

Data Driven Risk-based Monitoring

Ways of Trial Optimization and Cost Reduction

Artem Andrianov, PhD

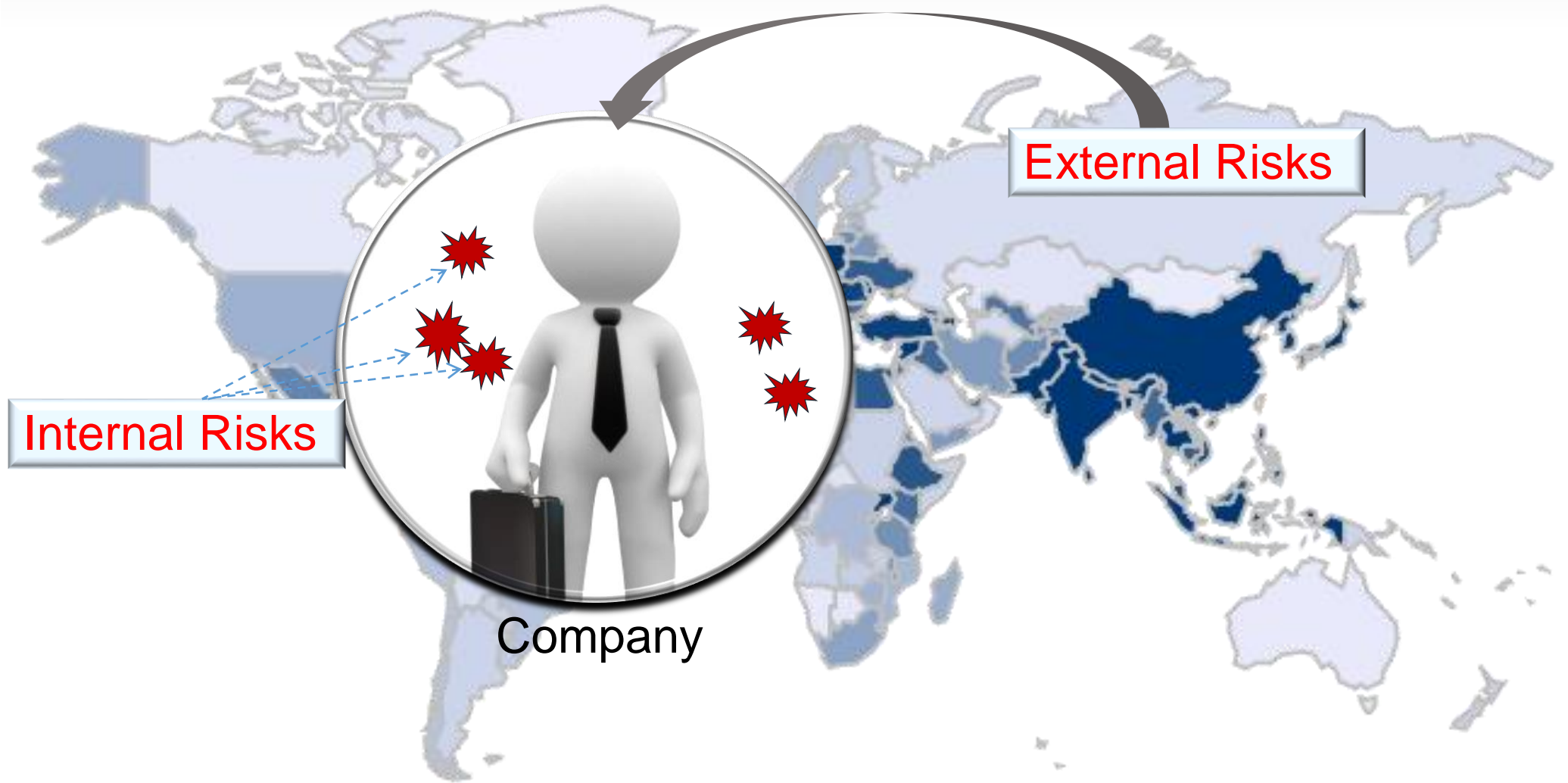
Cyntegrity

Speaker's Profile:

