



Medical Affairs Monitoring

12th Annual Pharmaceutical Regulatory and Compliance
Conference and Best Practices Forum

November 3, 2011

 **ERNST & YOUNG**
Quality In Everything We Do

Objectives

- ▶ Understand the drivers for monitoring Medical Affairs activities
- ▶ Review leading practices in developing and deploying compliance monitoring
- ▶ Discuss approaches to monitoring common Medical Affairs activities

Role of Medical Affairs

- ▶ Unique to a company
- ▶ Unique to various company business units
- ▶ Common potential “high risk” Medical Affairs activities
 - Meetings with HCPs (advisory boards, formulary presentations, dissemination of medical information)
 - Medical information inquiries
 - Product information and materials preparation/review
 - Educational grants
 - Research grants
 - Speaker training
 - Post market studies
 - Publications
 - Compendia submissions

Why is monitoring important?

- ▶ Trust but verify
- ▶ Assess effectiveness of compliance controls
- ▶ Assess relevance of controls in place

Cost of non-compliance

- ▶ Record-level settlements
 - 2010 recovery of >\$4B from pharma and medical device related settlements
 - Recoveries in the billions for off-label settlements

- ▶ CIA monitoring obligations applicable to Medical Affairs
 - Medical inquiries
 - Materials disseminated to HCPs
 - Medical affairs interactions with HCPs
 - Educational grants
 - Research grants
 - Publications
 - Compendia materials

Monitoring defined

- ▶ Monitoring is the process and technology used to detect issues associated with the organization's compliance controls
 - Informs key stakeholders and fosters transparency
 - Establishes compliance baselines and measures progress over time
 - Focuses judgmental audits

Maturity model

Monitoring controls

	Basic	Evolving	Established	Advanced/ Optimized
Monitoring Ownership	<ul style="list-style-type: none"> No formal monitoring program in place 	<ul style="list-style-type: none"> Monitoring responsibilities have been delegated to management 	<ul style="list-style-type: none"> Areas that required proactive monitoring for high risk activities have been identified and accountability assigned 	<ul style="list-style-type: none"> Proactive monitoring activities for high risks activities embedded into daily functional operations
Monitoring Activities	<ul style="list-style-type: none"> Monitoring is conducted is on an ad hoc basis 	<ul style="list-style-type: none"> Some monitoring is performed on a subset of controls; however no formal monitoring plan in place across the organization 	<ul style="list-style-type: none"> Monitoring calendar and protocols, including responsible parties are in place for areas where risks have been identified 	<ul style="list-style-type: none"> Monitoring calendar and protocols in place for all controls with results linked to risk assessment and compliance training activities.
Upward Reporting	<ul style="list-style-type: none"> No formal process in place to track and report findings of monitoring activities or escalate compliance issues 	<ul style="list-style-type: none"> Informal processes in place for receiving and escalating incidents of non-compliance identified through the monitoring process 	<ul style="list-style-type: none"> Formal processes for reporting results of standard monitoring activities and escalating compliance issues to management 	<ul style="list-style-type: none"> Monitoring results used to update controls for high risk activities and compliance training

Observed trends in monitoring

► Metrics monitoring:

- Repeated calculation of key indicators within relevant focus areas
- Identification of outliers within a period and trends over time

Examples:













Focus area	Indicators	Frequency
Educational grants	<ul style="list-style-type: none">• Number of grants to a specific organization in the previous 18 months• Aggregate value of donations paid to an organization in the previous 18 months	<ul style="list-style-type: none">• Semi-annually
Research grants	<ul style="list-style-type: none">• Number of grants to a specific HCP in the previous 18 months• Aggregate value of grants paid to an HCP in the previous 18 months	<ul style="list-style-type: none">• Semi-annually
Medical Affairs interactions with HCPs	<ul style="list-style-type: none">• Number of Medical Affairs meetings per HCP• Number of meetings with HCPs per field-based Medical Affairs professionals	<ul style="list-style-type: none">• Quarterly

Enablers: common transactions systems, advanced reporting capabilities

Observed trends in monitoring

► Process monitoring through self-testing:

- Sample testing performed on transactions
- Diagnostic based upon guidance and controls
- Dashboard reporting

