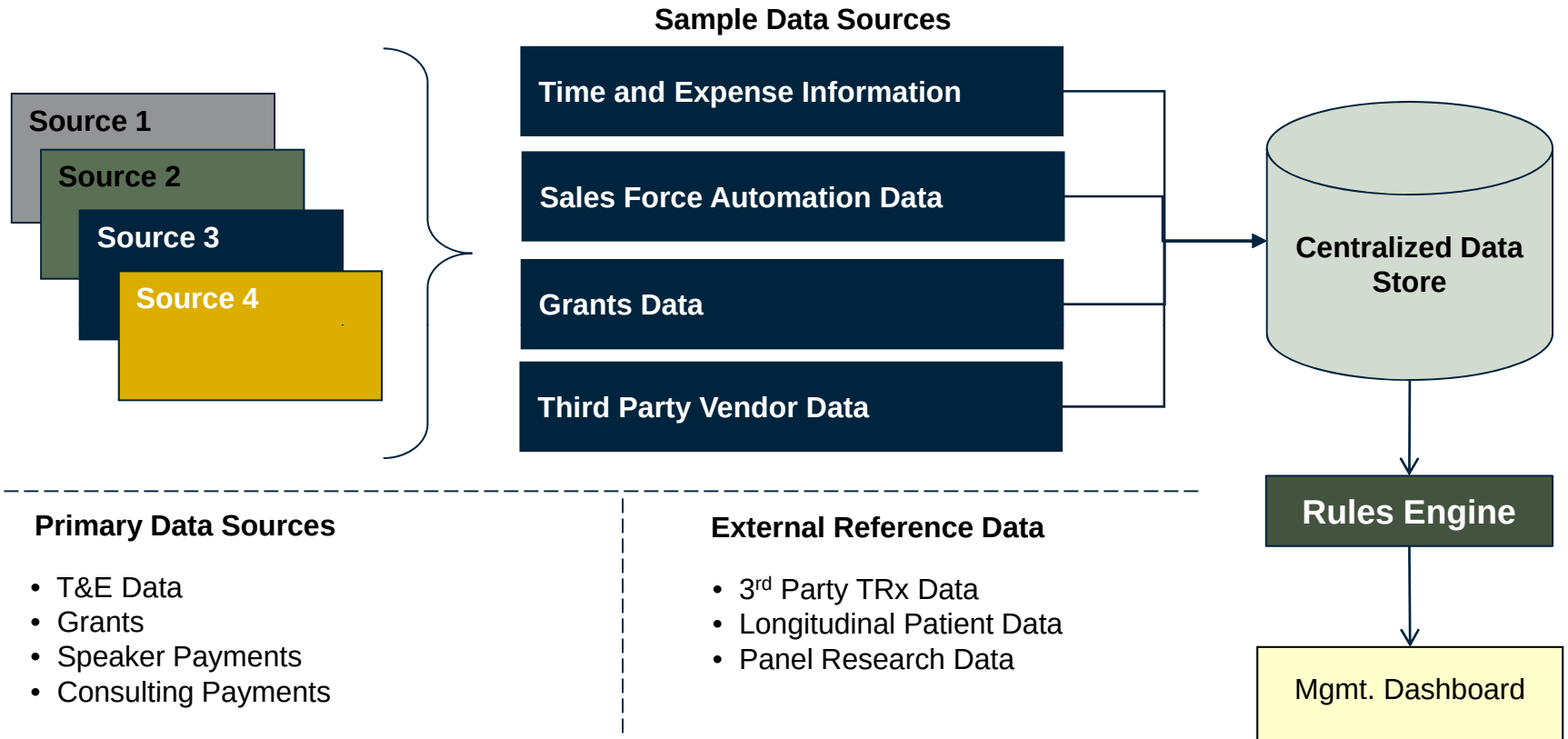


Enterprise Data	Third-Party Data	Reference Data
Travel & Expense	Speaker Programs	HCP Master
Accounts Payable	Advisory Boards	HCO Master
Sales Force Automation	Patient Advocacy	Affiliations Master
Grants	Meeting Management	
KOL Tracking		
Clinical Trial Activity		