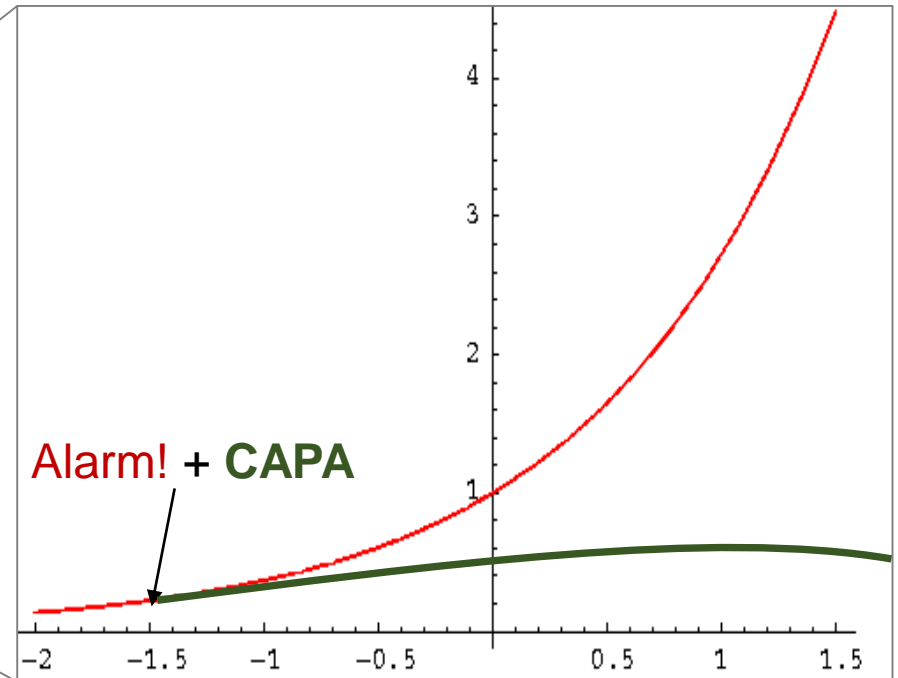
- PhD in Engineering & Executive MBA
- 12 years of Experience in
Pharma Data Quality



