# Data Driven Risk-based Monitoring

## Ways of Trial Optimization and Cost Reduction

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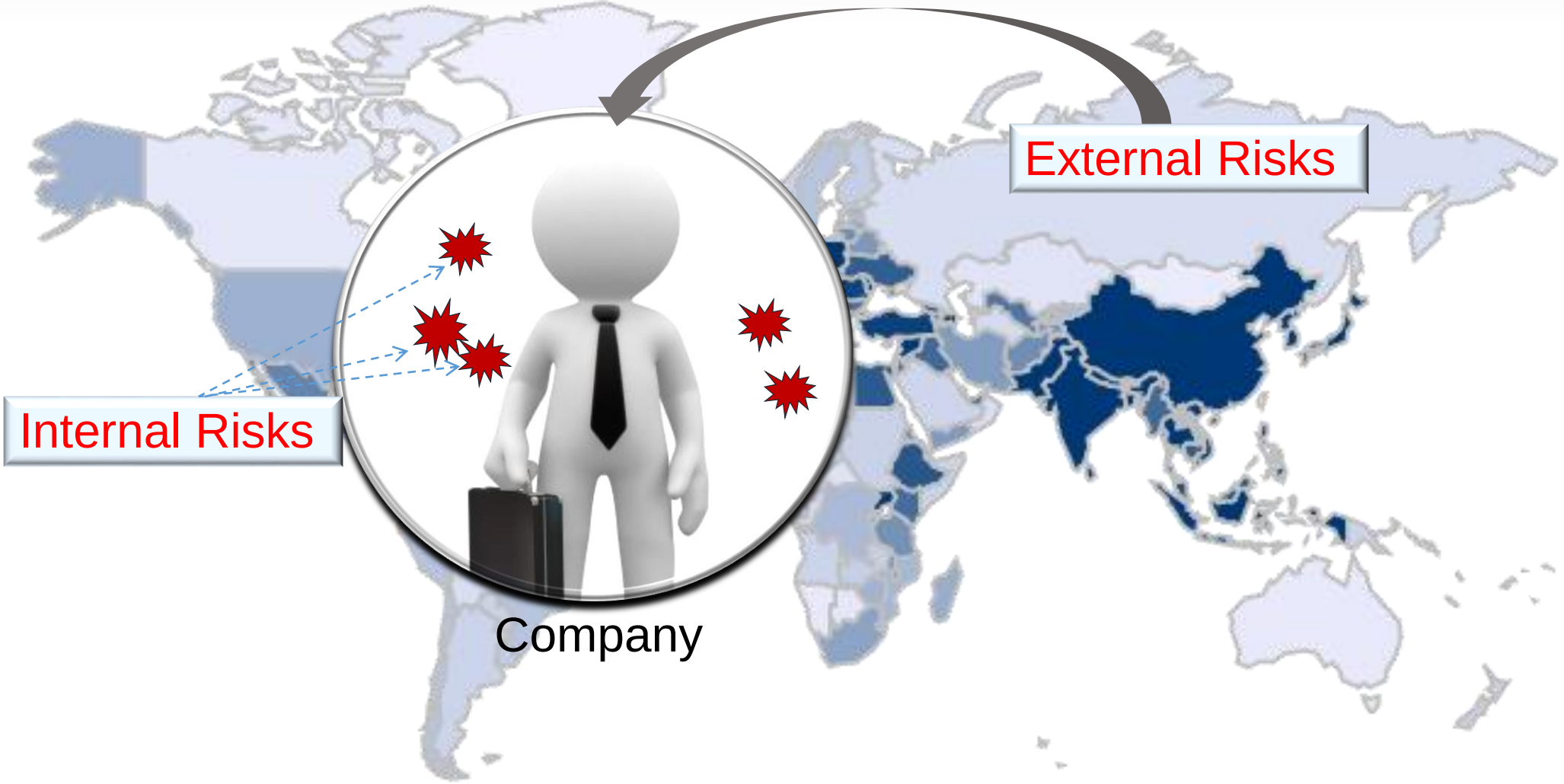
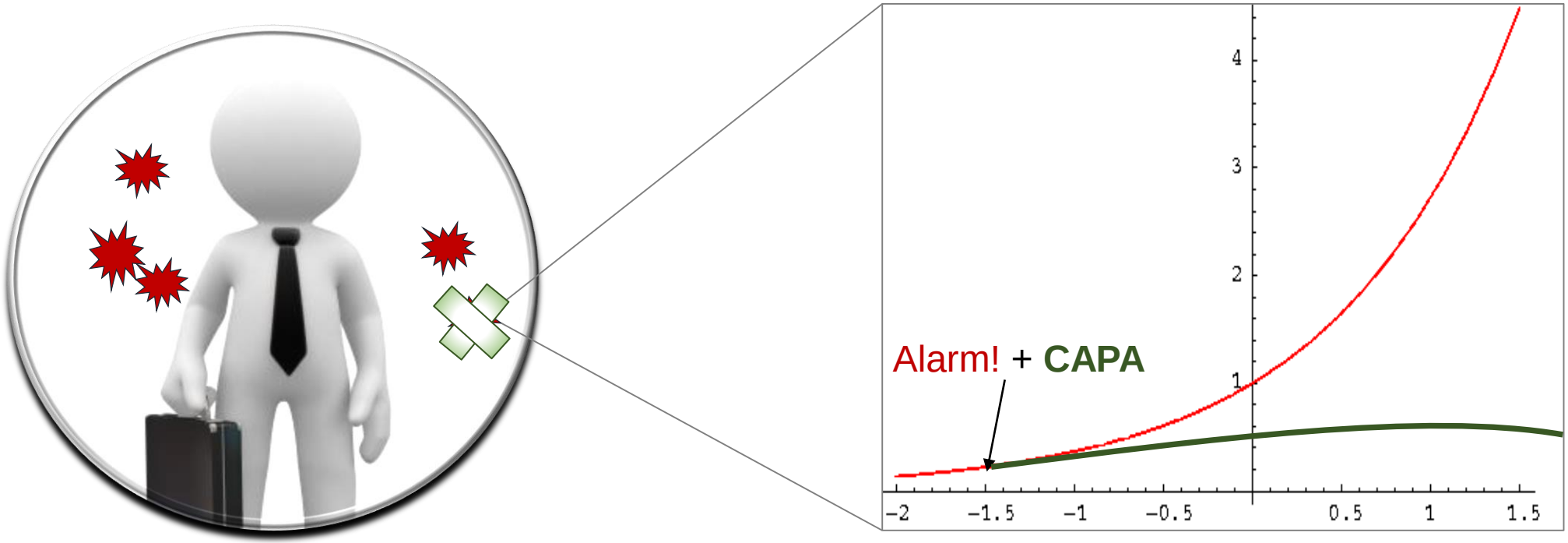
Cyntegrity

