



IsENBIS 21.10.2012

Integrating Operational and Financial Risks

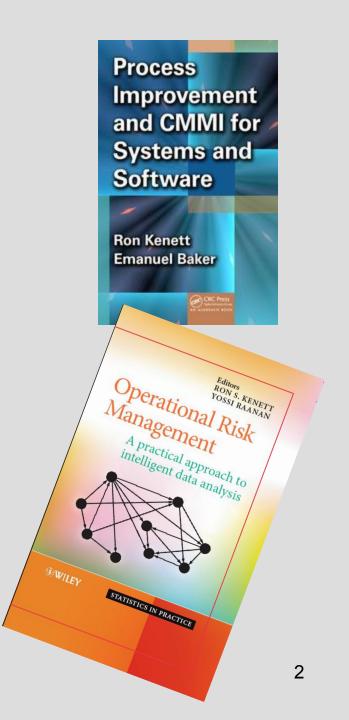
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Agenda

- Risk data
 - Qualitative Data
 - Semantic Daa
 - Financial data
 - Operational data
- 2. Case studies
- 3. Integrating risks





FCTN	FAILURE MODE	Failure Effects EFFECT	Severity (S)	Causes of Failure	Occurrence (O)	CONTROL	Detection (D)	RPN (Risk)	Plan PLAN
HPLC DS Impurities Method	Unknown Impurity is quantified which is not present in batch	Repeat Testing (if specification initially fails or atypical result is observed)	3	Contamination - glassware	4	Method states that Wheaton vial should be used in preference to volumetric flasks. Blank Injections	4	48	Develop wash procedure for Volumetric flasks (Detergent could react with Drug Substance)
		Repeat Testing (if specification initially fails result is		Contamination -	2	iny aberrant peaks	2	12	Ensure Blank Solutions are prepared exactly the way as for sples
		or pical rest	7	mination -	3	Injections should pick up any aberrant peaks Method states that Wheaton vial should be used in	2	10	same samples Develop wash
		Report invalid results Report invalid results	10	Contamination - glassware Contamination - sample handling	2	preference to volumetric flasks. Blank Injections Blank Injections should pick up any aberrant peaks	2	160	procedure for Volumetric flasks Ensure Blank Solutions are prepared exactly the same way as for samples
		Report invalid results	10	Contamination - solvents	3	Blank Injections should pick up any aberrant peaks	2	60	Ensure Blank Solutions are prepared exactly the same way as for samples Brainstorm what
		Report invalid results	10	HPLC method cannot detect it	2	Orthogonal analytical techniques should pick up other unknowns	3	60	potential impurities can be produced by process. Assess whether current methodology would pick these up
		Report invalid results	10	Co-elution with another named peak	2	None although considerable elevation in named impurity would lead to repeat testing	3	60	Assess impurity profile against historical batches
	-	Repeat Testing (if specification initially fails or atypical result is observed)	3	Poor quantification of peaks (setting of RT window)	2	Test mixture with elevated imps.	2	Qua 12	alitative Improve HPLC training

INTERNATIONAL STANDARD

ISO 31000



First edition 2009-11-15 GUIDE 73

SI 31010

מקן ישראלי ת"י 31010

Risk management — Principles and guidelines

Management du risque — Principes et lignes directrices

Risk management — Vocabulary

Management du risque — Vocabulaire

SI 14971

תקן ישראלי ת"י 14971 ISO 14971: 2000, FDAM 1: 2002

February 2003 ICS CODE: 11.040.01 אדר א התשס"ג - פברואר 2003



IEC/ISO 31010

Edition 1.0 2009-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Risk management - Risk assessment techniques

Gestion des risques - Techniques d'évaluation des risques

התקנים רפואיים - יישום ניהול סיכונים להתקנים רפואיים

Medical devices - Application of risk management to medical devices

BS 31100:2011

Risk management – Code of practice and guidance for the implementation of BS ISO 31000

System 1950 Update Beta Customer Survey

Dear custome

As part of the Beta test that your company is taking part of I would like to ask you some questions regarding the System 1950 Update. We value your feedback and intend to use it as the basis for future improvements of the hardware and software. Please answer the following questions, which should take an estimated 30 minutes of your time.

Before starting with the questions let me explain that on this survey you will be asked about the various new features of the System 1950 Update. The questionnaire objective is to hear your opinion regarding the improvements made in the System 1950 Update compared to the System 1950. The questionnaire will focus on your level of satisfaction from the improvement in your productivity, print quality and profleatibility generated by the new features.

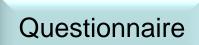
In order to answer these questions please state the number which best reflects how satisfied you

- feel about the subject asked, on a scale from 1 to 5 when:
- 5 means Very high satisfaction level
- 4 means High satisfaction level 3 means Average satisfaction level
- 2 means Low satisfaction level
- 1 means Very Low satisfaction level

And 0 means Not relevant- you did not use the feature

Thank you in advance for your cooperation

John Doe Technical Marketing Systems Inc.