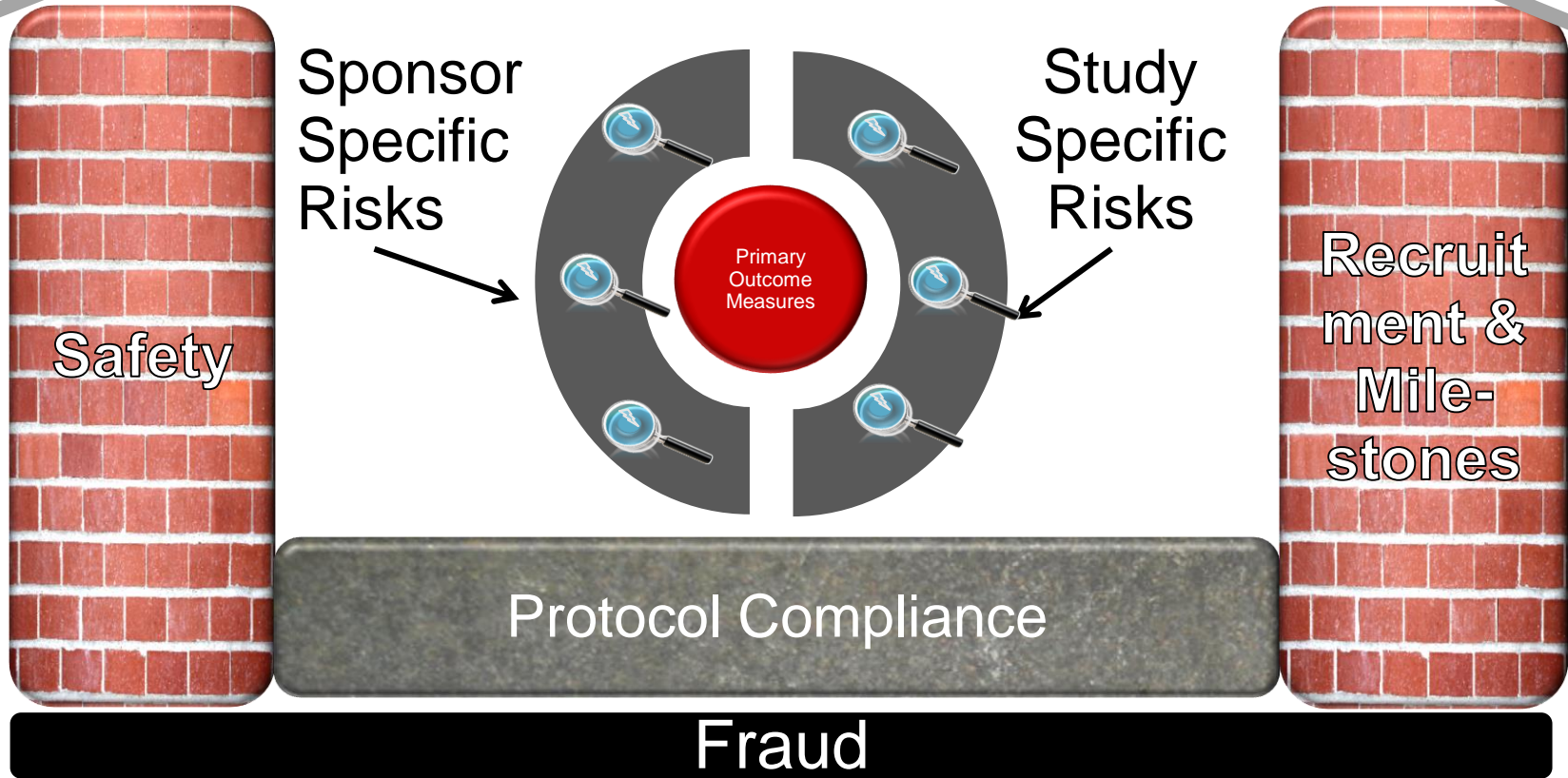
Internal and External Risks



Right Actions in Right Time



Key Risk Defense Strategy



Key Risk Indicators

Examples of Recording Systems from 3d Parties (and/or Sponsor)

EDC

IVRS

...