- The data governance strategy must be implemented across all enterprise systems, third-party data sources, and reference data sources in the organization.
- The strength of an organization's spend reporting framework is as good as the "weakest link" in the process (internal and external sources)

Developing an Analytical Architecture

Building an Data Infrastructure



Primary Data Sources

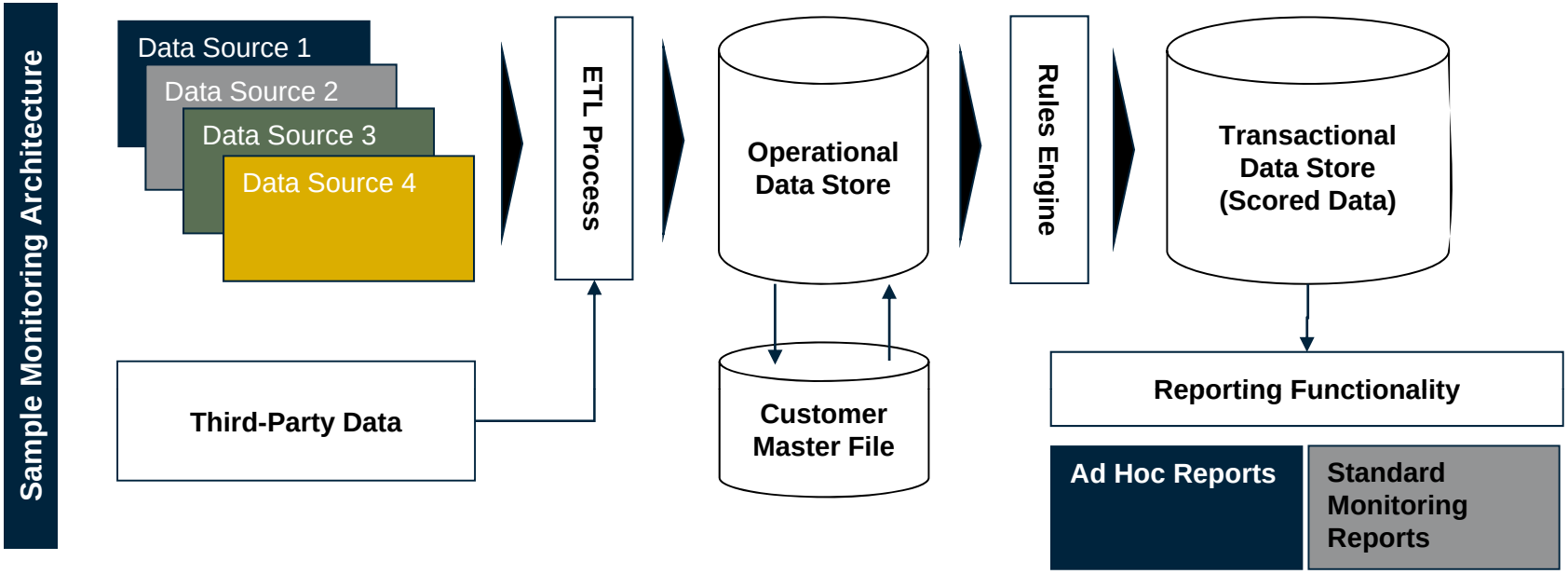
- T&E Data
- Grants
- Speaker Payments
- Consulting Payments

External Reference Data

- 3rd Party TRx Data
- Longitudinal Patient Data
- Panel Research Data

- An analytical architecture should consider a centralized data store for aggregate spend data monitoring and analysis
- Consideration must be given to the selection of a flexible analytical platform such as a rules engine

