



Anti-Bribery & Anti-Corruption Assessments

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Quality In Everything We Do

Agenda

- What are the risks?
 - Areas of corruption and bribery risk
 - Instrumentalities of fraud
- What should I do?
 - Considerations and expectations by US and UK regulators
 - Risk assessment
 - Targeted process
 - Anti-corruption analytics
 - Transaction review
 - Due diligence – “know your partners”
 - Assess gaps in compliance program
 - Monitoring and remedial efforts
- Practical considerations

Sample areas of corruption and bribery risk

Interaction with government officials/entities

- ▶ Sales
- ▶ Research & clinical development
- ▶ Regulatory approvals
- ▶ Immigration
- ▶ Customs
- ▶ Construction
- ▶ Tax/audit
- ▶ Product pricing
- ▶ Lobbying
- ▶ Manufacturing operations
- ▶ Interaction with HCP's working for state-owned hospitals
- ▶ Other licenses and permits
- ▶ Audits, inspections & other inquiries
- ▶ Tender process
- ▶ Formulary placement & reimbursement
- ▶ Legal proceedings
- ▶ Government inquiries

Sales-related third parties

Sales agent

- ▶ Any person or company that represents the company in an actual or proposed sales transaction and is paid a commission or any other remuneration for its services

Distributor

- ▶ Any person or company that sells company products and whose compensation is based on the mark-up it receives from these sales.
- ▶ Distributors may also act as agents on some transactions and receive a commission for their services.
- ▶ Distributors usually take title to the goods before reselling them.

Non-sales related third parties

- ▶ Consultants
- ▶ Lawyers
- ▶ Accountants
- ▶ Customs clearance agents
- ▶ Freight forwarders
- ▶ Lobbyists
- ▶ Contract research organizations (CRO)
- ▶ Contract manufacturing organizations (CMO)
- ▶ Agents
- ▶ Other third parties who provide education, marketing/legal research, event planning, assistance with congress planning or travel arrangements
- ▶ Other

Sample areas of instrumentalities of fraud

- Contracts and side agreements
- Payments and kickbacks
- Commissions and bonuses
- Credits, rebates, discounts
- Margins
- Advances and reimbursements
- Petty cash
- Distributors, contractors, consultants
- Donations
- Licenses, fees, duties, penalties

- Gifts
- Travel and entertainment
- Education, training, congresses
- Promotional activities
- Joint ventures
- Government partnerships
- Tender bidding
- Facilitation payments

Evaluate your global business units

Where should I go next?

- ▶ Evaluate policies and procedures
- ▶ Review the existing business units and locations analyzing information for at least a 2-year period including:
 - ▶ Points of government interaction, both direct and indirect
 - ▶ Revenues broken down by BU and locations
 - ▶ Expenses (totals as a % of revenue, high risk expense categories, variances)
 - ▶ Customer lists, including government customers
 - ▶ Personnel FTE's such as sales force, marketing, finance, legal and compliance
 - ▶ Sales model and compensation structure for commercial personnel
 - ▶ Review locations by Transparency International Corruption Perceptions Index ("CPI")
 - ▶ Prior audit history, hotline issues and other information obtained from legal
 - ▶ Identify any other high risk business activities such as joint ventures, acquisitions, R&D, clinical trials, changes in business practices, changes in economic conditions or competition, changes in compensation or incentive structure, etc.
- ▶ Assess gaps in global compliance program

“Know your business partner”

Open source research

- ▶ Global database research
- ▶ Reported criminal activity, regulatory violations/sanctions, negative press, and litigation activity on the company and members of the company’s executive team, board members, and significant shareholders
- ▶ Comprehensive check of all available sanctions and embargo and watch lists including Politically Exposed Persons (PEPs) databases
- ▶ Searches in both English and local languages
- ▶ Include business journals, websites, industry publications, and mainstream and local media

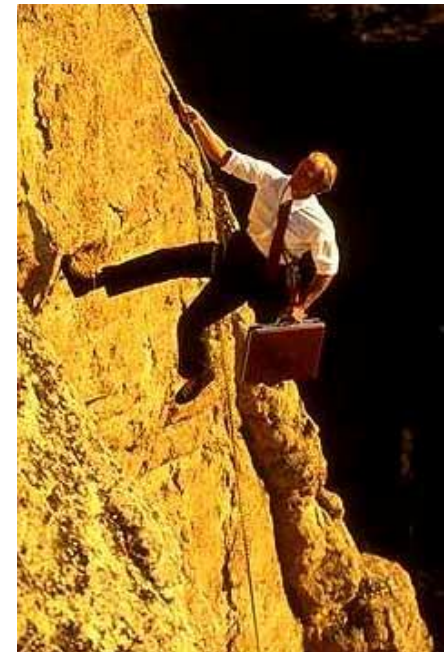
“Know your business partner”