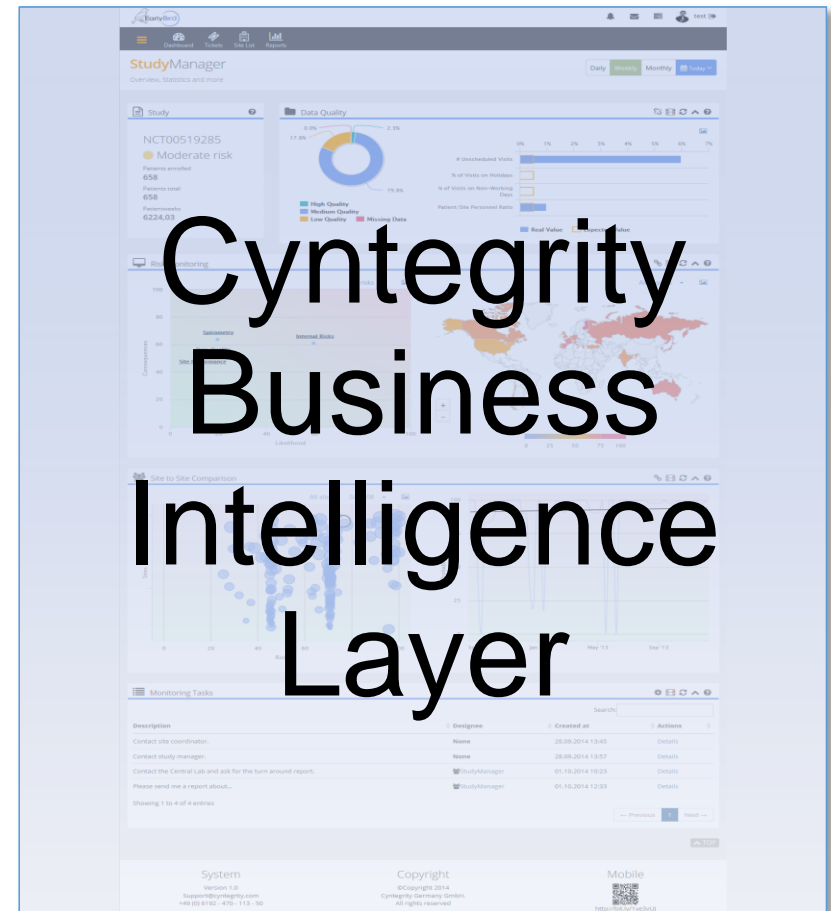
CTMS

KRI

KRI

KRI

KRI



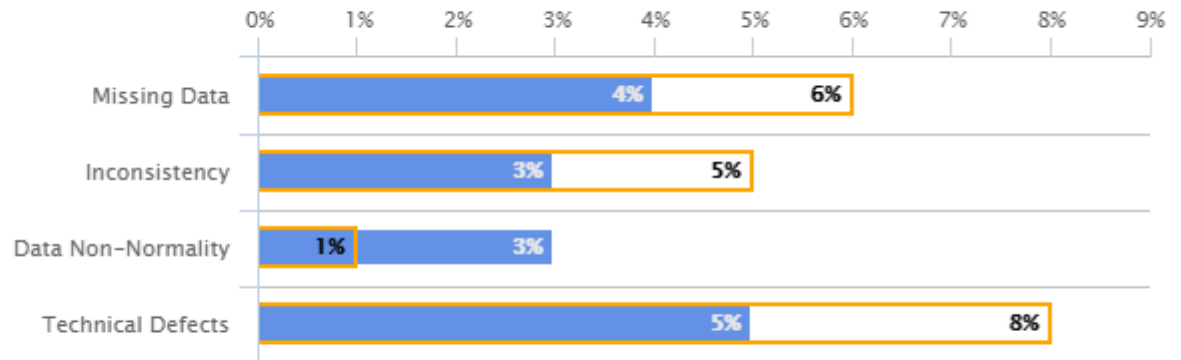
Cyntegrity
Business
Intelligence
Layer

Data Quality Evaluation

Data Quality



High Quality Medium Quality
Low Quality Missing Data

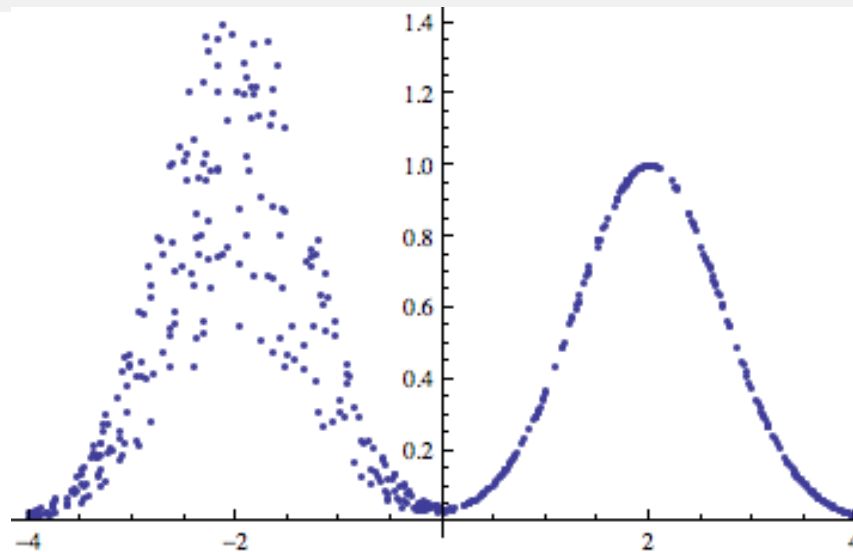