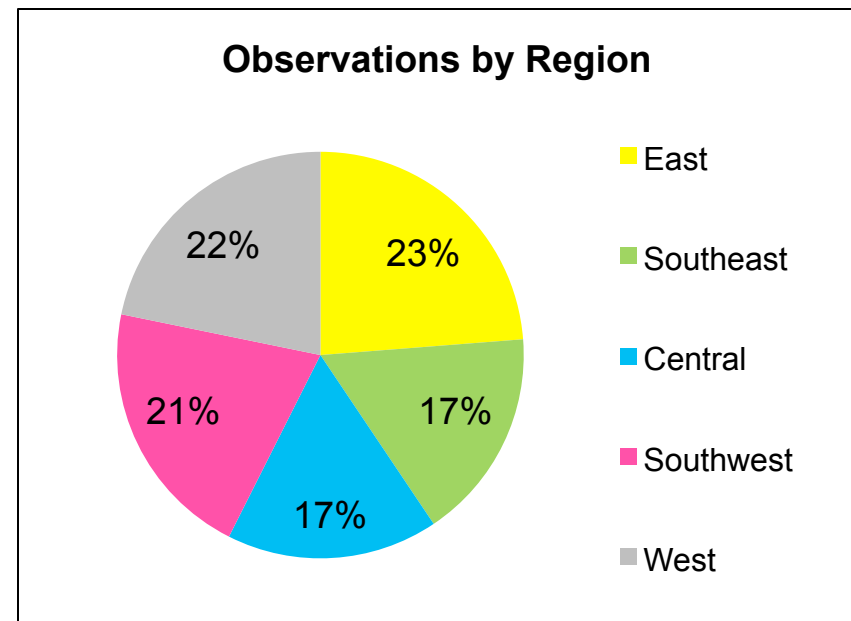
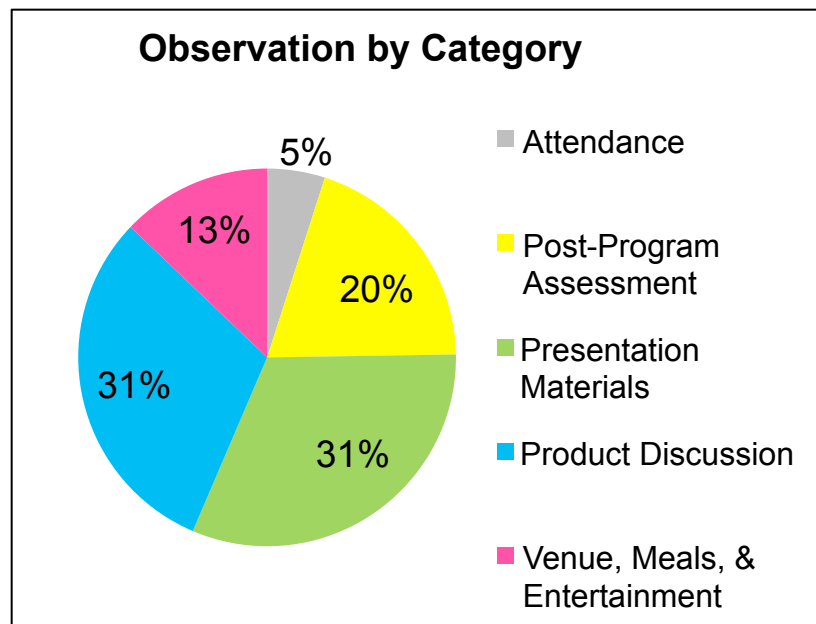
For example:	Division A			Division B		
	Results	Systemic drivers (SD)	Results less SD	Results	Systemic drivers (SD)	Results less SD
Medical information response		<ul style="list-style-type: none"> No centralized tracking of field-based medical affairs responses to unsolicited requests received by sale reps 				
Materials review and approval		<ul style="list-style-type: none"> Lack of documentation of re-approval of Medical Affairs materials disseminated to HCPs 				
Formulary meeting presentations		<ul style="list-style-type: none"> No documentation of unsolicited request for presentation of non-approved information 			<ul style="list-style-type: none"> No documentation of review and approval of Formulary meeting presentations 	

Observed trends in monitoring

► Field-based monitoring:

- Sample testing performed on events (e.g., ride-alongs, speaker programs, exhibits)
- Diagnostic based upon guidance and controls
- Trend analysis

For example:



Leading monitoring practices

Overall

- ▶ Monitoring plan informed by prioritized risks
- ▶ Local ownership
- ▶ Automated where possible
- ▶ Monitor unstructured data where possible
- ▶ Use of third-party resources when needed

Leading monitoring practices

Medical inquiries

▶ Metrics monitoring

- Number of medical inquiries submitted overall and per field-based Medical Affairs professional
- Number of medical inquiries per response delivery mechanism (e.g., Medical Information email response, field-based Medical Affairs professional direct response)
- Source of medical inquiries addressed by field based Medical Affairs professionals overall and per field-based Medical Affairs professional