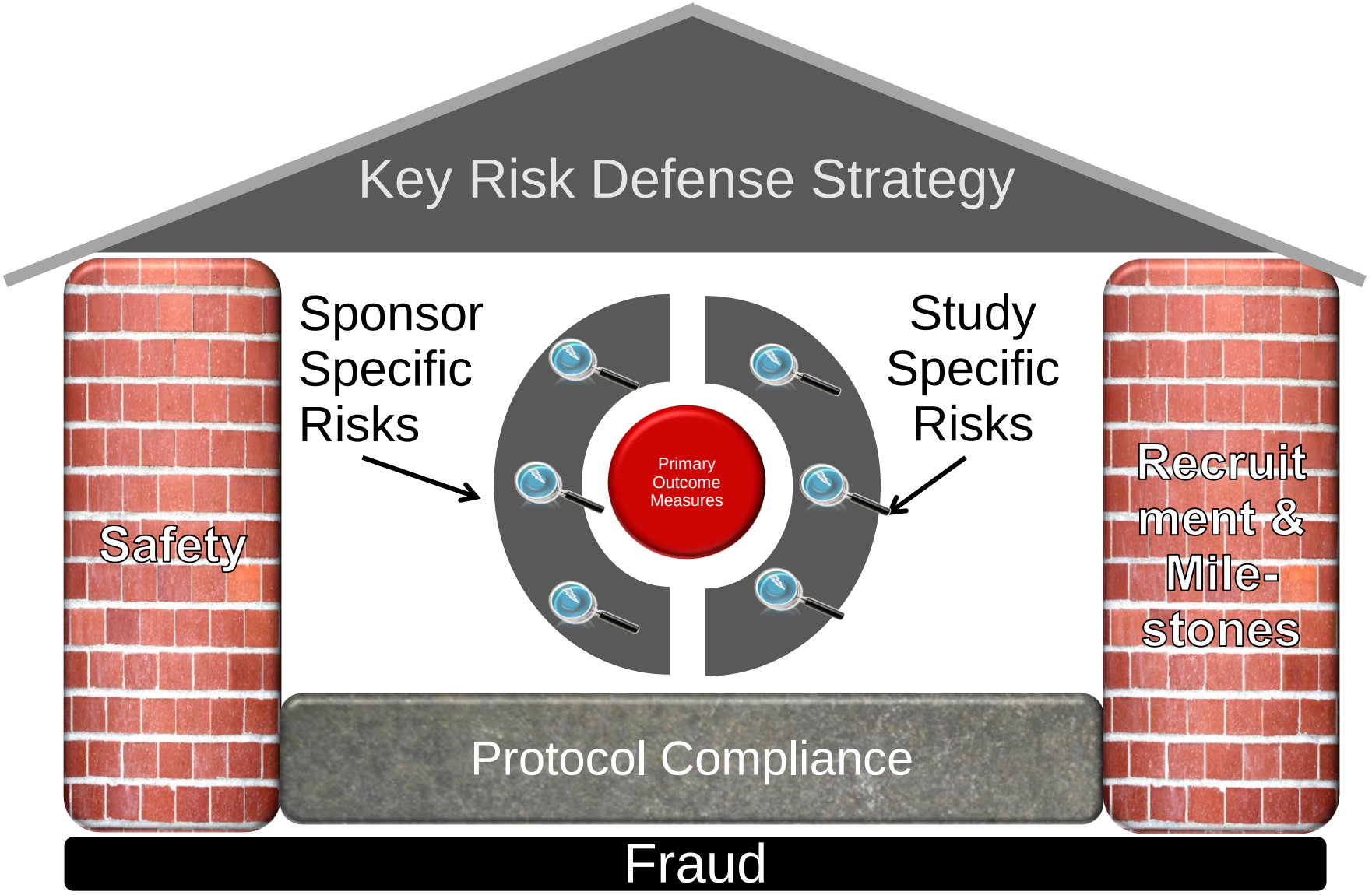
Speaker's Profile:
- PhD in Engineering & Executive MBA
- 12 years of Experience in Pharma Data Quality