Real Value Expected Value

Random Error



Equality



Precision

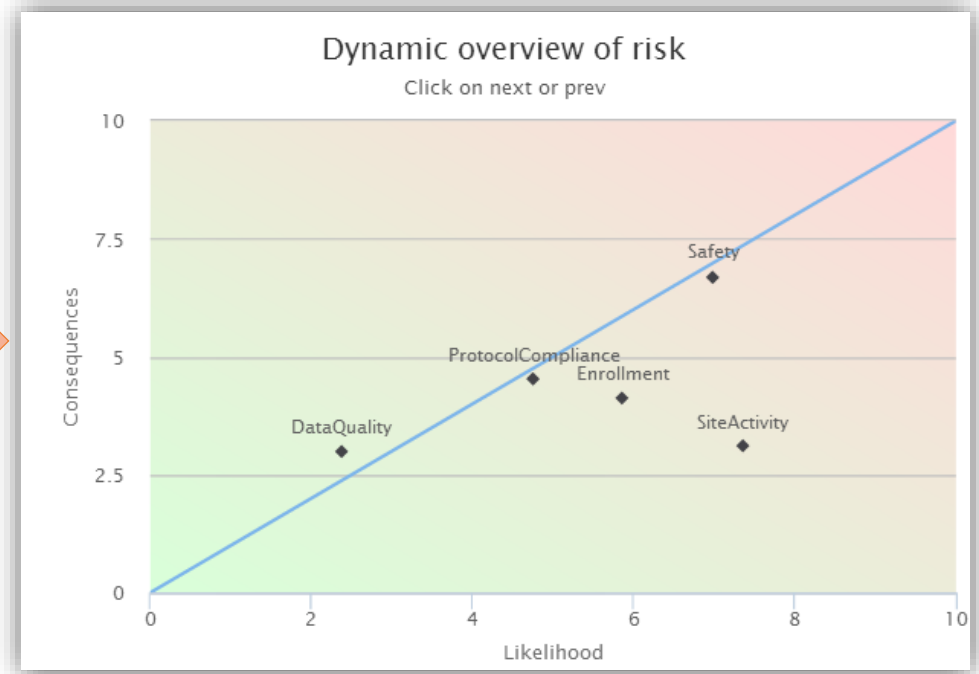
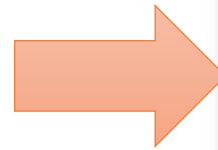


Equality

Analysis of Risks

		Impact				
		1	2	3	4	5
Likelihood	5	5	10	15	20	25
	4	4	8	12	16	20
	3	3	6	9	12	15
	2	2	4	6	8	10
	1	1	2	3	4	5