▶ Process monitoring

- Request submission process (e.g., documentation of request, submission mechanism)
- Response process (e.g., mechanism, documentation)
- Response materials (e.g., approval process)

▶ Field-based monitoring

- Ride-along observation
- Exhibit observation

Leading monitoring practices

Materials disseminated to HCPs

- ▶ Metrics monitoring
 - Number of Medical Affairs submitted medical inquiries by type of request (e.g., formulary dossiers, slide decks)
- ▶ Process monitoring
 - Review and approval of materials disseminated by Medical Affairs
 - Re-approval of materials disseminated by Medical Affairs
- ▶ Field-based monitoring
 - Ride-along observation
 - Advisory board observation
 - Exhibit observation

Leading monitoring practices

Medical Affairs interactions with HCPs

▶ Metrics monitoring

- Number of HCP meetings overall and per Medical Affairs professional
- Number of HCP meetings overall and per Medical Affairs professional where sales was present
- Number of HCP meetings per meeting purpose (e.g., response to Medical inquiry, introductory meeting, researcher identification, formulary committee presentation) overall and per Medical Affairs professional

▶ Process monitoring

- Documentation of interaction

▶ Field-based monitoring

- Ride-along observation
- Advisory board observation
- Exhibit observation
- Joint Sales/Medical Affairs internal meeting observation

Leading monitoring practices

Educational/research grants

▶ Metrics monitoring

- Number of grant requests overall and per grant recipient and therapeutic area
- Number of approved grants overall and per grant recipient and therapeutic area
- Value of approved grants overall and per grant recipient and therapeutic area
- Number of denied grants overall and per grant recipient and therapeutic area

▶ Process monitoring

- Request process
- Review and approval process
- Payment process

▶ Field-based monitoring

- Ride-along observation

Leading monitoring practices

Publications (non-promotional)

▶ Metrics monitoring

- Number of approved publications overall and per therapeutic area
- Number of approved publications per authorship type (e.g., internal authors, contracted HCPs, contracted medical education provider) overall and per therapeutic area
- Funding for publication support per therapeutic area

▶ Process monitoring

- Review, approval and tracking of publication plan
- Review and approval of publication materials
- Contracting process for external support
- Disclosure confirmation

▶ Field-based monitoring

- Ride-along observation
- Advisory board observation

Leading monitoring practices

Compendia submissions

- ▶ Metrics monitoring
 - Current listings per product
 - Number of new/revised compendia submissions overall and per product
 - Number and amount of funding to each compendium
- ▶ Process monitoring
 - Review and approval of compendia submission materials
 - Review of existing compendia information
 - Approval of compendia payments
- ▶ Field-based monitoring
 - Advisory board observation
 - Formulary committee presentation observation

How important is data?