# Internal and External Risks



# Right Actions in Right Time




Key Risk Defense Strategy
Sponsor Specific Risks
Study Specific Risks
Primary Outcome Measures
Safety
Recruit ment & Mile- stones
Protocol Compliance
Fraud

# Key Risk Indicators

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

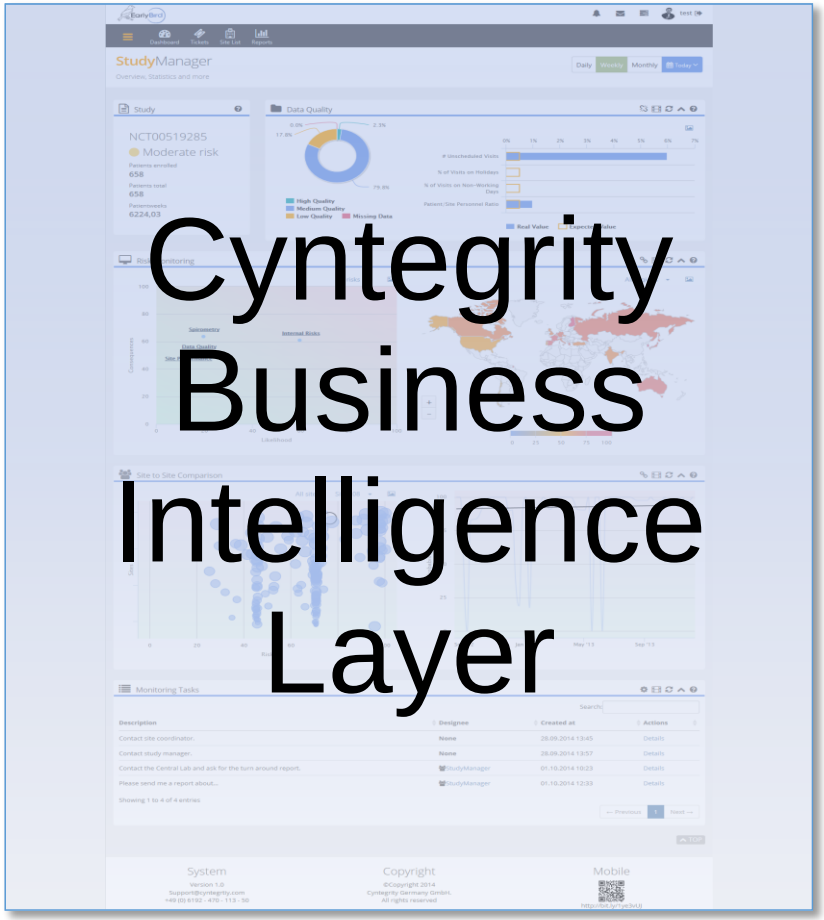
- EDC
- IVRS
- …
- CTMS

KRI