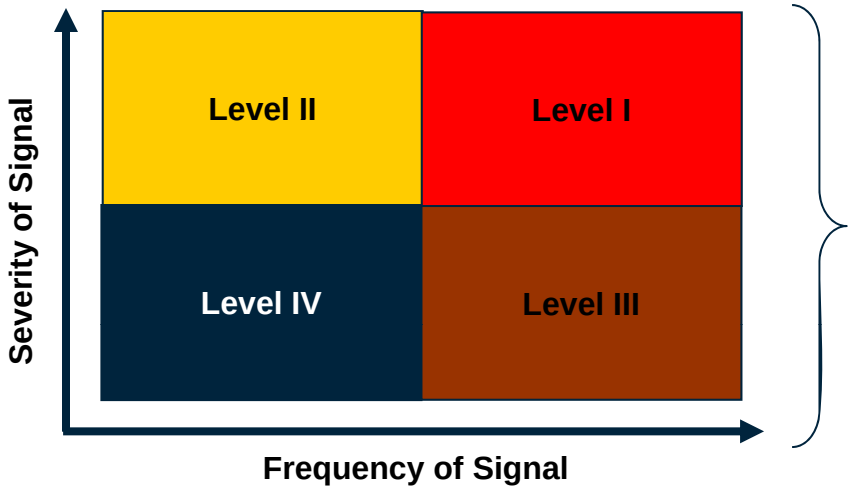
Scaling an Architecture Built to Support Aggregate Spend Tracking



- Most organizations have developed a framework for State Reporting and Sunshine Act provisions that can likely be leveraged for monitoring and analytics.
- Companies should consider how the existing architecture can be scaled based on the needs of broad based analytics and monitoring objectives.
- Various levels of reporting functionality can be incorporated into the architecture through existing reporting applications (e.g., Cognos, Business Objects, etc.) to accommodate both standard reporting and ad hoc reporting needs.

Developing a Framework of Predictive Analytics

Integrating Core Transactional Datasets to Develop Risk-Based Scores



Developing a Risk Based Scoring Mechanism

By developing a risk-based weighting to various types of transactional signals, a broad predictive model can be developed to identify specific brands, sales teams, districts, or individuals responsible for transactions that have caused a threshold alert to be created. Based on the level of the alert, a secondary review could be initiated based on the level of the transaction.

Threshold Score = $W_1(A) + W_2(B) + W_3(C) + W_4(D)$

- Companies could use its experience with compliance monitoring and investigations to develop risk based scores that are good indicators of predictive risk for issues such as "off-label" messaging or promotional quality.
- The models could score individual employee transactions and physician behaviors based on pre-assigned values weighted for the individual's activity.
- The transactions would typically be aggregated and analyzed through a predictive model. The model would then create a risk alert based on the severity of the score.

Developing Various Levels of Monitoring Models

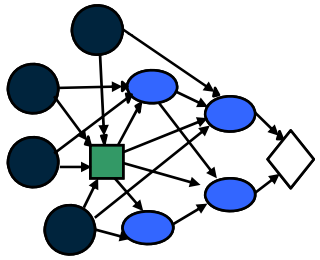
An Iterative Approach to Development and Implementation

Develop HCP Level Decision Models at the Channel Level

Create Risk Curves Based on Specific Tolerance Thresholds

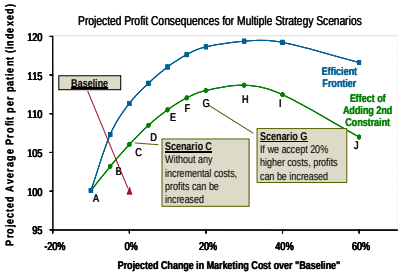
Roll-up Channel Models Into Strategic Risk Management Model & Optimize for Alerts

Providing Predictive Analytics to Address Key Monitoring Objectives



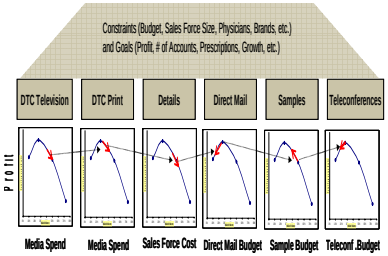
Determines risk sensitivity to channel tactics