#	Questions	Respon	ses				
1	What is your company name?						\neg
	What is your name?						-
	What is your title? Technical, Supervisor, plant manager, other (please specify)	1. Operator	2. Supervisor	3. Manager	4. Other:		
	Site Preparation	VeryLow	Low	Average	High	Very High	Not relevant
4	Your satisfaction level with the site preparation instructions	1	2	3	4	5	0
	Your satisfaction level with the site preparation timing	1	2	3	- 4	- 5	0
	Your satisfaction level with the site preparation requirements	1	2	3	- 4	- 5	0
_	Installation	VeryLow	Low	Average	High	Yery High	Not relevant
7	Your satisfaction level with the shipment timing	1	2	3	4	- 5	0
	Your satisfaction level with the installation length	1	2	3	4	- 5	0
	Your satisfaction level with the cleanliness of equipment after installation	1	2	3	4	5	0
_	Training	VeryLow	Low	Average	High	Very High	Not relevant
10	Your satisfaction level with the operator training	1	2	3	4	- 5	0
	Your satisfaction level with the technical training	1	2	3	4	5	0
	Your satisfaction level with the on site training	1	2	3	4	- 5	0
12	Production ramp up	VeryLow	Low	Average	High	Yery High	Not relevant
13	What was the expected usage of system 1950 Update	1	2	3	4	- 5	0
	Actual usage of system 1950 Update during beta test	1	2	3	4	5	0
	What is the billable usage during the beta test? (%)	5	25	50	75	95	0
- 13	Diagnostics	VeryLow	Low	Average	High	Very High	Not relevant
16	In how many problems did you use the diagnostics tools (%)	- 5	25	50	75	95	0
	In how many of these cases did the diagnostics tool help resolve the problem? (%)	5	25	50	75	95	-
- 17	Reliability and maintenance	VeryLow	Low	Average	High	Very High	Not relevant
10	How many cases of part replacements did you experience during the beta test?	1	5	10	15	20	0
	Your satisfaction level with component A replacement procedure	1	2	3	4	- 5	0
	Your satisfaction level with component B replacement procedure	1	2	3	4	5	0
	Your satisfaction level with component C replacement procedure	1	2	3	4	5	0
	Your satisfaction level of other replacements and handling procedures	1	2	3	4	5	0
	Comments:						
23	Overall productivity	VersLow	Low	Average	High	Yery High	Not relevant
24	Rate the overall productivity od System 1950 Update	1	2	3	4	5	0
	Rate the failure rate in the System 1950 Update	1	2	3	4	5	0
	Rate the improvement in supplies that can be used in the System 1950 Update	1	2	3	4	5	0
	Rate the improvement in the System 1950 Update utilization level	1	2	3	4	5	0
	Rate the performance of system user interface	1	2	3	4	5	0
	Rate the ease-of-use when fixing a technical problem	1	2	3	4	5	0
20	Software	VeryLow	Low	Average	High	Very High	Not relevant
30	The number of restarts needed when using the System 1950 Update was	- 5	25	50	75	95	0
	Comments on main software restart cause:	_					
	Rate the user interace connectivity	1 1	2	3	4	5	0
	Comments on user interface connectivity:	_					
- 30	Overall satisfaction level	VeryLow	Low	Average	High	Very High	Not relevant
34	Your satisfaction level of improvements in the quality of the System 1950 Update	1	2	3	4	- 5	0
	Your satisfaction of improvements in the ease-of-use of the System 1950 Update	1	2	3	- 4	- 5	0
	What is your overall satisfaction level from the System 1950 Update?	1	2	3	4	5	0
- 30	If you were in the market to buy a system, with what likelihood would you purchase the System	1	2	3	4	5	0
	1950 Update?						
38	General comments on the System 1950 Update:						

Heavy/Light Workload SME/Large Company Basic/Sophisticated Usage

Basis/Copilisticated Osage									
Group	Workload	Size	Usage						
1	HW	SME	В						
2	LW	SME	В						
3	HW	LC	В						
4	LW	LC	В						
5	HW	SME	S						
6	LW	SME	S						
7	HW	LC	S						
8	LW	LC	S						

Group	Workload	Size	Usage
2	LW	SME	В
3	HW	LC	В
5	HW	SME	S
8	LW	LC	S



1 site per run 8 systems 9 respondents per site:

- 3 decision makers
- 3 technical experts
- o 3 operations staff

2 sites per run 8 systems 9 respondents per site



What is your overall level of satisfaction from the system under test:

Very Low

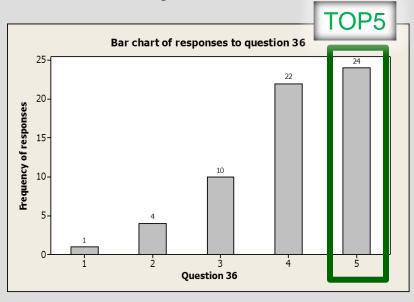
Low

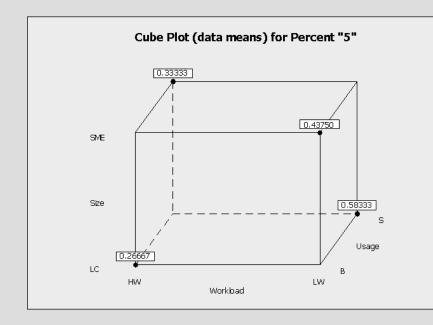
Average

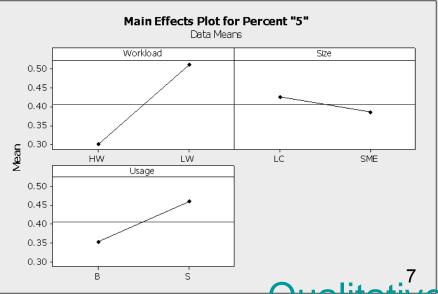
High

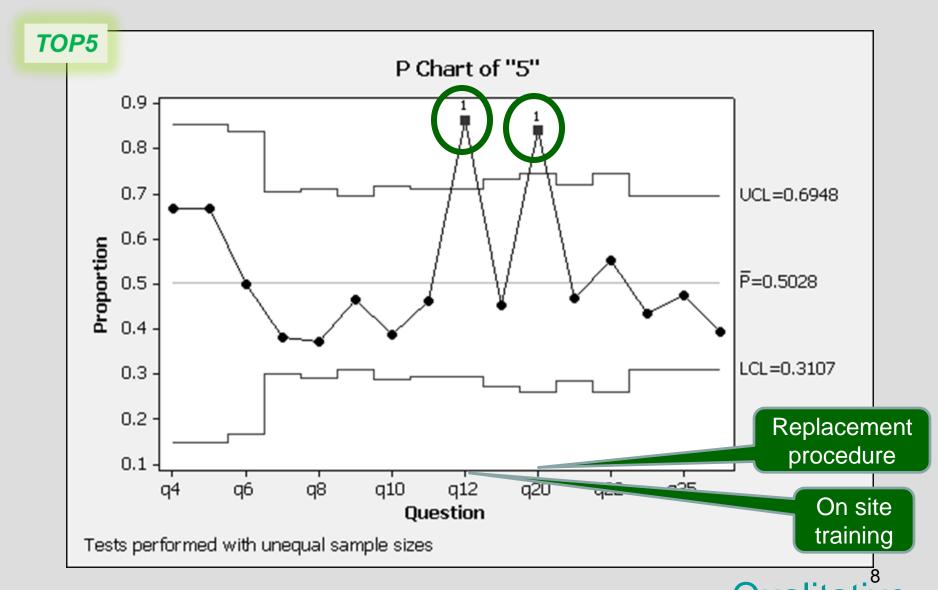
Very High

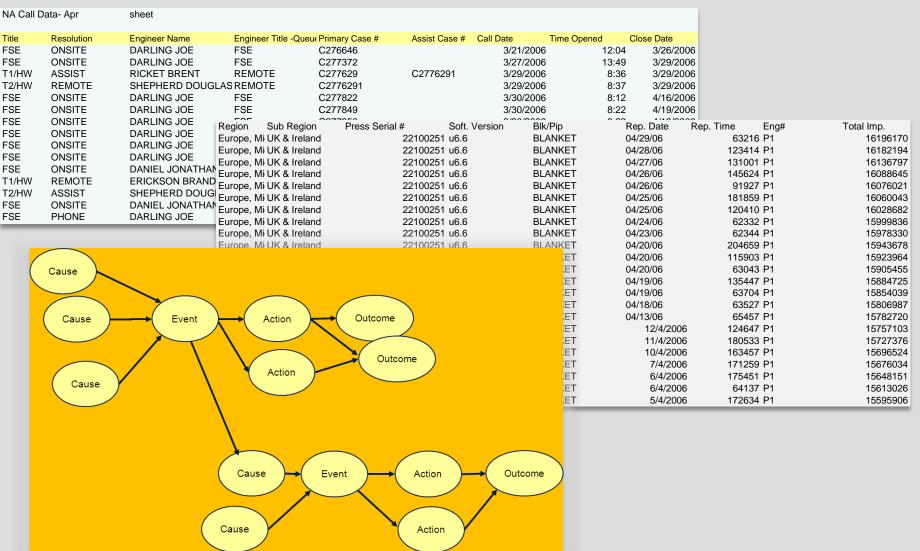
TOP5

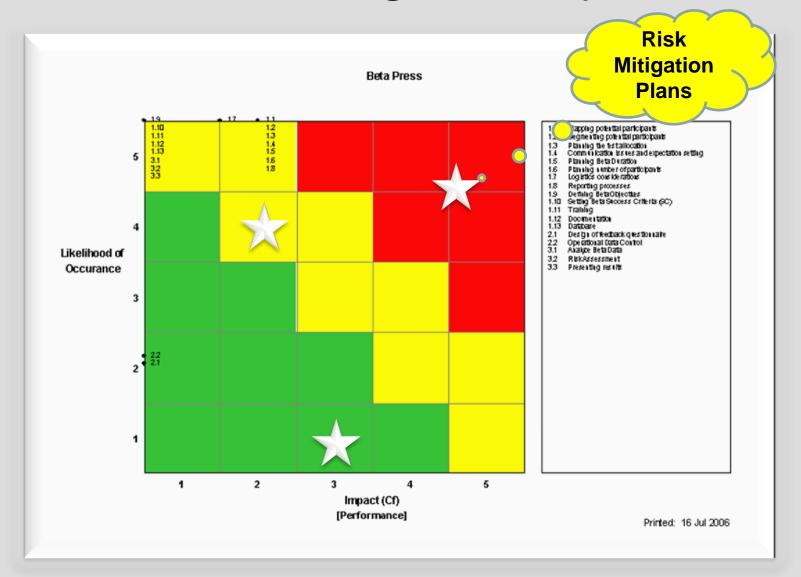












Semantic Data in a Bank Logbook

Booked on fixed income trade that was in the wrong partfund code. Have cancelled trade res Cash contribution not invested due to incorrect fax number used by client. Not a BGI error bu

Client sent in an instruction to invest £1.7m in their M& S Investment Portfolio (MSIP) o

Barclays Private Clients (BPC) conduct the asset allocation for the LIPS (L& G Investment

pa

"Booked on fixed income trade that was in the wrong partfund code.

The The Table 1 The Table 1 The Table 1 The Table 1 The Table 2 Th

"Cash contribution not invested due to incorrect fax number used by client. Not our error but noted due to performance impact on the

Clier

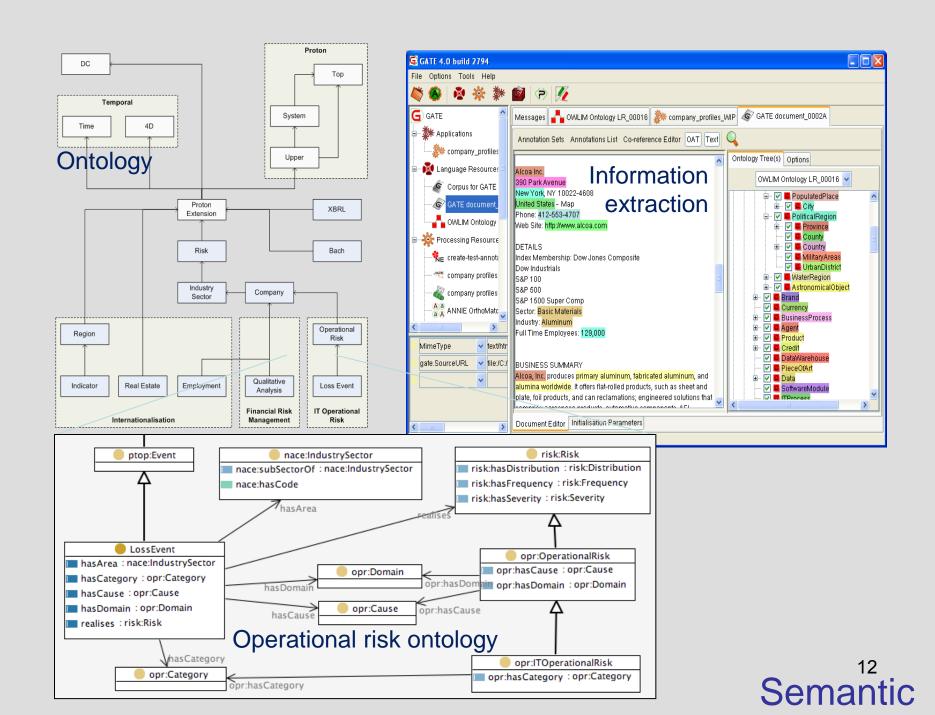
fund."

