

THE EVOLUTION OF RISK ASSESSMENT AND USING RISK ASSESSMENT TO DESIGN COMPLIANCE PROGRAMS

MINI-SUMMIT VII

ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

OIG Seven Elements (2003)

1. Policies & Procedures
2. Compliance Officer / Committee
3. Training
4. Communication
5. Auditing & Monitoring
6. Disciplinary Guidelines
7. Corrective Action

DOJ Guidance (2017)

1. Analysis & Remediation of Misconduct
2. Senior & Middle Management
3. Autonomy & Resources
4. Policies & Procedures
5. **Risk Assessment**
6. Training & Communication
7. Confidential Reporting & Investigations
8. Incentives & Disciplinary Measures
9. Continuous Improvement, periodic Testing & Review
10. Third Party Management
11. Mergers & Acquisitions

COMPLIANCE ASSESSMENT AND RISK EVALUATION

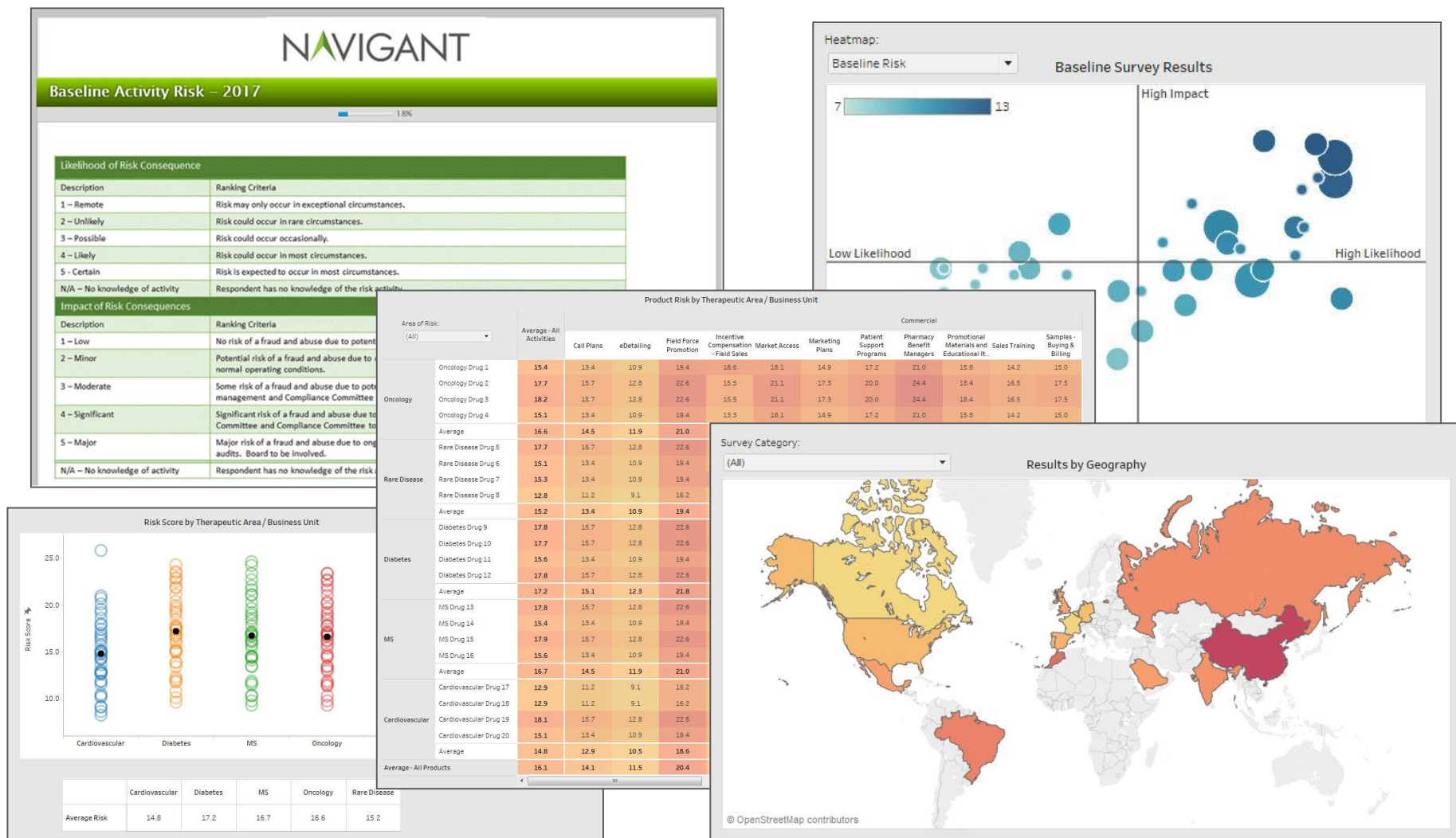
Proven propriety risk assessment methodology

Evaluates, quantifies, and prioritizes risk by involving stakeholders across the organization