Theory



Practice

L	Low risk
M	Moderate risk
H	High risk
E	Extreme risk



Risk Development Video.webm

Comparison – the key for understanding

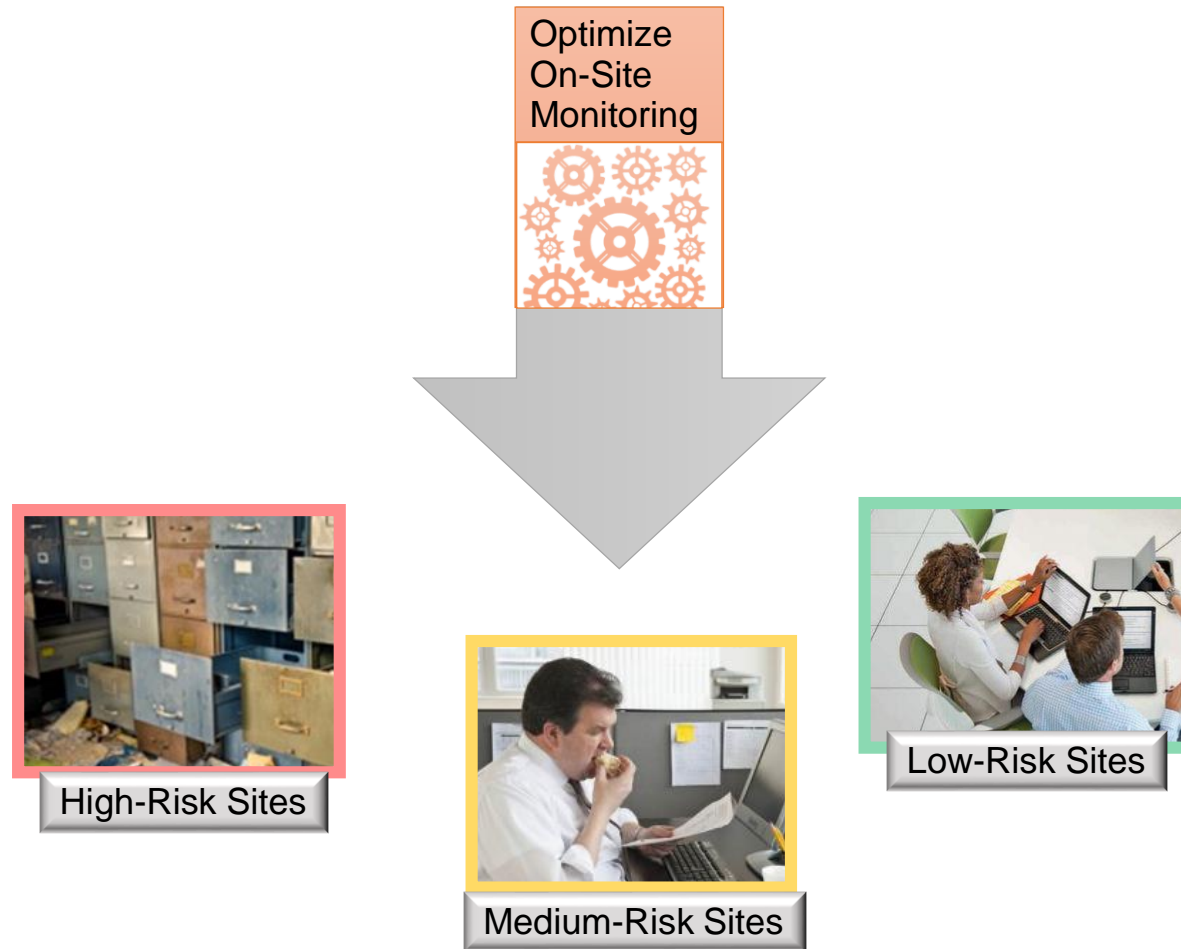


Applied Statistical Methods

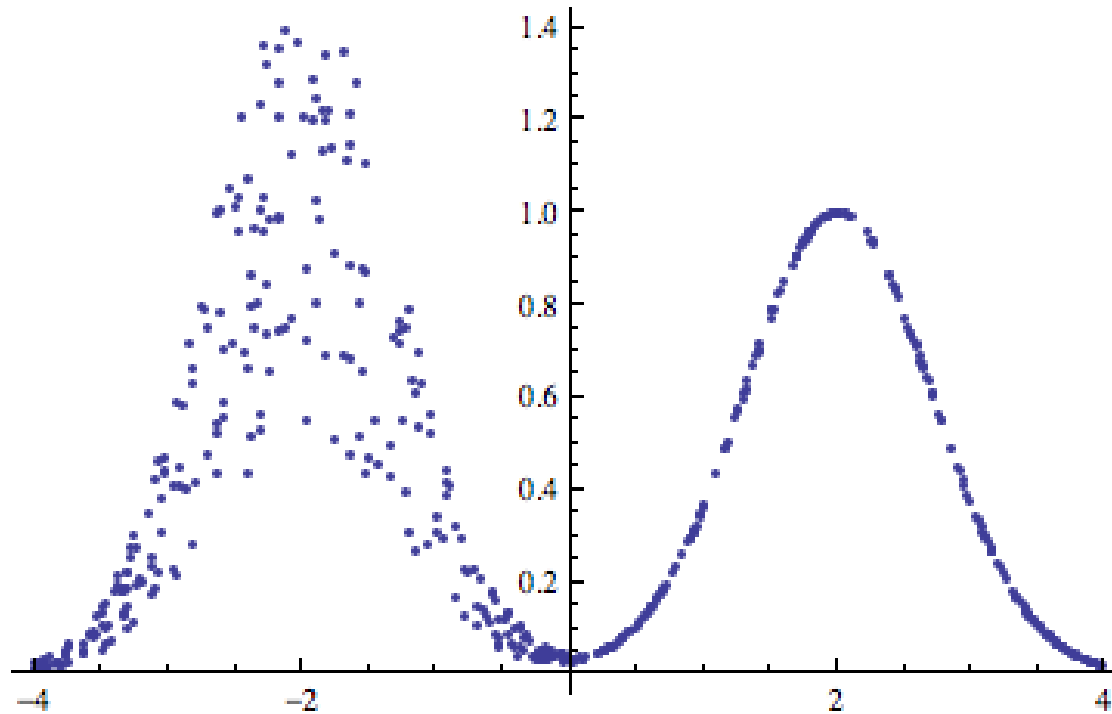


- ✓ Distributions and Properties Variables
- ✓ Proportion of missing values
- ✓ Means
- ✓ Global variances within patient variances
- ✓ Proportion of week days
- ✓ Proportions of Outliers
- ✓ Correlation between variables
- ✓ Event counts

Result 1: Site Visits Optimization



Result 2: Absolute Data Quality



Equality



Equality

Result 3: Effective Communication and Knowledge Sharing within Team and among Trial Groups

Internal Risk-Chat

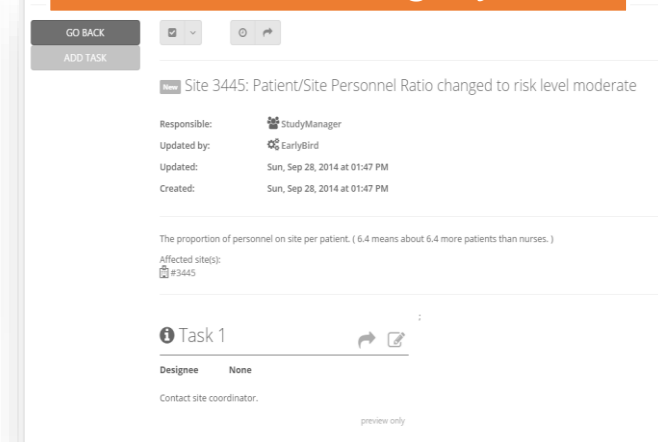


Risk Mitigation To-Do plan

MessageId	Subject	Priority	AssignedTo	CreatedAt	Actions
343	Check a patient signature in patient agreement is different to handwriting in the CRFs.	3	Ms. Mandy M. Young	5/6/2014 1:30 PM	Details
344	Check if patient agreement form is available.	3	Ms. Courtney E. Payne	5/6/2014 1:30 PM	Details
345	Check if returned investigational drug is very clean for all patients and has no signs of use.	3	Ms. Wendy G. Cox	5/6/2014 1:30 PM	Details
346	Known correlation between age and blood pressure could not be detected.	3	Mr. Kevin J. Salazar	5/6/2014 1:30 PM	Details
347	No free text and no comments found in questionnaires.	2	Ms. Debra D. Kaplan	5/6/2014 1:30 PM	Details

Showing 1 to 5 of 14 entries

Internal Ticketing System



Result 4: Continuous Improvement



Risk varies inversely with **Knowledge**



Irving Fisher (1867-1947)