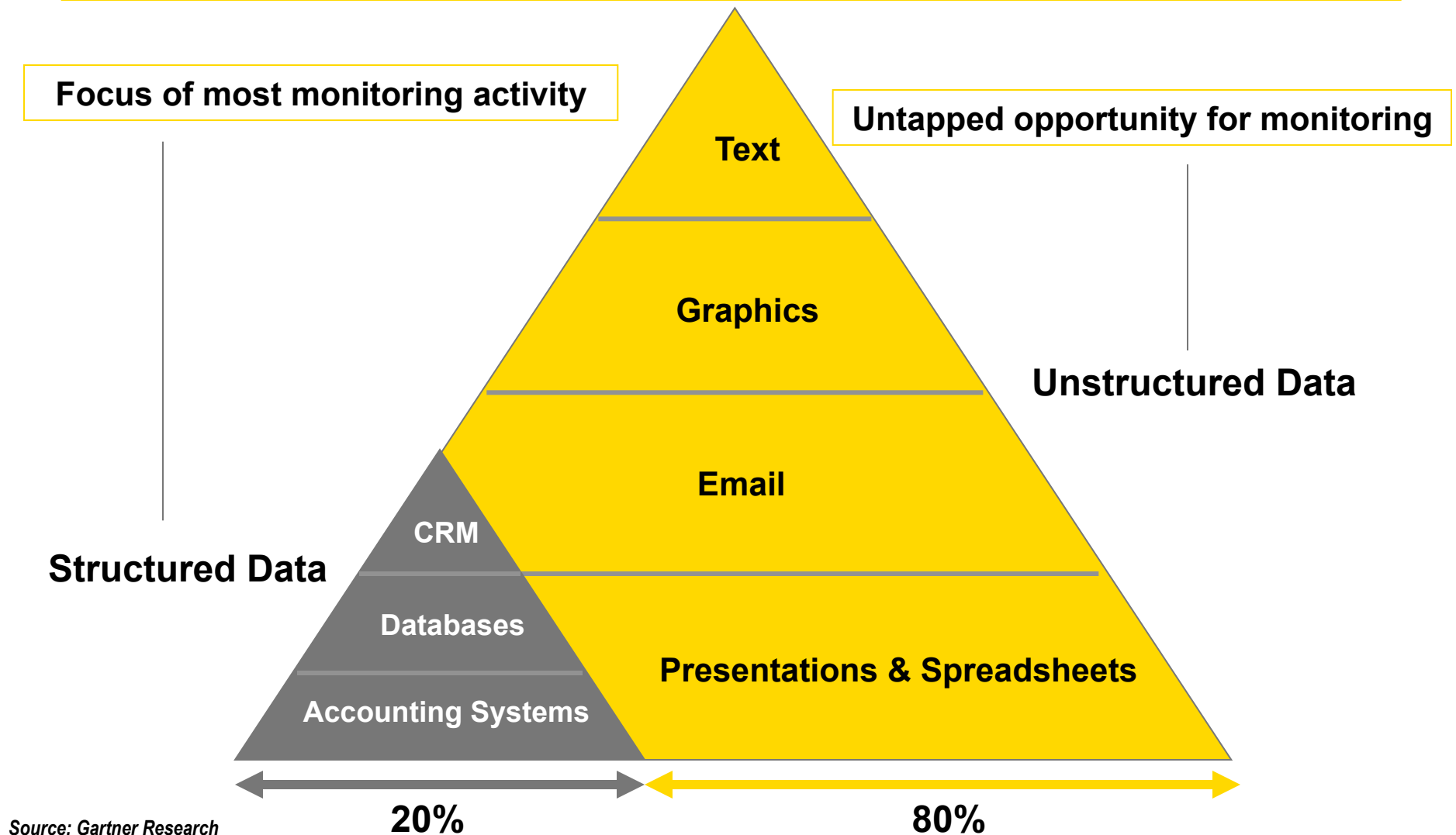
***“O.K. – let’s review
what you
didn’t know and
when you
didn’t know it.”***

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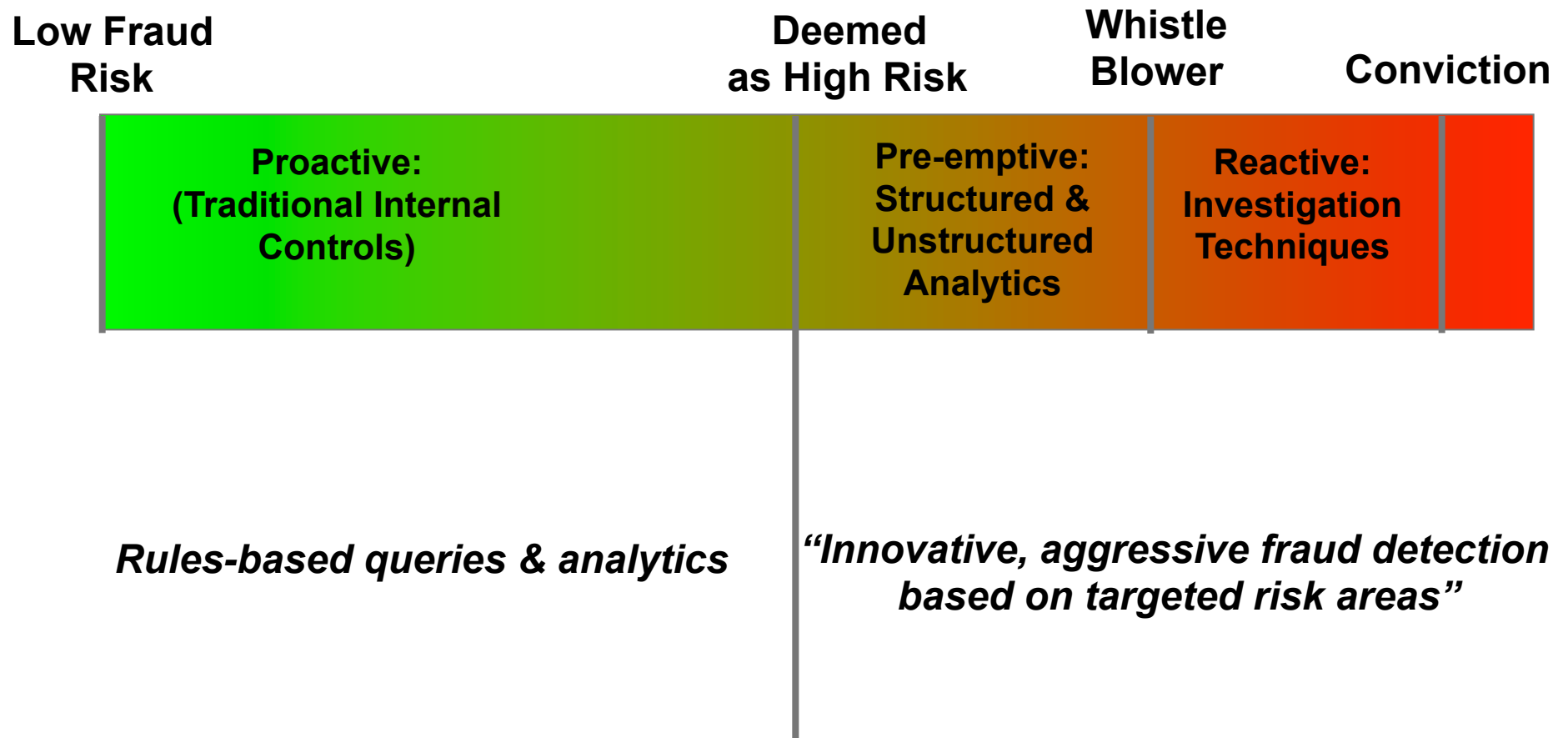