The client sent a disinvestment instruction that was incorrectly processed as an investment. Due to a positive movement in the equity markets the correction of the error led to a gain."

Historic prices were sent to Hewitts with a zero price by Fund Accounting in error on 03.03.03 Purchase instruction was received from Transitions for 16,264,591,827 Indonesian Rupiah, (ID

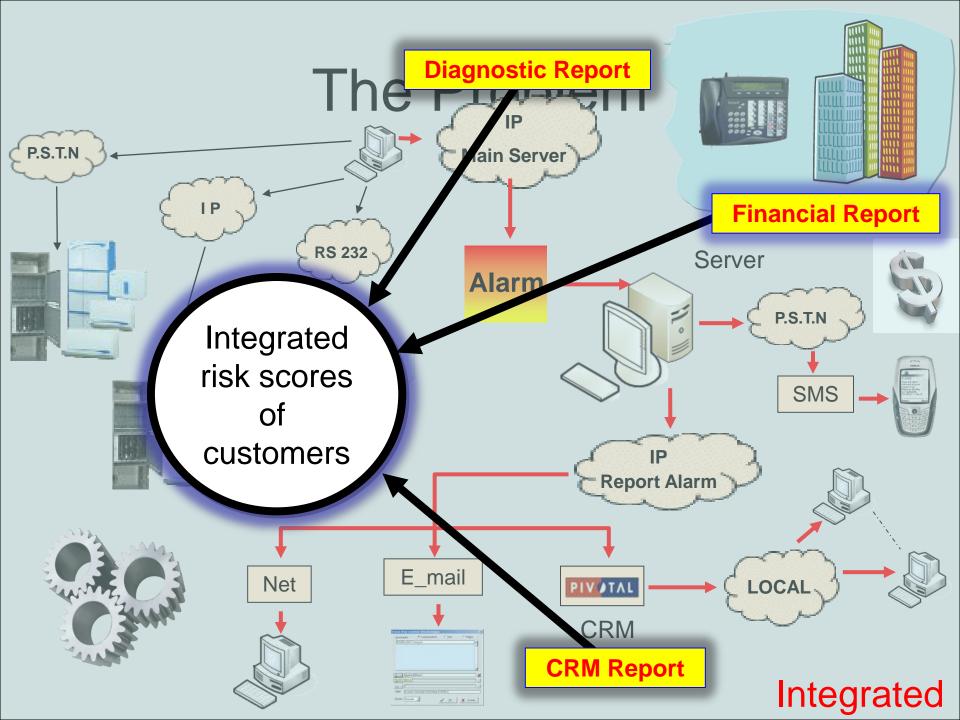
Asset Allocation provided Alex with a paper trade instruction to buy £2.6m index-linked gilts

Income was posted to the Capital account in error which caused the fund to breach. I rebalan Client instructed a disinvestment of \$195,070.00, however the cashflow inst**Semantic** th



A Telcom Operator Case Study

- Compute operational risk scores by combining information from PBX logs with CRM and technical data.
- Combine XBRL data to determine credit scores.
- Integrate risk scores for overall integrated risk management.





Logs of Telecom System

SITE NAME	VERS	SYS. TYPE	GC DUP	GC VER	LAST BOOT & CAUSE	DC_ SNAP	SNAP	NET	ALARMS	POOL FAULT	RESOURCES	SYSTEM & TASK RESTART	TESTI DATE-T
90006	14.66.35	HDC		8.4	2-SEP -2007 09:20		0			pl4_tab-177 cpn_tab-10	DTMF-15	RESET_POWER_UP-1 TOTAL_RESTARTS-1	
90009	11.11.17	SX		7.23	AUG -07-20 08:06 AM		116			p14_tab-255 p16_ma-4 call_tab-24 call_rec-25		NMI_WD-1 SUSPECT_ACF-1 RESET_POWER_UP-1 TOTAL_RESTARTS-1	11-Sep- 04:03:1
90021	11.11.17	MEX		38.13	6-JUN -2006 11:38		0			p14_tab-235			11-Sep 04:10:7
90033	11.11.16	SX		7.19	14-FEB -2007 05:56	[0		PCM TIME SLOT	p14_tab-39	-1		11-Sep- 04:13:1
90049	11.11.17	SX		7.23	4-AUG -2007 13:29		0		ή	status-255 features-255 timers-255 ts_pool-255			11-Sep- 04:17:2
90067	11.11.17	SX		7.23	25-MAY -2007 10:31		0			pl4_def-1 pl4_tab-177 call_tab-1 call_rec-1	DTMF-9	OVERLOAD-1	11-Sep 04:32:
90098	11.11.16	SX		38.13	25-JUL -2007 11:47		0			pl4_tab-219 call_tab-5			11-Sep- 04:40:3
90100	11.11.16	SX		7.5	1-APR -2007 23:22		0			pl4_tab-29 pl6_ma-2 call_tab-12 call_rec-32			11-Sep; 04:42:0
90105	15.68.14	IPX50		8.5	14-AUG -2007 15:54		0		CARD SUBUNIT	p]4_tab-106			11-Sep 04:44:5
90118	11.11.11	SX		38.10	23-NOV -2006 16:31		0		CARD SUBUNIT	p14_tab-38			11-Sep
90125	11.11.16	5X		0.0	19-AUG -2007 15:10		0			status-255 features-255 timers-255 #:-3		POWER_FAIL-1 SUSPECT_ACF-1 RESET_POWER_UP-1 TOTAL_RESTARTS-1	11-Sep4 04:58:1
90126	14.66.35	svc		38.10	SEP -25-20 11:42 AM		0			p14_def-9 p14_tab-227			11-Sep- 05:01:1
0128	11.11.16	SX		38.10	4-JUN -2006 07:48		0			pl4_tab-19	-1	RDY_TMOUT-2 OVERLOAD-7 PC %_F/AL-12	11-Sep- 05:04

