

Regulatory Management

Many industries must operate in tightly regulated environments with government reporting and substantiation of filings critical to product and service delivery. Manufacturers, transportation, defense, consumer goods and food, pharmaceutical, telecommunications, financial services, insurance and utilities are just a few of the industries that must furnish regulatory information. Engineering, manufacturing and legal professionals perform analyses on performance against pre-determined and internal standards. Business intelligence provides basic analyses such as performance versus standard levels as well as statistical significance of acceptance or failure rates.

Key Performance Indicators

- Variance to Expected Outcome
- Top 10 Malfunctions
- Top 10 Side-effects
- Variance to Acceptable Levels
- Average Result of All Tests
- Predicted Outcome
- Statistical Significance of Results
- Standard Deviation of Results

Sample Report: Clinical Trial Results, HIPAA Compliant

Clinical Trial: A2B3452				
Patient Code	Gender	Group	6 Mo. Effectiveness Rate	Patient Reported Side Effects
P1102	M	Test	90%	None
P1105	F	Control	N/A	None
P1107	F	Test	70%	Nausea
P1110	F	Test	95%	Slight nausea on one occasion
P1117	M	Test	50%	Nausea, sleeplessness, cough
P1118	M	Control	N/A	Cough
P1122	F	Test	88%	Sleeplessness
P1124	M	Control	N/A	None
P1125	F	Test	86%	Occasional nausea

This reports shows a sample of the results of a clinical trial for a new drug compound, and is a good example of a report containing mostly qualitative data. Due to HIPAA and confidentiality requirements, patient identities have been masked but a Clinical Manager can see who received a trial drug versus placebo, the patient's gender and reported side effects. A next level of analysis is drilling into the details on the side effects for each patient during monthly visits -- the same as drilling into individual transactions with other analyses. While this example addresses regulatory needs in the pharmaceutical industry, the concept can easily be adapted to meet the needs of a manufacturer with regulatory requirements.

COMMON BUSINESS QUESTIONS

- What is my products performance versus approval standards?
- What clinical trials are currently underway?
- What is the user acceptance rate of a new product?
- Are any products in noncompliance with government or industry standards?
- How do trial results vary from expectations?
- Can these results be extrapolated to the general user population?
- What are the countries of origin for all my production components?
- What countries have we sold products to? Where are service calls coming from?