Captures the action-reaction dynamic of activities that may influence HCP behavior



Map field and home office actions to identify potential risk thresholds

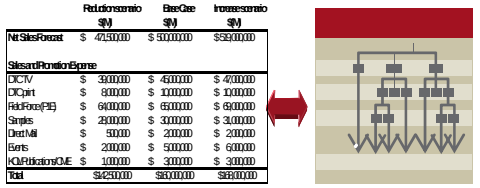
Allows for the application of multiple factors on a weighted basis



Captures interaction effects of channel tactics

Addresses carryover effect from various channels

Derives strategic - level activity reports

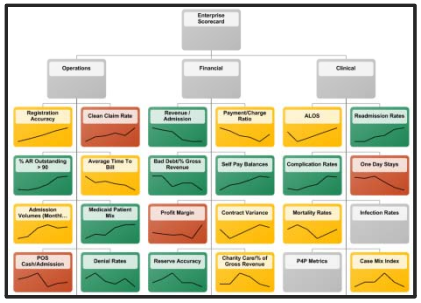
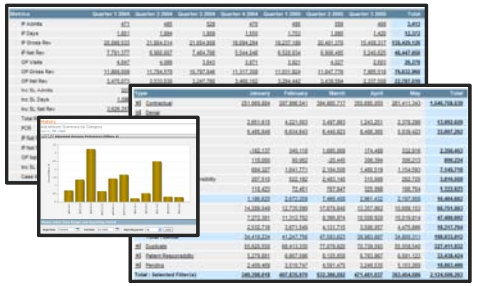
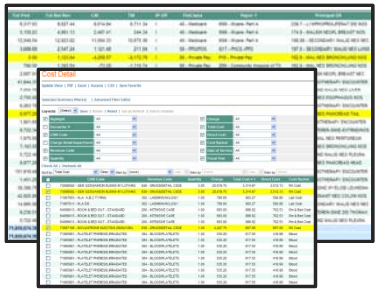


	Reduction scenario $M	Base Case $M	Increase scenario $M
Net Sales Forecast	$ 475.0000	$ 500.0000	$ 590.0000
Sales and Promotion Expense			
DTC TV	$ 30.0000	$ 45.0000	$ 40.0000
DTC print	$ 8.0000	$ 10.0000	$ 10.0000
Field Force (FTE)	$ 60.0000	$ 65.0000	$ 65.0000
Samples	$ 25.0000	$ 30.0000	$ 30.0000
Direct Mail	$ 5.0000	$ 20.0000	$ 20.0000
Events	$ 2.0000	$ 5.0000	$ 6.0000
KOL Publications/CME	$ 1.0000	$ 3.0000	$ 3.0000
Total	$ 425.0000	$ 500.0000	$ 590.0000