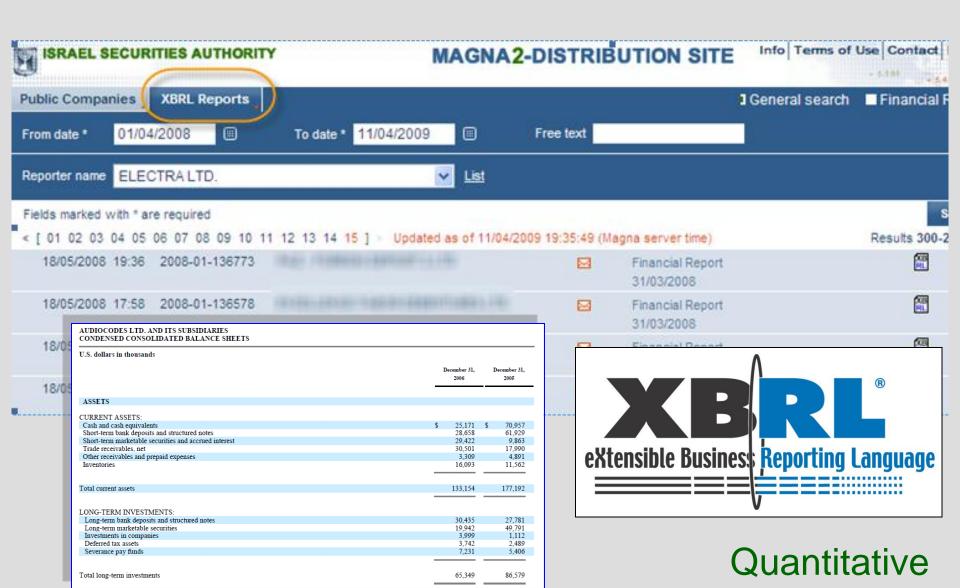


CRM Data

Site	Туре	Ports	Trunks	Phones	Complaint	Action
90009	High Tech	956	246	116	ENDING: "In Telephone, Tables, 1974)	White and their facilities, name
90009	High Tech	956	246	116	TERRITOR SPERS TOTAL SPEED	PERS FREE CA
90009	High Tech	956	246	116	ESSENCE OF TENSIONS TAXABLE VALUE	
90009	High Tech	956	246	116	ESHIBIL 'a TERRITOR TERRITORI	GOTTO SHIPMA SALTHANA IN
90009	High Tech	956	246	116	TERRITOR STREET TO FE AND THE	SS was O
90009	High Tech	956	246	116	Children or represent training spray	Zinorea file?h
90021	Municipalities	66	34	2	Children or Table of State of the Control of the Co	Principal and the Section 19 to 19 t
90033	Transportation	491	316	123	TERRITOR STEERS SERVE	#F090
90033	Transportation	491	316	123	TERRITOR STREET TOTAL SERVICE	2805-3-3416-3166-91
90033	Transportation	491	316	123	GATHAN CONS	# 40
90033	Transportation	491	316	123	TOTAL MARKES WITCHISH SHOWN	+ +
90033	Transportation	491	316	123	Per Team call That	
90033	Transportation	491	316	123	TERRITOR TERRITORS	ACTION 2 win abstract come as
90033	Transportation	491	316	123	72200100-712300-10100	#1879 D
90049	Municipalities	423	114	119	CORNEL OF SERVICE STATE STATE	
90049	Municipalities	423	114	119	TORONO STAR THE APPRI	75000 a a
90049	Municipalities	423	114	119	manufles multiple	Plant is to
90049	Municipalities	423	114	119	Specific Temperature Tables (single	8
90049	Municipalities	423	114	119	reported acres (cort agree)	Territor Name No. 19
90049	Municipalities	423	114	MAQ	AND THE RESERVE OF THE PARTY OF	and the same of the same of



Israel Security Authority Site



The Data

CRM Report

PBX	Open On	Code	Problem	Sevirity	Trunk	SLT	DKT	Туре
94095	28/05/2009 09:38	23	version change from support	2	170	103	383	Finance
94095	12/05/2009 09:26	23	version change from support	2	170	103	383	Finance
94095	03/05/2009 15:11	23	version change from support	2	170	103	383	Finance
94095	10/05/2009 16:00	333	Customer remote handling	3	170	103	383	Finance
94095	10/05/2009 14:50	333	Customer remote handling	3	170	103	383	Finance
94095	19/05/2009 12:28	334	Customer remote handling	3	170	103	383	Finance
94095	11/05/2009 16:27	334	Customer remote handling	3	170	103	383	Finance
94095	26/05/2009 17:02	E202	Remote Programing	3	170	103	383	Finance
94095	26/05/2009 10:32	E202	Remote Programing	3	170	103	383	Finance
94095	24/05/2009 13:00	E202	Remote Programing	3	170	103	383	Finance
94095	10/05/2009 17:39	E202	Remote Programing	3	170	103	383	Finance
94095	05/05/2009 18:58	E202	Remote Programing	3	170	103	383	Finance
94095	05/05/2009 14:26	E202	Remote Programing	3	170	103	383	Finance
94095	05/05/2009 07:59	E202	Remote Programing	3	170	103	383	Finance
94095	04/05/2009 15:39	E202	Remote Programing	3	170	103	383	Finance