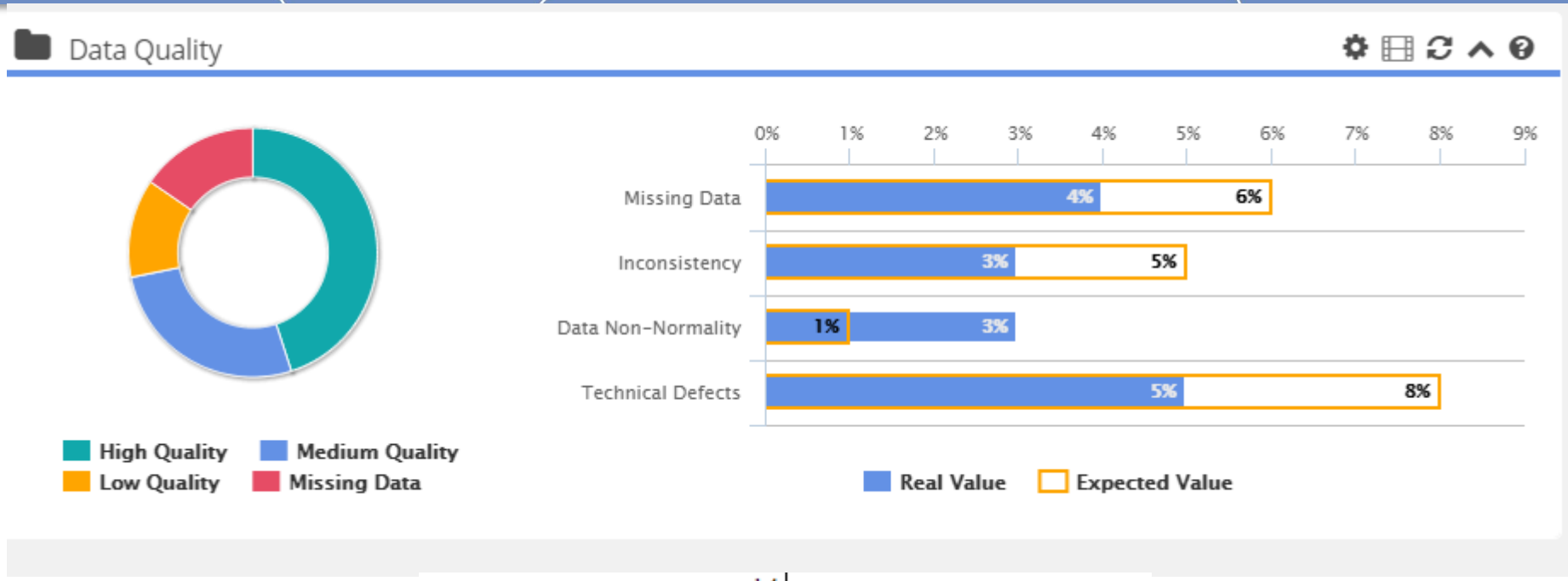
KRI

KRI

KRI

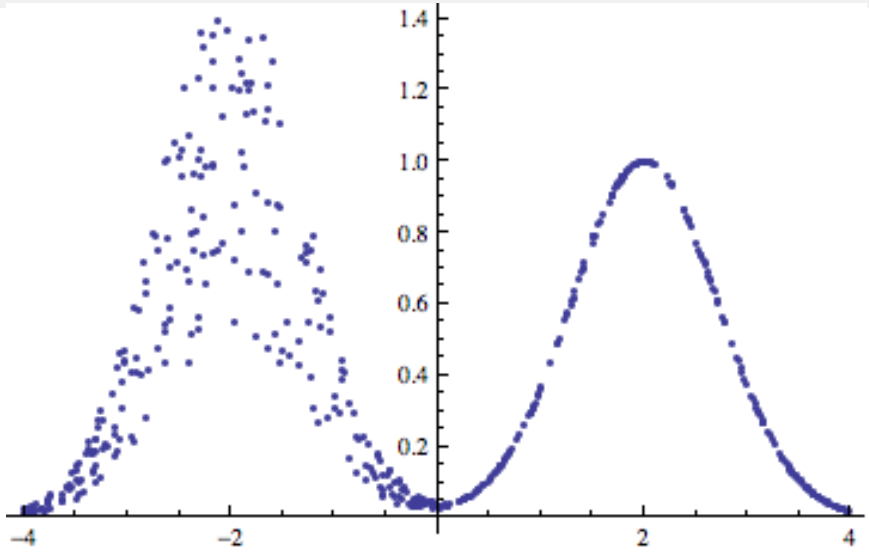


# Data Quality Evaluation




Random Error

Equality

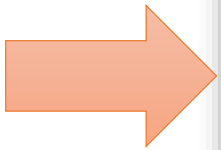


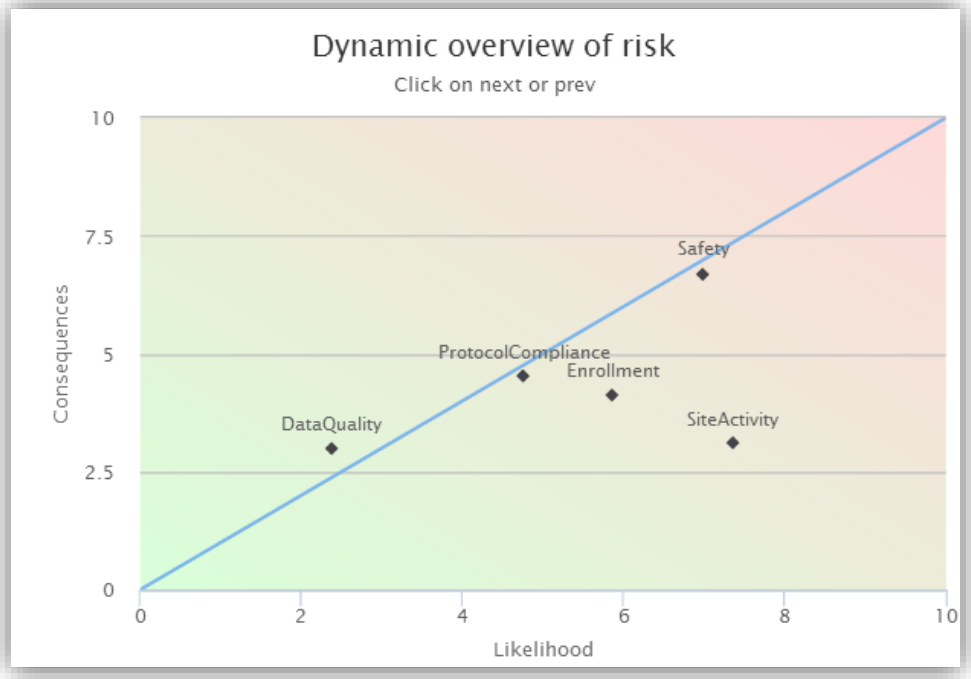

Precision

Equality

# Analysis of Risks

| Likelihood | Impact 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| 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