Strategic to tactical linkage enables guidance and optimization of Risk alerts

Creates optimized monitoring reports by objective

Developing Templates and Reports

Strategic View	Manager View	Operational View	Work List View
			
Executive Scorecards	Personal Dashboards	Root-Cause Analysis	Transaction Detail

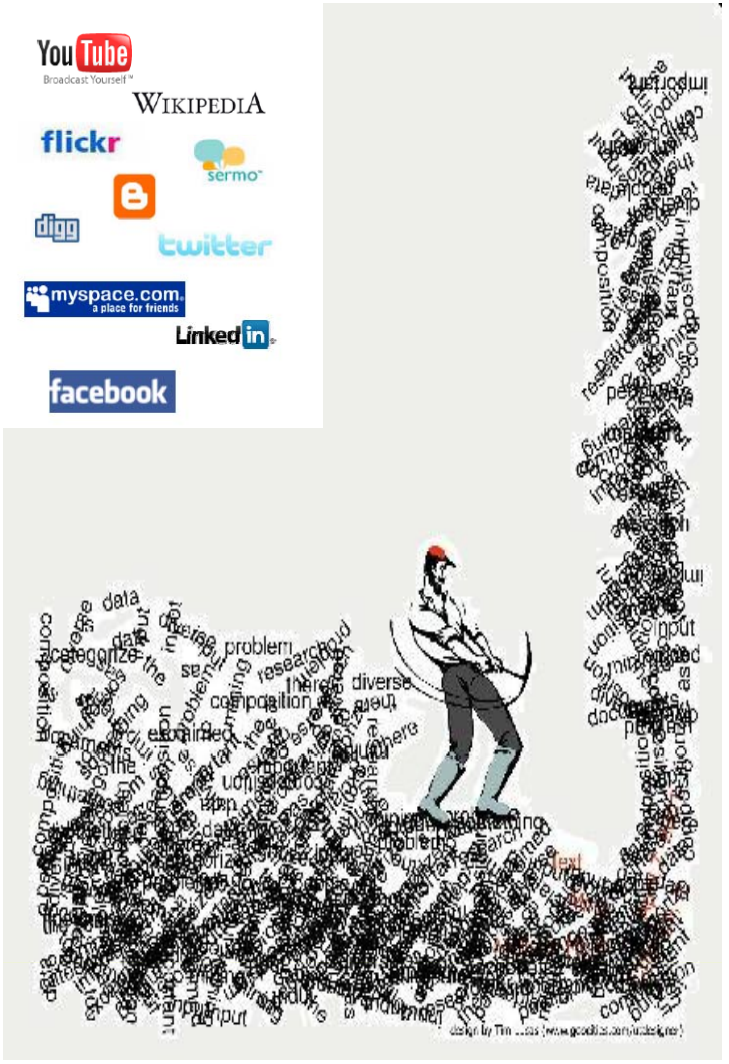
- In developing the longer-term vision for data driven monitoring, the appropriate architecture can allow companies to use various levels of reporting and analytics across the organization to address needs ranging from compliance to operations (e.g., spend optimization, field force management, etc.).
- A flexible platform would allow an organization to set user based access to control the usage of data and ensure appropriate application of the information by the user.

Text Mining / Analytics for Risk Management

Text Mining Can Broaden Compliance Monitoring to Other 3rd Party Sources

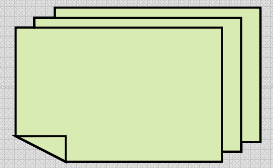
Advanced text mining technology can:

- Leverage vectors to automatically identify predictive patterns in unstructured data
- Identify previously unknown word associations that are predictive of a particular outcome
- Improve predictive model performance of off-label promotions
- Provide “reason codes” that structured data cannot and tailor treatment business rules for alerts
- Create models not supported by structured data
- Identify trends not easily seen in structured data
- Search for missing/inconsistent data
- Gain behavioral insight



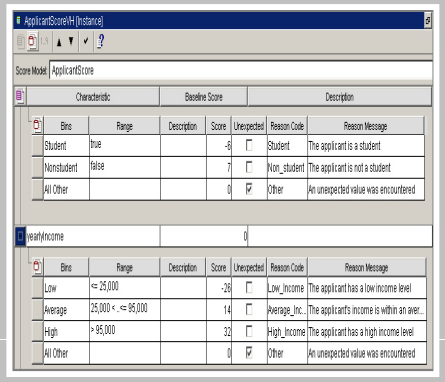
Information Driven Business Decisioning

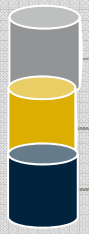
Data	Advanced Analytics	Business Rules
Structured / Unstructured	Data Mining / Scorecard	Decision Technology



Aggregate Spend Data

- Data Analysis
-Suspicious Activity
- Additional Data Sets
-Historical violations



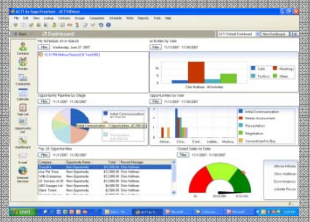


T&E Reports

A/P Reports

MI Requests

Dashboard



Alerts

Business Rules Service component

Business Rules, Trees, Models

Experience.**Redefined.**™

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