Prevent Data Quality Issues That Derail Drug Approvals

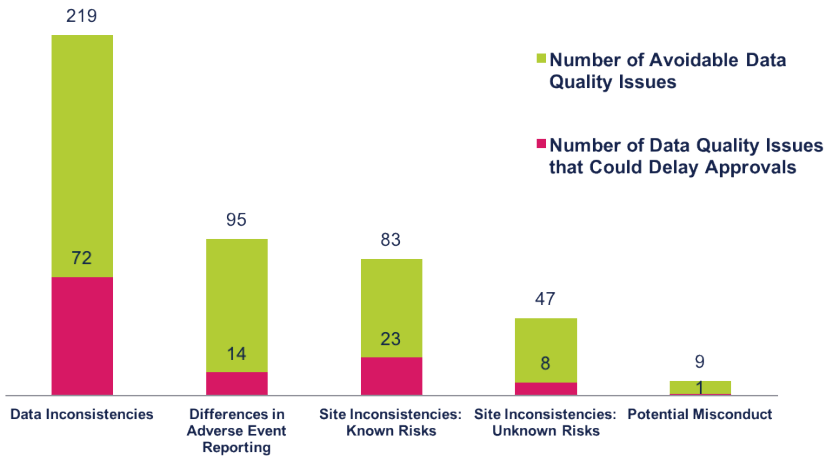
The Challenge

Nearly 50 percent of new molecular entities (NME) submissions fail their first FDA approval, and 32 percent of these failures are attributed to data quality, data integrity and data inconsistency issues.[1] Avoidable data quality issues have clear scientific and economic implications. NMEs with first-cycle approvals beat others to regulatory approval by a median 17.9 months. The delay to market represents an enormous loss in revenue and keeps drugs from patients who are waiting.

The Solution

A Top 25 global pharma company used Rave Trial Assurance on 10 of its ongoing trials to identify data quality issues. The results were astounding for the sponsor but were typical findings for Trial Assurance.

Data Quality Issues in 10 Studies



Note: Issues due to misconduct were not all marked as issues with potential approval impact because they were not found on the primary or secondary efficacy variables

26%

Of data quality issues found across 10 studies had potential to **delay** drug approval

[1] Sacks LV, Shamsuddin HH, Yasinskaya YI, Bouri K, Lanthier ML, Sherman RE. Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000-2012. JAMA.2014;311(4):378–384. doi:10.1001/jama.2013.282542

Medidata's team of data analysts, led by former FDA statistical reviewers, identified **453 avoidable data quality issues across all 10 studies** in five areas commonly examined by regulators:

- **Site inconsistency for unknown risks:** Inconsistencies in site evaluations of endpoints, whether inconsistencies in subjective interpretation (pain levels) or calibration inconsistencies in objective diagnostics. Are sites enrolling participants who violate inclusion/exclusion criteria?
- **Site inconsistency for known risks:** Inconsistencies in how sites follow the protocol—enrolling patients that don't meet study criteria, fraction of visits that are missing during the study, etc. Are sites conducting activity in ways that may correlate to potential compliance or performance concerns?
- **Differences in adverse event reporting:** Differences in sites' adverse event reporting (reduce dose or interrupt study drug) for each severity level.
- **Potential Misconduct:** Sites that fabricate data out of neglect or forgetfulness.
- **Data inconsistency:** Anomalous data values due data entry errors (vitals, visit dates, etc.)

These data quality issues aren't a result of process or an organization's best practices, they occur in every trial. **Data quality issues may be inevitable, but they are avoidable.**

Minimize exposure to data quality questions from regulators with the right combination of machine learning anomaly detection and centralized issue management.

Drastically reduce risk in your NDA submissions by implementing a plan to tackle these common data inconsistencies.

Prevent avoidable data issues from reaching FDA with machine learning anomaly detection. With Rave Trial Assurance, gain immediate, actionable insights to improve data quality for the benefit of study integrity.

ANOMALY CATEGORIES DETECTED IN 10 STUDIES

Percent of **studies** with at least one category anomaly

Trial Assurance By The Numbers

Using Machine Learning to De-Risk Your Trials

Findings For A Top 25 Global Pharma Company

6
Therapeutic Areas

10
Studies

3,288
Patients

13M+
Data Points

41k
Rules Learned

453
Avoidable Data Quality Issues Identified

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers.

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