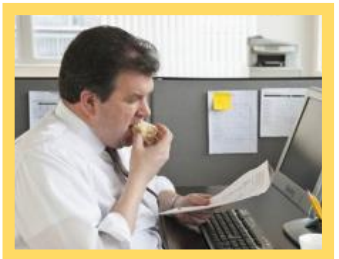
# Applied Statistical Methods

- ✓ 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

Optimize On-Site Monitoring

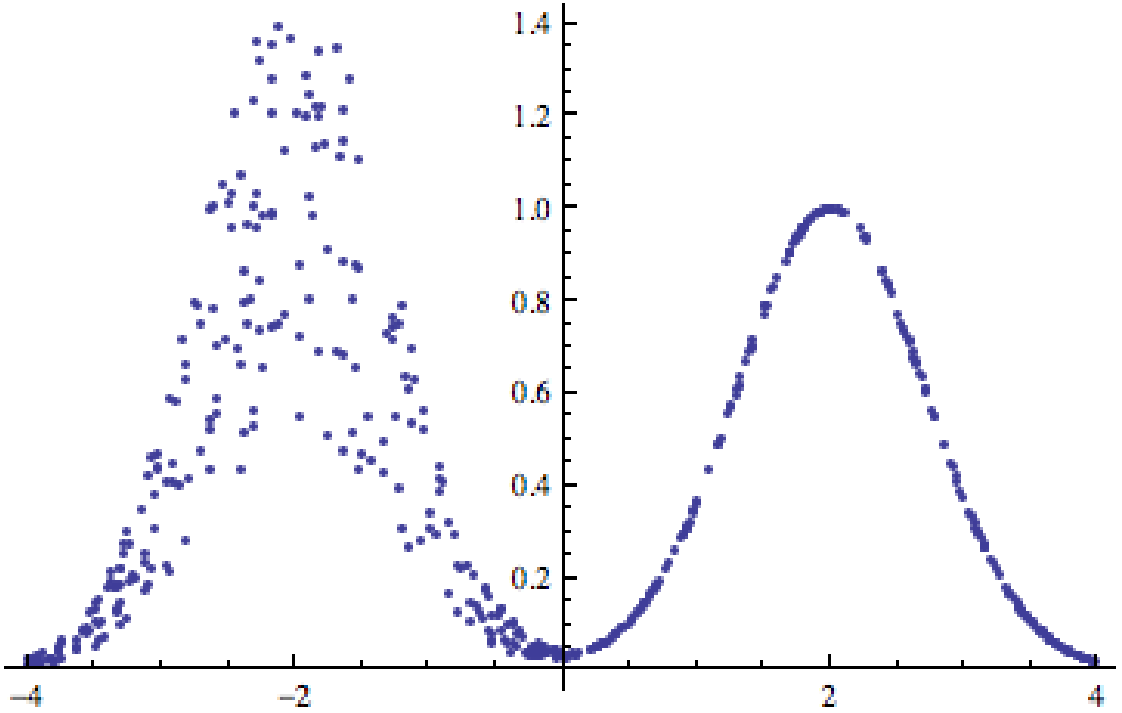
High-Risk Sites



Medium-Risk Sites

Low-Risk Sites

# Result 2: Absolute Data Quality



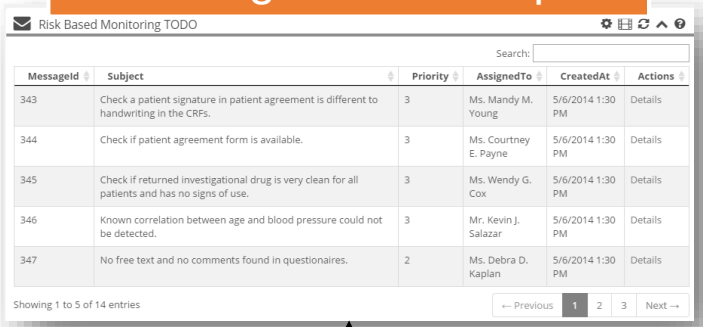
Equality

Equality