Financial Report

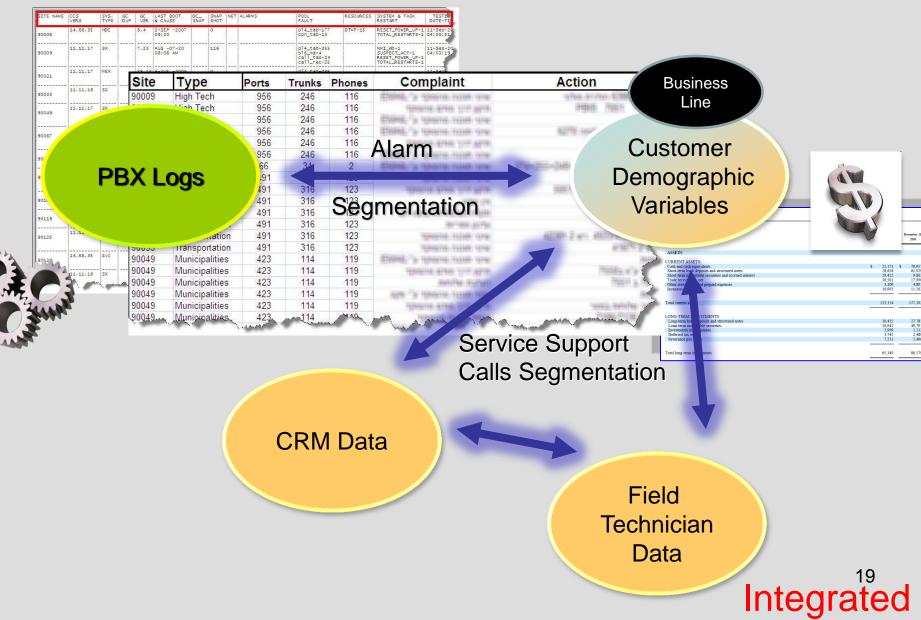
PBX 91068		
Period (Quarter & Year or Annual)	Jan-08	Sep-09
IFRS	IFRS	IFRS
Balance Sheet		
Balance Sheet Total	114,677	150,808
Current Assets	58,935	73,681
Non-Current Assets	55,742	77,128
Equity	26,963	37,073
Of which: Minority Rights	0	3,564
Current Liabilities	82,884	106,720
Non-Current Liabilities	4,831	7,016
Profit & Loss Statement		
Total Revenues	161,560	162,790
Gross Profit	66,506	65,708
Operational Profit	9,001	7,192
Pre-Tax Profit	4,826	5,667
Net Profit	4,876	6,136
Net Profit attributed to Share Holders	#VALUE!	6,193
Basic Ernings Per Share	5	6
Additional Data		
Dividend		
Net Cash from regular Operations	18,874	17,141
Finanacial Ratios		
Market to Equity		
Multiplier		
Equity to Balance Sheet		
Return on Equity		



Diagnostic Report

SITE NAME	CCS VERS	SYS. TYPE	GC VER	LAST BOOT & CAUSE	DC_ SNAP		POOL FAULT	RESOURCES	SYSTEM & TASK RESTART	TESTING DATE-TIME
91068	11.11.17	4gc	7.23	SEP-12-2009 06:15	 	0	pl4_tab-101	DTMF-12		08-APR-2010 06:22:06
92780	15.85.16	HDC	7.23	21-MAY -2009 13:20		0	 p14_tab-70	 	 	08-APR-2010 06:45:36
94486	10.21.05	4gc	7.23	07-Feb -2008 09:45 PM			status-31 features-2 timers-2 ts_pool-34	 	 RESET_POWER_UP-7 TOTAL_RESTARTS-9 GENERAL_P-1	
94095	15.68.28	4gc	7.23	16-Jun-2009 06:17 PM		İ	 pl4_tab-197 pl6_ma-78 call_tab-7 call_rec-15		 RESET_POWER_UP-7 TOTAL_RESTARTS-9 GENERAL_P-1 	

ETL Integration













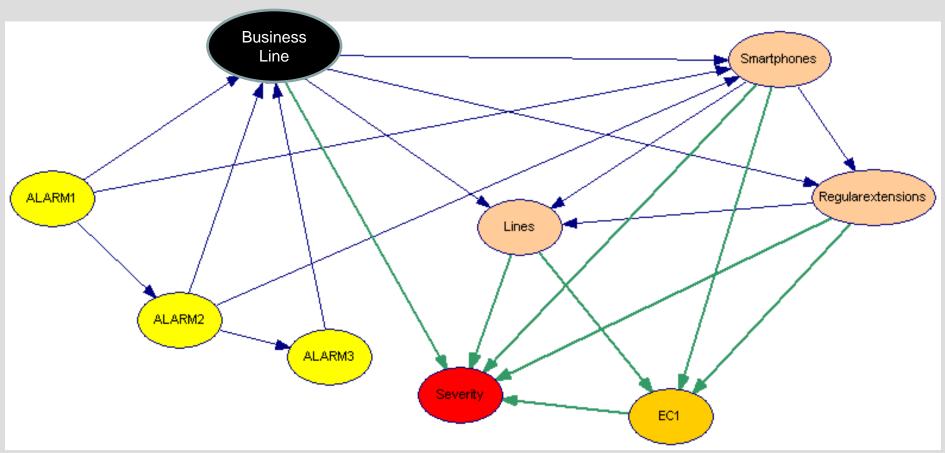


Business Line	Total Events
Health	699
Banking	481
Defence	323
General	270
Finance	260
Industry	248
Cooperatives	225
Municipalities	221
Government owned company	209
Hotels	197
Leisure and Consumerism	153
Transportation	134
Lawyer/accountant offices	83
Education	56
Computers	49
Operating company	49
Electronics	42
Elderly citizens' home	40
Government	25
Construction	4



Bayesian Network Cause and Effect Analysis





OpR Data - by problem severity



		H	ardware	•		Software	9	
PBX	Business Line	H_H	H_M	H_L	SF_H	SF_{M}	SF_L	
1	Banking	0	0	2	1	0	3	
2	Defence	0	0	1	1	3	0	
3	Health	2	0	0	1	1	1	
4	Finance	0	1	0	2	1	0	
		• • •						
n		2	0	1	2	0	1	



OpR Data - by max severity

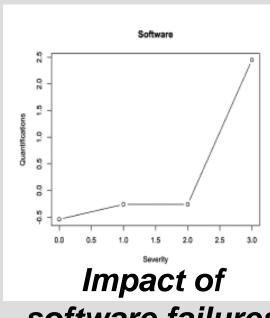
PBX	BusinessLine	Software	Network_com	Security
20006	Industry	3	3	0
21205	General	3	1	3
21900	General	0	2	0
22002	General	0	2	0
22595	General	3	0	3
25098	General	2	2	0
30266	General	0	0	0
50039	Finance	0	2	0
50090	Industry	2	0	2
50092	Hotels	3	0	3
50005	Finance	2	0	2
50012	Hotels	2	2	3
50080	Finance	0	2	0
50105	General	3	0	0
60158	Finance	0	2	0
60160	General	0	2	0
60308	Finance	0	0	2
60323	Industry	0	1	0
60501	General	2	3	0