Level II research

- ▶ Regional business registries
- ▶ Local government records
- ▶ Regional court/litigation databases
- ▶ Local press archives
- ▶ Other information sources within the geographic market area

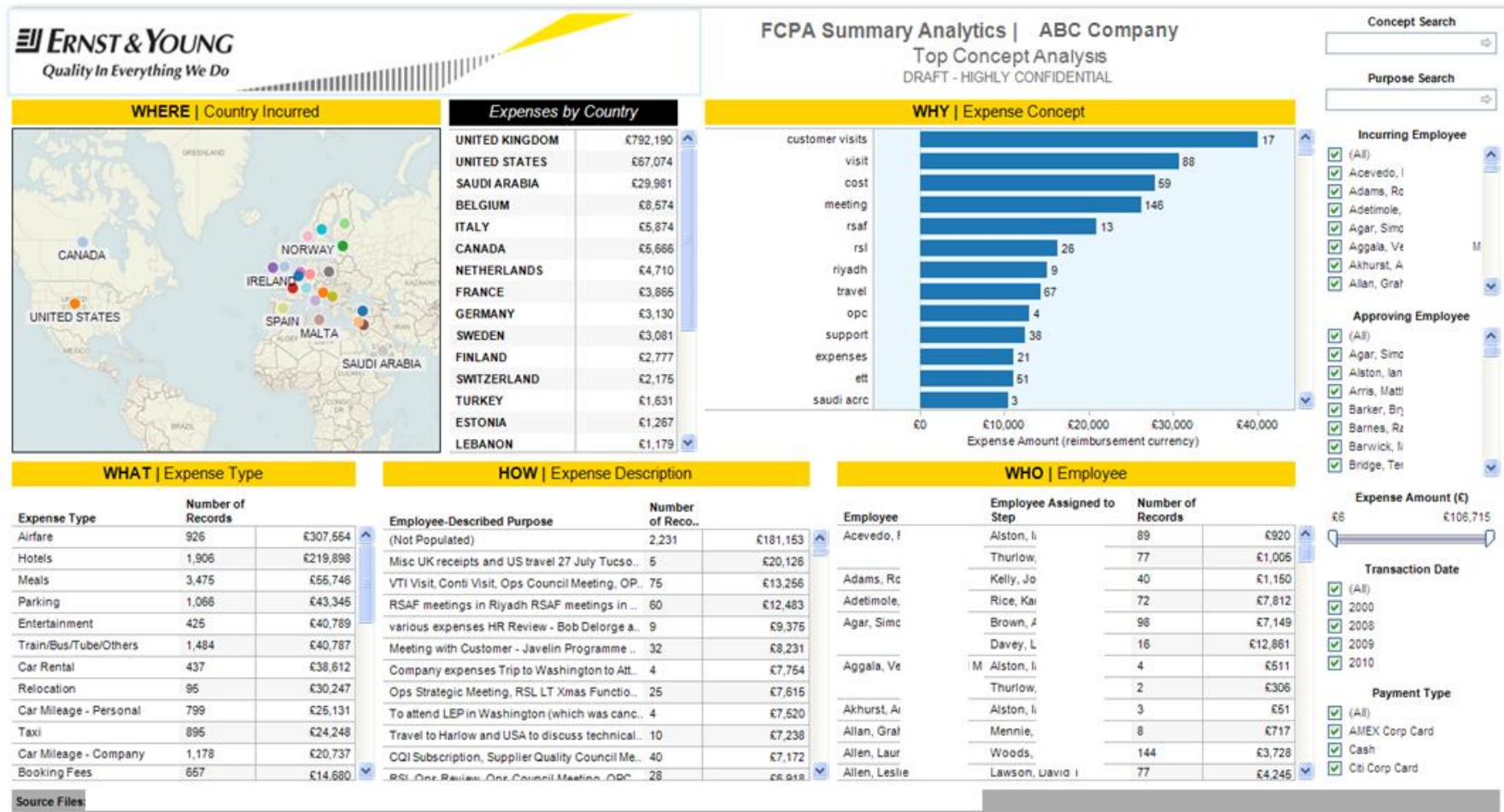
Anti-Bribery & Corruption (ABC) Analytics

- ▶ Enhance the risk assessment process through targeted data analytics
- ▶ Leverage text mining to identify potentially suspicious transactions/trends in the financial accounting data
- ▶ Focus on portions of the general ledger, travel and entertainment, business development activities, vendor payments data, cash payments
- ▶ Develop an analysis “dashboard”



ABC Analytics: expense review

Who, what, where, why, how...