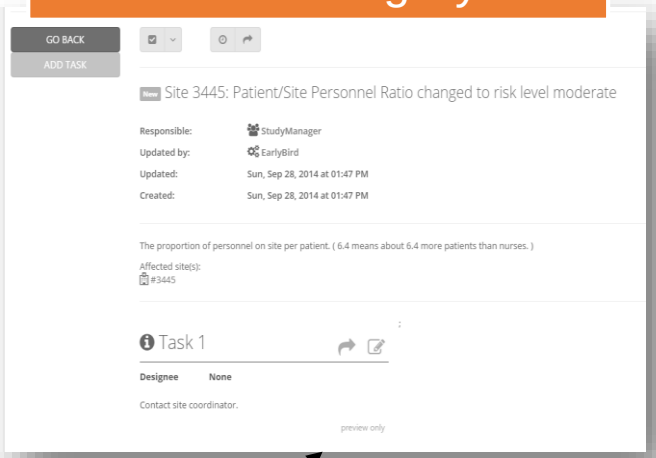
# Result 3: Effective Communication and Knowledge Sharing within Team and among Trial Groups

## Internal Risk-Chat

## Risk Mitigation To-Do plan

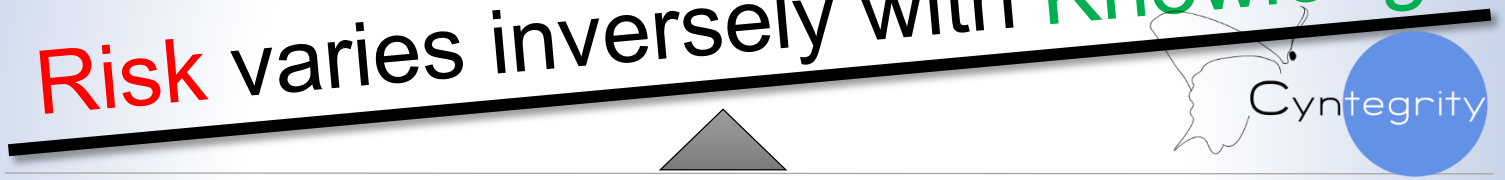



## Internal Ticketing System



# Result 4: Continuous Improvement

# Risk varies inversely with Knowledge




Irving Fisher (1867-1947)