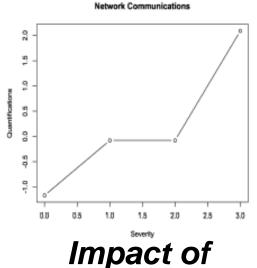


Non Linear Principal Components Analysis

Dimension Crophach's α		Variance Accounted For Eigenvalue % of Variance		
	1	,503	1,505	50,161
	2	-,009	,994	33,130
	Total	,900	2,499	83,290

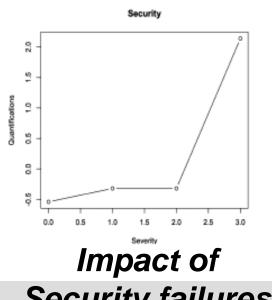


software failures



Netcom failures





Security failures

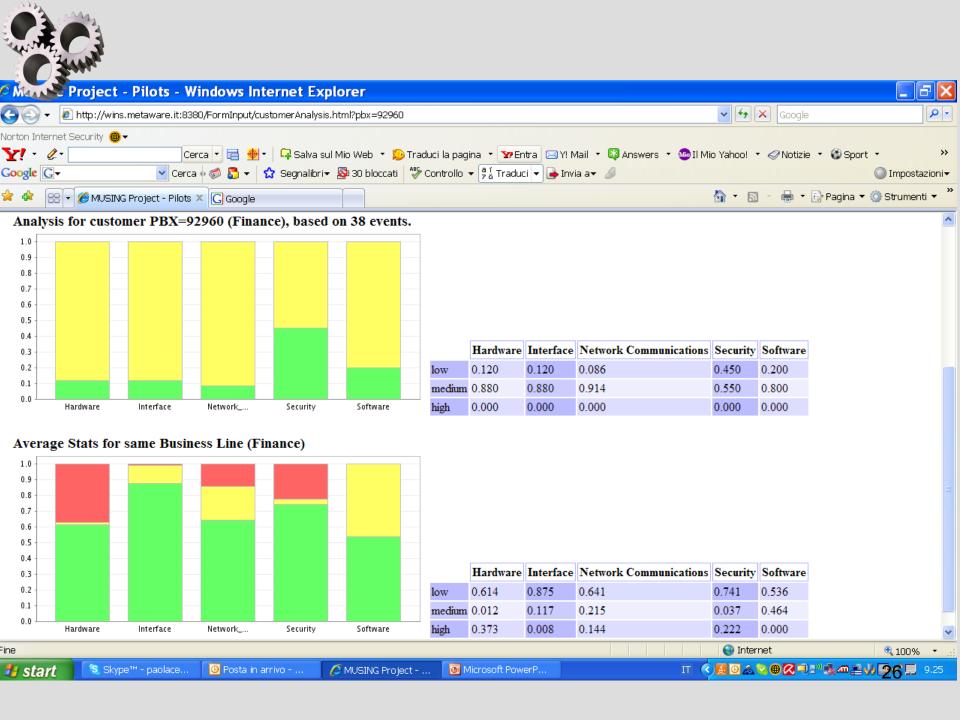
Security failures

software failures

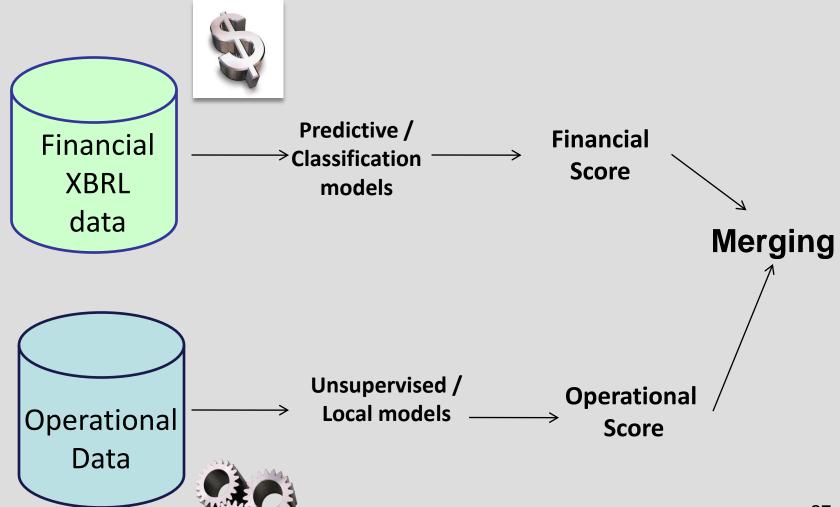
Non Linear Principal Components Analysis

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V		7	
1		7	
	▼		

					,
PBX	BusinessLine	Software_Quan	Network_com_Quan	Security_Quan	Scores
31116	Industry	2.45	2.09	-0.54	0.593
32315	General	2.45	-0.08	2.14	0.913
32910	General	-0.54	-0.08	-0.54	0.043
33113	General	-0.54	-0.08	-0.54	0.043
33595	General	2.45	-1.17	2.14	0.867
35098	General	-0.26	-0.08	-0.54	0.087
40366	General	-0.54	-1.17	-0.54	0.000
50049	Finance	-0.54	-0.08	-0.54	0.043
50091	Industry	-0.26	-1.17	-0.32	0.076
50093	Hotels	2.45	-1.17	2.14	0.867
50115	Finance	-0.26	-1.17	-0.32	0.076
50123	Hotels	-0.26	-0.08	2.14	0.493
50181	Finance	-0.54	-0.08	-0.54	0.043
50215	General	2.45	-1.17	-0.54	0.463
60258	Finance	-0.54	-0.08	-0.54	0.043
60260	General	-0.54	-0.08	-0.54	0.043
60408	Finance	-0.54	-1.17	-0.32	0.033
60434	Industry	-0.54	-0.08	-0.54	0.043
60502	General	-0.26	2.09	-0.54	0.173