ABC Analytics: disbursements analysis

Who said what in the journal entries?



FCPA Risk Assessment & Monitoring XYZ Manufacturing

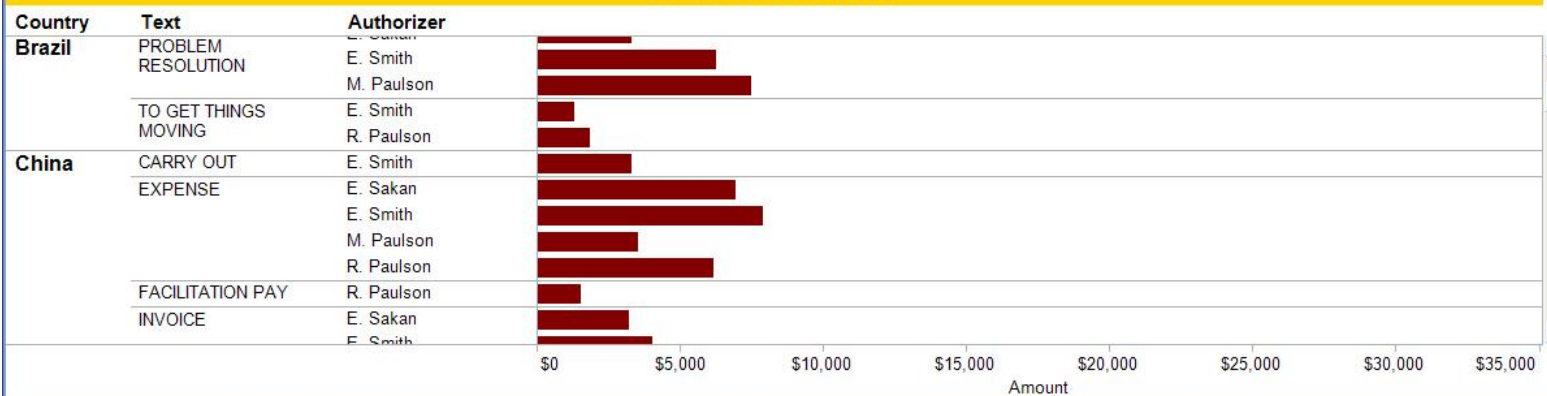
Disbursements to Review

199

Disbursements by Country



Disbursement Totals



My Filter Selections

Payment Type

- ☒ (All)
- ☒ Foreign Official
- ☒ Foreign Political Party
- ☒ Legitimate

Payment Authorizer

- ☒ (All)
- ☒ E. Sakan
- ☒ E. Smith
- ☒ J. Nelson
- ☒ M. Paulson
- ☒ R. Paulson

Disbursement Description

- ☒ (All)
- ☒ AIRPORT CONTROLLER
- ☒ CARRY OUT
- ☒ EXPENSE
- ☒ FACILITATION PAY
- ☒ HELP FEE
- ☒ INVOICE
- ☒ LOAD UP
- ☒ LOAD UP FEE
- ☒ MGMT FEE
- ☒ PROBLEM RESOLUTION
- ☒ REIMBURSE

Payment Date

- ☒ (All)
- ☒ February 2008
- ☒ March 2008
- ☒ April 2008
- ☒ May 2008
- ☒ June 2008
- ☒ July 2008
- ☒ August 2008

Practical considerations

▶ Preparation

- ▶ Involve cross-functional and global audit and compliance resources
- ▶ Use of questionnaires to scope business practices and risks
- ▶ Availability of information and people
 - ▶ Privacy issues
 - ▶ Local language
 - ▶ Data, financial documents, agreements
 - ▶ Holidays
 - ▶ Visas
- ▶ Internal audit
- ▶ Notice to local country

▶ Attorney-client privilege

Practical considerations

- ▶ Interviews
- ▶ Transaction review and sampling
- ▶ Third party audits
 - ▶ Audit rights
 - ▶ Third party database
- ▶ Due diligence procedures and protocol for addressing red flags
- ▶ Training as an opportunity
- ▶ Post integration review
- ▶ Intersection with anti-competition issues