“O.K.—let’s review what you didn’t know and when you didn’t know it.”

Data sources in today's organization



Proactive analytics



The Fraud Triangle¹

Applying theory to electronic communications



1. Donald R. Cressey's "Fraud Triangle" ; Incentive/Pressure, Opportunity and Rationalization are present when fraud exists.

Advanced e-mail analytics

WHO



Social Networking

“Who is talking to whom?”

- People-to-people analysis
- Entity-to-entity analysis
- Map communication lines to organization chart

WHAT

Concept	Global	%	N	%
web site	13,736	321	15	
nearest store location	10,911	256	12	
help learning	8,558	200	9	
customer care	7,317	171	8	
change rate plans	4,322	101	4	
ring tones	3,851	90	4	
line work	3,766	88	4	
needed help	3,68	86	4	
minute charges	3,295	77	3	
new phone asao	3,295	77	3	
text messagino	2,867	67	3	
change address	2,781	65	3	
technical support	1,883	44	2	13
new faceplate	1,883	44	2	13
new plan	1,883	44	2	13
new phone	1,883	44	2	13
basic phone usage	1,626	38	1	
internet service	1,626	38	1	
manager asao	1,54	36	1	
oda	1,284	30	1	
new phone number	1,284	30	1	
new number	0,941	22	1	
xxx	0,813	19	0	92
metropolitan area	0,685	16	0	

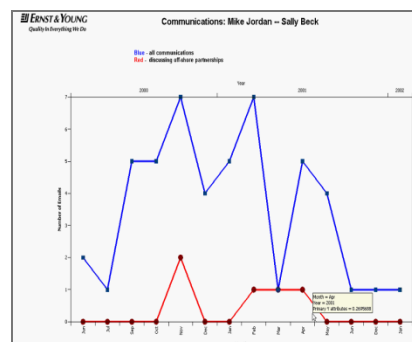
Concepts selected for scoring: 30 Total concepts available: 30

Concept Clustering

about what?

- Top words mentioned
- Key concepts / topics
- Top or unusual dollar amounts
- Sensitive words / phrases

WHEN

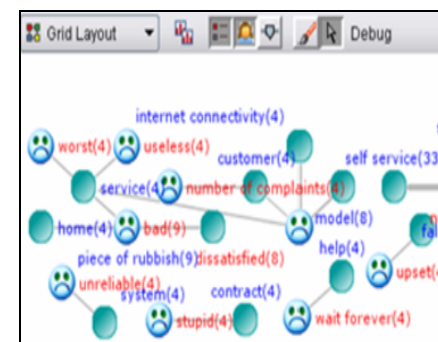


Communication Over Time

over which time period?

- When communications occur
- Communication spikes around key business events

WHY



Sentiment Analysis

how do they feel?”

- Positive vs. Negative Sentiment
- Top 10 angry emails
- Top 10 most concerned emails
- Customer survey analysis
- Employee survey analysis

Thank You!

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