Feeds auditing and monitoring plan

Accepted next-gen risk assessment process by the Office of Inspector General

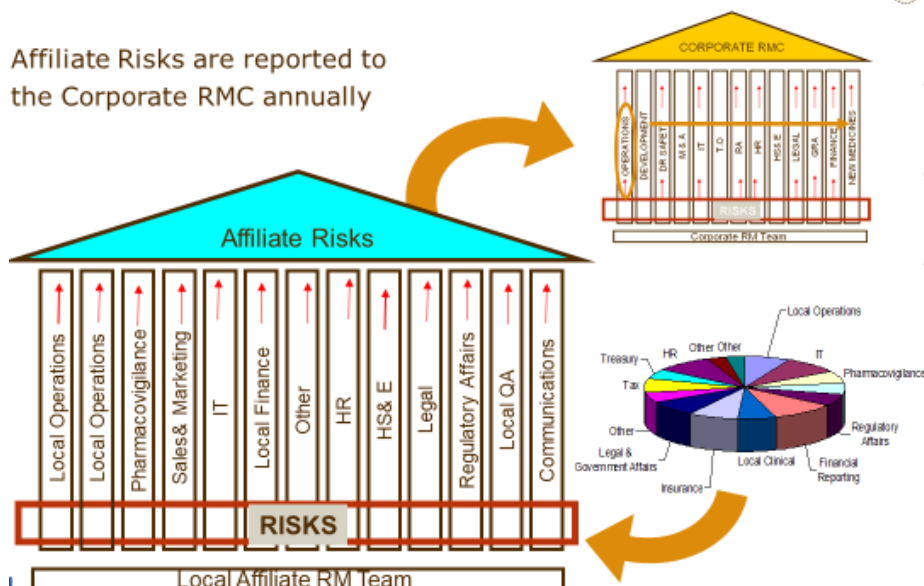
CARE RESULTS



ONE COMPANY'S RISK MEASUREMENT EVOLUTION

Risk Management in 2010

Affiliate Risks are reported to the Corporate RMC annually



To define the level of **IMPACT** locally, the following rating scale should be used:

To define the local **LIKELIHOOD**, the following rating scale should be used:

To define the local **MANAGEMENT CONTROL (MC)**, the following rating scale should be used

The colour of the risk placed on the Risk Matrix should match the colour as below

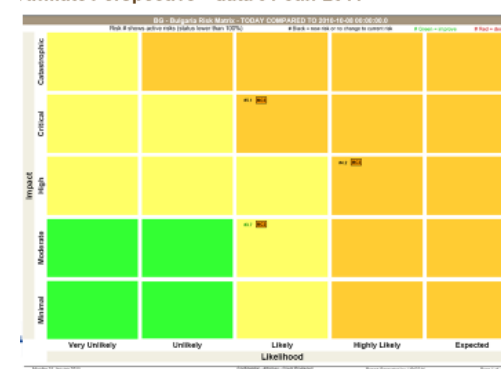


Ranking	Probability	Percentage of Probability
5	Highly ineffective	Management activities and/or controls are non-existent or have major deficiencies and don't operate as intended
4	Ineffective	Limited Management activities and/or controls in place, high level of risk remain
3	Significant improvement needed	Key management activities and/or controls in place, with significant opportunities for improvement identified
2	Limited improvement needed	Management activities and/or controls properly designed and operating, with opportunities for improvement identified
1	Effective	Management activities and/or controls properly designed and operating as intended

Risk Evolution Report

Risk Evolution for: BG - Bulgaria Comparison between 08-Jun-2010 and today						
#	Area	Summary	Tag	10-15	6-9	Status
1.1	Communications	Contracts with HCPs	Top Risk 2009		9	100%
2.1	HR	Back-ups for departments with 1 person	Top Risk 2009	10		
3.1	Medical Affairs	Local clinical experience needed	Top Risk 2009	11	7	100%
3.2	Medical Affairs	Local Clinical Experience - Reimbursement	Top Risk 2009	11	7	100%
3.3	Medical Affairs	Distillate for Activities Between Medical and Marketing Budgets	Top Risk 2009	10	8	100%
3.4	Medical Affairs	Cross Border Activities and ANP	Top Risk 2009	10	6	100%
3.5	Medical Affairs	Regional Stand Alone Events	Top Risk 2010	10	6	100%
3.6	Medical Affairs	Insurance in SPOT's trial with roflumilast	Top Risk 2010	10	6	100%
3.7	Medical Affairs	Compassionate Use Program	Top Risk 2010	10	8	50%
3.8	Medical Affairs	Med JPC and PV Reports	Top Risk 2010		8	100%
4.1	Regulatory Affairs	SDA Audit & Update to PV Procedure	Top Risk 2009	9		100%
4.2	Regulatory Affairs	Business agreements with VCS-pharmaceuticals	Top Risk 2010	10		50%
5.1	Financial Reporting	Local transfer price documentation	Top Risk 2010	10		25%

Affiliate Perspective – data 31-Jan-2011



ONE COMPANY'S RISK MEASUREMENT EVOLUTION

Risk Management in 2018

	A	B	C	D	E	F	G	H	I	J	K	L	M				
1	CONFIDENTIAL																
2			Analysis and Remediation of Underlying Misconduct	Senior and Middle Management	Autonomy and Resources	Standards, Policies and Procedures	Risk Assessment	Training and Communications	Confidential Reporting and Investigation	Incentives and Disciplinary Measures	Continuous Improvement, Periodic Testing and Review	Third Party Management	Mergers and Acquisitions (Due Diligence)				
3			How mature is your Affiliate's process for serious deviations and concerns tracking, analysis, reporting, follow up, and discipline?	How mature is the compliance-oriented culture in your Affiliate (tone at the top, open communication, etc.)?	How mature is the Compliance structure within your Affiliate (e.g., staff experience, qualified professionals, autonomy, independence from operational management)?	What is your	For current activities,	How mature is your	How mature is your	How mature is your	How mature is your	If your Affiliate	What is your Affiliates				
4						Area of CPM	A	B	C	D	E	F	G	H	I	J	K
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