Risk assessment



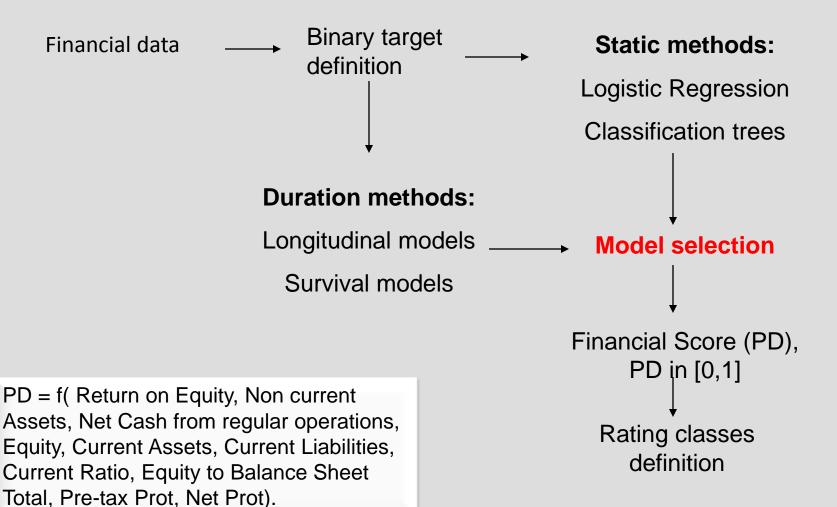
Financial data

- Collect Balance Sheets
- Extract quantitative information from XBRL balance sheets data
- Derive financial ratios useful to predict the default probabilities of companies
- The target variable is binary (0: good,1: bad)
- The final data matrix is composed of n companies and p covariates

Financial data: an example

Customer	Financial Ratio 1	Financial Ratio 2	Financial Ratio 3	Financial Ratio p
1	11794200	10921774	393717	627750
2	47947	34813	13134	27058
•••	519440	130111	389330	62568
•••	111200	94573	16627	12914
•••	160747	120877	39870	111038
•••	2303915	1101978	1201937	591154
•••	97970	70909	27061	34268
n	127953	75586	52367	16526

Predictive/Classification models



Financial score

Customer	LogReg 1	LogReg 2	LogReg 3
1	0.590413725	0.483517201	0.60105205
•••	1	1	1
•••	0.198422752	0.288418151	0.193413586
•••	0.311519917	0.25348666	0.4165347
•••	0.58567025	0.481172502	0.59679867
•••	0.593873953	0.487455978	0.604682691
•••	0.606705681	0.499173616	0.616373138
n	0.59845664	0.492608605	0.609354881

The resulting PD are based on logistic regression. More precisely, Reg 1, Reg 2 and Reg 3 consider backward, forward and stepwise selection respectively.

Financial and Operational scores

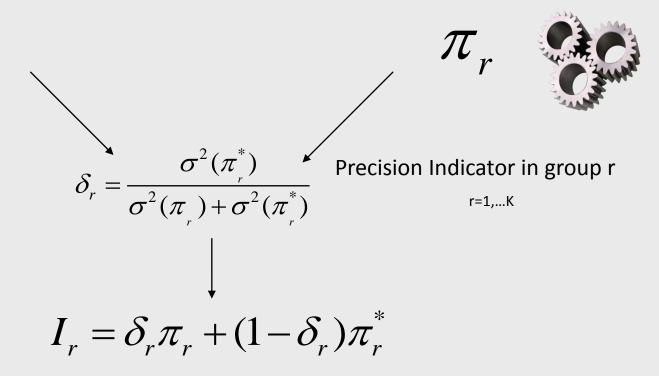
Customer	Financial Score	Operational Score
1	0.60105205	0.453472222
2	1	1
•••	0.193413586	0.440277778
•••	0.4165347	0.247916667
•••	0.59679867	0.534722222
•••	0.604682691	0.360416667
•••	0.616373138	0.417361111
n	0.609354881	0.47222222

Financial Score

Operational Score



$$\pi_r^*$$



Integrated Score

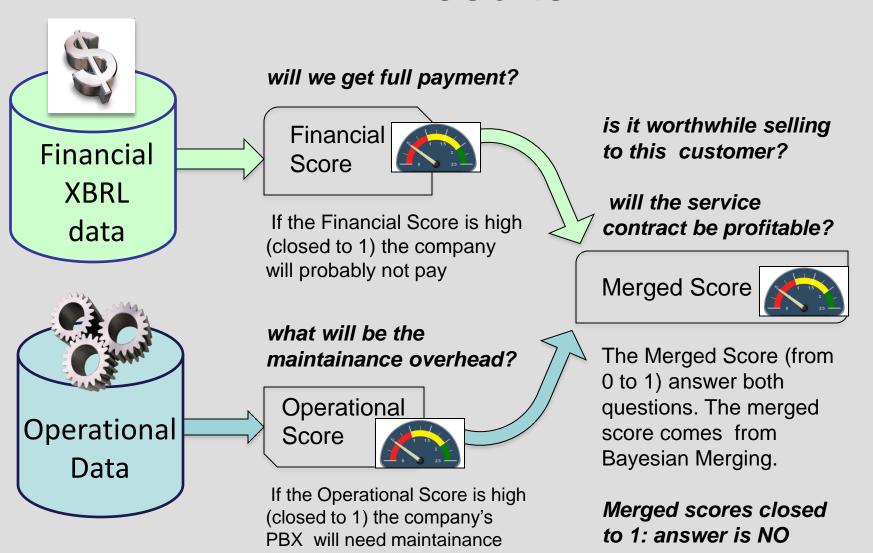
The precision indicator is derived on the basis of the variances estimated across "r" bootstrapped data sets.

Bayesian merging

Customer	Financial Score	Operational Score	Delta	Merged Score
1	0,60105205	0,453472222	0,78431851	0,569221813
2	1	1	1	1
•••	0,19341359	0,440277778	0,35931949	0,351574662
•••	0,4165347	0,247916667	0,76715999	0,377273676
	0,59679867	0,534722222	0,4185012	0,56070129
•••	0,60468269	0,360416667	0,86303567	0,571226958
	0,61637314	0,417361111	0,75822335	0,568256677
n	0,60935488	0,47222222	0,52974872	0,544868073

Integrated

Results



Integrated

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Tankyou for your attention







New methods and tools

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